

Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on
Cadmium and its compounds in Artist's Paints

ECHA/RAC/RES-O-0000004990-69-02/F

Adopted

26 November 2014

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Opinion of the Committee for Risk Assessment

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	Cadmium and its compounds (in Artist paints)
EC No.:	231-152-8 (Cadmium)
CAS No.:	7440-43-9 (Cadmium)

This document presents the opinion adopted by RAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Sweden has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on 19 March 2014. Interested parties were invited to submit comments and contributions by 19 September 2014.

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: **Frank Jensen**
Co-rapporteur, appointed by RAC: **Urs Schlüter**

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on 26 November 2014.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted **by consensus** of all members having the right to vote.

OPINION

The originally proposed restriction by the Dossier Submitter is:

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 OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction is not justified because in reducing the risks from cadmium in artists' paints alone, this restriction under REACH is not considered to be the most appropriate EU wide measure to address the negligible level of risk identified by RAC in terms of its effectiveness. RAC notes however, that the proposed measure would be efficient if it is considered necessary to address this minor contribution to the overall cadmium input across the EU.

JUSTIFICATION FOR THE OPINION OF RAC

IDENTIFIED HAZARD AND RISK

The restriction proposed by the Dossier Submitter is based on the following assumptions:

- Cadmium pigments in artists' paints released to waste water will to some extent end up in the sewage sludge at the waste water treatment plant (WWTP). Some of the sludge is then used as a fertiliser in agriculture. As described in section B.4, of the Background Document, the cadmium compounds contained in the pigments used in artists' paints will eventually dissolve in the soil and hence there is a potential crop uptake and consequently exposure to humans via food.
- 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 (compared to baseline), which is equivalent to 0.006% of the total intake via food. About 0.003 % decrease is expected after 50 years.
- EFSA has in 2009 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.
- The toxicity of all cadmium compounds is related to the Cd(II) 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 risk estimation from EFSA 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. More recent studies also suggest an association between cancer and cadmium exposure. The dossier submitter chose 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.
- In 150 years from now, the reduction of number of incidences are calculated to be:
 - 48 bone fractures per year (37 in females and 11 in males);
 - 13 cases of breast cancer/per year;

based on emissions of 0.11 tonnes of cadmium to agricultural land from artists' paints via sludge.

- Alternatives, i.e. colours, imitating cadmium, already exist. Cadmium based pigments are mainly substituted by organic pigments. The properties (from an artists point of view, not from a toxicological perspective) 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.

This opinion considers the evidence presented in the restriction dossier and comments submitted during public consultation and RAC discussions.

Description of the risk to be addressed by the proposed restriction

- Information on hazard(s)

Only human health hazards are considered for this proposal.

The harmonised classification is shown below (Table 11 from the BD).

Table 1. 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.

Some of the cadmium compounds (like cadmium sulphate and cadmium fluoride) have a more stringent CMR-classification as Carc. 1B, Mut. 1B and Repr. 1B.

The dossier submitter has focused in their proposal on the effects of cadmium on the kidney (as documented by EFSA) and on bone fracture and cancer (in particular breast cancer); these effects are discussed below.

The toxicity of all cadmium compounds is related to the Cd(II) 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, they are in practice irreversible due to continued internal exposure.

RAC observes that the toxic properties which cause the harmful effects are related to the Cd(II) ion. Therefore the degradation of the pigments is important (see later). Cadmium accumulates in humans due to the long biological half-time and therefore the exposure through the whole life is relevant.

Addressing the EFSA opinions on Cadmium in food

EFSA (2012) stated (slightly edited for readability):

"The general population is exposed to cadmium from multiple sources, including smoking, but in the non-smoking general population food is the dominant source. Cadmium is primarily toxic to the kidney, but can also cause bone demineralisation and has been statistically associated with increased risk of cancer in the lung, endometrium, bladder, and breast.

In 2009 and subsequently confirmed in 2011, the Panel on Contaminants in the Food Chain issued an opinion in which they recommended that the PTWI [Provisional Tolerable Weekly Intake] of 7 µg/kg body weight should be reduced to a tolerable weekly intake (TWI) of 2.5 µg/kg body weight in order to ensure a high level of protection of all consumers, including exposed and vulnerable subgroups of the population.

A Provisional Tolerable Weekly Intake (PTWI) for cadmium of 7 µg/kg body weight was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1988. In 2010, the JECFA reviewed its previous evaluation and established a provisional tolerable monthly intake (PTMI) of 25µg/kg body weight corresponding to a weekly intake of 5.8 µg/kg body weight. In 2009 and subsequently confirmed in 2011, the Panel on Contaminants in the Food Chain issued an opinion in which they recommended that the PTWI should be reduced to a tolerable weekly intake (TWI) of 2.5µg/kg body weight in order to ensure a high level of protection of all consumers, including exposed and vulnerable subgroups of the population.

In 2011 the CONTAM Panel of EFSA stated: Based on the current state of knowledge, the CONTAM Panel concluded that for cadmium the current TWI of 2.5 µg/kg b.w. established in 2009 should be maintained in order to ensure a high level of protection of consumers, including subgroups of the population such as children, vegetarians or people living in highly contaminated areas. Taking non-dietary exposure into account, it is anticipated that the total exposure of some subgroups of the population could exceed the JECFA PTMI as well as the CONTAM TWI.

The CONTAM Panel reaffirmed its previous conclusion that adverse effects are unlikely to occur in an individual with current dietary exposure, but there is a need to reduce exposure to cadmium at the population level.

By using the more detailed and refined food consumption information now available the average middle bound lifetime cadmium dietary exposure for the European population as a whole is estimated at 2.04 µg/kg body weight per week. It was highest in toddlers with an average of 4.85 µg/kg body weight per week and lowest in the elderly population group at 1.56 µg/kg body weight per week. Potential 95th percentile middle bound lifetime exposure, with the assumption that the same individuals retained high exposure throughout life, was estimated at 3.66 µg/kg body weight per week with a high of 8.19 µg/kg body weight per week for toddlers and a low of 2.82 µg/kg body weight per week for the elderly.

Often it is not the food with the highest cadmium levels, but foods that are consumed in larger quantities that have the greatest impact on cadmium dietary exposure. This was true as the broad food categories of grains and grain products (26.9%), vegetables and vegetable products (16.0%) and starchy roots and tubers (13.2%) were identified as major contributors to the cadmium dietary exposure.

The EFSA Panel concluded that although adverse effects are unlikely to occur in an individual with current dietary exposure, there is a need to reduce exposure to cadmium at the population level because of the limited safety margin".

The current review [EFSA 2012] confirmed "that children on average and adults at the 95th

percentile dietary exposure could exceed health-based guidance values.” RAC also recognises that the EFSA Panel opinion was extensively discussed (also in their public consultation) and not all stakeholders (including some member states) are on the same line as stated in the opinion regarding e.g. dietary intake and Cd levels in humans.

The dossier submitter has not questioned these conclusions and has used them as a basis for the proposed restriction.

Conclusion 1:

RAC has no information that contradicts the overall conclusions made by EFSA (2012) “that children on average and adults at the 95th percentile dietary exposure could exceed health-based guidance values.” Regarding the PTWI, RAC notes the different values between WHO and EFSA but has no information that would contradict the conclusion made by EFSA. Input from the public consultations (International Cadmium Association, ICdA) suggests that the time trends in Cd intake in the future will decrease with 15% over the next 100 years. Information about a decrease in average urinary levels is also mentioned. RAC cannot validate this information based on the data presented.

Bone fracture and breast cancer

The dossier presents data, calculations and discussions regarding other effects than kidney effects. The focus is on bone fractures and breast cancer.

If the cadmium originating from artist paints is removed, it will – according to the background document – in 150 years from now result in a yearly reduction of:

- 37 bone fractures in females;
- 11 bone fractures in males and;
- 13 cases of breast cancer.

The time frame of 150 years is based on an assessment on when the proposed restriction will reach its full effects. The most important reasons for this are the time needed for cadmium to move from the sludge to the crop (can take decades) and the extremely long human half-life (up to 40 yrs), which means that cadmium accumulates in the body and toxic concentrations are mostly attained late in life (> 50 years of age).

Such long time scales are rare but were used before e.g. when modelling long-term changes in soil concentrations in the discussions of the amendment of the fertilizers regulation (EG 2003/2003).

Some of the conclusions in the background document regarding hazard are:

“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."

Regarding the risk it is stated in the background document:

"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 [...]**:

Table 2 (from the background document). Risk reduction capacity in terms of number of prevented fractures and breast cancer cases 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."

It is noted, that EFSA is mentioning effects on bone fractures and breast cancer, but do not discuss them in details.

RAC has the following observations on these approaches:

1. It is acknowledged that since the EFSA opinion from 2009 several studies have been published on health effects of cadmium. This has strengthened the concern expressed by EFSA in their risk assessment, in particular for other endpoints than kidney toxicity e.g. cases of bone fractures and postmenopausal breast cancer.

2. A review on non-renal effects and risk assessment of environmental cadmium exposure was published earlier this year (Åkesson et al., 2014). The authors concluded that there is reason to challenge the basis of the existing health risk assessment for cadmium, from focus on kidney effects to bone effects and cancer.

RAC also recognises that during the public consultation the ICdA questioned the scientific background of a relationship between dietary Cd exposure and these effects.

3. Evaluation of these effects difficult due to e.g.:

- a. The time scale for 150 years when predicting diseases is very long.

If seen in isolation such a long time frame might be justified, but since the effects in this particular case is based on predicting how sewage sludge will be deposited, it is too speculative. The deposition of sewage sludge is a very sensitive issue where different Member States currently have different approaches: some have targets for increasing the amount of deposited sewage sludge on agricultural land, where as others are going in the opposite direction. So even in a very short time frame of a couple of years, predicting the future use of sewage sludge is a difficult task.

Additional aspects that depend on the chosen time frame are:

- Better acceptance of Cd-free alternatives;
- Technical improvements regarding the treatment of waste water and thus the environmental fate of Cd;
- Different intake of cadmium in food due to change in eating habits or development of different food products;

These aspects will have an influence on the anticipated risk reduction capacity but are at the moment not quantifiable as it is just not possible to predict how the progress in the above mentioned topics will develop and how they will interact.

- b. The anticipated impact of the proposed restriction are only limited to a very few actual cases when looked upon as factual numbers (less than a hundred out of the total population in the EU). It is recognised, that the DS has noted that the estimated number of cases for fractures and breast cancer are only two of the many different effects that can be caused by cadmium compounds. Fractures and breast cancer were chosen according to the DS because there are suitable data for these endpoints that make a quantitative assessment possible.

The risk reduction capacity (number of avoided fractures and cases of breast cancer) is negligible compared to the total numbers of fractures and breast cancer in Europe. This is probably also true for all the other effects of cadmium exposure attributable to artist's paints.

Even natural variability within a great population of several hundred millions will influence the numbers significantly given the small actual numbers. It is recognised that the DS have used dose-response relationships from studies on fractures and breast cancer for calculating number of cases and that they have used middlebound values for these relationships.

Conclusion 2:

The dossier submitter provided a thorough description of the possible effects – a description that is not challenged by RAC. However, the very small impact from the proposed restriction (estimated by the Dossier Submitter to be 48 bone fractures and 13 breast cancer incidents per year in 150 years) is considered to be of little or no relevance when compared to the conclusion of the EFSA opinion. Additionally, for the prediction of numbers of bone fractures and breast cancer, the uncertainties are not quantifiable but definitely high. A quantitative and reliable scientific evaluation of the risk reduction capacity is therefore not possible.

This conclusion should be seen in combination with the conclusion regarding the low exposure from cadmium in artist paints and the conclusion related to the EFSA opinion.

Exposure ("From artist paints to soil and food")

As stated above, one of the basic premises for the proposal is that humans are exposed to cadmium from artist paints via food. During use and brush cleaning procedures, cadmium based artists' paint is released to the waste water. At the WWTP the cadmium pigments will mainly end up in the sewage sludge. Sludge can then be applied as fertiliser in agriculture. The cadmium compounds used in artists' paints will eventually dissolve in the soil, hence there is a potential for crop uptake and consequently exposure to humans via food.

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 (compared to baseline), which is equivalent to 0.006% of total intake via food.

These premises, their quantification and uncertainties are discussed in the following.

From cadmium in artist paints to cadmium in the environment (release factor)

A very crucial assumption for the whole proposal is the release "factor" of cadmium from cleaning of used artists brushes. In the Background Document this part can be found in chapter B.9.3 "User Scenario –Release from usage of artists' paints". Some highlights are given below:

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 of cadmium originating from artists' paints. It was further assumed that 5% of the paint will be released to waste water during usage mainly by cleaning of used brushes in a sink.

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 down the sink (Weiss 2006). According to the results 1.8, respectively 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 of Stockholm.

Analyses performed on behalf of the City of Gothenburg indicated substantial release of cadmium from art schools which called upon action from the community (GöteborgsStad 2006). The municipal waste water company estimated that 10% of the cadmium reaching the treatment plant derived from artists' paints. A follow-up project 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. 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 6 out of 10 art schools despite earlier voluntary efforts by the schools to reduce the releases.

The CSRs relevant to this restriction (Lead Registrant 2013a, Lead Registrant 2013b) use the environmental release category (ERC) number 8c for consumer use of artists' paints. The default worst case 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 artist paints (Description of ERC 8c: Indoor use of substances (non-processing aids) by the public at large or 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 dossier submitter disagrees with this release assessment since their consultation and literature search have shown that the release is most likely higher.

According to the dossier submitter's summary, assessed literature studies show that it is difficult to estimate the amount of cadmium released during the use of paint. Simultaneously it is clear that current cleaning procedures can cause cadmium release to the waste water. Despite voluntary efforts releases of cadmium-based paints occur. The dossier submitter's consultation 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 the report a release to waste water of 5 % of the used paint is assumed. This is based on Enskog (2000). Also, 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 the dossier submitter has 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 the background document. During the public consultation a relevant number (approx. 150) of artists (teachers, professionals and amateurs) claimed especially that the assumption of a release factor of 5% is too conservative. Additionally, one producer of artists' paints organised independently a survey in order to contribute meaningful information to the public consultation. Amongst other issues information was gathered about how the the amount of paint is minimized going down the drain during cleanup (see below).

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

In reaction to the criticism voiced during the public consultation and the discussions in ECHA the dossier submitter reassessed the reliability of a 5% release factor using an EU exposure model for washing out of a brush used to apply paint.¹ This model was primarily developed for biocidal products and skin exposure but the DS has concluded 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.

If one estimates 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 the DS consulted a supply store in Stockholm, Konstnärernascentralköp.² 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 Konstnärernascentralköp their best seller for acrylics is a 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. For the reliability assessment the DS used the medium brush assuming that all of the brushes included in the set are used with the same frequency.³ The

¹HEEG opinion on exposure model Primary exposure scenario – washing out of a brush which has been used to apply paint. Ispra, 07/07/2011

² Established in 1962, http://www.konstnarernas.se/omoss.html?submenu_id=-1

³ Size of small brush: 1.1 x 0.5 x 0.2, large brush: 2.7 x 1.5 x 0.5 (cm)

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 in the BD, cadmium colours are denser and less paint is needed during use. A use of 2 ml paint provides a potential release of 6.3% (0.125ml/2 ml). RAC notes that the model for washing out of a brush used to apply paint (from Heeg 2011) is a worst case scenario assessment not specifically meant for artist painting or for deriving a release factor, but it is used in lack of better alternatives.

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 consultation⁴ 64% (based on 500 respondees out of the total of approximately 1000) of the EU respondents claim they take steps to minimise the amount paint released to the waste water:

- 39% responders to the survey stated they prevent all cadmium from going into the wastewater system. Methods specified included utilization of hazardous waste collection events or services; letting cleaning water evaporate and disposing of solids as solid waste or reusing residue in artwork; using waterless cleaning methods; and on-site disposal.
- 35% indicated that they do wash brushes in the sink, but are careful to first wipe or pre-clean (using solvent, or waterless cleaner) excess paint from the brushes, allow it to dry and then dispose of it in the trash or reuse it in artwork.
- 12% replied that they use disposable palettes, or that excess paint is allowed to dry on the palette, scraped off and disposed of in the trash.
- 8% considered their careful and sparing use of cadmium colors as waste minimization.
- 5% attempt to filter or decant wastewater prior to disposal.

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). 12% 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. Some artists have mentioned that the palettes with oil based paints can be used for several weeks without cleaning. The survey also indicates that specialised cleaning methods are complicated, for example less than 5% are attempting to use e.g. flocculation and filtering.

However, the validity of the survey cannot be evaluated by RAC at this point.

Comments received during public consultation state that there are important differences in how oil and water based paints are handled. Brushes used for oil based colours are for most part wiped with tissues and left in turpentine or solvent. 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 in the BD) 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

⁴ by Golden Artist Colors, A total of 1518 survey responses were received from EU and outside EU

general default value presented by the lead registrant). This would however only include release from brushes whereas the 5% used in the proposal also includes release from e.g. washing of palettes.

Furthermore, a study by Risk & Policy Analysts Limited⁵ (2000) 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 default release rate of 1% (coming from the ECHA guidance from 2012) used by the registrants is based on substances physically or chemically bounded into a matrix, whereas the subject in the proposal is release of cadmium from cleaning of brushes etc. The DS is of the opinion that according to their actual studies on release from artists' paints (described in the BD) the release is most likely higher, as also supported by their consultation with different stakeholder (see section G in the BD).

The DS summarises their conclusions as follows: *"To evaluate the reliability of the 5% release rate used in the dossier the DS has 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, the DS assesses that a 5% release considering all cadmium based colours is a realistic release scenario. This release rate is also assumed (based on consultation) in a RPA report prepared for the European Commission, DG Enterprise, which is described above (Risk & Policy Analysts Limited 2000)".*

RAC has the following observations:

- RAC considers the reliability assessment made by the DS to justify a release factor of 5% as a starting point. RAC also recognises that this factor is very difficult to verify. It is also recognised that the default value of 1% is meant for substances that are chemically or physically bound into a matrix.

Here the issue is a release of cadmium from the cleaning of the brushes etc..This situation is very different from what is the basis for the default value of ERC 8c of 1%. Hence, the release factor of 5% is better supported than the default release factor of 1%.

During public consultation a release factor of 5% has been challenged. This challenge was not quantified but only described. Therefore it is not possible to derive a different release factor on this basis.

It is also not possible to evaluate whether or not the estimations from the art school in Stockholm are representative for other art schools in the EU.

⁵Risk & 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.

- Use of a 1% release factor will result in a reduction to 1/5 of the calculated numbers (9-10 bone fractures and 2-3 cases of breast cancer per year).
- It is also unknown how much cadmium will be released over time from paintings. It is not likely that all paintings will last forever, even when they are painted in Europe using cadmium-containing paints. Finally the cadmium in those paintings (with the exemptions of a probably little fraction which is considered as cultural heritage or valuable art) will be treated during waste handling and will thus not end in waste water sewage treatment plants.
- RAC assumes that there is no release of cadmium based paints to the waste water from surplus paints. Surplus paints containing cadmium are assumed to be treated by painters as hazardous waste (legal requirement according to the European Waste Catalogue EWC 0801 11 - Commission Decision No. 2000/532/EC and this is also indicated in several responses to the public consultation.

Conclusion 3:

RAC considers the release factor of 5% to be better justified based on the reliability assessment made by the DS than the default value of 1 %. Therefore this figure will be used as the basis for the calculations of the effects recognising the uncertainty in this kind of calculations. However, it is recognised by RAC that the release factor of 5 % is not really a reliable figure and adds significantly to the uncertainties of this assessment.

Oil based vs water based artist paints

Another key aspect is whether or not there is a difference in the release of cadmium from water based paints versus oil based paints; is it right to say that the two different types of paints are cleaned in the same way or are painters cleaning the oil based paints in a way that will prevent release to the waste water?

With the purpose to estimate the amount paint released during use and cleaning the dossier submitter has been in contact with art schools and practising artists (for details see section G of the BD). 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 wiped with tissues and then left in turpentine or solvent. 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.

In an analysis on cadmium based artists' paints conducted by the Swedish Chemicals Agency 2013 (see Appendix 5 of the BD) the following concentrations of cadmium were found and are presented in the table below

If these are representative for the whole EU market is not discussed by the DS (15 of 20 samples are from the same supplier). RAC cannot conclude on this question.

In the calculations that are used by the DS, 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.

The DS has also looked at the market shares of the different types of paints.

Table 3. Market share of different types of artists' paints and their cadmium content (revised table 16 from the BD)

Type of colour	% of EU market (based on value)	% of EU market Included sum of pastels & pencils and others (proportionally divided) In terms of quantity	Quantity on EU market Tonnes/year	Concentration of Cd in the paint	Cadmium Quantity Kg/year
Oil	17	14	5.3	15-50 %	1897
Acrylics	33	79	30.8	6-17 %	3710
Water colours	10	4	1.6	30-45 %	563
Gouache	4	3	1.3	Approx.15 %	187
Dry techniques	20			-	
Others	16			-	
Total	100	100	39	-	6357

Red: oil based

Orange: Water based

RAC has the following observations:

- a) There are large differences in the content of cadmium in the different paints, both within the individual types and between the different types of paints. No general picture can be drawn, but paints containing generally from 6% to 50% cadmium with the lowest general content in acrylics with 6%-17% in the examined paints.
- b) The water based paints constitute the majority on the EU market both in terms of quantity of paints and quantity of cadmium. Water based paints seems to be the most relevant type of paint regarding the release to waste water.
- c) Disposal of water-based and oil-based paints from brushes is different as described in the above chapter regarding the release factor. This is also described in many of the comments received in the public consultation. However, it is difficult to evaluate how many artists choose which cleaning method for brushes and the potential release to waste water. Neither is it possible to evaluate if professional and amateur painters treat the cleaning process differently. Oil paints are claimed to be used primarily by professionals, but this cannot be verified by available data.
- d) Watercolour paints (aquarelles) are suspended in water and may be reasonably expected to be washed down the drain. Gouaches are less common and suspended in a natural organic binder. However, the largest overall usage by artists is of acrylics and while water based, these paints are designed to polymerise and dry hard in an hour or less, indicating a possibly particulate behaviour in sewers and WWTP. Oil paints are usually diluted before application in a linseed oil painting medium, i.e.

vegetable triglycerides and will form micelles in water; the oil medium polymerises only over weeks. These aspects might influence the fractions arriving at the WWTP. But this cannot be evaluated and quantified from any data presented in the background document or during public consultation

- e) A differentiation in the restriction between the 2 types of paints has been proposed in the public consultation, where the restriction should only cover water based paints.
- f) Another proposal was to only ban cadmium containing paints for the general public, so only professional painters would be allowed to buy and use the cadmium containing paints

Since it is not possible from the available data to evaluate whether or not these two suggestions have an influence on the exposure, these proposals are not considered further by RAC.

- g) It is mentioned in the public consultation that the cost of these cadmium containing paints is significantly higher than the other types of paints. This gives uncertainty to the overall calculations on the total volumes and could perhaps be considered further by authorities.

Conclusion 4:

The cadmium content differs between the different types of artist paints and also within the individual types of paints. The acrylics have, according to the figures presented, the lowest content of cadmium (6-17%) and this category constitutes the majority (3.7 t out of 6.4 t) of the paints on the EU market when it comes to total cadmium volume. If only water-based artist paints would be restricted, then the effects would be estimated to be reduced by roughly 1/3.

It is not possible from the available data to evaluate whether or not a differentiation between sale to the general public or only to professionals would have a significant impact on the exposure.

Release of cadmium from pigments

An important issue is the release of cadmium from pigments; does it differ from other substances, i.e. is cadmium more tightly bound to pigments than other cadmium containing substances and will it therefore not be bioavailable?

Cadmium adsorption in soil and by this its bioavailability is strongly controlled by soil pH and soil organic matter, but is also influenced by a range of soil constituents. Therefore the dossier submitter provided extensive information about the most relevant parameters.

One major basis of the risk assessment provided by the dossier submitter is a consultancy report prepared by Jon Petter Gustafsson (Professor in Soil and Groundwater Chemistry at the Department of Land and Water Resources Engineering, KTH Royal Institute of Technology in Stockholm, Sweden). RAC evaluated this report about available information in the scientific literature.

In his report (Annex III of the background document) Prof. Gustafsson demonstrated that cadmium sulphides and selenides in pigments are thermodynamically unstable in the surface horizon of agricultural soil (strictly speaking Gustafsson's argumentation is restricted to Swedish soils, from the background document it is not clear whether this is relevant for the whole of Europe). The presence of oxygen and trivalent iron 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. Additionally the

dissolution rate of cadmium-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, cadmium will be dissolved completely after 1-3 years. The presence of crystalline zinc sulphide can extend the life span of cadmium sulphide to 1-2 decades; however, sewage sludge contains mostly amorphous zinc sulphide that will dissolve more quickly.

From the data assembled in this review it was concluded that cadmium pigments probably will dissolve completely in soils over a time-frame of years to decades. It is therefore 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. However, this report does not substantiate its findings by experimental data for paints or pigments.

During public consultation the International Cadmium Association (ICdA) has confirmed the conclusions by Prof. Gustafsson that Cd in pigments will become bioavailable in the timespan of years. It has also been concluded that there is no data that oppose that Swedish soils are representative for the same types of soils throughout Europe.

The assumption of equal availability of cadmium from pigments in sludge as the entire soil cadmium is considered an overestimation in most cases. The reason for this is the so-called sludge protection hypothesis, probably caused by other micronutrients added via sludge that compete with cadmium for uptake. This means that the cadmium exposure in the sludge scenario is likely somewhat overestimated by that assumption. It is however unclear whether this effect will last for decades as this is anticipated by the dossier submitter as a relevant timeframe for the risk assessment.

Additionally, industry also criticizes that the dossier submitter did not use the mean soil pH of 5.8. The value used for the risk characterization (with pH 6.5, a value that increases the exposure in the average scenario) is considered representative for the 65th percentile of pH but not of the mean or median. As this is one of the most important parameters changing the overall cadmium mass balance industry asks for reflection on this aspect.

RAC has the following observations/questions:

- a) The argumentation by Gustafsson's is restricted to Swedish soils. However ICdA has confirmed that Swedish soils are not different from other EU soils in general. RAC notes that UK and Irish soils might have a higher Cd content, but this has not been evaluated further
- b) Industry has indicated that Cd in sewage sludge is less bioavailable (by about a factor of 2) than in soil alone and that should lead to lower bioavailability of cadmium. However, for the chosen timeframe this 'sludge protection' will not prevent that cadmium from becoming bioavailable.
- c) Cadmium can be found in crops, so it is clearly bioavailable. This is demonstrated in the EFSA opinions as well as the background document. It is also shown that different crops contain different levels of cadmium and therefore the uptake of cadmium by the population is depending upon the diet, but this is not looked into further by RAC as the overall conclusion is that is out of the scope for RAC and as EFSA has already made their conclusions on this.

Conclusion 5:

In summary and taking into account the information described above, it is assumed in this assessment that cadmium in soil, originating from pigments, in the long-term will be equally available to plants as cadmium from other sources.

Cadmium from artist paints in relation to other sources

Based on the conclusions above that cadmium released from artist paints will (eventually) be bioavailable and thus can be found in crops it is important to look at the contribution from this source in relation to other sources of cadmium.

The figures from the background document are very clear when taking into account that the background document operates with a loss to the sewage systems of 5% of the total amount of artist paints.

It is estimated in the BD that 0.32 tonnes cadmium from use of artists' paints is released to the waste water each year in Europe based on a 5% release factor. 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.

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 the background document.⁶

Using the median value of 1.4 mg Cd/kg dry substance (Table 18 in the BD) and estimates of sludge production (11 811 000 tonnes, table 21 in the BD) give a total of **16.5 tonnes** cadmium in EU produced sewage sludge.⁷ RAC has calculated that **0.11 tonnes** originate from artists' paints which is **0.7%**⁸ of the total cadmium in EU produced sludge.

Other sources

The figures are taken from section B.9.3, B.9.4 and B.9.5 in the background document where the different scenarios are described.

The cadmium found in agricultural land originates mainly from fertilizers and sewage sludge from WWTP used as fertilizer (and sometimes soil improvement). The contribution from artist paints is very small when looking at absolute and relative numbers: The total amount of cadmium applied on agricultural land from sludge in the EU is estimated to be 7.4 tonnes cadmium annually of which only 0.11 tonnes (also estimated, see page 19) originates from artist paints equivalent to less than 1% of cadmium from sludge.

However, when looking at the total amount as given in table 28 of the background document (see below), then the percentage is an order of magnitude lower (0.2%) depending on which scenario is used (see Annex 1 for a description of the scenarios).

⁶The DS assumes 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)

⁷ 1.4 g Cd/tonne ds x 11 811 000 tonnes ds = 16.5 x 10⁶ g Cd = 16.5 tonnes Cd

⁸(0.11/16.5) * 100

Table 4 (Table 28 from the background document, revised). Sources of cadmium in soil.

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
Artist paints	0.11			
Deposition from atmosphere	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

RAC has the following observations:

- The contribution of cadmium from artist paints to soil and thereby crops is negligible compared to other sources (0,086%⁹).
- The importance of this source is therefore questionable. On the other hand it contributes to the general pool of cadmium that can be taken up by crops.
- Other sources like e.g. mineral fertiliser are clearly more important.
- During the public consultation member states, organisations and individuals pointed frequently at the fact that other sources like e.g. cadmium in fertilisers are far more important.

Conclusion 6:

The contribution of cadmium from artist paints to soil and thereby crops is negligible compared to other sources. This is of course true for many uses/sources as a single use will often be small on a relative scale.

However, also this source contributes to the general pool of cadmium that can be taken up by crops. EFSA concluded that the cadmium contribution from food intake is too high for certain parts of the population.

Alternatives

The product assortment of two online stores (www.winsornewton.com and www.sennelier.fr) was analyzed by the dossier submitter for cadmium free paints. In these stores 24 unique pigments were found in products that were cadmium free but where the names of the products contained the word cadmium.

⁹ $[0,1 / (7.2+23.7+84.6+1)] * 100$

RAC notes the Dossier Submitter has looked at the hazards to human health and the environment of a number of the non-cadmium alternative paints/pigments, which in their assessment are less hazardous than the substances subject to the restriction.

A limited number (< 20 out of 666) of the contributions in the public consultation state that cadmium-free alternatives are available and that these are feasible from an artist's point of view. The vast majority of the contributions deny the availability of suitable alternatives.

Since the question of suitable alternatives is an aesthetic and technical issue RAC did not evaluate the suitability of such alternatives further, particularly as there was no request from SEAC to do so.

RAC observes that the use of cadmium in the names of the cadmium free products could have had an influence on at least some of the many submissions during the public consultation strongly arguing for the continued use of cadmium, depending on in which types of shops the paints are sold. If people think that the colours contain cadmium then they might respond to this, even though the colours are cadmium-free. On the other hand, it could be argued that painters are very keen on how the paints perform and might have a personal preference for a very specific tone of the color where others don't notice the difference or have another preference.

Conclusion 7:

The question of suitable alternatives, including their hazard, has not been evaluated by RAC.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

The main reason for acting on a Union-wide-basis would be the serious health hazards associated to cadmium and its compounds and the statement from the EFSA. This use of cadmium and its compounds is 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.

The demonstrated effects are an EU wide issue not related to any regional differences except for the use of WWTP sludge as a fertiliser etc., that could be different now and in the future between individual member states.

Conclusion 8:

As RAC is of the opinion that the proposed restriction is not the most appropriate measure to address the negligible risk, then consideration of whether action is required on an EU-wide basis is not relevant. However, for several reasons (e.g. time frame of 150 years, ongoing discussions about the use of sludge in the individual member states, statistically insignificant contribution to the number cases of breast cancer and fractures) it is unclear whether this restriction proposal would have the same impact all over Europe.

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

It is clear that there are several sources of cadmium to the soil and thereby to crops and food intake.

The justification for the restriction relies on assumptions that cadmium from artist paints will enter the sewage system and thereby ending in sludge that is spread to soil. The contribution from artist paints is however negligible compared to other sources, but if it is deemed appropriate to do something about this source, a restriction would be the most efficient risk management measure in reducing cadmium from artist paints.

The proposed exemption for restoration and maintenance of works of art and historic buildings and their interior will reduce the effect; the argumentation for the exemption is a socio-economic issue and is therefore referred to SEAC.

Other measures have been proposed by the dossier submitter.

The dossier submitter has rejected inclusion in the authorisation list primarily because of lack of classification of the cadmium containing substances that are used in the pigments, and therefore they do not fulfil the criteria as such.

A voluntary agreement is also discussed by the dossier submitter and dismissed as being non-efficient primarily due to lack of enforcement mechanisms. Also risk of free-riders could be mentioned.

Economic policy instruments have been discussed, but the efficiency of such an instrument is dealt with by SEAC.

Stricter limit values in the sewage sludge directive are also discussed by the dossier submitter. Since the most important source to cadmium in the soil is use of fertiliser, a reduction of this source will of course be the most efficient in order to reduce uptake of cadmium. However, since the proposal is about cadmium in artist paints, this option is out of scope for an evaluation by RAC, even though it is recognised that this would be the most efficient way of reducing cadmium in soils.

Labelling has not been discussed as a risk management measure in the proposal. However during public consultation several contributions pointed out that a clear labelling could be an effective and less controversial measure. RAC notices that some contributions in the public consultation mention that at least some of the cadmium containing paints are labelled already, but RAC cannot judge if this is true for all paints. A distinct warning label could raise awareness among artist painters so they would clean brushes and palettes in an environmentally better way, but it is not possible say anything about the effectiveness.

Conclusion 9:

In terms of its effectiveness in reducing the risks from cadmium in artists paints alone, RAC is of the opinion that the proposed restriction is not the most appropriate EU wide measure to address the negligible level of risk but if it was deemed appropriate to do something about this small contribution to the overall input from cadmium, RAC considers the proposed restriction would be very efficient.

Effectiveness in reducing the identified risks

The contribution to reducing the impact of the identified risk is negligible as described

above. However, as stated, EFSA in 2009 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 dossier submitter has modelled a scenario where effects on bone fractures and breast cancers have been calculated on a very long time scale in order to show the full effect of the contribution from artist paints.

Practicality, including enforceability

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

An exemption from the ban would however require additional enforcement to make sure that the selling of the products is justified by the exemption.

RAC agrees that the proposal would be practical to implement. The scope is clear even though the exemptions might create some difficulties when interpreted by different member states.

RAC has taken into account the FORUM advice.

Monitorability

The dossier submitter states that 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.

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.

RAC suggests that the most direct way of assessing compliance will be random sampling of articles by companies and authorities; although the use of contractual obligations is also an option for companies. A range of paints are already subject to analysis for cadmium due to existing legislation.

Conclusion 10:

The proposed restriction by the Dossier Submitter is monitorable, when seen from the point of view that enforcement can address whether or not stakeholders are complying with the proposed measure.

However, the numbers are so small that it will not be possible to monitor any effects of the restriction in the population. A decrease of 48 cases/year of bone fractures out of a population of several hundred million people would be impossible to monitor.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

Considering the information in the Background document and the information submitted in the public consultation RAC does not consider the proposed restriction to be the most appropriate EU wide measure to address the negligible level of risk in terms of its effectiveness in reducing the risks from cadmium in artists paints.

References not included in the Background Document

Åkesson, A et al.: Non-renal Effects and the Risk Assessment of Environmental Cadmium Exposure. *Environmental Health Perspectives*, volume 122, no 5, 2014.

This section is taken from the BD and explains the different scenarios used in Table 4 on page 19 in the opinion.

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 fertilisers¹⁰. This gives a cadmium input with sludge and mineral fertilisers of 0.2 and 2.2 g ha⁻¹ year⁻¹ respectively¹¹.

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⁻¹¹² 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.

Scenario 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

¹⁰ $0.12/(0.12+1)$ and $1/(0.12+1)$

¹¹ $11\% \times 30 \text{ kg P ha}^{-1} \times 60.5 \text{ mg Cd P}^{-1}$ (Table 19) + $89\% \times 30 \text{ kg P ha}^{-1} \times 83 \text{ mg Cd P}^{-1}$

¹² $7.4 \text{ tonnes Cd (see section B.9.3.2.3)}/102 \text{ 961 800 ha}$

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/ha¹³. Using the cadmium concentration of 1.4 mg/kg ds (Table 19) 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 Table-28](#) presents the estimations that will be used for further calculations in the human exposure via food assessment (section B.9.7).

¹³ (5+10)/2