

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Cadmium and its compounds in Artist's Paints

Draft

26 November 2014

(Draft)

27 November 2014

Opinion of the Committee for Socio-economic Analysis

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 and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

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|--------------------------|---|
| 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 opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed grounds 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 SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on 26 November 2014.

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

The draft opinion was published at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **10 December 2014**. Interested parties were invited to submit comments on the draft opinion by **8 February 2015**.

OPINION

THE OPINION OF SEAC

SEAC 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. Taking into account RAC's conclusions that the proposed restriction is not justified because the restriction under REACH is not considered to be the most appropriate EU wide measure to address the identified negligible risks in terms of its effectiveness in reducing the risks, SEAC considers that the proposed restriction is not the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

SEAC agrees with the dossier submitter that the annual intake of Cd to agricultural soil is 120 tons (see Table 27 in the background document, sum of 118.4 t/a reduced to 2 significant digits). The largest intake fraction is from mineral fertilizer (72%), followed by atmospheric deposition (20%) and sewage sludge (6%). The dossier submitter estimated that from the Cd content in artists' paints sold in Europe 5 % of the cadmium is released to waste water by cleaning brushes at the sink (release factor), 4.1% are transferred to a waste water treatment plant (average connection rate to WWTP 82%) and 1.7 % are spread on agricultural land (sewage sludge utilization rate 40%), in terms of mass this would mean 6400 kg Cd in artists' paints, 320 kg Cd released to waste water, 260 kg Cd reaching WWTP and 110 kg Cd ending on agricultural land. In Tables 19-21 of the background document it is shown that Cd containing sewage sludge is applied in all European countries to various extents. If Cd from artists' paints was a significant source of Cd in sewage sludge, action on EU wide basis would be justified to ensure 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.

A prediction of the Cd intake to agricultural soil influencing the projected health benefits is highly speculative for such a long time frame. RAC concluded 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. The dossier submitter estimates that the proposed restriction will lead to a reduction of the Cadmium concentration in agricultural soil of 0.011% in addition to a reduction of 1.6% occurring as a result of the Cd fluxes to soil (input and output balance) over a period of 100 years. However, a recent paper on the future trends in soil Cd concentration predicts a decrease of 15% rather than 1.6% in 100 years (Six and Smolders, 2014). This underlines the uncertainty involved and casts doubt on the significance of the estimates made by the dossier submitter, such as those assumptions discussed in the following paragraph.

A very crucial presumption for the whole dossier is the release factor of cadmium from cleaning of the brushes. In the public consultation, numerous comments stated that artist's paints users handle paints economically and clean brushes with e.g. waste paper resulting in a transfer to solid waste management rather than to the waste water cycle. SEAC considers that the release factor of 5% used by the Dossier Submitter is uncertain. It is accepted that the usage of Cd containing artists' paints may result in emissions to the waste water. However, the value of 1% from the Chemical Safety Reports from the Lead registrants could also be a correct assumption, as long as no measurements on the release exist.

The consumer surplus arising from using Cd containing artists' paints is calculated in a highly subjective manner. The dossier submitter assumes that the maximum loss in consumer surplus (i.e. all users find the alternatives to be of no use at all) was 3.4 million EUR per year (i.e. 50% of the consumer expenditure). For the estimates in the dossier it was further assumed that between 10% and 20% of the estimated extreme value is lost in reality (i.e. 0.34 – 0.69 million EUR/a). SEAC notes the DS does not present any evidence that the actual consumer surplus is in reality approaching this value. A quantification of consumer surplus from using Cd containing paints is hardly achievable because the slope of the demand curve is not known (see section F.2 in the background document).

It should also be noted that these paints have mainly an aesthetic function. Most public consultation comments received on this issue stated that alternatives are often regarded as inadequate. These statements are supported by comparative measurements of light

fastness, opacity and tinting strength of artists' paints containing Cd and alternatives presented in the comments of the International Cd Association.

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

Effectiveness in reducing the identified risks, proportionality to the risks

Overall SEAC conclusion

As stated above, RAC have concluded that 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, the uncertainties for the prediction of numbers of bone fractures and breast cancer are not quantifiable but definitely high. A quantitative and reliable evaluation of the risk reduction capacity is therefore not possible.

Building on the RAC opinion, the opinion of SEAC is that based on the information given in the Background Document and obtained during the Public Consultation, a restriction of Cadmium in artists' paint would be disproportionate.

Costs and benefits

This opinion is based on an assessment of the estimates from the dossier submitter, who state that the projected benefits from the restriction¹ could outweigh the costs² after either 19 years³ or only after 115 years⁴ after implementation of the restriction. However, if the release factor of 1% is taken into account then the benefits from the restriction could outweigh the costs after 75 years⁵ or would not reach break-even in the proposed time frame of 150 years⁶.

There are large uncertainties in costs (such as loss in consumer surplus (see above)) and in benefits.

Benefits were calculated with two different approaches:

- 1.) from benefits from avoiding socio-economic costs from fractures and breast cancer cases (break-even of cost and benefits occurs after 115 years (20 % loss of consumer surplus, growth over time)), and
- 2.) from benefits from avoiding socio-economic costs from fractures and the willingness to pay (WTP) to avoid breast cancer cases (break-even of cost and benefits occurs after 46 years)

In approach, 2 a value for WTP of 396.000 EUR was used (Alberini and Ščasný, forthcoming).

¹ Monetised impacts resulting from fewer bone fracture and breast cancer cases

² Reduction in consumer surplus, administrative costs for proposed exemption and cost for discarded products

³ Table 58 in the BD, benefits calculated according to alt. 2, costs according to assumption b

⁴ Table 58 in the BD, benefits calculated according to alt. 1, costs according to assumption c

⁵ Table 58 in the BD alt. 2, assumption b – 1% release factor

⁶ Table 58 in the BD alt. 2, assumption c – 1% release factor

SEAC acknowledges that even small reductions of cadmium from any source and anywhere in the food chain may result in reductions in health impacts. However, SEAC considers that taking into account the uncertainties in the restriction dossier, it does not present sufficient scientific argumentation regarding the option for 150 years of full effect of the restriction. The small reductions, especially over the quoted time period, appear to be statistically of very low impact (particularly in terms of public health impact) and therefore any measurable benefits from the proposed action are questionable.

Therefore SEAC are of the opinion that the proportionality of the proposed restriction is questionable taking into account the scale of uncertainty regarding the impact pathway disease burden estimation of the number of cases.

Availability and technical feasibility of alternatives

Alternatives to Cd-containing artists' paints are available. However, during public consultation it has been brought up by industry and by a large number of comments (341 out of 666) by artists using the paints that alternatives to artists' paints containing Cd do not provide the same technical specifications as Cd pigments e.g. regarding lightfastness, opacity and tinting strength (at least more paint has to be put on the canvas to achieve similar results). These parameters are mainly associated with aesthetic aspects of the paintings and therefore cannot be monetized easily. In addition to the familiar concept of technical feasibility of alternatives, the aesthetic aspects of the paints needs to be fully taken into account due to their role in painting/production of art. There is a strong assertion from public consultation that the alternatives are not of equal value.

In addition to the uncertainty around the proportionality of the proposed measure, there are a number of alternative risk management options for managing the risk.

In the restriction report other risk management options than restriction are discussed. One of these alternative options is a stricter limit for Cd in the sewage sludge directive (86/278/EEC) than that of 20-40 mg Cd/kg. For sewage sludge a decrease of the average Cd concentration (1.4 mg Cd/kg) in the order of 0.021 mg/kg (or 0.004 mg/kg for the lower release factor) would have the same effect as the proposed restriction and is likely to be in the same range of costs (see BD Section E.1.3, paragraph on Stricter limit in sewage sludge directive). Depending on the distribution pattern of Cd concentrations in sewage sludge this could be achieved by the exclusion of only a small mass of highly contaminated sewage sludge, e.g. by voluntary quality assurance measures. The same is valid for mineral fertilizers (see below, not discussed in the dossier).

Although not assessed in the restriction report, there are two other possibilities for risk management.

The amount of Cd originating from artists' paints on agricultural land is according the restriction dossier 110 kg per annum within 120 tons in totals (see background document, Table 27) and only 22 kg with the lower release factor of 1%. A decrease of the average Cd concentration in mineral fertilizers (7.4 mg Cd/kg) in the order of 0.0096 mg/kg (or even 0.0019 mg/kg for the lower release factor) would have the same effect as the proposed restriction. Cd concentrations in mineral fertilizers range from 0.7 to 42 mg/kg (Nziguheba and Smolders, 2008) thus such a minute reduction could be achieved by excluding a small mass of products with high concentrations.

Public consultation has also revealed that some users of artists' paints containing Cd are not aware of the potential hazards to environment and human health. An alternative risk management option would therefore be labeling the paint tubes with appropriate warnings and instructions on disposal.

In addition, a Cadmium tax could be introduced as previously practiced in Sweden for fertilisers with more than 5 mg Cd per kg P (Oosterhuis et al., 2000). A national Cd tax could also help to exclude sewage sludge with high Cd concentrations from agricultural application (see section E.1.3 in the background document, paragraph on Economic policy instruments). It is obvious that the projected reduction by the proposed restriction is so small that it can be achieved also by alternative measures with the same range of costs. In any case the estimated emission of Cadmium to agricultural soil of the proposed restriction is hardly observable. Likewise is the impact on human health hardly observable. According to the restriction dossier the health impacts is growing linearly within 150 years from zero to 13 fewer cases of breast cancer among 374,200 cases, 37 fewer fractures for females among 4,600,000 cases, 11 among 2,400,000 for males (release factor 5%). For the release factor of 1% the data are even lower by a factor of 5.

Given the uncertainties in the complex exposure scenario, the considerable Cd input from other sources, and given the economic, societal and technological developments over next 100 years, which are of course not predictable and therefore not included in the restriction dossier, SEAC considers that a restriction of Cd in artists' paints is not the most appropriate and effective measure to reduce the Cd intake of consumers and the associated health risks. In addition, other risk management measures with the same range of costs could be used to achieve greater risk reduction but the detailed information to fully assess these alternatives are not readily available to SEAC.

Practicality, incl. enforceability

SEAC is of the opinion that the proposed exemption for restoration and maintenance of historical pieces of art from the ban would require additional enforcement to make sure that the selling of the products is justified by the exemption. However, as this discretion of the MS to decide on such an exemption, MS would have to take also enforceability into consideration.

However, SEAC considers that based on available information (Background Document, Public Consultation) no further action concerning REACH restrictions is to be taken to manage the possible risks arising from Cd containing artists' paints the assessment of the practicality of the different identified RMOs is no longer relevant.

However, public consultation revealed that enforceability of a ban might be difficult. Numerous commentators announced that they will order artists' paints outside EU via Internet (e.g. from the US).

Monitorability

SEAC agrees with the dossier submitter that the monitoring of the restriction for cadmium and its compounds in artists' paints would primarily be done through enforcement. Additional monitoring could not be exercised, e.g. through measuring cadmium levels in waste water from artist schools or artist's workshops.

SEAC considers that based on available information (Background Document, Public Consultation) no further action concerning REACH restrictions is to be taken to manage the risks arising from Cd containing artists' paints the assessment of the monitorability of the different identified RMOs is no longer relevant.

BASIS FOR THE OPINION

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

Basis for the opinion of SEAC

SEAC has no basis to support the proposed restriction as proposed in the Annex XV restriction dossier submitted by Sweden.

References not included in the BD

Alberini, A. and Ščasný, M. (forthcoming). 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.

Cookson, R. (2003). Willingness to pay methods in health care: a sceptical view. *Health Economics* 12, 891-894.

Nziguheba, G. and Smolders, E. (2008). Inputs of trace elements in agricultural soils via phosphate fertilizers in European countries. *Science of The Total Environment* 390(1), 53-57.

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.

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(0), 319-328.