EUROPEAN CHEMICALS AGENCY

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Background document
to the Opinion on the Annex XV dossier proposing restriction on

CADMIUM AND ITS COMPOUNDS IN ARTISTS' PAINTS

ECHA/RAC/RES-O-0000004990-69-02/F
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

IUPAC NAME: CADMIUM
EC NUMBER: 231-152-8 (cadmium)
CAS NUMBER: 7440-43-9 (cadmium)

Draft
26 November 2014

Table of contents

PROPOSAL FOR A RESTRICTION

About this report

The overall objective is to reduce the risk to human health from cadmium that ends up in food. The objective of this dossier is to reduce the risk related to the release to the sewage system of cadmium from the use in artists´ paints. A restriction of placing on the market and use of cadmium and its compound in artists´ paints is a delimited action directed to the source of release which is, from a practical point of view, relatively easy to implement, compared to actions against other sources of cadmium in sewage sludge described in section B.9.3. The proposed restriction is also in line with one of the priority objectives in the 7th Environment Action Programme[1] (which according to the European Commission will be guiding European environment policy) as well as the Union policy on the environment in the Treaty on European Union[2]. **Both of them state that pollution should, as a priority, be rectified at source** (Article 2.2 in the 7th EAP and Article 191.2 in the Treaty).

The proposed restriction in this report therefore concerns placing on the market and use of cadmium and its compounds in artists' paints, TARIC code [3213] and pigments TARIC code [3212] intended for the manufacture of artists' paints. The current restriction in REACH Annex XVII, Entry 23 restricts the use of cadmium and its compounds in paints covered by TARIC codes [3208] and [3209]. The uses of cadmium in artists' paints and pigments that can be used for the manufacture of artists' paints are thus excluded from the current restriction since these products belong to other TARIC codes; [3213] and [3212]. The current restriction does not either include placing on the market. A transitional period of 1 year after entry into force of the restriction is proposed.

An exemption from the restriction is proposed. The exemption applies to restoration and maintenance of works of art and historic buildings and their interior with reference to cultural-historical values. Member States decide on the exemption and how it should be administrated.

EFSA has expressed concern that the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small. EFSA therefore suggest that exposure to cadmium at population level should be reduced (EFSA 2009). The estimation is based on effects on kidney function but more recent research has pointed out osteoporosis as a serious effect of cadmium exposure which may occur at even lower exposure levels compared to the kidney effects. In EU many cadmium compounds have a harmonized classification for cancer. More recent studies suggest an association between cancer and 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. In this restriction proposal we have chosen to perform quantitative risk assessments using two different endpoints, i.e. bone fractures in males and females more than approximately 50 years of age and postmenopausal breast cancer. The exposure to cadmium is via food.

During use and cleaning procedures cadmium based artists' paint is released to the waste water. At the waste water treatment plant (WWTP) the cadmium pigments will for a predominating part end up in the sewage sludge. Sludge is then applied as fertiliser in the agriculture. The cadmium compounds used in artists' paints will eventually dissolve in the soil (Gustafsson 2013, Appendix 3) and hence there is a potential crop uptake and in the extension exposure to humans via food.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1386&from=EN
[2] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%206655%202008%20REV%207

Colours, imitating cadmium, already exist. Cadmium based pigments are mainly substituted by organic pigments. The properties of the organic pigments are in many ways similar to cadmium colours but cannot be considered identical and thus have to be evaluated on a case- by- case basis by the individual artist.

The proposed restriction will effectively reduce the identified risk. The monetary costs of this restriction option are likely to be small or negative. If expected losses in consumer utility are accounted for, then the quantified economic costs are larger initially, but in the longer term the estimated benefits outweigh the estimated costs. The main trade-off in the discussion on proportionality of the proposed restriction is that of paint consumers' (artists) consumer surplus and the adverse effects of cadmium exposure on human health. The proposed restriction is considered to be proportional, implementable, manageable, enforceable, and monitorable.

A. Proposal

A.1 Proposed restriction(s)

A.1.1 The identity of the substance(s)

Name (IUPAC)	EC number	CAS number	Molecular formula
Cadmium	231-152-8	7440-43-9	Cd

Since the toxic properties which causes the harmful effects is due to the cadmium ion, the restriction proposal includes all possible cadmium compounds. Elemental cadmium is however selected and presented as prototype for all other cadmium compounds.

A.1.2 Scope and conditions of restriction

The overall objective is to reduce the risk to human health from cadmium that ends up in food. The objective of this dossier is to reduce the risk related to the release to the sewage system of cadmium from the use in artists´ paints. A restriction of placing on the market and use of cadmium and its compound in artists´ paints is a delimited action directed to the source of release which is, from a practical point of view, relatively easy to implement, compared to actions against other sources of cadmium in sewage sludge described in section B.9.3. The proposed restriction is also in line with one of the priority objectives in the 7th Environment Action Programme[3] (which according to the EU commission will be guiding European environment policy) as well as the Union policy on the environment in the Treaty on European Union[4]. **Both of them state that pollution should, as a priority, be rectified at source** (Article 2.2 in the 7th EAP and Article 191.2 in the Treaty).

The proposed restriction concerns placing on the market and use of cadmium and its compounds in artists' paints, TARIC code [3213] and pigments TARIC code [3212] intended for the manufacture of artists' paints.

The use of cadmium and its compounds in paints is restricted in REACH Annex XVII, Entry 23. The restriction is however limited to the TARIC codes [3208] and [3209]. Zinc based paints with a residual concentration of cadmium below 0,1 % are exempted from the ban (see Appendix 1). Artists' paints, TARIC code [3213], are hence not included in the current restriction. Nor are pigments covered in TARIC code [3212] which could be used by the artists to manufacture their own artists' paint. The current restriction does not either include placing on the market.

In the RMO and in the Registry of Intention a restriction covering also the use of cadmium and its compounds in pigments for enamel, ceramics and glasses was announced. The objective in the dossier is to minimize the risk to human health caused by cadmium that ends up in in the food via emissions to the sewage system.. It is doubtful if colouring of enamel, ceramics and glasses

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1386&from=EN
[4] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%206655%202008%20REV%207

contributes to this exposure and if that is the case, then available data is too limited. The uses in enamel, ceramics and glasses are therefore not included in the restriction proposal.

An exemption from the restriction is proposed. The exemption applies to restoration and maintenance of works of art and historic buildings and their interior with reference to cultural-historical values. Member States decide on the exemption and how it should be administrated. To be in consistence with the current restriction on cadmium in paints (Entry 23, paragraph 2), the same limit value for the residual concentration of cadmium in artists' paints containing zinc is proposed. If a general limit value for cadmium as an impurity in paints (which is proposed in the ongoing ECHA dossier on Cadmium in paints) would be included in the current restriction in Entry 23, it is for consistency and enforceability reason, reasonable that such a limit value also would apply to cadmium in artists' paints.

A proposal for an addition in REACH Annex XVII, Entry 23 is compiled in the Table 1.

Table 1 Proposal for an addition in REACH Annex XVII, Entry 23

Cadmium CAS No. 7440-43-9 EG No. 231-152-8 and its compounds	1. Shall not be placed on the market or used in: • artists' paints TARIC code [3213] • pigments, TARIC code [3212] used in the manufacture of artists' paints. 2. For artists' paints or pigments used in the manufacture of artists' paints containing zinc with a zinc content exceeding 10 % by weight of the paint or the pigment, the concentration of cadmium (expressed as Cadmium metal) shall not be equal or greater than 0,1 % by weight.. 3. Member States may exempt the placing on the market, manufacture and use of artists` paints and pigments from paragraph 1 for restoration and maintenance of works of art and historic buildings and their interior

The proposed restriction is to be applied 12 months after the amendment of the REACH Annex XVII comes into force.

A.2 Targeting

Under Regulation 793/93/CEE, an extensive EU Risk assessment Report (RAR) on cadmium metal and cadmium oxide was made (ECB 2007). Part of the information in the RAR is also valid for the cadmium compounds used in pigments, since the toxicity of all cadmium compounds is related to the Cd^{2+} ion. Cadmium and cadmium compounds are associated with a large number of health hazards, many of which are quite serious. Among all effects caused by exposure to cadmium, the specific effects focused on in this dossier are the effects on bone (decrease in the bone mineral density, increased risk of osteoporosis or increased risk of fractures) and breast cancer (see section B.5). The route of exposure to cadmium in this dossier is cadmium that ends up in in the food via emissions to the sewage system and sludge application on agricultural land.

Although the contribution from cadmium in artists' paints only represents a minor part of the total cadmium exposure, the exposure should be seen in the light of the statement from the EFSA. EFSA has expressed concern that the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small. EFSA therefore suggest that exposure to cadmium at population level should be reduced (EFSA 2009). The estimation is based on effects on kidney function but more recent research has pointed out osteoporosis as a serious effect of cadmium exposure which may occur at even lower exposure levels compared to the kidney effects (see section B.5). The biological half-life of cadmium in humans is extremely long (10-30 years) and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. This means that most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level. The long half-life also means that once these critical levels have been attained, and effects occur, these are in practice irreversible due to a continued internal exposure (see section B.5).

If the cadmium input originating from artists' paints is removed the average intake via food over 100 years is estimated to be reduced by **0.001 µg cadmium day^{-1}** (compared to baseline), which is equivalent to **0.006% of total intake via food.** About 0.003 % increase is expected after 50 years (see section B.9.7).

Based on the assumption (see section B.10) that the effects of cadmium on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation the following effect levels will be reduced after 150 years:

- Female fractures: 37 fewer cases/year
- Male fractures: 11 fewer cases/year
- Breast cancers: 13 fewer cases/year

EU has since 1988 had a common aim to substitute the use of cadmium as far as possible. This aim has resulted into, amongst others, the restriction entry 23 in REACH, Annex XVII for cadmium (CAS No 7440-43-9, EC No 231-152-8) and its compound. Regarding the use of cadmium in paints, the restriction is limited to the TARIC codes [3208] [3209]. Artists' paints [TARIC code 3213] are hence not included in these regulations. Nor are pigments covered in TARIC code [3212] which could be used by the artists to manufacture their own artists' paints. The current restriction does not either include the placing on the market. The TARIC codes can be viewed in TARIC database (EC 2013b).

A.3 Summary of the justification

A.3.1 Identified hazard and risk

During use and cleaning procedures cadmium based artists' paints are released to the waste water. At the waste water treatment plant (WWTP) the cadmium pigments will for a predominating part end up in the sewage sludge. Sludge is then applied as fertiliser in the agriculture. The cadmium compounds used in artists' paints will eventually dissolve in the soil (Gustafsson 2013) and hence there is a potential crop uptake and in the extension exposure to humans via food.

The general population in Europe are exposed to levels of cadmium that, already today, may cause effects on kidney and bone for a significant part of the population. The margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small (EFSA 2009). Cereals and root vegetables contribute the most to the general population exposure to cadmium via food.

The toxicity of all cadmium compounds is related to the Cd^{2+} ion. For long-term effects, also less soluble cadmium compounds contribute to the pool of cadmium that humans are exposed to. The biological half-life of cadmium in humans is extremely long (10-30 years) and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. This means that most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level. The long half-life also means that once these critical levels have been attained, and effects occur, these are in practice irreversible due to a continued internal exposure. Cadmium is further considered to cause carcinogenesis. In the general population increased risks have mainly been shown in hormone-related organs, such as breast, endometrium and prostate.

If the cadmium input originating from artists' paints is removed the average intake via food over 100 years is estimated to be reduced by **0.001 µg cadmium day^{-1}** (compared to baseline), which is equivalent to **0.006% of total intake via food.** About 0.003 % increase is expected after 50 years (see section B.9.7).

Although other toxic effects of cadmium have not been assessed in this report, it is expected that these will also decrease in a similar manner. Furthermore, the impact of the proposed restriction on the cadmium exposure via food will be higher among individuals eating locally grown potatoes and cereals, where sludge has been used as fertiliser (see *scenario C* in sections B.9.4 and B.9.7). Also *scenario A* described in sections B.9.4 and B.9.7 is of importance in some parts of EU. This scenario represents farming systems with high input, 30 kg P ha^{-1}, which according to the EU RAR (ECB 2007) may be found in e.g. wheat and corn rotations.

A.3.2 Justification that action is required on a Union-wide basis

Based on the EFSA concern that subgroups of the EU population, such as children and vegetarians, can significantly exceed the tolerable intake of cadmium there is a need to reduce further exposure to cadmium. Moreover, most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level. The long half-life of cadmium means that once these critical levels have been attained, and effects occur, these are in practice irreversible due to a continued internal exposure.

The current restriction in REACH Annex XVII, Entry 23 restricts the use of cadmium and its compounds in paints covered by TARIC codes [3208] and [3209]. Artists' paints and pigments that can be used for the manufacture of artists' paints belong to other TARIC codes; [3213] and [3212] and are thus excluded from the current restriction. Since the current restriction is valid throughout the EU, a modification to the entry, covering also the use and placing on the market of artists' paints and pigments which could be used by the artists to manufacture their own artists' paints., needs to be made on an EU-wide basis. Except ensuring a similar protection of human health across the Union, an EU-wide restriction would remove the potentially distorting effect that national restrictions or corresponding measures may have on the free circulation of artists' paints. A "level playing field," among EU producers and importers of artists' paints, would also be ensured. Thus, a Union-wide restriction is found justified.

A.3.3 Justification that the proposed restriction is the most appropriate Union-wide measure

The proposed restriction is will lead to a reduction in cadmium intake via food which will lead to a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation to the following levels after 150 years:

- Female fractures: 37 fewer cases/year
- Male fractures: 11 fewer cases/year
- Breast cancers: 13 fewer cases/year

The socio-economic benefits of the proposed restriction depend on the time frame chosen for the analysis. The (present value of) annual benefits are continually increasing throughout the 150 years analysed. The cumulative benefits are estimated to be €14-44 million after 50 years and €91-306 million after 150 years. This does not take into account other possible negative health effects of cadmium exposure via food – such as kidney damage, endometrial cancer, and developmental neurotoxicity – that have not been quantified in this report.

The monetary costs of this restriction option are likely to be small or negative. The one-off costs and administrative costs are projected to be surpassed by the benefits 10-22 years, while it will take 19-115 years for the benefits to surpass the costs if expected losses in consumer surplus are included.

Two Union-wide restriction options were analysed. These options differ in two ways. The complete ban in restriction option 1 will cause losses in public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art. In option 2 (the proposed restriction), an exemption is included to allow for the use of cadmium based artists' paints for the purpose of restoration of pieces of art that are considered to be of cultural-historical value. This will avoid most of the losses in public good values experienced under option 1, but will on the other hand lead to some additional administrative costs. Since the differences in risk reduction, cost, practicality and monitorability is relatively small between the two options, and since an exemption for restorative activities would moderate the losses in public good values associated with a restriction, option 2 is the proposed risk management option.

B. Information on hazard and risk

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

The restriction proposal concerns cadmium and cadmium compounds in artists' paints. Since the toxic properties which causes the harmful effects is due to the cadmium ion, the restriction proposal includes all possible cadmium compounds.

Concerning the most commonly used cadmium pigments there are several CAS-numbers and names of substances consisting of cadmium sulphoselenide and cadmium zinc sulfide. The difference between for example cadmium sulfoselenide red (CAS number 58339-34-7), cadmium sulfoselenide orange (CAS 12656-57-4) and cadmium selenide sulfide (CAS 12626-36-7) is not obvious, which is one reason to include all cadmium compounds in the restriction proposal.

It is however not considered relevant to present substance identity for all possible compounds. Substance identity is therefore only shown for metallic cadmium and for two families of pigments currently identified by registrants using the EC/CAS identifiers for "cadmium sulfoselenide red" and "cadmium zinc sulfide yellow".

B.1.1 Name and other identifiers of the substance(s)

Table 2 Substance identity for cadmium and the family of pigments cadmium sulfoselenide red and cadmium zinc sulfide yellow

EC name	cadmium	cadmium sulfoselenide red[5]	cadmium zinc sulfide yellow[6]
EC number	231-152-8	261-218-1	232-466-8
CAS number (in the EC inventory)	7440-43-9	58339-34-7	8048-07-5
CAS name	cadmium	C.I. Pigment Red 108	C.I. Pigment Yellow 35
IUPAC name	cadmium	cadmium sulfoselenide red	cadmium zinc sulfide yellow
Index number in Annex VI of the CLP Regulation	048-002-00-0 048-011-00-X	-	-
Molecular formula	Cd	CdS(1-x)Se(x) 0<x<1	(Cd(x).Zn(1-x))S 0<x<1
Molecular weight range	112.41	>144,47 – <191,37	>97,44 – <144,47
Synonyms	Cd rod Cd stangen kadmium stangen	C.I. 77202	C.I. 77205
Structural formula	Cd		

Examples of identifiers covering cadmium sulfide, cadmium sulphoselenide, cadmium selenides and cadmium zinc sulfides, with other synonyms and other EC- and CAS numbers than above, are found in Appendix 2.

Several other cadmium sulfides and cadmium selenides, doped with mainly other metals, are preregistered under Reach, as well as a few multi-constituent substances where cadmium selenide and cadmium sulphide are among the main constituents, see Appendix 2.

Due to the large number of CAS numbers and synonyms of cadmium pigments it is important not to

[5] The columns for cadmium sulfoselenide red and cadmium zinc sulfide yellow specifies names and identifiers for families of pigments and shall therefore be understood as generic identifiers which may eventually cover multiple substances.

[6] See above.

exclude any compounds by limiting the proposal to only cover the two most commonly used cadmium pigments today. The restriction proposal shall therefore cover cadmium and all its compounds.

B.1.2 Composition of the substance(s)

The substance cadmium is itself a mono-constituent substance which presents a concentration level in cadmium of typically 80-100%. The examples of substances mentioned in this dossier, "Cadmium sulfoselenide red" and "cadmium zinc sulfide yellow", on the other hand designate families of pigments. Information on the composition of the different pigments covered by these families is not relevant for the purpose of this restriction proposal, since it concerns cadmium and its compounds.

B.1.3 Physicochemical properties

Table 3 Overview of physicochemical properties for cadmium (from dissemination database according to REACH, Article 119) (ECHA 2013a)

Property	Value
Physical state at 20°C and 101.3 kPa	Solid, in form of cast or powder. Powder is brownish, the cast form is shiny silver. Odourless.
Melting/freezing point	In nitrogen, the powder starts melting at 309°C, in air it starts melting at 321°C. In nitrogen, the cast cadmium particles starts melting at 309°C, in air they start melting at 313°C. In nitrogen, the substance does not decompose; sublimation temperature is ca. 450°C for the powder and ca. 400°C for the cast particles. In air, the substance starts oxidizing at ca. 270°C (powder) and at ca. 470°C (cast metal).
Relative density	8.64 g/cm^3 in powder form and 8.6 g/cm^3 in particulate form.
Water solubility	The average water solubility of Cd for the powder and bar samples was 2.3 and 8.7 mg/L, respectively. Corresponding value for pure cadmium was also calculated with HSC 7.0 software. The obtained value was 5.4 mg/L.
Granulometry	The D50 of the powder is 16.27 µm, the D80 is <20 µm. The D50 of the crushed cast particles is 2103 µm, the D80 is > 2380 µm.

Table 4 Overview of physicochemical properties for cadmium sulfoselenide red (from dissemination database according to REACH, Article 119) (ECHA 2013a)

Property	Value
Physical state at 20°C and 101.3 kPa	Solid powder. Red. Odourless.
Melting/freezing point	Melting of cadmium sulfoselenide starts at 593°C in nitrogen atmosphere and oxidation at 555°C.
Relative density	5.15 g/cm³
Water solubility	The acute (7d) Transformation/Dissolution Test on CdSSe in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of 0.24 +/- 0.09 µg/L Cd. The Chronic (28d) Transformation/Dissolution Test on CdSSe in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of 0.23 +/- 0.13 µg/L Cd. The acute (7d) Transformation/Dissolution Test on CdSSe in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of <0.1µg/L Cd The Chronic (28d) Transformation/Dissolution Test on CdSSe in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of 0.14 +/- 0.03 µg/L Cd. Fate in agricultural soils is further described in section B.4. It is the Dossier Submitters point of view that, within a time frame of a couple of years to several decades, cadmium from pigments has a similar solubility and bioavailability as an easily soluble cadmium salt such as cadmium chloride.
Granulometry	The D50 of the substance by volumic distribution is 2.846 µm

Table 5 Overview of physicochemical properties for cadmium zinc sulfide yellow (from dissemination database according to REACH, Article 119) (ECHA 2013a)

Property	Value
Physical state at 20°C and 101.3 kPa	Solid powder. Yellow. Odourless.
Melting/freezing point	Decomposition of cadmium zinc sulphide starts at 892°C in nitrogen atmosphere and oxidation at 597°C.
Relative density	4.7 g/cm³
Water solubility	The acute (7d) Transformation/Dissolution Test on CdZnS in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of 0.61 +/- 0.05 µg/L Cd. The Chronic (28d) Transformation/Dissolution Test on CdSSe in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of

Property	Value
	1.97 +/- 0.63 µg/L Cd. The acute (7d) Transformation/Dissolution Test on CdZnS in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of 0.18 +/- 0.13 µg/L Cd. The Chronic (28d) Transformation/Dissolution Test on CdZnS in a standard aqueous medium at pH 6 and with a 1 mg/L loading showed an average dissolved cadmium concentration of 0.98 +/- 0.95 µg/L Cd. Fate in agricultural soils is further described in section B.4. It is the Dossier Submitters point of view that, within a time frame of a couple of years to several decades, cadmium from pigments has a similar solubility and bioavailability as an easily soluble cadmium salt such as cadmium chloride.
Granulometry	The D50 of the substance is 338 µm, the D80 is 831 µm. The D50 of the substance by volumic distribution is 2.525 µm.

B.1.4 Justification for grouping

This restriction proposal targets the health effects of cadmium. Exposure levels of cadmium are already exceeding the tolerable intake for parts of the European population (EFSA 2009). Cadmium compounds in artists paints are contributing to the increased concentrations of cadmium in soil from sludge, applied as a phosphorous source on agricultural land and consequently to increased exposure to humans via food. This grouping is justified by the following facts:

1. The toxic properties which causes the harmful effects is due to the cadmium ion itself

2. The cadmium compounds present in artists paints could vary in chemical structure and thereby also include several individual CAS numbers

3. Analyzing and identifying specific cadmium compounds in products are most likely more complicated and more expensive than just analyzing the cadmium content.

In order to minimize the level of human exposure to cadmium via food, the proposal thus covers cadmium and all cadmium compounds.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of cadmium

The total tonnage band according to the REACH registration is 1 000 – 10 000 tonnes (17 February. 2013). This is based on data from 22 registrants from Germany, Norway, Italy, Belguim, Austria, Poland, UK, Bulgaria, the Netherlands, Sweden, France and Luxembourg.

The annual world production of cadmium during 1990 to 1999 was 18 000 to 21 000 tonnes (Kirk-Othmer 2004). Most of the world's primary cadmium metal was produced in Asia and the Pacific-specifically China, Japan, and the Republic of Korea, followed by North America, Central Europe and Eurasia, and Western Europe. Secondary cadmium production takes place mainly at Ni-Cd battery recycling facilities (USGS 2012).

European countries contributed to 9.3 % of world production in 2010 (Table 6). The Netherland was the largest European producer accounting for 28 % of the EU production, followed by Poland (22 %), Bulgaria (21 %), Germany (14 %) and Norway (14 %) (BGS 2012). The production level was stable around 2000 tonnes per annum during 2006 to 2010 (Table 6). This production level is within the "total tonnage band" registered to ECHA (see above).

The historical growth in production volumes during the years 1967 to 1982 was 0.6 %, and increased between 1982 and 1995 to 0.8 % (Kirk-Othmer 2004). The refined primary cadmium production has shown decreases in recent years as secondary recycled cadmium production has increased. Recycling of cadmium was estimated to 15-20% of the total production, of which >11% origin are from Ni-Cd-batteries. This trend is expected to increase in the future (Kirk-Othmer 2004).

Table 6 Primary production of cadmium in Europe 2006 to 2010 (BGS 2012)

Country	Unit	2006	2007	2008	2009	2010
The Netherlands	tonnes	524	495	530	490	580
Poland	tonnes	373	421	603	534	451
Bulgaria	tonnes	320	318	376	413	440
Germany	tonnes	490	475	420	250	300
Norway	tonnes	125	269	178	249	300
France	tonnes	90	50	-	-	-
Total	**tonnes**	**1900**	**2000**	**2100**	**1900**	**2100**

Manufacture of cadmium pigments used in artists' paints etc.

According to data from the registrations dossiers, an acidic cadmium solution is mixed with an alkaline sulphide solution to precipitate raw cadmium pigment with chemical additives depending on the shade required. The precipitate is then separated from the liquor, washed and dried before being fired at about 600°C. It is during this step that the chemical transforms into a pigment with different crystal structure and particle size (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances).

Another way to describe the manufacture of cadmium based pigment is illustrated in the flow chart below (Figure 1).

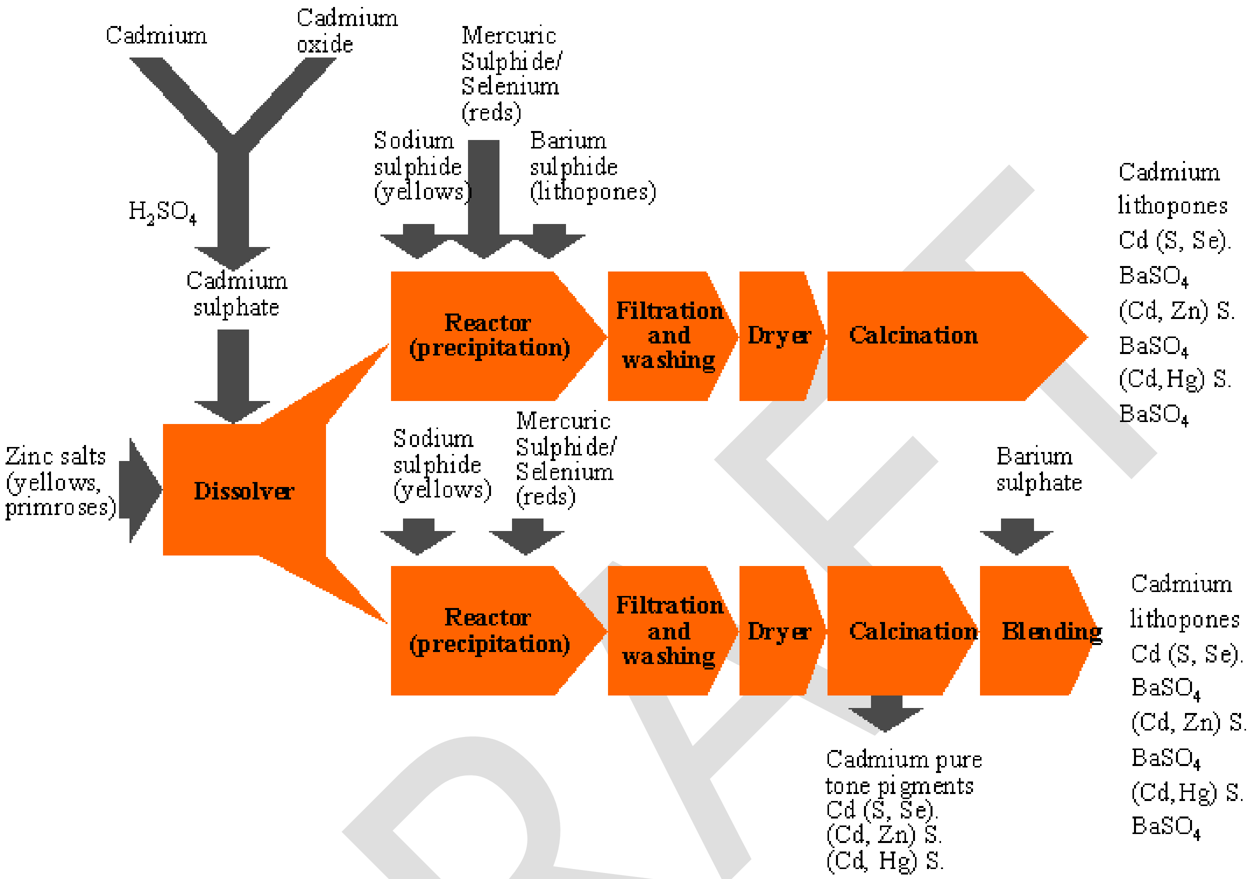


Figure 1 Manufacture of cadmium pigments (ICdA, Europe, 2013)

B.2.2 Uses

The total international cadmium consumption is dominated by the production of Ni-Cd batteries (Table 7). Japan is the largest producer of raw material for Ni-Cd-batteries in the world (Kirl-Othmer 2004). Other relevant uses are as pigments and anti-corrosion coatings of metals. A quantification of the cadmium flow in EU3 has been made by Lig & Held (2009).

Table 7 Patterns of cadmium consumption (ICdA 2012)

Use	**International uses** (2003)
Ni-Cd Batteries	79%
Pigments	11%
Coatings/Plating	7%
Stabilisers	2%
Others	1%

The highest concentrations of cadmium are used in Ni-Cd batteries and some alloys, up to 25% (Table 8). The concentrations in pigments are in general less than 1%. Regarding artists' paints, the content of cadmium is considerably higher but varies depending on the kind of artists' paints. Cadmium may occur as impurity in fertiliser, fossil fuel, cement and in different metals. The concentrations as impurities are normally in the range of 0.1 to 90 ppm. For many literature data on impurities it is unclear if it is in the form of pure metal.

Table 8 Concentration of cadmium in different types of uses (US 2003, ICdA 2012b)

Product	% Cd	Use type	Comment
Ni-Cd batteries	7-25%	Intentional	Cd, CdO, $Cd(OH)_2$
Cd pigments	~1%	Intentional	Cd(Zn)S(Se)
Cd coatings	~0.2%	Intentional	Cd, CdO, Cd-Ti, Cd-Sn
Cd stabilisers	~1%	Intentional	Cd-laurate, Cd-stearate
Cd alloys *et.al.*	1-25%	Intentional	Cu-Cd, Ag-CdO
Phosphate fertilisers	3 – 90 ppm	Unintentional	impurity
Fossil fuels	0.1 – 1.5 ppm	Unintentional	impurity
Cement	2.0 – 2.5 ppm	Unintentional	impurity
Iron and steel	0.1 – 5.5 ppm	Unintentional	impurity
Nonferrous metals	1 – 5 ppm	Unintentional	impurity

Use in pigments

The use of cadmium and its compounds in paints are restricted in REACH Annex XVII, Entry 23. The restriction is however limited to the TARIC codes [3208] [3209]. Artists' paints (TARIC code 3213) are hence not included in the regulation. Nor are pigments covered in TARIC code [3212] which could be used by the artists to manufacture their own artists' paints. The TARIC codes can be viewed in the TARIC code database (EC 2013b).

Naturally-occurring cadmium-sulfide based pigments were used as early as 1850 because of their brilliant red, orange and yellow colors, and appeared prominently in the paintings of Vincent Van Gogh in the late 1800s (ICdA Europe 2013).

The pigments are based upon cadmium sulphide which produces a golden yellow pigment. Cadmium pigments are stable inorganic colouring agents which can be produced in a range of brilliant shades of yellow, orange, red and maroon. Their greatest use is in plastics but they also have significant application in ceramics, glasses and specialist paints. Cadmium zinc sulphide and cadmium sulphoselenide are used as bright yellow to deep red pigments in plastics, ceramics, glasses, enamels and artists colours. They are well known for their ability to withstand high temperature and high pressure without chalking or fading, and therefore are used in applications where high temperature or high pressure processing is required (Cook 1994, ICdA Europe 2013). Cadmium pigments have a number of other minor uses in rubber, paper and inks although these are small in terms of cadmium consumption (ICdA 2013).Cadmium pigments are characterised by their particular brilliant shades, high hiding power, good intensities of colour, good temperature stability (up to 600 °C) and absolute migration resistance (Zorll 2001). Cadmium sulfide occurs in two natural forms (hawleyite and greenockite) which differ in their crystal structure, see Figure 2. Using cadmium sulphide as a base makes it possible to create a variety of pigments. Different substances may be placed into the basic configuration, substituting sulphur and/or cadmium. Partial substitution of sulphur by selenium creates a range of intercrystalline compounds resulting in different colours, from yellow and orange to red. Also, partial replacement of Cd^{+2} by Zn^{+2} ions in the lattice produces progressively greener shades of yellow (Eastaugh et al. 2008). The concentration of cadmium in the pigment depends on the ratio cadmium sulphide-cadmium selenide when sulphide is replaced and/or to what extent e.g. zinc is substituted for cadmium. Literature reveals that a Se-Cd ratio of 10-90 results in orange colours, 20-80 gives a bright red colour whereas a dark maroon shade is obtained with a ratio of 30-70. Cadmium zinc sulphide is formed by partly substituting cadmium for zinc, $Cd_{1-x}Zn_xS$, with up to approximately 25% zinc (Eastaugh et al. 2008).

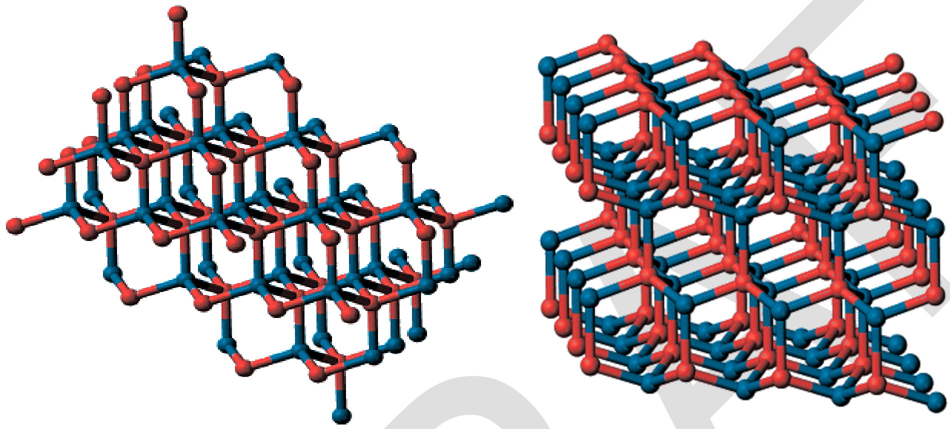


Figure 2 Left: Hawleyite (cubic). Right: Greenockite (hexagonal). (General Chemistry 2013)

The cadmium compounds most frequently used in artists' paints are cadmium sulphoselenide red, cadmium sulphoselenide orange and cadmium zinc sulphide yellow. However, other combinations exist, e.g. partly substitution of cadmium for mercury or barium. $BaSO_4$ is used as filler in some commercial varieties of pigments (normally 5-62%). These types of pigments are called "lithopone" pigments. Zinc sulphide can also be used together with barium. Lithopone pigments where developed due to the high cost of pure cadmium sulphide (Eastaugh 2008, Perez 2003).

Additives can be incorporated into cadmium pigments in different ways. The most common techniques are, as a "solid solution" and "co-precipitation". Compounding may also occur. The different techniques will influence the initial mobility of the cadmium sulphide molecule. In short, in co-precipitation the different substances will be found in different crystals, as opposed to solid solutions, where the dissimilar substances will be located in the same colloidal aggregates.

As mentioned above there are two crystalline forms of cadmium pigments: a hexagonal form with wurtzite lattice, alpha-CdS (Zorll 2001), and a cubic form, beta-CdS. In addition an amorphous form may also be synthesized. This phase reportedly coexist with other crystalline forms at room temperature (Eastaugh 2008). The more stable hexagonal CdS is the only one used for high-temperature pigment applications, i.e. for thermoplastic, glass, enamel and ceramic (Lussiez et al. 1989).

In Table 9 cadmium containing pigments identified from the ECHA database on Registered substances are listed (ECHA 2013a).

Table 9 Pigment substances containing cadmium as registered under REACH 2013.

Substance	EC Number	CAS Number	Other information
Cadmium sulfoselenide red	261-218-1	58339-34-7	Pigment red 108
Cadmium zincsulphide	232-466-8	8048-07-5	Pigment Yellow 35

The two cadmium compounds have been registered at ECHA in June 2013 in the tonnage band 100 – 1 000 tonnes/year.

A rough estimate is that the annual quantity of artists' paints sold on the EU-market ranges between 7 700 – 11 000 tons of which 33-44 tons per year is estimated to be based on cadmium compounds (CEPE, 2013). The concentration of cadmium pigment varies depending on the type of artists' paint (CEPE, 2013).

In an analysis on cadmium based artists' paints conducted by the Swedish Chemicals Agency 2013 (see Appendix 5) the following levels of cadmium were found:

Oil: 15-50 %
Acrylic: 6-17 %
Water: 30-45 %
Gouache: Approximately 15 %

The sales statistics from CEPE and the cadmium analysis results presented above are used in the release/exposure scenario (section B.9.3).

B.2.3 Uses advised against by the registrants

No information is available in the registration dossiers neither on cadmium sulfoselenide red nor on cadmium zinc sulphide.

B.3 Classification and labelling

B.1.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Cadmium (non-pyrophoric) is listed as Index number 048-002-00-0 and cadmium (pyrophoric) is listed as Index number 048-011-00-X in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, as follows:

Table 10 *Table 5: Harmonised classification of cadmium Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008*

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling	
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram Signal Word Code(s)	Hazard Statement Code(s)
048-002-00-0	Cadmium (non-pyrophoric)	231-152-8	7440-43-9	Carc. 1B Muta. 2 Repr. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H341 H361fd H330 H372 H400 H410	GHS06 GHS08 GHS09 Dgr	H350 H341 H361fd H330 H372 H410

H350: May cause cancer.
H341: May cause genetic defects.
H361fd: May damage fertility. May damage the unborn child.
H330: Fatal if inhaled.
H372: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Table 11 *Table 12: Harmonised classification of cadmium (non-pyrophoric) according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008*

Index No	International Chemical Identification	EC No	CAS No	Classification	Risk phrases	Safety phrases	Indication(s) of danger
048-002-00-0	Cadmium (non-pyrophoric)	231-152-8	7440-43-9	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Repr. Cat. 3; R62 Repr. Cat. 3; R63 T+; R26 T; R48/23/25 N; R50/53	R45 R68 R62 R63 R26 R48/23/25 R50/53	S45 S53 S60 S61	T+ N

R45: May cause cancer.
R68: Possible risk of irreversible effects.
R62: Possible risk of impaired fertility.
R63: Possible risk of harm to the unborn child.
R26: Very toxic by inhalation.
R48/23/25: Toxic: danger of serious damage to health by prolonged exposure through inhalation or if swallowed.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Further, cadmium (pyrophoric) is listed as Index number 048-011-00-X in Annex VI, part 3 of Regulation (EC) No 1272/2008 and is in addition to the classifications for cadmium (non-pyrophoric) also classified as Pyr. Sol.1; H250 (Catches fire spontaneously if exposed to air) or F; R17 (Spontaneously flammable in air), Safety phrases S7/8 and S43.

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

The cadmium compounds usually used in artists' paints (cadmium sulfoselenide red, cadmium selenide sulfide, cadmium sulfoselenide orange, cadmium zinc sulfide yellow) do not have harmonised classifications. There is a general classification for cadmium compounds (Annex VI in the Regulation (EC) No 1272/2008) but '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). The reason that these compounds were exempted from the general classification is probably due to their low solubility in water according to standardized water solubility tests.

Industry self classification dossiers have been registered for three of the four compounds mentioned above, namely cadmium sulfoselenide red, cadmium sulfoselenide orange and cadmium zinc sulfide yellow (CAS No. 58339-34-7, 12656-57-4 and 8048-07-5). No classifications have however been proposed for cadmium zinc sulfide yellow and cadmium sulfoselenide orange. Three groups of registrants have proposed different classifications for cadmium sulfoselenide red. These differ from the proposal of no classification to more extensive proposals. The classification proposals are summarised in Table 12.

Table 12 Proposed self classification for cadmium sulfoselenide red (CAS No. 58339-34-7)

Proposal	**Proposed classification**		
	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Phrase
1	-	-	-
2	Acute Tox. 4	H302	Harmful if swallowed
	Acute Tox. 4	H312	Harmful in contact with skin
	Acute Tox. 4	H332	Harmful if inhaled
3	Acute Tox. 4	H302	Harmful if swallowed
	Skin Irrit. 2	H315	Causes skin irritation
	Acute Tox. 4	H332	Harmful if inhaled
	STOT SE 3	H335	May cause respiratory irritation

B.4 Environmental fate properties

Cadmium is a natural element, which is present in all environmental compartments. It occurs in the metallic state, or as cadmium compound, with one valence state (Cd^{2+}).

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 this RAR it is assumed that the toxicity of the cadmium-compounds is related (mainly) to the Cd^{2+} ion. This is also established in the chemical safety reports (CSRs) that were made for the REACH registration of most inorganic cadmium substances, including the CSRs for cadmium compounds used as pigments, and hence the EU RAR was used as the main reference for these CSRs.

In the CSRs it is noted that all environmental concentration data are expressed as "Cd", as toxicity is caused by the Cd^{2+} ion. For this reason, the sections on human toxicity and ecotoxicity in the CSR for cadmium are applicable to all cadmium compounds, from which Cd ions are released into the environment. In the environment cadmium compounds as well as released cadmium ions will interact with the environmental matrix. The fraction that is bioavailable will depend on various processes like dissolution, absorption, inclusion into (soil) matrix, etc. These processes are defining the fate of cadmium in the environment and, ultimately, its (eco) toxicological potential.

The time perspective is important when the fate of cadmium compounds is evaluated. The risk scenario assessed in this report refer to processes that may take years or decades, while available data mostly consider a more short-term perspective. Cadmium pigments like cadmium sulfoselenide red and zincsulphide yellow are for instance usually highly insoluble in water according to standardized water solubility tests, which makes them different from the more soluble cadmium-compounds.

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 of the cadmium compounds, exemplified in Table 13.

Table 13 Examples of transformation/dissolution results for different cadmium compounds.

	Dissolved cadmium (µg Cd/l)	Loading (mg/l)	pH	Durability (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

These data indicate the importance of the initial loading as well as the duration of the test for the dissolution of soluble cadmium from the different cadmium compounds.

This means that for the less soluble substances (CdS, CdZnS, CdSSe) much lower concentrations of available cadmium forms will be present in regular toxicity as well as ecotoxicity tests compared to what would be the case for the more soluble compounds (CdO, CdTe), and it will be conclude 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 have changed considerably. The information on fate of different cadmium compounds in such long-term perspectives is however scarce.

B.4.1 Degradation

Being a natural element, cadmium is not degradable but can occur in different speciation forms. For inorganic cadmium compounds, dissolution and transformation between different occurrence forms are the important processes for the fate and availability of cadmium and are discussed in the section below.

According to Column 2 of Annex VII of REACH regulation the studies on (ready) biodegradability do not need to be conducted if the substance is inorganic and according to the ECHA Guidance (ECHA 2008a) biotic and abiotic degradation rates should be set to zero for metals. Hence, in all registrations for cadmium and inorganic cadmium compounds the registrants have invoked data waiving for studies on stability and biodegradation.

According to Annex VIII of the REACH Regulation, information on hydrolysis is not required if the substance is highly insoluble in water. According to the registrants photo transformation in air, water and soil, are not applicable to the different cadmium compounds.

B.4.2 Environmental distribution

B.4.2.1 Distribution in the aquatic environment

Not relevant for this proposal since the endpoints for the proposal are focused on human health, exposed via sludge amended soil.

B.4.2.2 Distribution in soil

Cadmium can reach the environment as soluble forms in water or as particles. 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(II) oxidation state (Smolders and Mertens 2013) where it adsorbs to various reactive soil surfaces. The most important in this respect are soil organic matter, oxyhydroxides of iron, aluminium and manganese and clay minerals.

The soil pH and the redox potential are important parameter that affects 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.

Cadmium sorption data in different soils reveal that pH is generally the most important factor associated with cadmium sorption (factor 3–5 stronger sorption per unit pH increase) (Smolders and Mertens, 2013, ECB 2007), see below. 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. For instance soil pH increases upon waterlogging soils and this may explain immobilisation of cadmium when soils are submerged.

The redox potential of the soil is also of importance for the solubility of cadmium compounds. Sulphides that form in strongly reduced soil may precipitate cadmium ions as cadmium sulphides. Pure sulphides and mixed zinc/cadmium sulphides are formed. Lower solubility is predicted for cadmium substituted in the mixed sulphides than for cadmium in pure cadmium sulphide. Despite lower solubility of cadmium sulphides than zinc sulphide, the oxidation rate of sulphides with high content of cadmium is much faster than that of pure zinc sulphides. Oxidation kinetics show that the dissolution of cadmium ions is very limited for solid mixed zinc/cadmium in solutions if the molar ratio Zn:Cd >20 (Barret & McBride, 2007, Gustafsson 2013, Smolder & Mertens 2013).

B.4.2.3 Adsorption/desorption

Sorption processes could 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 makes the cadmium in soil less available with time, are not likely relevant in the environment, except at high pH.

Solid-liquid partition coefficients (K_D, L/kg) are used to describe sorption of cadmium to soil and to calculate leaching in mass balance models for cadmium in soil and is defined as:

$K_D = [Cd]_s/[Cd]_l$

in which $[Cd]_s$ represents the cadmium concentrations in the solid phase of the soil (µg/kg) and $[Cd]_l$ the cadmium concentration in pore water (µg/L).

K_D values for cadmium varies strongly with soil properties, and in the summary of reviewed data in the EU RAR (ECB 2007) a variation of about two orders magnitude in K_D for cadmium was found from different soil studies. For the modelling performed in the EU RAR, K_D was set to 280 L kg^{-1} which was considered a typical value for a soil with pH 6.5 and 2% organic matter. It is not clear from the registrations which partition coefficients that have been used for soil compartment in the CSRs for the different cadmium compounds. However, for the other compartments (water, sediment) the same partition coefficient are used as in the EU RAR, and hence it may be assumed that this is also the case for K_D for soil.

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).

Smolders and Mertens (2013) recently reviewed several independent data sources on K_D values and proposed a best fit empirical model reading:

$logK_D = -1.04 + 0.55pH + 0.70log(\%OC)$

in which %OC is the organic carbon content, given as percentage.

In another very recent (not per-reviewed) conference proceedings Smolders (2013) came to another best fit model: $logK_D = -0.94 + 0.51pH + 0.79log(\%OC)$

For pH 6.5 and 2 %OC the algorithm above from Smolder and Mertens (2013) results in a K_D of 557, i.e. a factor 2 higher value than the one used in the EU RAR. In the mass balance calculations this results in a reduced leaching with a factor 2. Leaching is the most important process for the output of cadmium from soils, especially in soils with low pH. This demonstrates that pH of the soil as well as the choice of K_D algorithm has a big impact on the outcome of the mass balance.

Different methods for measuring pH in soil exist, mainly differing regarding the extractants used. The International Standard (ISO 10390:2005) specifies a method for the determination of pH in suspension of soil in either water (pH in H_2O), in 1 mol/l potassium chloride solution (pH in KCl) or in 0.01 mol/l calcium chloride solution (pH in $CaCl_2$). The use of calcium chloride solution will in general yield a lower pH value than will distilled water. There is no unequivocal scientific support for choosing one or the other (TC WI, 2003). Another factor that can affect the pH is if the samples are dried or not before analysis (ibid).

Since different pH measurement methods give different results, it is important that the same method has been used in the studies that constitute the basis for the algorithms for K_D, as well as in the soils where the algorithms are applied to calculate leaching. It is not clear from the references if the algorithms above are based on pH data which are all obtained with the same method.

B.4.2.4 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. It has been argued that the cadmium compounds used in artists' paints, which reaches soil environments e.g. via sludge, would not be bioavailable due to its low water solubility. However, no scientific proof has been found, showing that this would be the case in a long term perspective. Therefore, Professor Jon Petter Gustafsson was asked to perform a literature review and to conclude on the solubility and availability in soil of a number of cadmium-containing substances used in paints (Gustafsson 2013, Appendix 3). Gustafsson 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.

It will therefore be assumed in this report that cadmium in soil, originating from pigments, in the long-term will be equally available to plants as cadmium from other sources.

Cadmium in sludge compared to cadmium in soil

Cadmium is recognized as one of the most mobile trace element, being more weakly bounded 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, aluminum, 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. Smolder and Mertens (2013) also concludes that increasing organic matter by adding biosolids such as sewage sludge does not immobilize cadmium strongly, unless in soils where the organic matter content is extremely low.

Therefore, it is assumed in this report that there is no difference in cadmium availability in sludge amended soils compared to native soils.

B.4.3 Bioaccumulation

Numerous data on bioconcentration and bioaccumulation of soluble cadmium compounds in the aquatic environment were reviewed in the EU RAR on cadmium. However bioaccumulation in the aquatic environment is not relevant for this proposal since the endpoints for the proposal are focused on human health, exposed via food grown on agricultural land.

Among the bioaccumulation data reported by the registrants, only one considered uptake in plants (Ma, 1987)[7]. This was a field study on pasture collected at a contaminated site and a control site. At the contaminated site, cadmium in soil originated from historical atmospheric deposition from a smelter. At the control site, cadmium originated from background deposition and natural background in soil. Soil and vegetation were sampled at 5 sites, 4 around the historically contaminated site and 1 at the control site (ECHA 2013a). The cadmium concentration in soil was 0.1 mg/kg dw at the control site, while it varied between 0.3 and 9.2 mg/kg dw at the contaminated sites. 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.

On the other hand, Smolders and Mertens (2013) who reviewed experimental studies came to the conclusions 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

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

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.

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 leafs of plants and for plants grown in the same soil accumulation decreases in the order: Leafy vegetables[8]> 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 in the exposure assessment of cadmium in artist' paints (chapter B.9.7). 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).

The assumption above may hence result in an underestimation in the calculation of risk in chapter B.10.

B.4.4 Secondary poisoning

Not relevant for this proposal.

B.5 Human health hazard assessment

Under Regulation 793/93/CEE, an extensive risk assessment (RAR) on cadmium metal and cadmium oxide was made by the Belgian authorities for the EU (ECB 2007). Part of the information in the RAR is also valid 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 less soluble, which affects short-term effects, such as acute toxicity.

The end-point specific summaries below are to a large extent based on the EU RAR on cadmium metal and cadmium oxide, but also on a risk assessment of cadmium from EFSA (2009) and an updated review of cadmium (Swedish Chemicals Agency 2011), where also newer studies, not included in the RAR, were assessed.

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

Cadmium and its compounds

According to (Swedish Chemicals Agency 2011), a gastrointestinal absorption of cadmium ranging between 1 and 10 % seems most likely, with men and individuals with adequate iron status in the lower range and those with low iron stores and iron deficiency (mainly women) in the higher range. Newborns and small children may have an even higher absorption, independent of iron status.

Lung retention 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 where cadmium induces metallothionein and forms a complex with this protein. The cadmium–metallothionein complex is released from the liver and transported in the blood to the kidneys. Metallothionein is inducible in

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

different tissues (e.g. liver, kidney, intestine, and lung) by exposure to various agents including cadmium. In the kidneys, cadmium–metallothionein is readily filtered at the glomerulus, and may be efficiently reabsorbed from the filtrate in the proximal tubules. In the tubules, the protein portion is rapidly degraded 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 (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 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).

B.5.2 Acute toxicity

Due to the low water solubility, the acute toxicity of cadmium pigments is expected to be low.

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.

B.5.3 Irritation

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.

B.5.4 Corrosivity

The cadmium pigments are not considered corrosive.

B.5.5 Sensitisation

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.

Cadmium compounds have not been properly tested for sensitisation. However, given the carcinogenic property of cadmium it was assumed that risk reduction measures would be in place and therefore no further testing would be required (ECB 2007).

B.5.6 Repeated dosed toxicity

B.5.6.1 Lung toxicity

Prolonged inhalation of fumes or dust containing cadmium can give rise to chronic pulmonary disorders, characterised by obstructive changes (ECB 2007). Lung effects are not expected after oral exposure to cadmium via food.

B.5.6.2 Kidney toxicity

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 RBP or 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 remains 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 B2M 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).

There is emerging evidence of low-level cadmium exposure causing toxic effects in other tissues. Bone effects, with decrease of bone mineral density, increased risk of osteoporosis and fractures, is an example where associations have been observed at very low cadmium exposure (Swedish Chemicals Agency 2011). Thus, there is reason to challenge the basis of the existing risk assessment paradigm for cadmium. In particular, it is necessary to include the effects on bone, resulting in osteoporosis and fractures, since such effects may occur at lower exposures and have extensive public-health importance in terms of suffering and societal costs. Other effects associated with cadmium that need to be considered are cancer.

In the present Annex XV report we have chosen to perform the quantitative risk assessment on other effects than effects on kidney function. This decision is based on eg. the ongoing debate on the suitability of measuring exposure and effects in the same matrix (i.e. urine) at low exposure levels. Further, it was also considered difficult to assess and quantify the long-term health effects of minor tubular damage. It needs to be emphasized though, that kidney effects are an important part of the risk panorama of cadmium and thus adds to the risks calculated for other end-points.

B.5.6.3 Bone toxicity

In the EU RAR of cadmium metal and cadmium oxide (ECB 2007) it was concluded (based on previous extensive reviews) that it is evident that bone tissue constitutes a target organ for the general and occupational populations exposed to cadmium compounds. The hazard was considered relatively well identified both in experimental and epidemiological studies. The mechanism is, however, not fully understood. The most severe form of cadmium intoxication is Itai-itai disease, which comprises severe signs of osteomalacia and osteoporosis associated with renal disease in aged women.

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 Mammography Cohort (SMC) and the new American National Health and Nutrition Examination Survey (NHANES) studies 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. 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).

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."*

<u>Osteoporosis and fractures</u> (from Swedish Chemicals Agency 2011)

Osteoporosis is characterized by low bone mass and microarchitectural deterioration of the skeleton, leading to fragility and increased risk of fractures. The disease is silent until the first fracture occurs. Common osteoporotic fractures are those at the hip, spine and forearm. These fractures are a considerable public health problem causing a lot of suffering and a burden to society in terms of cost, morbidity and mortality. 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.

The prevalence of osteoporotic complications, fragility fractures, is particularly high in Sweden, as in Norway and Iceland. Statistically, every other women and one out of four men in Sweden will suffer from an osteoporotic fracture during their lifetime. The incidence of hip fractures is more than seven-fold higher in Northern Europe than in the rest of Europe. In fact, it is higher in men in Scandinavia than in women in Central Europe. The reason(s) for the large age-standardized geographical differences is still not known. It is concluded that the differences cannot be explained by differences in risk of slipping, low calcium intake, vitamin D deficiency or by inactivity. The fracture incidence has increased substantially since the 1950ies. As the number of old and very old people in the population increases, a further increase in the prevalence of fractures is to be expected. Although several risk factors have been identified, they cannot fully explain the above mentioned differences, suggesting that several unknown risk factors or combinations of risk factors are involved.

How to study effects on bone in humans: The most adverse endpoint with respect to effects on bone is a fracture. A study investigating the risk of fractures in relation to biomarkers of cadmium exposure requires a large sample size in order to be adequately powered. In these studies the risk is calculated based on comparison of exposure in those who developed a fracture and those who did not. Bone mineral density (assessed by x-ray in g/cm^2) gives an estimation of the status of the skeleton, but is not the only factor predicting the risk of fractures. The bone mineral density can be expressed as it is

– a continuous variable – or by calculation of T-score or Z-score. These two scores are used to predict the risk of fractures clinically. Biochemical markers of bone remodelling are measured in serum or urine and give an indication of the activity of the continuously ongoing formation and degradation of bone tissue. Although these markers may increase our understanding of possible mechanisms involved and may also support inference with respect to causality, they cannot independently be used as markers of an adverse effect.

Fractures

Whereas several epidemiological studies have observed an association between cadmium and bone mineral density (for a review see Swedish Chemicals Agency 2011), only few published studies have so far considered fracture incidence – the most adverse endpoint with respect to effects on bone.

CadmiBel: In their prospective cohort, including 506 subjects, the observed risk ratios associated with doubled urinary cadmium concentrations were 1.73 (95% CI 1.16–2.57; $P = 0.007$) for fractures in women and 1.60 (95% CI 0.94–2.72, $P = 0.08$) for height loss in men. Similar risk estimates were observed if cadmium concentrations in soil, leek and celery sampled in the relevant districts of residence were used as proxy of cadmium exposure instead of the urinary cadmium concentration (In: Swedish Chemicals Agency 2011).

OSCAR: Fracture incidence was also assessed retrospectively in the Swedish OSCAR study. For 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). The relatively high cadmium exposure in this study could be attributed to the inclusion of workers occupationally exposed to cadmium. Associations between cadmium and fracture risk were absent before the age of 50 (Alfvén et al. 2004).

Swedish Mammography Cohort: 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 (Engström et al. 2011a). 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 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 (Engström et al. 2012).

Cohort of Swedish Men: In a population-based prospective cohort study, where individual cadmium intake was estimated using a food frequency questionnaire in the same manner as in the Swedish Mammography Cohort (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).

In a recent study the association between hip fracture risk and cadmium in erythrocytes (Ery-Cd) was investigated (Sommar et al. 2013b). 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 (OR = 3.33, 95 % CI 1.29-8.56).

Dietary cadmium and fractures – a previous risk and cost evaluation

In a recent report from the Swedish Chemicals Agency (2013) the economic cost of fractures caused by dietary cadmium exposure was assessed and it was estimated that the Swedish annual cost amounts to approximately 4.2 billion SEK (approx. 450 million Euros). This figure is based on the estimation that 7 and 13 %, in males and females respectively, of all fractures in Sweden are caused by cadmium exposure, mainly via food, and include direct treatment and care costs for bone fractures (approx. 1.5 billion SEK), as well as a valuation of a lower quality of life and shortened life expectancy for those who suffer fractures, mostly the elderly. For more details, see the text below, which is copied from the Swedish Chemicals Agency report.

Studies of the association between cadmium exposure and effects on people's bone health are a relatively new area of research. It was not until 2011 that two very well conducted studies showed associations between dietary cadmium intake and increased number of fractures.

Previous studies have shown associations between cadmium content in urine and risk of osteoporosis (low BMD in bone density measurements), and it has long been known that massive exposure to cadmium leads to a condition that has given rise to multiple fractures, for example 'itai-itai disease' (Toyoma in Japan).

An association is not regarded as clarified in medical epidemiological research until several independent studies can verify the result. Best available data are often used in economic analyses. This economic study is based on two Swedish population-based prospective studies that point to a clear association between dietary intake of cadmium and increased number of fractures:

- Reference study A1. Engström A. (2011) Cadmium As A Risk Factor For Osteoporosis And

Fractures In Women, Academic thesis at Karolinska Institutet, which is based on the following two published articles:

1) *Engström A, Michaëlsson K, Suwazono Y, Wolk A, Vahter M, Åkesson A. (2011) Longterm cadmium exposure and the association with bone mineral density and fractures in a population-based study among women. J Bone Miner Res. 26:486-95; 2011.*
2) *Engström A, Michaëlsson K, Vahter M, Julin B, Wolk A, Åkesson A. (2012) Associations between dietary cadmium exposure and bone mineral density and risk of osteoporosis and fractures among women. Bone. 50:1372-8.*

- Reference study A2. Thomas, L DK, Michaëlsson K, Julin B, Wolk A and Åkesson A.

(2011) Dietary Cadmium Exposure and fracture incidence Among Men: A population-Based Prospective Cohort Study, J Bone Miner Res, 7:1601-8, 2011.

How cadmium intake increases women's risk of fractures

Some key results from the thesis "Cadmium As A Risk Factor For Osteoporosis And Fractures

In Women" (reference study A1) are presented here. This thesis studies the effects on bone health of long-term low level exposure to cadmium in Swedish women. The study relates to a population-based study on approximately 2,700 women aged 54 to 69. Cadmium exposure was assessed both through measurements of cadmium in the urine and by estimating the dietary intake of cadmium through a food frequency questionnaire linked to a database containing the cadmium contents of foodstuffs. The cadmium concentration in urine is a good proxy of long-term cadmium intake. The group of women studied was divided into two equally large groups (median split), one with lower dietary cadmium exposure and one with higher dietary cadmium exposure.

Table 4. Characteristic (mean) values for the women participating in the study on women[47]

	Group with low Cd exposure (n=1338)	*Group with high Cd exposure (n=1338)*
Dietary cadmium exposure (mean micrograms/day)	*11*	*15*
Age at time of sampling/measurement of bone density, years	*64*	*64*
Education, > 9 years %	*54*	*55*
BMI, Body mass index, kg/m^2	*24*	*24*
Ever taken postmenopausal hormones, %	*59*	*61*
Physical activity, MET hours/day	*41*	*42*
Never smokers , %	*44*	*47*
Alcohol consumption, g /day	*6.8*	*5.8*
Dietary calcium, mg/day	*1081*	*970*
Dietary magnesium, mg/day	*301*	*337*
Dietary iron, mg/ day	*9.9*	*12*
Dietary fibre, g/day	*19*	*24*

As can be seen from the table, the listed factors do not differ greatly between the women who have a high (above the median) and those who have a low dietary cadmium exposure (Table 4). Women with a high dietary exposure to cadmium generally eat somewhat more nutritious food than those with lower exposure as cadmium is often contained in nutritious food such as whole-grain products and vegetables. The estimates that are presented below and form the basis for our calculations have been adjusted using multivariable analysis with respect to the above factors. The results have also been merged with the results on the association between cadmium levels in urine and the risk of fractures. The combined results are shown in the table below (Table 5).

Table 5. Risk (odds ratio) of any first fracture in women with high cadmium intake through food (above the median) compared with women with low intake (below the median) during 11 years of follow-up.

	Women with low dietary cadmium exposure	Women with high dietary cadmium exposure
Average dietary cadmium exposure (µg /day)	11.0	15.0
Number of fractures	183	211
Odds ratio and 95% confidence interval for fractures where the risk in women with low intake is set at 1.*	1.00 (reference)	1.31 (1.02-1.69)

** Multivariable-adjusted analysis taking account of the factors in Table 3*

How cadmium intake increases men's risk of fractures

The study reference study A2, examines how much the fracture risk increases for men with increased dietary intake of cadmium. This study is based on 20 173 men and 2183 fractures. Here too the results are adjusted using multivariable analysis to control for other factors such as age and smoking status, to minimize the possibility of the results pointing to associations other than that investigated.

Table 6. Relative risk of a first fracture for men in relation to the tertile with the lowest dietary cadmium exposure.*

	Men in the lowest tertile of dietary cadmium exposure	Men in the middle tertile of dietary cadmium exposure	Men in the highest tertile of dietary cadmium exposure
Number of fractures	724	709	750
Average dietary cadmium exposure (µg /day)	15.5	18.6	22.2
Relative risk and 95% confidence interval for fracture where the risk is set at 1 in men in the lowest tertile of cadmium intake.	1.0	1.09 (0.98-1.22)	1.19 (1.06-1.34)

** Multivariable-adjusted analysis taking account of around twenty different factors*

The results of this study indicate that there is also an association between cadmium intake and a first fracture for men. The associations are well within the 95% confidence interval.

In the report from Swedish Chemicals Agency (2013) calculations regarding the proportion of fractures that could be explained by cadmium exposure through food were performed; see citation from the report below.

"The association between dietary cadmium exposure and fractures

The calculations are based on data from both women and men produced at Karolinska

Institutet. The increase in risk is based on a comparison between the risk above the median in cadmium intake and the risk below the median. The aetiological fraction, see the table below, is the part of the morbidity explained by a particular exposure. In this case we estimate the proportion of fractures that can be explained by cadmium exposure through food. The formula for calculation is:

$$\text{Aetiological fraction} = p\ (RR - 1)/RR$$

where p is the prevalence of exposure among the cases, i.e. the number of cases in the exposed group divided by the total number of cases and RR is the relative risk. Both p and RR are obtained from studies A1 and A2, where RR is adjusted for a number of confounding

Table 8. Basis of calculation for men (Study A2). Note that the relative risk is converted from three exposure levels (presented in Table 6 on page 34) to two levels (above and below the median).

	All
Number of fractures in the group with cadmium intake above the median	1115
Total number of fractures	2183
p, prevalence of exposure among cases	0.5108
RR (at a cadmium intake above compared with below the median)	1.153
Aetiological fraction; the proportion of the fracture cases that can be attributed to dietary exposure to cadmium.	6.78
95% CI of the aetiological fraction Lower (=5%)	2.4
95% CI of the aetiological fractionHigher (=95%)	10.9

Table 9. Basis of calculation for women (Study A1).

	All
Number of fractures in the group with cadmium intake above the median	211
Total number of fractures	394
p, prevalence of exposure among cases	0.5355
Odds ratio*	1.31
Aetiological fraction; the proportion of the fracture cases that can be attributed to dietary exposure to cadmium.	12.7
95% CI of the aetiological fraction Lower (=5%)	0.8
95% CI of the aetiological fraction Higher (=95%)	23

factors.

As the formula for the aetiological fraction is based on the relative risk (RR) and reference study A1 (but not A2) was based on the odds ratio, a sensitivity analysis was performed in which RR was estimated on unadjusted values and compared with the equivalent odds ratio to see whether RR deviates clearly from OR. RR (= the incidence in those with cadmium intake above the median/the incidence in those with cadmium intake below the median [a/(a+c)] /[b/(b+d)] = (211/1338)/(183/1338) = 1.15

*OR according to a*d/b*c = 211*1155 / 183*1127 = 1.18. There is thus no major deviation*

(RR=1.15 vs OR=1.18), but a small suggestion of overestimation of the risk.

Calculation of the aetiological fraction is based on the assumptions that i) there is a causal relation between cadmium exposure and fractures (section 4.2.1) and ii) that the relationship between cadmium intake and increase in risk is fairly proportional at different intakes above the median. Both studies A1 and A2 provide support for a linear increase in the risk of fracture at increasing cadmium intake."

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/dag, which assuming a body weight of 60 kg, corresponds to a weekly intake of 1.5 mg Cd per kg 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).

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

B.5.7 Mutagenicity

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."*

B.5.8 Carcinogenicity

B.5.8.1 Harmonized classification

Like other toxic effects caused by cadmium compounds, carcinogenic effects are most likely caused by the cadmium ion. Some cadmium compounds have a harmonized classification for carcinogenicity. Cadmium (metal), cadmium oxide, cadmium sulphide, cadmium chloride, cadmium sulphate and cadmium fluoride are classified as Carc. Cat 1B, whereas cadmium formate, cadmium cyanide, cadmium fluorosilica and cadmium iodide are classified as Carc. Cat 2.

B.5.8.2 Cancer - tissues (Swedish Chemicals Agency 2011 and references therein unless indicated otherwise)

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.

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 a statistically significant positive association between dietary cadmium intake and prostate cancer risk, RR= 1.14 (95% CI 1.04-1.24) (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.

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.

The significance of the estrogen-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 % confidence interval; CI) 1.04-1.85; P for trend 0.02). To reduce the influence of endogenous estrogen 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 estrogen 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 estrogen (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 estrogen-like effects of cadmium as well as possible involvement of classical/non-classical estrogen 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 estrogen-like effects do not involve classical estrogen 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 estradiol/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 estrogen 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) [rate ratio (RR), 1.21; 95% confidence interval (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^+ tumors (RR, 1.25; 95% CI, 1.03–1.52) and similar, but not statistically significant associations, were found for ER^- tumors (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, suggest a positive association with U-Cd (Adams et al. 2011); this lends support to the association between Cd and breast cancer risk.

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).

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 harmonized classification for cancer (Carc. Cat 1B or 2). More recent studies suggest an association also 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.

B.5.9 Toxicity for reproduction

B.5.9.1 Harmonized classification

Some cadmium compounds have a harmonized 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.

B.5.9.2 Developmental toxicity

Neurotoxicity and child development

The risk assessments of Cd and CdO performed according to the Existing Substances legislation (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 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.[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).

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

B.5.10 Other effects

B.5.10.1 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 the Belgian study has even included repeated measurements of exposure. Still, it is difficult to judge whether the results could be due to confounding. 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. Noteworthy, is 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).

B.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 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 $\mu g/m^3$ 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."*

For the present restriction proposal a quantitative risk assessment of bone toxicity will be performed. This assessment is based on the difference in risk of bone fractures among males and females in the general Swedish population having a higher or lower, compared to the median, intake of cadmium via food. For further information, see Swedish Chemicals Agency (2013) and section B10 (Risk characterization).

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).

For the present restriction proposal a quantitative risk assessment of breast cancer will be performed. This assessment is based on results from a large prospective population-based cohort of 56 000 postmenopausal women in Sweden, where the effect of dietary cadmium was assessed (Julin et al, 2012a,b). For further information, see section B10 (Risk characterization).

B.6 Human health hazard assessment of physico-chemical properties

B.6.1 Explosivity

Not relevant for this proposal.

B.6.2 Flammability

Not relevant for this proposal.

B.6.3 Oxidising potential

Not relevant for this proposal.

B.7 Environmental hazard assessment

B.7.1 Aquatic compartment (including sediments)

Not relevant for this proposal.

B.7.2 Terrestrial compartment

Not relevant for this proposal.

B.7.3 Atmospheric compartment

Not relevant for this proposal.

B.7.4 Microbiological activity in sewage treatment systems

Not relevant for this proposal.

B.7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

Not relevant for this proposal.

B.8 PBT and vPvB assessment

Not relevant for this proposal.

B.8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Not relevant for this proposal.

B.8.2 Emission Characterisation

Not relevant for this proposal.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of the existing legal requirements

Cadmium has been a substance of concern for many years. This is reflected in a large number of sector specific Union legislative acts which restrict the use and emission of cadmium. The legislations are based on risk to human health as well as risk to the environment. Regarding the use of cadmium based pigment in paints the current EU restriction (REACH, Annex XVII, entry 23) is limited to TARIC codes not including artists' paints.

The wording of REACH Annex XVII, entry 23 is listed in Appendix 1. Other relevant EU legislations on cadmium and its compounds can be found in in a non-exhaustive inventory in Appendix 4.

B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

The overall effect of the Union legislative acts which restrict the use and emission of cadmium has not been studied in detail during the preparation of this restriction proposal. Although some of the restrictions concern food and materials coming into contact with food, an assessment of their effect on the exposure to cadmium via food has not been possible to carry out. However, according to EFSA the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small. EFSA therefore suggest that exposure to cadmium at population level should be reduced (EFSA 2009). Thus, any additional exposure from food should be avoided. A feasible way of achieving further exposure reduction would be an extension of the current restriction on cadmium in paints in REACH Annex XVII, Entry 23 to also cover cadmium in artists' paints.

B.9.2 Manufacturing

B.9.2.1 Occupational exposure

The manufacturing stage of cadmium based artist's paint has not been assessed as it is not within the scope of this report.

B.9.2.2 Environmental release

In 2013 the manufacture volume of the pigments cadmium sulfoselenide red and cadmium zinc sulphide in the EU was in the range of 100 – 1 000 tonnes/year (see section B.2.1). A part of this is used in the manufacture of artists' paints. The cadmium pigment manufacturing will result in an increase of cadmium concentrations locally but is here estimated to be not relevant from an EU wide perspective. However, discharges of a facility exceeding pollutant and activity thresholds according to the E-PRTR regulations are discussed in section B.9.4.

B.9.3 User Scenario –Release from usage of artists' paints

B.9.3.1 General information on releases

The aim of this chapter is to describe the release to waste water from usage of cadmium based artists' paints. The release from this source will be compared to other sources that have the potential to contribute to the cadmium found in sewage sludge at the WWTP.

Cadmium release occurs from two major source categories, natural sources and anthropogenic sources. The emitted cadmium will end up in three major compartments of the environment, water, air and soil. There can however be substantial transfer between the three compartments where discharges to air tend to be most movable whereas most stability occurs in the soil.

Anthropogenic cadmium emissions can occur during production, use and disposal of products containing cadmium. The presence of cadmium in products is either a result from deliberate use or from impurities with no function (Table 14).

Table 14 Products containing cadmium (ICdA 2013)

Cadmium containing products
Nickel-Cadmium Batteries
Cadmium Pigmented Plastics, Ceramics, Glasses, Paints and Enamels
Cadmium Stabilised Polyvinylchloride (PVC) Products
Cadmium Coated Ferrous and Non-ferrous Products
Cadmium Alloys
Cadmium Electronic Compounds
Products containing cadmium as an impurity
Non-ferrous Metals and Alloys of Zinc, Lead and Copper
Iron and Steel
Fossil Fuels (Coal, Oil, Gas, Peat and Wood)
Cement
Phosphate Fertilisers

B.9.3.1.1 Release from usage of artists' paints

Cadmium pigments in artists' paints released to waste water will for a predominating part end up in the sewage sludge at the WWTP. The sludge is in turn partly used as a fertiliser in the agriculture. As described in section B.4, the cadmium compounds used in artists' paints will eventually dissolve in the soil and hence there is a potential crop uptake and in the extension exposure to humans via food (Gustafsson 2013, Appendix 3).

Literature search and consultation with stakeholders

Cadmium in artists' paints has been in focus for numerous years in Sweden. In 2000/2001 the Stockholm Water Association did sampling of sewage lines outside art schools. Since high levels of cadmium were detected the organisation initiated a dialog with different art schools with the aim to improve the situation. Information has also been distributed throughout the artists' community dealing with use and release of cadmium based colours. Despite these efforts studies show that releases to waste water from use of cadmium based artists' paints still occur on a regular basis. The studies we have reviewed (described in short below) are of somewhat different character, some include analyses using a sampling method giving indicative responses i.e. whether the substance in question[10] has been used in the operation during a defined time period. However, the quantity of the substance is not determined. Other base their conclusions on responses from questionnaires sent out to practicing artists's.

In a study from 2000 different sources for the cadmium ending up in the sewage sludge were identified (Enskog 2000). Sales figures were used to quantify the amount cadmium originating from artists' paints. It was further assumed, based on a qualified estimation that 5% of the paint will be released to the waste water during usage. The average cadmium amount sold was approximately 70 kg in Stockholm which corresponds to 3.5 kg cadmium release to the waste water and 10% of the total cadmium reaching the WWTP.

An additional study (Hammarlund and Mimovic 2005) analysed the contributions of cadmium from artists' paints at a municipal waste water plant in Stockholm. The estimated concentrations of cadmium release from use of artists' paints were based on both questionnaires and indicative analyses of the sewerage at art schools. According to the findings artists' paints contribute to the cadmium in the sewage sludge even though no amounts could be estimated.

In 2006 the cadmium release from use of artists' paints in Stockholm was estimated based on the number of practising artists and art students in the area and the amount of cadmium colour each artists' might pour out in the sink (Weiss 2006). The information was gathered through data registers and email or telephone calls to concerned artists. It was assumed that each art student and hobby artist release 2.5 mg Cd/l waste water. This was based on two previous studies where analyses showed release of either 3 or 2 mg Cd/l (Printsmann 1999 and Svanberg 1998). It was also taken into consideration that organised established artists tend to use more cadmium based colours and contribute to 4 mg Cd/l per person. This group was expected to paint two or five days a week, 48 weeks /year. Art students were assumed to be active one or five times/week, during 45 weeks/year whereas hobby painters were predicted to paint once a week. All participants in the survey were thought to discharge one litre of waste water each practising day. Over 6 500 artists were included of which 15% were assumed to be hobby painters. According to the results 1.8 respective 2.2 kg Cadmium will be released to the WWTPs from artists' paints users in Stockholm annually which in 2005 corresponded to 7.2 to 8.8% of the total cadmium content in waste water.

Analyses performed on behalf of the City of Gothenburg indicated substantial release of cadmium from art schools which called upon action from the community (Göteborgs Stad 2006). The municipal waste water company estimated that 10% of the cadmium reaching the treatment plant derived from

[10] Cadmium (Cd) in different cadmium pigments

artists' paints[11]. This resulted in a project two years later with visits to art work shops using cadmium based paints and stores selling artists' supplies. The aim was to involve the users and with voluntary efforts reduce the usage and release of cadmium based paints. The visits demonstrated large flaws when handling the waste from cadmium paints. Cadmium pigments were released to the waste water when the artist's brushes and paint containers were washed after usage in the sink. None of the schools that permitted students to use cadmium colours could demonstrate a proper routine to avoid the paint to be released to the waste water, especially when it came to water based colours. One finding was that since cleaning methods tend to be rather complicated the most effective approach to avoid release to waste water is to totally discontinue the use of cadmium paints.

During the second half of 2012 The Swedish Water & Waste water Association, SWWA (SWWA 2012) measured elevated concentrations of cadmium in the waste water at art schools despite of earlier voluntary efforts to reduce the releases. During a month analyses were performed at ten artists' schools in Stockholm and Gothenburg using an indicative analysis method. The waste water at six of the schools contained cadmium concentrations above average background values. The report also comprised findings from questionnaires sent to different stakeholders including distributors, suppliers and art schools. It could be concluded that cadmium based paints are frequently sold and used. According to the report the concentration of cadmium (Cd) in the paint differs between brands and type of paint. According to analyses water based colours may comprise of up to 45% while the content in acrylic colours is approximately 15%[12].

With the purpose to estimate the amount paint released during use and cleaning we have been in contact with art schools and practising artists (for details see section G). How paint leftovers are handled and which cleaning procedure is used differs between artists depending on tradition, experience etc. Brushes used for oil based colours can be left in turpentine or solvent and then wiped with tissues. It is also common to wash the brushes and cans with soap under running water where cadmium compounds have the potential to be released. When water based paints are used most cleaning occurs under running water in the sink. Studies show (SWWA 2012, City of Gothenburg 2006) that even after providing knowledge regarding cleaning procedures cadmium based paint is still released to the waste water. We assume that it is analogous for the whole EU, something that students and lecturers at the Royal Institute of Art in Stockholm agreed with[13]. Since available cleaning methods are rather complex it is difficult to avoid paint to be released to the waste water (Svensson and Weiss 2005).

A study by Risk & Policy Analysts Limited (2000) also uses a 5% release to waste water in its estimates. This report was prepared for the European Commission, DG Enterprise. The report argues that part of the paint is removed from the brush with e.g. a rag before rinsing in either soap/water or solvent. Moreover it is discussed that water based colours have a larger potential to disappear down the drain whilst oil colours are less likely to be released to the waste water. Based on consultation with stakeholder the report assumes a general release rate of 5% as a result of brush washing etc. during use of artists' paints.

The CSRs (Lead Registrant 2013a, Lead Registrant 2013b) use the Environmental release category (ERC) number 8c, "*Wide dispersive indoor use resulting in inclusion into or onto a matrix",* for consumer use of artists' paints. The release factor to waste water resulting from this use category is 1%. However, this is a default value used for different purposes and not specifically for artists' paints. (Description of ERC 8C: *Indoor use of substances (non-processing aids) by the public at large or*

[11] 2 kg cadmium from artist paint of totally 20 kg estimated cadmium in incoming waste water
[12] Analyses performed by Stockholm Water in the early 2000'
[13] Meeting at Royal Institute of Art in October 2013, for more details see section G.

professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyeing of textile fabrics.)

The ECHA guidance (ECHA 2012) acknowledges that the ERCs should be seen as a staring point for release estimations. ECHA (2012) states that *"If specific information on market data, downstream uses and release of the substance is available, a higher tier assessment may be performed.*

The release estimation can most directly be improved by refining the daily or annual use and the release factor,"

According to actual studies on release from artists' paints (described above) the release is most likely higher. This is also supported by our consultation with different stakeholder (see section G). Therefore the release assessment according to the CSR is here assessed to be an underestimation. .

To summarise, gathered literary studies described above show that it is difficult to estimate the amount cadmium released during the use of paint. Simultaneously it is clear that current cleaning procedures entail cadmium release to the waste water. Despite voluntary efforts releases of cadmium based paints occur. Our consultation (see section G) gives the same indications, e.g. at art institutes in general there is insufficient information on how students should take care of their brushes and paint waste. It is however difficult to estimate the release amount since artists are a heterogeneous group. In this report a release to waste water of 5 % is assumed. This is based on Enskog (2000) described in short above. This release rate is also used in a UK report prepared for the European Commission, as described above (Risk & Policy Analysts Limited 2000). Furthermore, this release estimation is not expected to have changed over the last decade and is therefore assumed to still be applicable. This assumption is rather an underestimation than an overestimation, especially when water based colours are used there might be a higher release to waste water (City of Gothenburg 2006). However, during literature search we have not found any other studies estimating the release of artists' paints to waste water and therefore a release of 5% of the used paint is used in further calculations in this report.

Reliability assessment of a 5% release and difference between oils and water based colours

To assess the reliability of a 5% release we have used an EU exposure model for washing out of a brush used to apply paint.[14] This model was primarily developed for biocidal products and skin exposure but we assess that some parameters and estimates can also be applied for artists' paints and release to waste water. *In this EU model it is assumed that after painting 1/8 of the volume of the brush is paint.* We will use this estimate to measure the reliability of a 5% release to waste water.

Thus if estimating the volume of a typical artist's paint brush and the volume used per painting session an average release can be calculated.

To get access to such information we visited a supply store in Stockholm, Konstnärernas centralköp.[15] The store is run by a group of professional artists and cooperates with over 50 suppliers and delivers artists' paint within Sweden and abroad. Artist's paint brushes come in a variety of shapes and sizes, with natural or synthetic hairs. According to Konstnärenas centralköp their best seller for acrylics is a

[14] HEEG opinion on exposure model Primary exposure scenario – washing out of a brush which has been used to apply paint. Ispra, 07/07/2011

[15] Established in 1962, http://www.konstnarernas.se/omoss.html?submenu_id=-1

set of three different brush sizes. These sizes are the most popular both for beginners and professional artists. The difference is that beginners buy cheaper products and professionals tend to purchase brushes of higher quality. In this estimate we are using the medium brush assuming that all of the brushes included in the set are used with the same frequency.[16] The average brush has a size of 2 x 1 x 0.5 cm, which corresponds to a volume of *1 ml*. Using the EU model results in that *0.125 ml (1/8) paint will remain in the brush after painting.*

According to consultation at the store *2 ml* cadmium based paint (mainly acrylics) is used at each painting occasion. Even though this is assumed to be a realistic example, there are obviously differences amongst artists. Since cadmium based paints are expensive they are however not used in excess. This has been communicated through the public consultation. As indicated in the stakeholder consultation in section G cadmium colours are denser and less paint is needed during use. A use of 2 ml paint provides *a potential release of 6.3%* (0.125/2).

This average potential release of 6.3% only covers release from brushes. There are other routes for the paint (especially water based paint) to reach the waste water, e.g. cleaning of palettes and emptying cans in the sink. On the other hand there are artists making efforts to avoid release of paint during usage. In a survey received during public consultation[17] 64% of the EU respondents claim they take steps to minimise the amount paint released to the waste water. Close to 25% of all answers stated they prevent all cadmium from going down the drain. Other waste minimising methods were using disposable palettes, wipe of paint excess before washing and minimise their use of cadmium based paints. This is important information even though a majority of artists taking minimising steps still cause some degree of release. Also, the survey reveals that there are a lot of artists not taking any measurements at all (36% of the EU respondents). 8.5% of the respondents use disposable palettes or dispose of excess paint in the trash. This suggests that an important release route might be via cleaning of palettes in the sink. The survey also indicates that cleaning methods are complicated; fewer than 4% attempt to use e.g. flocculation and filtering.

Comments received during public consultation imply that there is a difference in how oil and water based paints is handled. Brushes used for oil based colours are for most part left in turpentine or solvent and then wiped with tissues. (Also excess of water based paint on the brush after usage is in some cases wiped off before cleaning.) Therefore a lower release to waste water can be assumed for oil colours, even though release from oil based paint occurs to some extent according to consultation (section G) and comments received during public consultation. An alternative to using a 5% release for all cadmium based artists' paints would be to separate oils from water based colours and use a higher release rate for water based colours (6.3%) and a 1% release for oils (according to the general default value presented by the lead registrant). This would however only include release from brushes whereas the 5% used in the dossier also includes release from e.g. washing of palettes.

To summarise, to evaluate the reliability of the 5% release rate used in the dossier we have used an EU exposure model in combination with consultation. This resulted in a release of 6.3% from cleaning of brushes. The estimated 6.3% is mainly applicable for water based colours. Since oil colours in general have a lower release to waste water an average release for the whole group of artists' paints is most likely lower. On the other hand, there are other potential release routes when paint is used (e.g. washing of palettes) which suggests that 6.3%, which only reflects washing of brushes, might be an underestimation. Taking all this into account, we assess that a 5% release considering all cadmium based colours is a realistic release scenario. This release rate is also assumed (based on

[16] Size of small brush: 1.1 x 0.5 x 0.2, large brush: 2.7 x 1.5 x 0.5 (cm)
[17] by Golden Artist Colors, A total of 1518 survey responses were received from EU and outside EU

consultation) in a RPA report prepared for the European Commission, DG Enterprise, which is described above (Risk & Policy Analysts Limited 2000).

According to our analysis a 5% release rate is a restrained assumption that may very well be an underestimation.

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

SEAC opinion on the release factor

A very crucial presumption for the whole dossier is the release factor of cadmium from cleaning of the brushes. The release factor of 5 % used in the default scenario by the dossier submitter is based on 1.) an estimate in a Swedish report for Stockholm Vatten (Stockholm Water Supply), 2.) an assumption in a report prepared by RPA dealing with Risks to Health and Environment by Cadmium and 3.) an exposure model for washing out of a brush used to apply paint primarily developed for biocidal products and skin exposure. The value is not supported by measuring results. In practice, the exact release factor for all paints containing Cd sold in Europe can hardly be measured at all. It is not enough to measure elevated Cd concentrations in the waste water (see section B.9.3.1.1). For measurement of the release factor at a particular site (e.g. at an art school) a.) the concentration in the waste water (mg Cd/l), b.) the flow of waste water (l/a) and c.) the consumption of Cd containing artist paints with respective Cd percentages ((kg Cd-paint x % Cd)/a, for x see Table 15) has to be estimated. The release factor RF is then given by $RF=a \cdot b/c$. In a sensitivity analysis performed by the dossier submitter it was shown that the benefits would increase by a factor of 2 with a release factor of 10 % instead of 5 % and would be reduced by a factor of 5 with a release factor of 1 %. There is a linear correlation, there is no real sensitivity assessment, the result indicates a simple multiplying or dividing exercise.

In Public Consultaion more than 150 commenters (out of 666) explained their techniques to clean their brushes (using waste paper and rags) to avoid transfer to waste water.

B.9.3.2 Exposure estimation

For humans in general cadmium exposure originates from ingestion of food, which ascends from the uptake of cadmium by crop via soil. Anthropogenic cadmium input to soils originates from sewage sludge, fertilisers, manure and atmospheric deposition (ICdA 2013). For the purpose of this report the exposure scenario is centred on indirect exposure of humans via food that has grown on soil using sewage sludge as fertiliser. This is discussed further down in this section (B.9.3.2.3). The exposure route in focus is demonstrated in Figure 3. In addition to use of sludge, other fertilisers, atmospheric deposition and lime pose as significant sources for the cadmium in the soil and thus in the crop. This is considered in section 9.4. The results from sections B.9.3.2.3 and B.9.4 are then used in the human exposure via food assessment in section B.9.7.

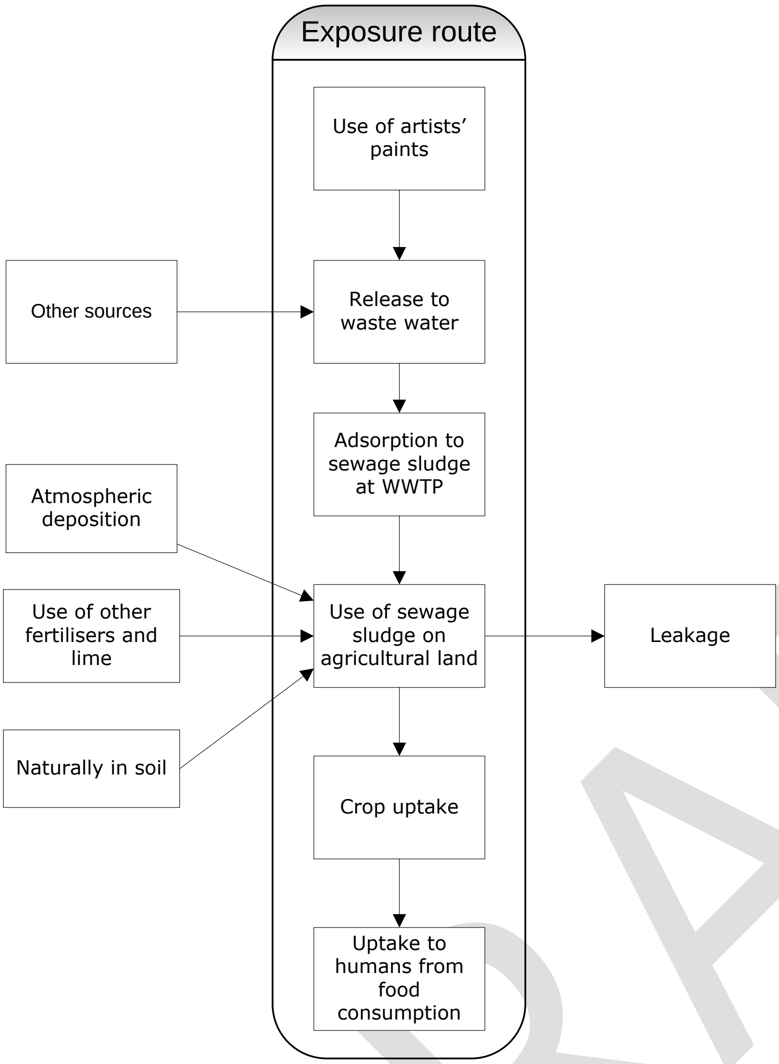


Figure 3 Exposure to cadmium from use of cadmium based artists' paints

B.9.3.2.1 Workers exposure

Not relevant for this proposal

B.9.3.2.2 Consumer exposure

Exposure of artists during usage of paint has not been assessed since it is not within the scope of the proposed restriction. Since cadmium based colours are considered high quality products and come at a high price the primary consumer tends to be practicing artists. However hobby artists also use cadmium based paints.

According to the Chemical Safety Reports cadmium pigments are chemically (and/or physically) contained in a stable matrix, and therefore not directly obtainable for exposure of the consumer during usage (Lead registrant 2013a and Lead registrant 2013b).

B.9.3.2.3 Indirect exposure of humans via the environment

The aim of this section is to assess the cadmium content in sludge originating from artists' paints and compare it to other major sources for the cadmium released to waste water. The results of the calculations in this section are together with results from section B.9.4 (other sources of cadmium in the soil) used in the assessment of human exposure via food (section B.9.7).

Artists' paints

There are few studies published where the cadmium content in artists' paints has been tested. The Swedish Chemicals Agency has therefore performed tests to further evaluate the quantity of cadmium in different artists' paints. Consulting with manufactures and suppliers (ColArt 2013, Kreatima 2013) resulted in a representative selection of colours. Different compositions of cadmium pigments (CdSSe and/or CdZnS) were included, representing colours ranging from yellow to orange and red. The test included four different types of colours; oil colours, water based colours, acrylics and gouache. 16 representative colours of different brands were analysed of which four were tested twice. The result is presented in Table 15 and the analysis report is available in Appendix 5. The cadmium concentration differs depending on type of colour. This is considered in our further calculation. However the variation within the same colour type is dealt with by using the average value of each colour type. The arithmetic mean is assumed to be a representative value since the geometric mean and the median give similar results.

Table 15 Analysis results of cadmium in artists' paints

Type of colour	Cd pigments (*Colours*) included	Range (g Cd/kg paint)	Average cadmium content (g Cd/kg paint)	Cadmium Percentage (%)
Oil	PR 108 (*Deep Red*), PR 108 (*Red*), PO 20/PY35 (*Orange*), PO 20/PY35 (*Yellow deep*), PY35 (*Lemon*)	150-517	355	36
Acrylics	PR 108 (*Red Medium*), PO 20 (*Orange*), PY 35/PO 20 (*Yellow Medium*), PY 35 (*Yellow Pale*)	56-169	121	12
Water based	PR 108 (*Scarlet*), PR 108 (*Red Deep*), PY 35/PR 108 (*Orange*), PY 35/PO 20 (*Yellow*), PY 35/PR 108 (*Yellow Deep*), PY 35 (*Lemon*)	280-448	352	35

Gouache	PY 35 (*Lemon*)	134-156*	145	15

*one double analysis

The members of the trade association CEPE represent some 90% of the European artists' colour market. On the basis of consultation with CEPE the estimated total quantity of cadmium based paints placed on the EU market is approximately 39 tpa[18]. Since the information from CEPE was based on their extrapolations from a limited sample of members this is a rough estimation but the best one available. The cadmium colours are included within the so called fine arts sector.

According to 2012 members' statistics acrylics represent one-third (33%) of the fine arts sales (based on value). Oil colours represent 17%, watercolours 10% and gouache 4%. Dry techniques, i.e. pastels and pencils make up 20% of the sales. The rest is "others" such as inks, auxiliaries (medium, solvent, fixative etc.), including materials for art work restoration which comprise 0.2%. These proportions have basically remained intact over the last decade and there have been no major changes in the relative quantities. Price of cadmium based paints differs between different colour types (see section F) which leads to the partitioning presented in Table 16 when quantity is considered.

Calculations using trade statistics and the analysis results in Table 15 make a total of more than **6.4 tpa** cadmium in artists' paints used in EU. This is demonstrated in Table 16. It is assumed that the percentages for different types of cadmium based colours are the same as for the fine art sector in general. The sum of pastels & pencils and others have been proportionally divided into the other groups.

[18] Ranging between 30-40 tpa for CEPE members. This gives an average of 35 tpa. Taking into account that CEPE represents 90% of the EU market results in a total of approximately 39 tpa.

Table 16 Market share of different types of artists' paints and their cadmium content

Type of colour	% of EU market	% of EU market Included sum of pastels & pencils and others (proportionally divided) In terms of value	% of EU market Included sum of pastels & pencils and others (proportionally divided) In terms of quantity	Quantity on EU market Tonnes/year	Cadmium Quantity Kg/year
Oil	17	27	14	5.3	1897
Acrylics	33	52	79	30.8	3710
Water colours	10	16	4	1.6	563
Gouache	4	6	3	1.3	187
Dry techniques	20				
Others	16				
Total	**100**	**100**	100	**39**	**6357**

We have not been able to get any quantity data concerning private import from outside EU. However according to manufactures and suppliers (ColArt 2013, Konstnärernas centralköp 2013, Kreatima 2013) private import occurs primarily from other EU countries and thus included in the statistics from CEPE. Private import from outside EU is therefore not accounted for in the quantity estimations above, which may lead to an underestimation.

Taken into account that, as stated above, 5% of the paint is released during use results in a total cadmium release to waste water of **0.32 tpa**.

Other major sources

With the aim to identify and estimate the magnitude of different sources in sludge, data from substance flow analysis in Stockholm is used. Data is up-scaled to an EU-level with the assumption that the use pattern of cadmium is similar across the EU. In Table 17 different sources of cadmium in sludge are listed. Information from the Cohiba project of industrial release to the MWWTP (according to the Substance Flow Analysis, SFA) is also included (Andersson et al. 2012). Cadmium from sources such as atmospheric deposition and traffic has the potential to reach the WWTP via storm water. As storm water runoff runs across the land surface, it assembles and transports cadmium straight into water bodies (separate system) or to a WWTP (combined system). The estimations in Table 17 are based on data from Stockholm with approximately 40% combined systems where cadmium might reach the sludge at the WWTP.

The information is the most recent one found and is presented to roughly compare the size of the different sources. In our calculations of cadmium amounts originating from artists' paints information from stakeholders and analysis results, presented in Table 15 and Table 16, are used. A couple of reports from the EU commission (Milieu 2008 and Milieu 2010) present more recent data on total cadmium quantity in sludge which is used in estimations in this report.

Table 17 Major sources of cadmium in waste water (Mainly Swedish data up-scaled to EU level)

Source	Quantity (tonnes/year)	Percentage (%)	Year of data	Literature reference
Car washing and degreasing	5.1		2003	Månsson and Bergbäck 2005
Manufacture of products	0.8			Andersson et al. 2012
Manufacture of basic metals	4.3			Andersson et al. 2012
Sewerage & waste excl urban waste water treatment plants	0.5			Andersson et al. 2012
Traffic	1.7		2002	Bergbäck et al. 2006
Detergents	1.3[a]		2002	Bergbäck et al. 2006
Consumption of food	1.9[b]		2003	Bergbäck et al. 2006
Tap water	0.26[c]		2003	Bergbäck et al. 2006
Pollutant in Zn. Emission of Cd from the use of Zn in construction materials, due to corrosion.	0.006- 6.4		2003	Bergbäck et al. 2006

a) With new legislation cadmium content should be reduced
b) Refers to that 95% passes through the human body and 5 % of the intake is accumulated.
c) Mean value (range from approx. 0.2 to 0.5 tonnes). Includes quantity in produced water (below detection limit) and input from pipes and taps.

Cadmium in sludge and use in agriculture

Approximately 95% of the cadmium in the waste water connected to treatment ends up in the sludge at the WWTP (Stockholm Water Company 2013). Information on cadmium, phosphorus and nitrogen content in sewage sludge are listed in Table 18. The data was submitted by 18 Member States between 2004 and 2006 and presented in a report launched by the European Commission as a part of the revision of the Sewage Sludge Directive (Milieu 2008 and Milieu 2010). The values should be considered with some caution, as they are the average values reported by the individual countries. Poland, Cyprus and Latvia have the most cadmium contaminated sludge according to the study, both related to dry matter as well as to the amount of phosphorous.

The EU limit value for cadmium in sludge for use in agriculture is 20 to 40 mg/kg dry matter and the maximum value for cadmium which may be added annually to agricultural land (based on a 10-year average) is 0.15 kg ha^{-1} y^{-1} (Council directive 86/278/EEC). However, most European countries have lower limit values for cadmium in sludge, Denmark having the lowest at 0.8 mg/kg (JRC 2012).

According to Directive 86/278/EEC[19] the use of sludge is prohibited on

- fruit and vegetable crops throughout the growing season (exception of fruit trees)
- ground intended for cultivating fruits and vegetables which are in immediate contact with the soil and usually eaten raw (ten months prior to and during the harvest).
- forage or grassland crops (certain conditions)

Since the data listed in Table 18 is the most recent from an EU perspective, the median values from this data set (mg Cd/kg ds, total P and mg Cd/kg P) will be used in further calculations in this report.

Table 18 Quality of sewage sludge recycled to agriculture in 2006 (Milieu 2008)

Member State	Cd (mg/kg ds)	Total N (% ds)	Total P (% ds)	mg Cd/kg P	mg Cd/kg N
Belgium	1	3.9	6.7	14.9	25.6
Germany	1	4.3	3.7	27.0	23.3
Spain	2.1	4.5	3.6	58.3	46.7
Finland	0.6	3.4	2.4	25.0	17.6
Italy	1.3	4.1	2.1	61.9	31.7
Portugal	<0.4	1.7	2	20.0	<23.5
Sweden	0.9	4.5	2.7	33.3	20
United Kingdom	1.3	2.8	2.2	59.1	46.4
Bulgaria	1.6	7.2	4.3	37.2	22.2
Cyprus	6.9	4.1	4.9	140.8	168.3
Czech Republic	1.5	3.6	1.9	78.9	41.7
Estonia	2.8	4.9	3.4	82.4	57.1
Hungary	1.4	3	1.4	100.0	46.7
Lithuania	1.3	2.3	0.9	144.4	56.5
Latvia	3.6	3.9	1.3	276.9	92.3
Poland	4	0.9	0.6	666.7	444.4
Slovenia	0.7	3.2	3.9	17.9	21.9
Slovakia	2.5	3.8	1.8	138.9	65.8
Average	**2**	**3.7**	**2.8**	**110.2**	**69.5**
Median	**1.4**	**3.9**	**2.3**	**60.5**	**44.0**

Current and future estimations of sludge production and use in agriculture

In Table 19 total sludge production (2003-2007) and quantity used in the agriculture within the EU is presented. In some Member States, such as Portugal, Spain and the UK, sewage sludge quantities recycled to agriculture have continued to increase, while in some countries, e.g. the Netherlands and some regions of Belgium, Austria and Germany, agricultural application has effectively been banned due to i.e. growing public concerns (Milieu 2008). France and United Kingdom had the highest relative amount of sludge recycled to agriculture (70 and 68%). For EU 27 close to 4 million tonnes are used

[19] Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture

on arable soil.

Table 19 Sewage sludge production and amounts distributed to agricultural soil in the EU 27 (Milieu 2008)

Member State Sludge production	**Year**	**Sludge production (t ds)**	**Recycled to Agriculture**	
			(t ds)	**(%)**
Austria (a)	2006	252,800	38 400	16
Belgium				
-Brussels region	2006	2 967	0	0
-Flemish region	2006	101 913	0	0
-Walloon region (b)	2007	31 380	10 927	35
Denmark	2002	140 021	82 029	59
Finland (c)	2005	147 000	4 200	3
France	2007	1 125 000	787 500	70
Germany (d)	2007	2 056 486	592 552	29
Greece	2006	125 977	56 400	<1
Ireland	2003	42 147	26 743	63
Italy	2006	1 070 080	189 554	18
Luxembourg (e)	2005	8 200	3 780	46
Netherlands	2003	550 000	34	<1
Portugal	2006	401 000	225 300	56
Spain	2006	1 064 972	687 037	65
Sweden	2006	210 000	30 000	14
United Kingdom	2006	1 544 919	1 050 526	68
Sub-total EU 15		*8 874 862*	*3 728 638*	*42*
Bulgaria	2006	29 987	11 856	40
Cyprus	2006	7 586	3 116	41
Czech republic (f)	2007	231 000	59 983	26
Estonia (g)	2005	26 800	3 316	12
Hungary	2006	128 380	32 813	26
Latvia	2006	23 942	8 936	37
Lithuania (h)	2007	76 450	24 716	32
Malta (i))		Nd	nd	nd
Poland	2006	523 674	88 501	17
Romania	2006	137 145	0	0
Slovakia	2006	54 780	33 630	62
Slovenia	2007	21 139	18	<1
Sub-total EU 12		*1 260 883*	*266 885*	*21*
Total		**10 135 745**	**3 995 523**	**39**

a) Austria: in addition in 2006, 177,000 t DM of industrial sludge (mainly from cellulose and paper industry) were produced and 3% of this was recycled to agriculture.
b) Wallonia: in addition in 2007, 48,000 tds of industrial sludge (mainly from paper industry,) were also recycled to agriculture.
c) Finland: the remaining is recycled in landscaping operations including landfill cover.
d) Germany: in 2007, 18% were also recycled in landscaping operations.

e) Luxembourg: in 2005, in addition 32% were reported to be composted – no final outlet provided
f) Czech republic: it is reported that up to 2/3 of sewage sludge is ultimately recycled to agriculture mainly after composting
g) Estonia: estimate based on 20 kg/pe and 90% collection and treatment as no figures were reported for total sludge production.
h) Lithuania: in addition in 2007, 11% were recycled on other land
i) No data for Malta, assumed zero

In Table 20 the total amount of cadmium applied on agricultural land with sludge have been estimated for the different countries for which average cadmium content was available, based on the data in Table 18 and Table 19. The estimations in Table 20 are *only* presented as a comparison between different Member States and *not* used in our further calculations. It should be noted that the reporting years for amount applied sludge (2002-2007) and the average cadmium content in sludge (2006) may not match. Among the countries for which cadmium data were available, Spain and UK spread by far the highest amount of cadmium with sludge on agricultural land. The total cadmium amount added with sludge in Sweden was estimated in another study (Swedish Chemicals Agency 2011) to 46 kilo year 2008.

Table 20 Cadmium applied in different Member States

Member States	Sludge in agriculture (tds/y)[20]	Cd in sludge (g/t ds)[21]	Cd applied in agriculture with sludge (kg/y)
Austria	38 400		
Belgium	10 927	1	11
Denmark	82 029		
Finland	4 200	0.6	3
France	787 500		
Germany	592 552	1	593
Greece	56 400		
Ireland	26 743		
Italy	189 554	1.3	246
Luxembourg	3 780		
Netherlands	34		
Portugal	225 300	<0.4	<90
Spain	687 037	2.1	1443
Sweden	30 000	0.9	27
United Kingdom	1 050 526	1.3	1365
Bulgaria	11 856	1.6	19
Cyprus	3 116	6.9	22
Czech republic	59 983	1.5	90
Estonia	3 316	2.1	7
Hungary	32 813	1.4	46
Latvia	8 936	3.6	32
Lithuania	24 716	1.3	32
Malta	Nd		
Poland	88 501	4	354
Romania	0		
Slovakia	33 630	2.5	84
Slovenia	18	0.7	<1
Total	**3 995 523**		

[20] Reporting year varied between 2002 -2007 for the different countries.
[21] Reported for 2006.

Based on reviews of individual EU countries Milieu (2010) estimated the sludge production and fractions to different disposal routes in EU27 in year 2010 and 2020. This is demonstrated in Table 21 below.

Table 21 Estimates of annual sludge production and percentages to agriculture (Milieu 2010)

Member State	Total (tds) 2010	Agriculture (%)	Total (tds) 2020	Agriculture (%)
Bulgaria	47 000	50	180 000	60
Cyprus	8 000	50	16 000	50
Czech Republic	260 000	55	260 000	75
Estonia	33 000		33 000	15
Hungary	175 000	77	200 000	60
Latvia	25 000	30	50 000	30
Lithuania	80 000	30	80 000	55
Malta	10 000		10 000	10
Poland	520 000	38	950 000	25
Romania	165 000	0	520 000	20
Slovakia	55 000	50	135 000	50
Slovenia	40 000	10	50 000	15
Austria	273 000	5	280 000	5
Belgium	170 000	9	170 000	10
Denmark	140 000	50	140 000	50
Finland	155 000	5	155 000	5
France	1 600 000	60	1 600 000	75
Germany	2 000 000	30	2 000 000	25
Greece	260 000	10	260 000	5
Ireland	135 000	75	135 000	70
Italy	1 500 000	50	1 500 000	35
Luxembourg	10 000	90	10 000	80
Netherland	560 000	0	560 000	0
Portugal	420 000	50	420 000	50
Spain	1 280 000	70	1 280 000	70
Sweden	250 000	10	250 000	15
United Kingdom	1 640 000	65	1 640 000	65
Total	**11 811 000**	**45**	**12 884 000**	**48**

The production of sludge and the quantity used in the agriculture has increased during the last years. This increase is expected to continue due to different reasons (Milieu 2010). For calculation in human exposure via food scenario (section B.9.7) we will use the most recent data available. Therefore we assume a sludge production of 11 811 000 tpa of which 45% is applied on agricultural land (Table 21). Even though this is estimated data it is expected to be more representative than older reported data.

Cadmium in sludge and the contribution from artists' paints

As estimated above, 0.32 tonnes cadmium from use of artists' paints is released to the waste water each year. A majority will end up in the sewage sludge at the municipal waste water treatment plant (MWWTP). However not all households are connected to such a treatment.

Approximately 80% of the inhabitants in Northern and Southern European countries are connected to waste water treatment (EEA 2013). The part of the population connected is even higher in Central European countries (exceeding 90%). The connection rate in Eastern Europe is about 67% whereas the part connected in South-East Europe (Turkey, Romania and Bulgaria) is about 40%. According to the Seventh Report on the Implementation of the Urban Waste Water Treatment Directive, 91/271/EEC (EC 2013a) 82% of the waste water in the EU was put through secondary treatment in year 2009/2010.[22] Ten Member States had levels of compliance of 97-100%. However, among EU-12 Member States there were countries with only 39% of the waste waters obtaining sufficient secondary treatment.

As a result of stricter waste water treatment demands this suggests that the percentage presented in the EC implementation report might be somewhat higher today. However, a connection rate to WWT of 82% as stated in the report (EC 2013a) is assumed for EU and used in calculations in this dossier.[23]

On the basis of the argument above 0.26 tonnes cadmium from artists' paints use reach the WWTP.[24] As stated earlier around 95% ends up in the sewage sludge which results in **0.25 tonnes** annually.

Using the median value of 1.4 mg Cd/kg dry substance (Table 18) and estimates of sludge production (11 811 000 tonnes, Table 21) give a total of **16.5 tonnes** cadmium in EU produced sewage sludge.[25] According to our calculations **0.25 tonnes** originate from artists' paints which is **1.5%**[26] of the total cadmium in EU produced sludge.

Application of cadmium via sewage sludge in the agriculture

As demonstrated in Table 18 sludge consists of approximately 2.3% phosphorus which suggests that more than **0.12 million tonnes** phosphorus originating from sludge is annually used in the agriculture.[27]

An average of 45% of the produced sludge is applied on agriculture land (Table 21, year 2010). A cadmium concentration of 1.4 mg/kg ds (Table 18) results in **7.4 tonnes** cadmium annually applied on EU agriculture land of which **0.11 tonnes** originate from artists' paints. A summary of cadmium content in artists' paints (based on analyses and sales statistics) is presented in Table 22.

Table 22 Overview of cadmium content and release from artists' paint use and quantity in sewage sludge

Content in artists' paints (tpa)	Release to waste water, 5% (tpa)	Reaching WWTP, 82% (tpa)	Ending up in sewage sludge (tpa)	Used in agriculture (tpa)
6.4	0.32	0.26	0.25	0.11

Other sources of cadmium in the soil such as fertilisers, deposition and lime are described in section B.9.4. At the end of that section a summary table (Table 27) presents the calculation results (the cadmium amounts from sewage sludge and other sources of cadmium in soil). The results are then

[22] A four percentage point improvement
[23] In this report we are assuming that the produced sludge is from a plant with secondary treatment. A majority of the EU Member States gather their waste waters in collecting systems with an average compliance rate of 94%. However, there are Member States where there is only partial or in some cases no sewage collection (EC 2013a)
[24] 0.32 x 0.82
[25] 1.4 g Cd/tonne ds x 11 811 000 tonnes ds = 16.5 x 10^6 g Cd = 16.5 tonnes Cd
[26] 0.25/16.5
[27] 0.023 x 11811000 x 0.45

used in the human exposure via food assessment (section B.9.7).

RAC assessment:
RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

B.9.3.2.4 Environmental exposure

Not relevant for this proposal

B.9.4 Other sources of cadmium in soil

B.9.4.1 Point source emission and Deposition

Three available estimations of air emissions of cadmium are described below, with the EMEP values finally chosen for the further calculations of this dossier.

EU Risk Assessment Report

According to the EU Risk Assessment Report (ECB 2007) the atmospheric deposition values in rural areas differ between Member States. Measured deposition ranged from **0.15 to 4 g ha^{-1} y^{-1}**, depending on Member State and the testing method. **1 g ha^{-1} y^{-1}** was estimated as a rough EU average. The deposition is generally decreasing from northern part of Europe to the

central parts, and for the southern European countries no available data could be found. In addition, an EU deposition average of **0.4 g ha^{-1} y^{-1}** was calculated based on direct emissions from different sources in 16 member states, see Table 23. The overall area used was 3.56 10^6 km^2. The predicted EU average was lower than a majority of the measured data. The report points out that it is unclear whether the net deposition is overestimated (since even data of wet-only deposition might include cadmium re-suspended from the soil) or underestimated.

Table 23 Direct atmospheric cadmium emission in EU-16, tonnes cadmium/year (ECB 2007)

Source	**EU total (tonnes)**	**% of total**
Cadmium alloys and batteries production and recycling	0.853	0.6
Cd/CdO production	3.9	3.1
Other non—ferrous metals	9.7	7.7
Production of iron and steel	31	24.7
Oil/Coal combustion	54	43.0
Processing phosphates	0.7	0.6
Municipal incineration	3.2	2.6
Wood/Peat combustion	1.7	1.4
Other (cement, glass prod., traffic)	>19	>15.1
TOTAL	**>124**	

The European Pollutant Release and Transfer Register, E-PRTR

E-PRTR contains data on pollutant releases to air, land and water. The data base covers the European Union and EFTA countries and consists of annual information reported by approximately 28 000 industrial facilities comprising 65 economic activities in different industrial sectors. The emission of cadmium from different activities is demonstrated in Table 24. Figure 4 present the emission distribution to air per industry. Reported release to soil is dominated by the paper and wood production and processing (85 % according to Table 24), which is of local concern. Release to water is not within the scope of this report and therefore not included.

Table 24 Point source release of cadmium 2011 (E-PRTR 2013)

Industry activity	**No Facilities**	**Release to air (tonnes)**	**Release to soil (tonnes)**
Energy sector	109	3.20	-
Production and processing of metals	94	6.03	-
Mineral industry	43	0.557	-
Chemical industry	28	0.251	-
Waste and waste water management*	189	0.327	0.0201
Paper and wood production and processing	57	0.471	0.170
Animal and vegetable products from the food and beverage sector	1	-	0.0097
Other activities ○ Pretreatment or dyeing of fibres or textiles	1	-	-
○ Surface treatment of substances, objects or products using organic solvents	4	-	-

○ Production of carbon or electro-graphite through incineration or graphitization	1	-	-
Total	**527**	**10.8**	**0.2**

*Including a) Disposal or recovery of hazardous waste, (b) Incineration of non-hazardous waste included in Directive 2000/76/EC - waste incineration, (c) Disposal of non-hazardous waste, (d) Landfills (excluding landfills closed before the 16.7.2001, (e) Disposal or recycling of animal carcasses and animal waste, (f) Urban waste-water treatment plants, (g) Independently operated industrial waste-water treatment plants serving a listed activity.
The release to soil of approximately 20 kg is disposal of non-hazardous waste. However no more information is available. Therefore more clarified source information is used in the sewage sludge calculations in section B.9.3.

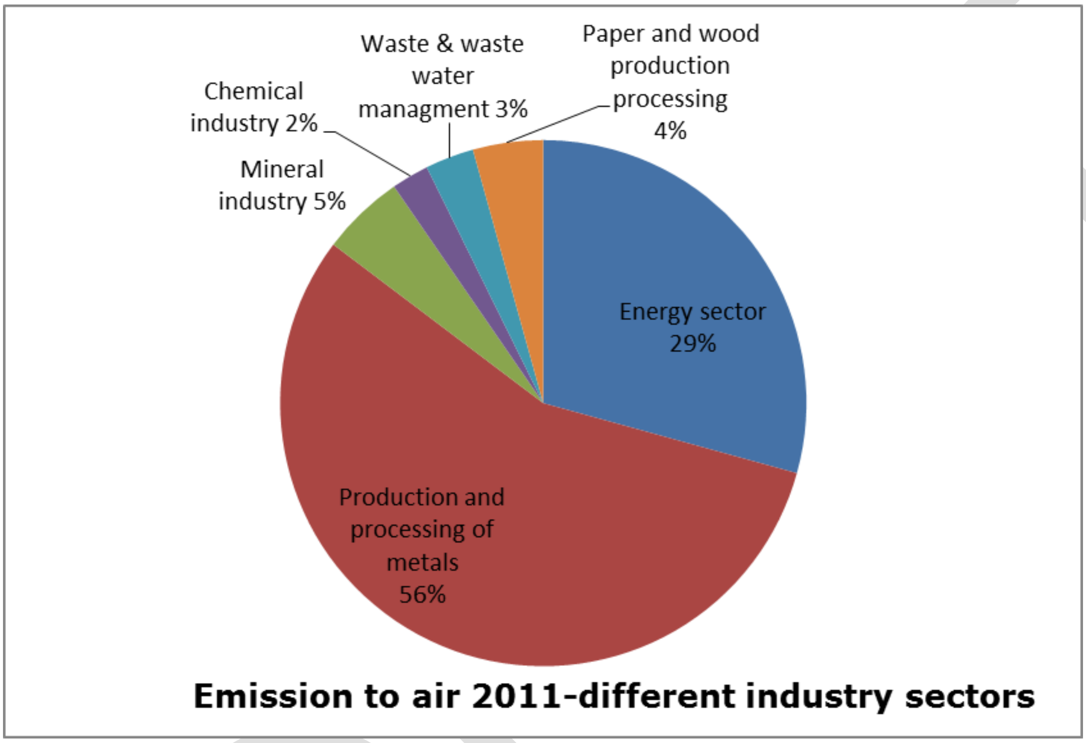


Figure 4 Release of cadmium per industry activity in EU 27 (E-PRTR 2013)

On the basis of the data from the E-PRTR it is difficult to estimate the actual deposition. It should be noted that releases and transfers must be reported to the register only if the emissions of a facility are above the activity and pollutant annual thresholds set out in the E-PRTR regulations (for cadmium 10 kg to air, 5 kg to water and land). Therefore it is probable that the total emission is underestimated.

The European Monitoring and Evaluation Programme (EMEP)

EMEP is a programme under the Convention on Long-range Transboundary Air Pollution (CLRTAP). It is a co-operation for monitoring and evaluation of long-range transmissions of air contaminants in Europe. *Parties* carry out monitoring at regional observing sites within Europe. The data is submitted to the EMEP Chemical Coordinating Centre at NILU, Norwegian Institute for Air Research (Aas and Breivik 2011). Cadmium wet deposition data at 55 monitoring sites distributed over 18 Member States, 2 Candidate Countries (Iceland and Serbia) and Norway are presented in Appendix 6. The gathered data demonstrates that the deposition of cadmium differs quite substantial between monitoring sites with values ranging **from 0.005 to 1.2 g ha^{-1} y^{-1}.** Also during periods of plant growth some of the cadmium deposition will fall onto the leaf surfaces and not reach the soil[28]. Another uncertainty is that differences because of natural variations, due to different background concentrations, are not considered. Therefore it is difficult to present a general picture for EU as a whole. Calculations based on data in Appendix 6 give a median deposition of **0.23 g ha^{-1} y^{-1}** and an average of **0.32 g ha^{-1} y^{-1}**.[29]

In this report the median value from EMEP **0.23 g ha^{-1} y^{-1}** will be used in the exposure assessment (section B.9.7) since we assess it to be the most reliable data in between the two other estimates described above. The median value is preferable as it places equal weight on all observations.

The total arable land area in EU 27 is approximately 102 961 800 ha (Eurostat 2013c, EC 2012a). A deposition of 0.23 g ha^{-1} y^{-1} results in a total of approximately **24 (23.7) tonnes** cadmium annually to the arable land in EU.

B.9.4.2 Mineral (phosphate) Fertilisers

Phosphate fertilisers contain cadmium. The quantity of cadmium depends on the phosphate rock from which the fertiliser was produced and can vary from very low concentrations to amounts over 300 mg/kg P_2O_5 (IFA 2013a). Based on P, the cadmium concentrations are about 2.3 times higher[30]. Low cadmium rock phosphates with concentrations under 100 mg Cd/kg P are typically found in Russia (Kola) and Florida. Rock phosphates from Morocco and Togo in Africa have average to high cadmium amounts of 100-350 mg Cd/kg P (ECB 2007). Because of the difference in quality, input of cadmium in agricultural soils via phosphorous fertilisers varies in the EU. Cadmium concentrations in used fertilisers have been reduced over the years. Presently there is no EU regulation limiting the maximum level of cadmium in fertilisers. However, some Member States have permanent derogations from the 'no EU regulations' to use national recommendations.

Based on different studies the EU RAR (ECB 2007) reported the cadmium flux per year to agricultural soils originating from phosphate fertilisers. This can be viewed in Table 25. There is a considerably large variation in the data where most of the information is estimated from the total amount phosphorous consumed per Member State, the cadmium concentrations in phosphorous fertilisers plus the used arable surface in the individual country. Since these data are country averages nothing can be said about existing differences between cropping systems.

Table 25 Annual cadmium input to agricultural soil from phosphate fertilisers in different European countries (cited from the EU RAR (ECB 2007))

Country	Cadmium input		Information source
	tonnes	g/ha	
Austria	2.9	1.1	Pearse 1996, data based on the OECD questionnaire (1995), conversion to cadmium flux (g ha^{-1}y^{-1}) made by Landner et al. 1995
Austria		0.8	Hutton et al 2001
Belgium	1.5	0.59-1.40	Hutton et al 2001

[28] The potential uptake or retranslocation of Cd when it is deposited on leaf surfaces is considered negligible. This is further discussed in section B.9.7

[29] Using the reported data for cadmium deposition at the 55 monitoring sites and converting µg/m^2 to g/ha

[30] P=0.436 x P_2O_5

Denmark	0.707	0.79-1.44	Hutton et al 2001
France	92	3.2	Landner et al. 1996, data from 1990
Finland	0.2	<0.1	Pearse 1996, data based on the OECD questionnaire (1995), conversion to cadmium flux (g $ha^{-1}y^{-1}$) made by Landner et al. 1995
Finland		0.02-0.1	Landner et al. 1996, data from 1990
Finland	0.052	0.03	Finnish Environmental Institute 1997
Finland		0.025	Hutton et al 2001
Germany	20.4	1.7	Pearse 1996, data based on the OECD questionnaire (1995), conversion to cadmium flux (g $ha^{-1}y^{-1}$) made by Landner et al. 1995
Germany	22.1	1.28	Kiene 1999
Greece	10	2.8	Landner et al. 1996, data from 1990
Ireland	9	1.8	Landner et al. 1996, data from 1990
Ireland	7.4	1.67	Hutton et al 2001
Italy	44	3.0	Landner et al. 1996, data from 1990
The Netherlands	3	1.5	Pearse 1996, data based on the OECD questionnaire (1995), conversion to cadmium flux (g $ha^{-1}y^{-1}$) made by Landner et al. 1995
The Netherlands		4.5	Moolenaar and Lexmond 1998
Norway	0.072	0.12-0.21	Hutton et al 2001
Portugal	5	1.4	Landner et al. 1996, data from 1990
Spain	30	1.5	Landner et al. 1996, data from 1990
Sweden	1.1	0.5	Pearse 1996, data based on the OECD questionnaire (1995), conversion to cadmium flux (g $ha^{-1}y^{-1}$) made by Landner et al. 1995
Sweden		0.8	Landner et al. 1996, data from 1990
Sweden		0.20	Hellstrand and Landner 1998
United Kingdom	11.3	0.9	Pearse 1996, data based on the OECD questionnaire (1995), conversion to Cadmium flux (g $ha^{-1}y^{-1}$) made by Landner et al. 1995
United Kingdom		1.0-2.1	Hutton et al 2001
EEC (1990)	231	2.5	Landner et al. 1996, data from 1990

In the year 2001 the EU Member States assessed the risk to health and the environment from cadmium in fertilisers (ERM 2001). Using values from nine Member States and the reported utilisation of phosphorous fertilisers a weighted average of cadmium concentration in fertilisers was achieved, that of 68 mg Cd/kg P (or 30 mg Cd/kg P_2O_5). When the total EU[31] was taken into account a higher average of 81.7 mg Cd/kg P (35.7 mg Cd/kg P_2O_5) was obtained (where a value of 60 mg Cd/kg P_2O_5 was assigned to the non-reporting MS).

An additional study from 2007 analysed the trace element content in phosphate fertilisers sold on the EU market. 196 samples from 12 EU countries were analysed for cadmium and other metals. The cadmium concentrations varied from below 0.7 up to 42 mg Cd/kg with an average of 7.4 mg Cd/mg (median 5.0 mg Cd/kg). Expressed on P basis the average is **83 mg Cd/kg P** (36 mg Cd/kg P_2O_5). Around 20% of the analysed samples had concentrations over 140 mg Cd/kg P (61 mg Cd/kg P_2O_5) (Nziguheba and Smolders 2008).

According to statistics (Eurostat 2013a) the quantity of commercial phosphorus (P) consumed in the agriculture (EU27) was 1 026 000 tonnes in year 2011[32]. If using the more recent survey that indicates an average of 83 mg Cd/kg P a total release of cadmium to EU27 soils would be approximately **85 tonnes**[33] from use of phosphorous fertilisers.

The application rate of mineral fertiliser, kg P or P_2O_5 per ha and year, is a key parameter in determining the cadmium load from fertilisers. The actual requested fertiliser amount varies with the crops considered and soil conditions.

In 2010 approximately 40% of the total EU 27 land area comprised of utilised agricultural area (UUA). Arable land stood for three fifths or 60% of the UUA (Eurostat 2013c). In 2011 the UUA in the EU27 was 171 603 000 ha (EC 2012a) which include **102 961 800 ha arable land** (assuming the same share as for 2010). Using the estimated cadmium amount of 85 tonnes cadmium will result in an annual input of **0.82 g Cd/ha** (which assumes that all arable land is fertilised with mineral fertiliser). Also, it is important to emphasize that this is an uncertain value since the obtainability of phosphate rock containing low cadmium concentration varies with time.

B.9.4.3 Manure

Animal manure contains cadmium since the heavy metal appears in domestically produced and imported animal feed as well as in grazed herbage. However low, there are also cadmium contaminations in phosphate feed additives. Typical cadmium amounts in different kinds of manure in European countries are presented in Table 26.

Table 26 Cadmium (Cd) concentrations in EU produced manure (cited from Smolders 2013)

Country	Manure types	Min. mg Cd/kg DM	Median mg Cd/kg DM	Max mg Cd/kg DM
United Kingdom (Nicholson et al. 1999)	Dairy cattle manure	<0.1	0.38	0.53
	Dairy cattle slurry	<0.1	0.33	1.74
	Beef cattle manure	<0.1	0.13	0.24
	Beef cattle slurry	0.11	0.26	0.53

31 15 Member States

32 Most recent available data found. This figure is marked 'provisional' in the database. In year 2010 the consumption was 1 104 000 tonnes and the year before that 1 004 000 tonnes

33 83 mg Cd/kg P= 83 g Cd/tonne P. 83 g Cd/tonne P x 1 026 000 tonnes P = $85.x10^6$ g Cd = 85 tonnes Cd

	Pig manure	0.19	0.37	0.53
	Pig slurry	<0.1	0.30	0.84
Sweden (Eriksson 2001)	Pig slurry	0.27	0.28	0.32
	Pig manure	0.19	0.25	0.36
	Dairy cattle slurry	0.09	0.12	0.18
Austria (Sager 2007)	Cattle manure		0.27	
	Pig manure		0.46	
	Pig dung		0.33	
	Poultry dung		0.46	
Average (standard deviation)			**0.2 (0.1)**	

Cadmium input from manure is for a major part recycled cadmium since over 90% of the cadmium eaten by animals routes into manure (IFA 2013a). A net input of cadmium occurs at a continental scale with a net import of feed crops (ECB 2007). Previous mass balance studies have shown that manure is of little importance for the accumulation of cadmium in soil (Blombäck et al. 2000, Eriksson 2009). However, when large amounts of manure are spread on limited land regions for disposal reasons, there is a substantial pollution risk. This occurs in areas with intensive livestock operations, in the EU mainly in North Germany, Denmark, the Netherlands, Belgium and Brittany in France. According to the EU Risk Assessment Report it is not likely that manure application pose as a significant net cadmium source in EU agricultural soil. A parallel analysis is made regarding application of compost. The EU RAR also emphasises that the Cd:P ratio concerning manure is lower compared to most mineral fertilisers. Thus, lower cadmium concentrations are obtained in farming procedures where mineral fertilisers are partly replaced by manure as a phosphorous source.

According to a mass balance for EU 27+1 performed by Smolders (2013) the net cadmium input from manure is 0.006-0.014 g Cd $ha^{-1}y^{-1}$ (or **1-2 tonnes totally**). This was based on an EU feeds import of 30 million tonnes feed.[34] In the following calculations **0.01 g Cd ha^{-1} y^{-1}** was used as a net cadmium input. This will also be an assumed input in the human exposure assessment (section B.9.7).

B.9.4.4 Lime

Lime is added to arable soils to uphold the soil pH_{CaCl2} between 6.0 and 6.5. The reason is to compensate for acidifying processes and to warrant optimal nutrient availability as well as crop growth (Smolders 2013). Similar to phosphorus fertilisers, lime may comprise high levels of cadmium. Some decades ago the recommended average lime rate in Sweden was 100-150 kg CaO $ha^{-1}y^{-1}$. The average cadmium content in lime currently on the Swedish market is approximately 0.4 mg/kg CaO (Sternbeck et al 2011) which results in an annual input of 0.04-0.06 mg Cd/ha. Smolders

[34] In year 2010 and assuming cereal based feed with a concentration of 0.02-0.05 mg Cd/grain

(2013) estimated the application rates based on data from UK and France. The larger application charges in England gave a higher cadmium input (0.14 g Cd $ha^{-1}y^{-1}$ and an average of 0.3 mg Cd/kg CaO) whereas for France an annual input was 0.04 g Cd $ha^{-1}y^{-1}$.

Requirements for liming are dependent on soil pH. A majority of Western Europe has a soil pH_{CaCl2} between 4.5 and 5.0 (Eurosoil 2010). In the Mediterranean territory soil pH_{CaCl2} is usually higher, 6.0 to 7.5. However, in these measurements non-agricultural soils are included. According to mapping of only agricultural soils the pH_{CaCl2} is 5.8 (median value, NGU 2011). Smolders (2013) sets the liming requirement (EU average) to be 250 kg CaO $ha^{-1}y^{-1}$. Together with a cadmium content of 0.35 mg Cd/kg CaO[35] will give an input of **0.09 g Cd $ha^{-1}y^{-1}$.** This is used in the human exposure assessment (section B.9.7).

B.9.4.5 Summary of calculation results in section B.9.3 and B.9.4

In this report three fertilising scenarios are discussed and used in calculations in the human exposure via food assessment (section B.9.7).

A) Application of 30 kg P ha-1 year-1 (mineral as well as sludge fertilisers) according to realistic worst case, high input – low output scenario from the EU Risk Assessment Report (ECB 2007)

B) Average- A low application scenario where all sludge use in agriculture is spread over all arable land in EU together with other fertilisers

C) A realistic local worst case scenario where it is assumed that all fertilising of potatoes is performed with sewage sludge

As described in section B.4 it is in this dossier assumed that cadmium in soil, originating from artists' paints pigments, over time will be equally available to plants as cadmium from other sources. It is further expected that there is no difference in cadmium availability in sludge amended soils compared to native soils.

For *scenario A* an input of 30 kg P ha-1 year-1 is used. This is based on estimations from the EU RAR (ECB 2007). This scenario represents farming systems with high input, which according to the EU RAR may be found in e.g. wheat and corn rotations. Phosphorus applications in these systems are usually 30 kg P ha^{-1}. It is in this dossier assumed that the 30 kg P consists of both sludge and mineral fertilisers in the same relative amount as is used in the whole EU. According to the calculations in section B.9.3 approximately 0.12 million tonnes P, originating from sludge is annually used in the agriculture. Estimations above show that around 1 million tonnes P is applied by mineral fertilisers. If using this relation between used sludge and mineral fertilisers in scenario A, 11% will come from sludge and 89% from mineral fertilisers[36]. This gives a cadmium input with sludge and mineral fertilisers of 0.2 and 2.2 g ha-1 year-1 respectively[37].

Scenario B is the only scenario that can be applied on the whole EU population and therefore used to estimate the general risk for EU. However, this scenario is based on diluted data since all fertilisers are distributed evenly over all arable land. In addition to sludge with an input of 0.07 g Cd ha^{-1} $year^{-1}$ [38] and mineral fertilisers with an input of 0.82 g ha-1 year-1, manure contributes with 0.01 g ha-1 year-1 according to calculations above.

[35] Average of Sweden (0.4 mg Cd/kg CaO) and UK (0.3 mg Cd/kg CaO)
[36] 0.12/(0.12+1) and 1/(0.12+1)
[37] 11% x 30 kg P ha^{-1} x 60.5 mg Cd P^{-1} (Table 18) + 89% x 30 kg P ha^{-1} x 83 mg Cd P^{-1}
[38] 7.4 tonnes Cd (see section B.9.3.2.3)/102 961 800 ha

S*cenario C* is a worst case local scenario where we assume that only sludge is used for fertilising in a crops rotation system. The European Commission report (Milieu 2010) mentioned above states that the limiting factor for sludge application is normally the maximum permissible supplement of total nitrogen (N_{tot}) which for most uses is 250 kg N ha^{-1} y^{-1}. The limit is set out in the Nitrates Directive 91/676/EEC and will be reduced to 175 kg N ha^{-1} y^{-1} in vulnerable zones. Under certain conditions it may also be allowed to apply 500 kg N ha^{-1} every second year if the nitrogen availability of the fertiliser is low (which is possible for dewatered sludge). However, sewage sludge is a phosphorus rich fertiliser in respect to the P/N ratio related to the P/N demands of crops. This will result in an excess of P if the N demands of crops are met. Milieu (2010) emphasises that if the application rate of sludge is limited by P requirements of the crop it would have consequences for the operational capacity of using sludge in the agriculture since the application rate would have to be reduced. Also other studies show that N requirements of crop appear to be the limiting factor for the sludge application rate due to P fixation by components in the soil (Rappaport et al 1987). According to Milieu (2010) the application rate of sludge is often 5-10 tonnes ds/ha. This gives an estimated average rate of 7.5 tonnes ds/ha[39]. Using the cadmium concentration of 1.4 mg/kg ds (Table 18) gives a load of **10.5 g Cd ha^{-1} y^{-1}** which is used in the human exposure via food assessment. However, in scenario C it is assumed that only potatoes are grown using sludge. Other vegetables and cereals are expected to be cultivated according to the average scenario.

For all three scenarios the annual deposition and lime are accounted for.

Table 27 presents the estimations that will be used for further calculations in the human exposure via food assessment (section B.9.7).

[39] (5+10)/2

Table 27 Sources of cadmium in soil used in the exposure assessment (section B.9.7)

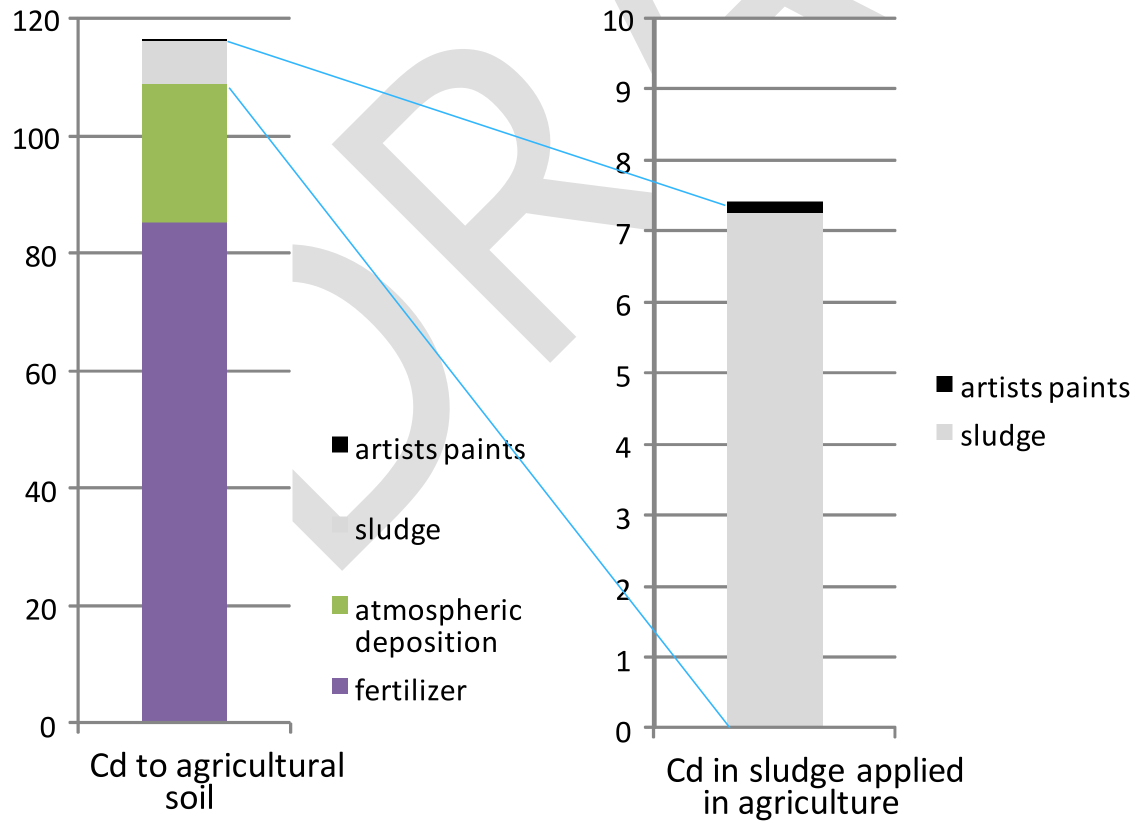
Source	**Cd (t/y) EU total**	**Scenario A 30 kg P ha^{-1} y^{-1} Cd (g ha^{-1} y^{-1})**	**Scenario B Low application rate Cd (g ha^{-1} y^{-1})**	**Scenario C Only fertilising with sludge Cd (g ha^{-1} y^{-1})**
Sludge	7.4	0.2	0.07	10.5
thereof Artists paints	0.11			
Deposition	24 (23.7)	0.23	0.23	0.23
Mineral fertiliser	85 (84.6)	2.2	0.82	-
Manure	1-2	-	0.01	-
Lime	-	0.09	0.09	0.09
Sum	**118.4**			

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

SEAC opinion on section B.9.4.5

The graphic illustration of the data in Table 27 shows the minimal contribution of Cd originating from artists paint to the overall Cd flow.



Graphic illustration of numerical data in Table 28

B.9.5 Overall environmental exposure assessment

Not relevant for this proposal.

B.9.6 Combined human exposure assessment

Not relevant for this proposal.

B.9.7 Human exposure via food

The main exposure routes of cadmium for the general populations are via food and smoking (ECB 2007). The sources to the cadmium exposure were described by EFSA (2009) according to Figure 5.

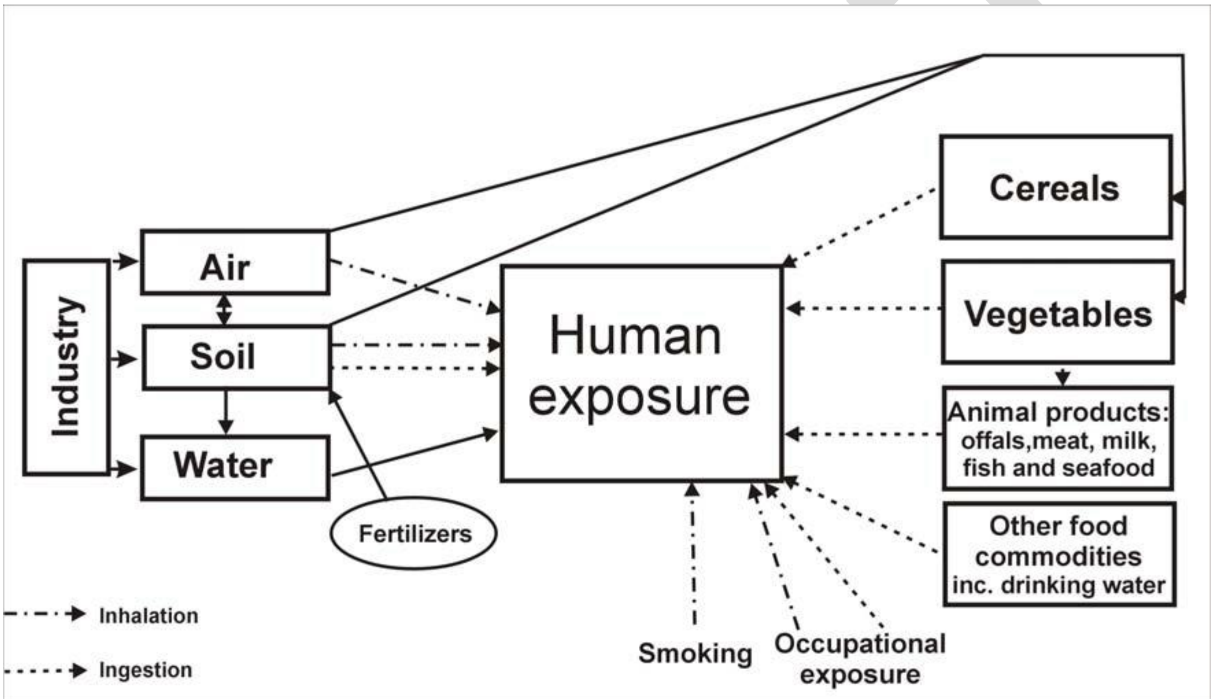


Figure 5 Sources of human exposure to cadmium (Figure 1 in EFSA 2009).

B.9.7.1 Intake of cadmium via food in Europe

Different reviews have reported cadmium concentrations in food items in Europe. Detailed summaries were done by EFSA (2009 and 2012). Typical occurrence data for different food categories are presented in Table 28.

Table 28 Typical cadmium occurrence in different food categories (EFSA 2012).

Food Categories (Food Ex Level1)	Occurrence Means[40] (µg/kg)	Food with outstanding high concentrations within the group
Grains and products	15.2-38.1	
Vegetables and products	4.4-1122	seaweeds
Starchy roots and tubers	14.1-21.7	
Legumes, nuts and oilseeds	4.5-371	oilseeds
Fruit and fruit products	0.5-8.0	
Meat and edible offal	2.7-362	horse meat, edible offal
Fish and seafood	19-317	water molluscs
Milk and dairy products	4.6-17.2	
Eggs and products	3.3-10.4	
Sugar and confectionary	2.3-135	chocolate
Fats and oils	2.3-30	
Fruit and vegetable juices	1.0-9.6	
Non-alcoholic beverages	0.7-44.5	
Alcoholic beverages	0.5-6	
Drinking water	0.2-3.4	
Herbs, spices and condiments	3.5-90	
Food for children	1.2-14.5	
Special nutritional products	0.5-1515	algal formulations
Composite food	3.3-58.7	
Snacks, desserts, other foods	4.1-28	

Dietary exposure to cadmium from food sources is determined not only by cadmium levels in foods, but also by consumption patterns. Some of the food items that contain high cadmium levels as reported in Table 28 are rarely consumed by the general European population (e.g. seaweeds, oilseeds and edible offal) and might therefore not be important for overall intake. Other food items with high consumption in the total population or in some sub-populations can be major contributors to the overall cadmium intake even if they contain only low cadmium levels (EFSA 2009 and 2012).

Intake estimates from different countries were summarised by EFSA (2009, 2012) and the intake of cadmium from different food categories was calculated. The contribution of different food groups to overall cadmium exposure were expressed for different age groups separately for each food category (EFSA 2012). Cereals and cereal products as well as vegetables, nuts and pulses are consistently the categories with the greatest contributions for the adult population in all countries (EFSA 2009).

[40] Called middle bound means in the EFSA report.

Substantial variation occurs in the minimum and maximum contributions in different countries of some other food categories like tap water (partly due to the recording of water consumption), miscellaneous foods/foods for special dietary uses and fish and seafood. The mean weekly dietary exposure to cadmium via food for adults (60 kg) was estimated to be 2.3 µg kg^{-1} body weight (bw) and varied between 1.89 (Bulgaria) to 2.96 (Hungary) µg kg^{-1}bw in the 16 European countries for which data were available in the EFSA report from 2009. High exposure (sum of 95th percentile for cereals and vegetables and mean exposure for the other food categories) in the different countries was estimated to be 3.54-3.91 µg kg^{-1} bw. The food categories in this review are very broad and the cadmium concentrations in each category are based on a compilation of data reported from the Member States, taking into account the period from 2003 to 2007. This leads to uncertainty in the results. The result obtained for Sweden in the EFSA report, mean weekly exposure of 2.3 µg kg^{-1} bw was compared with the result from a more detailed intake analysis in Sweden (Sand and Becker 2012). The estimated median weekly exposure, 1 µg kg^{-1} bw, was about a factor 2 lower in the Swedish study compared to the exposure estimated for Sweden in the EFSA report. The difference in the results is partly explained by differences in methodologies applied in the exposure assessments.

EFSA (2012) analysed the intake of cadmium with food for different age groups, based on cadmium occurrence data in food from 22 EU Member States combined with the EFSA Comprehensive European Food Consumption Database (version, published by EFSA 2011, including results from 32 different dietary surveys). According to this study the average and 95th percentile lifetime cadmium dietary exposure for the European population was estimated at 2.04 and 3.66 µg kg^{-1} body weight and week, respectively. The dietary cadmium exposure was highest in toddlers and lowest in the elderly population. From the different surveys covering the "adult" age group an average exposure of 1.77 (range 1.50-2.33) µg kg^{-1} body weight and week was calculated, while the 95th percentile exposure was 3.13 (range2.47-4.81) µg kg^{-1} body weight.

From different detailed Swedish studies (Amzal et al. 2009; Sand and Becker 2012; Swedish National Food Agency 2012) it is clear that different crops contribute with the largest part of the cadmium intake via food; typically cereals (39-50%), potatoes (19-25%) and vegetables (10-14%). The intake estimates made by EFSA (2012) also showed that food consumed in larger quantities had the greatest impact on cadmium dietary exposure, although crops contributed a bit less compared to the Swedish data. On average for Europe the main contributions to cadmium intake via food, based on broad food categories, were 26,9 % from grains and grain products, 16 % from vegetables and vegetable products, and 13.2 % from starchy roots and tubers. For EU-members in the age group "adults" (18- < 65 years) the average contributions from different crops to the total intake with food were 26.6 % from grain and grain-based products, 17.4 % from vegetables and vegetable products, 12.3 % from starchy roots and tubers (mainly potatoes and potato products) and 1,7 from beans and oil seeds.

B.9.7.2 Cadmium in crops

Cadmium concentrations vary between different crops. Smolders and Mertens (2013) summarised surveys reporting cadmium concentrations in crops and calculated typical average values for different types of crops (Table 29). If soil Cd data and/or soil pH data were available, crop Cd were calculated for a soil Cd concentration of 0.40 mg kg^{-1} and pH=6.5. Crops are sorted in increasing order of dry weight based concentrations. As mentioned above, the crops contributing most to the exposure of cadmium via food do not contain the highest concentrations of cadmium.

Table 29 Average (or median) crop Cd concentrations of different surveys and compilations (Cited from Smolders and Mertens, 2013).

Plant	Cadmium concentration (µg kg $^{-1}$ fresh weight)	Cadmium concentration (µg kg $^{-1}$ dry weight)	Notes
Non-durum wheat	22–80	25–92	Means/medians of five surveys (n=1,733)
Green bean (pod)	7	67	n = 47
Durum wheat	~90	~100	
Grassland (mainly drygrass)	14	116	n = 900
Potatoes	23	117	n = 239
	15-32	75-160	Means/medians of three surveys (n = 296)
Fodder maize (entire shoot)	23	195	n=197
Leek (edible part)	20	200	n=139
Tomato (fruit)	10	210	n=57
Onion	13	270	n=83
Carrots	31	282	n=172
	32-44	290-400	n=191 means/median of two surveys
Lettuce	39	780	n=170
Spinach	76	850	n=95

B.9.7.3 Uptake in crops

Due to its mobility in soil, cadmium can easily be taken up by plants.

In the EU RAR for cadmium metal and cadmium oxide (ECB, 2007) constant (linear) transfer factors between cadmium in soil and cadmium in crops were proposed for diffuse sources. It is stated in the RAR that these transfer factors should not be used for assessing the risk of sludge borne cadmium, because increasing sludge levels in soil increases the metal sorption capacity of the soil why a curvilinear increase in crops is expected with increased sludge borne cadmium. As discussed in section B4 there are long-term field studies which indicate that use of sludge does not result in higher sorption of cadmium in the soil. It was also concluded in the RAR that there were not enough data from long-term sludge field trails that allowed identifying specific transfer factors for sludge.

In the more recent review by Smolders and Mertens (2013), the authors observed that studies where cadmium is administered as a Cd^{2+} salt indicate that uptake increases linearly with soil cadmium, provided that all other soil properties remain constant. However, they also observed that when soil properties differ total soil cadmium concentrations are poor predictors of cadmium concentrations in crops. This is because bioavailability varies largely in different soils, due to differing conditions such as pH, organic matter content, chloride salinity and zinc deficiency. The authors had noted that instead of constant transfer factors, Freundlich type functions are often used to account for soil factors explaining the transfer factors and for possible non-linearity between soil and crop cadmium for all kinds of soils (and sources of Cd) i.e. $\log[Cd_{plant}] = a + b\log[Cd_{soil}] + c[pH] + d\log[\%OM]$ where Cd_{soil} is the total cadmium concentrations in soil and OM is the organic matter content in soil. The authors conclude from the compiled functions that mostly $b < 1.0$, indicating that there is some non-linearity, that c is 0.05–0.40 and that d is often not statistically significant (indicating a weak relationship with OM).

It may be argued that the availability of cadmium in pigments may be lower than other cadmium compounds due to its low water solubility. However as was discussed in chapter B.4 cadmium sulphides and selenides in pigments are thermodynamically unstable in the surface horizon of agricultural soil, and will probably 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 several decades, cadmium from pigments has a similar solubility and bioavailability as an easily soluble cadmium salt such as cadmium chloride.

It will therefore be assumed in this report that cadmium in soil, originating from pigments, in the long-term will be equally available to plants as cadmium from other sources (in the time perspective of decades to a hundred years).

A fraction of cadmium that is measured in plants may have been taken up directly from air. Smolders and Mertens (2013) cite a recent compilation of studies which show that the fraction airborne cadmium in plant cadmium varied markedly. Based on this compilation, a prediction was made on the fraction airborne cadmium in lettuce. It was estimated that air borne cadmium would make up 1 % of cadmium in lettuce at current air concentrations (0.2 ng Cd/m^3) in rural areas in EU and background soil concentration (0.2 mg/kg ds). In areas closer to point sources emitting to air the relative contribution from air in plant may be higher. The contribution of airborne cadmium to crop cadmium is often neglected, but may explain the weak associations of crop cadmium with soil cadmium, especially in areas with high cadmium concentrations in air (Smolders and Mertens 2013). Three studies on the fraction of airborne cadmium are reviewed in the EU RAR (ECB 2007. One study indicates that at ambient cadmium concentrations in soil (0.3 mg/kg) and moderate air concentrations (0.3-0.5 ng Cd m^{-3}, corresponding to a deposition rate of 1.6-2.9 g ha^{-1} $year^{-1}$) the airborne cadmium can contribute significantly (21%) to the cadmium in wheat flour, whereas the contribution to cadmium in spinach and carrot root was non-significant under these conditions. It is concluded in the RAR (ECB 2007) that the fraction air-borne cadmium can be neglected in crops grown in contaminated soils if the atmospheric cadmium deposition is low. Hence, in the risk characterization for humans exposed via the environment in the EU RAR, the fraction airborne cadmium in crops was not taken into account. In the calculations below ambient conditions will (as regards concentrations in air and soil) be assumed and hence the possible fraction airborne cadmium will be neglected.

For the purpose of this assessment the following is assumed:

- Linear relationship between cadmium in soil and cadmium in crops (when other soil properties are constant), as was assumed in the EU RAR (ECB, 2007).
- Similar transfer factors between cadmium in soil and cadmium in crops, independent of the source of cadmium to soil (atmospheric deposition, mineral fertiliser, sludge, lime, manure).

- Similar availability of all cadmium in sludge, independent of the source of the cadmium to the sludge, i.e. cadmium from pigments has the same availability as cadmium from other sources to sludge (and soil).
- The contribution of airborne cadmium directly taken up by crops is considered negligible.

B.9.7.4 Modelling future cadmium concentrations in soil, and the contribution from artists' paints

The bulk concentration of cadmium in agricultural soils (and the bioavailability, see section B.4) determines the uptake of cadmium in crops.

The bulk cadmium concentration is dependent on the parent material of the soil, the input of cadmium via deposition and fertilisers and other agricultural measures (such as liming) and the output via leaching and crop offtake. It is also dependent on how the roots of the plants are distributed into the soil layers. It is therefore very difficult to estimate how much of the cadmium in crops that come from the parent material and how much comes from the anthropogenic input. However, since linear relationship between cadmium in soil and cadmium in crops is assumed Increases in crops concentrations can be related to increases in soil concentrations, which can be measured/estimated. The cadmium concentrations in soil increase when cadmium input to the soil exceeds the output (i.e. via crop offtake and leakage). In the EU RAR (ECB 2007) the future (after 60 years) soil concentrations were predicted for eight scenarios representative for European agriculture, assuming todays input and output conditions. Increased concentrations (between 2.8 and 46 %) were predicted for six of the seven scenarios.

In a Swedish field study with long-term sludge amended arable soil it was shown that, after 41 (1956-1997) years of sludge amendment, cadmium concentrations in the uppermost 20 cm was approximately a factor 4 higher compared to control soils (Bergkvist et al 2005). The accumulated amount of sludge applied during these 41 years was about 250 tons (ds) ha^{-1}, hence corresponding to a yearly sludge application of 6 tons (ds) ha^{-1}(which is in accordance with European application rates today, B.9.4.5.). It was estimated that totally about 1500 g cadmium per hectare (37 g Cd ha^{-1} yr^{-1}) had been supplied on the sludge amended field (sewage sludge contributed with about 1400 g, P fertiliser with about 90 g and atmospheric deposition with about 20 g (Bergkvist et al 2003) compared to 130 g Cd ha^{-1} (3.2 g Cd ha^{-1} yr^{-1}) supplied on the control field.

In another Swedish field study either zero, one or three tons (ds) sludge per hectare have been applied on a yearly basis to experimental fields during 30 years (Andersson, 2012). There are no estimates of how much the total input of cadmium have been over the years (including sludge, atmospheric deposition and NPK fertilisers), but the cadmium content in the applied sludge have varied between 3.5 and 0.5 mg/kg ds between the application years. It is apparent that cadmium concentrations in the sludge amended soils are higher compared to fields where no sludge has been applied. On average application of one ton sludge per hectare and year have resulted in 4-5 % higher soil concentrations after 30 years and application of three tons of sludge per hectare and year have resulted in about 9-11 % higher soil concentrations after 30 years compared to soils without sludge application (Andersson, 2012).

According to what it said above it can be assumed that cadmium in crops increases approximately linearly with cadmium in soil, provided that all other soil properties remain constant. With these assumptions it can be estimated how much of predicted change in crops concentration is due to cadmium in sewage sludge, and further how much originates from cadmium in artists' paints.

High input-low output scenario (A)

For the purpose of this assessment one of the scenarios from the EU RAR, Scenario number 5, will be used to illustrate a European worst case scenario regarding input and output conditions. This scenario represents high input farming systems which may be found in e.g. wheat/corn rotations, with a soil pH of 6.8 resulting in low output (ECB 2007). The ambient cadmium concentration in soil at start is assumed to be 0.3 mg Cd kg^{-1} ds. The input and output figures are adjusted with more recent data, compared to the values used in the EU RAR, but will be considered to be steady over the modelled period of up to 100 years. In the EU RAR a yearly application rate of phosphorus of 30 kg P ha^{-1} $year^{-1}$ was assumed, which was based on data from France, Italy and Germany (ECB 2007). There are comprehensive statistical data available on the use of phosphorus fertilisers in Sweden 2010/2011 (Statistics Sweden 2012), see excerpts in Table 30. These data indicate that a worst case yearly application rate of 30 kg P ha^{-1} $year^{-1}$ is not unrealistic, although the total use of phosphate fertilisers has decreased in Europe during the last ten years (i.e. since the compilation in the EU RAR) (IFA 2013b).

Table 30 Selected statistics from Sweden regarding yearly application of phosphorous fertilisers (year 2010/2011). The values are averages for Sweden. Values within brackets () are averages for worst case region(s) as regards supply with phosphate (mineral) fertilisers.

Crops	**Land area used for crop (1000 ha)**	**% of that area fertilised with phosphate fertilisers and/or manure**	**Average application (kg P /ha)**	**% of that area fertilised with only phosphate fertilisers**	**Average application (kg P/ha)**
All types	2450 (413)	62 (63)	25 (25)	25 (33)	16 (19)
Cereals	993 (277)	72 (73-79)	22 (24-28)	40 (37-43)	15 (19-20)
Other crops[41]	361 (65)	61 (83)	28 (33)	34 (28)	21 (23)
Wheat[42]	350	68	25	39	18
Potatoes[43]	20	92	44	73	43
Sugar beats	40	83	27	52	20

However, a revised value for the cadmium concentration in the added fertilisers will be used; 83 mg Cd (kg P)$^{-1}$, which is the average concentration in P-fertilisers in Europe according to more recent studies (see section B.9.4). As demonstrated in Table 27 this gives a cadmium input with **sludge** and **mineral fertilisers** of **0.2** and **2.2** g ha^{-1} $year^{-1}$ respectively.

For the **atmospheric deposition** the median value from EMEP **0.23 g ha^{-1} $year^{-1}$** (see section B.9.4) is used.

The annual leaching loss is dependent of the soil concentration and (L) is estimated with following equations (ECB, 2007, ERM 2000):

[41] Cereals, hayfields and grazing fields not included
[42] Sown in autumn
[43] For food

$L = [Cd]_l 10\ F$ (g ha^{-1} yr^{-1}) (equation 1)

where $[Cd]_l$ represents the cadmium concentration in the soil pore water (µg L^{-1}) and F is the annual precipitation excess (m), here set to 0.2 m $year^{-1}$ a typical value for temperate regions according to the EU RAR.

The concentration of cadmium in pore water is calculated from the solid-liquid distribution coefficient, K_D (L kg^{-1}), and the cadmium concentration in in the solid phase of the soil $[Cd]_s$ (µg kg^{-1}) (ECB, 2007):

$[Cd]_l=[Cd]_s / K_D$ (equation 2)

K_D is calculated from the best fit empirical model presented by Smolders and Mertens (2013) (sect. B.4):

$\log K_D = -1.04 + 0.55\ pH + 0.70\log(OC)$ (equation 3)

where OC is the organic carbon content in %, for this scenario set to 2 % according to the presumptions in the EU RAR (ECB, 2007). This results in a K_D of 814 (L kg^{-1}), and assuming a soil concentration $[Cd]_s$ of 0.3 mg Cd kg^{-1} ds the **yearly leaching loss (L)** becomes **0.7 g ha^{-1} $year^{-1}$ at start.**

Crop harvest is a major output of cadmium from arable soils, which vary markedly depending on type of crop and crop rotation on the individual fields. The crop offtake is assumed to increase linearly with the concentration in soil. In the realistic worst case scenario 5 in the EU RAR the initial offtake with crops was set to 0.3 g ha^{-1} $year^{-1}$ which was assumed to represent a farming system with high cadmium recycling (corn used for roughage). In the very recent (not peer-reviewed) paper by Smolders (2013) examples of crop offtake was calculated for different crops, and a soil cadmium concentration of 0.3 mg cd kg^{-1}. The estimated offtake was 0.21 and 0.47 g ha^{-1} $year^{-1}$ for cereals and potatoes respectively. For the purpose of this assessment an average **crops offtake rate** of **0.3 g ha^{-1} $year^{-1}$** is used (as in the EU RAR) since the modelling will be used for estimating cadmium concentrations in different crops used for food.

Liming of soil can add to the cadmium input with an average of 0.09 g ha^{-1} $year^{-1}$ (see Section B.9.4) and is added to the input in this scenario. Use of manure is considered non relevant for this specific worst case scenario.

The long term changes of cadmium concentrations in soil will be calculated according to an analytical approach as proposed by ERM (2000).

$Cd_s (t) = Cd_s (0)\ e^{-(kp + kl)\ t} + \{k_i/(10\ \rho\ dp)(k_p + k_l)\}\ \{1 - e^{-(kp + kl)\ t}\}$ (equation 4)

Cd_s = cadmium concentration in soil (mg kg^{-1} dry weight)

k_i = input rate of cadmium (g ha^{-1} yr^{-1})
k_p = cadmium offtake rate by plants (yr^{-1})
k_l = cadmium leaching rate (yr^{-1})
t = time (yr)
ρ = soil bulk density (1300 kg m^{-3})
dp = depth of plough layer (0.23 m)

The leaching is dependent on the change in soil concentration and hence equation (4) requires the leaching rate constant k_l in units of (yr^{-1}). Equation (1) can be converted to units of (yr^{-1}) by dividing L (g ha^{-1} yr^{-1}) by the initial quantity of cadmium in the soil, Cd_s (t0) mg kg^{-1}, contained in one hectare of soil to ploughing depth. Inserting equation (2), the composite algorithm for k_l is as follows:

$\mathbf{k_l}$ = 1000 F/[K_D dp ρ] (yr^{-1}) = 1000*0.2/[814*0.23*1300]=**0.0008 yr^{-1}**

Similarly, equation (4) requires the cadmium offtake rate (k_p) to be expressed in units of (yr^{-1}). This can be achieved by dividing the offtake rate as expressed in units of (g ha^{-1} a^{-1}) by the initial quantity of cadmium in in the soil, Cd_s (t0) mg kg^{-1}, contained in one hectare of soil to plough depth, using the following transformation:

$\mathbf{k_p}$ = (g ha^{-1} yr^{-1}) /[10 dp ρ Cd_s (0)] (yr^{-1})= 0.3 /[10*0.23*1300*0.3)= **0.00033 yr^{-1}**.

The concentration in soil 100 hundred years ahead will then be

Cds (100) = 0.3*$e^{-(0.00033+0.0008)*100}$+{(2.4+0.23+0.09)/(10*1300*0.23)(0.00033+0.0008)}{1-$e^{-(0.00033+0.0008)100}$}=
0.353 mg Cd kg^{-1} ds, which corresponds to a 17.7 % increase in the soil concentration.

In this general high input-low output scenario it is assumed that the cadmium input with fertilisers is divided between sludge and mineral fertilisers in the same relation as the total input of cadmium with these sources to the arable land in EU (Section B.9.4, Table 27). This can be motivated by the fact that the average cadmium content per phosphorous is almost in the same range in mineral fertilisers and sludge in EU. This gives a cadmium input with sludge and mineral fertilisers of 0.2 and 2.2 g ha-1 year-1 respectively (section B.9.4.5). Assuming that 1.5 percent of cadmium in EU produced sludge originates from cadmium in artists' paints (section B.9.3.2.3) this would mean that 0.015*0.20=0.003g ha^{-1} year $^{-1}$ is the input of cadmium with sludge originating from artists' paints. If this amount is subtracted from the total input with fertilisers the increase in soil concentration in 100 years will be **0.030 %** less compared to the calculated value above. This is hence the effect on this scenario if cadmium in artists' paints is restricted, in a one hundred years perspective.

Average scenario (B)

An average input scenario can be constructed by dividing all input of cadmium with sludge and mineral fertilisers evenly over all arable land in EU resulting in an input per hectare (Scenario B in Table 27, section B.9.4) of 0.07 and 0.82 g ha^{-1} year $^{-1}$ from sludge and mineral fertiliser respectively. The average input with manure and lime in Europe is 0.01 and 0.09 g ha^{-1} year $^{-1}$ respectively (section B.9.4) and these values are used in this scenario. The total input with fertilisers would then be 0.89 g ha^{-1} $year^{-1}$ for this scenario, and the predictions for one hundred years of application results in slightly decreasing concentrations in soil (1.6% decrease). In this case cadmium from artists' paints is two percent of the input with sludge i.e. 0.015*0.07= 0.0011 g ha^{-1} year $^{-1}$. If this amount is subtracted from the total input, the decrease in soil concentration in a 100 years perspective will be

0.011 % larger compared to the value calculated above for scenario B.

Worst case local scenario – only fertilising with sludge (C).

A worst case local scenario will be used where it is assumed that only sludge is used for fertilising in a crops rotation system (and that all potatoes in the food basket are grown locally, see section B.9.7.5 Table 37.

Table 37). Using the estimated average application rate of sludge of 7.5 tonnes ds/ha (see section B.9.4.5), results in a yearly input of 10.5 g Cd ha^{-1} y^{-1}. In crop rotation systems including potato the crop offtake is somewhat higher than in system with only cereals, an offtake rate of 0.5 g Cd $ha^{-1}yr^{-1}$ is therefore used for this scenario, a value recommended by Environmental Resources Management (ERM, 2000) to be used by member states when calculating cadmium mass balances in arable soil. The local sludge-fertilised scenario result in increased soil concentration of 94.5 % in the 100 years perspective, and the corresponding contribution from artists' paints is 1.6 %. The different scenarios are summarised in Table 31 and the input/output parameters and results of calculations are presented in Table 32.

Table 31 Summary of the different fertiliser scenarios used in the assessment.

Scenario	Description of fertiliser regime	pH
A	Application of 30 kg P ha-1 year-1 (mineral as well as sludge fertilisers) according to realistic worst case, high input – low output scenario from EU RAR,	6.8
B	Total EU input (mineral fertilisers and sludge) distributed over all arable land	6.5
C	Local scenario – potatoes only fertilised with sludge, at average application rate	6.5

Table 32 Summary of the different parameters used, and the outcome of the different scenarios for which cadmium accumulation is modelled (T= 0 is today; T= + 50 and +100 is after 50 or 100 years of application respectively).

Scenario	A.	B.	C.
Atmospheric deposition (g ha^{-1} yr^{-1})	0.23	0.23	0.23
Input with mineral fertilisers (g $ha^{-1}yr^{-1}$)	2.2	0.82	-
Input with sludge (g $ha^{-1}yr^{-1}$)	0.2	0.07	10.5
- *part originating from artists' paints (g $ha^{-1}yr^{-1}$)*	*0.003*	*0.0011*	*0.16*
Input with lime/ manure (g $ha^{-1}yr^{-1}$)	0.09[44]	0.1	0.09[44]
Total input, Ki (g $ha^{-1}yr^{-1}$)	2.72	1.22	10.82
Leaching at T=0 (g ha^{-1} yr^{-1})	0.7	1.1	1.1
Crops off-take at T=0 (g ha^{-1} yr^{-1})	0.3	0.3	0.5
Factor leaching, Kl (yr^{-1})	0.00082	0.00082	0.00120

[44] Input with manure not considered relevant for this scenario

Scenario	A.	B.	C.
Factor crops, Kp (yr^{-1})	0.00033	0.00033	0.00056
K_D (Lkg^{-1})	814	557	557
Cd_{soil} at T=0, (mg kg-1 ds)	0.3	0.3	0.3
Cd_{soil} at T= +50, (mg kg^{-1} ds)	0.327	0.298	0.448
Cd_{soil} at T= +100, (mg kg-1 ds)	0.353	0.295	0.583
Increase Cd_{soil},T0 to T+ 50 (%)	9.1	- 0.8	49.3
Increase Cd_{soil},T0 to T+100 (%)	17.7	-1.6	94.5
Change due to Cd in artists' paints T+50 (%)	**0.016**	**0.006**	**0.84**
Change due to Cd in artists' paints T+100 (%)	**0.030**	**0.011**	**1.6**
Change due to Cd in artist pain at pH 5.8 in soil T+100 (%)	0.027	0.010	1.48

Time dependence

In the scenarios above the change in soil cadmium concentrations, due to use of artists' paints, was estimated after 100 years. A time frame of 60-100 years have been used in earlier European risk assessments (Hutton et al, 2001;). In the EU RAR modelling was done over 60 years (ECB, 2007). In a recent study by Six and Smolders (2014) 100 years was used. The calculations can be done for other time scales, and was done for 25, 50 and 75 years of application. As in the calculations above it was assumed that cadmium in soil, originating from pigments, is equally soluble and occur in the same forms as cadmium from other sources at all these time points. This assumption may result in an overestimation of the soluble amount of cadmium in the first decade/-s (see discussions in sections B.4.2.4) and hence the amount available for leakage as well as the amount of cadmium available for uptake by the crops. With this assumption, it was shown that the relative change in soil cadmium concentration, due to the use of artists' paints, was almost linearly related to time for the three scenarios, see Figure 6. The change in soil concentrations after 50years of application is shown in Table 32. The possible fault caused by the assumption above about equal solubility, is relatively lager during the first decade that the modelling covers, when newly applied pigment make up a bigger fraction of the total amount of pigment born cadmium in the soil. Due to the possible slower dissolution of pigment born cadmium in soil we have chosen to model the contribution of artists paints on cadmium in soil, and the calculation of risk, after 50 and one hundred years of sludge application.

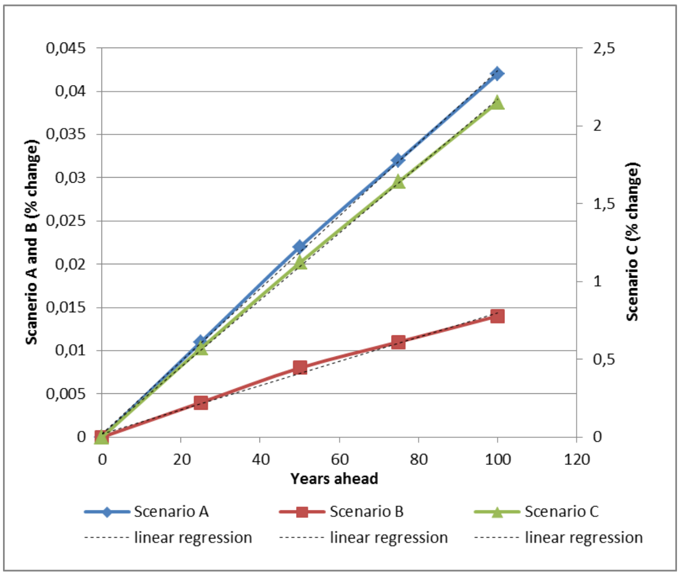


Figure 6 Modelled relative change (%) in cadmium concentrations in soil with time, due to use of cadmium in artists' paints.

Impact of pH

As mentioned in section B.4. pH has a large influence on the K_D and hence on the leaching estimates in the mass balances. Since different pH measurement methods give different results, it is important that the same method has been used in the studies that constitute the basis for the equations above as well as in the soils for which the equations are applied. It is not clear which method have been used for the equation 3 above. However, Smolders (2013, Six and Smolders 2014) recently raised a concern that cadmium accumulation may have been overestimated in earlier mass balance calculations (e.g. the EU RAR). In the new estimates Smolders used a comprehensive new database (not publically available yet) on pH in European agricultural soil based on the CaCl-extraction method (NGU 2012). From this new database an average pH_{CaCl} of 5.8 for European agricultural soils was estimated. This is a significantly lower value compared to the EU representative values that the same author used in earlier calculations (e.g. pH 6.5 in the EU RAR). It is not clear which measuring method the earlier value relates to and we foresee a discussion on which are the most relevant pH values to be used in this kind of calculations. Therefore, this proposed EU value (pH 5.8.) was used to estimate the sensitivity due to pH for the calculations above on the impact of cadmium in artists' paints. Applying this pH value to the scenarios above resulted in a negligible effect on the change due to cadmium in artists' paints (last row in Table 32). The alternative pH value did though result in a significant decrease in the total accumulation rate when the lower pH was applied in the model, i.e. -1.9, -16 and +73 % in 100 years for scenarios A, B and C respectively. This is in agreement with the 15 % decrease that Six and Smolders (2014) reported for their average EU scenario. It should be emphasised that a decrease with 15 % in 100 years is still a very slow recovery rate compared to the reported increase in soil cadmium, by factors 1.3-2.6, during the 19th and 20th century (Six and Smolders 2014).

B.9.7.5 Potential reduction in intake of cadmium via food if cadmium in artists' paints is restricted

In the EU RAR (ECB 2007) four different intake scenarios are modelled based on type of soil where the crops are grown; Scandinavian neutral soils, Scandinavian acid soil, Central Western Europe and Mediterranean. The food consumption and basal cadmium intake are based on data of European market food basket studies (EUR 17527, 1997 cited in ECB 2007) and cadmium soil-plant transfer factors (ECB 2007). The third intake scenario corresponds well with the realistic worst case scenario that was used for modelling future soil concentrations in this report. Intake with crops based on the scenario from the EU RAR at a cadmium soil concentration of 0.3 mg/kg ds is described in Table 33. It is assumed that potatoes, vegetables and cereals (wheat grain) are 100% grown within the continent, while cadmium in all other food groups (basal cadmium intake) is assumed to be unaffected by the soil cadmium content. Hence, according to these calculations the crops affected by the soil content make up 77 percent of the cadmium intake.

Table 33 Description of the intake scenario for Central Western Europe according to ECB (2007).

Food group	**Consumption (g fresh weight day^{-1})**	**Cadmium soil-plant transfer factor (dimensionless)**	**Dietary cadmium intake (µg Cd day^{-1})**
Potatoes	240	0.08	5.8
Leafy vegetables	47	0.12	1.7
Other vegetables	155	0.03	1.4
Cereals	224	0.11	7.4
Basal intake			4.9
Total			**21.1**

Alternatively the most recent EFSA compilation on dietary exposure in the European population can be used (EFSA, 2012). On average for EU the main contributions to cadmium intake with different crops in the adult age group are 26.6 % from grain and grain-based products, 17.4 % from vegetables and vegetable products, 12.3 % from starchy roots and tubers (mainly potatoes and potato products) and 1.7 % from beans and oil seeds. In total these food categories make up 58 % of the total intake, which is lower than in the EU RAR scenario above. The EFSA figures also give a lower contribution from these food categories compared to what have been estimated for Sweden (>68 %,) in different recent studies (Amzal et al. 2009; Sand & Becker 2012; Swedish National Food Agency 2012). This indicates that the new EFSA compilation may be a low estimate of the contribution from these food categories, but since it is the most recent estimate for the European population it will still be used in this report to calculate the change in intake of cadmium via food. The EFSA figures above on food category contribution and the 'adult' age group average weekly intake of 1.77 µg Cd kg^{-1} body weight (equals 0.25 µg Cd kg^{-1} day^{-1}) from this study (EFSA 2012) will be used to calculate the average EU intake of cadmium from these food categories. An assumed average body weight of 60 kg results in a total intake of15.2 µg Cd day^{-1}. The resulting intake with the different crop categories is listed in Table 34.

Table 34 Contributions to cadmium intake for "adults" (18- < 65 years, 60 kg) from different food categories, specified for crops, according to EFSA (2012) based on a total dietary cadmium intake of 15.2 µg Cd day^{-1}

Food group	**Contribution to total food intake (%)**	**Dietary cadmium intake (µg Cd day^{-1})**
Grains and grain products	26.6	4.0
Vegetables and vegetable products	17.4	2.6

Starchy roots and tubers	12.3	1.9
Beans and oil seeds	1.7	0.3
Other	42	6,4
Total	**100**	**15.2**

In accordance with the EU RAR (ECB 2007), it is here assumed that all other food categories is independent of the cadmium content in soil, but this is probably not totally true. It is concluded by EFSA 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. 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)* (EFSA 2009). The assumption above, and the use of a comparatively low figure on the relative contribution of crops in the food basket (see above), may result in some underestimation of intake of cadmium in the calculations below.

Based on this intake scenario, and the modelled increase in soil for the different fertilising scenarios described above (Scenarios A, B and C), the increase in intake due to the use of cadmium in artists' paints can be estimated. The intake has been estimated for three exposure scenarios (a, b, c) below. In these estimates a linear relation between increased concentrations in soil and increased concentrations in crops is assumed. Other factors such as dietary habits and conditions in the soils are considered constant over the modelled time interval of one hundred years.

Exposure scenario a: The resulting increase for a general high input – low output scenario is presented in Table 35. It is here assumed that all crops in the table are grown under cadmium input output conditions in the soil according to the fertilising scenario A above, where the change in soil due to 100 years use of cadmium in artists' paints is **0.030 %.** It is assumed that people living in such areas eat (products of) cereals and vegetables cultivated under these conditions.

Table 35 Exposure scenario a. Changed cadmium intake due to artists' paints if the use of cadmium in artists' paints today is continued for 100 years, for the high input –low output scenario (all crops fertilised according to scenario A). Change in soil due to use in artists' paints is 0.030 %.

Food group	**Total intake at t0 (µg Cd day^{-1})**	**Intake due to artists' paints at T=100 (µg Cd day^{-1})**
Grains and grain products	4	0.0012
Vegetables and vegetable products	2.6	0.00078
Starchy roots and tubers	1.9	0.00057
Beans and oil seeds	0.3	0.00009
Other	6.4	-
Total (µg Cd day^{-1})	15.2	0.00264
Relative to total intake (%)		0.017 %

Exposure scenario b: In the second scenario it was assumed that all cadmium input is distributed evenly over all arable land in EU (average application scenario according to fertilising scenario B) and the use of artists' paints contributes with **0.011 %** of the change in soil over 100 years. This is the average EU scenario. It is assumed that (products of) cereals and vegetables in the food basket for the European population are cultivated under these conditions. The resulting change in cadmium intake with crops is presented in Table 36.

Table 36 Exposure scenario b: Changed cadmium intake due to artists' paints if the use of cadmium in artists' paints today is continued for 100 years, where all crops have been grown according to the EU average scenario (Scenario B). Change in soil due to use in artists' paints is 0.011 %.

Food group	**Total intake at t0 (µg Cd day^{-1})**	**Changed intake due to artists' paints at T=100 (µg Cd day^{-1})**
Grains and grain products	4	0.00044
Vegetables and vegetable products	2.6	0.00029
Starchy roots and tubers	1.9	0.00021
Beans and oil seeds	0.3	0.00003
Other	6.4	-
Total (µg Cd day^{-1})	15.2	0.00097
Relative to total intake (%)		0.0064 %

Exposure scenario c: A realistic worst case **local** scenario where it is assumed that **only sludge is used as fertiliser** in a crop rotation system (at average application rate of sludge application according to fertilising scenario C above) and use of artists' paints contributes with **1.61 %** of the change in soil over 100 years. As a realistic worst case scenario it is assumed that the **potatoes in the food basket are grown locally** where only sludge is used as fertiliser People living in this area are expected to eat potatoes that are grown locally but cereals and other vegetables are expected to have been cultivated in other areas and hence fertilised according to Scenario B, where use of artists' paints contributes with 0.011 % of the change in soil in the 100 years perspective. This assumption is done since it is not probable that all cereal products is from local producers and sludge application is prohibited for cultivating fruits and vegetables which are in immediate contact with the soil and usually eaten raw. The resulting increased cadmium intake is presented in Table 37.

Table 37 Exposure scenario c: Changed cadmium intake due to artists' paints if the use of cadmium in artists' paints today is continued for 100 years. The people eat locally grown potatoes that have been fertilised only with sludge (according to fertilising scenario C) and the other crops have been fertilised according to the average scenario B.

Food group	**Total intake at t0 (µg Cd day^{-1})**	**Changed intake due to artists' paints at T=100 (µg Cd day^{-1})**
Grains and grain products	4	0.00044
Vegetables and vegetable products	2.6	0.00029
Starchy roots and tubers	1.9	0.03059
Beans and oil seeds	0.3	0.00003
Other	6.4	-
Total (µg Cd day^{-1})	15.2	0.0314
Relative to total intake (%)		0.21 %

The contribution from the use of artists' paints to cadmium intake via food, assuming that the use of cadmium in artists' paints today is continued for up to 100 years are summarised in Table 38 for the three scenarios. If cadmium in artists' paints is restricted, this is what would be the effect compared to continuous use for 100 years.

The change in cadmium intake was also calculated in 50 years perspective. Since the change in cadmium concentrations in soil with time is estimated to be almost linear (Figure 6) the calculated change in the intake within 50 years would be about half the values after 100 years, Table 38 Table 38, under the presumption that cadmium from artists' paints is equally soluble and occur in the same forms as cadmium in soil from other sources. This assumption may result in an overestimation of the soluble cadmium during the first decade/-s and hence a possible overestimation of the bioavailable cadmium (see Section B.4). Therefore, the risk modelling (chapter 10) has been done for the 50 and 100 years perspective as regards changes in intake due to cadmium in artists' paints.

Table 38 Summary of the contribution from the use of artists' paints to cadmium intake via food for the three exposure scenarios, assuming that the use of cadmium in artists' paints today is continued for 50 (T =+50) and 100 (T= +100) years

Exposure scenario	**Total (µg Cd day^{-1})**		**Relative to total intake (%)**	
	T= +100	T=+50	T= +100	T= +50
a	0.0026	0.0014	0.017	0.009
b	0.0010	0.0005	0.006	0.003
c	0.031	0.016	0.21	0.11

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

B.10 Risk characterisation

B.10.1 User Scenario – Release from usage of artists' paints

B.10.1.1 Human health

B.10.1.1.1 Workers

Not relevant for this proposal.

B.10.1.1.2 Consumers

Not relevant for this proposal.

B.10.1.1.3 Indirect exposure of humans via the environment

The general population in Europe is exposed to levels of cadmium that, already today, may cause effects on kidney and bone in a significant part of the population. The margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small (EFSA 2009). It should also be noted that the studies used for the quantitative risk assessment in the present restriction proposal show adverse effects in the general population when comparing individuals with a dietary cadmium exposure above the median with those below the median. All possible exposure sources should therefore be reduced.

In the present restriction proposal we have chosen to perform quantitative risk assessments using two different endpoints, i.e.

- bone fractures in males and females more than approximately 50 years of age and
- postmenopausal breast cancer.

The exposure to cadmium is via food. It should be noted though that these endpoints are just two out of many effects that may be caused by cadmium exposure (for more information see section B.5). Although most effects in the general population are expected to occur later in life (due to the accumulation of cadmium in the body over the years), recent studies also indicate possible developmental effects.

Most previous risk assessments of cadmium are based on kidney toxicity, for example the evaluation by EFSA in 2009, where it is concluded that "*as the earliest effect of cadmium exposure is tubular damage, it seems most appropriate to base the risk assessment on this outcome. However, in light of recent studies, it seems appropriate also to consider data on adverse skeletal effects in the risk assessment once more data become available.*" In the EFSA report it was also concluded that "*the studies evaluated indicate a range of urinary cadmium for possible effects on bone effects starting from 0.5 µg/g creatinine, which is similar to the levels at which kidney damage occurs*."

A reason for not choosing kidney effects for the quantitative risk assessment in the present Annex XV report is the ongoing debate on the suitability of measuring exposure and effects in the same matrix (i.e. urine) at very low exposure levels. Further, it was also considered difficult to assess and quantify the long-term health effects of minor tubular damage. It needs to be emphasized though, that kidney effects are an important part of the risk panorama of cadmium and thus adds to the risks calculated for other end-points

The chosen studies on the incidence of fractures and breast cancer are from Sweden. They have been used because we consider them to be the most appropriate ones when evaluating effects in the general population by dietary cadmium exposure. The studies used large prospective population-based cohorts of the general Swedish population. The participation rates were relatively high allowing generalization of the results to the Swedish population.

We consider the results also to be relevant for the EU population:

- The dietary exposure to cadmium in Sweden is similar to the average EU exposure (EFSA 2012). Notably, the average intake in Sweden, according to the EFSA report, is 1.77 µg/kg bw per week, which is the same as the median value for EU (assessed from data from 14 member states, representing a large part of the EU population).
- The incidences of breast cancer in EU countries vary with a factor 2-3 (Ferlay 2013). The data from Sweden are in the middle of this range.
- For fractures, the incidences in Sweden are higher than in most other EU countries. The reason for the higher incidence in the northern part of Europe is not known. The attributable factor (in %) of dietary cadmium to this effect on bone tissue is assumed to be the same in the different EU countries; there are no data indicating otherwise.

Considered effects and exposure/response relationships

Bone toxicity: Fractures

The studies on fractures by Engström et al. (2012) and Thomas et al. (2011), reported in the KemI report No 4/13 (Swedish Chemicals Agency 2013), and described in section B.5.6.3 of the present report, will be used. Table 39 below summarises some relevant results from these studies. The aetiological fraction is the part of fractures that can be explained by a particular exposure, in this case dietary cadmium above the median exposure.

Table 39 Summary of results from two studies on fractures described in section B.5.6

Gender	**Median dietary intake of Cd** (□g/day)	**OR or RR** (comparing dietary Cd exposure above the median to that below)	**Average age** (years)	**Aetiological fraction, %** (95 % CI)
Females	13	1.31	64	**12.7** (0.8-23)
Males	19	1.15	60	**6.78** (2.4-10.9)

Breast cancer

A study from a population-based prospective cohort (Swedish Mammography Cohort) (Julin et al 2012a) will be used for estimating the number of breast cancer cases that can be explained by dietary cadmium. A short summary of the results is given in Table 40. For more details, see section B.5.8.2.

Table 40 Summary of results from the study on breast cancer by Julin et al. (2012a)

	Tertiles of cadmium intake, µg/day		
	<13	13-16	>16
Median cadmium intake, µg/day	12	15	17
Relative risk (95% CI)	1.00	1.06 (0.95-1.18	1.21 (1.07-1.36)

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 (95% CI 1.7-5.5 %) (exposure via food). The association was tested for non-linearity, but no support of a non-linear relationship was indicated (Julin 2012b).

Dietary exposure of cadmium from artists' paints

Cadmium pigments in artists' paints that is released to waste water will for a predominating part end up in the sewage sludge at the WWTP. The sludge is in turn partly used as a fertiliser in the agriculture. As described in section B.4, the cadmium compounds used in artists' paints will eventually dissolve in the soil and hence there is a potential crop uptake and in the extension exposure to humans via food (Gustafsson 2013).

The exposure of humans via food is explained in section B.9.7. Below important outcomes of this section are described in short.

Crops are the main contributor to cadmium intake via food, and cadmium in crops is dependent on soil concentrations. By assuming a linear relation between cadmium in soil and cadmium in crops we have estimated the change in cadmium concentration in crops due to change in cadmium concentration in soil.

Further in section B.9.7 the change in soil concentration after up to 100 years of sludge application has been estimated and the relative and absolute amount of this change originating from the use of artists' paints have been calculated.

The cadmium intake from food is estimated from the latest average EU food basket compiled by EFSA (2012). The data for the group "adults" (18-<65 years) is used and the food basket is considered to be constant both regarding composition and quantity eaten over the 100 years for which the change in soil concentration is modelled.

The change in the intake via food has been estimated for three different exposure scenarios:

a. A high input –low output scenario (from the EU RAR) where it is assumed that 30 kg P/ha is applied. The phosphorus is from both sludge and mineral fertilisers in the same relative amount as is used in the whole EU. As demonstrated in section B.9.4, 11% of the phosphorus input originates from sludge and 89% from mineral fertilisers. It is assumed that people living in such areas eat (products of) cereals and vegetables cultivated under these conditions.

b. An average scenario where it was assumed that all annual cadmium input from deposition, mineral fertilisers, sludge, manure and lime is distributed evenly over all arable land. It is assumed that (products of) cereals and vegetables in the food basket for the European population are cultivated under these conditions.

c. A worst case scenario where it is assumed that only sludge is used as fertiliser. In this scenario an application rate of 7.5 kg P/ha is used. People living in this area are expected to eat potatoes that are grown locally but cereals and other vegetables are expected to have been cultivated in other areas and hence fertilised according to the average scenario above.

The change in cadmium intake via food due to the use of artists' paints, if the use of cadmium in artists' paints today is continued for 100 years, are summarised in Table 41 for the three scenarios.

Table 41 Contribution from artists' paints to change in cadmium intake via food after 100 years of use, see section B.9.7.

Scenario	**Total amount (μg Cd day^{-1})**	**Relative to total intake (%)**
a	0.0026	0.017

b	0.0010	0.006
c	0.031	0.21

These calculated changes in intake of cadmium via food thus represent the decreased intake on a 100 year time frame if cadmium in artists´ paints is restricted.

It is not possible to estimate the number of people exposed according to scenarios **a** and **c**.

The exposure scenario **a** represents farming systems with high input which, according to the EU RAR, may be found in e.g. wheat and corn rotations. Phosphorus applications in these systems are usually 30 kg P ha^{-1}. Thus this is a realistic scenario even though it cannot be applied on the whole EU population since it is not possible to estimate how many people that live in such areasIt can nevertheless be concluded that the impact of cadmium in artists' paints is about 3 times higher in this scenario (**a**) than in the average (diluted) scenario below (scenario **b**).

The exposure scenario **c** is probably occurring as a local scenario within EU, but it is not possible to estimate the share of the population that this concerns. Therefore, as for the scenario **a** above, the impact on an EU level cannot be calculated. This scenario is used as a 'worst case' in terms of fertilising with sludge, but since it is only potatoes that are considered to be locally grown (and fertilised only with sludge) high exposure groups as regards food habits (e.g. people eating more crops as well as more locally grown crops) have not been considered. Hence, this worst case scenario is realistic on a local scale and can even be an underestimation. For individuals exposed according to this scenario, it is estimated that if cadmium in artists' paints is continued to be used in the same amount as today for 100 years, the exposure of cadmium from food intake would increase by about 0.2%. About half that increase is expected after 50 years (Table 38).

The average scenario (**b**) is the only scenario for which it is possible to estimate a general quantitative risk, since it can be applied on the whole EU population. However, this means that all cadmium input is distributed uniformly over all arable land resulting in a general risk assessment based on a diluted fertilising regime, in which cadmium in artists' paints, used for 100 years, contributes with a change in cadmium exposure via food of 0.006 %. About 0.003 % increase is expected after 50 years (Table 38).

Calculations of risk and number of affected individuals

The effects on health arising from a restriction of the use of cadmium based artists' paints are long term. This means that the effects are phased in over a time horizon spanning many decades. There are three major aspects of the exposure that contribute to this long time horizon:

- The cadmium contained in the pigments is not immediately bioavailable (see section B.4.2.4), but within a time frame of a couple of years to several decades, cadmium from pigments has a similar solubility and bioavailability as other cadmium compounds in the soil. It will therefore be assumed in this report that cadmium in soil, originating from pigments, in the long-term will be equally available to plants as cadmium from other sources. The possible fault caused by the assumption above about equal solubility, is relatively lager during the first decades which the modelling covers, when newly applied pigment make up a bigger fraction of the total amount of pigment born cadmium in the soil (B.9.7.4) .

- The impacts of restricting cadmium based artists’ paints on cadmium concentrations in soil, estimated in Section B.9.7, were therefore calculated over a 50 and 100 year time frame. The path towards the estimated reduction after 100 years is approximately linear.
- The cadmium induced health effects analysed in this report occur due to long term accumulation of cadmium in the human body.

All in all these three aspects thus indicate that the calculated impacts on a population level from restricting the use of cadmium based artists' paints will fully manifest itself after more than one generation, up to 150 years from the date of implementation. It is reasonable to assume that the health impacts from a restriction will grow linearly from zero at the time of implementation to the calculated levels after 150 years. A schematic illustration of this scenario is provided in Figure 7 below.

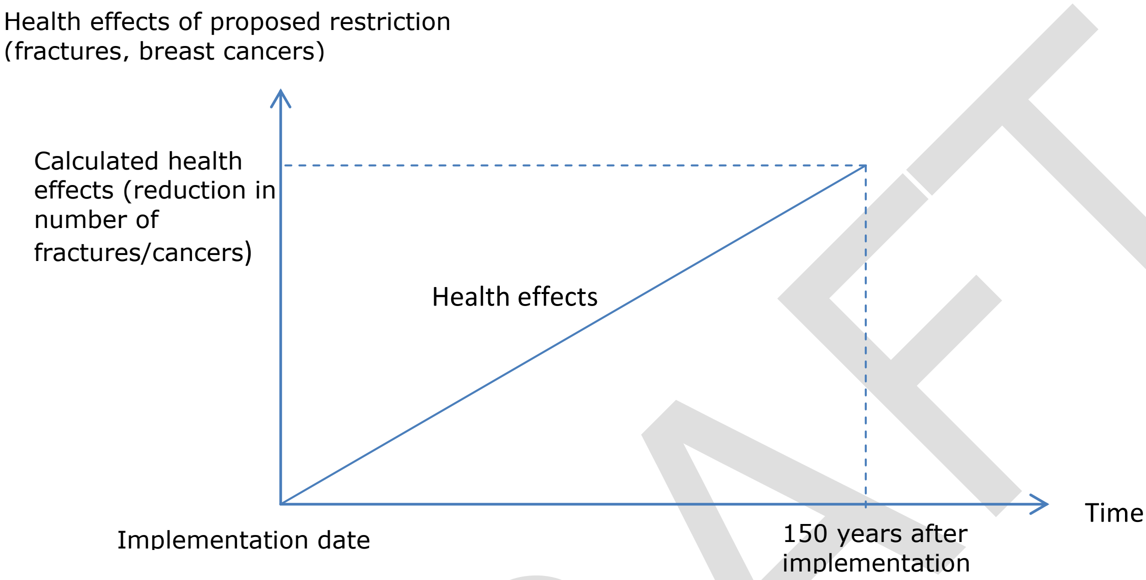


Figure 7 Schematic illustration of the health effects of a restriction over time

The length of the period of analysis can be questioned. The longer the time frame, the more likely are (e.g.) exogenous technological changes (such as changer in WWTP technology) to occur. On the other hand, on an individual level, cadmium once taken up in the body will more or less remain (biological half-life up to 30 years), and new technology will therefore not have immediate effects. The main argument for an inclusion of the full 150 year period in the analysis is that the health effects – under the baseline assumptions – are estimated to increase throughout the period. It is however important to note that the relevance of some of the assumptions may change over time.

Since the health effects of the restriction proposed in this report primarily are of long term nature, projections of future demographic changes in the EU 27 are taken into account when calculating the number of affected individuals. The population of women and men above 50 years is projected to increase over the coming decades, and is assumed to level off by mid-century. Eurostat (Table 42) provides demographic projections until 2060 (Eurostat 2013g), which will be used as a proxy for the demographic composition in the EU over the time horizon (0-150 years) assessed in this proposal. In 2060 there will be approximately 128 million women and 115 million men aged 50 years or above in EU 27. This is an increase by 25% and 34%, respectively, compared to 2012. Moreover, the increase is unevenly distributed within this age group. The number of 50-64 year old women and 50-59 year old men will decrease, while the older age groups will increase. The increase is most pronounced in the oldest age groups.

Table 42 EU 27 population (in millions) by age and gender

	Age group (years)								
	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+	50+
Year 2012*									
Females	17,8	16,7	15,8	12,9	12,2	10,5	8,3	8,0	102,2
Males	17,5	15,9	14,7	11,5	10,1	7,7	5,2	3,5	86,1
Year 2060**									
Females	15,4	14,8	14,8	15,4	15,8	15,4	13,9	22,5	128,0
Males	15,7	15,0	14,8	15,2	15,0	13,7	11,4	14,4	115,1

*Actual population in 2012; **Projected population in 2060; Reference: Eurostat (2013g)

Bone toxicity: Fractures

Estimation of the number of fracture cases related to cadmium from artists' paints is calculated as follows:

- Number of cases = aetiological fraction (for Cd in food originating from artists' paints) * total number of fractures (in the relevant age group, i.e. > 50 years)

Where the aetiological fraction for Cd from artists' paints is calculated as:

- % cadmium in food originating from artists´ paints (scenario b in Table 41) ∗ aetiological fraction (for Cd in food), as shown in Table 39.

The baseline estimation of total number of fractures among men and women above 50 years is dependent on the demographic changes expected in the EU 27 in the coming decades and the differences in fracture incidence for different age and gender groups. In Table 43, fracture incidence rates by age and gender are presented. These are derived from Ström et al. (2011) as the sum of incidence rates for four types on fractures (hip, vertebrate, forearm, and other). The fracture incidence increases by age, and is nearly ten times higher among those above 80 years compared to men and women in their 50s.

Table 43 Total fracture incidence (per 100 000) by gender and age in six EU countries (DE, UK, ES, IT, FR, SE)

Age group (years)	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+
Females	569	1131	947	1651	2480	3679	5464	9781
Males	465	974	825	1204	1678	1613	3809	7085

Since the population is projected to increase substantially within the age groups with the highest incidence rates, the baseline number of fractures calculated here is derived per age group. Using the population projections for the year 2060 in Table 42 and the fracture incidence rates in Table 43, the baseline estimation on number of fractures is derived per age group and gender in Table 44. The total number of fractures per year affecting women over 50 is estimated to be 4.6 million while men over 50 are estimated to suffer 2.4 million fractures.

Table 44 Estimated number of fractures (thousands) in the EU 27 per year

Age group (years)	**50-54**	**55-59**	**60-64**	**65-69**	**70-74**	**75-79**	**80-84**	**85+**	**50+**
Females	87	167	140	255	393	565	762	2201	4570
Males	73	146	122	183	251	221	436	1017	2448

Females

The aetiological fraction (for cadmium in food originating from artists' paints) thus equals:
0.0064 % * 12.7 % = 0.00081 %
The number of fractures each year in EU in females >50 years of age is 4.6 million (Table 44).
Number of fractures that can be attributed to dietary cadmium originating from artists' paints:
0.00081 % * 4.6 million = **37 extra fractures per year**

Males
The aetiological fraction (for cadmium in food originating from artists' paints) thus equals:
0.0064 % * 6.78 % = 0.00043 %
The number of fractures each year in EU in males >50 years of age is 2.4 million (Table 44)
Number of fractures that can be attributed to dietary cadmium originating from artists' paints:
0.00043 % * 2.4 million = **11 extra fractures per year**

Breast cancer

In order to estimate the annual number of breast cancer cases related to dietary cadmium intake the relative risk from the study, i.e. 3.6 % increased risk per µg Cd/day (exposure via food), must be converted to an absolute risk, such as number of cases. The REACH Guidance on information requirements and chemical safety assessment, Chapter R8 (Characterization of dose (concentration)-response for human health), Phase 8-B (Obtaining the DMEL) gives guidance on how to do this. A relevant part of this guidance is cited below.

"The relative risk must be projected onto the target population (workers or general population) to derive an Excess Lifetime Risk (ELR) at a given level of exposure, i.e. how many excess life time cases in absolute terms will result from a given relative estimate of risk (RR, OR, SMR or SIR). This necessitates the application of the relative risk estimates on actual population data (with person-year data and case occurrence data). There are two options to do this:

i) a simple direct method as described by van Wijngaarden and Hertz-Picciotto (2004) or the Dutch Health Council (1989), and

ii) a more sophisticated method including the use of a life table approach as described by e.g. Steenland et al., 1998.

*The direct method calculates the ELR as: ELR = Lifetime Risk * (RR-1). Lifetime Risk is the (background) risk of the relevant health effect in the target population. The simple direct method results in some overestimation of the lifetime risk, in particular if the background risk in the target population is high. This is mostly because the direct method is less accurate in taking into account the mortality from other causes of death. The life-table method calculates and accumulates the ELR for each life year during the lifetime of a virtual cohort (see Goldbohm et al 2006 for an example). It gives a more accurate estimate and can incorporate specific requirements, such as changing exposure* *patterns over a lifetime, competing risks due to effects of exposure on other endpoints, etc. The life-table method may be used if there is a need to calculate the risk more accurately. A life table should also be used if age-dependent RRs are indicated (see example on breast cancer above). Although the life-table method is the preferred option, the direct method can be used if the background rate of the disease and the potency of the substance are low or if the age for which the risk is considered relevant is relatively young (< 70 years) (Goldbohm et al 2006)."*

For the purpose of the present Annex XV restriction report we have chosen to use the simple direct method, i.e. use the equation:

Excess risk = annual incidence * (RR-1)

According to Ferlay et al (2013) there were 364 400 incident cases of breast cancer in EU27 in 2012. Data from Sweden for year 2011 (Swedish National Board of Health and Welfare 2012) indicate that 82 % of all breast cancer cases occurred in women > 50 years. Assuming that this figure is valid for the whole EU 27, this means that there were 298 800 incident postmenopausal breast cancer cases in EU27 in 2012. The EU 27 population of women aged 50 years and above was 102.2 million in 2012 (Eurostat 2013g), which indicates an incidence rate of 292 per 100 000. Assuming that this incidence rate will remain and that the EU 27 population of women aged 50 years or more will increase to 128 million (Table 42), the estimated number of postmenopausal breast cancer cases will be 374 200 per year.

Using the RR from the study by Julin et al (2012a,b), RR=1.036 per µg Cd/day, the excess risk thus equals:

374 200 cases * (1.036-1) = **13 472 extra cases each year (ages 50 and above) per µg Cd via food /day.**

The estimated quantity of cadmium in the food originating from artists' paints is 0.0010 µg Cd /day (see Table 41, Scenario b).

Thus, this exposure gives rise to:

0.0010 * 13 472 = **13 extra cases of breast cancer per year.**

Summary and conclusions

The change in cadmium intake, due to the proposed restriction of cadmium in artists' paints, is estimated to generate a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The decrease in fracture and breast cancer cases in the EU 27 due to a full restriction on the use of cadmium based artists' paints will **grow linearly from zero at the time of implementation to the following levels after 150 years**:

- **Female fractures: 37 fewer cases/year**
- **Male fractures: 11 fewer cases/year**
- **Breast cancers: 13 fewer cases/year**

The health effects per year and accumulated effects after implementation are presented in Table 45. The full effect on human health of the restriction will thus be reached after 150 years. This long time span is due to both factors in the soil, affecting when cadmium in food is changed, and the long time frame for changing the body burden of cadmium in humans.

Table 45 Risk reduction capacity in terms of number of prevented fractures and breast cancers per year

Years from implementation	Female fractures	Male fractures	Breast cancers
	Health effect per year		
50	12	4	4
100	25	7	9
150	37	11	13
	Accumulated effects after implementation		
50	316	90	111
100	1251	358	440
150	2804	802	987

Although other toxic effects of cadmium have not been assessed (quantitatively) in this report, it is expected that these will also decrease in a similar manner. Furthermore, the impact of the proposed restriction on the cadmium exposure via food will be higher among individuals eating locally grown potatoes and cereals, where sludge has been used as fertiliser (fertilising scenario C above). Individuals living in areas with conditions according to Scenario A are affected by cadmium in artists' paints at a 3 times higher level than in the average scenario and this situation may be relevant in some parts of EU.

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

B.10.1.1.4 Combined exposure

Not relevant for this proposal.

B.10.1.2 Environment

B.10.1.2.1 Aquatic compartment (including sediment and secondary poisoning)

Not relevant for this proposal.

B.10.1.2.2 Terrestrial compartment (including secondary poisoning)

Not relevant for this proposal.

B.10.1.2.3 Atmospheric compartment

Not relevant for this proposal.

B.10.1.2.4 Microbiological activity in sewage treatment systems

Not relevant for this proposal.

B.11 Summary on hazard and risk

B.11.1 Hazards

As shown in section B.5 cadmium and cadmium compounds are associated with a large number of health hazards, many of which are quite serious. This is also evident from the harmonized classification of cadmium compounds. The toxicity of all cadmium compounds is related to the Cd^{2+} ion and the solubility of the cadmium compound may therefore affect short-term effects, such as acute toxicity.

For long-term effects, also less soluble cadmium compounds contribute to the pool of cadmium that humans are exposed to. The biological half-life of cadmium in humans is extremely long (10-30 years) and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. This means that most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level. The long half-life also means that once these critical levels have been attained, and effects occur, these are in practice irreversible due to a continued internal exposure.

Toxic effects on kidney and bone are well recognized effects of cadmium. These effects are covered by the harmonized classification STOT RE 1. Also other organs may be affected.

Cadmium is further considered to cause carcinogenesis. An increased risk for lung cancer has been shown in workers. In the general population increased risks have mainly been shown in hormone-related organs, such as breast, endometrium and prostate. It is considered most likely that 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. Moreover, there are indications that cadmium may act as an estrogen. There are also recent epidemiological studies suggesting developmental effects.

Dose-response relationship

Most previous risk assessments have been based on kidney toxicity, for example the risk assessment by EFSA in 2009. In that case the TWI set (2.5 µg per kg body weight per week) was calculated from a urinary cadmium 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 $\mu g/m^3$ 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 recent risk assessment (KemI 2011), the data supporting an adverse effect of the present exposure to cadmium in the general population on the risk of osteoporosis have increased substantially during the last few years. Both the new Swedish Mammography Cohort (SMC) and the new American National Health and Nutrition Examination Survey (NHANES) studies suggest that even a urinary concentration around 0.5 µg/g creatinine is associated with increased risk of osteoporosis and fractures. This was also recognized in the scientific opinion from EFSA (EFSA 2009) where it is concluded that *"the studies evaluated indicate a range of urinary cadmium for possible effects on bone effects starting from 0.5 µg/g creatinine, which is similar to the levels at which kidney damage occurs."*

B.11.2 Risks

The general population in Europe is exposed to levels of cadmium that, already today, may cause effects on kidney and bone in a significant part of the population. The margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small (EFSA 2009). It should also be noted that the studies used for the quantitative risk assessment in the present restriction proposal show adverse effects in the general population when comparing individuals with a dietary cadmium exposure above the median with those below the median.

In the present restriction proposal we have chosen to perform quantitative risk assessments using two different endpoints, i.e.

- bone fractures in males and females more than approximately 50 years of age and
- postmenopausal breast cancer.

The exposure to cadmium is via food.

A reason for not choosing kidney effects for the quantitative risk assessment in the present Annex XV report is the ongoing debate on the suitability of measuring exposure and effects in the same matrix (i.e. urine) at very low exposure levels. Further, it was also considered difficult to assess and quantify the long-term health effects of minor tubular damage. It needs to be emphasized though, that kidney effects are an important part of the risk panorama of cadmium and thus adds to the risks calculated for other end-points. Although most effects in the general population are expected to occur later in life (due to the accumulation of cadmium in the body over the years), recent studies also indicate possible developmental effects.

The chosen studies on bone effects and breast cancer are from Sweden. They have been used because we consider them to be the most appropriate ones when evaluating effects in the general population by dietary cadmium exposure. The studies used large prospective population-based cohorts of the general Swedish population. The participation rates were relatively high allowing generalization of the results to the Swedish population.

We consider the results also to be relevant for the EU population:

- The dietary exposure to cadmium in Sweden is similar to the average EU exposure (EFSA 2012).
- The incidences of breast cancer in EU countries vary with a factor 2-3. The data from Sweden is in the middle of this range.
- For fractures, the incidences in Sweden are higher than in most other EU countries. The reason for the higher incidence in the northern part of Europe is not known. The attributable factor

(13 and 7 % in females and males, respectively) of dietary cadmium to this effect on bone tissue is assumed to be the same in the different EU countries; there are no data indicating otherwise.

Dietary exposure of cadmium from artists' paints

Cadmium pigments in artists' paints that is released to waste water will for a predominating part end up in the sewage sludge at the WWTP. The sludge is in turn partly used as a fertiliser in the agriculture. The cadmium compounds used in artists' paints will eventually dissolve in the soil and hence there is a potential crop uptake and in the extension exposure to humans via food.

Crops are the main contributor to cadmium intake via food, and cadmium in crops is dependent on soil concentrations. By assuming a linear relation between cadmium in soil and cadmium in crops we have estimated the change in cadmium concentration in crops due to change in cadmium concentration in soil.

As described in section B.10 the change in the intake via food has been estimated for three different exposure scenarios.

The contribution from the use of artists' paints to the cadmium intake via food for these three scenarios are summarised in the Table 46 below.

Table 46 Contribution from artists' paints to cadmium intake via food over 100 years

Scenario	Total (µg Cd day^{-1})	Relative to total intake (%)
a. High input-low output scenario	0.0026	0.017
b. Average scenario	0.0010	0.006
c. Worst case local scenario	0.031	0.21

It is not possible to estimate the number of people exposed according to scenario a and c.

The average scenario (b) is the only scenario for which it is possible to estimate a general quantitative risk, since it can be applied on the whole population. However, this means that all cadmium input is distributed uniformly over all arable land resulting in a general risk assessment based on a diluted fertilising regime, in which cadmium in artists' paints, used for 100 years, contributes with a change in cadmium exposure via food of 0.006%.

Risk characterization

The change in cadmium intake, due to the proposed restriction of cadmium in artists' paints, is estimated to generate a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will **grow linearly from zero at the time of implementation to the following levels after 150 years**:

- **Female fractures: 37 fewer cases/year**
- **Male fractures: 11 fewer cases/year**
- **Breast cancers: 13 fewer cases/year**

The length of the period of analysis can be questioned. The longer the time frame, the more likely are (e.g.) exogenous technological changes (such as changer in WWTP technology) to occur. On the other hand, on an individual level, cadmium once taken up in the body will more or less remain (biological half-life up to 30 years), and new technology will therefore not have immediate effects. The main argument for an inclusion of the full 150 year period in the analysis is that the health effects – under the baseline assumptions – are estimated to increase throughout the period. It is however important to note that the relevance of some of the assumptions may change over time.

The health effects per year and accumulated effects after implementation of the restriction are presented in the Table 47 below.

Table 47 Risk reduction capacity in terms of number of prevented fractures and breast cancers per year

Years from implementation	Female fractures	Male fractures	Breast cancers
	Health effect per year		
50	12	4	4
100	25	7	9
150	37	11	13
	Accumulated effects after implementation		
50	316	90	111
100	1251	358	440
150	2804	802	987

Although other toxic effects of cadmium have not been assessed in this report, it is expected that these will also decrease in a similar manner. Furthermore, the impact of the proposed restriction on the cadmium exposure via food will be higher among individuals eating locally grown potatoes and cereals, where sludge has been used as fertiliser (fertilising scenario C, section B.9.4). Individuals living in areas with conditions according to Scenario A are affected by cadmium in artists' paints at a 3 times higher level than in the average scenario and this situation may be relevant in some parts of EU.

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

Cadmium based pigments are mainly substituted by organic pigments. Artists' paints made with cadmium free red, yellow and orange pigments already exist. Often the word cadmium is a part of the colour name although there is no content of cadmium. The wording hue, sub or imit indicates that the product contains a cadmium free pigment.

C.2 Assessment of alternatives

Cadmium sulphide is used as a base to create a variety of pigments ranging from yellow and orange to red. A selection of pigments in those colours has thus been evaluated. The evaluation should not be regarded as recommendations for any specific use. The intention is to merely show that alternative substances are available, give an indication of the price levels and to show that the alternatives mostly have beneficial health and environmental hazard properties compared to the cadmium ion. An evaluation of a specific alternative solution needs to be done on a case by case basis by the artist.

C.2.1 Availability of alternatives

The product assortment of two online stores (www.winsornewton.com and www.sennelier.fr) was invented for cadmium free paints. In these stores 24 unique pigments were found in products that were cadmium free but who´s names contained the word cadmium. These are presented in Table 48 below. Examples of product names are cadmium red hue, cadmium yellow pale hue, cadmium orange hue, ton rouge de cadmium, ton jaune de cadmium, ton jaune de cadmium citron, rouge cadmium orange subst, and more.

In one online store invented (www.winsornewton.com) there seemed to be lower availability of cadmium free products marketed with names as "artists …" compared to products not specifically marked with the word "artists". Prices and technical feasibility is further discussed in section C.2.4.

Table 48 Examples of red, yellow and orange pigments used in different types of cadmium free paints marketed as alternatives to cadmium paints (www.winsornewton.com, www.sennelier.fr)

Type of paint	Pigments*
Oil	PR3, PR4, PR170, PR188, PR254 PY1, PY1:1, PY3, PY13, PY65, PY74, PY83, PY154 PO13, PO36, PO43, PO73
Acrylic	PR9, PR112, PR254 PY1:1, PY3, PY65, PY73, PY74 PO73
Water colour	PR149, PR188, PR254, PR255 PY65, PY83, PY97, PY175 PO43
Gouache	PR3, PR4 PY1, PY1:1, PY3
Pure pigments	PR3, PR4 PY1, PY3

*PR=C.I. Pigment Red, PY=C.I. Pigment Yellow, PO=C.I. Pigment Orange

Chemical identification and hazard classification of the pigments in Table 48 are found in appendix 7. Information on volumes in the Reach registrations for the pigments in Table 48 is found in appendix 8.

According to the International Cadmium Association, ICdA,[45] there has been a growth in organic and synthetic alternatives during the last couple of decades. Varying upon the needs of the artist, the closest available alternatives are based on the following pigments:

- For yellows the most used alternatives are Benzimadazolones (Pigment Yellow 154), some Arylamides and Bismuth vanadate (Pigment Yellow 184).
- For the orange shades these alternatives are Perinone ((Pigment Orange 43) and Diketopyrrollopyrrole DPP (Pigment Orange 73).
- For reds the most used alternatives are Diketopyrrollopyrroles DPP (Pigment Red 254 and 255).

These alternative pigments are all (aside from PY 184) mentioned in Table 48.

In addition alternatives marketed as cadmium substitutes there are also other yellow, orange and red paints, whose names don't contain the word cadmium. All the yellow, orange and red paints available on the market, but not being marketed specifically as alternatives, have for practical reasons not been evaluated in the dossier.

C.2.2 Human health risks related to alternatives

Hazard classifications for the pigments identified in Table 48 above are found in appendix 7. Based on the classifications and particularly on the exposure route (section B.9) the alternatives are considered as less hazardous to human health than the cadmium ion.

C.2.3 Environment risks related to alternatives

Hazard classifications for the pigments identified above are found in appendix 7. Based on the classifications and particularly on the exposure route (see section B.9) the alternatives are considered as less hazardous to the environment than the cadmium ion.

C.2.4 Technical and economic feasibility of alternatives

The technical feasibility and the economic impact of a substitution of cadmium pigments in artists' paints were deliberated with stakeholders representing artists as well as manufactures and suppliers of artists' paints (ColArt 2013, Kreatima 2013).

C.2.4.1 Technical feasibility

When assessing the alternatives both technical properties and preference based differences are considered. This section discusses more of the technical properties whereas the differences in regards

[45] Comments recieved during public consultation

to preference are deliberated in section C.2.5 below.

In regards of the technical feasibility important characteristics to consider comprise chroma or colour fullness, hue or colour position, opacity, indoor light-fastness, and tinting strength.

The International Cadmium Association, ICdA, also refers to these properties of cadmium colours during public consultation. The organisation specifically highlights three properties difficult to receive when using the alternatives. In their comments they give visual examples which are results from tests conducted by one member of the artists' paints trade organisation CEPE. According to ICdA the following can be said regarding the test results:

- Opacity – *"The cadmium colours have markedly superior hiding power"*
- Tinting strength - *"Better colour saturation is obtained with the cadmium colours"*
- Lightfastness (equivalent to around 50-75 years indoors) – *"For the mixed lemon yellow there was a small, but perceptible, difference in degree of fading between cadmium colours and alternatives; for the mixed orange and red shades the differences were substantial."*

The properties of the organic pigments are in many ways similar to cadmium colours. However the alternatives cannot be considered identical. One variation is how the colours mix to create new colours. The organic alternatives generally make cleaner, less muddy blends. Other colours, for example the iron oxides, might be added if muddier colours are required (www.goldenpaints.com).

In their comments during public consultation ICdA states that there are alternatives (see above) but these pigments *cannot "replace cadmium pigments as all-in-one alternatives for purity, colour saturation, opacity, indoor lightfastness and tinting strength, and which match their mixing characteristics."* This is in agreement with our assessment, i.e. that an evaluation of a specific alternative solution needs to be done on a case by case basis by the artist.

Consultation with stakeholders demonstrates that artists are a heterogeneous group. Different artists have different views on the technical aspects of the available alternatives and it is difficult to draw a general opinion. It depends on experiences, traditions etc. Also artists often mix their own individual palette. Further dissimilar pigments (regarding both cadmium colours and alternatives) require different binders. Each colour then has its own character (Kreatima 2013). Thus, the assessed alternatives should not be regarded as recommendations to replace any specific cadmium colour. The user needs to search for solutions that suit the conditions in its individual working process.

Because cadmium colours and the available alternatives are not identical there may be a need for derogation from the proposed restriction when it comes to certain restoration and maintenance of works of art and historic buildings. Since these works differ from each other the need for derogation must be decided on a case by case basis.

C.2.4.2 Economic feasibility

In Table 49 examples of different alternatives and cadmium colours are listed by type of colour. The comparison is based on consultation with suppliers (Kreatima 2013) and information from websites (shop.winsornewton 2013, Boesner 2013) and should merely be regarded as an indication of the price levels. According to CEPE[46] the Cadmium based artists' paints are typically 20-50% more expensive than their alternatives. However a larger quantity of paint is generally needed when using an alternative. This is because the alternatives are less powerful and therefore demand larger amounts.

[46] Consultation with CEPE, see section G

Due to strong pigmentation cadmium based colours require smaller quantities (ColArt 2013).

According to stakeholders (ColArt 2013, Kreatima 2013) hobby artists choose alternatives over cadmium based colours where price is one important reason.

Table 49 Price examples of different cadmium and alternative colours, VAT (25%) included (shop.winsornewton 2013, Boesner 2013, Kreatima 2013)

Type of colour	Cadmium colour	EUR	Alternative	EUR
Oil	Rembrandt 40 ml (Cadmium red deep, 306)	17.3-28.4	Rembrandt 40 ml (Perm. red deep, 371)	10.4-20.2
	Rembrandt 40 ml (Cadmium orange, 211)	17.3-28.4	Rembrandt 40 ml (Perm. orange 266)	10.4-20.2
	Rembrandt 40 ml (Cadmium yellow deep, 210)	17.3-28.4	Rembrandt 40 ml (Perm. yellow deep, 285)	10.4-20.2
	Winsor & Newton 37 ml (Cadmium lemon, 086)	21-23.2	Winsor & Newton 37 ml (Winsor lemon, 722)	10.9-13.4
	Winsor & Newton 37 ml (Cadmium red, 094)	21-23.2	Winsor & Newton 37 ml (Winsor red, 726)	10.9-13.4
Water Mixable Oil	Winsor & Newton Artisan, 37 ml (Cadmium red dark, 104)	7-10.7	Winsor & Newton Artisan, 37 ml (Cadmium red deep hue, 098)	5.6-7.4
	Winsor & Newton Artisan, 37 ml (Cadmium yellow medium, 116)	7-10.7	Winsor & Newton Artisan, 37 ml (Cadmium yellow deep hue, 115)	5.6-7.4
	Winsor & Newton Artisan, 37 ml (Cadmium yellow light, 113)	7-10.7	Winsor & Newton Artisan, 37 ml (Cadmium yellow pale hue, 119)	5.6-7.4
Water colour	Winsor & Newton, 5 ml (Cadmium yellow, 108)	10-14.7	Winsor & Newton, 5 ml (Winsor yellow, 730)	6.7-10.3
	Winsor & Newton, 5 ml (Cadmium red deep, 097)	10-14.7	Winsor & Newton, 5 ml (Winsor Red, 726)	6.7-10.3
Acrylic	Liquitex. 59 ml (Cadmium red medium, 154)	15.5-24.0	Liquitex, 59 ml (Cadmium red medium hue, 151)	9.6-13.5
	Liquitex. 59 ml (Cadmium yellow medium, 161)	11.5-16.1	Liquitex. 59 ml (Cadmium yellow medium hue, 830)	9.6-13.5
	Liquitex. 59 ml (Cadmium yellow light, 160)	11.5-16.1	Liquitex. 59 ml (Cadmium yellow light hue, 159)	11.5-16.1
Gouache	Winsor & Newton Designers Gouache (Cadmium lemon, 086)	9.4-17.5	Winsor & Newton Designers Gouache (Lemon yellow, 345)	5.5-7.3
	Winsor & Newton Designers Gouache 14 ml (Cadmium yellow deep, 111)	9.4-17.5	Winsor & Newton Designers Gouache 14 ml (Per. Yellow deep, 508)	5.5-7.3
Total		**192-284**		**125-188**

To summarise, the alternatives are generally less costly per volume unit but require larger volumes than cadmium based paints. In this report it is assumed that these aspects largely cancel each other out, if anything the proposed restriction will lead to a reduced cost for the user.

C.2.5 Other information on alternatives

An artist's survey performed by Golden Artist Colors[47] received 1518 responses. To the question if

[47] Artists survey results regarding the proposal for a restriction of cadmium pigments in artist paints. Golden Artist Colours, Inc. United States. Received during Public Consultation. 9 June 2014.

cadmium colours are irreplaceable on the palette 64 % of the EU respondents using cadmium pigmented artist colours answered that they consider them irreplaceable, thus more than one third did not answer that they are irreplaceable. In the comments as to why they are considered as irreplaceable the artists explain that, for example, the cadmium colours have opacity, tinting strength, vibrancy and intensity that they don't consider the alternative paints to have.

There was one question directed to artists not using cadmium colours asking why not, of which 6 % of responding artists avoid cadmium colours due to environmental and safety concerns, 2% do not use them for colouristic reasons and 1 % do not use them due to expense. The survey did not contain any question on why cadmium pigments could be considered as replaceable, perhaps resulting in that almost only one side of the question was argued in favour of.

In addition to comments on technical aspects the survey received a lot of partially emotional arguments from artists. Quoting the artists' own words on the question to why cadmium colours are irreplaceable; "Because I like those colors", "Because I´m so used to them", "…It is much more convenient to have these colors…", "…The cads are such a tradition over the centuries in all our historic masterpieces" and "The colors are so very beautiful. Better than substitutes". Artists have also responded, quoting their own words; "A hue is not the same. Doesn´t give me the right color I need…", "They produce a special look in my art that I cannot get anywhere else" and "There is nothing that gives the same results as cadmiums do".

A few supportive comments were also received from artists in the survey. One comment said, quote; "…It would require changing and working with an altered palette. The change would doubtlessly bring its own discoveries and that would be an adjustment". Another one reads, quote; "…I realize there could be a learning curve. Limiting my colors does not limit my artistic expression".

The survey results correspond well to what is written in section C.2.4.1 Technical feasibility, i.e. that the alternatives can not be considered as identical, much depends on experiences and traditions, and that the user needs to search for solutions that suit the conditions in its individual working process.

A visit to an art supply store in Stockholm (Konstnärernas centralköp 2014) also showed that much has to do with the artist´s personal experience. Based on the store´s experience, it has to do with tradition and habit when it comes to the artist's need of cadmium paints. To some extent it has also to do with how the artist has been trained during its education. Some artists claim to require cadmium paints, whilst other artists are more confident in using cadmium free paints.

D. Justification for action on a Union-wide basis

D.1 Considerations related to human health and environmental risks

During use and cleaning procedures cadmium based artists' paints are released to the waste water. At the waste water treatment plant (WWTP) the cadmium pigments will for a predominating part end up in the sewage sludge. Sludge is then applied as fertiliser in the agriculture. The cadmium compounds used in artists' paints will eventually dissolve in the soil (Gustafsson 2013, Appendix 3) and hence there is a potential crop uptake and in the extension exposure to humans via food.

The general population in Europe are exposed to levels of cadmium that, already today, may cause effects on kidney and bone for a significant part of the population. The margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small (EFSA 2009). Cereals and root vegetables contribute the most to the general population exposure to cadmium via food.

The toxicity of all cadmium compounds is related to the Cd^{2+} ion. For long-term effects, also less soluble cadmium compounds contribute to the pool of cadmium that humans are exposed to. The biological half-life of cadmium in humans is extremely long (10-30 years) and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. This means that most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level. The long half-life also means that once these critical levels have been attained, and effects occur, these are in practice irreversible due to a continued internal exposure. Cadmium is further considered to cause carcinogenesis. In the general population increased risks have mainly been shown in hormone-related organs, such as breast, endometrium and prostate.

If the cadmium input originating from artists' paints is removed the average intake via food over 100 years is estimated to be reduced by **0.0010 µg cadmium day^{-1}** (compared to baseline), which is equivalent to **0.006% of total intake via food** (see section B.9.7).

Based on the assumption (see section B.10) that the effects of cadmium on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation the following effect levels will be reduced after 150 years:

- Female fractures: 37 fewer cases/year
- Male fractures: 11 fewer cases/year
- Breast cancers: 13 fewer cases/year

Although other toxic effects of cadmium have not been assessed in this report, it is expected that these will also decrease in a similar manner. Furthermore, the impact of the proposed restriction on the cadmium exposure via food will be higher among individuals eating locally grown potatoes and cereals, where sludge has been used as fertiliser (see *scenario C* in sections B.9.4 and B.9.7). Also *scenario A* described in sections B.9.4 and B.9.7 is of importance in some parts of EU. This scenario represents farming systems with high input, 30 kg P ha^{-1}, which according to the EU RAR (ECB 2007) may be found in e.g. wheat and corn rotations.

D.2 Considerations related to internal market

A Community wide restriction of cadmium in artists' paints will create a level playground for trade. It will not discriminate between paints produced in the EU and those imported from third countries, and it will not hinder commercial relations on the internal market. It will also alleviate the risk that illegal imports – from Member States where cadmium paints are not restricted into Member States where they are restricted – might undermine acceptance and effectiveness of the restriction. There will however still be a risk of illegal imports from outside the Community with similar effects.

A Community wide restriction will create a harmonized, manageable regulatory situation which can reduce the administrative burden and the costs of compliance, and it will prevent the market distortions following from national regulations while still targeting the health concerns.

D.3 Other considerations

No other considerations.

D.4 Summary

The main reason for acting on a Union-wide-basis is the large number of serious health hazards associated with cadmium and its compounds and the statement from the EFSA. EFSA has expressed concern that the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small. The toxicity of all cadmium compounds is related to the Cd^{2+} ion. During use and cleaning procedures cadmium based artists' paints are released to the waste water. Thereby the cadmium compounds have a potential to end up in in the food via emissions to the sewage system and sludge application on agricultural land. The use of cadmium and its compounds are not included in the current restriction in REACH Annex XVII, Entry 23.

A Union-wide restriction would thus be the best way of ensuring a "level playing field" among both EU producers and importers of artists' paints. A Union-wide restriction would also be easy to communicate to the suppliers outside the EU.

E. Justification why the proposed restriction is the most appropriate Union-wide measure

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

This chapter calculates a baseline scenario of negative health effects emanating from use of cadmium based artists' paints. The health effects analysed here are limited to fractures suffered by men and women aged 50 years an above, and post-menopausal breast cancer. Most of the information and assumptions presented here have already been introduced throughout section B of this report.

Cadmium content in artists' paints sold/used

The quantities of cadmium based artists' paints sold in the EU are 39 (33-44) tons per year, according to the trade organization CEPE. The quantities sold of cadmium based artists' paints, and the distribution across paint types, has been stable over recent years and CEPE projects that it will remain stable in the future. Given results from analysis of cadmium content in different types of paint, and the respective market shares of these types, the amount of cadmium in artists' paints is assumed to be 6.4 tons per year. (Section B.9.3.2.3)

To our knowledge, there are no other plans to regulate cadmium in artists' paints. Therefore the baseline assumption here is that the amount of cadmium in artists' paints used in the EU will be **6.4 tons per year**.

Quantity of cadmium from artists' paints that ends up on agricultural land

Of the artists' paints used, 5% is assumed to be released to waste water (Section B.9.3.1), indicating that 0.32 tons (5% of 6.4 tons) of cadmium from artists' paints will be released to waste water each year.

Currently, around 82% of EU households are connected to secondary waste water treatment (Section B.9.3.2.3). This household connection rate is assumed to be a good proxy for the share of cadmium from artists' paints released to waste water that will reach a waste water treatment plant. This share will probably increase as the urban waste water directive (91/271/EEC) is assumed to be fully implemented within the next 5-15 years. In the baseline estimation we have however not taken this into account, and a connection rate of 82% is assumed. This estimation can be considered to be conservative. Of this 95% is assumed to end up in sludge (Section B.9.3.2.3). The baseline assumption is thus that 0.25 tons (95% of 82% of 0.32 tons) of cadmium from artists' paints ends up in sewage sludge in the EU every year.

The share of sludge from WWTPs applied on agricultural land in the EU is currently around 45%. This share is affected by a range of policy initiatives, of which some will probably increase the share while others will have a lowering impact (for a thorough review of this, see Milliue (2010)). The projected net effect is that the share will probably increase (Table 21 in Section B.9.3.2.3). In this baseline scenario the assumption is however that the current share of 45% will remain, which can be considered to be a conservative assumption. Consequently, the baseline assumption is that **0.11 tons per year** (45% of 0.25 tons) of cadmium from artists' paints ends up in sewage sludge.

Cadmium concentration in agricultural soils

Cadmium input – from various sources – to agricultural soils is described in detail in Section B.9.4. Scenario B is used in this baseline analysis. This is an average scenario where it is assumed that all cadmium input is distributed evenly over all arable land. This results in a general risk assessment applicable to the whole EU population. The values used are based on present day situation in the EU. Inputs in terms of grams cadmium per hectare per year are presented in Table 50.

Table 50: Cadmium input to agricultural soils

Input source	**($g\ ha^{-1}\ yr^{-1}$)**
Atmospheric deposition	0.23
Input with mineral fertilisers	0.82
Input with sludge	0.07
- ***part originating from artists' paints***	***0.0011***
Input with lime/ manure	0.1
Total input	**1.22**

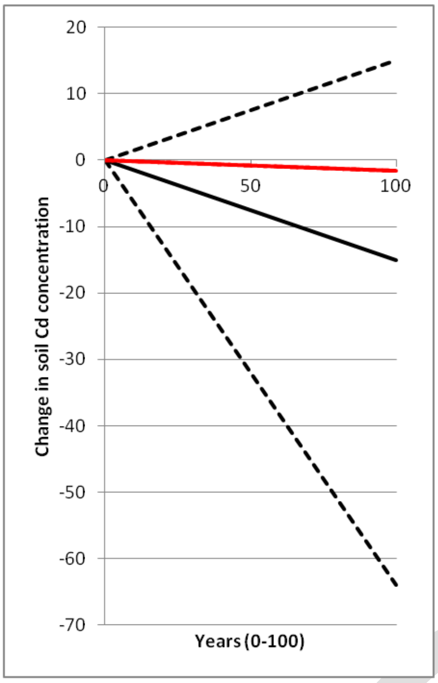
The implications for cadmium concentrations in agricultural soils of restricting the use of cadmium based artists' paints are modeled in Section B.9.7. Current cadmium concentration in agricultural soils in the EU is assumed to be 0.3 mg per kg dry weight. Based on the input levels in Table 50, the concentration is expected to decrease by 1.6% over a period of 100 years. If the cadmium input originating from artists' paints is removed the concentration will be reduced by a further 0.011%.

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

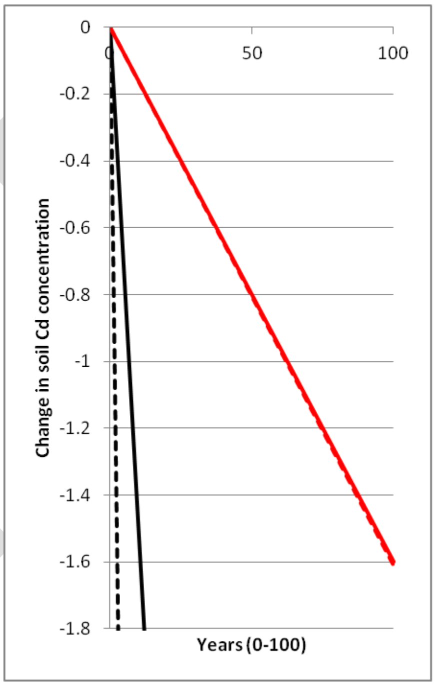
SEAC opinion on section E.1

The level of uncertainty in the whole restriction proposal is illustrated from the above paragraph stating that the concentration in agricultural soils in the EU is assumed to decrease by 1.6% over a period of 100 years. A recent peer-reviewed article by Six and Smolder (Six and Smolder, 2014) comes to the conclusion that the change will be on average -15 % (results from sensitivity analysis ranging from -64% to +15%). The comparison between the two estimates is illustrated in the following figure. Even in the magnification on the left-hand side the effect from the proposed restriction (additional -0.011%) is hardly visible.



Six and Smolders, 2014
average: black solid line,
sensitivity analysis: black dotted lines
regional differences (+15%, -21%)

Restriction dossier by KEMI
red line (base line -1.6%),
effect from restriction (red dotted line -1.611%)



Cadmium intake via food

Crops are the main contributor to cadmium intake via food, and cadmium in crops is dependent on soil concentrations. A linear relationship between cadmium in soil and cadmium in crops is assumed, and the change in crops due to change in soil was estimated in Section B.9.7.

The most recent EFSA compilation on dietary exposure in the European population (EFSA, 2012) is used. The average intake of cadmium via food is assumed to be **15.2 µg Cd day^{-1}**. Four crop categories (grain and grain-based products, vegetables and vegetable products, starchy roots and tubers (mainly potatoes and potato products) and beans and oil seeds) make up 58 % of the total intake. In this proposal we assume that this is a good proxy for the share of cadmium intake via food that can be affected by changes to cadmium inputs to agricultural soils in the EU. This does not take into account that some of these crops are imported to the EU. Imported crops make up around 6% of cereal consumption and less than 1% of potato consumption in the EU (Swedish Board of Agriculture 2013). These will not be affected by this proposal. On the other hand, the proposal will probably also affect the cadmium levels in meat and other animal products. Furthermore, the baseline scenario also assumes that there will be no major changes in diet composition or import shares.

If the cadmium input originating from artists' paints is removed per capita intake of via food in 100 years is estimated to be reduced by **0.0010 µg Cd day^{-1}** (compared to baseline), which is equivalent to **0.0064% of total intake via food**.

Total number of fracture and breast cancer cases per year in baseline

Since the health effects of the restriction proposed in this report primarily are of long term nature, projections of future demographic changes in the EU 27 are taken into account when calculating the number of affected individuals. The population of women and men above 50 years is projected to increase over the coming decades, and is assumed to level off by mid-21st century (Section B.10). Eurostat (2013g) provides demographic projections until 2060, which will be used as a proxy for the demographic composition in the EU over the time horizon assessed in this proposal. This approach will overestimate the health effects of the proposed restriction initially, especially during the initial two to three decades, but since the effects are more pronounced in the longer term (see below), this assumption will have minor impacts on the outcome of the analysis. In 2060 there will be approximately 128 million women and 115 million men aged 50 years or above in EU 27 (Table 42 in B.10). This is an increase by 25% and 34%, respectively, compared to 2012. Moreover, the increase is unevenly distributed within this age group. The number of 50-64 year old women and 50-59 year old men will decrease, while the older age groups will increase. The increase is most pronounced in the oldest age groups.

Current incidence rates of fractures for women and men over 50 and breast cancer for women over 50 are assumed to be stable and are used in the baseline estimation. Annual fracture incidence rates by age and gender are presented in Table 44 in B.10. These are derived from Ström et al. (2011) as the sum of incidence rates for four types on fractures (hip, vertebrate, forearm, and other). The incidence rates increases dramatically by age (nearly ten times higher among those above 80 years compared to men and women in their 50s) and are generally higher for women than for men. The incidence rates vary from 465 to 9781 per 100 000.

According to Ferlay et al (2013) there were 364 400 cases of breast cancer in EU27 in 2012. Data from Sweden for year 2011 (Swedish National Board of Health and Welfare 2012) indicate that 82 % of all breast cancer cases occurred in women > 50 years. Assuming that this figure is valid for the whole EU 27, this means that there were 298 800 postmenopausal breast cancer cases in EU27 in 2012. The EU 27 population of women aged 50 years and above was 102.2 million in 2012 (Table 42 in B.10), which indicates an incidence rate of 292 per 100 000.

Combining the incidence rates and the demographic projections above, baseline estimates of the number of fractures and breast cancer cases in the EU27 in the baseline scenario can be derived**.** The total number of **fractures per year** affecting **women over 50** is estimated to be **4.570 million** while **men over 50** are estimated to suffer **2.448 million** fractures per year (Table 44 in B.10). The baseline scenario of **breast cancer** is that there will be **374 200 cases per year**.

Number of fracture and breast cancer cases per year caused by cadmium from artists' paints in baseline

The studies on fractures by Engström et al. (2012) and Thomas et al. (2011), reported in the KemI report No 4/13 (Swedish Chemicals Agency 2013), and described in sections B.5.6.3 of this present, indicate that 12.7% of all fractures affecting women over 50, and 6.78% of all fractures affecting men over 50, can be explained by exposure to cadmium via food. Assuming that 0.0064% of the cadmium intake via food can be attributable to cadmium from artists' paints, and that there are 4.570 million female fractures and 2.448 million male fractures per year; cadmium based artists' paints are assumed to cause **37 female and 11 male fractures per year** (Section B.10).

A study from a population-based prospective cohort (Swedish Mammography Cohort) (Julin et al 2012a) has been used to estimate the number of breast cancer cases that can be explained by dietary cadmium (Section B.5.8.2). Expressed as a continuous risk, dietary cadmium was associated with a 3.6 % increased risk per µg Cd/day of exposure via food. Assuming that 0.0010 µg Cd/day of the cadmium intake via food can be attributable to cadmium from artists' paints, and that there are 374 200 breast cancer cases per year; cadmium based artists' paints are assumed to cause **13 breast cancer cases per year** (Section B.10).

E.1.2 Options for restrictions

The use of cadmium and its compounds in paints is restricted in REACH Annex XVII, Entry 23. The restriction is however limited to the TARIC codes [3208] and [3209]. Zinc based paints with a residual concentration of cadmium below 0,1 % are exempted from the ban (see Appendix 1). Artists' paints, TARIC code [3213], are hence not included in the current restriction. Nor are pigments covered in TARIC code [3212] which could be used by the artists to manufacture their own artists' paints. The current restriction does not either include placing on the market.

In the RMO and in the Registry of Intention a restriction covering also the use of cadmium and its compounds in pigments for enamel, ceramics and glasses was announced. The objective in the dossier is to minimize the risk to human health caused by cadmium that ends up in in the food via emissions to the sewage system and sludge application on agricultural land. It is doubtful if colouring of enamel, ceramics and glasses contributes to this exposure and if that is the case, then available data is too limited. The uses in enamel, ceramics and glasses are therefore not included in the restriction proposal.

The restriction options presented here – and assessed in E.2 – concerns placing on the market and use of cadmium and its compounds in artists' paints, TARIC code [3213], and pigments, TARIC code [3212], intended for the manufacture of artists' paints.

RMO 1: Complete ban of cadmium based artists' paints

This is a proposal for an addition in REACH Annex XVII, Entry 23, concerning cadmium and its compounds. Articles covered by TARIC codes [3212] and [3213] containing cadmium and its compounds shall not be placed on the market or used. An implementation period of 12 months is suggested.

To be in consistence with the current restriction on cadmium in paints (Entry 23, paragraph 2), the same limit value for the residual concentration of cadmium in artists' paints containing zinc is proposed. If a general limit value for cadmium as an impurity in paints would be included in the current restriction in Entry 23, it is for consistency and enforceability reason, reasonable that such a limit value also would apply to cadmium in artists' paints.

RMO 2 (*the proposed restriction*): Ban on cadmium based artists' paints, with an exemption for restoration and maintenance of historical pieces of art

This RMO is formulated as RMO 1 with the addition of an exemption. The exemption applies to restoration and maintenance of works of art and historic buildings and their interior with reference to cultural-historical values. Member States decide on the exemption and how it should be administrated.

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

Authorisation under REACH

The cadmium compounds used in artists' paints; cadmium zinc sulphide yellow (EC 232-466-8, CAS 8048-07-5), cadmium sulphoselenide red (EC 261-218-1, CAS 58339-34-7) and cadmium sulphoselenide orange (EC 235-758-3, CAS 12656-57-4) do not have a harmonized classification under CLP. These substances have low solubility and therefore the toxic effects will be underestimated in regular tests. Thereby they do not fulfil the criteria for classification, neither under CLP nor as substances of very high concern (SVHCs). Hence these substances cannot be included in Annex XIV and the subsequent authorisation processes.

Voluntary agreements

A recent review (Bryden et al 2013) of 47 studies on voluntary agreements between governments or government bodies and individual businesses or industry groups concluded that if properly implemented and monitored, voluntary agreements can be effective and businesses can help to achieve public policy aims. The most important characteristics of effective voluntary agreements are: a credible threat of legislation exists; there are substantial and financially important incentives and sanctions for non-participation or non-fulfilment of targets; the targets of the agreement are distinct and monitorable.

Voluntary agreements can potentially be used to mitigate the emissions of cadmium from artists' paints to waste water, and further into crops for human consumption. The producers and importers, or distributors, of artists' paints can either agree not to supply products with cadmium content to the market, provide information to consumers on recommended paint brush cleaning procedures, and/or agree to provide cleaning kits containing a flocculent to the consumers, as well as instructions for appropriate waste management. The artists' paint users can agree to either phase out the use of cadmium paints, or to follow recommended paint brush cleaning and waste management procedures.

Voluntary actions are dependent on accessible and reliable information – e.g. regarding exposure paths, health effects, cadmium content levels, and alternative substances – and that the actors take this information into account in their decision making. The actual effects on cadmium exposure are highly uncertain. The uncertainty is two-folded. First, there is an uncertainty regarding whether the necessary information reaches the affected actors, which is likely to be problematic if the measure is directed towards a large group of small actors, e.g. small scale paint users.

Another uncertainty is whether the affected actors are influenced in their decision making by the provided information. Unless the required actions generate positive by-effects, or unless non-participation or non-fulfilment of targets results in substantial sanctions, it is unlikely that the actions will be undertaken. Aside from avoiding a legislative ban on cadmium based artists' paints, there are no obvious positive by-effects for the actors in the paints supply chain to sign up to and implement a voluntary agreement. Sanctions for non-participation or non-fulfilment of targets are another option, but then the instrument is not so much voluntary, but rather an economic policy instrument.

In summary, the effectiveness of voluntary agreements is highly uncertain. This is primarily an effect of the lack of enforcement mechanisms. This lack of effectiveness makes this option non-feasible in terms of risk management.

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

SEAC opinion on section E.1.3

In a report from the Baltic Marine Environment Protection Commission the cost-effectiveness of numerous measure to reduce discharge of hazardous substances were evaluated (Baltic Marine Environment Protection Commission HELCOM, 2013). In the chapter on Cadmium public awareness raising is listed as measure 7. Quotation from the report: "In a Swedish case, where a campaign for raising awareness was carried out in the Stockholm area targeting painters and art schools, a reduction of 1 kg Cd in the sludge cost 5,000 euros." For this measure it was concluded in the report that the Cd discharge from these sources is relatively low and very specific to certain locations. Therefore the cost-effectiveness was expected to be medium.

Economic policy instruments

A fee or tax could be introduced to reduce the spreading cadmium (in sludge) on agricultural land. In order for such an instrument to be economically motivated, the external effect has to be clarified. External effects are uncompensated impacts on other individuals' welfare caused by actions by one individual or firm. These effects can be positive or negative. In the case investigated here, an emission of cadmium contaminated water (originating from paint brush washing) from one actor eventually leads to a negative impact on other peoples' welfare (i.e. negative external effects) in terms of reduced quality of life and increased health care costs. According to economic theory, external effects can be internalized by introducing a fee or a tax that forces the emitter to take the welfare losses of others into account. Two alternative points in the Cd-flow from paint production to human intake where an economic instrument potentially could be implemented have been identified. A fee or a tax could be charged on:

- **i.** the cadmium content in the artists' paints sold by producers and importers
- **ii.** the cadmium content in sewage sludge designated for agricultural use

Option **i**. would force the artists' paint users to take the external effects of cadmium emissions into account, but still allow those who find that the benefits of using cadmium paints are larger than the costs (including the fee or tax) related to the use to continue using them.

Option **ii**. would internalise the harmful effects of spreading cadmium (in sludge) on agricultural land. This option would also deal with cadmium from up-stream sources other than artists' paints. Sludge suppliers (WWTPs) will get an economic incentive to reduce the cadmium content in the sludge, and will – in theory – do so if they find it less costly than paying the tax. The effectiveness of introducing a tax on the cadmium content in sewage sludge designated for agricultural use depends on the ability of sewage sludge "producers" (WWTPs) to influence the amount of cadmium in their sludge. Broadly speaking, there are two potential ways for the WWTPs to affect this amount, either by exercising influence on their upstream sewage providers (including artists' paints users) or by implementing sewage/sludge treatment technologies such as struvite precipitation or sludge incineration with phosphorous recovery. Assuming that some of this additional cost (tax and/or abatement costs) would be carried over to the sludge price, the farmers decision on quantities of sludge used would also be affected.

The unanimity requirement in the tax area means that the possibility of using taxation as a Union-wide instrument is limited (EC 2007). There are few – if any – examples of an EU-wide tax regulation of the kind presented above. Member States may to some extent introduce these taxes, but it is highly questionable whether that is preferable to an EU-wide restriction, as these taxes would create an uneven playing field for market actors and increase the risk for illegal imports – from Member States where cadmium paints are not taxed into Member States where they are taxed. An EU-wide instrument is preferable, but it is unlikely that a tax regulation is viable. Therefore the tax options have not been analyzed further in this report.

SEAC opinion on section Economic policy instruments

A fee or tax could be charged on the Cd content in paints, sewage sludge as well as in fertilizers. Actually this option had been introduced in Sweden in 1994 with 30 SEK /g Cd when the Cd concentration is above 50 mg /kg P. This tax has been repealed some years ago. The Cd concentration as function of P content for phosphate fertilizers applied in European countries was studied by Nziguheba and Smolders (Nziguheba, G. and Smolders, E, 2008). From the following figure it can be seen that almost all fertilizers applied in Europe are above the limit of 50 mg/kg P.

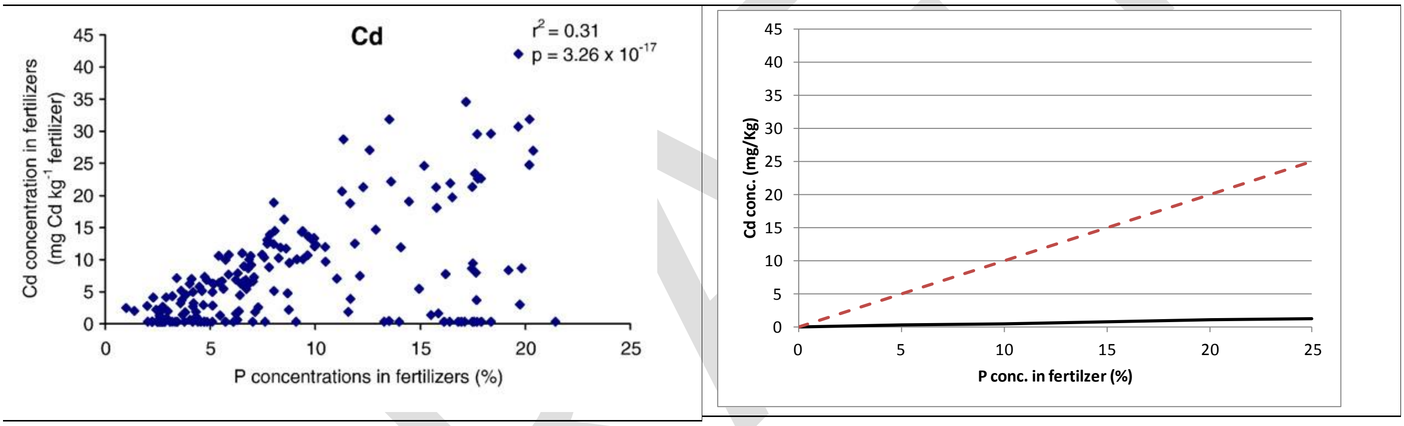


Figure: Distribution of Cd concentration in mineral fertilizers as function of P content (left). For comparison the graph on the right shows the limit above a tax was raised in Sweden (solid line).

The limit for the tax was set to such al low limit that no steering effect is possible, because it has to be paid by (almost) every user. Taxation of fertilizers with high Cd content only, e.g. 1000 mg Cd/kg P (see dotted line in figure), would most probably lead to an exclusion of fertilizers with high Cd content. Such a scenario and the impact on agriculture is discussed in the report of Oosterhuis et al. (Oosterhuis et al., 2000).

Stricter limit values in the sewage sludge directive

One potential RMO is to impose stricter quality standards on the use of sewage sludge on agricultural land. The sewage sludge directive (86/278/EEC) was adopted to regulate the use of sewage sludge in agriculture as to prevent harmful effects on soil, vegetation, animals and humans. The Directive provides limit values for heavy-metal concentrations in sludge for use in agriculture (Annex 1B of the directive). The limit for cadmium was set at 20-40 mg per kg of dry matter. The European Commission is currently assessing whether the current directive should be reviewed, and has launched a study to provide background material and revision options (Milieu 2008). The study suggested – in coordination with Member State officials and industry stakeholders – five different options for further analysis:

- **i.** no change (20-40 mg cadmium/kg of dry matter),
- **ii.** minor revision of limit values (10 mg cadmium/kg of dry matter),
- **iii.** larger revision of limit values (5 mg cadmium/kg of dry matter),
- **iv.** total ban on the use of sludge on land, and
- **v.** repeal of the Directive.

These alternatives are considered as the most probable outcomes of the revision process, and this assessment does not look in to any other possible alternatives. Option **iv** (total ban) and option **v** (repeal of the Directive) have large effects on issues that are outside the scope of this assessment, and are therefore not analysed in more detail here.

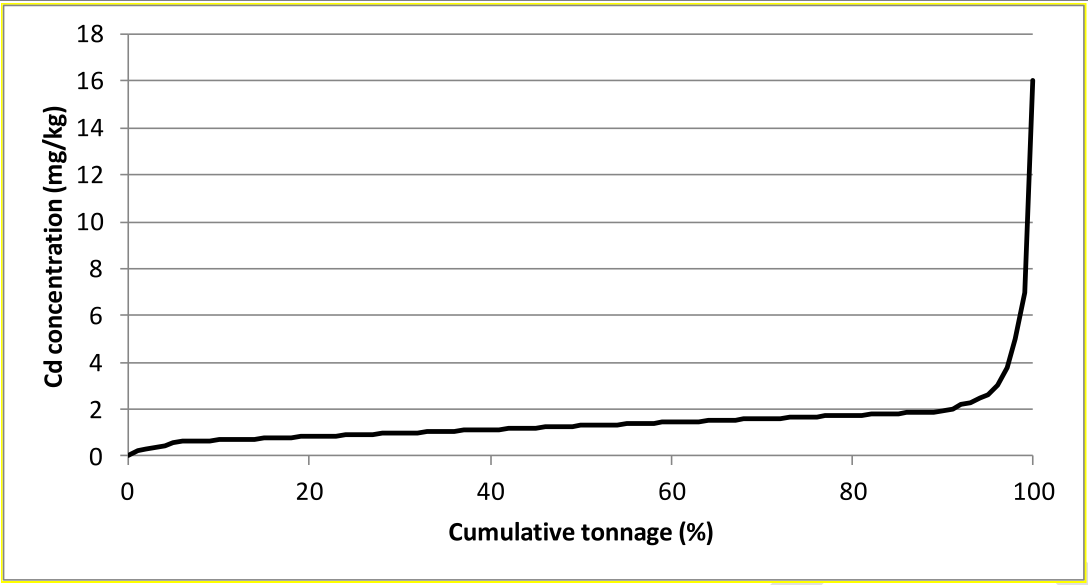
Data on current levels of average cadmium content in sludge from 19 Member States indicate that sludge from only one of them (Cyprus) fails to meet the limit values for cadmium suggested in option **iii**, and, consequently, that the suggested limit values for cadmium in options **i** and **ii** will – on average – not be binding for any of the investigated Member States.[48] The effectiveness of the suggested revisions on limit values for cadmium must thus be considered to be very low, or even insignificant.

In order for a revised limit value on cadmium to have any effect, a limit value around 1-3 mg Cd/kg dry matter would have to be considered. Too strict limit values would, on the other hand, have consequences on the ability to use sludge in agriculture and/or lead to costly cadmium abatement measures for those who fail to meet the new quality standards. The practicality and effectiveness of this measure is then reliant on the availability of sewage/sludge treatment technologies. These technologies are still under development and would require considerable costs and take several years to implement. Therefore this risk management option has not been analysed further in this report.

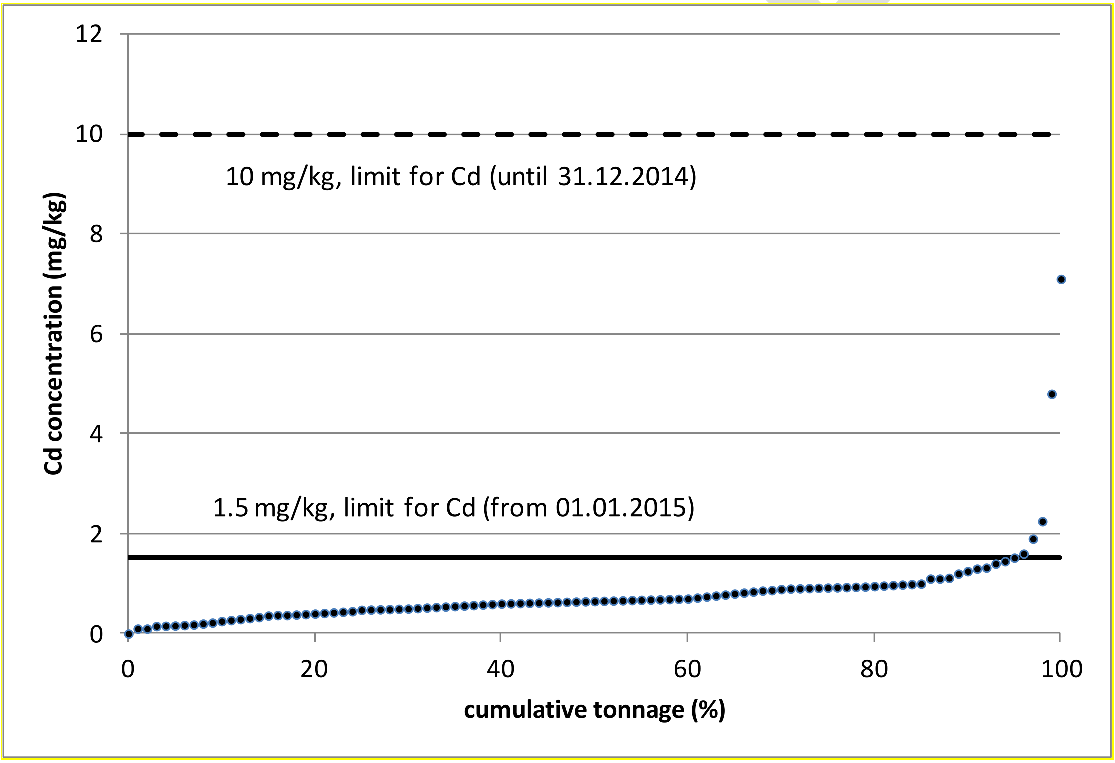
SEAC opinion on section Stricter Limits

The distribution of Cd in sewage is usually a S-curved function: a few very low concentrations in the beginning, a broad area of with concentrations increasing almost linearly with a small slope and a few high concentrations at the end. The result from an investigation from German DWA ("Klärschlammerhebung") is shown in the following figure (DWA 2005).

[48] Note that some of the suggested limit values for other heavy metals (notably Zn) and pathogens will have a restrciting effect on the availability of sewage sludge for agricultural uses.



A similar result was found in a recent study from German Federal State Mecklenburg-Vorpommern (Friedrich 2013).



In above displayed figure the limit value for Cd of 1.5 mg/kg (dry substance) according German Fertilizer Ordinance from 2012 is drawn. For a transisition period until 31.12.2014 the limit for Cd was at 10 mg/kg. As can be seen approximately 4 % of the sewage sludge in Mecklenburg-Vorpommern cannot be applied in agriculture after end of 2014. Projected to the total mass of sewage sludge applied in agriculture in Germany (593000 t, see Table 19 and 20) and assuming the same characteristics in concentration the new stricter limit leads to a reduction of Cd spread on agricultural land in Germany in the range of 60 kg.

It is expected that the rate of recovery of sewage sludge will remain at 100 % in Germany even with the stricter limit for Cd (and other heavy metals such as Mercury) after the end of the transition period. The recovery pathways are incineration (52%), agriculture (29%), landscape construction (16%) and other material recycling (3%) (DWA 2010). The costs for the non-thermal recovery options are in the same range: agriculture 25-45 EUR/t, landscape construction 30-45 EUR/kg. Thermal treatment by co-combustion or mono-incineration has slightly higher cost (co-combustion/incineration 50-120 EUR/kg) (Wichmann 2012).

The exclusion of sewage sludge with higher values of Cd might also be established by voluntary agreement on quality assurance or by a tax for sewage sludge above a certain Cd level (see box on Cd tax on fertilizers).

E.2 Assessment of risk management option

E.2.1 Restriction option 1.

RMO 1: Complete ban of cadmium based artists' paints (with a transitional period of XX years)

This restriction option means a total ban to place on the market or use cadmium and its compounds as a constituent in artists' paints. This will reduce the emissions to waste water and consequently the exposure of cadmium to humans via food.

E.2.1.1 Effectiveness

E.2.1.1.1 Risk reduction capacity

E.2.1.1.1.1 Changes in human health risks/impacts

A complete ban would have a high degree of effectiveness. Cadmium based artists' paints would be fully excluded from the European market. The effectiveness would however be reduced by any occurrence of illegal imports and/or by users stockpiling the paints before implementation.

Based on the classifications the alternatives are considered to be less hazardous to human health than the cadmium ion (Section C.2.2 and Appendix 7). Taking into account the exposure route (Section B.9), the alternative paints are assumed to constitute a far lower risk than the cadmium based paints.

This restriction option is assumed to fully remove the exposure (via the environment) from cadmium in artists' paints. This is estimated to reduce per capita intake of via food in 100 years by **0.0010 µg Cd day^{-1}** (compared to baseline), which is equivalent to **0.0064% of total intake via food** (Section B.9.7).

Taking into account also the time lags caused by the fact that the cadmium in the pigments are not immediately bioavailable, and that the health effects analysed in this report occur due to long term accumulation of cadmium in the human body, the calculated impacts on a population level from restricting the use of cadmium based artists' paints will fully manifest itself after approximately 150 years from the date of implementation (Section B.10). It is reasonable to assume that the health impacts from a restriction will grow linearly from zero at the time of implementation to the calculated levels after 150 years. Figure 7 provides a schematic illustration of this scenario.

The change in cadmium intake is estimated to generate a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will **grow linearly from zero at the time of implementation to the following levels after 150 years** (Section B.10):

- **Female fractures: 37 fewer cases/year**
- **Male fractures: 11 fewer cases/year**
- **Breast cancers: 13 fewer cases/year**

The health effects per year and accumulated effects after implementation are presented in Table 51. Although other toxic effects of cadmium have not been assessed in this report, it is expected that these will also decrease in a similar manner.

Table 51 Risk reduction capacity in terms of number of prevented fractures and breast cancers per year

Years from implementation	Female fractures	Male fractures	Breast cancers
	Health effect per year		
50	12	4	4
100	25	7	9
150	37	11	13
	Accumulated effects after implementation		
50	316	90	111
100	1251	358	440
150	2804	802	987

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

E.2.1.1.1.2 Changes in the environmental risks/impacts

Not relevant for this proposal.

E.2.1.1.1.3 Other issues

Not relevant for this proposal.

E.2.1.1.2 Costs

The quantified costs are described in detail in Section F.2. A condensed version of that analysis is presented here.

There are primarily three economic impacts of this restriction option; (1) the need for the users of cadmium based artists' paints to cease their use and switch to alternatives, (2) the costs for actors throughout the supply chain of cadmium based paints being discarded or sold at reduced prices due to the introduction of the proposed ban, and (3) losses of public good values related to historical art works in need of restoration and also to some extent the values related to the sustenance of historical forms of art.

Two other costs are also identified, but these are likely to be of marginal extent. One is the monetary implications for paint producers, importers, and distributors. These are likely to be small. Suppliers of pigments and artists' paints will lose revenue from the cadmium based products, but will probably be compensated by increased revenues from the alternative paints.

Another marginal source of costs from this proposal is the administrative effect on the public authorities. These are for example the costs related to the REACH legislative process itself, and the costs related to enforcement of the restriction at the Member State level.

Due to the eventual implement of the restriction option actors throughout the supply chain might have to discard cadmium based artists' paints – or be forced to sell them at reduced prices. The proposed implementation period for the restriction is one year. This should be enough time for the distributors and the retailers to be informed and to take the actions necessary to avoid most losses related to discarding products or having to sell them at reduced prices. Apart from adjusting their purchases of new stocks, distributors have the option of selling any remaining stock to distributors overseas that are not affected by the proposed restriction, this might however require price reductions or additional administrative costs. Given this, it is reasonable to assume that there will be some discards and other costs related to the introduction of the restriction. In this analysis it is assumed these costs will be equivalent to 20% of one year's revenue. Given the total annual quantity of 39 tons cadmium based artists' paints and a market value of around €0.18 per gram, the revenue on the retail market for cadmium based artists' paints is around €6.9 million per year. A one-off cost equivalent to one fifth of this – or €1.4 million – is assumed due to the introduction of the restriction.

As indicated in Section C.2.4 alternative paints are available at no additional cost (or at lower costs) relative to the cadmium based products. Assuming that the amount of paint required is around 20-50% higher when the alternatives are used, and that the alternatives cost 35% less than the cadmium paints, the financial costs for users of switching from cadmium based artists' paints to the alternatives are between zero and minus 20%[49], i.e. that the costs are reduced. A central estimate of minus 10% will be used below. Given the market revenuethe financial costs for the users of cadmium based paints due to the proposed restriction are approximately minus **€**0.7 million (with a likely range between minus **€**1.4 million per year and 0).

Two basic explanations are possible for the continued use of cadmium based artists' paints when the available alternatives are cheaper. The first is that the users prefer the characteristics of the cadmium paints and are willing to pay the additional cost they carry. Stakeholder consultations indicate that this is the case among some artists' paints users. The second explanation is that the users of cadmium paints are misinformed about the characteristics of the alternatives relative to the cadmium paints and would use the cheaper products if they had full information.

For the sake of simplicity, we can think of two types of artists' paints consumers. One type consists of consumers that – if fully informed – find no substantial difference in the characteristics of cadmium paints relative to alternative paints. This type will be referred to as **"Indifferent"**. If all artists' paints

[49] (1-0.35)*1.2=0.8; (1-0.35)*1.5=1

users always are "Indifferent" then the consumer utility loss of not being able to use cadmium paints is zero or lower. The other type of consumers analysed here is **"Pro cadmium"**, who finds the cadmium paints to be superior to the alternatives, and is willing to pay the (eventual) excess financial costs related to the cadmium paints. A "Pro cadmium" consumer will suffer utility losses if banned from using the cadmium paints. This utility loss is equivalent with the difference in consumer surplus – i.e. the additional amount the consumer would be willing to pay over and above the price offered – gained from the cadmium paints, relative to the alternatives.

An indication of the share of artists in the respective categories is given by an artist survey (see Section C.2.5). The survey was distributed through e-mail lists and Facebook groups, and the results should due to potential selection bias be treated cautiously. Of those who use cadmium based paints, 64% consider them irreplaceable. Based on the written comments, we can see that some of those who consider the cadmium based paints to be irreplaceable are, while others have never actually used the alternatives to cadmium based paints.

If all users are "Pro cadmium" in the extreme, i.e. that they find the alternatives to be of no use at all, then the consumer utility loss from the restriction is the aggregated consumer surplus of the cadmium paints market. A rough approximation of the size of the consumer surplus is that it is equivalent to consumer expenditure divided by two, i.e. €3.4 million per year.

A number of reasons indicate that a relatively small share of the total current consumer surplus will be lost (for a more detailed discussion, see Section F.2). The assumption made in this analysis is that this share is 10-20%, i.e. that the loss in consumer surplus due to the restriction is €0.34-0.69 million per year.

Assuming that the consumer surplus will grow in line with GDP and using the discounting procedure as described in Section F.1.1 the accumulated present value of the losses in consumer surplus will be €12 million over 50 years and €29 million over 150 years, when the loss share is assumed to be 10%. If the loss share is 20%, then the accumulated present value of the losses in consumer surplus will be €25 million after 50 years and €58 million after 150 years. If we assume no growth in consumer surplus over time, then the 10% share yields accumulated losses of €8 million over 50 years growing to €11 million after 150 years. The 20% share yields losses of €17 million after 50 years, growing to €22 million after 150 years. Note that, in the estimation of loss in consumer surplus, the effect on consumers' financial costs is included.The public good values related to the historical art works in need of restoration, and to a lesser extent the value related to the sustenance of historical forms of art, are important but very problematic to place monetary values on. These are arguments against a complete ban that are taken into account below in restriction option 2.

In summary, restriction option 1 is estimated to generate one-off costs of around €1.4 million due to products being discarded or sold overseas at reduced prices when the restriction is introduced. Artists' paints consumers are likely to experience financial costs reductions of approximately €0.7 million per year. The present value of aggregate cost savings are estimated to €17million over 50 years and €22 million over 150 years. Apart from this, the monetary effects on producers, distributors and retailers of cadmium based artists' paints are likely to be small. The major economic costs are probably not monetary, but rather in the form of losses in public good values and in reduced consumer surplus. The consumer surplus loss (with the financial cost savings factored in) is estimated to be €0.34-0.69 million per year. The present value of aggregate consumer surplus losses is estimated to €8-25 million over 50 years and €11-58 million over 150 years.

E.2.1.1.3 Proportionality

The socio-economic benefits or the restriction option

The socio-economic benefits are described in detail in Section F.1.1. A brief summary of that analysis is presented here.

It is important to note that the benefit estimation is partial in the sense that only two health endpoints have been monetized, while a range of other health impacts can be expected from the proposed restriction. Cadmium exposure can cause many different adverse effects in the human body, such as CMR effects and damage to kidney and bone (for details, see section B 5).

The human health impacts concerned in this analysis are bone fractures for men and women aged 50 years and above and post-menopausal breast cancers. In Sections B.10 and E.2.1.1.1 the risk reduction capacity from the proposed restriction was identified as: from implementation date the risk reduction will grow linearly from zero, and after 150 years there will be a reduction of 48 fracture cases and 13 breast cancer cases per year in the EU27.

Two alternative socio-economic benefit estimations are conducted in this analysis. In Alternative 1 the socio-economic costs arising from fractures and breast cancers are divided into three categories: direct costs, indirect costs, and intangible costs. The direct costs are those related directly to the treatment of affected patients, including hospitalization, outpatient consultations, and medications. Indirect costs are primarily related to production losses, either through sick leave, early retirement, premature death (before retirement age), or through care and other support from the patients' relatives. The third category of costs is the intangible costs related to losses in quality of life due to the prevalence of fractures or breast cancers. This category also includes the ultimate loss of life induced by premature death. The intangible costs are measured in terms of losses in quality adjusted life years (QALYs).

Direct costs per fracture or breast cancer case are in this analysis assumed to remain constant (in real terms) over time. Indirect and intangible costs are assumed to grow in line with gross domestic product (GDP) per capita. The indirect costs are largely related to lost production value due to absence from work and the value of lost production per work day lost will approximately increase in line with economic growth. The value of a QALY is also likely to increase in line with economic growth, as it is closely related to the willingness to pay for life enhancing, or life improving, activities.

The value per QALY used in this analysis is equivalent to two times annual GDP per capita within EU 27. In 2012 the EU 27 GDP per capita was €25 600, which indicates a value per QALY of €51 200.

Every breast cancer case is assumed to yield direct costs of €20 000 and indirect costs of €24 000 (Luengo-Fernandez et al 2013). In addition approximately 1.65 QALYs (Lidgren et al 2007), valued at €84 500, will be lost per case of breast cancer.

Every fracture affecting men and women over the age of 50 years is estimated to generate direct costs of €12 000 (Ström et al 2011). In addition a loss of life years and in quality of life equivalent to 0.34 QALYs, valued at €17 600, per fracture is expected. The indirect costs are assumed to be negligible for fractures (Borgström et al 2007).

In benefit estimation Alternative 2, avoided breast cancers are valued based on WTP-studies. QALY measures are based on the assumption that preferences over health risks depend only on the probabilities of each health outcome, while preferences over other aspects of the health risks, such as dread and controllability, are not incorporated (Hammitt 2002). Willingness to pay (WTP) studies can include such preferences, and it is widely believed that there is a WTP premium to avoid cancer (and other diseases associated with dread). The WTP for avoiding breast cancer used in this assessment is €550 000 per breast cancer case. The WTP is assumed to increase over time by the expected rate of economic growth.

A discount rate of 3.5% – the sum of the pure time preference rate (1.5%) and the expected growth rate (2%), as recommended by ECHA's guidance on socio-economic analysis (ECHA 2008b) – will be used for the first 50 years. Since the effects that occur later than that are intergenerational, the pure time preference rate is not used for the period after the first 50 years. From year 51 to 150 the discount rate will be set equal to the expected growth rate, i.e. 2% per year.

The present value of annual benefits of the restriction will increase throughout the 150 years after implementation that is analysed here (Table 52). This increase is explained by two characteristics of the analysis; (1) the number of prevented fractures and breast cancers per year is assumed to increase throughout the time period analysed, and (2) after the initial 50 years the discounting of indirect and intangible costs (and WTP) are completely compensated by the growth in their respective unit values.

In Alternative 1 the accumulated benefits are estimated to be €14 million after 50 years, and are expected to grow to €91 million after 150 years (Table 52). Most of the accumulated benefits are related to breast cancers. Reductions in intangible costs make up most of the benefits, and grow in relative importance the longer the analysed period is.

In Alternative 2 the value of avoided breast cancers is based on the estimated WTP, while fractures are valued in the same way as in Alternative 1. Since the socio-economic benefit per avoided breast cancer case here is more than four times larger than in Alternative 1, the breast cancer values dominate even more in this alternative. The accumulated benefits are estimated to be €44 million after 50 years, growing to €306 million after 150 years.

Table 52.Estimated present value of benefits (in million €) of restriction option 1

Years from implementation	**Benefit per year**		**Accumulated benefit**	
	Alt.1	**Alt.2**	**Alt.1**	**Alt.2**
50	0.4	1.3	14.4	44.1
100	0.8	2.6	44.1	143.0
150	1.1	3.9	91.1	305.8

Concluding remarks on the proportionality of restriction option 1

The analysis carried out throughout Section B (summarised in B.10) of this report identifies a risk related to cadmium based artists' paints. This restriction proposal implies an EU-wide ban targeted towards these paints, and should therefore adequately address the identified risk.

This restriction proposal is in line with the already existing entry on cadmium in Annex XVII, and is thus considered consistent with current legislation.

The relevant implementation time is assumed to be the time it takes to inform retailers about the restriction and the adjustment period the retailers need to sell out their remaining stocks of cadmium based artists' paints. An implementation period of 12 months is suggested for this restriction proposal. This should be enough for the retailers to get informed and adjust. This is discussed in more detail in Section E.2.1.2.1.

The restriction option is estimated to generate one-off costs of around €1.4 million due to products being discarded or sold overseas at reduced prices when the restriction is introduced. Artists' paints consumers are likely to experience financial costs reductions of approximately €0.7 million per year.

The present value of aggregate cost savings are estimated to €17 million over 50 years and €22 million over 150 years. Apart from this, the monetary effects on producers, distributors and retailers of cadmium based artists' paints are likely to be small. The consumer surplus loss (with the financial cost savings factored in) is estimated to be €0.34-0.69 million per year. The present value of aggregate consumer surplus losses is estimated to €8-25 million over 50 years and €11-58 million over 150 years. Even more important are probably the public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art.

The benefits are of the restriction depends on the time frame chosen for the analysis. The (present value of) annual benefits are continually increasing throughout the 150 years analysed. The cumulative benefits are estimated to be €14-44 million after 50 years, €44-143 million after 100 years, and €91-306 million after 150 years.

The one-off costs and administrative costs (Total cost A) are projected to be surpassed by the benefits after 22 years and 10 years, respectively for benefit Alternatives 1 and 2 (Table below). For benefit Alternative 1, it will take 50 to 115 years to reach break-even with Total cost C. For Alternative 2, the corresponding times are 19 to 34 years.

Table 53 Years to break-even under different cost-benefit combinations

	Total cost A	**Total cost C* (Total Cost A + CS loss)**			
		a	**b**	**c**	**d**
Benefits Alt.1	22	66	50	115	74
Benefits Alt.2	10	21	19	34	28

*a = 10% loss of consumer surplus, growth over time; b = 10% loss of consumer surplus, no growth over time; c = 20% loss of consumer surplus, growth over time; d = 20% loss of consumer surplus, no growth over time.

SEAC opinion on section E.2.1.1.3. Proportionality

There is no reference given by the dossier submitter for the value of 550000 EUR for willingness to pay to avoid breast cancer (per breast cancer case). In a recent report on a study perfomed under contract of ECHA a value of 396000 EUR was estimated as WTP value for cancer (Alberini and Ščasný, 2014). The years for break-even is then 46 years instead of 34 years (see Table 53, Benefits Alt. 2, column c, 20 % loss of CS, growth over time). There is a large difference between the benefits calculated with the two alternatives. Alternative 2 might be an overestimation because exaggerating implied monetary values for health is a potential problem in all WTP studies (Cookson, 2003).

This does however not take into account the expected losses in public good values, which are not quantified here. This makes it difficult to conclude whether the restriction is proportional or not. The trade-off between vastly different types of socio-economic value that this restriction represents make it difficult, if not impossible, to come up with an objective conclusion on proportionality.

The public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art are addressed in restriction option 2.

E.2.1.2 Practicality

E.2.1.2.1 Implementability and manageability

Implementability refers to the practical capability of involved actors to comply with the restriction. This implies that the necessary technology, techniques and alternatives should be available and economically feasible within the timeframe set in the restriction.

As described in section C.2.4 alternatives to cadmium based artists' paints are widely available and generally come at a lower cost to the paint user. A ban on cadmium based paints can therefore be considered to be economically feasible.

Cadmium based paints and the available alternatives have some differences in their respective characteristics. Consultations with stakeholders indicate that there are differing views within the artist community regarding the technical feasibility of the alternatives. This issue is subjective and a ban on cadmium based artists' paints will be considered to be technically feasible by some artists while it will be considered technically infeasible by others.

Manageability refers to the ability of the actors to understand the restriction and how to comply with it. Furthermore, the level of administrative burden for the actors concerned and for the authorities should be proportional to the risk avoided.

A ban on cadmium based artists' paints and pigments is a clear and distinct restriction which should be understandable to the affected parties, as long as they get informed about it. Making information about the ban available to the paint and pigment producers and distributors should be straight forward. Thereby a ban covering the placing of the market of the products can be considered manageable. A ban on the use of the products will require that also the artists and hobby users get the relevant information. This will probably be more difficult to manage, but if not else the consumers will be informed about the restriction from their respective retailers when the cadmium based artists' paints are no longer part of their assortment range.

The decision on implementation time should take into account the time allowed for the actors to comply with the restriction and avoid costs related to losses in the value of stocks throughout the supply chain. On the other hand, the longer the implementation time is the larger is also the possibility that end-users (i.e. artists) stockpile cadmium based artists' paints for future use, thereby diminishing the risk reduction of the proposal. Since the products will still be allowed outside the EU, large scale distributors can be expected to be able to sell any remaining stocks of cadmium based artists' paints to distributors abroad without any major losses. The relevant implementation time is therefore the time it takes to inform retailers about the restriction and the adjustment period the retailers need to sell out their remaining stocks of cadmium based artists' paints. An implementation period of 12 months is suggested for this restriction proposal. This should be enough for the retailers to get informed and adjust. This assumption has however not been addressed during the stakeholder consultation for this proposal, and is thus up for discussion during the public consultation process.

E.2.1.2.2 Enforceability

Enforceability refers to the ability of the authorities responsible for enforcing the restriction to check the compliance of relevant actors.

A ban on placing on the market of cadmium based artists' paints and pigments would require that producers and distributors have to be controlled. The required control of producers, importers, and distributors, is in line with regular monitoring procedures and shouldn't entail any specific challenges.

A ban on the use of the products is however more difficult to enforce. Some of the use is connected to well known locations, such as art schools and museums, which should – at least in theory – be possible to enforce. Otherwise, the enforcement agencies will have to rely on the control further up in the supply chain.

E.2.1.3 Monitorability

Monitorability refers to the possibility to monitor the results of the implementation of the restriction. The monitoring of the restriction for cadmium and its compounds in artists' paints would primarily be done through enforcement. Additional monitoring can be exercised, e.g. through measuring cadmium levels in waste water from artist schools or workshops.

E.2.1.4 Overall assessment of restriction option 1

The restriction option is assumed to fully remove the exposure from cadmium in artists' paints. Cadmium based artists' paints would be fully excluded from the European market.

A ban on cadmium based artists' paints and pigments is a clear and distinct restriction which should be understandable to the affected parties, as long as they get informed about it. Making information about the ban available to the paint and pigment producers and distributors should be straight forward. Thereby a ban covering the placing of the market of the products can be considered manageable. A ban on the use of the products will probably be more difficult to manage.

A ban on placing on the market of cadmium based artists' paints and pigments would require that producers and distributors have to be controlled. The required control of producers, importers, and distributors, is in line with regular monitoring procedures and shouldn't entail any specific challenges. A ban on the use of the products is likely to be more difficult to enforce. A ban on use may however have mitigating effects on the risk of stockpiling of cadmium based artists' paints for later use among the paint consumers. The monitoring of the restriction for cadmium and its compounds in artists' paints would primarily be done through enforcement.

The decision on implementation time should take into account the time allowed for the actors to comply with the restriction and avoid costs related to losses in the value of stocks throughout the supply chain. On the other hand, the longer the implementation time is the larger is also the possibility that end-users (i.e. artists) stockpile cadmium based artists' paints for future use, thereby diminishing the risk reduction of the proposal. An implementation period of 12 months is suggested for this restriction proposal. This should be enough for the retailers to get informed and adjust.

This restriction proposal is in line with the already existing entry on cadmium in Annex XVII, and is thus considered consistent with current legislation.

The change in cadmium intake is estimated to generate a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation to the following levels after 150 years:

- Female fractures: 37 fewer cases/year
- Male fractures: 11 fewer cases/year
- Breast cancers: 13 fewer cases/year

The restriction option is estimated to generate one-off costs of around €1.4 million due to products being discarded or sold overseas at reduced prices when the restriction is introduced. Artists' paints consumers are likely to experience financial costs reductions of approximately €0.7 million per year. The present value of aggregate cost savings are estimated to €17 million over 50 years and €22 million over 150 years. Apart from this, the monetary effects on producers, distributors and retailers of cadmium based artists' paints are likely to be small. The consumer surplus loss (with the financial cost savings factored in) is estimated to be €0.34-0.69 million per year. The present value of aggregate consumer surplus losses is estimated to €8-25 million over 50 years and €11-58 million over 150 years. Even more important are probably the public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art.

The benefits are of the restriction depends on the time frame chosen for the analysis. The (present value of) annual benefits are continually increasing throughout the 150 years analysed. The cumulative benefits are estimated to be €14-44 million after 50 years, €44-143 million after 100 years, and €91-306 million after 150 years.

The one-off costs and administrative costs (Total cost A) are projected to be surpassed by the benefits after 22 years and 10 years, respectively for benefit Alternatives 1 and 2 (Table below). For benefit Alternative 1, it will take 50 to 115 years to reach break-even with Total cost C. For Alternative 2, the corresponding times are 19 to 34 years.

Table 54 Years to break-even under different cost-benefit combinations

	Total cost A	**Total cost C* (Total Cost A + CS loss)**			
		a	**b**	**c**	**d**
Benefits Alt.1	22	66	50	115	74
Benefits Alt.2	10	21	19	34	28

*a = 10% loss of consumer surplus, growth over time; b = 10% loss of consumer surplus, no growth over time; c = 20% loss of consumer surplus, growth over time; d = 20% loss of consumer surplus, no growth over time.

This does however not take into account the expected losses in public good values, which are not quantified here. This makes it difficult to conclude whether the restriction is proportional or not. The trade-off between vastly different types of socio-economic value that this restriction represents make it difficult, if not impossible, to come up with an objective conclusion on proportionality.

An alternative restriction option which includes an exemption from the ban when the paints are used for restoration of historical pieces of art is analysed below.

RAC assessment:

RAC's conclusion on this issue is described in the justification to their opinion on the proposed restriction.

E.2.2 Restriction option 2

RMO 2 (*the proposed restriction*): Ban on cadmium based artists' paints, with an exemption for restoration and maintenance of historical pieces of art.

Member States may permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.

It is recommended that any exemption from the ban should be accompanied with a reservation on how the cadmium based artists' paints should be dealt with to avoid emissions to the waste water systems.

E.2.2.1 Effectiveness

E.2.2.1.1 Risk reduction capacity

E.2.2.1.1.1 Changes in human health risks/impacts

Allowing the sale of cadmium paints for some specified uses would reduce effectiveness slightly as the products would not be excluded from the market. This would entail a risk of illegal selling without the need for import, but it could also imply a higher degree of acceptance – due to a greater sense of proportionality – from the artist community relative to a complete ban.

The quantities of paint required for the exemptions allowed will probably be relatively small. If there will be around 10 exemptions per Member State per year, and if each of these exemptions will require 1 kg of cadmium based artists' paint, then the total use from all exemptions will be less than 1% of the quantities used currently within the EU.

It is recommended that any exemption from the ban should be accompanied with a reservation on how the cadmium based artists' paints should be dealt with to avoid emissions to the waste water systems. It is assumed in this analysis that the exemption does not lead to any reductions in risk reduction compared to the complete ban.

Hence, the risk reduction capacity in option 2 is assumed to be equivalent with the one in option 1, see Section E.2.1.1.1.

E.2.2.1.1.2 Changes in the environmental risks/impacts

Not relevant for this proposal.

E.2.2.1.1.3 Other issues

Not relevant for this proposal.

E.2.2.1.2 Costs

The costs for restriction option 2 are largely the same as for option 1. There are however two differences; (1) the exemption will lead to some administrative costs, and (2) it will also avoid most of the losses in public good value identified in option 1. Allowing for the use of cadmium based artists' paints for restoration of pieces of art that are considered to be of cultural-historical value, will avoid some of the losses in public good values associated with option the complete ban in option 1. The exemption will also to a limited extent facilitate the sustenance of historical forms of art.

The Member States will encounter costs for setting up a routine for dealing with the exemptions and costs for dealing with the applications for exemptions. Assuming that it per Member State takes about two man-weeks to implement the routine at a cost of €24 per hour[50], the total start-up cost would be around €60 000[51]. Each application is assumed to require about one man-day of administration at the Member State CA (for more details, see Section F.2). The number of applications for exemptions from the ban is very difficult to estimate. For illustrative purposes a scenario where each Member State will receive on average 10 applications (in total 300 for the entire EU) per year is analysed here. The annual costs for dealing with the exemption will then be €120 000[52]. Assuming that the annual costs will grow in line with the economic growth of the general economy (expected to be 2% per year), and using the same discounting procedure as described in F.1.1, the accumulated present value of the administrative costs of the exemption is €4.4 million over 50 years, €7.3 million over 100 years, and €10.2 million over 150 years.

In summary, this restriction option will lead to monetary costs due to administration of exemptions and also due to discards or price reductions arising from the eventual introduction of the restriction. Artists' paints consumers are likely to experience financial costs reductions. Apart from this, the monetary effects on producers, distributors and retailers of cadmium based artists' paints are likely to be small. The users who gain higher consumer surplus from cadmium paints than from the alternatives will however suffer utility losses if cadmium paints are banned.

The economic impacts quantified in this section are summarised in Table 75 and

Table **76**.The four types of cost quantified in this section are aggregated in three different ways.

Total cost A refers to the sum of administrative costs and costs of discarded products.

Total cost B also includes the financial costs to consumers. These are the estimated monetary costs (which actually are assumed to be reduced) of the proposed restriction. If the financial costs are at the upper end of the estimated range (i.e. 0), then the costs are identical to Total cost A. If on the other hand the financial costs are at the lower end of the range, Total cost B would be negative to an even larger degree.

Total cost C includes the estimated loss in consumer surplus instead of the consumers' financial costs. In the estimation of loss in consumer surplus, the effect on consumers' financial costs is already included. Variations a-d indicate combinations of assumptions regarding consumer surplus loss share (10% or 20%) and the growth in consumer surplus over time (2% or 0%).

Table 55 Summary of present value of accumulated costs (million €)

Years from implementation	**1. Consumer financial costs**	**2. Reductions in consumer surplus***				**3. Administrative costs of exemption**	**4. Costs of discarded products**
		a	**b**	**c**	**d**		

[50] Eurostat (2013e) has data (from 2011) on hourly labor costs for public administration workers for 15 Member States. These are in the range of €7-37 (adjusted for purchasing power). The data are primarily from MS with GDP per capita below the EU-average. An additional estimate has been obtained from Sweden (€33/hour, nominal). The unweighted average of these 16 estimates is €18, the median is €16, and the first and third quartiles are €12 and €24, respectively. Taking into account the lack of estimates from most of the wealthier Member States, the third quartile is assumed to be a good estimate for the average across the EU.
[51] 80 hours at €24/hour for ~30 authorities ➔ 80*25*30 ≈ 60 000
[52] 2*€200 per application, 300 applications per year ➔ 2*200*300 ≈ 120 000

50	-16.8	12.5	8.4	24.9	16.8	4.4	1.4
100	-20.7	20.8	10.3	41.5	20.7	7.3	1.4
150	-22.1	29.0	11.1	58.1	22.1	10.2	1.4

*2a = 10% loss of consumer surplus, growth over time; 2b = 10% loss of consumer surplus, no growth over time; 2c = 20% loss of consumer surplus, growth over time; 2d = 20% loss of consumer surplus, no growth over time.

Table 56 Present value of accumulated costs in three different aggregations (million €)

Years from implementation	Total cost A (=3+4)	Total cost B (=1+3+4)	Total cost C (=2+3+4)			
			a	b	c	d
50	5.8	-11.0	18.2	14.2	30.7	22.6
100	8.7	-12.0	29.4	19.0	50.2	29.4
150	11.6	-10.5	40.6	22.6	69.6	33.7

E.2.2.1.3 Proportionality

The analysis carried out throughout Section B (summarised in B.10) of this report identifies a risk related to cadmium based artists' paints. This restriction proposal implies an EU-wide ban targeted towards these paints, and should therefore adequately address the identified risk.

This restriction proposal is in line with the already existing entry on cadmium in Annex XVII, and is thus considered consistent with current legislation.

The relevant implementation time is assumed to be the time it takes to inform retailers about the restriction and the adjustment period the retailers need to sell out their remaining stocks of cadmium based artists' paints. An implementation period of 12 months is suggested for this restriction proposal. This should be enough for the retailers to get informed and adjust. This is discussed in more detail in Section E.2.1.2.1.

The restriction option is estimated to generate one-off costs of around €1.4 million due to products being discarded or sold overseas at reduced prices when the restriction is introduced. Artists' paints consumers are likely to experience financial costs reductions of approximately €0.7 million per year. The present value of aggregate cost savings are estimated to €17 million over 50 years and €22 million over 150 years. Apart from this, the monetary effects on producers, distributors and retailers of cadmium based artists' paints are likely to be small. The consumer surplus loss (with the financial cost savings factored in) is estimated to be €0.34-0.69 million per year. The present value of aggregate consumer surplus losses is estimated to €8-25 million over 50 years and €11-58 million over 150 years. Even more important are probably the public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art.

The benefits are of the restriction depends on the time frame chosen for the analysis. The (present value of) annual benefits are continually increasing throughout the 150 years analysed. The cumulative benefits are estimated to be €14-44 million after 50 years, €44-143 million after 100 years, and €91-306 million after 150 years.

The one-off costs and administrative costs (Total cost A) are projected to be surpassed by the benefits after 22 years and 10 years, respectively for benefit Alternatives 1 and 2 (Table below). For benefit Alternative 1, it will take 50 to 115 years to reach break-even with Total cost C. For Alternative 2, the corresponding times are 19 to 34 years.

Table 57 Years to break-even under different cost-benefit combinations

	Total cost A	**Total cost C* (Total Cost A + CS loss)**			
		a	**b**	**c**	**d**
Benefits Alt.1	22	66	50	115	74
Benefits Alt.2	10	21	19	34	28

*a = 10% loss of consumer surplus, growth over time; b = 10% loss of consumer surplus, no growth over time; c = 20% loss of consumer surplus, growth over time; d = 20% loss of consumer surplus, no growth over time.

It is important to note that the benefit estimation is partial in the sense that only two health endpoints have been monetized, while a range of other health impacts can be expected from the proposed restriction. Cadmium exposure can cause many different adverse effects in the human body, such as CMR effects and damage to kidney and bone (for details, see section B 5).

Based on these results, the restriction option is considered to be proportional.

E.2.2.2 Practicality

E.2.2.2.1 Implementability and manageability

Implementability and manageability of this option are expected to be equivalent to option 1, see Section E.2.1.2.1.

E.2.2.2.2 Enforceability

Enforceability of this option is similar to the enforceability of option 1 (Section E.2.1.2.2). An exemption from the ban would however require additional enforcement to make sure that the selling of the products is justified by the exemption.

E.2.2.3 Monitorability

Monitorability of this option is similar to the monitorability of option 1 (Section E.2.1.3). The number, extent and type of exemptions allowed by the Member States can be monitored by ECHA by requiring the Member States to document the exemptions in a common database.

E.2.2.4 Overall assessment of restriction option 2

The restriction option is assumed to fully remove the exposure from cadmium in artists' paints. Cadmium based artists' paints would be fully excluded from the European market.

A ban on cadmium based artists' paints and pigments is a clear and distinct restriction which should be understandable to the affected parties, as long as they get informed about it. Making information about the ban available to the paint and pigment producers and distributors should be straight forward. Thereby a ban covering the placing of the market of the products can be considered manageable. A ban on the use of the products will probably be more difficult to manage.

A ban on placing on the market of cadmium based artists' paints and pigments would require that producers and distributors have to be controlled. The required control of producers, importers, and distributors, is in line with regular monitoring procedures and shouldn't entail any specific challenges. A ban on the use of the products is likely to be more difficult to enforce. A ban on use may however have mitigating effects on the risk of stockpiling of cadmium based artists' paints for later use among the paint consumers. The monitoring of the restriction for cadmium and its compounds in artists' paints would primarily be done through enforcement.

The decision on implementation time should take into account the time allowed for the actors to comply with the restriction and avoid costs related to losses in the value of stocks throughout the supply chain. On the other hand, the longer the implementation time is the larger is also the possibility that end-users (i.e. artists) stockpile cadmium based artists' paints for future use, thereby diminishing the risk reduction of the proposal. An implementation period of 12 months is suggested for this restriction proposal. This should be enough for the retailers to get informed and adjust.

This restriction proposal is in line with the already existing entry on cadmium in Annex XVII, and is thus considered consistent with current legislation.

The change in cadmium intake is estimated to generate a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation to the following levels after 150 years:

- Female fractures: 37 fewer cases/year
- Male fractures: 11 fewer cases/year
- Breast cancers: 13 fewer cases/year

The restriction option is estimated to generate one-off costs of around €1.4 million due to products being discarded or sold overseas at reduced prices when the restriction is introduced. Artists' paints consumers are likely to experience financial costs reductions of approximately €0.7 million per year. The present value of aggregate cost savings are estimated to €17 million over 50 years and €22 million over 150 years. Apart from this, the monetary effects on producers, distributors and retailers of cadmium based artists' paints are likely to be small. The consumer surplus loss (with the financial cost savings factored in) is estimated to be €0.34-0.69 million per year. The present value of aggregate consumer surplus losses is estimated to €8-25 million over 50 years and €11-58 million over 150 years. Even more important are probably the public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art.

The benefits are of the restriction depends on the time frame chosen for the analysis. The (present value of) annual benefits are continually increasing throughout the 150 years analysed. The cumulative benefits are estimated to be €14-44 million after 50 years, €44-143 million after 100 years, and €91-306 million after 150 years.

The one-off costs and administrative costs (Total cost A) are projected to be surpassed by the benefits after 22 years and 10 years, respectively for benefit Alternatives 1 and 2 (Table below). For benefit Alternative 1, it will take 50 to 115 years to reach break-even with Total cost C. For Alternative 2, the corresponding times are 19 to 34 years.

Table 58 Years to break-even under different cost-benefit combinations

	Total cost A	**Total cost C* (Total Cost A + CS loss)**			
		a	**b**	**c**	**d**
Benefits Alt.1	22	66	50	115	74
Benefits Alt.2	10	21	19	34	28
Assuming Release factor 1 % instead of 5 %					
Benefits Alt. 1	22	>150	>150	>150	>150
Benefits Alt. 2	10	103	75	>150	102

*a = 10% loss of consumer surplus, growth over time; b = 10% loss of consumer surplus, no growth over time; c = 20% loss of consumer surplus, growth over time; d = 20% loss of consumer surplus, no growth over time.

It is important to note that the benefit estimation is partial in the sense that only two health endpoints have been monetized, while a range of other health impacts can be expected from the proposed restriction. Cadmium exposure can cause many different adverse effects in the human body, such as CMR effects and damage to kidney and bone (for details, see section B 5).

Based on these results, the restriction option is considered to be proportional.

E.3 Comparison of the risk management options

The risk reduction is similar in both options. Option 2 would result in slightly lower risk reduction than option 1, as the cadmium based artists' paints would not be excluded from the market. This effect is however likely to be marginal.

In terms of practicality and monitorability the two options are very similar. Both restriction options are in line with the already existing entry on cadmium in Annex XVII, and are thus considered consistent with current legislation.

The economic implications of the options differ in two ways. The complete ban in restriction option 1 will cause losses in public good values related to the historical art works in need of restoration and also the value related to the sustenance of historical forms of art. In option 2, an exemption is included to allow for the use of cadmium based artists' paints for the purpose of restoration of pieces of art that are considered to be of cultural-historical value. This will avoid most of the losses in public good values experienced under option 1.

Administrating the exemptions will however lead to some cost for enforcement agencies – and restorers applying for an exemption – in terms of setting up and maintaining an exemption system. These costs are estimated to be €4 million over 50 years, €7 million over 100 years, and €10 million over 150 years.

Since the differences in risk reduction and monetary cost is relatively small between the two options, and since an exemption for restorative activities would moderate the losses in public good values associated with a restriction, option 2 is the proposed risk management option.

E.4 Main assumptions used and decisions made during analysis

- *The quantities of cadmium based artists' paints sold in the EU are 39 ton per year. (Section B.9.3.2.3)*

  The sold quantities have varied only very slightly over the last ten years and CEPE expects that it will remain stable in the future. Since the information from CEPE was based on their extrapolations from a limited sample of members this is a rough estimation but the best one available. Also, direct import by consumers from non-EU countries is not included in these sale figures which might lead to an underestimation of used artists' paints.

- *The amount of cadmium in artist paints is assumed to be 6.4tons per year. (Section B.9.3.2.3)*

  This is based on analyses of a representative selection of different types of artists' paints on the EU market. Together with sales figures from CEPE this is most likely a fair estimation. (However, bare in mind that direct import is not included.)

- *Of the artists' paints used, 5% is assumed to be released to waste water (Section B.9.3.1).*

  This is a conservative assumption. During consultation (Royal Institute of Art and ColArt, see section G) we have been informed that there are weaknesses in the cleaning procedures when using cadmium based paint. Especially when water based colours are used there might be a higher release to waste water (City of Gothenburg 2006). However, during literature search we have only found one study estimating the percentage paint release to waste water (5%). Thus, this assumption poses as a potential source of error leading to a significant underestimation of cadmium release from artists' paints.

- *82% of EU households are connected to secondary waste water treatment (Section B.9.3.2.3).*

  This is based on data from 2009/2010 (EC 2013a) and a four percentage point improvement from previous report (two years earlier). As a result of stricter waste water treatment demands this suggests that the percentage presented in the EC report might be somewhat higher today. However, this is the latest solid information found and therefore used in this dossier. The increasing connection rate suggests that this assumption is an underestimation by a few percent.

- *95% of the cadmium that reaches WWTPs is assumed to end up in sludge (Section B.9.3.2.3).*

  This is based on information from the waste water industry (Stockholm Water Company 2013) and assessed to be reliable.

- *The share of sludge from WWTPs applied on agricultural land in the EU is around 45% (Section B.9.3.2.3).*

  This is estimations taken from an EC report (Milieu 2010). The report demonstrates the increasing amount sludge produced in the EU and proportion used in the agriculture. Reported Member States data from 2003-2007 revealed that 39% of the produced sludge was recycled to the agriculture, in year 2010 that percentage is estimated to be 45% and in 2020 48%.

Simultaneously the sludge production has increased. The assumption of 45% used in this report might be somewhat (a few percentages) higher today since this is an estimation based on year 2010.

- *Similar availability of all cadmium in sludge, independent of the source of the cadmium to the sludge, i.e. cadmium from pigments has the same availability as cadmium from other sources to sludge (and soil) (B.9.4.2).*
  It is assumed that all cadmium in cadmium pigments may be solubilised within years to decades. This assumption is based on a literature review and analysis made for the Swedish CA by professor Gustafsson (Appendix 3)

- *Linear relationship between cadmium in soil and cadmium in crop (B.9.7).*

  This was also assumed in the EU RAR (ECB 2007)

- *Similar transfer factors between cadmium in soil and cadmium in crops, independent of the source of cadmium to soil (atmospheric deposition, mineral fertiliser, sludge, lime, manure) (B.9.7).*
  It is assumed that in the long-term perspective which is employed in this assessment and the influence of differing conditions in soil, cadmium compounds have been transformed to other speciation independent of in which form cadmium originally entered the soil. Cadmium is recognized as one of the most mobile trace elements. The adsorption in soil is strongly controlled by soil pH and organic matter. Hence, the availability of cadmium to plants is assumed to be the same independent of the original source of the (anthropogenic) cadmium in soil.

- *The contribution of airborne cadmium directly taken up by crops is considered negligible (B.9.7).*
  This was also assumed in the EU RAR (ECB 2007). Smolders and Mertens (2013) cite a recent compilation of studies in which it was estimated that air borne cadmium could make up 1 % of cadmium in lettuce at current air concentrations (0.2 ng Cd/m^3) in rural areas in EU and background soil concentration (0.2 mg/kg ds). This report is concerning rural areas. In areas closer to point sources emitting to air the relative contribution from air in plant may be higher.

- *All annual cadmium input from deposition, mineral fertilisers, sludge, manure and lime is distributed evenly over all arable land (B.9.4, B.9.7 and B.10)*

  This is the only scenario for which it is possible to estimate a general quantitative risk, since it can be applied on the whole population. However, this means that the risk assessment is based on a diluted fertilising regime. On a local scale higher exposure might occur.

- *The pH in agricultural soil in is assumed to be 6.5 in the "average" EU scenario (B.9.7.4).*
  This pH was used for the average EU scenario in the EU RAR (ECB 2007). Recent data from a new data base (not yet officially available) indicate lower average pH in agricultural soil

(Smolders 2013). pH is important for the algorithms that are used to estimate of accumulation in soil. Different analysis methods give different result and it is not clear which methods have been used for the data that make up the basis for the algorithms used. However, as a test the lower pH was also used in the calculations and did not significantly affect the contribution to intake of cadmium due to use of artists' paints

- *It is assumed that potatoes, vegetables and cereals (wheat grain) are 100% grown within the continent and are affected by cadmium changes in soil, while cadmium in all other food groups (basal cadmium intake) is assumed to be unaffected by the soil cadmium content t (B.9.7.5).* This was also assumed in the EU RAR (ECB 2007).EFSA also concluded data available on biomagnification are not conclusive. 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) (EFSA 2009). The assumption above may result in some underestimation of intake of cadmium in the calculations of changed intake of cadmium via food (due to restrictions of artists' paints).

- *No change in composition of diets is assumed over 100 years (B.9.7.5).* This is probably not a totally realistic assumption, but it is not possible to predict how and how much food habits will change.

- *The Swedish epidemiological studies on cadmium in food and bone effects are relevant for EU.*

  The dietary exposure to cadmium in Sweden is similar to the average EU exposure (EFSA 2012). For fractures, the incidences in Sweden are higher than in most other EU countries. The reason for the higher incidence in the northern part of Europe is not known. The attributable factor (in %) of dietary cadmium to this effect on bone tissue is assumed to be the same in the different EU countries; there are no data indicating otherwise.

- *The Swedish epidemiological study on cadmium in food and breast cancer is relevant for EU.*

  The dietary exposure to cadmium in Sweden is similar to the average EU exposure (EFSA 2012). The incidences of breast cancer in EU countries vary with a factor 2-3 (Ferlay 2013). The data from Sweden are in the middle of this range.

- *The fracture incidence rate per age and gender group in the EU as a whole is assumed to be the average rates of the six EU countries in 2010 presented in Table 43.*

  DE, UK, ES, IT, FR and SE represent a large part of the EU population. Both countries with low (FR, ES), medium (DE, IT, UK) and high (SE) incidence rates are included.

- *The breast cancer incidence rate is assumed to be 292 per 100 000 for women aged 50 years and above.*

  Statistics on incident cancer cases are considered reliable and represent EU27 from year 2012. It is not expected that the proportion of breast cancer cases occurring at age 50 or above is different in Sweden versus other EU member states.

- *Age-dependent incidence rates (fractures and breast cancer) are assumed to be unchanged for 150 years.*

  This is of course highly uncertain, but nevertheless considered as the most appropriate approximation.

- *No change in the relevant trade patterns (i.e. share of imported cereals, root vegetables, and leafy vegetables) is assumed.*

  This is uncertain, but considered as the most relevant approximation.

- *The demographic projections from Eurostat for the year 2060 are assumed to be a good approximation for the whole time frame of the analysis.*

  As the effects of the proposed restriction are long term, and since the demographic composition of the EU population is projected to undergo substantial over the coming decades, the projected population for 2060 is used. This is assumed to be a reasonable proxy for most of the entire time period analysed, but it might overestimate the effects in the initial period (when there will be fewer people in the affected age groups), especially during the first two to three decades. The results here indicate that this is of relatively small importance. An approximate calculation yields that the aggregated number of fractures will be reduced by around 40 cases over the initial 40 years, while the effects on breast cancer cases is negligible. The undiscounted costs of 40 cases of fracture are €1.2 million. This is equivalent with 7% of the aggregated benefits after 50 years, or 1% of the aggregated benefits after 150 years.

- *Assumptions and uncertainties regarding the socio-economic analysis (Section F.1.1) are discussed in Section F.6.*

  These are assumptions regarding estimation of costs and benefits of the proposed restriction.

E.5 The proposed restriction(s) and summary of the justifications

The proposed restriction is RMO 2: Ban of cadmium based artists' paints, with an exemption for restoration and maintenance of historical pieces of art.

The exemption applies to restoration and maintenance of works of art and historic buildings and their interior with reference to cultural-historical values. Member States decide on the exemption and how it should be administrated.

This is a proposal for an addition in REACH Annex XVII, Entry 23, concerning cadmium and its compounds. Articles covered by TARIC codes [3212] and [3213] containing cadmium and its compounds shall not be placed on the market or used. An implementation period of 12 months is suggested.

To be in consistence with the current restriction on cadmium in paints (Entry 23, paragraph 2), the same limit value (0.1%) for the residual concentration of cadmium in artists' paints containing zinc is proposed. If a general limit value for cadmium as an impurity in paints would be included in the current restriction in Entry 23, it is for consistency and enforceability reason, reasonable that such a limit value also would apply to cadmium in artists' paints.

The proposed restriction is will lead to a reduction in cadmium intake via food which will lead to a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation to the following levels after 150 years:

- Female fractures: 37 fewer cases/year
- Male fractures: 11 fewer cases/year
- Breast cancers: 13 fewer cases/year

The socio-economic benefits of the proposed restriction depend on the time frame chosen for the analysis. The (present value of) annual benefits are continually increasing throughout the 150 years analysed. The cumulative benefits are estimated to be €14-44 million after 50 years and €91-306 million after 150 years. This does not take into account other possible negative health effects of cadmium exposure via food – such as kidney damage, endometrial cancer, and developmental neurotoxicity – that have not been quantified in this report.

The monetary costs of this restriction option are likely to be small or negative. The one-off costs and administrative costs are projected to be surpassed by the benefits 10-22 years, while it will take 19-115 years for the benefits to surpass the costs if expected losses in consumer surplus are included.

The proposed restriction is considered to be implementable, manageable, and enforceable.

A Union-wide restriction of cadmium in artists' paints will create a level playground for trade. It will not discriminate between paints produced in the EU and those imported from third countries, and it will not hinder commercial relations on the internal market. A Community wide restriction will create a harmonized, manageable regulatory situation which can reduce the administrative burden and the costs of compliance, and it will prevent the market distortions following from national regulations while still targeting the health concerns.

F. Socio-economic Assessment of Proposed Restriction

F.1 Human health and environmental impacts

The objective of this report has been to develop a proposal for a restriction under REACH Annex XVII of cadmium in artists' paints.

From the available information on the quantities of cadmium released from the uses targeted by the proposed restriction that eventually ends up in food crops, the risk evaluation has shown that the implications for human health in terms of incidence of fractures and cancers are considerable (Section B.10. The assessment in chapter E also concludes the proposed restriction would effectively reduce this risk.

Note here that focus is on impacts on the incidence of fractures and breast cancer. The socio-economic assessment will include these impacts. Other health effects (see Section B.5), such as renal failures, should also be noted, but these are not of primary concern here.

F.1.1 Human health impacts

The human health impacts concerned in this analysis are bone fractures for men and women aged 50 years and above and post-menopausal breast cancers. In Sections B.10 and E.2.2.1.1 the risk reduction capacity from the proposed restriction was identified as: from implementation date the risk reduction will grow linearly from zero, and after 150 years there will be a reduction of 60 fracture cases and 16 breast cancer cases per year in the EU27.

In this analysis of the socio-economic benefits of the proposed restriction, the following approach has been used. Estimated costs per case of fracture or breast cancer are gathered through a survey of relevant publications in scientific journals. These yield the costs related to each case of fracture or breast cancer, discounted to generate the estimated lifetime cost at the time of diagnosis. Along with the estimated reduction in cases of fractures and breast cancers per year, an undiscounted socio-economic benefit per year is identified for each of the 150 years covered by the analysis. After that each yearly cost is discounted - and also adjusted to account for the growth in some of the unit costs over time – to generate a present value of the benefits.

The length of the period of analysis can be questioned. The longer the time frame, the more likely are (e.g.) exogenous technological changes (such as changer in WWTP technology) to occur. On the other hand, on an individual level, cadmium once taken up in the body will more or less remain (biological half-life up to 30 years), and new technology will therefore not have immediate effects. The main argument for an inclusion of the full 150 year period in the analysis is that the health effects – under the baseline assumptions – are estimated to increase throughout the period. It is however important to note that the relevance of some of the assumptions may change over time.

Categorization of costs related to health impacts

The socio-economic costs arising from fractures and breast cancers are in this analysis divided into three categories (Table 59). The direct costs are those related directly to the treatment of affected patients. The direct costs generally include hospitalization, outpatient consultations, and medications. Indirect costs are primarily related to losses in productivity, either through sick leave, early retirement, or premature death (before retirement age). The indirect costs in some cases also include time spent by the patients' relatives on care and other support. The third category of costs is the intangible costs related to losses in quality of life due to the prevalence of fractures or breast cancers. This category also includes the ultimate loss of life induced by premature death. The intangible costs are measured in terms of losses in quality adjusted life years (QALYs). **Table 59** Categorization of costs in socio-economic analysis

Cost type	Explanation and examples	Assumed change over time
Direct costs	Costs related to the treatment of the affected individuals, including costs for medication, hospitalization and outpatient consultations	Assumed to be constant over time
Indirect costs	Primarily costs related to production losses, which occur due to e.g. sick leave, early retirement, mortality, or caring for relatives	Assumed to grow at the same as the gross domestic product (GDP) of the EU 27

Intangible costs	Losses in quality of life and life years. Measured as losses in number of quality adjusted life years (QALYs), multiplied by a value per QALY.	Assumed to grow at the same as the gross domestic product (GDP) of the EU 27

QALY measures are based on the assumption that preferences over health risks depend only on the probabilities of each health outcome, while preferences over other aspects of the health risks, such as dread and controllability, are not incorporated (Hammitt 2002). Willingness to pay (WTP) studies can include such preferences, and it is widely believed that there is a WTP premium to avoid cancer (and other diseases associated with dread). Therefore, an alternative estimation (to the one presented above) based on WTP will be conducted for breast cancer.

Due to the long term nature of this analysis, it is important to approximate how the costs will evolve over time. There are two counteracting impacts on direct costs. Labor costs are a relatively large share of the direct costs[53] and the unit costs of labor can be assumed to grow in real terms, approximately in line with the growth of the economy at large. On the other hand the cost of medication, hospitalization and consultations can be assumed to decrease over time due to productivity improvements. In this report, an assumption is made that the two effects will cancel each other out and that the direct costs will remain stable in real terms throughout the whole period. This is probably an underestimation of future costs, as recent trends suggest that real health care cost unit increases[54] (Smith et al 2009, EC 2012b).

The value of indirect costs and QALYs are – on the other hand – expected to increase in line with real economic growth. The indirect costs are largely related to lost production value due to absence from work. The value of lost production per work day lost will approximately increase in line with economic growth.

The value of a QALY is also likely to increase in line with economic growth, as it is closely related to the WTP for life enhancing and life improving activities. If society becomes more wealthy (i.e. real GDP increases) then the WTP for a QALY will most probably also increase. This implies an assumption of a QALY as a normal good. A recent report (EC 2012b) from the European Commission's working group on ageing populations and sustainability concludes (p.162-163, and Box 2) that the income elasticity of health care demand at the national level is positive, and the estimates cited range from 0.72 to 1.35. It is reasonable to assume that the societal demand for QALYs has a relationship to income similar to that of health care demand in general, which implies that a 1% increase in real GDP will increase society's WTP for a QALY by around 1%.

By the same reasoning the WTP for avoiding breast cancer is also assumed to increase at the expected rate of growth in real GDP.

Value per quality adjusted life year (QALY)

A quality adjusted life-year (QALY) is the arithmetic product of life expectancy and a measure of the

[53] Around half in EU15 and a third in EU12 (EC (2012b))

[54] Smith et al (2009) estimates excess medical care price inflation of 0.2-0.9% per year in the US 1960-2007. EC (2012b) notes that health care expenditures have risen as a share of GDP in the EU, but does not specify the unit cost increases. The most important cost driver, wages, have however grown at a rate of around 1% per year in excess of GDP from 1999-2008.

quality of the remaining life years (ECHA 2008b). A year of perfect health is worth 1, a year of less than perfect health is worth less than 1, and death is equivalent to 0. The time spent in one health state is weighted by the utility score given to that health state. For example, a health impact that reduces the utility score by 0.1 for 10 years causes a loss of 1 QALY, as does an impact that reduces the utility score by 0.5 for 2 years. The socio-economic value of a QALY is not unanimous. ECHA's guidance on socio-economic analysis (ECHA 2008b) refers to two studies which have estimated the value of a QALY.

The UK Health and Safety Executive use the value of a life year (VOLY) as a proxy for the value of a QALY. VOLY is estimated as the annualized value of a statistical life (VSL) – which in turn is based on the willingness to pay to avoid the risk of death – to £27 150 (ECHA 2008b). Adjusting to the income level in EU 27 and taking account of inflation from 2008 to 2012, this equates to approximately €32 700.

The socio-economic guidelines (ECHA 2008b) also refer to results from the EU-wide research program NewExt. The mean estimate of VOLY is there €55 800 in 2003 price levels. In 2012 price levels this is approximately €69 100.

The European Commission guidelines for impact assessments (EC 2009) provides an indicative range of €50 000 - €100 000 for the value of a life year (VOLY).

Another approach is to relate the value of a QALY to the annual GDP per capita in the countries analyzed. A review (Eichler et al. 2004) of value per QALY estimates indicate a range of 0.7-16 (with a median of 2.8) times annual GDP per capita in the countries/regions analyzed. Borgström et al (2006) and Ström et al (2011) suggest a value of QALY equal to two times annual GDP per capita. In 2012 the EU 27 GDP per capita was €25 600. The approach suggested by Borgström et al (2006) and Ström et al (2011) indicates a value per QALY of €51 200, which is almost identical to the average of the two estimates provided in ECHA's guidance above (€50 900). This value per QALY (€51 200) is used as the central estimate for the socio-economic analysis of the proposed restriction.

Lifetime cost per case of breast cancer

As indicated above, two alternative estimates of the socio-economic cost per breast cancer case will be presented here. First, an assessment based on the categories in **Table 59**, and then an assessment based on the WTP to avoid cancers.

A range of published studies on the lifetime cost of breast cancer have been reviewed. An overview of the estimated costs in these studies is given in Table 60.

Table 60 Breast cancer cost per patient/case/individual

Study	Country and year of cost estimation	Direct costs	Indirect costs	Comments
Dahlberg et al (2009)	Sweden 2006	865 000 SEK		Treatment of disseminated cancer, which affects 20-25% of women with breast cancer
Lidgren et al (2007)	Sweden 2002	135 135 SEK	317 832 SEK	Derived as total costs in 2002 divided by the incidence that year.

Luengo-Fernandez et al 2013	EU 27 2009	€18 469	€22 613	Derived as total costs in 2009 divided by the incidence that year.
Stokes et al (2008)	USA 2004	US$8-20 000		10 year costs for patients with breast cancer recurrence relative to costs for breast cancer patients with no recurrence
Will et al (2000)	Canada 1995	C$26 000		Ranges between C$23000 and C$36000 depending on cancer stage at initial diagnosis

The cost estimates adjusted by income levels (purchasing power adjusted GDP) and inflation are presented in Table 61 and Table 62. The estimated direct costs vary considerably between the studies. The results from Dahlberg et al (2009) stand out as much higher than the results from the other studies. This is for the most part explained by the fact that Dahlberg et al only investigates disseminated breast cancers. This type of breast cancers is severe and only affects around 20-25% of all women with breast cancer. At the lower end of estimates is the study by Stokes et al (2008). This study differs from the others in the sense that it only looks at the difference in costs between patients with recurring breast cancers and patients without recurrence.

The results from the study by Luengo-Fernandez et al (2013) are used in this socio-economic analysis, for three main reasons; (1) the estimated direct cost of this study is the median of the five studies analyzed, (2) the original cost estimation is carried out based on EU 27 data, and (3) it is the most recent of studies analyzed. The study derives total costs in EU 27 in 2009, which for this analysis was divided by the incidence in EU 27 in 2012 (364 400 according to Ferlay et al 2013) to yield a cost per case estimate.

Luengo-Fernandez et al used information on the total number of contacts with each type of health service (primary care, emergency care, outpatient care, and hospital inpatient care) and calculated costs by applying country-specific unit costs. Drug costs were derived from the share of breast cancer related drugs in total drug expenditure in Germany and the Netherlands, and then multiplied by total drug expenditure in the EU 27. The cost for breast cancer drugs was €3.07 billion while the other breast cancer related health care services cost €3.66 billion, for a total of €6.73 billion. Divided by the incidence this yields a direct cost per breast cancer case of €18 500 in 2009, which is equivalent with €20 000 in 2012.

Table 61 Direct costs per case of breast cancer

Study	in original currency, country and year	in € in original country and year*	in € in EU27 in original year**	in € in 2012***
Dahlberg et al (2009)	865 000	93 469	76 124	88 118
Lidgren et al (2007a)	135 135	14 751	10 114	12 799
Luengo-Fernandez et al (2013)	18 469	18 469	18 469	**19 951**

Stokes et al (2008) - low	8 000	6 431	3 954	4 789
Stokes et al (2008) - high	20 000	16 078	9 884	11 973
Will et al (2000)	36 000	20 058	14 847	23 784

*adjusted by exchange rate of original year (Eurostat 2013b); **adjusted by GDP-PPP relationship in original year (Eurostat 2013f & IMF 2013); ***adjusted by EU27 HICP ratio between 2012 and original year (Eurostat 2013d)

Only two studies estimating the indirect costs of breast cancer have been found in this review. The result from the study by Luengo-Fernandez et al is used in this analysis, for similar reasons as above; the original cost estimation is carried out based on EU 27 data, and it is the most recent of studies analyzed. The estimate is somewhat lower than in Lidgren et al (2007), and can thus be considered conservative.

Luengo-Fernandez et al estimated mortality costs by using mean annual earnings and the number of working years of employment lost, and then transforming it to a present value through a discount rate of 3.5%. Informal care costs were derived from estimates on the total hours of informal care required and the mean hourly wage (if carer was employed) or hourly minimum wages (if carer was unemployed or retired). The costs related to temporary sick leave were derived by multiplying the share of annual sick leave that was attributable to breast cancer with the country-specific annual days of sickness and the mean daily earnings. The costs related to early retirement was derived in a similar manner. The sick leave and early retirement costs however only takes into account the so called friction period – the time it takes (assumed to be 90 days) for an employee to be replaced. An alternative would have been to use the human capital approach, where the worker is valued for the whole period of absence. This would nearly double the morbidity cost (temporary sick leave and early retirement) for all cancer types in the study. The estimated indirect costs for breast cancers in the EU 27 in 2009 were €8.24 billion, of which mortality cost €3.25 billion, informal care cost €3.20 billion, and morbidity €1.79 billion.[55] Divided by the incidence this yields an indirect cost per breast cancer case of €22 600 in 2009, which is equivalent with €24 400 in 2012.

[55] If the human capital approach was used instead of the worker friction cost the indirect costs would be approximately 17% higher. This is based on the assumption that the additional costs are assigned to the different cancer types based on their respective proportion of total morbidity costs. This would yield indirect costs per case of €28 600 in 2012.

Table 62 Indirect costs per case of breast cancer

Study	in original currency, country and year	in € in original country and year*	in € in EU27 in original year**	in € in 2012***
Lidgren et al (2007a)	317 832	34 694	23 787	30 103
Luengo-Fernandez et al (2013)	22 613	22 613	22 613	**24 428**

*adjusted by exchange rate of original year (Eurostat 2013b); **adjusted by GDP-PPP relationship in original year (Eurostat 2013f); ***adjusted by EU27 HICP ratio between 2012 and original year (Eurostat 2013d)

Estimates of QALYs lost due to breast cancer have been obtained from two studies by Lidgren et al (2007a & 2007b). In Lidgren et al (2007b) 361 breast cancer patients were surveyed about their health related quality of live (HRQoL) levels, using two different methods: the EQ-5D self-classifier and a time trade-off (TTO) question. The results from the EQ-5D survey were that the HRQoL was in the range 0.69-0.78 depending on the state of breast cancer that the patients were in. This indicates that a fully healthy individual that is afflicted with breast cancer suffers a decline in HRQoL of approximately 0.22-0.31. The results from the EQ-5D survey have been referenced in several studies on cost-effectiveness of breast cancer care, e.g. Blank et al 2010 and Purmonen et al 2011. The TTO method generated higher estimates, ranging from 0.82-0.90.

Lidgren et al (2007a) estimated the QALYs lost due to breast cancer in Sweden in 2002. This year there was an incidence of 6 623 new cases of breast cancer and at the end of the year there was a 5-year prevalence of 27 525 persons with breast cancer in Sweden.

Lidgren et al (2007a) assumed that the prevalent cases average utility decreases of 0.01, or in total 275 QALYs. During the year 1 213 with breast cancer died from other causes. These were also assumed to have an average utility loss of 0.01 due to breast cancer, leading to a total loss of 6 QALYs (given that they were alive for half that year on average). There were 1 148 deaths caused by breast cancer. These were assumed to have an average utility loss of 0.31 – corresponding to the loss caused by progressive metastatic breast cancer in Lidgren et al (2007b) – indicating a loss of 178 QALYs (1148x0.31). In total there were 459 QALYs (275+6+178) lost due to morbidity.

The 1 148 deaths caused by breast cancer lead to approximately 20 575 life years lost, derived from the average life expectancy at the time if death. Discounting these lost life years with a rate of 3% yields a present value of 14 502 life years lost. These were translated to QALYs lost using health state utilities from the general population in relation to age, which lead to an estimate of 10 497 QALYs lost due to breast cancer mortatlity.

Adding the QALYs lost to morbidity and mortality together yields 10 956 lost QALYs in total. Dividing this with the incidence of 6 623 yields an estimate of 1.65 QALYs lost per new case of breast cancer.

In the socio-economic in this proposal the estimate on QALYs lost from Lidgren et al (2007a) will be used. Their estimate of 1.65 QALYs per case of breast cancer multiplied with the value per QALY identified above (€51 200) gives an intangible cost of €84 500 per case.

In conclusion, every breast cancer case is assumed to yield direct costs of €20 000 and indirect costs of €24 400. In addition approximately 1.65 QALYs, valued at €84 500, will be lost per case of breast cancer.

Willingness to pay to avoid breast cancer

QALY measures are based on the assumption that preferences over health risks depend only on the probabilities of each health outcome, while preferences over other aspects of the health risks, such as dread and controllability, are not incorporated (Hammitt 2002). Willingness to pay (WTP) studies can include such preferences, and it is widely believed that there is a WTP premium to avoid cancer (and other diseases associated with dread).

Two examples of studies that have attempted to quantify the relative size of such a premium are Hammitt & Liu (2004) and Van Houtven et al (2008). Hammitt & Liu (2004) estimate that WTP to reduce the risk of cancer is about one-third larger than WTP to reduce the risk of similar chronic and degenerative diseases. Van Houtven et al (2008) find a preference for avoiding cancer risks relative to auto-accident risks. With a 5-year latency, cancer risks are valued roughly three times greater than immediate accident risks, declining to 50% greater for a 25-year latency.

The guidelines for socio-economic assessment for restrictions (ECHA 2009) cites (on p.84) WTP estimates of €400 000 per non-fatal cancer case and €1 million for fatal cases. The guidelines refer these estimations to one of the reports that were part of the impact assessment for REACH (DHI 2005), which in turn refers to a literature review in a report prepared for the UK government (Eftec 2004). Eftec's review does not include any estimates on breast cancer, but gives estimates for non-fatal cases of other cancer forms ranging from €50 000 to €1 950 000 (in 1999 terms). A recent report to CARACAL (Risk & Policy Analysis 2014) refers to ECHA (2009) when using an estimate of €450 000 per non-fatal cancer case.

There are to our knowledge no recent peer-reviewed studies on the WTP for avoiding breast cancer. There is however a working paper by Cameron et al (2009) that estimates the WTP for reductions in the risk of death by various illnesses. Their results imply that a 60 year old[56] with an annual income of $42 000 values a fatal breast cancer at $4.4-7.0 million. Adjusting for the lower income level in the EU, this valuation translates to €3.6-5.8 million[57]. The mortality rate in breast cancer is around 25% (Ferlay et al 2013). Using the estimate from Cameron et al (2009), WTP for the risk of mortality alone would imply a value of avoiding breast cancer at €0.9-1.4 million (25% of €3.6-5.8 million).

The estimate from Cameron et al (2009) is considerably higher than the heuristic values in ECHA's guidelines, but since it is not published (to our knowledge) it is difficult to justify using it in this restriction proposal. It does however indicate that the guidelines values are potentially an underestimation of the WTP for avoiding breast cancer. For the sake of the assessment of the proposed restriction the WTP estimates cited in ECHA (2009) will be used. According to Ferlay et al (2013), around 25% of breast cancer cases are fatal, and consequently 75% are non-fatal. The WTP for avoiding breast cancer used in the assessment of the proposed restriction is therefore €550 000[58] per breast cancer case.

[56] Younger respondents report higher WTP values.
[57] Using the current exchange rate of $1.36 per € (i.e. $42 000 = €31 000), and that GDP per capita in EU27 was €25 600 in 2012.
[58] 25%*1 000 000 + 75%*400 000 = 550 000

Cost per case of fracture

This section is based on an overview study on the societal burden of osteoporosis (Ström et al 2011). The study estimates the number of osteoporotic fractures – and the socio-economic costs of these fractures – afflicting men and women over the age of 50 years in the five largest EU countries (Spain, Germany, Italy, United Kingdom, and France) plus Sweden. The risk of osteoporotic fractures is considered negligible at a societal level for people below the age of 50.

Indirect costs related to production losses (see Table 59) are only applicable to individuals less than 65 years of age. Since most fractures affect individuals above the age of 65 years, productivity losses are a relatively small share of total costs. Borgström et al (2007) estimated that the indirect costs constitute 3% of total direct and indirect costs of osteoporosis in Sweden. These costs are not reported separately here, but are instead grouped together with the direct costs.

The average direct and indirect (see above) costs per fracture identified in Ström et al (2011) will be adjusted by GDP per capita level to generate estimates relevant for EU27. The average loss of quality adjusted life years (QALYs) per fracture are used as estimates for EU27 without any further adjustments. The direct costs and the QALY losses are given in aggregate terms for men and women.

The average direct and indirect cost per fracture is given by Table 63. Ström et al provides data for different fracture types. In the risk reduction capacity identified in this report no distinction between fracture types is made, therefore the aggregated average of all fracture types will be used to estimate costs.

Table 63 Average direct and indirect cost in Euros per fracture in six EU countries in 2010 (Ström et al 2011)

Member State	Hip fractures	Vertebral fractures	Forearm fractures	Other fractures	All fractures
Sweden	39 482	8 885	2 423	7 978	13 242
Spain	46 908	2 536	1 264	8 338	14 124
France	35 919	2 954	1 508	9 498	12 513
Italy	41 228	3 525	1 268	10 593	13 955
UK	33 301	2 599	1 323	8 086	10 316
Germany	34 389	6 024	1 222	10 235	12 469
Total	37 154	4 255	1 341	9 449	**12 477**

Since the cost data in Ström et al is derived for only six EU countries, adjustments needs to be made to account for the different cost level that can be expected in the EU as a whole. An additional adjustment is done to account for cost inflation from 2010 to 2012. (Table 64)

Table 64 Estimated direct and indirect cost in Euros per fracture in EU27 in 2012

Cost per fracture in 6 Member States in 2010	12 477
Cost per fracture in EU 27 in 2010*	11 344
Cost per fracture in EU 27 in 2012**	**12 005**

*Adjusted to EU27 average by purchasing power adjusted GDP per capita (Eurostat 2013f); **Adjusted from 2010 to 2012 by HICP price index for EU27 (Eurostat 2013d)

Ström et al (2011) calculate the losses in QALYs from all fractures in six EU countries. Some of these losses in life years lost and in quality of life appear in the same year as the fracture occurs, while some occur in subsequent years. Assuming that these proportions over time are stable and that the proportion between fracture types are stable, the total estimated QALY loss in one year divided by the total number of fractures that year – regardless of if the QALY losses are from fractures that occurred that same year or from older fractures – is a reasonable proxy for average QALY loss per fracture. Performing these calculations result in the average QALY losses per fracture presented in Table 65. These results from six EU countries are assumed to be a good proxy for the EU as a whole.

Table 65 QALYs lost per fracture (by fracture type) in six EU countries. Men and women.

Member State	Hip	Vertebral	Forearm	Other	All
Sweden	0.99	0.70	0.03	0.12	0.36
Spain	0.98	0.69	0.03	0.12	0.36
France	0.98	0.69	0.03	0.11	0.36
Italy	1.01	0.68	0.03	0.11	0.36
UK	1.00	0.67	0.03	0.11	0.31
Germany	0.98	0.68	0.03	0.12	0.35
Total	0.99	0.68	0.03	0.11	**0.34**

In conclusion, every fracture affecting men and women over the age of 50 years is estimated to generate direct and indirect costs of €12 000 on average. In addition a loss of life years and in quality of life equivalent to 0.34 QALYs, valued at €17 600, per fracture affecting a woman or a man over 50 is expected.

Discounting

The estimated risk reduction will mainly occur in the long term, as it is gradually phased in over 150 years. Therefore the health impacts will primarily affect future generations of EU population. This far reaching time frame has considerable implications on the choice of discount rate in the socio-economic analysis.

The approach taken in this analysis is that estimated costs per case of fracture or breast cancer are gathered through a survey of relevant publications in scientific journals. These yield the lifetime costs related to one case of fracture or breast cancer, which are generally discounted to generate the estimated cost at the time of diagnosis.

A simple definition of the discount rate – recommended in ECHA's guidance on Socio-Economic Analysis (ECHA 2008b) – is that it is the sum of the pure time preference rate and the expected real growth in income. If the impacts of the proposed restriction are of intergenerational nature it is recommended that the pure time preference rate is only applied to an initial time period, spanning the length of about one generation. This way the impatience of the current generation is taken into account, while future generations are given the same opportunities for consumption as the current generation.

The pure time preference rate recommended in the guidelines is 1.5%, while the real growth rate is expected to be around 2%, with a range of 1-3%.

In this analysis a discount rate of 3.5% – the sum of pure time preference and expected growth – will be used for the first 50 years. From year 51 to 150 the discount rate will be set equal to the expected growth rate, i.e. 2% per year. The rates used and the length of the initial period will be varied in a sensitivity analysis.

As discussed above, direct costs per fracture or breast cancer case are assumed to remain constant in real terms over time, while indirect costs and the value of QALY losses are assumed to increase at the rate of economic growth. The time adjustment factors presented in Table 66 take into account the discount rates as well as the increasing unit costs of QALYs and indirect costs. The factor for direct costs decreases continuously over time, although the decrease is faster in the initial 50 year period. The factor for indirect costs and value of QALYs decreases in the initial 50 year period, when the discount rate is higher than the economic growth rate, before flattening out after year 50, when the discount rate is equal to the expected rate of economic growth.

Table 66 Time adjustment factors at three points in time for the different cost types

Years from implementation	Direct costs	Indirect costs, value of QALY losses, and WTP
50	0.179	0.475
100	0.067	0.475
150	0.025	0.475

Socio-economic benefits from the proposed restriction

Cadmium exposure can cause many different adverse effects in the human body, such as CMR effects and damage to kidney and bone (for details, see section B 5). In this restriction proposal we have performed quantitative assessment of only two of these adverse effects (i.e. fractures and breast cancers) that cadmium is known to cause.

The present value of annual benefits of the restriction will increase throughout the 150 years after implementation that is analysed here (Table 67 & Table 68). This increase is explained by two characteristics of the analysis; (1) the number of prevented fractures and breast cancers per year is assumed to increase throughout the time period analysed, and (2) after the initial 50 years the discounting of indirect and intangible costs are completely compensated by the growth in their respective unit values.

When breast cancer is valued according to Altenative 1 (i.e. the sum of direct, indirect and intangible costs) the present value of the annual benefit is estimated to €0.4 million after 50 years, and €1.1 million after 150 years. The expected impact on the number of breast cancers is the main source of benefits from the proposed restriction (Table 67). The reduction in intangible costs (value of avoided QALY-losses) is considerably larger than the avoided direct and indirect costs (Table 68).

Table 67 Annual socio-economic benefit of restriction, by health effect (Alternative 1)

Years from implementation	Female fractures	Male fractures	Breast cancers	Total

50	131 630	37642	244 176	413 448
100	229 807	65 718	468 793	764 319
150	326 068	93 246	692 291	1 111 604

Table 68 Annual socio-economic benefit of restriction, by type of avoided cost (Alternative 1)

Years from implementation	Direct costs	Indirect costs	Intangible costs	Total
50	49 785	51 278	312 385	413 448
100	36993	102 556	624 770	764 319
150	20 616	153 833	937 155	1 111 604

The accumulated benefits (in Alternative 1) are estimated to be €14 million after 50 years, and are expected to grow to €91 million after 150 years (Table 69 & Table 70). Most of the accumulated benefits are related to breast cancers. Reductions in intangible costs make up most of the benefits, and grow in relative importance the longer the analysed period is.

Table 69 Accumulated socio-economic benefit (million €) of restriction, by health effect (Alternative 1)

Years from implementation	Female fractures	Male fractures	Breast cancers	Total
50	4.8	1.4	8.3	14.4
100	13.9	4.0	26.2	44.1
150	27.8	8.0	55.4	91.1

Table 70 Accumulated socio-economic benefit (million €) of restriction, by type of avoided cost (Alternative 1)

Years from implementation	Direct costs	Indirect costs	Intangible costs	Total
50	2.4	1.7	10.3	14.4
100	4.7	5.6	33.9	44.1
150	6.1	12.0	73.1	91.1

In Alternative 2 the value of avoided breast cancers is based on the estimated WTP, while fractures are valued in the same way as in Alternative 1. Since the socio-economic benefit per avoided breast cancer case here is more than four times larger than in Alternative 1, the breast cancer values dominate even more in this alternative. After 50 years the annual benefits are estimated to be €1.3 million, growing to €3.9 million after 150 years (Table 67).

Table 71 Annual socio-economic benefit of restriction, by health effect (Alternative 2)

Years from	Female	Male	Breast	Total

implementation	fractures	fractures	cancers	
50	131 630	37 642	1 154 544	1 323 816
100	229 807	65 718	2 309 088	2 604 613
150	326 068	93 246	3 463 633	3 882 946

The accumulated benefits are estimated to be €44 million after 50 years, growing to more than €300 million after 150 years (Table 69).

Table 72 Accumulated socio-economic benefit (million €) of restriction, by health effect (Alternative 2)

Years from implementation	Female fractures	Male fractures	Breast cancers	Total
50	4.8	1.4	38.0	44.1
100	13.9	4.0	125.1	143.0
150	27.8	8.0	270.0	305.8

Sensitivity analysis of the socio-economic benefits calculation

Five variables are tested in this sensitivity analysis. These have been judged to be the most important ones from the analysis above. The central estimates used in the socio-economic analysis so far are presented in Table 73 along with estimates used in the following sensitivity analysis.

The expected economic growth rate is 2% per year. This is recommended in the ECHA guidelines for socio-economic analysis (ECHA 2008b) along with a range of 1-3% per year to be used in sensitivity analyses. The guidelines also recommend are pure time preference rate of 1.5% per year. In this analysis a range of 1-2% per year will be tested.

Since the impacts of the proposed restriction are of intergenerational nature the pure time preference rate is only applied to an initial time period, spanning the length of about one generation. This way the impatience of the current generation is taken into account, while future generations are given the same opportunities for consumption as the current generation. The central estimate is that this initial period is 50 years; in the sensitivity analysis a range of 30-70 years is tested.

Direct costs of fractures and breast cancers are in the analysis above assumed to be constant over time. There are two counteracting impacts on direct costs. Labor costs are a relatively large share of the direct costs and the unit costs of labor can be assumed to grow in real terms, approximately in line with the growth of the economy at large. On the other hand the cost of medication, hospitalization and consultations can be assumed to decrease over time due to productivity improvements. A range of -1% to +1% per year will be tested in the sensitivity analysis.

Most of the socio-economic benefits from the proposed restriction come from avoided losses of quality adjusted life years (QALYs). Therefore the value per QALY is of high importance for the analysis. The appropriate value per QALY is however not easily established. The central estimate has been set to two times annual GDP per capita within the EU. In sensitivity analysis values of one to three times GDP per capita is tested, as these have been suggested in the literature on socio-economic costs of fractures (Borgström et al. 2006 and Ström et al. 2011).

Table 73 Variable estimates used in the socio-economic analysis and in the sensitivity analysis

	Central estimate	**Low estimate**	**High estimate**
Economic growth rate	2% per year	1% per year	3% per year
Pure time preference rate	1.5% per year	1% per year	2% per year
Length of first generation	50 years	30 years	70 years
Direct cost growth rate	0	-1% per year	1% per year
Value per QALY*	€51 200	€25 600	€76 800

The results of the sensitivity analysis are given in Table 74. The central estimate results are identical to the values in Table 69 & Table 70. In the sensitivity analysis one estimate at a time has been varied, while the central estimate is used for the others variables. The results are given as changes in relation to the central estimate.

Table 74 Results from the sensitivity analysis (million €)

Time after implementation	50 years	100 years	150 years
Central estimate	17.9	54.7	113.0
Economic growth rate – Low	+0.9	+3.7	+7.5
Economic growth rate – High	-0.6	-1.8	-2.7
Pure time preference rate – Low	+2.9	+13.0	+29.0
Pure time preference rate – High	-2.4	-10.3	-22.8
Length of first generation – Low	+1.7	+14.2	+34.0
Length of first generation – High	0	-8.0	-22.8
Direct cost growth rate – Low	-0.7	-2.2	-3.4
Direct cost growth rate – High	+1.0	+4.1	+8.5
Value per QALY – Low	-6.4	-21.0	-45.4
Value per QALY – High	+6.4	+21.0	+45.4

The results in Table 74 indicate that variations in expected economic growth and in the growth of direct costs are of minor importance. The choice of pure time preference rate and first generation length is of higher importance, and they affect the total benefit by 20-30%. The variable estimate with the highest importance in this sensitivity analysis is the value per QALY which affect the outcome by plus/minus 35-40%.

F.1.2 Environmental impacts

Not relevant.

F.2 Economic impacts

There are primarily three economic impacts of the proposed restriction; (1) the need for the users of cadmium based artists' paints to cease their use and switch to alternatives, (2) the administrative costs related to the proposed exemption from the ban, and (3) the costs for actors throughout the supply chain of cadmium based paints being discarded or sold at reduced prices due to the introduction of the proposed ban. These costs will in the following be analysed.

The cost for users of switching to alternatives

As indicated in Section C.2.4 alternative paints are available at no additional cost, or at lower costs, relative to the cadmium based products. According to the trade organization CEPE the unit price of the alternatives is 20-50% lower than for the cadmium paints. This statement is supported by retail price data gathered for this report (Table 49 in Section C.2.4.2), which indicate that the alternatives cost around 35% less than the cadmium paints. The volume of paint required to perform an equivalent aesthetic effect is however higher for the alternatives. Assuming that the amount of paint required is around 20-50% higher when the alternatives are used, and that the alternatives cost 35% less than the cadmium paints, the financial costs for users of switching from cadmium based artists' paints to the alternatives are between zero and minus 20%[59], i.e. that the costs are reduced. A central estimate of minus 10% will be used below.

Market price data for the different paint types from 4 Member States (DE, FR, SE, UK) have been obtained from two online based retailers (Boesner and Winsor & Newton), and after applying country specific price adjustment factors, the average market price (weighted with market shares per paint type from Table 16) is €0.23 per ml of cadmium based paint (including VAT). The specific density of the paints is around 1.3 g/ml, according to one artists' paints producer consulted for this report. This indicates that the price per gram of cadmium paint is €0.18. Given the total annual quantity of 39 tons (Section B.9.3.2.3), the revenue on the retail market for cadmium based artists' paints is around €6.9 million per year.

Given the market revenue the financial costs due to the proposed restriction are approximately minus **€**0.7 million (with a likely range between minus **€**1.4 million per year and 0).

Two basic explanations are possible for the continued use of cadmium based artists' paints when the available alternatives are cheaper. The first is that the users prefer the characteristics of the cadmium paints and are willing to pay the additional cost they carry. Stakeholder consultations indicate that this is the case among some artists' paints users. The second explanation is that the users of cadmium paints are misinformed about the characteristics of the alternatives relative to the cadmium paints and would use the cheaper products if they had full information. The use of cadmium paints has a long history and the alternatives are relatively new, which could indicate that many first time users opt for the traditionally used cadmium paints based on incomplete information.

For the sake of simplicity, we can think of two types of artists' paints consumers. One type consists of consumers that – if fully informed – find no substantial difference in the characteristics of cadmium paints relative to alternative paints. This type will be referred to as **"Indifferent"**. If all artists' paints users always are "Indifferent" then the consumer utility loss of not being able to use cadmium paints is zero or lower. Given that the financial costs of alternatives are likely to be lower than those of cadmium paints, these consumers might even gain from an introduction of a ban on cadmium based artists' paints.

The other type of consumers analysed here is **"Pro cadmium"**, who finds the cadmium paints to be

[59] (1-0.35)*1.2=0.8; (1-0.35)*1.5=1

superior to the alternatives, and is willing to pay the (eventual) excess financial costs related to the cadmium paints. A "Pro cadmium" consumer will suffer utility losses if banned from using the cadmium paints. This utility loss is equivalent with the difference in consumer surplus – i.e. the additional amount the consumer would be willing to pay over and above the price offered – gained from the cadmium paints, relative to the alternatives. An indication of the share of artists in the respective categories is given by an artist survey (see Section C.2.5). The survey was distributed through e-mail lists and Facebook groups, and the results should due to potential selection bias be treated cautiously. Of the EU respondents, 48% consider themselves as professional or serious artists, and 88% use cadmium based paints. Of those who use cadmium based paints, 64% consider them irreplaceable. Based on the written comments, we can however see that some of those who consider the cadmium based paints to be irreplaceable are conservationists (who are proposed to be exempted from the restriction), while others have never actually used the alternatives to cadmium based paints.

If all users are "Pro cadmium" in the extreme, i.e. that they find the alternatives to be of no use at all, then the consumer utility loss from the restriction is the aggregated consumer surplus of the cadmium paints market. A rough approximation of the size of the consumer surplus is that it is equivalent to consumer expenditure divided by two. This is based on an assumption of a linear demand curve and a price elasticity of demand of -1. Given the annual revenue derived above the consumer surplus lost due to the proposed restriction, if all consumers are "Pro cadmium" in the extreme, is €3.4 million per year.

In reality there are probably a limited share of consumers of this type. Even among those who responded that they consider cadmium paints to be irreplaceable, the alternatives will most probably provide some consumer surplus.

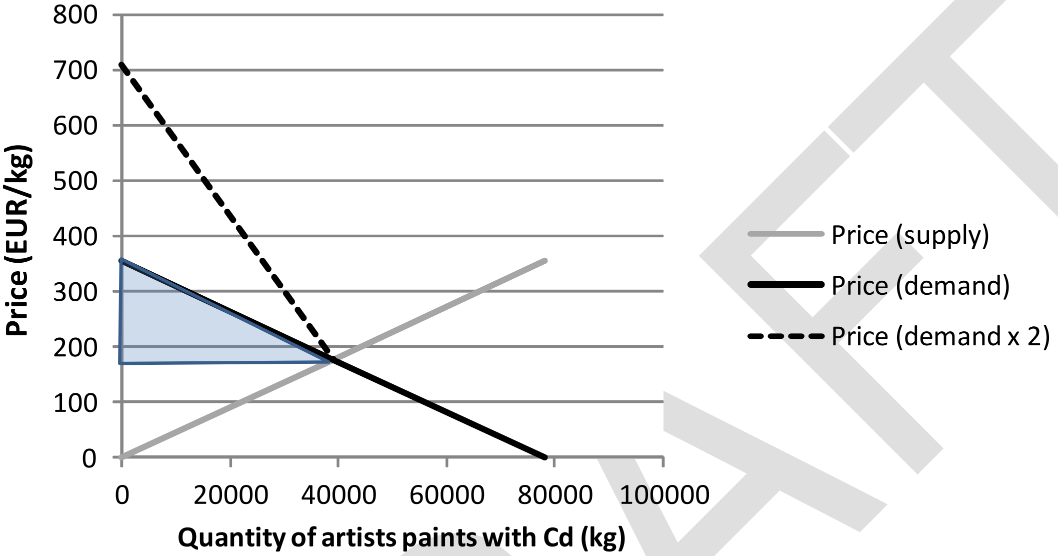
As indicated above, a ban on cadmium paints might be of benefit for some users, if the reduction in financial cost is larger than the loss in consumer utility. The proposed exemption for restoration purposes will also alleviate some of the loss in consumer surplus.

If there is a considerable demand, the paint producers are likely to develop additional alternative paints with characteristics that are even closer to the cadmium based paints, than the current alternatives. This would mitigate the loss of consumer surplus in the longer run.

All in all this indicates that a relatively small share of the maximum amount indicated above will be lost. Assuming that this share is 10%, the loss in consumer surplus due to the restriction is €0.34 million per year, while a share of 20% yields a loss of €0.69 million.

SEAC opinion on section F.2 Economic impacts

The consumer surplus was calculated in a highly subjective manner by the dossier submitter. The following figure illustrates the assumption made in section F.2. The consumer surplus was calculated from the consumer expenditure divided by two (highlighted area in blue). Then the assumption was made that only 10 % (or 20 % in the sensitivity analysis) of consumer surplus is lost by the proposed restriction. However, 1.) the 10 % assumption is arbitrary (public consultation suggests a higher share, even 20 % could be too low) and 2.) the demand curve was arbitraryly set to a slope of -1. An alternative demand curve with a slope of -2 is also displayed in the following graph. This would lead to a higher value of the consumer surplus.



Assuming that the consumer surplus will grow in line with GDP and using the same discounting procedure as described in Section F.1.1 the accumulated present value of the losses in consumer surplus will be €12 million over 50 years and €29 million over 150 years, when the loss share is assumed to be 10%. If the loss share is 20%, then the accumulated present value of the losses in consumer surplus will be €25 million after 50 years and €58 million after 150 years.

If we assume no growth in consumer surplus over time, then the 10% share yields accumulated losses of €8 million over 50 years growing to €11 million after 150 years. The 20% share yields losses of €17 million after 50 years, growing to €22 million after 150 years.

The expected decline in financial costs is equivalent (in size) with the 20% and no growth case for consumer surplus above. Note that, in the estimation of loss in consumer surplus, the effect on consumers' financial costs is already included.

The costs of administrating the proposed exemption

The Member States will encounter costs for setting up a routine for dealing with the exemptions and costs for dealing with the applications for exemptions. Assuming that it per Member State takes about two man-weeks to implement the routine at a cost of €24 per hour[60], the total start-up cost would be

[60] Eurostat (2013e) has data (from 2011) on hourly labor costs for public administration workers for 15 Member

around €60 000[61].

The number of applications for exemptions from the ban is very difficult to estimate. Experiences from the case of lead sulphate (Entry 17 in Annex XVII) which has an almost identical exemption as the one proposed here could be used to give an indication of the number of exemptions to expect. The experience from the Swedish Chemicals Agency is however that this exemption has been applied very sparsely, less than one application per year. For illustrative purposes a scenario where each Member State will receive on average 10 applications (in total 300 for the entire EU) per year is analysed here.

Each application is assumed to require about one man-day of administration at the Member State CA. This assumption is based on experience of administrating exemptions for the use of some industry chemicals in Sweden (Trichloroethylene & Methylene chloride) which requires 10-15 hours per application. These exemptions do however include administrative elements (such as an analysis of potential alternatives and why they are not suitable, and a description of risk control measures) that are not considered necessary for the exemption we are proposing. The exemption proposed here will mainly require a motivation for why the objects to be restored require cadmium based paints, which should require a considerably smaller amount of administrative work. An assumption of 8 hours per application will be used when calculating the administrative costs of the exemption. This is probably an overestimate, especially after an initial phase when criteria for exemption are established. Given the hourly cost from above, 8 hours equates to around €200. The applicant will also face some administrative costs, and a relevant assumption is that this is of equal degree to the authorities' costs.

The annual costs for dealing with the exemption will then be €120 000[62]. Assuming that the annual costs will grow in line with the economic growth of the general economy (expected to be 2% per year), and using the same discounting procedure as described in F.1.1, the accumulated present value of the costs €4.4 million over 50 years and €10.2 million over 150 years.

The costs of products discarded or sold at reduced prices due to the introduction of the proposed ban

The proposed implementation period for the restriction is one year. This should be enough time for the distributors and the retailers to be informed and to take the actions necessary to avoid most losses related to discarding products or having to sell them at reduced prices. Apart from adjusting their purchases of new stocks, distributors have the option of selling any remaining stock to distributors overseas that are not affected by the proposed restriction, this might however require price reductions or additional administrative costs. Given this, it is reasonable to assume that there will be some discards and other costs related to the introduction of the restriction. In this analysis it is assumed these costs will be equivalent to 20% of one year's revenue.

The retail value of cadmium based artists' paints was above estimated to be €6.9 million per year. A one-off cost equivalent to one fifth of this – or €1.4 million – is assumed due to the introduction of

States. These are in the range of €7-37 (adjusted for purchasing power). The data are primarily from MS with GDP per capita below the EU-average. An additional estimate has been obtained from Sweden (€33/hour, nominal). The unweighted average of these 16 estimates is €18, the median is €16, and the first and third quartiles are €12 and €24, respectively. Taking into account the lack of estimates from most of the wealthier Member States, the third quartile is assumed to be a good estimate for the average across the EU.

[61] 80 hours at €24/hour for ~30 authorities ➔ 80*24*30 ≈ 60 000

[62] 2*€200 per application, 300 applications per year ➔ 2*200*300 ≈ 120 000

the proposed restriction.

Summary of economic impacts

The economic impacts quantified in this section are summarised in Table 75 and

Table **76**.The four types of cost quantified in this section are aggregated in three different ways.

Total cost A refers to the sum of administrative costs and costs of discarded products.

Total cost B also includes the financial costs to consumers. These are the estimated monetary costs (which actually are assumed to be reduced) of the proposed restriction. If the financial costs are at the upper end of the estimated range (i.e. 0), then the costs are identical to Total cost A. If on the other hand the financial costs are at the lower end of the range, Total cost B would be negative to an even larger degree.

Total cost C includes the estimated loss in consumer surplus instead of the consumers' financial costs. In the estimation of loss in consumer surplus, the effect on consumers' financial costs is already included. Variations a-d indicate combinations of assumptions regarding consumer surplus loss share (10% or 20%) and the growth in consumer surplus over time (2% or 0%).

Table 75 Summary of present value of accumulated costs (million €)

Years from implementation	1. Consumer financial costs	2. Reductions in consumer surplus*				3. Administrative costs of exemption	4. Costs of discarded products
		a	b	c	d		
50	-16.8	12.5	8.4	24.9	16.8	4.4	1.4
100	-20.7	20.8	10.3	41.5	20.7	7.3	1.4
150	-22.1	29.0	11.1	58.1	22.1	10.2	1.4

*2a = 10% loss of consumer surplus, growth over time; 2b = 10% loss of consumer surplus, no growth over time; 2c = 20% loss of consumer surplus, growth over time; 2d = 20% loss of consumer surplus, no growth over time.

Table 76 Present value of accumulated costs in three different aggregations (million €)

Years from implementation	Total cost A (=3+4)	Total cost B (=1+3+4)	Total cost C (=2+3+4)			
			a	b	c	d
50	5.8	-11.0	18.2	14.2	30.7	22.6
100	8.7	-12.0	29.4	19.0	50.2	29.4
150	11.6	-10.5	40.6	22.6	69.6	33.7

F.3 Social impacts

Health effects from exposure to cadmium via food are only realised in the long term. The positive health impacts of the proposed restriction will therefore primarily benefit future generations of EU population.

F.4 Wider economic impacts

No wider economic impacts such as overall impacts on the economic growth or development, changes to competition within the EU or direct impacts on the macro-economic stabilization, if the proposed restriction were to be implemented, have been identified.

F.5 Distributional impacts

Health effects from exposure to cadmium via food are only realised in the long term. The positive health impacts of the proposed restriction will therefore primarily benefit future generations of EU population.

Paint artists, hobby painters, and consumers of painted art, who prefer cadmium based paints over the alternatives, will be negatively affected by the restriction.

Paint producers, distributors, and retailers only have small shares of their total revenue in cadmium based paints, and they will probably also be compensated by increased demand for the alternative paints and pigments.

F.6 Main assumptions used and decisions made during analysis

The assumptions discussed here are those that are primarily related to the socio-economic analysis of the proposed restriction. For an analysis of the assumptions and uncertainties relating to previous sections, see Section E.4.

- *Estimates of direct and indirect costs, and QALY losses of fractures and breast cancers*

The estimates used (Table 77) are obtained from available literature on the subject. The assumptions are therefore dependent on the validity of those studies. The studies are all published in reviewed journals. For a more thorough discussion on why the respective estimate has been used, see Section F.1.1.

Table 77 Summary of estimated direct and indirect costs, and QALY-losses, per fracture and breast cancer case

	Fracture	Breast cancer
Direct costs	€12 005	€19 951
Indirect costs	0	€24 428
QALY-losses	0.34	1.65

- *QALY valuation*

Most of the socio-economic benefits from the proposed restriction come from avoided losses of quality adjusted life years (QALYs). Therefore the value per QALY is of high importance for the analysis. The socio-economic guidelines (ECHA 2008b) refer to two estimates at €32 700 and €69 100, respectively. The average of these two estimates is approximately two times annual GDP per capita within the EU, which has been suggested as a reasonable QALY estimate in the literature on socio-economic costs of fractures (Borgström et al (2006) & Ström et al (2011)). This is the value used in the socio-economic analysis. In sensitivity analysis values of one to three times GDP per capita (€25 600 – €76 800) are tested, and these affect the estimation of socio-economic benefits by up to plus/minus 40%.

- *Direct costs per fracture and breast cancer are assumed to be constant*

The direct costs are those directly related to health care and medication. These are in this analysis assumed to be constant (in real terms) over time. This is probably an underestimation of future costs, as recent trends suggest that real health care cost unit increases (Smith et al 2009, EC 2012b). Smith et al (2009) estimates excess medical care price inflation of 0.2-0.9% per year. Assuming that the direct costs increase or decrease with 1% per year has small effects on the outcome of the analysis, the estimated benefits would increase or decrease by less than 10%.

- *Revenue on the market for cadmium based artists' paints*

The revenue is approximated to be €10.6 million, or €8.5 million when VAT is excluded, per year. This approximation has been derived from a limited sample of price estimates, an assumption that this sample is representable, and then adjusted downwards to account for the generally high consumer prices (relative to the EU average) in Sweden. This is an approximation based on limited data but should still serve the purpose of giving a rough indication on the size of the market.

- *The financial costs for users of switching from cadmium based artists' paints to the alternatives are between zero and minus 20%, i.e. that the costs are reduced*

This is based on assumptions that the amount of paint required is around 20-50% higher when the alternatives are used, and that the alternatives cost 35% less than the cadmium paints.

From consultation with different stakeholders (Kreatima 2013, ColArt and the Royal Institute of Art, see section G) we understand that the quantity of paint used differs depending on colour type and the artist in question. A more specific estimate on the excess amount of paint required has however not been given. The 20-50% used here is therefore a rough estimation.

In general the alternatives are much less costly (20-50% according to CEPE, and around 35% according to the market survey done for this report) than the cadmium paints.

If only considering the cost artists tend to choose the alternative paints (Kreatima 2013). Therefore the assumption that the financial costs for consumers are negative is assessed to be realistic.

- *Consumer surplus loss is assumed to be* €0.53 million per year*. Assuming that 10% of cadmium paint use is non-substitutable*

A rough approximation of the size of the total consumer surplus from cadmium based artists' paints is that it is equivalent to consumer expenditure divided by two. This is based on an assumption of a linear demand curve and a price elasticity of demand of -1. Due to lack of other information, this demand curve has been used. Given the annual revenue (including VAT) of €10.6 million per year, the consumer surplus from cadmium paints is €5.3 million per year.

In this analysis the assumption is that 10% of the consumer surplus (i.e. €0.53 million per year) will be lost due to the proposed restriction. This can be regarded as a relatively small share, but there are several arguments for why this share should be relatively small.

- The alternative paints also provide a consumer surplus. This will increase if cadmium paints are banned.
- A ban on cadmium paints might even be of net benefit for some users, if the financial costs decrease and the utility experienced from using the alternatives are equivalent to that from cadmium paints.
- The stakeholder consultations undertaken for this proposal (Section G) indicate that the preferences regarding cadmium paints differ substantially among active artists. Some of the cadmium paints is sold to hobby users or serious amateurs – rather than to professional artists – who are more likely to be indifferent between the two paint types.
- The use of cadmium paints will still be allowed – albeit only for the uses that are exempted from the ban – which will mitigate some of the utility losses.
- If there is a considerable demand, the paint producers are likely to develop additional alternative paints with characteristics that are even closer to the cadmium based paints, than the current alternatives.

A change in this estimate has considerable effects on the outcome of the analysis. If the share of consumer surplus lost is 20%, instead of 10%, then it would take approximately 135 years before the estimated benefits outnumber the estimated costs of the proposed restriction.

- *Expected economic growth rate*

The expected economic growth rate is set to 2% per year, as recommended in ECHA's guidance on Socio-Economic Analysis (ECHA 2008b). Since the most important costs and benefits are assumed to increase in line with the growth rate, the impacts of a change in this assumption – in a range of 1-3% per year – have small impacts on the outcome of the analysis.

- *Pure time preference rate*

The pure time preference – or impatience – rate is set to 1.5% per year, as recommended in ECHA's guidance on Socio-Economic Analysis (ECHA 2008b). Since the annual benefits of the restriction grow over time, while the (undiscounted and not adjusted with growth) major costs are assumed to be constant over time, a lower (higher) rate increases (decreases) the benefit-cost-ratio of the proposed restriction. As long as the rate is within a range of 1-2% the effects on the outcome of the analysis is small.

- *Length of initial period ("first generation") in discounting*

This assumption decides when the pure time preference rate is removed from the calculation of present values. Since the annual benefits of the restriction grow over time, while the (undiscounted and not adjusted with growth) major costs are assumed to be constant over time, a shorter (longer) initial period increases (decreases)) the benefit-cost-ratio of the proposed restriction. As long as the initial period is within a range of 30-70 years the effects on the outcome of the analysis is small.

F.7 Summary of the socio-economic impacts

The estimated benefits (Section F.1.1) and costs (Section F.2) of the proposed restriction are presented in Table 78.

The two alternative benefit estimations differ in how the avoided breast cancer cases are valued. In benefit altenative 1, a breast cancer case (as well as a fracture case) is valued as the sum of direct and indirect costs, and the value of QALYs. In benefit alternative 2 the value of avoided breast cancers is based on the estimated WTP, while fractures are valued in the same way as in Alternative 1.

Using Total cost A or B (see Table 75 &

Table **76**), the net benefits are clearly positive. Total costs C – which includes the estimated losses in consumer surplus – are initially larger than the estimated benefits in Alternative 1, but over a time frame of 100-150 years the proposed restriction has a positive net benefit in all cost-benefit combinations.

Table 78 Accumulated benefits and costs (million €) of the proposed restriction

Years from implementation	**Benefits 1**	**Benefits 2**	**Total cost A**	**Total cost B**	**Total cost C***			
					a	**b**	**c**	**d**
50	14.4	44.1	5.8	-11.0	18.2	14.2	30.7	22.6
100	44.1	143.0	8.7	-12.0	29.4	19.0	50.2	29.4
150	91.1	305.8	11.6	-10.5	40.6	22.6	69.6	33.7

*a = 10% loss of consumer surplus, growth over time; b = 10% loss of consumer surplus, no growth over time; c = 20% loss of consumer surplus, growth over time; d = 20% loss of consumer surplus, no growth over time.

The one-off costs and administrative costs (Total cost A) are projected to be surpassed by the benefits after 22 years and 10 years, respectively for benefit alternatives 1 and 2 (Table below). For benefit alternative 1, it will take 50 to 115 years to reach break-even with Total cost C. For benefit alternative 2, the corresponding times are 19 to 34 years.

Table 79 Years to break-even under different cost-benefit combinations

	Total cost A	**Total cost C**			
		a	**b**	**c**	**d**
Benefits 1	22	66	50	115	74
Benefits 2	10	21	19	34	28

In the table below we can see that consumer surplus loss shares below 7-10% are needed to have a positive net benefit within 50 years for benefit alternative 1, while benefit alternative 2 require shares below 31-44%.

Table 80 Break-even share of consumer surplus (CS) loss, at 50 years from implementation

	2% annual growth in CS	No growth in CS
Benefits 1	7%	10%
Benefits 2	31%	44%

It is important to note that the benefit estimation is partial in the sense that only two health endpoints have been monetized, while a range of other health impacts can be expected from the proposed restriction. Cadmium exposure can cause many different adverse effects in the human body, such as CMR effects and damage to kidney and bone (for details, see section B 5).

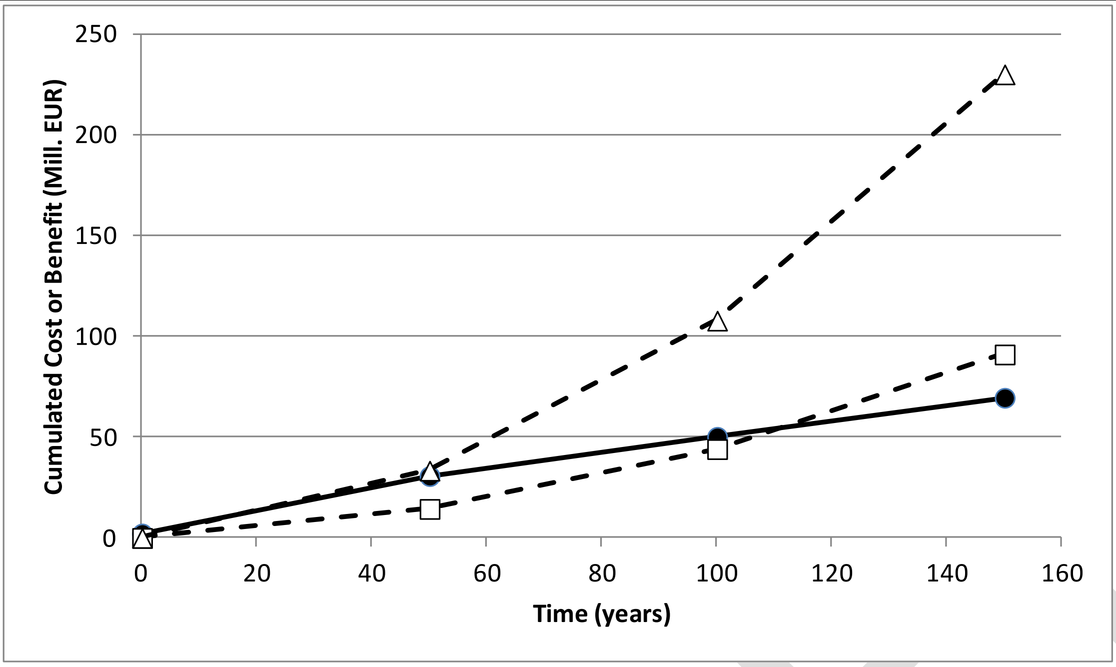
SEAC opinion on section F.7

The calculation of the benefits using alternatives 1 and 2 (see section E.2.1.1.3) resulted in large differences. For the cost 4 different approaches have been chosen by the dossier submitter with likewise different results. In the following table benefits from alternative 1 and 2 are listed together with cost (approach c, 20 % loss in consumer suplus with groth over time). Approach c with higher loss of consumer surplus assumed is according public consultation more likely than a, b or d.

Years from implementation	**Benefits (alt. 1)**	**Benefits (alt. 2)**	**Total cost C c**
0	0.00	0.00	2.20
50	14.40	33.40	30.70
100	44.10	107.90	50.20
150	91.10	230.20	69.60

c = 20% loss of consumer surplus, growth over time

alt. 2: WTP, 396000 EUR instead of 550000 EUR



Break-even of the benefits with cost takes place after 46 years (WTP method, 396000 EUR) or only after 115 years. With lower a lower release factor the time for break vent would be even longer. The values from the table are displayed in the figure (cost: solid line; benefits: dotted lines).

G. Stakeholder consultation

G.1 Industry

G.1.1 Actors within the EU

Manufactures and importers
A questionnaire was sent to **CEPE** (European Council of the Paint, Printing Ink and Artists Colour) which is the branch association representing the artists' colours industry in Europe. CEPE contacted their approximately 20 members in the artists' colours sector. The members, ranging from SMEs to larger (multi-national) companies cover about 90% of the artists' colours market within in the EU according to CEPE´s estimation. The feed back from CEPE, which has been of great value for the work with the restriction dossier, is based on members who interact with CEPE on European level, which represents approximately half of the members. The questionnaire included the following questions:

- What is the total annual quantity sold on the EU-market (and country specific/variations between countries) of artists' paints (and pigments used in enamels, ceramic and glasses) *in general*?
- What is the annual quantity sold on the EU-market (and country specific/variations between countries) of *cadmium based* artists' paints (and pigments used in enamels, ceramic and glasses) and what is the *concentration of cadmium* pigment in the paint?
- Which alternative chemical substances are available and most common for substitution of cadmium pigments in artists' paints (and for cadmium pigments used in enamels, ceramic and glasses)?
- To what extent are the alternatives used compared to cadmium based pigments?
- What is the annual quantity sold on the EU-market of the alternative paints?
- What is the price of cadmium based artists' paints vs. the alternatives?
- Can you say anything about the trend regarding cadmium in artists' paints (and pigments used in enamels, ceramic and glasses) and regarding the alternatives on the EU-market?
- If there are areas where use of cadmium based artists' paints are required, what is the reason for the need?
- Do you have knowledge of any studies dealing with:
    - Who the users are of these cadmium based paints and pigments used in enamels, ceramic and glasses
    - Management regarding release to waste water
    - Waste management

As CEPE has no activities regarding pigments used in enamels, ceramic and glasses, a questionnaire regarding this area of uses was sent to Eurocolor. The questionnaire was sent before the decision not to include cadmium based paints and pigments used in enamels, ceramic and glasses in the dossier. The questions were focused on area of uses, exposure to waste water, alternatives and annual quantity sold (cadmium based pigments and alternatives). No feed back was given but since these areas of use were excluded from the scoop, no further contact was taken.

The same questions that were sent to CEPE were also sent to the **International Cadmium Association (ICdA)** and to **Rockwood pigments in the United Kingdom.** No further information was provided or a reference was made to information obtained from CEPE.

Comments were received from **ICdA** on the "Registry of current Restriction proposal intentions" published on the ECHA website. The Swedish Chemicals Agency therefore invited ICdA to a meeting but a meeting however could not be held.

In March 2013 the Swedish Chemicals Agency invited **ColArt** to a meeting with the aim to gather information. ColArt provides cadmium based artists' paints in oil colours, acrylic colours, water colours and gouache. ColArt businesses are operating in 16 countries and their products are sold worldwide (www.colart.com). The meeting was attended by two representatives from the Swedish subsidiary, one of whom was a practicing artist. The agenda focused on certain issues with the intention to take part of the experience and knowledge of the company. ColArt showed some examples of cadmium and alternative colours in different shades of red, yellow and orange.

Information gathered from the contacts has been taken into account in relevant parts of the dossier.

Users of artists' paints

According to personal contacts with the Swedish art academies **The Royal Institute of Art** and **The University College of Art, Crafts and Design** the cooperation between arts academies, both within the EU and with schools outside the EU, seems to be focused on the development of art, interface between different art forms, etc. rather than on environmental issues.

At a meeting with students and lecturers at **The Royal Institute of Art** in October 2013 different issues were discussed such as cleaning procedures and alternatives to cadmium based colours. Among the participants was also a lecturer in material studies from the Finnish Academy of Fine Arts in Helsinki.

Regarding the alternatives the students and lectures corresponded that it is difficult to compare them to cadmium based colours. For one thing cadmium colours are denser and less paint is needed during use. On the other hand the alternatives are much less costly than cadmium based colours.

The meeting participants agreed that there are deficiencies in the cleaning procedures at art schools. There is a lack of knowledge, equipment and teaching on environmental issues. At art institutes in general there is insufficient information on how students should take care of their brushes and paint waste. It is basically up to each student. According to the experiences of the lecturers and students this is probably the case for art institutes throughout EU (except for Finland which has set out environmental policies). Therefore there is a need for recurrent courses in cleaning methods, obligatory cleaning equipment at each institutes and a possible license to purchase cadmium based paint. However, it was pointed out that there are artists (professional and hobby) outside art institutes which might be difficult to reach with information on the environmental problems with cadmium based paint. Artists are a heterogeneous group which does not tend to share knowledge and experience on such subjects.

At a meeting with Stockholms Målerikonservering, which is a Swedish conservation company founded and run by two trained art conservators, information on the conservation DistList was obtained. The Cons DistList is a worldwide online Forum that has been in operation since 1987 and targets conservators from several specialties, scientists, curators, archivists, librarians, and academics from a number of disciplines. An example of topics discussed in the Forum includes queries and answers about technical issues. At the behalf of the Swedish Chemical Agency Stockholms Målerikonservering forwarded the following questions to the Cons DistList:

1. Do you use alternative pigments for substitution of cadmium pigments in artists' paints
   a. If not, why?
   b. If there are areas where use of cadmium based artists' paints are required, what is the reason for the need?
   c. If you use alternative pigments, to what extent?
2. Which alternative chemical substances are available and most common for substitution of cadmium pigments in artists' paints?
3. Are there any technical differences between the uses of cadmium pigment based paint compared to alternative pigments?
   a. If so, what are the differences?

No comments were received.

G.2 Request for Information from Member States and EEA

In March 2013 Sweden published a questionnaire at CIRCABC with the aim to gather information on:

- The scope of a restriction
- Annual quantity placed on the national market and the EU market as a whole
- Alternatives in use
- National risk management measures
- The occurrence of cadmium in sewage sludge
- Unpublished information on hazards, risks and exposure
- Contact details of relevant stakeholders

Information was provided from Denmark, Norway and the Netherlands.

G.3 Public consultation on the Annex XV restriction report

After submission of the Annex XV restriction report, ECHA organised a six-month public consultation on the restriction dossier on Cadmium in artists' paints from 19 March until 19 September 2014. During the consultation, 666 comments were received from stakeholders, representing individuals, industry, trade unions, NGOs and Member State Competent Authorities.

In addition, there were 44 comments received via another public consultation (on Cadmium in paints) which had run in parallel until 17 June 2014. As it was clear from the content of the comments submitted that they were addressed to the Cadmium in artists' paints restriction proposal, it was considered possible to take those comments into account in the opinion development of the Cadmium in artists' paints.

Therefore, all relevant comments received, as well as the responses from the dossier submitter (Sweden) and from the rapporteurs of the Committees for Risk Asessment and Socio-economic Analysis are to be made available on the ECHA website.

H. Other information

No additional information included.

References

Aas, W. and Breivik, K., 2011. *Heavy metals and POP measurements*. (EMEP/CCC-Report 4/2013). Available from: http://www.nilu.no/projects/ccc/reports.html [Accessed 4 September 2013]

Adams, S.V., Newcomb, P.A., Shafer M.M., Atkinson, C-, Bowles, E.J., Newton, K.M. and Lampe, J.W., 2011. Urinary cadmium and mammographic density in premenopausal women. *Breast Cancer Res. Treat.* **128(3)**, 837-844.

Alfvén, T., Elinder, C.G., Hellström. L., Lagarde. F. and Järup, L., 2004. Cadmium exposure and distal forearm fractures. (2004) J. *Bone Miner. Res.* **19(6)**, 900-905.

Ali, I., 2013. Modulation of hormone signaling by cadmium: From molecular mechanisms to health implications. Academic thesis at Karolinska Institutet.

Amzal, B., Julin, B., Vahter, M., Wolk, A., Johanson, G., Åkesson, A., 2009. Population Toxicokinetic Modeling of Cadmium for Health Risk Assessment. Environ. Health Perspect. 117, 1293-1301.

Andersson, H., Palm-Cousins, A., Munthe, J., Brorström-Lundén, E., Wickman, T., Pettersson, M., Holmström, K., Jamtrot, A., Parkman, H., Fischer, S., Mehtonen, J., Krupanek, J., Zielonka, U., Piasecka. J., Pilch, A., Nielsen, U. and Menger Krug, E., 2012. *WP4 Background Paper Identification of Sources and Estimation of Inputs to the Baltic Sea.* COHIBA (Control of Hazardous Substances in the Baltic Sea Region). (Version 2.0 2012).

Andersson, P.G., 2012. *Slamspridning på åkermark fältförsök med kommunalt avloppsslam från Malmö och Lund under åren 1981–2011* (in Swedish). (Hushållningssällskapets rapportserie 16).

Barrett, K.A. and McBride, M.B., 2007. Dissolution of Zinc-Cadmium sulfide solid solutions in aerated aqueous suspension. *Soil Sci. Soc. Am. J.* **71**, 322-328.

Bergbäck, B., Hjortenkrans, D. and Månsson, N., 2005. *Kadmium i Stockholm – en substansflödesanalys*, (in Swdish). Environment and Health Administration. City of Stockholm.

Bergkvist, P., Jarvis, N. and Berggren, D., 2005. Cadmium solubility and sorption in a long-term sludge-amended arable soil. *J Environ Qual.* **34(5)**, 1530-8.

Bergkvist, P., Jarvis, N., Berggren, D. and Carlgren, K., 2003. Long-term effects of sewage sludge applications on soil properties, cadmium availability and distribution in arable soil. Agriculture, *Ecosystems and Environment* **97**, 167-179.

BGS, British Geological Survey, 2012. European Mineral Statistics 2006-2010. www.bgs.ac.uk/downloads/start.cfm?id=1389.

Blank, P.R., Schwenkglenks, M., Moch, H., Szucs, T.D., 2010. Human epidermal growth factor receptor 2 expression in early breast cancer patients: a Swiss cost-effectiveness study of different predictive assay strategies. *Breast Cancer Res Treat* **124**, 497-507

Blombäck, K., Kallvi, M., Eriksson, J. and Öborn I., 2000. *Cadmium accumulation in agricultural soils and uptake by plants as an effect of cadmium in phosphate fertilisers.* Model estimations. In KemI PM 4/00.

Boesner, 2013. Available from: www.boesner.se [Accessed 15 October 2013]

Borgström, F., Johnell, O., Kanis, J.A., Jönsson, B., Rehnberg, C., 2006. At what hip fracture risk is it cost-effective to treat? International intervention thresholds for the treatment of osteoporosis. *Osteoporosis International* **17**, 1459-1471

Borgström, F., Sobocki, P., Ström, O., Jönsson, B., 2007. The societal burden of osteoporosis in Sweden. *Bone* **40**, 1602-1609

Bryden, A., Petticrew, M., Mays, N., Eastmure, E., Knai, C., 2013. Voluntary agreements between government and business – A scoping review of literature with specific reference to the Public Health Responsibility Deal. *Health Policy* **110**, 186-197

Chaumont, A., Voisin, C., Deumer, G., Haufroid, V., Annesi-Maesano, I., Roels, H., Thijs, L., Staessen, J. and Bernard, A., 2013. Associations of urinary cadmium with age and urinary proteins: Further evidence of physiological variations unrelated to metal accumulation and toxicity. *Environ. Health Perspect.* **121(9)**, 1047-1053.

Chen, X., Zhu, G., Jin, T., Åkesson, A., Bergdahl, I.A., Lei, L., Weng, S and Liang, Y., 2009. Changes in bone mineral density 10 years after marked reduction of cadmium exposure in a Chinese population. *Environ. Res.* **109**, 874-879.

Cho, Y.A., Kim, J., Woo, H.D. and Kang, M., 2013. Dietary cadmium intake and the risk of cancer: A meta-analysis. *PLOS ONE* **8(9)**, e75087.

Ciesielski, T., Weuve, J., Bellinger, D.C., Schwarz, J., Lanphear, B. and Wright, R.O., 2012. Cadmium exposure and neurodevelopmental outcomes in U.S. children. *Environ. Health Perspect.* **120**, 758-763.

City of Gothenburg, 2006. *Ateljéprojektet - kadmium och bly I konstnärsfärger och keramikglasyrer,* (in Swedish). (Göteborgs Stad PM 2006:3).

ColArt, 2013. *Personal communication with Catrin de Rooij, Marketing Coordinator, ColArt, Sweden.* Several occasions March-September 2013.

Cook, M. E., 1994. "Cadmium Pigments: When Should I Use Them?," Inorganic Pigments.. Environmental Issues and Technological Opportunities, Industrial Inorganic Chemicals Group, Royal Society of Chemistry, London, January 12, 1994

Dahlberg, L., Lundkvist, J., Lindman, H., 2009. Health care costs for treatment of disseminated breast cancer. *European Journal of Cancer* **45**, 1987-1991

DHI, 2005. *The impact of REACH on the environment and human health* ENV.C.3/SER/2004/0042r. Report to DG Environment. Revised final report September 2005.

Eastaugh N., Walsh V., Chaplin T., and Siddall R., 2008. *Pigment compendium. A dictionary and optical Microscopy of historical pigments*. ISBN 978-0-7506-8980-9.

Eftec, 2004. *The Health Benefits of Pollution Control: a review of the literature on mortality and morbidity effects.* Paper prepared for UK Department for environment, Food and Rural Affairs. Workshop on Valuation of Health Benefits of Reductions in Air Pollution and Use Values in UK Appraisal. Revised and extended version: August 2004.

EC, European Commission, 2012a. *Agriculture in the European Union statistical and economic information report 2012.* Directorate-General for Agriculture and Rural Development. December 2012.

EC, European Commission, 2007. Green paper on market-based instruments for environment and related policy purposes. COM(2007) 140 final.

EC, European Commission, 2009. *Impact Assessment Guidelines.* SEC(2009) 92. 15 January 2009.

EC, European Commission, 2013a. *Seventh Report on the Implementation of the Urban Waste Water Treatment Directive, 91/271/EEC.* (SWD(2013) 298 final).

EC, European Commission, 2013b. TARIC consultation. Taxation and customs union. Available from: http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Lang=en [Accessed 13 November 2013]

EC, European Commission, 2012b. *The 2012 Ageing Report: Economic and budgetary projections for the 27 EU Member States (2010-2060).* European Economy 2/2012 (provisional version). Directorate-General for Economic and Financial Affairs. Available from: http://europa.eu/epc/pdf/economic_and_budgetary_projections_for_the_27_eu_member_states__en.pdf [Accessed 13 December 2013]

ECB, European Chemicals Bureau, 2007. *European Union Risk Assessment Report- Cadmium oxide and Cadmium metal Part I – Environment*. 3rd Priority List, Vol.72 and *European Union Risk Assessment Report- Cadmium metal Part II – Human Health.* 3rd Priority List, Vol. 74. European Chemicals Bureau, European Commission. (EUR 22919 EN and EUR 22767 EN).

ECHA, European Chemicals Agency, 2008a. Guidance on information requirements and chemical safety assessment, Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds. Available from: http://echa.europa.eu/documents/10162/13632/information_requirements_r7_13_2_en.pdf

ECHA, European Chemicals Agency, 2008b. Guidance on Socio-Economic Analysis – Restrictions. May 2008

ECHA, 2012. Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation. Version 2.1, October 2012. Available from: https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

ECHA, European Chemicals Agency, 2013a. The ECHA database for registered substances.

ECHA, European Chemicals Agency, Classification and Labelling inventory, 2013b. Available from: http://echa.europa.eu/information-on-chemicals/cl-inventory [Accessed 16 September 2013]

EEA, European Environment Agency, 2013. *Urban waste water treatment (CSI 024) - Assessment published Jan 2013.* Available from: http://www.eea.europa.eu/data-and-maps/indicators/urban-waste-water-treatment/urban-waste-water-treatment-assessment-3 [Accessed 11 October 2013]

EFSA, European Food Safety Authority, 2009. Cadmium in food. Scientific opinion of the panel on contaminants in the food chain. *The EFSA Journal* 980, 1-139.

EFSA, European Food Safety Authority, 2012. Cadmium dietary exposure in the European population. *The EFSA Journal* **10(1),** 2551.

Eichler, H-G., Kong, S.X., Gerth, W.C., Mavros, P. and Jönsson, B., 2004. Use of Cost-Effectiveness Analysis in Health-Care Resource Allocation Decision-Making: How Are Cost-Effectiveness Thresholds Expected to Emerge*? Value In Health.* **7(5)**, 518-528.

Engström, A., 2011b. *Cadmium as a risk factor for osteoporosis and fractures In women.* Academic thesis at Karolinska Institutet.

Engström, A., Michaëlsson, K., Suwazono, Y., Wolk, A., Vahter, M. and Åkesson, A., 2011a. Long-term cadmium exposure and the association with bone mineral density and fractures in a population-based study among women. *J Bone Miner. Res.* **26(3)**, 486-495.

Engström, A., Michaëlsson, K., Vahter, M., Julin, B., Wolk, A. and Åkesson, A., 2012. Associations between dietary cadmium exposure and bone mineral density and risk of osteoporosis and fractures among women. *Bone* **50(6)**, 1372-8.

Enskog, L., 2000. *Kadmium- miljö- och hälsoaspekter vid slamspridning* (Cadmium- environmental and health aspects of sludge application, in Swedish). The Stockholm Water Company.

E-PRTR, The European Pollutant Release and Transfer Register, 2013. Available from: http://prtr.ec.europa.eu/PollutantReleases.aspx [Accessed 15 August 2013]

Eriksson, J. 2009. *Strategi för att minska kadmiumbelastningen i kedjan mark-livsmedelmänniska* (in Swedish). (Rapport MAT21, nr 1/2009 SLU).

Eriksson, J., 2001. Concentration of 61 trace elements in sewage sludge, farmyard manure, mineral fertiliser, precipitation and in oil and crops. (Agency SEP. 5159)

ERM, Environmental Resources Management ,2001. ERM on behalf of Enterprise DG of the European Commission. *Analysis and Conclusions from Member States' Assessment of the Risk to Health and the Environment from Cadmium in Fertilisers.* Contract No. ETD/00/503201 October 2001

ERM, Environmental Resources Management, 2000. *A study to establish a programme of detailed procedures for the assessment of risk to health and the environment for cadmium in fertilisers.* February 2000.

Eurosoil, 2010. *pH in Europe.* Available from: http://eusoils.jrc.ec.europa.eu/library/data/ph/Resources/ph2.pdf [Accessed 29 October 2013]

Eurostat 2013a. *Agri-Environmental Indicators Database*. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/agri_environmental_indicators/data/database [Accessed 30 October 2013]

Eurostat, 2013b. *Exchange rates Statistics*. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/exchange_rates/data/database [Accessed 28 October 2013]

Eurostat, 2013c. *Farm structure statistics, Table 4 Land use, 2010.* Available from: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Farm_structure_statistics#Further_Eurostat_information [Accessed 30 October 2013]

Eurostat, 2013d. *Harmonized Indices of Consumer Prices (HICP) Statistics*. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/hicp/data/database [Accessed 16 October 2013]

Eurostat, 2013e. *Labour costs Statistics*. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/labour_market/labour_costs/database [Accessed 3 December 2013]

Eurostat, 2013f. *National accounts (including GDP) Statistics*. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/national_accounts/data/database [Accessed 28 October 2013]

Eurostat, 2013g. *Population statistics*. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/population/data/database [Accessed November 2013]

Eurostat, 2013h. Purchasing power parities (PPPs) Statistics. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/purchasing_power_parities/data/database [Accessed 11 December 2013]

Ferlay, J., Steliarova-Foucher, E., Lortet-Tieulent, J., Rosso, S., Coebergh, J.W.W., Comber, H., Forman, D. and Bray, F., 2013. Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012. *Eur. J Cancer* **49**, 1374-1403.

Finnish Environment Institute, 1997. *Cadmium in fertilizers: risk to human health and the environment.* Study report of the Finnish Ministry of Agriculture and Forestry.

Gallagher, C.M., Chen, J.J. and Kovach, J.S., 2010. Environmental cadmium and breast cancer risk. *Aging* **2(11),** 804-814.

General chemistry, 2013. Available from: http://www.vias.org/genchem/chem_cds.html [Accessed 11 November 2013]

Gustafsson, J.P., 2013. *Soil chemical behaviour of cadmium pigments from paints.* Jon Petter Gustafsson, Professor in Soil and Groundwater Chemistry, Department of Land and Water Resources Engineering, KTH Royal Institute of Technology. Swedish Chemicals Agency. (PM 4/13).

Hammarlund, L. and Mimovic, D., 2005. *Kadmium från konstnärsfärger- Källor till kadmiumutsläpp och konstnärers bidrag vid Käppalaverket*, (in Swedish). Master degree project. Stockholms Miljöcenter (currently Installatörernas Utbildningscentrum Stockholm). (MIT03).

Hammitt, J.K. & Liu, J-T., 2004. Effects of Disease Type and Latency on the Value of Mortality Risk. *Journal of Risk and Uncertainty.* **28(1)**, 73-95.

Hammitt, J. K., 2002. QALYs Versus WTP. Risk Analysis. **22(5)**, 985–1001. DOI: 10.1111/1539-6924.00265.

Hellström, L., Elinder, C.G., Dahlberg, B., Lundberg, M., Järup, L., Persson, B. and Axelson, O., 2001. Cadmium exposure and end-stage renal disease. *Am. J. Kidney Dis.* **38(5)**, 1001-8.

Hutton, M., Eduljee, G. and de Meeûs, C., 2001. *Analysis and conclusions from Member States' assessment of the risk to health and the environment from cadmium in fertilisers.* (ERM Interim Report 7440).

IARC, 2012. Cadmium and cadmium compounds. In Monographs, Vol 100C, A review of Human carcinogens, pp 121-145. Available from: http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-8.pdf [Accessed November 2013]

ICdA, International Cadmium Association, 2013. Available from: http://www.cadmium.org/pg_n.php?id_menu=13 [Accessed 18 September 2013]

IFA, International Fertilizer Industry Association, 2013a. Available from: http://www.fertilizer.org/ifa/Home-Page/SUSTAINABILITY/Cadmium/Cadmium-in-fertilizers.html [Accessed 12 August 2013]

IFA, International Fertilizer Industry Association, 2013b. Available from: http://www.fertilizer.org/ifa/ifadata/search [Accessed 4 November 2013]

IMF, International Monetary Fund, 2013. *World Economic and Financial Surveys. World Economic Outlook Database.* Available from: http://www.imf.org/external/pubs/ft/weo/2013/02/weodata/index.aspx [Accessed 28 October 2013]

ISO 10390:2005: Soil quality -- Determination of pH.

JRC, Joint Research Centre, 2012. *Occurrence and levels of selected compounds in European Sewage Sludge Samples*. Results of a Pan-European Screening Exercise (FATE- SEES). JRC Scientific and Policy Reports.

Julin, B., 2012b. *Dietary cadmium exposure and the risk of hormone-related cancers.* Academic thesis at Karolinska Institutet.

Julin, B., Wolk, A., Bergkvist, L., Bottai, M. and Åkesson, A., 2012a. Dietary cadmium exposure and risk of postmenopausal breast cancer: A population-based prospective cohort study. *Cancer Res.* **72**, 1459-1466.

Kido, T., Honda, R., Tsuritani, I., Yamaya, H., Ishizaki, M., Yamada, Y. and Nogawa, K., 1988. Progress of renal dysfunction in inhabitants environmentally exposed to cadmium. *Arch. Environ. Health* **43(3),** 213-217.

Kiene, A.,1999. *Methodische Fragen der Bilanzierung von Ein-und Austrägen in Böden am Beispiel Cadmium.* **In:** Pflanzenbelastung auf Kontaminierten Standorten (Plant impact at contaminated sites). Edited by UBA. Berichte 1/99. Erich Schmidt Verlag.

Kippler, M., Tofail, F., Hamadani, J.D., Gardner, R.M., Grantham-McGregor, S.M., Bottai, M. and Vahter, M., 2012. Early-life cadmium exposure and child development in 5-year-old girls and boys: A cohort study in rural Bangladesh. *Environ. Health Perspect.* **120(10)**, 1462-1468.

Kirk-Othmer (2004). The Encyclopedia of Chemicals Technology, 5th Ed.

Konstnärernas centralköp, 2013. *Personal communication with staff at the artist paint store Konstnärernas centralköp.* 30 September 2013.

Kreatima, 2013. *Personal communication with Kaj Hammarlund and staff at the art paint store Kreatima in Stockholm*. Several occasions August-September 2013.

Landner, L., Folke, J., Öberg, M.O., Mikaelsson, H. and Aringberg-Laanatza M., 1996. *Cadmium in Fertilisers*. Consultants report prepared for the OECD cadmium workshop, Sweden, 16-20 October 1995 by the European Environmental Research Group Inc. on commission by The National Chemicals Inspectorate, Sweden.

Lead registrant, 2012. *Cadmium sulphide, CAS Number: 1306-23-6.* Chemical Safety Report, 2012-11-21 (CSR-PI-5.2.1)

Lead registrant, 2013a. *Cadmium sulfoselenide red, CAS Number: 58339-34-7*. Chemical Safety Report, 2013-05-08. (CSR-PI-5.4.0)

Lead registrant, *2013b. Cadmium zinc sulphide, CAS Number: 8048-07-5*. Chemical Safety Report, 2010-05-08. (CSR-PI-5.4.0).

Lidgren, M., Wilking, N., Jönsson, B., 2007a. Cost of breast cancer in Sweden in 2002. *European Journal of Health Economics* **8**, 5-15

Lidgren, M., Wilking, N., Jönsson, B., Rehnberg, C., 2007b. Health related quality of life in different states of breast cancer. *Quality of Life Research* **16**, 1073-1081

Lig, R. and Held, M., 2009). Cadmium flows in Europe. Online publication December 8, 2009. Revue de Métallurgie, 106 , pp 559-565 doi:10.1051/metal/2009089

Luengo-Fernandez, R., Leal, J., Gray, A., Sullivan, R., 2013. Economic burden of cancer across the European Union: a population-based cost analysis. *The Lancet Oncology* **14(12)**, 1165-1174

Lussiez., G.W., Chou E.C. and Beckstead L.W., 1989. *United States Patent 4,810,303*. March 7, 1989.

List of Substances, 2013. Ämnesregistret, Swedish Chemicals Agency. Available from http://apps.kemi.se/Amnesregistret/ [Accessed September 2013]

Ma WC, 1987. Heavy metal accumulation in the mole, Talpa europea, and earthworms as an indicator of metal bioavailability in terrestrial environments. *Bull. Environm. Contam. Toxicol.* **39**, 933-938.

Månsson, N. and Bergbäck, B., 2007. *Bly, kadmium och kvicksilver - flöden och lager i Stockholms teknosfär,* (in Swedish). Environment and Health Administration. City of Stockholm.

McElroy, J.A., Shafer, M.M., Trentham-Dietz, A., Hampton, J.M. and Newcomb, P.A., 2006. Cadmium exposure and breast cancer risk. *J. Natl. Cancer Inst.* **98(12)**, 869-873.

Milieu, 2008. *Environmental, economic and social impacts of the use of sewage sludge on land Final Report, Part I: Overview Report.* Prepared by Milieu Ltd, WRc and RPA for the European Commission, DG Environment under Study Contract DG ENV.G.4/ETU/2008/0076r. Available from: http://ec.europa.eu/environment/waste/sludge/pdf/part_i_report.pdf [Accessed 30 October 2013]

Milieu, 2010. Environmental, economic and social impacts of the use of sewage sludge on land, Final Report, Part III: Project Interim Reports. Prepared by Milieu Ltd, WRc and RPA for the European Commission, DG Environment under Study Contract DG ENV.G.4/ETU/2008/0076r. Available from: http://ec.europa.eu/environment/waste/sludge/pdf/part_iii_report.pdf [Accessed 30 October 2013]

Moolenaar, S.W. and Lexmond, T.M., 1998. Heavy-metal balances of agro-ecosytems in The Netherlands. *Netherlands J. Agri. Sci.* **46**, 171-192.

Nagata, C., Nagao, Y., Nakamura, K., Wada, K., Tamai, Y., Tsuji, M., Yamamoto, S. and Kashiki, Y., 2013. Cadmium exposure and the risk of breast cancer in Japanese women. *Breast Cancer Res. Treat.* **138(1)**, 235-239.

NGU, 2011. *The EuroGeoSurveys geochemical mapping of agricultural and grazing land soils project (GEMAS).– Evaluation of quality control results of total C and S, total organic carbon (TOC), cation exchange capacity (CEC), XRF, pH, and particle size distribution (PSD) analysis*. (Report 2011.043). Available from: http://www.ngu.no/upload/Publikasjoner/Rapporter/2011/2011_043.pdf [Accessed

29 October 2013]

Nicholson, F.A., Chambers, B.J., Williams, J.R. and Unwin, R.J., 1999. Heavy metal contents of livestock feeds and animal manures in England and Wales. *Bioresource Technol* **70,** 23-31.

Nziguheba, G. and Smolders, E., 2008. Input of trace elements in agricultural soils via phosphate fertilizers in European Countries. *Science of the Total Environment* **390**, 53-57.

OECD, 2001. OECD Environment, Health and Safety Publications, Series on Testing and Assessment, No. 29, Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media. Available from: http://www.oecd.org/ehs/ [Accessed November 2013]

Pearse, J., 1996. *Cadmium: Some aspects of risk reduction*. **In:** Publikatiereeks Stoffen, Veiligheid, Straling, Ministerie van Volkshuisvesting. Ruimtelijke Ordening en Milieubeheer, Bilthoven. The Netherlands.

Perez M., Castro K., Rodriguez M.D., Olazabal M.A. and Madariaga J.M., 2003*. A critical analysis of commercial pigments*.

Printsmann, R., 1999. *Treatment of Wastewater from Artists', Schools/Studios Containing Heavy Metals (Cadmium.* Master degree project.(Trita-KET-IM, 1402-7615;1999:14)

Püringer, J., 2011. Derived Minimal Effect Levels (DMELs): Shortcomings one year after the REACH registration deadline. Available from: (http://www.auva.at/mediaDB/884917_DMELs_Shortcomings_one_year_after.pdf) [Accessed November 2013]

Purmonen, T.T., Pänkäläinen, E., Turunen, J.H.O., Asseburg, C., Martikainen, J.A., 2011. Short-course adjuvant trastuzumab therapy in early stage breast cancer in Finland: Cost-effectiveness and value of information analysis based on the 5-year follow-up results fo the FinHer Trial. *Acta Oncologica* **50**, 344-352

Rappaport, B.D., Scott, J.D., Martens, D.C., Reneau, Jr., R.B. and Simpson, T.W., 1987. *Availability and Distribution of Heavy Metals, Nitrogen, and Phosphorus from Sewage Sludge in the Plant-Soil-Water Continuum.* Department of Agronomy Virginia Polytechnic Institute and State University. (Bulletin 154).

Risk & Policy Analysis, RPA. 2014. *Final Report on the extension of the obligation to perform a chemical safety assessment and to document a chemical safety report to CMR 1A and 1B substances manufactured or imported between 1 and 10 tonnes per year*. Report prepared for DG Environment, 30 June 2014

Risk & Policy Analysts Limited, 2000. *The risks to health and environment by cadmium used as a colouring agent or a stabiliser in polymers and for metal plating*. Final report prepared for the European Commission, DG Enterprise. Loddon, Norfolk. Available at: http://www.rpaltd.co.uk/documents/J316-Cadmium.pdf, accessed 25/06/2014.

Sager, M., 2007. Trace and nutrient elements in manure, dung and compost samples in Austria. *Soil Biol Biochem* **39:** 1383-1390.

Sand, S., and Becker, W., 2012. Assessment of dietary cadmium exposure in Sweden and population health concern including scenario analysis. *Food and Chemical Toxicology* **50**, 536–544.

SCOEL/SUM/136, February 2009. For public consultation. Recommendation from the Scientific Expert

Group on Occupational Exposure Limits for Cd and its organic compounds.

Sennelier, 2013. Available from: http://www.sennelier.fr/ [Accessed 6 September 2013]
shop.winsornewton, 2013. Available from: http://shop.winsornewton.com [Accessed 15 October 2013]

Six, L. and Smolders, E., 2014. Future trends in soil cadmium concentration under current cadmium fluxes to European agricultural soils. Science of the Total Environment, **485-486**, ppg 319-328.

Smith, S., Newhouse, J.P., Freeland, M.S., 2009. Income, Insurance, and Technology: Why Does Health Spending Outpace Economic Growth? *Health Affairs* **28(5)**, 1276-1284

Smolders, E. and Mertens, J., 2013. Chapter 10, Cadmium. In B.J. Alloway (ed.) *Heavy Metals in Soils: Trace Metals and Metalloids in Soils and their Bioavailability*. Environmental Pollution 22, DOI 10.1007/978-94-007-4470-7_10.

Smolders, E., 2013. *Revisiting and updating the effect of phosphorus fertilisers on cadmium accumulation in European agricultural soils*. International Fertiliser Society. (Proceeding No. 724).

Sommar, J.N., Pettersson-Kymmer, U., Lundh, T., Svensson, O., Hallmans, G. and Bergdahl, I.A., 2013b. Hip fracture risk and cadmium in erythrocytes: A nested case-control study with prospectively collected samples. *Calcif. Tissue Int*. Oct 8 (Epub ahead of print).

Sommar, J.N., Svensson, M.K., Björ, B.M., Elmståhl, S.I., Hallmans, G., Lundh, T., Schön, S.M., Skerfving, S. and Bergdahl, I.A., 2013a. End-stage renal disease and low level exposure to lead, cadmium and mercury; a population-based, prospective nested case-referent study in Sweden. *Environ Health.* **12:9**. doi: 10.1186/1476-069X-12-9.

Statistics Sweden, 2012. *Gödselmedel i jordbruket 2010/11 Mineral- och stallgödsel till olika grödor samt hantering och lagring av stallgödsel - Use of fertilisers and animal manure in agriculture in 2010/11*. Sveriges officiella statistik. (MI 30 SM 1203).

Sternbeck. J., J. Eriksson & AH Österås, 2011. *The role of mineral fertilisers for cadmium in Swedish agricultural soil and crops*. Annex 4 in KemI report 1/11: Kadmiumhalten måste minska– för folkhälsans skull. En riskbedömning av kadmium med mineralgödsel i fokus. Swedish Chemicals Agency, ISSN: 0284-1185.

Stockholm Water Company, 2013. *Personal communication* with Environmental Engineer Agneta Bergström 3 June 2013.

Stokes, M.E., Thompson, D., Montoya, E.L., Weinstein, M.C., Winer, E.P., Earle, C.C., 2008. Ten-Year Survival and Cost Following Breast Cancer Recurrence: Estimates from SEER-Medicare Data. *Value in health* **11(2)**, 213-220

Ström, O., Borgström, K., Kanis, J., Compston, J., Cooper, C., McCloskey, J. and Jönsson, B., 2011. Osteoporosis: burden, health care provision and opportunities in the EU: a report prepared in collaboration with the International Osteoporosis Foundation (IOF) and the European Federation of Pharmaceutical Industry Associations (EFPIA). *Arch. Osteoporos*. **6(1-2)**, 59-155.

Svanberg 1998. *Flockulering av tvättvatten från konstnärsfärger,* (in Swedish). Master degree project. ColArt, Miljö- och teknikcenter Stockholm and The Stockholm Water Company. (R nr 2 jan 2000).

Svensson, S. and Weiss, J., 2005. *Kadmium i konstnärsfärger*, (in Swedish). Project report. The Stockholm Water Company. (MIT-04 2005-06-03).

Swedish Board of Agriculture, 2012. *Market overview – plant production (English summary).* Jordbruksverket (Rapport 2012:26).

Swedish Chemicals Agency, 2013. *Economic costs of fractures caused by dietary cadmium exposure*. (KemI Report No 4/13). Available from: http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport-4-13-cadmium.pdf [Accessed November 2013]

Swedish Chemicals Agency, 2011. *Kadmiumhalten måste minska– för folkhälsans skull. En riskbedömning av kadmium med mineralgödsel i focus,(partly in Swedish)*. (KemI Rapport 1/11). Available from: http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/KemI_Rapport_1_11.pdf [Accessed November 2013]

Swedish National Board of Health and Welfare, 2012. *Cancer incidence in Sweden 2011*. Socialstyrelsen Official Statistics of Sweden. Statistics – Health and medical care.

Swedish National Food Agency, 2012. *Market basket 2010 - chemical analysis, exposure estimation and health-related assessment of nutrients and toxic compounds in Swedish food baskets.* (Livsmedelsverkets report nr 7).

SWWA, Swedish Water & Wastewater Association, 2012. *Kadmiumgult är fult – en rapport om farliga konstnärsfärger,* (in Swedish). (M136).

TC WI, 2003. Sludge, Treated Biowaste and Soil – Determination of pH. Available from: https://www.ecn.nl/docs/society/horizontal/pH_standard_for_validation.pdf [Accessed November 2013]

The Color of Art: Pigment Database Quick Reference Index, 2013. Available from: http://www.artiscreation.com/color_index_index.html, [Accessed September 2013]

Thomas, L.D.K., Michaelsson, K., Julin, B., Wolk, A. and Åkesson, A., 2011. Dietary cadmium exposure and fracture incidence among men: A population-based prospective cohort study. *J. Bone Mineral Res.* **26(7)**, 1601-1608.

USGS (2012). Cadmium. Mineral Commodity Summaries 2012. U.S. Geological Survey. http://minerals.usgs.gov/minerals/pubs/mcs/2012/mcs2012.pdf

Van Houtven, G., Sullivan, M.B, Dockins, C., 2008. Cancer premiums and latency effects: A risk tradeoff approach for valuing reductions in fatal cancer risks. *Journal of Risk and Uncertainty*. **36(2)**, 179-199. DOI: 10.1007/s11166-008-9032-2

Weiss, J., 2006. *Rening av tvättvatten från konstnärer – kadmium,* (in Swedish). Master degree project. Stockholms Miljöcenter (currently Installatörernas Utbildningscentrum Stockholm).

Will, B.P., Bethelot, J-M., Le Petit, C., Tomiak, E.M., Verma, S., Evans, W.K., 2000. Estimates of the lifetime costs of breast cancer treatment in Canada. *European Journal of Cancer* **36**, 724-735

Winsor & Newton, 2013. Available from: http://www.winsornewton.com/ [Accessed 6 September 2013]

Zorll U., 2001. *European Coatings handbook*. ISBN 3-87870-559-X.

Åkerström, M., Barregård, L., Lundh, T. and Sällsten, G., 2013. The relationship between cadmium in kidney and cadmium in urine and blood in an environmentally exposed population. *Tox. Appl. Pharm.* **268**, 286-293.

References used in boxes

Alberini, A. and Ščasný, M. (2014). Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union, Part III: Carcinogens. Environment Center, Charles University Prague (CZ), FD7. Final Report, Service contract for the European Chemicals Agency No. ECHA/2011/123.

Baltic Marine Environment Protection Commission HELCOM (2013). Palette of measures on cost-effective management options to reduce discharges, emissions, and losses of hazardous substances, HELCOM Ministerial Declaration.

Cookson, R. (2003). Willingness to pay methods in health care: a sceptical view. Health Economics 12, 891-894.

DWA (2005). Stand der Klärschlammbehandlung und –entsorgung in Deutschland, Ergebnisse der DWA-Klärschlammerhebung, DWA German Water Association 2003

DWA (2010) Positionen zur Klärschlammentsorgung, DWA Positionen.

Friedrich, M (2013) Zunkunftsfähige Behandlung und Entsorgung von Klärschlamm in Mecklenburg-Vorpommern. Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz (MV), Druckschrift, Schwerin.

Oosterhuis, F.H., Brouwer, F.M. and Wijnants, H.J. (2000). A possible EU wide charge on cadmium in phosphate fertilisers: Economic and environmental implications. IVM Institute for Environmental Studies, Amsterdam, NL, Final Report to the European Commission, E-00/02.

Wiechmann, B, Dienemann, C, Kabbe, C, Brandt, S, Vogel, I and Roskosch, A (2012) Klärschlammentsorgung in der Bundesrepublik Deutschland. Umweltbundesamt, Dessau.

Appendices

Appendix 1 The content of Entry 23 of Annex XVII of REACH

Cadmium CAS No 7440-43-9, EC No 231-152-8 and its compounds…..

1. *Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material):*

- *polyvinyl chloride (PVC) [3904 10] [3904 21]*
- *polyurethane (PUR) [3909 50]*
- *low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10]*
- *cellulose acetate (CA) [3912 11]cellulose acetate butyrate (CAB) [3912 11]*
- *epoxy resins [3907 30]*
- *melamine-formaldehyde (MF) resins [3909 20]*
- *urea-formaldehyde (UF) resins [3909 10]*
- *unsaturated polyesters (UP) [3907 91]*
- *polyethylene terephthalate (PET) [3907 60]*
- *polybutylene terephthalate (PBT)*
- *transparent/general-purpose polystyrene [3903 11]*
- *acrylonitrile methylmethacrylate (AMMA)*
- *cross-linked polyethylene (VPE)*
- *high-impactpolystyrenepolypropylenePP)[390210]*

Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.
By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011.
The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC and acts adopted on its basis.
By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted.

1. *Shall not be used in paints [3208][63] [3209][64].*

For paints with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight.
Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.
3. By way of derogation, paragraphs 1 and 2 shall not apply to articles colored with mixtures containing cadmium for safety reasons.
4. By way of derogation, paragraph 1, second subparagraph shall not apply to:
— mixtures produced from PVC waste, hereinafter referred to as "recovered PVC",
— mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd 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; EN L 134/4 Official Journal of the European Union 21.5.2011
(c) decks and terraces;

[63] Paints and varnishes (including enamels and lacquers) based on synthetic polymers or chemically modified natural polymers, dispersed or dissolved in a non-aqueous medium; solutions as defined in note 4 to this chapter
[64] Paints and varnishes (including enamels and lacquers) based on synthetic polymers or chemically modified natural polymers, dispersed or dissolved in an aqueous medium

(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 compliance with paragraph 1 above.

Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: "Contains recovered PVC" or with the following pictogram:

In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017.

5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface.

Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:

(a)equipment and machinery for:

food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11],

-agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436],

-cooling and freezing [8418],

-printing and book-binding [8440] [8442] [8443]

(b) equipment and machinery for the production of:

-household goods [7321] [8421 12] [8450] [8509] [8516],

-furniture [8465] [8466] [9401] [9402] [9403] [9404],

-sanitary ware [7324],

-central heating and air conditioning plant [7322] [8403] [8404] [8415]

In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited.

6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below:

(a)equipment and machinery for the production of:

-paper and board [8419 32] [8439] [8441], textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452]

(b)equipment and machinery for the production of:

-industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431],

-road and agricultural vehicles [chapter 87],

-rolling stock [chapter 86],

-vessels [chapter 89]

7. However, the restrictions in paragraphs 5 and 6 shall not apply to:

— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels,

— electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed.

8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight.

Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight.

For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C.

9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.

10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in:

(i) metal beads and other metal components for jewellery making;

(ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including:

-bracelets, necklaces and rings,

-piercing jewellery, wrist-watches and

-wrist-wear,

-brooches and cufflinks.

11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 January 2012 and jewellery more than 50 years old on 10 December 2011.

Appendix 2 Examples of identifiers for some cadmium compounds

Examples of identifiers covering cadmium sulfide, cadmium sulphoselenide, cadmium selenides and cadmium zinc sulfides, with other synonyms and other EC- and CAS numbers than for the two families of pigments currently identified by registrants using the EC/CAS identifiers for "cadmium sulfoselenide red" (CAS 58339-34-7) and "cadmium zinc sulfide yellow" (CAS 8048-07-5), are shown in Table A2:1. The list shall not be seen as an exhaustive list of pigments or families of pigments covered by the restriction proposal.

Table A2:1 Names and CAS numbers of some cadmium sulfide, cadmium sulphoselenides, cadmium selenide and cadmium zinc sulfides pigments and families of pigments (List of Substances 2013)

Substance name	Synonyms, examples	EC number	CAS number	Notes
Cadmium sulfide	Cadmium sulfide yellow	215-147-8	1306-23-6	Registered
Cadmium selenide sulfide	Cadmium sulfide selenide Cadmium sulphoselenide	235-724-8	12626-36-7	Pre-registered
Cadmium sulfoselenide orange	C.I. Pigment Orange 20 C.I. 77202 Cadmium orange	235-758-3	12656-57-4	Pre-registered
Cadmium selenide sulfide	Dicadmium selenide sulphide Cd_2SSe	235-392-4	12214-12-9	Pre-registered
Cadmium selenide, solid solution with cadmium sulfide	Cadmium selenide sulfide	275-290-7	71243-75-9	Pre-registered
Cadmium selenide sulfide	Cadmium sulfide selenide Cadmium sulphoselenide	234-342-9	11112-63-3	Pre-registered
Cadmium selenide		215-148-3	1306-24-7	Pre-registered
Cadmium zinc sulfide		234-372-2	11129-14-9	Pre-registered
Cadmium zinc sulfide		235-672-6	12442-27-2	Pre-registered

REACH pre-registered cadmium sulfides and cadmium selenides, doped with mainly other metals, and multi-constituent substances where cadmium selenide and cadmium sulphide are among the main constituents, are shown in Table A2. Since the pre-registrations don´t contain information on uses, we have no evidence that these compounds are used or are intended to be used as pigments in artist paints. The list shall not be seen as an exhaustive list of pigments and families of pigments covered by the restriction proposal.

Table A2:2 Examples of cadmium containing substances that are preregistered, but not yet registered under Reach (ECHA 2013a)

EC-Number	CAS-Number	Name
292-386-4	90604-90-3	Cadmium lithopone yellow Note: According to the website "The Color of Art: Pigment Database Quick Reference Index" (http://www.artiscreation.com/color_index_index.html) the CAS number is known under several synonyms, e.g. Cadmium-Barium Yellow deep, Pigment Yellow 37:1, C.I. 77199:1.
215-717-6	1345-09-1	Cadmium mercury sulfide Note: According to the website "The Color of Art: Pigment Database Quick Reference Index" (http://www.artiscreation.com/color_index_index.html) the CAS number is known under several synonyms, e.g. C.I. Pigment red 113, C.I. 77201, Mercadmium red, cadmium mercury red, C.I. Pigment orange 23, C.I. 77201, cadmium mercury orange.
309-897-6	101357-00-0	Cadmium selenide (CdSe), solid soln. with cadmium sulfide, zinc selenide and zinc sulfide, aluminum and copper-doped
309-898-1	101357-01-1	Cadmium selenide (CdSe), solid soln. with cadmium sulfide, zinc selenide and zinc sulfide, copper and manganese-doped
309-899-7	101357-02-2	Cadmium selenide (CdSe), solid soln. with cadmium sulfide, zinc selenide and zinc sulfide, europium-doped
309-900-0	101357-03-3	Cadmium selenide (CdSe), solid soln. with cadmium sulfide, zinc selenide and zinc sulfide, gold and manganese-doped
309-901-6	101357-04-4	Cadmium selenide (CdSe), solid soln. with cadmium sulfide, zinc selenide and zinc sulfide, manganese and silver-doped
272-539-1	68876-98-2	Cadmium sulfide (CdS), aluminum and copper-doped
272-540-7	68876-99-3	Cadmium sulfide (CdS), aluminum and silver-doped
272-581-0	68891-87-2	Cadmium sulfide (CdS), copper and lead-doped
272-541-2	68877-00-9	Cadmium sulfide (CdS), copper chloride-doped
272-542-8	68877-01-0	Cadmium sulfide (CdS), silver chloride-doped
272-220-7	68784-10-1	Cadmium sulfide (CdS), solid soln. with zinc sulfide, aluminum and cobalt and copper and silver-doped
270-979-9	68512-51-6	Cadmium sulfide (CdS), solid soln. with zinc sulfide, aluminum and copper-doped
271-538-3	68584-41-8	Cadmium sulfide (CdS), solid soln. with zinc sulfide, aluminum and silver-doped
269-773-1	68332-81-0	Cadmium sulfide (CdS), solid soln. with zinc sulfide, copper and lead-doped
270-978-3	68512-50-5	Cadmium sulfide (CdS), solid soln. with zinc sulfide, copper and manganese-doped
271-539-9	68584-42-9	Cadmium sulfide (CdS), solid soln. with zinc sulfide, copper and nickel-doped
271-511-6	68583-43-7	Cadmium sulfide (CdS), solid soln. with zinc sulfide, copper and silver-doped
270-977-8	68512-49-2	Cadmium sulfide (CdS), solid soln. with zinc sulfide, copper chloride-doped
271-512-1	68583-44-8	Cadmium sulfide (CdS), solid soln. with zinc sulfide, nickel and silver-doped
271-513-7	68583-45-9	Cadmium sulfide (CdS), solid soln. with zinc sulfide, silver chloride-doped
292-385-9	90604-89-0	Cadmium zinc lithopone yellow Note: According to the website "The Color of Art: Pigment Database Quick Reference Index"

EC-Number	CAS-Number	Name
		(http://www.artiscreation.com/color_index_index.html) the CAS number is known under several synonyms, e.g. cadmium lithopone yellow, C.I. pigment yellow 35:1, C.I. 77205:1, cadmium-barium yellow.
		Reaction mass of cadmium selenide and cadmium sulphide
		Reaction mass of cadmium selenide and cadmium sulphide and lead sulfochromate yellow and zinc chromate
309-029-6	99749-34-5	Zircon, cadmium orange
277-135-9	72968-34-4	Zircon, cadmium yellow

On the website "The Color of Art: Pigment Database Quick Reference Index" (http://www.artiscreation.com/color_index_index.html), more cadmium containing pigments and/or synonyms can be found, for example:
C.I. Pigment Yellow 37, C.I. 77199, pigment yellow, cadmium lemon/orange deep/sulphide, CAS 68859-25-6;
C.I. Pigment red 113:1, C.I. 77201:1, mercadmium lithopone red, cadmium sulfide-mercuric sulfide co-precipitated on barium sulfate;
C.I. Pigment orange 20:1, C.I. 77202, cadmium barium orange, cadmium selenosulphide co-precipitated with barium sulfide.

Appendix 3 Soil chemical behaviour of cadmium pigments from paints

Soil Chemical behaviour of cadmium pigments from paints

June 2013

Consultancy report
Agreement registration number 240-H12-00152

Jon Petter Gustafsson, Professor in Soil and Groundwater Chemistry

Department of Land and Water Resources Engineering, KTH Royal Institute of Technology, Teknikringen 76, 100 44 Stockholm, Sweden

Foreword

This report was commissioned to Professor Jon Petter Gustafsson at the Royal Institute of Technology (KTH), Sweden, by the Swedish Chemicals Agency (KemI). The task was to describe the solubility and availability of a number of cadmium-containing substances, used in paints.

The responsibility for the report contents rests entirely with the author. The views here shall not necessarily be taken to reflect the official opinion of Swedish Chemicals Agency.

Contents

Abstract

A review focusing on the thermodynamic stability and dissolution rates of Cd-containing sulphides and selenides from paints is presented. In the surface horizon of Swedish agricultural soils, cadmium sulphide, CdS(s), and cadmium selenide, CdSe(s), are shown to be thermodynamically unstable. The presence of electron acceptors such as oxygen gas and iron(III) will lead to gradual dissolution of these compounds. The dissolution rate of Cd-containing sulphides is dependent on the amount of crystalline zinc sulphide in contact with the cadmium, as zinc will be dissolved preferentially from a mixed cadmium zinc sulphide mineral. In the absence of crystalline zinc sulphide, Cd will be dissolved completely after 1-3 years. The presence of crystalline zinc sulphide can extend the life span of CdS to 1-2 decades; however, sewage sludge contains mostly amorphous ZnS that will dissolve more quickly. In conclusion, if a time frame of several decades is applied, it is very likely that Cd from Cd pigments has a similar solubility and bioavailability as an easily soluble Cd salt such as cadmium chloride.

1. Objective

This review has been carried out for the Swedish Chemicals Agency. The task was to describe the solubility and availability of a number of cadmium-containing substances used in paints. These substances include the following:

CAS number	**Name**
1306-23-6	Cadmium sulphide
8048-07-05	Cadmium zinc sulphide yellow
12656-57-4	Cadmium sulphoselenide orange
58339-34-7	Cadmium sulphoselenide red
12442-27-2	Cadmium zinc sulphide
12626-36-7	Cadmium sulphoselenide

The objective of this report is to supply information on the solubility of these cadmium compounds and compare to a reference compound with higher solubility, such as cadmium chloride. From this an assessment may be made on the availability for plant uptake in a scenario in which these compounds end up in a sewage sludge that is then applied to agricultural land. The time frame considered is 50 years (after application of the sludge).

The review does not cover the processes determining the overall solubility and bioavailability of cadmium ions in soils, as these have already been studied extensively in connection with the EU risk assessment for cadmium (European Chemicals Bureau, 2007)

2. Introduction

Cadmium-containing sulphides and selenides give rise to a range of different clear colours. Cadmium sulphide pigments are synthesized using either a wet or a dry process using cadmium oxide or cadmium metal as a starting material. From the 1840s, cadmium pigments have been commercially available and quickly became popular among the 19th century artists. The bright yellow colour, its wide applicability and suitability for mass production were three reasons. In addition, CdS was thought to be highly stable in oil paint and water colours (Curtis and Wright, 1954; van der Snickt et al., 2009), which was an advantage over other available alternatives such as chrome yellow ($PbCrO_4$). The CdS pigments also have excellent heat stability, and can withstand temperatures higher than 3 000^{o}C (Cepriá et al., 2005). Artists who made frequent use of the yellow CdS pigments include Claude Monet, Vincent van Gogh, Juan Miró, and Pablo Picasso.

By partial substitution of cadmium in the crystal lattice of CdS by selenium, a range of additional clear colours can be obtained, such as orange, red and maroon. Further, by substituting part of the Cd ions for Zn, intermediate colors in the lemon-yellow to maroon range of cadmium colors can be obtained (Cepriá et al., 2005). During the 20th century, the use of Cd pigments was expanded to include colouring of plastics etc.

Today, the use of Cd pigments in Europe is decreasing, and the reasons for their decline may include the following:

- Due to increased environmental awareness, a number of restrictions limit the use of Cd pigments in the European Union. For example, the use of Cd in certain plastics (except for in recycled PVC) has been banned (European Union, 2012).

- The long-term stability of Cd pigments is now known to be lower than was originally believed, especially in cases when the paint is exposed to light and humidity. Paintings from the 19th century show clear signs of fading of the yellow CdS pigment colours (Leone et al., 2005; van der Snickt et al., 2009). These authors have convincingly demonstrated that the reason is that CdS with time is dissolved because of sulphide oxidation. Fading, however, is not unique for CdS; other frequently used pigments, such as chrome yellow ($PbCrO_4$) also fade with time. In this case the reason is reduction of chromate to chromium(III) (Monico et al., 2011). These findings should have important implications for methods of conservation of a long list of famous paintings by, e.g., van Gogh and Picasso.

In the following, a review is made on the general chemical properties of cadmium sulphide and selenide. Of these, cadmium sulphide is the one most well studied; a number of observations can be made also from studies of zinc sulphide. All these compounds are similar to one another in many respects, as cadmium and zinc, as well as sulphur and selenium, are similar to one another and readily substitutes for one another in the pigments.

3. Cadmium sulphide, CdS(s) – Equilibrium chemistry

3.1. Solubility of cadmium sulphide

Cadmium sulphides can exist as different forms. In nature, pure CdS minerals are relatively rare. Greenockite and hawleyite are the two recognized natural CdS minerals. Much more commonly, CdS occurs as a minor constituent of other sulphide minerals such as sphalerite, ZnS(s). CdS(s) can also be synthesized on the laboratory. Freshly precipitated CdS(s) has a low degree of structural order, and it also has a solubility that is about two magnitudes higher than that of crystalline forms, such as the mineral greenockite (Daskalakis and Helz, 1992). In general, the dissolution reaction of CdS(s) can be written as follows:

$$CdS(s) + H^+ \leftrightarrow Cd^{2+} + HS^- \qquad \log {}^*K_s \qquad (1)$$

In equation 1, the solubility constant $^*K_s$ is defined according to $^*K_s = \{HS^-\}\{Cd^{2+}\}/\{H^+\}$. The log $^*K_s$ value of for crystalline CdS minerals is in the range of -14 to -14.5 (*e.g.* Daskalakis and Helz, 1992; Gustafsson, 2012). It should be noted that equation 1 does not provide the full picture to the solubility of Cd^{2+} in sulphide-containing systems, as Cd^{2+}, once dissolved, will also form a number of soluble complexes with HS^-. In any case, the solubility of CdS(s) is low in systems where both cadmium and sulphide ions occur. However, in the presence of electron acceptors such as O_2(g) and Fe(III), CdS(s) becomes less stable due to the oxidation of sulphide (HS^-) ions to sulphate (SO_4^{2-}) ions.

The *redox potential* is often used to indicate the electrochemical conditions of different environments. In other words, the redox potential indicates the availability of electron acceptors, which are present in soils and waters. A high redox potential will cause the oxidation of sulphide into sulphate, and thereby lead to dissolution of CdS.

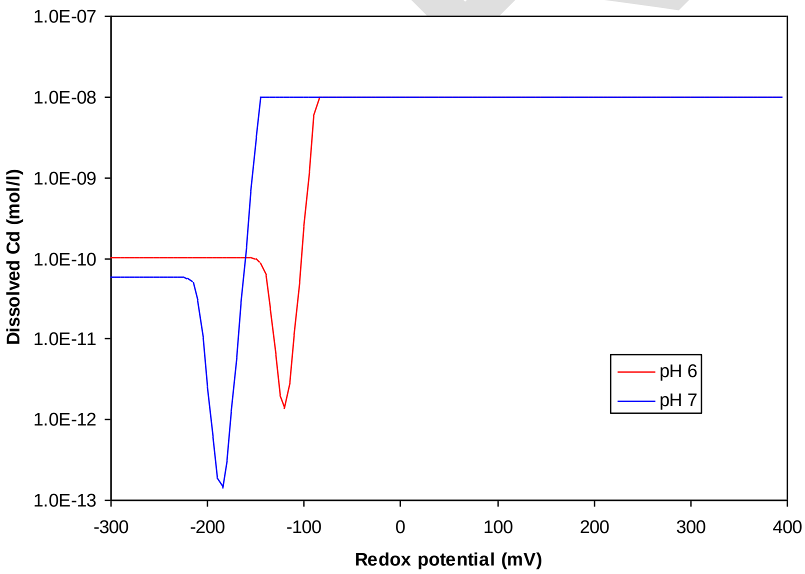


Fig. 1. Solubility of Cd in equilibrium with greenockite, CdS(s) as a function of redox potential, at two different pH values, 6 and 7. Conditions: 0.001 M NaCl, 20°C, dissolved S = 0.1 mM.

With a geochemical model such as Visual MINTEQ, it is possible to relate the solubility of CdS(s) to the redox potential. In the simulation shown in Fig. 1, the solubility of 1×10^{-8} mol/l CdS(s) (about 1.45 µg/l) is shown as a function of the redox potential at environmentally realistic conditions. Two pH values, 6 and 7 have been chosen as they represent typical conditions in the surface horizon of agricultural soils. At low redox potentials, Cd solubility will be small. A minimum solubility occurs between -200 and -100 mV. This can be explained on the basis of the stability of dissolved Cd-HS complexes, which dominate Cd speciation at low redox potential, but these begin to dissolve at higher redox potential. At between -100 to -150 mV, the lines flatten at 1×10^{-8} mol/l Cd; this is because under these conditions, CdS(s) is completely dissolved.

3.2. Stability of CdS in the environment

Because the redox potential in the surface horizon of agricultural soils is a lot higher, between 200 and 500 mV (Nilsson, 1988; Macsik, 2000), CdS(s) in paints is thermodynamically unstable in agricultural soils. However, due to its crystal structure, it is very likely that dissolution is not instant, but controlled by kinetically constrained dissolution ("weathering"), c.f. section 5 below.

The importance of the redox conditions for CdS(s) solubility is important to consider when interpreting the results from leaching tests that are reported, e.g. in the ECHA database. As indicated above, when dissolving pure CdS(s) in water in a closed batch system, the availability of electron acceptors is very small (the presence of sulphide will buffer the redox potential to a low value), leading to very low values of dissolved Cd as CdS(s) is relatively stable under these conditions. When purging with O_2(g), however, the availability of electron acceptors increases drastically, leading to an increased redox potential and hence to sulphide oxidation. Under these conditions, CdS(s) will be converted gradually to $CdSO_4$(s), which is very soluble.

In other words, when geochemical modeling is used to predict leaching of Cd from pigments (using codes such as, e.g., Visual MINTEQ or HSC 7.0), it is important to include the effect of the redox potential in the environment to allow sulphide oxidation; otherwise the results obtained will be irrelevant for the real situation in the field.

4. Cadmium selenide, CdSe(s) – Equilibrium chemistry

The general properties of cadmium selenide are expected to be rather similar to cadmium sulphide because of the similar properties of sulphur(-II) and selenium(-II). However, the solubility of cadmium selenide is quite low, much lower than that of cadmium sulphide. For the dissolution reaction:

$$CdSe(s) + H^{+} \leftrightarrow Cd^{2+} + HSe^{-} \qquad \log {}^{*}K_s \qquad (2)$$

I equation 2, the solubility constant log $^{*}K_s$ (see text under equation 1 for definition) is equal to -20.2 at 25°C, according to the Visual MINTEQ thermodynamic database (Gustafsson, 2012). Therefore in the absence of electron acceptors, under reducing conditions, cadmium selenide will be stable and the release of cadmium ions very small.

However, similarly to the case for cadmium sulphide, the stability of cadmium selenide is very sensitive to the redox potential, as selenide is oxidized to higher oxidation states. In the case of selenium, there are several oxidation states that may be formed at higher redox potential, i.e. Se(0), Se(IV) and Se(VI). Fig. 2 shows the result from a geochemical model simulation of the Se solubility in a similar way as Fig. 1, i.e. using an initial concentration 10^{-8} mol/l cadmium selenide. The value used for dissolved Se in the simulation, 5×10^{-10} M, is representative of Swedish waters (Örnemark and Olin, 1995).

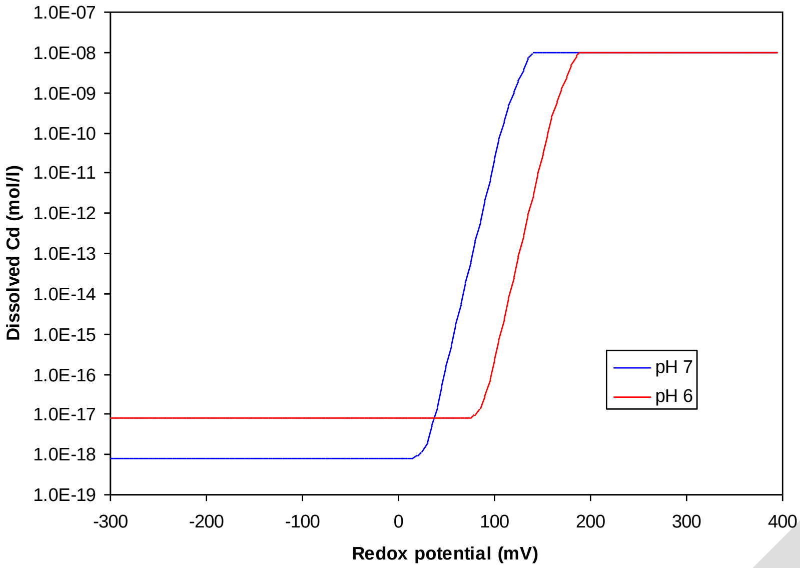


Fig. 2. Solubility of Cd in equilibrium with cadmium selenide, CdSe(s) as a function of redox potential, at two different pH values, 6 and 7. Conditions: 0.001 M NaCl, 20°C, dissolved Se = 5 × 10^{-10} M.

As Fig. 2 shows, cadmium selenide is stable up to a redox potential of around 100 mV. Above about 150 mV, dissolved Cd reaches 1 × 10^{-8} mol/l, which means that all CdSe(s) has dissolved and that cadmium selenide can be considered unstable. This means that cadmium selenide, as well as cadmium sulphide, are expected to be thermodynamically unstable in the A horizon of most agricultural soils.

5. Dissolution kinetics of Cd-containing sulphide (and selenide) minerals

5.1 Summary of literature findings

As shown in preceding sections, cadmium sulphide is expected to be thermodynamically unstable in agricultural soil environments. The release of cadmium ions to the environment and the bioavailability of this cadmium would therefore be dependent on the dissolution rate of the cadmium sulphide supplied to this environment through sewage sludge.

The dissolution of sulphide minerals, if deposited through sludge, will be more or less slow due to a number of factors: (i) the crystallinity and surface area of the minerals; (ii) the diffusion rate of electron acceptors, which for soils are mainly O_2(g) and Fe(III) (see, e.g., Barrett and McBride, 2007); (iii) surface reactions with other dissolved substances in soils, which may either retard or enhance dissolution. There has been relatively little research into factors determining the dissolution rates of Cd-containing sulphides. Some highlights are listed below:

- Pure cadmium sulphide is much more sensitive to oxidative dissolution compared to a zinc sulphide mineral such as sphalerite. Therefore, the dissolution rate of pure CdS may be up to 20 times that of sphalerite (Barrett and McBride, 2007).

- The dissolution rate of Cd (as for Zn) sulphide is pH-dependent, although different samples behave differently (Salmon and Malmström, 2006; Barrett and McBride, 2007). An estimate based on published results is that the dissolution rate of sphalerite will decrease with a factor 5 for a pH increase of 2 units.

- When Cd occurs as mixed ZnCdS, the dissolution rate of Cd is much lower than that of Zn as long as the Zn/Cd ratio is higher than 1 (Barrett and McBride, 2007; Stanton et al., 2008; de Livera et al., 2011). Based on the results obtained by these authors, it can be estimated that the Cd dissolution rate will be a factor 30 to 300 lower than that of Zn as long as there is an excess of Zn in the dissolving sulphide mineral. The reason for the preferential dissolution of Zn is not precisely known, but it is generally thought to be a result of the lower solubility of CdS as compared to that of ZnS (e.g., Barrett and McBride, 2007).

- Short-term toxicity tests carried out for Cd sulphides generally show rather small toxic effects; this is particularly the case for ZnCdS when Zn occurs in excess (National Academies, 2004); the likely reason is the low dissolution rate of Cd in these minerals, as mentioned above.

5.2 Simulation of Cd and Zn dissolution rates

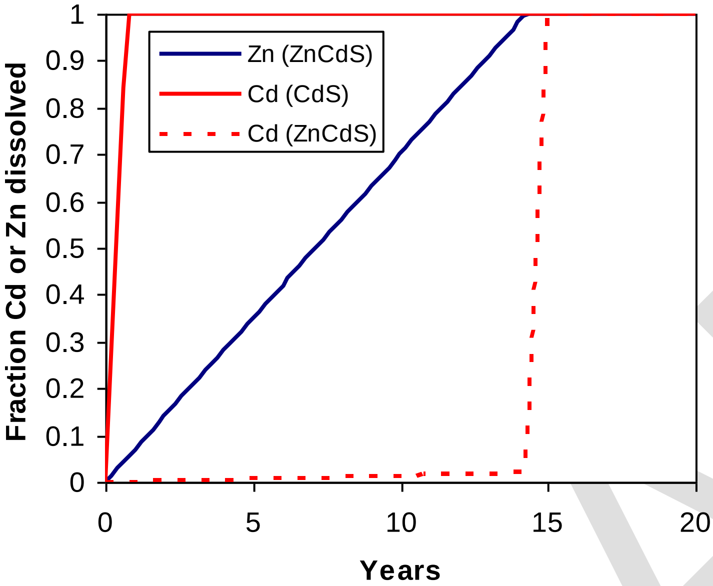


Fig. 3. Dissolution of Cd or Zn (expressed as the fraction of total applied) as a function of time after application, depending on the form of metal added. Assumptions: Specific surface area 3 m^{2}/g, Zn dissolution rate 2.3×10^{-11} mol m^{-2} s^{-1}, for ZnCdS the initial ZnS/CdS ratio was 100, Cd dissolution rate 50 times lower than Zn in ZnCdS when Zn > Cd, otherwise Cd dissolution rate is 20 times higher than Zn.

In Fig. 3 the results from a simulation is presented that shows the dissolution of Cd and Zn sulphides as a function of time, assuming that these are added to a surface horizon of an agricultural soil with a pH value of 6. It should be stated that the dissolution rates are based on the estimates of sphalerite weathering rates provided in the above references, but nevertheless they are uncertain with maybe a factor 3-10. It is, however, encouraging that the simulation produced Zn dissolution rates similar to those obtained in field trials with sphalerite added to soils (Voegelin et al., 2011). In the latter study, between 26 and 75 % of the added ZnS had been dissolved during four years (compared to 25 % in Fig. 3).

Therefore Fig. 3 may serve as an indication of the time scales involved for the dissolution of Cd and Zn sulphides once added to an agricultural soil environment. According to the simulation, cadmium when added as pure CdS will dissolve completely within only one year. The cadmium dissolved will then add to the reactive Cd pool in soils and behave in an equivalent manner as if cadmium chloride had been added to the soil.

When, however, there is an excess of zinc sulphide (as compared to cadmium sulphide), in this case a factor 100, the dissolution of Cd progresses much more slowly, and after 13 years still only 2 % is dissolved. However, once ZnS has been dissolved completely, the remaining Cd will dissolve as for CdS, leading to quick dissolution of the remainder. In other words, applied Cd may have a rather low short- and medium-term availability if it is supplied together with an excess amount of sphalerite.

It should be noted that the simulation in Fig. 3 uses the assumption that the surface area is around 3 m^2/g, as was the case for spharelite fragments with a particle size of 10 µm (Stanton et al., 2008). Usually, cadmium pigments have smaller particle sizes, in the range of 0.1 to 3.5 µm (USEPA, 1988), which most likely means a higher surface area and quicker dissolution. Therefore it is possible that the time scales shown in Fig. 3 is longer than the real ones.

5.3. Availability of ZnS in sewage sludge components

The zinc sulphide needed for cadmium stabilization may originate either from the pigments themselves, or from other sludge components. However, even though zinc sulphide is one of the most common zinc species in fresh sewage sludge (Donner et al., 2011), the zinc sulphide for most part will dissolve already during the initial drying and stockpiling (which lasted from 6 to 24 months). The reason is probably that most of the ZnS in sludge is non-crystalline; this ZnS will dissolve faster than the crystalline sphalerite used in the simulation of Fig. 3. In conclusion, long-term stabilization of Cd in applied sludge is possible only if there is an excess of *crystalline* ZnS components. However, the amount of crystalline ZnS in sewage sludge applied to agricultural land is not known.

Apul et al. (2010) reported that less Cd was dissolved from fresh sewage sludge than expected from geochemical modelling – this may be consistent with Cd binding in a ZnS component in the sludge. However, earlier studies focusing on Cd solubility in soils subjected to long-term applications of sewage sludge did not find evidence for a drastically reduced Cd solubility because of long-term sludge application (and possible binding to a ZnS component) (Bergkvist et al., 2003; Bergkvist et al., 2005). Indeed, the Cd sorption affinity did increase somewhat after sludge application, but this was attributed to the increased organic matter content causing increased Cd-organic matter complexation (Bergkvist et al., 2005); in fact, the increased Cd sorption was smaller than would have been expected as a result of the increase of organic matter only. This shows that ZnS, if anything of it remained in the sludge-amended soil, did probably not affect the behaviour of Cd in the soils. This in turn may be due either to (i) complete, or nearly complete, dissolution of the ZnS component within just a few years in agreement with Donner et al. (2011), and/or to (ii) heterogeneous distribution of the ZnS component, which may affect Cd only in certain pores, but not in the bulk material.

6. Implications for the soil environment

As shown above, cadmium sulphides and selenides in pigments are thermodynamically unstable in the surface horizon of agricultural soils. The presence of O_2(g) and Fe(III) will lead to the gradual dissolution of these compounds in the soil environment. Sulphide-bound Cd can persist in soils over a time scale of years only if there is an excess of sulphide-bound Zn. Therefore the dissolution rate of Cd is crucially dependent on the amount of crystalline ZnS that may be supplied through the sludge. However, available evidence show that most of the ZnS supplied through sludge is non-crystalline in nature and will dissolve completely within just a few years.

The conclusions above apply for sulphide-bound Cd, for which there are direct evidence. Much less is known about the dissolution rate of selenide-bound Cd, but most likely the general trends are the same, as the compounds are rather similar.

Taken together, most evidence assembled suggest that Cd pigments will probably dissolve completely in soils over a time scale of years to decades. Therefore the long-term solubility and availability of Cd is likely to be the same regardless if the Cd is supplied in sulphide- or selenide-bound forms (as in pigments) or in easily soluble forms such as cadmium chloride.

Theoretically it seems that if a sufficient amount of crystalline ZnS is supplied to a soil on a regular basis, and mixed thoroughly with the soil material, dissolution of Cd could be substantially slower (in the order of centuries). However, the available literature evidence does not indicate whether this could be a realistic Cd stabilization method; it seems clear, however, from the studies of Bergkvist et al. (2003; 2005) that this does not happen in soils subjected to long-term applications of sewage sludge.

Because the Cd pigments will, most likely, dissolve rapidly in soils, the long-term behaviour of Cd dissolved from the pigments will be determined by retention mechanisms in the soil. Today the factors responsible for Cd solubility and bioavailability in soils are reasonably well understood. We know that organic matter is usually the most important sorbent for Cd, and the binding of Cd to organic matter is determined to a large extent by pH (dissolution of Cd increases with decreasing pH), and also by competition from Al and to a certain extent Ca. Soil chemical models have been developed that are able to successfully predict these processes (Gustafsson et al., 2003; Bonten et al., 2008; Khai et al., 2008).

7. Conclusions

- Cadmium-containing sulphides and selenides in pigments are not thermodynamically stable under the conditions that prevail in the surface horizons of Swedish agricultural soils.

- Under aerated conditions, the dissolution rate of pure CdS is comparably high. In a soil environment containing sufficient electron acceptors such as O_2(g) and Fe(III), pure CdS will be dissolved completely within one year.

- When sulphide-bound Cd is supplied to soils together with an excess amount of sulphide-bound Zn, the dissolution rate of Cd will slow down to low levels, as long as sulphide-bound Zn persists in the soil.

- Crystalline ZnS (such as sphalerite) can persist in soils for a time period of 1 to 2 decades, making CdS dissolution slow during this period. However, most evidence suggest that most of the ZnS added in sewage sludge is amorphous, and will dissolve completely within just a few years.

- Soil samples subjected to long-term applications of sewage sludge do not show a reduced Cd solubility because of the additions of ZnS through sludge.

- Based on the evidence assembled, it is concluded that Cd supplied in the form of sulphides or selenides should be considered fully available (similar to easily soluble cadmium chloride) when a time scale of 50 years is applied.

8. References

Apul, D.S., Díaz, M., Gustafsson, J.P., Hundal, L.S. 2010. Geochemical modeling of trace element release from biosolids. *Environmental Engineering Science* **27,** 743-755.

Barrett, K.A., McBride, M.B. 2007. Dissolution of zinc-cadmium sulfide solid solutions in aerated aqueous suspension. *Soil Science Society of America Journal* **71,** 322-328.

Bergkvist, P., Berggren, D., Jarvis, N. 2005. Cadmium solubility and sorption in a long-term sludge-amended arable soil. *Journal of Environmental Quality* **34,** 1530-1538.

Bergkvist, P., Jarvis, N., Berggren, D., Carlgren, K. 2003. Long-term effects of sewage sludge applications, soil properties, cadmium availability and distribution in arable soil. *Agriculture Ecosystems and Environment* **97,** 167-179.

Bonten, L.T.C., Groenenberg, J.E., Weng, L., van Riemsdijk, W.H. 2008. Use of speciation and complexation models to estimate heavy metal sorption in soils. *Geoderma* **146,** 303-310.

Cepriá, G., García-Gareta, E., Pérez-Arantegui, J. 2005. Cadmium Yellow Detection and Quantification by Voltammetry of Immobilized Microparticles. *Electroanalysis* **2005**, 17, No. 12.

Curtis, P.J., Wright, R.B. 1954. Cadmium pigments. *Journal of the Oil and Colour Chemists' Association* **37,** 26-43.

Daskalakis, K.D., Helz, G.R. 1992, Solubility of CdS (greenockite) in sulfidic waters at 25^{o}C. *Environmental Science and Technology* **26,** 2462-2466.

De Livera, J., McLaughlin, M.J., Beak, D., Hettiarachchi, G.M., Kirby, J. 2011. Release of dissolved cadmium and sulfur nanoparticles from oxidizing sulfide minerals. ***Soil Science Society of America Journal*** 75, 842-854.

Donner, E., Howard, D.L., de Jonge, M.D., Paterson, D., Cheah, M.H., Naidu, R., Lombi, E. 2011. X-ray absorption and micro X-ray fluorescence spectroscopy investigation of copper and zinc speciation in biosolids. *Environmental Science and Technology* **45,** 7249-7257.

European Chemicals Bureau 2007. Cadmium oxide and cadmium metal. Part I. Environment. European Risk Assessment Report. European Communities, Luxembourg.

Gustafsson, J.P. 2012. Visual MINTEQ ver. 3.0. Available at: http://www2.lwr.kth.se/English/OurSoftWare/Vminteq/index.html.

Gustafsson, J.P., Pechova, P., Berggren, D. 2003. Modeling metal binding to soils: the role of organic matter. *Environmental Science and Technology* **37,** 2767-2774.

Khai, N.M., Öborn, I., Hillier, S., Gustafsson, J.P. 2008. Modeling of metal binding in tropical Fluvisols and Acrisols treated with biosolids and wastewater. *Chemosphere* **70,** 1338-1346.

Leone, B., Burnstock, A., Jones, C., Hallebeek, P., Boon, J., Keune, K. 2005. The deterioration of cadmium sulphide yellow artists' pigments. In *Preprints of the 14th Triennial Meeting of ICOM Ineternational Committee for Conservation* Vol 2., pp. 803-813.

Macsik, J. 2000. Försurningspotential I sulfidjord – Metodutveckling/förstudie. Luleå Tekniska Universitet. Web: http://www.botniabanan.se/vitbokmiljo/dokument/5%206%203%20F%C3%B6rsurningspotential%20i%20sulfidjord%20-%20metodutveckling%20och%20f%C3%B6rstudie.pdf

Monico, L., van der Snickt, G., Janssens, K., De Nolf, W., Milani, C., Verbeeck, J., Tian, H., Tan, H., Dik, J., Radepont, M., Cotte, M. 2011. Degradation process of lead chromate in paintings by Vincent van Gogh studied by means of synchrotron X-ray spectromicroscopy and related methods. 1. Artificially aged model samples. *Analytical Chemistry* **83,** 1214-1223.

National Academies 2004. Health effects of Project Shad chemical agent: zinc cadmium sulfide. The Center for Research Information Inc., Silver Spring, MD, USA.

Nilsson, Å. 1988. Syrediffusion och redoxpotential vid olika markvattenhalter I styv lera. Examensarbete, Lantbrukets Hydroteknik, SLU. Web: http://pub.epsilon.slu.se/5127/1/nilsson_a_100915.pdf

Örnemark, U., Olin, Å. 1994. Determination of dissolved selenium(VI) in freshwater. *Talanta* **41**, 1675-1681.

Salmon, S.U., Malmström, M.E. 2006. Quantification of mineral dissolution rates and applicability of rate laws: Laboratory studies of mill tailings. *Applied Geochemistry* **21,** 269-288.

Stanton, M.R., Gemery-Hill, P.A., Shanks, W.C., Taylor, C.D. 2008. Rates of zinc and trace metal release from dissolving sphalerite at pH 2.0-4.0. *Applied Geochemistry* **23,** 136-147.

U.S. Environmental Protection Agency 1988. Cadmium emissions from pigment and stabilizer manufacturing – Phase I Technical report. EPA 450-3-88-004. US Environmental Protection Agency, Research Triangle Park, NC, USA.

van der Snickt, G., Dik, J., Cotte, M., Janssens, K., Jaroszewicz, J., de Nolf, W., Groenewegen, J., van der Loeff, L. 2009. Characterisation of a degraded cadmium yellow (CdS) pigment in an oil painting by means of synchrotron radiation based X-ray techniques. *Analytical Chemistry* **81,** 2600-2610.

Voegelin, A., Jacquat, O., Pfister, S., Barmettler, K., Scheinost, A.C., Kretzschmar, R. 2011. Time-dependent changes of zinc speciation in four soils contaminated with zincite or sphalerite. *Environmental Science and Technology* **45, 2**55-261.

Appendix 4 Existing legal requirements

Table A4:1 List of EU regulations on use and emissions of cadmium

Legislative act	Requirement
REACH Regulation (1907/2006/EU)	***Annex XVII, entry 23****: In summary,* cadmium and its compounds shall not be used in/for: - mixtures and articles produced from a number of designated plastic materials - paints (applies for tariff codes not including artists' paints) - cadmium plating in designated sectors/applications - brazing fillers - jewellery The detailed wording of entry 23 can be found in Annex x. ***Annex XVII, entry 29*****:** Substances classified as carcinogen category 1A or 1B, may not be placed on the market and made available to consumers, neither as pure substance or in mixtures, at higher concentration than classification limit. This affects cadmium compounds listed in Appendix 2 to Annex XVII. By way of derogation artists' paints covered by Directive 1999/45/EC are exempted from the prohibition.
Regulation (EC) No 1223/2009 on cosmetic products	Cadmium and its compounds are included in the list (Annex II) of prohibited substances in cosmetic products.
Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)	Electric and electronic equipment must not contain cadmium at levels 0,01 % by weight of each homogenous material in the equipment. Several exemptions are listed in Annex III and IV to the Directive.
Directive 2000/53/EC on end-of life vehicles (ELV Directive)	Materials and components of vehicles must not contain more than 0,01 % cadmium by

	weight of each homogeneous material unless listed as exempted in Annex II.
Legislative act	**Requirement**
Directive 2009/48/EC about the safety of toys (Toys Directive) Directive 2012/7/EC (Adopted January 2013)	Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys. This affects cadmium compounds. In Annex II the following migration limits for cadmium, in toys or components of toys are listed - 1,3 mg/kg in dry, brittle, powder-like or pliable toy material - 0,3 mg/kg I liquid or sticky material - 17 mg/kg in scraped-off toy material
Directive 94/62/EC on packaging and packaging waste	The concentration level of cadmium present in packaging or packaging components shall not exceed 100 ppm by weight.
Directive 2006/66 on batteries and accumulators and waste batteries and accumulators (Battery Directive)	Portable batteries or accumulators, including those incorporated into appliances, that contain more than 0,002 % of cadmium by weight is prohibited to place on the market. Batteries, accumulators and button cells containing more than 0,002 % of cadmium shall be marked with the chemical symbol for the metal concerned: Cd. Recycling requirements with the target of 75 % by average applies.
Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive, WFD)	Cadmium is included in the list of priority of hazardous substances. Emission limit values and environmental quality standards are established referring to the Cadmium Discharges Directive (83/513/EEC)
Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community	Member States shall are required to the appropriate steps to eliminate pollution of the waters referred to in Article 1 by dangerous substances in the families and groups of substances in List I of Annex I where cadmium is listed.

Legislative act	**Requirement**
Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.	The limit value for cadmium concentration in sludge for use in agricultural is 20 – 40 mg/kg dw The limit value for amounts of cadmium added annually to agricultural land based on 10-years average is 0,15 kg/ha/year The limit value for cadmium in soil is 1-3 mg/kg of dry matter in a representative sample
Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)	Sets an average emission limit value of 0,05 (mg/Nm3) for cadmium and its compounds, expressed as cadmium, over a sampling period of a minimum of30 minutes and a maximum of 8 hours. The Emission limit value for cadmium and its compounds, expressed as cadmium, for discharges of waste water from the cleaning of waste gases is 0,05 mg/L.
Regulation (EC) No 2003/2003 relating to fertilisers	Contains a method for determination of cadmium content in fertilisers and liming materials

Table A4:2 List of EU regulations on cadmium in food or materials in contact with food

Legislative act	Requirement
Commission Regulation (1881/2006) setting maximum levels for certain contaminants in foodstuffs	Cadmium in 16 categories of food must not exceed specific limits ranging from 0,05 mg/kg wet weight to 3,0 mg/kg wet weight.
Directive 98/83/EC on the quality of water intended for human consumption	Cadmium content in water for human consumption must not exceed 5,0 µg/L.
Directive 88/388/EEC on flavourings for use in foodstuffs and to source materials for their production	Cadmium content in flavourings must not exceed 1 mg/kg.
Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs	Migration limits for cadmium are: -0,07 mg/dm2 for articles that cannot be filled or which can be filled but not deep (25 mm) - 0,3 mg/l for all other articles which can be filled -0,1 mg/l for cooking ware; packaging and storage vessels having a capacity of more than three litres

Table A4:3 List of regulations addressing the working environment

Legislative act	Requirement
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC	Currently there is no established occupational exposure limit value for cadmium. The Scientific Committee on Occupational Exposure Limits (SCOEL) has published the following recommended levels for cadmium and its inorganic compounds (SCOEL/SUM/!#&, February 2010): - Biological Limit Value (BLV): 2 µg cadmium/creatinine - Occupational Exposure Limit (OEL): 0,004 mg CD/m^3

Table A4:4 International conventions

Convention	Requirement
UN Convention on Long–Range Transboundary Air Pollution on heavy metals The 1998 Aarhus Protocol on Heavy Metals	Parties will have to reduce their emissions for cadmium below their levels in 1990 (or an alternative year between 1985 and 1995). The protocol aims to cut emissions from industrial sources (iron and steel industry, non-ferrous metal industry) combustion processes (power generation, road transport) and waste incineration. It lays down stringent limit values for emissions from stationary sources and suggests best available techniques (BAT) for these sources.

Table A4:5 Regulations in countries outside EU

Country	Restriction
USA California	In December 2012 the Environmental Protection (EPA) published a final rule that requires manufactures and importers of articles containing cadmium and cadmium compounds to provide EPA with unpublished health or safety data (Toxic Substances Control Act (TSCA), section 8(d) Paints and surface coatings on children´s jewelry must not contain more than 75 mg/kg of cadmium based on the weight of the dried paint film (Consumer Product Safety Improvement Act) Children's jewelry that is manufactured, sold, or offered for sale and transported within California shall not have more than 0.03% (300 ppm) cadmium by weight. Cadmium restrictions apply to any children's jewelry component or material Health and Safety Code section 25214.2)
Canada	The limit values for leachable cadmium in glazed ceramics and glass food wares are 0,25 - 0,50 mg/L depending of the size and shape of the product. *(Glazed Ceramics and Glassware Regulations* (GCGR)

L1321046

267IFK27EGC

Appendix 5 Analysis Report

Project: Kadmium i konstnärsfärg

Kemikalieinspektionen: Jenny Ivarsson

Box 2, 172 13 Sundbyberg

Analysis: I2-SA

Your ID	**PR 108, Red Deep Cobra, Royal Talens Oil**				
LabID	U10888081				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**150000**	mg/kg	1	S	SVS

Your ID	**PR 108, Red Windsor & Newton Oil**				
LabID	U10888082				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**343000**	mg/kg	1	S	SVS

Your ID	**PO 20/PY35, Orange Rembrandt,RoyalTalens Oil**				
LabID	U10888083				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**517000**	mg/kg	1	S	SVS

Your ID	**PO 20/PY35, Yellow deep Rembrandt,RoyalTalens Oil**				
LabID	U10888084				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**398000**	mg/kg	1	S	SVS

Your ID	**PY35, Lemon Windsor & Newton Oil**				
LabID	U10888085				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**334000**	mg/kg	1	S	SVS

Your ID	**PY35, Lemon. Windsor & Newton Oil**				
LabID	U10888086				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**404000**	mg/kg	1	S	SVS

ALS Scandinavia AB
Aurorum 10
977 75 Luleå
Sweden

Web: www.alsglobal.se
Email: info.lu@alsglobal.com
Tel: + 46 920 28 9900
Fax: + 46 920 28 9940

The document is approved and digitally signed by

L1321046

267IFK27EGC

Your ID	**PR 108, Red Medium** **Liquitex, Acrylic**				
LabID	U10888087				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**169000**	mg/kg	1	S	SVS

Your ID	**PO 20, Orange** **Windsor & Newton, Acrylic**				
LabID	U10888088				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**55700**	mg/kg	1	S	SVS

Your ID	**PO 20, Orange.** **Windsor & Newton, Acrylic**				
LabID	U10888089				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**90700**	mg/kg	1	S	SVS

Your ID	**PY 35/PO 20, Yellow Mediu** **Windsor & Newton, Acrylic**				
LabID	U10888090				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**101000**	mg/kg	1	S	SVS

Your ID	**PY 35, Yellow Pale** **Cryla Artist's, Acrylic**				
LabID	U10888091				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**139000**	mg/kg	1	S	SVS

Your ID	**PR 108, Scarlet** **Windsor & Newton, Water**				
LabID	U10888092				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**402000**	mg/kg	1	S	SVS

Your ID	**PR 108, Scarlet.** **Windsor & Newton, Water**				
LabID	U10888093				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**393000**	mg/kg	1	S	SVS

L1321046

267IFK27EGC

Your ID	**PR 108, Red Deep Windsor & Newton, Water**				
LabID	U10888094				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**280000**	mg/kg	1	S	SVS

Your ID	**PY 35/PR 108, Orange Windsor & Newton, Water**				
LabID	U10888095				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**448000**	mg/kg	1	S	SVS

Your ID	**PY 35/PO 20, Yellow Windsor & Newton, Water**				
LabID	U10888096				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**289000**	mg/kg	1	S	SVS

Your ID	**PY 35/PR 108, Yellow Deep Windsor & Newton, Water**				
LabID	U10888097				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**373000**	mg/kg	1	S	SVS

Your ID	**PY 35, Lemon Windsor & Newton, Water**				
LabID	U10888098				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**326000**	mg/kg	1	S	SVS

Your ID	**PY 35, Lemon Windsor & Newton, Gouache**				
LabID	U10888099				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**134000**	mg/kg	1	S	SVS

Your ID	**PY 35, Lemon. Windsor & Newton, Gouache**				
LabID	U10888100				
Analysis	**Results**	**Unit**	**Method**	**Issuer**	**Sign**
Cd*	**156000**	mg/kg	1	S	SVS

L1321046

267IFK27EGC

	Method specification
1	1 gram sample was leached with 20 ml 7M HNO_3. The leaching was carried out in autoclave at 200 kPa (120°C) in 30 minutes. The analytical sample was diluted to 100 ml using high purity water prior to analysis, according to method DS 259. For determination of Ag, a sub sample was stabilised with HCl prior to analysis. Analyses were carried out according to USEPA Methods 200.7 (ICP-AES) and 200.8 (ICP-SFMS) respectively.

	Approver
SVS	Svetlana Senioukh

	Issuer[1]
S	ICP-SFMS

* indicates unaccredited analysis.

[1] The technical unit within ALS Scandinavia where the analysis was carried out, alternatively the subcontractor for the analysis.

Appendix 6 EMEP Cadmium deposition data (Aas and Breivik 2011)

Country	Monitoring site	Cadmium/Precipitaion	Year	**Cd (µg/m2)**, precipitation (mm)	Cd (µg/m2)
Belgium	BE0014R	cadmium	2011	**82,169**	**82,169**
	BE0014R	precipitation_amount	2011	691,48	**20,625**
Czech Republic	CZ0001R	cadmium	2011	**20,625**	**33,096**
	CZ0001R	precipitation_amount	2011	617,536	**10,953**
	CZ0003R	cadmium	2011	**33,096**	**13,81**
	CZ0003R	precipitation_amount	2011	642,25	**22,788**
Germany	DE0001R	cadmium	2011	**10,953**	**19,027**
	DE0001R	precipitation_amount	2011	693,648	**23,228**
	DE0002R	cadmium	2011	**13,81**	**55,389**
	DE0002R	precipitation_amount	2011	595,067	**26,324**
	DE0003R	cadmium	2011	**22,788**	**41,519**
	DE0003R	precipitation_amount	2011	1544,362	**34,447**
	DE0007R	cadmium	2011	**19,027**	**4,88**
	DE0007R	precipitation_amount	2011	739,7	**80,827**
	DE0008R	cadmium	2011	**23,228**	**44,494**
	DE0008R	precipitation_amount	2011	1108,743	**74,374**
Denmark	DK0005R	cadmium	2011	**55,389**	**26,653**
	DK0005R	precipitation_amount	2011	617,89	**24,872**
	DK0008R	cadmium	2011	**26,324**	**10,816**
	DK0008R	precipitation_amount	2011	559,842	**10,652**
	DK0022R	cadmium	2011	**41,519**	**18,784**
	DK0022R	precipitation_amount	2011	806,046	**25,788**
	DK0031R	cadmium	2011	**34,447**	**21,03**
	DK0031R	precipitation_amount	2011	821,937	**20,119**
Estonia	EE0009R	cadmium	2011	**4,88**	**11,311**
	EE0009R	precipitation_amount	2011	675,454	**15,893**
	EE0011R	cadmium	2011	**80,827**	**7,254**
	EE0011R	precipitation_amount	2011	761,434	**7,361**
Spain	ES0008R	cadmium	2011	**44,494**	**10,093**
	ES0008R	precipitation_amount	2011	445	**10,284**
	ES0009R	cadmium	2011	**74,374**	**14,598**
	ES0009R	precipitation_amount	2011	460	**11,76**
Finland	FI0008R	cadmium	2011	**26,653**	**28,453**
	FI0008R	precipitation_amount	2011	464,376	**120,712**
	FI0017R	cadmium	2011	**24,872**	**4,644**
	FI0017R	precipitation_amount	2011	721,773	**15,367**

	FI0022R	cadmium	2011	**10,816**		**38,936**
	FI0022R	precipitation_amount	2011	528,932		**14,029**
	FI0036R	cadmium	2011	**10,652**		**15,635**
	FI0036R	precipitation_amount	2011	606,606		**43,429**
	FI0053R	cadmium	2011	**18,784**		**18,755**
	FI0053R	precipitation_amount	2011	435,002		**29,053**
	FI0092R	cadmium	2011	**25,788**		**22,34**
	FI0092R	precipitation_amount	2011	596,973		**31,159**
	FI0093R	cadmium	2011	**21,03**		**83,114**
	FI0093R	precipitation_amount	2011	635,896		**41,201**
France	FR0009R	cadmium	2011	**20,119**		**49,349**
	FR0009R	precipitation_amount	2011	890,542		**11,315**
	FR0013R	cadmium	2011	**11,311**		**87,771**
	FR0013R	precipitation_amount	2011	568,788		**39,983**
	FR0090R	cadmium	2011	**15,893**		**27,972**
	FR0090R	precipitation_amount	2011	678,575		**75,073**
Great Britain	GB0006R	cadmium	2011	**7,254**		**74,413**
	GB0006R	precipitation_amount	2011	1907,25		**48,25**
	GB0013R	cadmium	2011	**7,361**		**17,544**
	GB0013R	precipitation_amount	2011	644,1	***Mean***	***32,25***
	GB0017R	cadmium	2011	**10,093**	***Median***	***23,23***
	GB0017R	precipitation_amount	2011	383,554		
	GB0036R	cadmium	2011	**10,284**		
	GB0036R	precipitation_amount	2011	476,6		
	GB0048R	cadmium	2011	**14,598**		
	GB0048R	precipitation_amount	2011	10349,756		
	GB0091R	cadmium	2011	**11,76**		
	GB0091R	precipitation_amount	2011	708,3		
Hungury	HU0002R	cadmium	2011	**28,453**		
	HU0002R	precipitation_amount	2011	377,9		
Ireland	IE0001R	cadmium	2011	**120,712**		
	IE0001R	precipitation_amount	2011	1716,484		
Iceland	IS0090R	cadmium	2011	**4,644**		
	IS0090R	precipitation_amount	2011	641,52		
	IS0091R	cadmium	2011	**15,367**		
	IS0091R	precipitation_amount	2011	1423,3		
Latvia	LV0010R	cadmium	2011	**38,936**		
	LV0010R	precipitation_amount	2011	866,457		
Netherlands	NL0009R	cadmium	2011	**14,029**		
	NL0009R	precipitation_amount	2011	709,74		
	NL0091R	cadmium	2011	**15,635**		

	NL0091R	precipitation_amount	2011	785,094
Norway	NO0001R	cadmium	2011	**43,429**
	NO0001R	precipitation_amount	2011	1590,35
	NO0039R	cadmium	2011	**18,755**
	NO0039R	precipitation_amount	2011	1499,427
	NO0056R	cadmium	2011	**29,053**
	NO0056R	precipitation_amount	2011	1032,58
Poland	PL0004R	cadmium	2011	**22,34**
	PL0004R	precipitation_amount	2011	651,561
	PL0005R	cadmium	2011	**31,159**
	PL0005R	precipitation_amount	2011	604,271
Portugal	PT0002R	cadmium	2011	**83,114**
	PT0002R	precipitation_amount	2011	831,14
	PT0004R	cadmium	2011	**41,201**
	PT0004R	precipitation_amount	2011	412,01
Serbia	RS0005R	cadmium	2011	**49,349**
	RS0005R	precipitation_amount	2011	456,5
Sweden	SE0005R	cadmium	2011	**11,315**
	SE0005R	precipitation_amount	2011	492,997
	SE0011R	cadmium	2011	**87,771**
	SE0011R	precipitation_amount	2011	649,4
	SE0014R	cadmium	2011	**39,983**
	SE0014R	precipitation_amount	2011	645,305
Slovenia	SI0008R	cadmium	2011	**27,972**
	SI0008R	precipitation_amount	2011	1057,074
Slovakia	SK0002R	cadmium	2011	**75,073**
	SK0002R	precipitation_amount	2011	764,1
	SK0004R	cadmium	2011	**74,413**
	SK0004R	precipitation_amount	2011	668,1
	SK0006R	cadmium	2011	**48,25**
	SK0006R	precipitation_amount	2011	640,781
	SK0007R	cadmium	2011	**17,544**
	SK0007R	precipitation_amount	2011	399,9

Appendix 7 Summary of classification for the alternative pigments

To make a rough estimation of the risks related to the alternative pigments, data on their classifications was gathered from ECHA´s Classification & Labelling Inventory Database (September 16th 2013) (ECHA 2013b). Classification of cadmium metal (non-pyrophoric) and cadmium oxide (non-pyrophoric), which were evaluated in the "existing programme" (COUNCIL REGULATION (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances) is shown for comparison in Table A7:1, Table A7:2, Table A7:3 and Table A7:4 respectively show the classifications for reported alternative red, yellow and orange pigments. The pigments listed shall not be seen as an exhaustive list of all alternative pigments. The data presented is the classification as notified by a majority of manufacturers and importers. A minority may have notified a more severe classification. A substance that is "not classified" is not a guarantee that the substance has no hazards. "Not classified" may be due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification.

To only compare the classifications for the pigments cadmium sulfoselenide and cadmium zinc sulfide with cadmium free alternatives wouldn´t give the full picture. Due to the low water solubility of cadmium sulfoselenide and cadmium zinc sulfide, these substances are excluded from the general harmonized classification of cadmium compounds not specified elsewhere in annex VI of CLP (Index number 048-001-00-5). However, as mentioned in section B.4 of this report, the cadmium pigments are unstable in the agricultural soil, and within a timeframe of years to several decades cadmium from cadmium pigments has a similar solubility and bioavailability as easily soluble cadmium salts, which are classified for a number of endpoints. See for example cadmium chloride that has the same classification as cadmium and cadmium oxide.

Compared to the classification of cadmium metal, the inherent properties of the cadmium free pigments are less severe. Hazard class and category codes for the alternatives are, in addition to the far most common notification "not classified", Aquatic chronic 4, Skin Sens 1, Skin irrit 2 and Eye irrit 2.

The main justification is that switching to cadmium free compounds results in a phase out of cadmium and thus avoiding the long term effects of the cadmium ion (section B.5 in this report). Since none of the alternatives are cadmium based, they don't contribute to the cadmium pool.

Table A7:1 Classification of cadmium metal and cadmium oxide (Annex VI of Regulation (EC) No 1272/2008, Table 3.1)

Substance name: Cadmium (non-pyrophoric)**,** Cadmium oxide (non-pyrophoric) **CAS-number:** 7440-43-9, 1306-19-0 **EC-number:** 231-152-8, 215-146-2 **Molecular formula:** Cd CdO	**Classification:** Acute Tox. 2* H330 Fatal if inhaled Muta. 2 H341 Suspected of causing genetic defects Carc. 1B H350 May cause cancer Repr. 2 H361fd Suspected of damaging fertility. Suspected of damaging the unborn child STOT RE 1 H372** Causes damage to organs Aquatic Acute 1 H400 Very toxic to aquatic life Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects Harmonized classification

Table A7:2 Summary of classification for reported alternative red pigments (C&L Inventory database, ECHA 2013b)

Colour Index number and name	**CAS-No**	**EC-No**	**Molecular formula**	**Substance name**	**Classification**
C.I. 12120 C.I. Pigment red 3	2425-85-6	219-372-2	$C_{17}H_{13}N_3O_3$	1-(4-methyl-2-nitrophenylazo)-2-naphthol	Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life. Classification according to 93 notifiers. Not classified by 327 notifiers, joint entries.*
C.I. 12085	2814-77-9	220-562-2	$C_{16}H_{10}ClN_3O_3$	1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol	Not classified by 371 notifiers.*

Colour Index number and name	CAS-No	EC-No	Molecular formula	Substance name	Classification
C.I. Pigment red 4					
C.I. Pigment Red 9 C.I. 12460	6410-38-4	229-104-6	C24H17Cl2N3O3	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	Not classified by 32 notifiers.*
C.I. 12370 C.I. Pigment Red 112	6535-46-2	229-440-3	C24H16Cl3N3O2	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life. Classification according to 93 notifiers. Skin Sens.1 H317 May cause an allergic skin reaction, classification according to 70 notifiers, joint entries Not classified by 357 notifiers, joint entries.*
C.I. 71137 C.I. Pigment Red 149	4948-15-6	225-590-9	C40H26N2O4	2,9-bis(3,5-dimethylphenyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life. Classification according to 93 notifiers. Not classified by 298 notifiers, joint entries.*
C.I.	2786-	220-	C26H22N4O4	4-[[4-(aminocarbonyl)phenyl]azo]-N-	Not classified by 538 notifiers, joint

Colour Index number and name	CAS-No	EC-No	Molecular formula	Substance name	Classification
12475 C.I. Pigment Red 170	76-7	509-3		(2-ethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	entries.*
C.I. 12467 C.I. Pigment Red 188	61847-48-1	263-272-1	$C_{33}H_{24}Cl_2N_4O_6$	methyl 4-[[(2,5-dichlorophenyl)amino]carbonyl]-2-[[2-hydroxy-3-[[(2-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]benzoate	Not classified by 107 notifiers, joint entries.*
C.I. Pigment red 254	84632-65-5	401-540-3	$C_{18}H_{10}Cl_2N_2O_2$	3,6-bis(4-chlorophenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Not classified by 165 notifiers, joint entries.*
C.I. Pigment red 255	54660-00-3	402-400-4	$C_{18}H_{12}N_2O_2$	3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Not classified by 143 notifiers, joint entries.*

*"Not classified" may be due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification

Table A7:3 Summary of classification for reported alternative yellow pigments (C&L Inventory database, ECHA 2013b)

Colour Index	CAS-No	EC-No	Molecular formula	Substance name	Classification
C.I. 11680 C.I. Pigment yellow 1	2512-29-0	219-730-8	$C_{17}H_{16}N_4O_4$	2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide	Not classified by 311 notifiers, joint entries.*
C.I. Pigment yellow 1:1	Not found	Not found	Not found	Not found. Probably the barium salt of pigment yellow 1.	Not found.
C.I. 11710	6486-23-3	229-355-1	$C_{16}H_{12}Cl_2N_4O_4$	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-	Not classified by 481 notifiers, joint

Colour Index	**CAS-No**	**EC-No**	**Molecular formula**	**Substance name**	**Classification**
C.I. Pigment Yellow 3				oxobutyramide	entries.*
C.I. 21100 C.I. Pigment Yellow 13	5102-83-0	225-822-9	$C_{36}H_{34}Cl_2N_6O_4$	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	Not classified by 508 notifiers, joint entries.*
C.I. 11740 C.I. Pigment Yellow 65	6528-34-3	229-419-9	$C_{18}H_{18}N_4O_6$	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	Not classified by 213 notifiers, joint entries.*
C.I. 11738 C.I. Pigment Yellow 73	13515-40-7	236-852-7	$C_{17}H_{15}ClN_4O_5$	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	Not classified by 52 notifiers, joint entries.*
C.I. 11741 C.I. Pigment Yellow 74	6358-31-2	228-768-4	$C_{18}H_{18}N_4O_6$	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	Skin Irrit. 2 H315 Causes skin irritation. Eye Irrit. 2 H319 Causes serious eye irritation. Classification according to 59 notifiers. Not classified by 632 notifiers, joint entries.*
C.I. 21108 C.I. Pigment Yellow 83	5567-15-7	226-939-8	$C_{36}H_{32}Cl_4N_6O_8$	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	Not classified by 599 notifiers, joint entries.*

Colour Index	CAS-No	EC-No	Molecular formula	Substance name	Classification
C.I. 11767 C.I. Pigment Yellow 97	12225-18-2	235-427-3	$C_{26}H_{27}ClN_4O_8S$	N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide	Not classified by 71 notifiers, joint entries.*
C.I. 11781 C.I. Pigment Yellow 154	68134-22-5	268-734-6	$C_{18}H_{14}F_3N_5O_3$	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxo-2-[[2-(trifluoromethyl)phenyl]azo]butyramide	Not classified by 295 notifiers, joint entries.*
C.I. 11784 C.I. Pigment Yellow 175	35636-63-6	252-650-1	$C_{21}H_{19}N_5O_7$	dimethyl 2-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]terephthalate	Not classified by 35 notifiers, joint entries.*

*"Not classified" may be due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification

Table A7:4 Summary of classification for reported alternative orange pigments (C&L Inventory database, ECHA 2013b)

Colour Index	CAS-No	EC-No	Molecular formula	Substance name	Classification
C.I. 21110 C.I. Pigment Orange 13	3520-72-7	222-530-3	$C_{32}H_{24}Cl_2N_8O_2$	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]	Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life. Classification according to 93 notifiers. Not classified by 502 notifiers, joint entries.*
C.I.	12236	235-	$C_{17}H_{13}ClN_6O_5$	2-[(4-chloro-2-nitrophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-	Not classified by 365 notifiers, joint

Colour Index	CAS-No	EC-No	Molecular formula	Substance name	Classification
11780 C.I. Pigment Orange 36	-62-3	462-4		benzimidazol-5-yl)-3-oxobutyramide	entries.*
C.I. 71105 C.I. Pigment Orange 43	4424-06-0	224-597-4	$C_{26}H_{12}N_4O_2$	bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione	Not classified by 302 notifiers.*
C.I. 561170 C.I. Pigment Orange 73	Deleted 84632-59-7	416-250-2	$C_{26}H_{28}N_2O_2$	3,6-Bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Not classified by 98 notifiers.

Appendix 8 Availability of alternatives

Table A8:1 shows the registered volumes of the pigment substances found in cadmium free artists paints on the market. The list shall not be seen as an exhaustive list of all possible pigments. Finishing processes to achieve the desired pigment quality, and their volumes, have not been considered.

Table A8:1 Tonnage data from Reach registrations at ECHA (ECHA 2013a)

Colour Index name	**CAS-No**	**EC-No**	**Substance name**	**Tonnage band** (tonnes per annum)
Red pigments				
C.I. Pigment red 3	2425-85-6	219-372-2	1-(4-methyl-2-nitrophenylazo)-2-naphthol	10 - 100
C.I. Pigment red 4	2814-77-9	220-562-2	1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol	100 - 1,000
C.I. Pigment Red 9	6410-38-4	229-104-6	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	Pre-registered
C.I. Pigment Red 112	6535-46-2	229-440-3	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	1,000 - 10,000
C.I. Pigment Red 149	4948-15-6	225-590-9	2,9-bis(3,5-dimethylphenyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	100 - 1,000
C.I. Pigment Red 170	2786-76-7	220-509-3	4-[[4-(aminocarbonyl)phenyl]azo]-N-(2-ethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	100 - 1,000
C.I. Pigment Red 188	61847-48-1	263-272-1	methyl 4-[[(2,5-dichlorophenyl)amino]carbonyl]-2-[[2-hydroxy-3-[[(2-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]benzoate	100 - 1,000
C.I. Pigment red 254	84632-65-5	401-540-3	3,6-bis(4-chlorophenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Tonnage Data Confidential 1 - 10 10 – 100 10 - 100 10 – 100

Colour Index name	**CAS-No**	**EC-No**	**Substance name**	**Tonnage band** (tonnes per annum)
C.I. Pigment red 255	54660-00-3	402-400-4	2,5-dihydro-3,6-diphenylpyrrolo[3,4-c]pyrrole-1,4-dione	10 – 100
Yellow pigments				
C.I. Pigment yellow 1	2512-29-0	219-730-8	2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide	100 - 1,000
C.I. Pigment yellow 1:1	Not found	Not found	Not found. Probably the barium salt of pigment yellow 1.	Not found
C.I. Pigment Yellow 3	6486-23-3	229-355-1	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide	100 - 1,000
C.I. Pigment Yellow 13	5102-83-0	225-822-9	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	1,000 - 10,000
C.I. Pigment Yellow 65	6528-34-3	229-419-9	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	100 - 1,000
C.I. Pigment Yellow 73	13515-40-7	236-852-7	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	100 - 1,000
C.I. Pigment Yellow 74	6358-31-2	228-768-4	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	1,000 - 10,000
C.I. Pigment Yellow 83	5567-15-7	226-939-8	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	1,000 - 10,000
C.I. Pigment Yellow 97	12225-18-2	235-427-3	N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide	100 - 1,000
C.I. Pigment Yellow 154	68134-22-5	268-734-6	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxo-2-[[2-(trifluoromethyl)phenyl]azo]butyramide	100 - 1,000
C.I. Pigment Yellow 175	35636-63-6	252-650-1	dimethyl 2-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]terephthalate	10 - 100
Orange pigments				
C.I. Pigment Orange 13	3520-72-7	222-530-3	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]	100 - 1,000

Colour Index name	**CAS-No**	**EC-No**	**Substance name**	**Tonnage band** (tonnes per annum)
C.I. Pigment Orange 36	12236-62-3	235-462-4	2-[(4-chloro-2-nitrophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide	100 - 1,000
C.I. Pigment Orange 43	4424-06-0	224-597-4	bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione	Pre-registered
C.I. Pigment Orange 73	84632-59-7	416-250-2	3,6-bis[4-(1-methylethyl)phenyl]-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione	Tonnage Data Confidential 10 - 100 1 - 10 10 - 100