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*(Information)*INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
AND AGENCIES

EUROPEAN COMMISSION

COMMUNICATION FROM THE COMMISSION

**on the termination of the restriction process on cadmium in artists' paints under Regulation (EC)
No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation,
Authorisation and Restriction of Chemicals (REACH)***(Text with EEA relevance)*

(2015/C 356/01)

1. INTRODUCTION

On 17 December 2013, in accordance with Article 69(4) of Regulation (EC) No 1907/2006 ⁽¹⁾ (REACH), Sweden submitted to the European Chemicals Agency (ECHA) an Annex XV dossier proposing to prohibit the placing on the market in the EU of cadmium and its compounds for use in artists' paints (harmonised customs code [3213]) and pigments used in artists' paints (harmonised customs code [3212]), and to prohibit the use of such paints and pigments.

The proposal intended to minimise the risk to human health resulting from dietary exposure to cadmium, in particular that resulting from the consumption of food crops cultivated on soils which have been treated with sewage sludge containing cadmium. Sweden was concerned that cadmium-containing artists' paint is released into waste water during the normal use and cleaning procedures of paint brushes and containers and that, following treatment at municipal waste water treatment plants, cadmium pigments mainly end up in sewage sludge, some of which is applied in agriculture to provide nutrients to plants. Sweden considered that eventually, the cadmium compounds may dissolve in the soil and be taken up by crops causing exposure to humans via food.

On 26 November 2014, the ECHA Committee for Risk Assessment (RAC) adopted its opinion ⁽²⁾ on the proposed restriction in accordance with Article 70 of REACH in which it concluded that the contribution from artists' paints to cadmium input to soil, and thereby to crops, (via the chain involving release into waste water, incorporation into sewage sludge used in agriculture and uptake into crops from the soil) is negligible compared to the contribution from other sources. RAC, therefore, also concluded that the risk presented to human health associated with cadmium releases to waste water from the use of cadmium and its compounds in artists' paints is negligible.

On 9 March 2015, the ECHA Committee for Socioeconomic Analysis (SEAC) adopted its opinion ⁽²⁾ on the proposed restriction in accordance with Article 71 of REACH in which it concluded that, given the negligible risk identified by RAC, the socioeconomic costs of the proposed restriction were not proportional to its socioeconomic benefits.

On 9 April 2015, ECHA submitted the RAC and SEAC opinions to the Commission in accordance with Article 72 of REACH.

⁽¹⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁽²⁾ <http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1907/term>

2. MAIN ELEMENTS CONSIDERED BY THE COMMISSION IN ITS EVALUATION

Article 73(1) REACH provides that the Commission shall prepare a draft amendment to Annex XVII within three months of receipt of the SEAC opinion, when there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Union-wide basis.

The Commission must therefore examine whether, in the light of the opinions submitted to it by ECHA, the conditions laid down in Article 68 of REACH, and referred to in Article 73(1) are satisfied in relation to the proposed restriction.

It is clear from the opinions of the two ECHA committees that the first of these conditions is not met. In particular, RAC concluded that the presence of cadmium and its compounds in artists' paints alone does not lead to an unacceptable risk to human health, as considered by the submitter of the Annex XV dossier.

The Commission notes that RAC confirmed the conclusion of the European Food Safety Agency (EFSA) in 2012 that 'children on average and adults at the 95th percentile dietary exposure [to cadmium] could exceed health-based guidance values'. However RAC considered that the very small health impact in terms of incidence of bone fractures and breast cancer of the proposed restriction was of little or no relevance to this conclusion and thereby to addressing the concerns about dietary exposure to cadmium highlighted by EFSA.

The Commission further notes that RAC accepted the assumption made by Sweden – on which no comments were made during the public consultation — that 5 % of the paint will be released to waste water during usage mainly by cleaning of used brushes in a sink, as the basis for the proposed restriction, whilst observing that this was not a reliable figure and added significantly to the uncertainties of the assessment as it did not take into account the wide variation of cadmium content in different types of artists' paints (e.g. oil-based, acrylics, water-based paints, gouaches).

According to RAC, EU-produced sewage sludge contains a total of 16,5 tonnes of cadmium each year, around 45 % of which (7,4 tonnes) is applied on agricultural land. Based on a release factor of 5 %, it was estimated that 0,32 tonnes of cadmium deriving from artists' paints is released into waste water each year in the EU, most of which (0,25 tonnes per year) ends up in sewage sludge generated by municipal waste water treatment plants. Therefore 0,11 tonnes (45 % of 0,25 tonnes) of cadmium derived from artists' paints is applied to agricultural land. This represents 1,5 % of the total amount of cadmium in EU-produced sludge applied to agricultural land.

On the basis of these observations, RAC concluded that the overall contribution to cadmium in soil from artists' paints, and thereby to crops, is negligible (less than 0,1 %) compared to contributions from other sources (more than 100 tonnes/year), such as manure, mineral fertilisers and deposition from the atmosphere.

While recognising that even small reductions of cadmium exposure from any source anywhere in the food chain may result in reductions in health impacts, SEAC considered that, taking into account the uncertainties, the small reductions expected from the proposed restriction, especially over the quoted time period of 150 years, appeared statistically of very low impact (particularly public health impact) and therefore the proportionality and measurable benefits of the proposed restriction are questionable.

Furthermore, SEAC took note of RAC's conclusions that the proposed restriction was not justified to address the identified negligible risks in terms of its effectiveness in reducing the risks.

On the basis of the RAC evaluation, the Commission considers that the negligible risk identified by RAC is not an 'unacceptable risk' in the sense of Article 68(1) of REACH and consequently, does not need to be addressed.

3. CONCLUSION

The Commission concludes that, from indirect exposure via the environment through the release of cadmium to waste water and the application of sewage sludge on agricultural soil, the presence of cadmium in artists' paints does not present an unacceptable risk to human health giving rise to a need to restrict the placing on the market of cadmium or its compounds for use in artists' paints, or to restrict the use of artists' paints containing cadmium or its compounds.

The Commission considers that the conditions laid down in Article 68 of REACH, and referred to in Article 73(1), are not fulfilled and will therefore not prepare a draft amendment to Annex XVII requiring a decision under Article 73(2) of REACH. Accordingly, the restriction procedure initiated by Sweden is terminated.

Since Title VIII of REACH harmonises the conditions for the manufacture, use and placing on the market of chemical substances, measures equivalent to those that have been examined in the course of a restriction procedure under that Title and did not ultimately result in the adoption of a new restriction or the amendment of an existing restriction under Article 73(2) of REACH may not be maintained or introduced by Member States, unless there is new evidence that would necessitate a renewed evaluation.
