Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing

AMENDMENT TO A RESTRICTION

CADMIUM AND ITS COMPOUNDS - Paints

ECHA/RAC/[Opinion No (same as opinion number)]
ECHA/SEAC/[Opinion No (same as opinion number)]

	EC NUMBER	CAS NUMBER
Cadmium	**231-152-8**	**7440-43-9**

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AMENDMENT TO A RESTRICTION

About this report

Entry 23 paragraph 2 of REACH Annex XVII covers cadmium in paints (Taric codes 3208 and 3209). The entry prohibits the use of cadmium in paints (with a derogation for zinc-based paints). This means that the existing restriction does not apply to placing on the market of paints which contain cadmium as an impurity (and hence where cadmium is not intentionally used), and this does not per se restrict the importation of paints containing cadmium (even if use of such paints was restricted).

In November 2012, the European Commission requested ECHA to propose and justify to extend the existing restriction to the placing on the market of paints with TARIC codes [3208][3209] containing cadmium. For enforceability reason, the dossier should also propose the necessary specific limit values of cadmium for such paints if it is seen necessary to have a limit value acknowledging the work being currently done on (within the frame of) the EU legislation on Biocidal Products.

Consistent with the limits given elsewhere in Entry 23, a concentration limit of 0.01% for cadmium in paints is proposed in this dossier[1]. During the course of ECHA's work on this issue, considerable consultation has taken place with relevant industry representatives. Based on information and data submitted by industry, it is apparent that concentrations of cadmium in paints in the EU, including copper-based anti-fouling paints, are currently (and also expected to be in the future) well below the proposed concentration limit of 0.01%. The positive limit value allows continuing use of recycled copper and having the same limit value as elsewhere in the entry simplifies both entry and the enforcement efforts. No separate limit for copper-based anti-fouling paint is necessary.

Neither the extension of the scope nor the proposed concentration limit of 0.01% are estimated to have in practise any economic impacts on European industry or impacts on human health or the environment from cadmium releases. The main objective of the proposal is to improve implementability and enforceability of the restriction, which should bring benefits in terms of reduced compliance and enforcement costs. The only costs are expected to relate to the REACH legislative process. Reflecting this approach, and given that the restriction entry already exists in Annex XVII, it is not intended to give a complete risk assessment as the unacceptable risk from this substance is evident because of its existing entry. A similar modification was already earlier discussed in the REACH Committee meeting of November 2010.

A. Proposal

A.1 Proposed restriction(s)

ECHA is proposing that Entry 23 Paragraph 2 of Annex XVII in the REACH Regulation should be modified to read as follows (text to be deleted is stroked out and new text is underlined):

A.1.1 The identity of the substance(s)

Cadmium and its compounds

[1] This is well above the detection limit for cadmium in paints were limits of 9.6 ng L(-1) have been reported(Wang Z, Wang S, Cai M. (2007) Determination of cadmium in paint samples by graphite furnace atomic absorption spectrometry with optical temperature control. Talanta. Jul 31;72(5):1723-7.

CAS No 7440-43-9,

EC No 231-152-8

A.1.2 Scope and conditions of restriction(s)

Cadmium

CAS No 7440-43-9, EC No 231-152-8 and its compounds.

2. ~~Shall not be used in paints [3208] [3209].~~

Shall not be used, or placed on the markets, in paints [3208] [3209], if the concentration of cadmium (expressed as Cd metal) is greater than 0.01% by weight.

For paints with a zinc content exceeding 10% by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0.1% by weight.

Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.1% by weight of the paint on the painted article.

It is not proposed that the current derogation for zinc-based paint and the restriction on painted articles be revised.

A.2 Targeting

The proposed modification relates only to Entry 23 Paragraph 2 of REACH Annex XVII, and the need to extend its scope in order to also cover the placing on the market of paints which contain cadmium as an impurity or are imported (containing cadmium). In practice, this means the focus is on anti-fouling paints for ships and other marine equipment, which can contain cadmium as an impurity, as there is no evidence that other paints in the EU contain cadmium.

A.3 Summary of the justification

A.3.1 Identified hazard and risk

Since 1988, the EU has had a common aim of substituting the use of cadmium as far as possible. This goal has resulted in, *inter alia*, Entry 23 of Annex XVII of REACH.

There is high concern regarding the toxicity of cadmium. According to the 2007 EU Risk Assessment Report (RAR), cadmium is a non-threshold carcinogen although SCOEL (2010) was of the opinion that 'the mechanism of the carcinogenic activity of Cd is not exactly known, but involves, at least in part, genotoxic events mediated by indirect mechanisms for which a threshold can be identified'. EFSA (2009) concluded that 'newer data on human exposure to cadmium in the general population have found statistical associations with increased risk of cancer such as in the lung, endometrium, bladder, and breast. However, the CONTAM Panel did not consider the dose-response data as a sufficient basis for quantitative risk assessment'. In the CLP Regulation (EC) No 1272/2008 Annex VI, cadmium has been classified as a category 1B carcinogen, as well as a category 2 mutagen and reproductive toxicant. Recent assessments show that

subgroups of the EU population, such as children and vegetarians, can significantly exceed the tolerable intake of cadmium, and suggest that exposure to cadmium at the population level should be reduced (EFSA, 2009). Similarly, EFSA (2012) has stressed the need to reduce exposure to cadmium at the population level because of the limited safety margin. The ultimate toxicity of cadmium compounds is due to cadmium ion, which may form after transformation or degradation and subsequent dissolution. Thus, restrictions of any remaining presence of cadmium compounds in paints which may result in reduced emissions of cadmium compounds to the environment could contribute to a reduction in human exposure to cadmium.

Entry 23 Paragraph 2 in REACH Annex XVII prohibits the use of cadmium and cadmium compounds in the formulation of paints (TARIC codes 3208, 3209). However, "use" is considered intentional, whereas cadmium can be present in paints also unintentionally. In ECHA's consultation with Member States (MS) in 2012, only very few reports of cadmium in paints were received (see ECHA (2012)). In those cases where it was reported, the cadmium content was either related to the use of zinc (where a derogation already exists) or the impurity occurred at very low levels from the use of other metals, for example from the use of copper in antifouling paints.

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

The existing Entry 23 Paragraph 2 of REACH Annex XVII applies across the EU, and there is no information available suggesting to reconsideration of the EU-wide basis. Therefore, any modifications to the entry clearly need to be made on a Union-wide basis.

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

The proposed Entry 23 Paragraph 2 in REACH Annex XVII is comprehensive, covers also the importation, and given a specific limit value it is more easily enforced. Paints which might contain cadmium as an impurity would now be identifiable as falling within the scope of the restriction. This further ensures, that any potential risks from cadmium impurities in paints are treated equivalently to any generated by paints where cadmium is intentionally used. Paint formulators inside and outside of the EU are treated equally under the proposed modified entry. The addition of a specific limit value permits enforcement in a cost-effective manner. Based on information available, no direct benefits are expected. Given reported levels of cadmium in paints, and in anti-fouling paints in particular, neither negative impacts on industry nor on the consumers will be generated. No separate limit value for anti-fouling paints is necessary, and the current numerical limit values in the derogation for zinc-based paint and in the restriction on paint on painted articles remain[2].

B. Information on hazard and risk

A full risk assessment of cadmium and cadmium oxide has been carried out under the auspices of the Existing Substances Regulation (EU RAR 2007) and the Scientific Opinion on Cadmium in food (EFSA 2009). Therefore, the full hazard and risk profile of these substances will not be repeated here. Cadmium and cadmium oxide have been included on the candidate list as substances of very high concern, for their carcinogenic properties

[2] For paints with a zinc content exceeding 10% by weight of the paint, and for paint on the painted article the limit value for cadmium remains 0.1% by weight. Zinc tends to have cadmium as impurity, therefore the higher limit value is found necessary. In case of (dry) paint on a painted article the limit value is higher as there is not as much solvent left in the in dry paint.

and for having probable serious effects on human health (Article 57 (f)). A brief summary of these key properties (carcinogenicity and repeated dose toxicity) has been included for reference.

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

The restriction proposal concerns cadmium and cadmium compounds in certain paints. The proposal suggests only a modification to the existing Entry 23 Paragraph 2 of REACH Annex XVII, and it includes cadmium and its compounds as is the case in the current entry.

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

Cadmium and its compounds

CAS No 7440-43-9 (cadmium),

EC No 231-152-8 (cadmium)

B.1.2 Composition of the substance(s)

Not relevant to this proposal.

B.1.3 Physicochemical properties

Not relevant to this proposal.

B.1.4 Justification for grouping

The existing Entry 23 in REACH Annex XVII is concerned with all cadmium compounds. There is no intention to affect this grouping with the modification proposed in this report.

B.2 Manufacture and uses

Based on ECHA's investigation there is no intentional use of cadmium in paints covered by Entry 23; indeed, it appears only as impurity in antifouling paints. Existing relevant studies on cadmium (e.g. RPA, 2000, 2010, EU RAR 2007) do not report any uses of cadmium or its compounds in any type of paints in the EU. Neither the European Council of the Paint, Printing Ink and Artists' Colour Industry (CEPE) nor the International Cadmium Association (ICdA) reported any awareness of paints currently placed on the market in the EU which contain cadmium with an intentional use. Furthermore ECHA (2012) did not find evidence of intentional use of cadmium in paints. Therefore, it is concluded that there is no intentional use in the EU of cadmium in the paints covered by Entry 23 Paragraph 2 of REACH Annex XVII.

Copper-based antifouling paints

Anti-fouling paint is a specialized coating applied for its biocidal properties to the hull of a ship in order to slow the growth of organisms – such as algae, barnacles and other marine organisms - which attach to the hull and can affect the vessel's performance and durability. Hull coatings may have other functions in addition to their anti-fouling properties, such as acting as a barrier against corrosion on metal hulls, or improving the flow of water past the hull. As a result of banning Tributyltin (TBT) compounds in antifouling paints copper-based antifouling paints are now used by shipping industry.

Statistics are not readily available on the volumes used and the value of antifouling paints. KTN (2010) estimated that the global market for antifouling coatings represents around 80 000 tonnes of paint (around €1bn). Out of this, 80% was said to be for ocean-going ships, and the remainder for leisure boats and off-shore structures. According to an IPPIC (International Paint & Printing Ink Council) report, the global marine coatings market had a volume of 840 million litres in 2007, and a value of about €3 billion, forecast to be about €3.5 billion in 2012 on a volume of 904 million litres (Wright, 2009). The global marine-coatings industry is heavily consolidated, with 80% of the market owned by five companies. In terms of regional distribution, the Asia-Pacific accounts for 56% of the market, followed by Europe with 24% (Wright, 2009).

ECHA validated the volumes quoted in Wright (2009) in discussions held with the EU Copper Antifouling Task Force (AFTF). EU AFTF estimated that around 7700 tonnes of copper is used in the EU each year for the manufacture of anti-fouling paints. EU manufacture is considered to represent around 20% of the global total output (broadly consistent with the 24% market share for Europe in the IPPIC report cited by Wright (2009)), giving total global use of copper of around 38 000 tonnes. The copper content of anti-fouling paint varies according to brand, application and so on, but a general average of 30% by weight is considered representative. Therefore, EU production of paint is estimated to be around 25,000 tonnes per annum, with global production around 125,000 tonnes. This is not radically different from the KTN estimates of 80,000 tonnes, which could be obtained with an assumption of a slightly lower average copper concentration across the entire anti-fouling paints sector.[3] These figures obtained in consultation with the EU AFTF will be taken forward in this dossier.

CEPE has reported that cadmium impurities can be present when recycled copper is used as a raw material for antifouling paints. In anti-fouling paints, normal practice is to use copper recyclates, and the level of impurities depends on previous uses of the copper.

B.2.3 Uses advised against by the registrants

Not relevant to this proposal.

B.3 Classification and labelling

B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Cadmium and some cadmium compounds have harmonised classifications and therefore have an entry in table 3.1 in part 3 of Annex VI to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures.

Cadmium and cadmium oxide are classified for carcinogenicity (category 1B), mutagenicity (category 2) and reproductive toxicity (category 2. In addition they have the following hazard class and category: Acute Tox. 2 (*) (by inhalation), STOT RE 1, Aquatic Acute 1 and Aquatic Chronic 1.

[3] Copper concentrations can vary significantly across the sector, for instance to account for different types of water and ecosystem type, which can lead to a greater or lesser need for biocidal effectiveness. For instance, Blue Water Marine Paints (http:/www.boatzincs.com) are available in concentrations of 45% copper oxide for 'moderate' conditions and 67% copper oxide for 'severe' conditions where high levels of biocidal effectiveness are required.

A number of other cadmium compounds (as well as pyrophoric cadmium) have individual entries in Annex VI to the CLP Regulation.

In addition, there is a single entry in Annex VI to the CLP Regulation for cadmium compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), reaction mass of cadmium sulphide with zinc sulphide (xCdS.yZnS), reaction mass of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in the Annex. The harmonised hazard classes and categories for this entry are: Acute Tox. 4 * (by the oral, dermal and inhalation routes), Aquatic Acute 1 and Aquatic Chronic 1.

Furthermore, it should be noted that the registration dossiers for several cadmium compounds covered by the general entry above, include data indicating further human health and environmental effects above and beyond those covered by the harmonised classification. For instance, for cadmium carbonate (EC Number 208-168-9, CAS Number 513-78-0) the registrants have assessed the available human health information as justifying classification as Acute Tox. 2 (H330); Repr. 2 (H361); Muta. 2 (H341); Carc. 1B (H350); and RE Exp. 1 (H372). This is consistent with the Annex VI entry (human health) for cadmium and cadmium oxide.

Table 1 – Harmonised classification and labelling of cadmium

Identif-ication	Index number Table 3.1, Annex VI, CLP	Classification		Labelling			Specific Conc. Limits, M-factors
EC CAS Name		Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s	Hazard state-ment Code(s)	Suppl. Hazard state-ment Code(s)	
231-152-8 7440-43-9 cadmium (non-pyrophoric)	048-002-00-0	Acute Tox. 2 * Muta. 2 Carc. 1B Repr. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H341 H350 H361fd H372 ** H400 H410	GHS06 GHS09 GHS08 Dgr	H330 H341 H350 H361fd H372 ** H410	-	-

Source: Table 3.1 of Annex VI to the CLP Regulation (2008)

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

In addition to those with harmonised classifications, numerous distinct cadmium compounds are listed in the classification and labelling inventory.

B.4 Environmental fate properties

Not relevant to this proposal

B.5 Human health hazard assessment

The relevant parts of the cadmium and cadmium oxide are briefly presented below for completeness. The subchapters B.5.1 – B.5.5 outlined for an Annex XV restriction report are not separately discussed for this proposal. A full description of all endpoints can be found in EU RAR (2007).

B 5.6 Repeated dosed toxicity

This section is based on EU RAR (2007).

The weight of evidence of cadmium compounds' adverse effects on multiple organ sites supports the classification as T; R 48/23/25 (STOT RE category 1 under CLP). This classification is supported by 'a substantial body of information available indicating that the lung, kidney and bone are the target organs upon repeated exposure to CdO in occupational settings (mainly by inhalation). Environmental exposure to Cd (generic, not specifically CdO), mainly by the oral route, is associated with bone and kidney toxicity.'

Long-term inhalation exposure of experimental animals to CdO results in similar effects as seen upon acute exposures, i.e. pneumonia accompanied by histopathologic alterations and changes in the cellular and enzymatic composition of the bronchoalveolar fluid. Several authors concluded that, in humans, long-term inhalation exposure to cadmium (generic) leads to decreased lung function and emphysema. Chronic obstructive airway disease has been reported to lead in severe cases to an increased mortality. This increase in residual volume is considered a critical effect.

The bone tissue is another target organ for the general and occupational populations exposed to cadmium compounds, including CdO and/or Cd metal. The most severe form of bone disease caused by cadmium intoxication is Itai-Itai disease which was associated in the past kidney and bone lesions in aged Japanese women. Thus there are solid experimental and clinical arguments to demonstrate that chronic Cd poisoning is associated with bone lesions, generally in association with overt kidney damage. In humans, the mechanism of bone toxicity is not fully elucidated and types of bone lesions associated with cadmium exposure are not clearly identified. In workers exposed to cadmium compounds (not specifically CdO or Cd metal), clinical bone disease has been described but the number of cases is limited.

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

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

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

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

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

This assessment is further confirmed in the EFSA (2009) report, which states cadmium is primarily toxic to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. Cadmium can also cause bone demineralisation, either through direct bone damage or indirectly as a result of renal

dysfunction. After prolonged and/or high exposure the tubular damage may progress to decreased glomerular filtration rate, and eventually to renal failure.

B 5.7 is not discussed for this proposal.

B 5.8 Carcinogenicity

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

In the absence of specific information for Cd metal, but given the Cat 2 (T; R45) classification of CdF2, CdSO4, CdCl2 and the Cat 2 (T; R49) a classification was agreed for CdO, as a Cat 2 carcinogen (T; R45, i.e. may cause cancer by inhalation) and agreed for cadmium metal by analogy. Under CLP, this would equate to a Carcinogenicity Category 1b classification.

B 6 – B 8 are not discussed for this proposal.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of the existing legal requirements

The use of cadmium in paints is currently regulated according to Entry 23 Paragraph 2 of REACH Annex XVII.[4] The wording of the entry is as follows:

'Cadmium (CAS No 7440-43-9, EC No 231-152-8) and its compounds shall not be used in paints [3208] [3209].

'For paints with a zinc content exceeding 10% by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0.1% by weight.

'Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.1% by weight of the paint on the painted article.'

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) was adopted on 22 May 2012 and is applicable from 1 September 2013, with a transitional period for certain provisions. It repeals the Biocidal Products Directive (BPD, Directive 98/8/EC).

All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must have been previously

[4] According to REACH legislation use "means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation"

approved. There are, however, certain exceptions to this principle. For example, active substances under the Review Programme as well as biocidal products containing these active substances can be placed on the market under national rules while awaiting the final decision on the approval under the BPR. Provisional product authorisations for new active substances that are still under assessment are also allowed on the market.

In order to minimise exposure appropriate risk mitigation measures can be set (see article 19(5) second paragraph of the BPR and Annex VI), however, as not a single antifouling active substance has been approved yet, there is no more specific information concerning use restrictions.

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

Given that the current concentration of cadmium in paints is below 0.01% (Table 2) there are no specific operating conditions and risk management measures that are implemented with regard to cadmium in newly applied paints.

B.9.2 Manufacturing

Not relevant to this proposal.

B.9.3 "Use 1"

Not relevant to this proposal.

B.9.3.1 General information

Not relevant to this proposal.

B.9.3.2 Exposure estimation

B.9.3.2.1 Workers exposure

Not relevant to this proposal.

B.9.3.2.2 Consumer exposure

Not relevant to this proposal.

B 9.3.2.3 Indirect exposure of humans via the environment

Please see Section B.9.3.2.4 below.

B.9.3.2.4 Environmental exposure

According to the so called 'five-batch' analysis of the levels of cadmium observed in copper raw materials used for copper-based antifouling paints (EU AFTF, 2013) the average concentration of cadmium in copper oxide used in antifouling paints is currently very low (see also Section E.1.3).

The EU AFTF, on behalf of copper suppliers has provided confidential analytical data for calculating and setting an impurity maximum for copper to be used in antifouling paint under BPD/BPR. Due to the confidentiality the data cannot be published in this report.

However, on the basis of these data and the methodology for calculating limit values for cadmium in copper-based antifouling paints under the BPD[5], the suggested cadmium specification (i.e. the maximum permitted cadmium concentration in copper (II) oxide) for copper raw materials to be used in antifouling paints[6] would be at such a level that the current cadmium concentration in antifouling paints is about an order of magnitude lower than the limit value of 0.01% proposed in this dossier.

In other words, if it is assumed the concentration of cadmium in the copper raw material is exactly an order of magnitude lower than the proposed limit value, this would mean that, in the majority of cases, the current concentration of cadmium in antifouling paints is below 0.001%. This is the "implied approximate maximum" cadmium concentration in copper currently used for antifouling paints. Assuming that the five-batch analysis data are normally distributed, such that the mean and standard deviation are equal, the "implied approximate mean" cadmium concentration in paints would be one quarter of the implied approximate maximum, i.e. 0.00025%.

Table 2 – Illustration of cadmium content and volume based on observed cadmium concentrations in copper materials used in anti-fouling paints in the EU in 2012

	Estimated concentration of cadmium in copper-based anti-fouling paints*	Estimated amount of cadmium in copper-based anti-fouling paints produced in EU
Implied approximate mean	0.00025%	62.5 kg
Implied approximate maximum	0.001%	250 kg

Source: Based on information in EU AFTF (2013)
*) It is assumed that an average copper content in copper-based paints is 30% by weight and a copper content in copper oxide of 88%.

Given the estimated annual production of copper-based paints in the EU of 25 000 tonnes (Section B), and the implied maximum from above it is estimated that the cadmium content in anti-fouling paints placed on the market in the EU is below 250 kg per annum. Using the estimated mean, the cadmium content is about 62.5 kg.

In a stable market (where replacement is just equal to depreciation and thus the amount annually applied is not changing), this same amount of cadmium would also be leached into waterways each year. However, this is not necessarily a reliable estimate of the annual amount of cadmium leached into EU waters, because some of this cadmium will be leached into international or other national waters. In addition, use of copper-based paints in the EU might also include some proportion of imports. Finally, significant part of cadmium will be leached into EU waters from foreign-owned vessels having anti-fouling paints applied outside of Europe. Note also that the relevant measure of the impact of the (modified) restriction proposed in this dossier is the (net) effect on cadmium releases from the use of copper-based paints in the EU.

Safinah (2010) estimated the total amount of copper leached from antifouling paints into EU waters to be 4418 tonnes per year. This would amount to 37kg of cadmium (using the implied approximate mean) or at the maximum about 150kg.

[5] The limit value is set at the mean value + (3 * sd) (standard deviations) from the mean concentration measured in the five-batch analysis.
[6] It is assumed here that an average copper content in copper-based antifouling paints is 30% by weight, and a copper content in copper oxide is 88%.

OSPAR (2009) estimated that 201 kg of cadmium would leach to the Greater North Sea. This appears relatively large compared to the numbers above reported for the whole EU due to different basis used for the OSPAR estimate. (Graphs: 0.2, 3.3, 4.14, 5.2 of OSPAR (2009)).

All in all the leaching of cadmium from antifouling paints of ships to seas is estimated to be relatively small.

B.10 Risk characterisation

Not relevant to this proposal.

B.11 Summary on hazard and risk

Cadmium as such is hazardous. However, it is not intentionally used in paints. Still it can be present in anti-fouling paints containing copper, as copper may include cadmium as an impurity. The cadmium content of copper-based anti-fouling paints is very low, i.e. below 0.001%.

Anti-fouling paints are used on ships and other marine equipment. The environmental exposure and indirect human exposure via the environment take place through leaching. This leaching is estimated to be very small, less than 250 kg per annum and very likely just a fraction of that in EU. In conclusion, the exposure is low because the cadmium content in anti-fouling paints is very low.

C. Available information on alternatives

Cadmium is not intentionally used in paints and the impurity of cadmium in anti-fouling paints is very low. Therefore, potential alternatives to cadmium are not assessed.

D. Justification for action on a Union-wide basis

The existing Entry 23 Paragraph 2 of REACH Annex XVII applies across the EU, and there is no information available suggesting to reconsideration of the EU-wide basis. Therefore, any modifications to the entry clearly need to be made on a Union-wide basis.

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

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

Table 3 – Illustration of cadmium content and volume in anti-fouling paints in the EU in 2012 and in 2022

		Cadmium content (kg)	
Implied cadmium concentration in 30% copper paint (%)	Concentration of cadmium in copper-based antifouling paints	2012	2022
Implied approximate mean	0.00025%	62.5 kg	76 kg
Implied approximate	0.001%	256 kg	312 kg

maximum			

Source: Based on information in EU AFTF (2013)
Notes: It is assumed that an average copper content is 30% by weight and a copper content in copper oxide of 88%. It is also assumed that the growth of the amount of antifouling paints is 2% per annum (along with the growth of the GDP)

Given the estimated amount of cadmium in anti-fouling paints (Table 2), Table 3 presents the projected amounts in 2022 assuming a growth rate of the application of paints to be roughly the same as the growth of the gross domestic product of 2 percent per annum. The projected amount of cadmium in antifouling paints is still very low.

There is some uncertainty about the cadmium content in the future as the shares of lower and higher grade copper may be different in the future. Low grade recycled copper is likely to contain somewhat higher amounts of cadmium. It is also possible that the relative prices of virgin and different grades of recycled copper change in the future. In the future, market and regulatory trends could make the use of low grade copper more attractive, and could therefore cause higher concentrations of cadmium in the copper-based antifouling paints. However, the proposed limit value would allow such development to certain extent.

Other legislation governing the use of recycled material may also have an effect. For instance, stricter regulations on approved uses of low-grade recycled copper could cause supply-push of low-grade recycled copper and thus make it more attractive as a raw material. Copper-based paints became more popular due to restrictions on TBTs, but technological innovations (e.g. in Teflon and silicone coatings) might also affect the relative demand for copper-based paints in the future. This means that the demand for copper based anti-fouling paints may decrease leading to a corresponding decrease in cadmium. Overall it is conjectured that the differences in relative prices will not have a major effect on the main conclusion: given the very low amounts of cadmium in copper based anti-fouling paints placed on the market currently in the EU, and no significant changes foreseen, it is estimated that the amounts will also be very low in the future.

E.1.2 Options for restriction

Option 1 – Restriction on placing on the market with concentration limit value 0.01%

The current wording of Entry 23 Paragraph 2 is considered as not covering the presence of impurities, and it does not cover the importation of paints. Therefore, it is proposed that the wording of the entry should be modified to restrict placing on the market of paints containing cadmium with in addition a concentration limit of 0.01% for enforceability reasons. The restriction on the "use" is complemented by a restriction on the "placing on the market", and by adding a concentration limit. This extends the restriction to cover also importation of paints, however, in practise, the modification does not cause a change in use of paints covered by the existing restriction, rather it allows for a more efficient enforcement.

A concentration limit of 0.01% is consistent with the concentration limits in other parts of Entry 23 of REACH Annex XVII (e.g. for plastics and brazing fillers).

Accordingly, the proposed entry would read as indicated in section A.1

Option 2 - Restriction on placing on the market with concentration limit 0.01%, with a derogation for copper-based anti-fouling paint with a concentration limit of 0.0175%

At REACH Committee in November 2010, there was a discussion of a derogation, which would permit a concentration limit value of 0.0175% for paints with a copper content exceeding 20% by weight of the paint. Option 2 is otherwise as Option 1 apart from also including this derogation.

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

Indirectly, the use of cadmium in paints is also regulated by the Biocidal Products Regulation (BPR). Under the Biocides Regulation ((EU) No 528/2012) there is a requirement to identify relevant and significant impurities of an active substance[7] and to set specifications for these impurities. The relevance of a significant impurity is determined on the basis of its known toxicological and eco-toxicological properties and should be chemically identified if technically possible, and included in the technical specification, with stated maximum concentrations.

Under this regulatory framework, an assessment is on-going of antifouling paints based on copper compounds (copper oxide, copper (II) oxide (EC No: 215-270-7; CAS No: 1317-39-1) and copper thiocyanate (EC No: 214-183-1; CAS No: 1111-67-7)). ANSES[8] is the evaluating body appointed by the French Ministry for the Environment (which is the Competent Authority for biocides in France) to perform the assessment of these copper compounds. It has the task of proposing a specification for cadmium, if present, in these copper compounds, as cadmium is considered a relevant impurity. The analysis is based on the five-batch analysis provided by the EU AFTF. The Competent Authorities for the Biocide Directive confirmed this in July 2011[9]. France is expected to report on its evaluation of copper compounds in antifouling paints in 2014.

Uses of copper compounds in antifouling paints are covered in Chemical Safety Reports registered under biocides legislation rather than REACH as indicated in Article 15 of REACH. As might be expected, therefore, a search in the REACH [Registration] database on the main reported copper compounds (copper oxide, copper (II) oxide and copper thiocyanate), on which existing antifouling applications are based, found no registered use of cadmium and its compounds in any type of paints. Section A-1 in ECHA (2012) presented information obtained from REACH Registration and Downstream Users' reports and Classification and Labelling notifications for these specific copper compounds.

E.2 Assessment of risk management options

E.2.1 Option 1

E.2.1.1 Effectiveness

The proposed modification of Entry 23 is done in order to extend the scope of the restriction, by including also the placing on the market of paints, and by adding a numerical limit value, which makes its monitoring and enforcement clearer and more efficient. The modification does not affect the raw materials or techniques used as the industry information shows that current cadmium levels in paints are already below the limit values proposed in this report.

E.2.1.1.1 Risk reduction capacity

[7] The technical guidelines at http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_DATA_REQUIREMENTS/TNsG-Data-Requirements.pdf

[8] Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail

[9] Representatives of Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (42nd CA meeting, CA-July 11-Doc.3.4). This document is confidential as it contains information on the composition of the active substance.

The proposed modification is not expected to affect human health or environmental risks. Thus, no health or environmental impacts are foreseen due to the modification.

E.2.1.1.2 Costs

No direct costs are estimated to occur due to the proposed modifications. Proposed modification in the entry would not require any changes in current practice. No changes are foreseen either in the markets for virgin or recycled copper. Some costs are expected to relate to the REACH legislative process. These costs depend on the time that ECHA's Scientific Committees use during the opinion making and on the time that the Commission and Member States spend on this modification.

E.2.1.1.3 Proportionality

No direct benefits are estimated to take place due to the proposed modification. Instead, this should have indirect benefits in terms of reduced compliance and enforcement costs as the status of imports is clarified and as setting a limit value makes enforcement more efficient thus reducing to some extent admintrative costs. This reduction in ambiguity is the only benefit of the proposed modification. Given that the anti-fouling paints placed on the market and used in the EU already contain less that 0.01% of cadmium, the change in Entry 23 is not estimated to incur any compliance costs to manufacturers or importers, nor to consumers of copper based anti-fouling paints in the EU. It is estimated that ECHA's Scientific Committees will not use a lot of time to deliberate this change and correspondingly the Commission and Member States will also spend the minimum amount of time. In sum, the change in Entry 23 as proposed in Option 1 is considered proportionate.

E.2.1.2 Practicality

The limit value is the same one used e.g. for plastics and brazing fillers in the same entry. This clarifies and supports enforcement of the entry.

E.2.1.3 Monitorability

The specific concentration limit for the paints clarifies and supports monitoring.

E.2.2 Option 2

The specific derogation for antifouling paints included in Option 2 is not considered to add any value. The limit value of 0.01% proposed for Option 1 is also suitable for anti-fouling paints, as these paints already contain less than 0.01% of cadmium. Thus, a derogation would not have any impacts to industry or consumers. A specific derogation for antifouling paints would not offer any further benefits, and indeed would make the enforcement more ambiguous. Therefore, this option is not analysed further.

F. Socio-economic Assessment of Proposed Restriction

Given the main objective of the proposed modification and subsequent limited economic impact, a separate socio-economic assessment of the proposed modifications has not been undertaken.

G. Stakeholder consultation

During the investigation ECHA has consulted extensively stakeholders. These comprise CEPE, ANSES, EU Copper Antifouling Task Force (AFTF). Australian administrators working on chemicals were also contacted concerning a limit value on cadmium used there. Details of these consultations are given below.

In 2012 ECHA requested from CEPE a justification for the suggested specific limit value 0.0175% for the special case of copper. CEPE had claimed that the proposed derogation would match closely the Australian Pesticides and Veterinary Medicines Authority (APVMA) standard for copper oxide in marine antifouling paints and in the proposed Green Label for marine antifouling coatings in China. CEPE had claimed that restricting to 0.01% the amount of cadmium in antifouling-grade scrap copper would reduce the availability of high grade scrap copper and/or necessitate an additional re-purification stage which would increase the cost of scrap copper, both financially and environmentally (e.g. in terms of energy use). However, CEPE has not been able to provide to ECHA any cost analysis to estimate the additional burden. ECHA requested additional information on a number of aspects (see Section A-4 of the ECHA report 2012), but CEPE was unable to provide this information. Therefore, no economic impacts has been shown to occur to paint manufacturers, ship builders, operators, consumers or any other economic operator from a possible restriction of cadmium on the basis of currently available information.

ECHA asked the representative of the EU AFTF to report this conclusion including ECHA's plan of i) proposing the concentration limit to be 0.01% and ii) not having a separate derogation for the copper-based paints. This took place in a CEPE Antifouling Working Group in May 2013. ECHA has not received any reaction to this presentation until the time of writing of this report (October 2013) (please, note below also the consultation of EU AFTF).

During 2013 ECHA has been in contact ANSES, which is the evaluating body appointed by the French Ministry for the Environment (which is the Competent Authority for biocides in France) to perform the assessment of these copper compounds. ANSES has not been able to provide information when they will finalize the Biocidal Products Regulation dossiers and neither any indicative results of the dossiers.

Based on the recommendation of ANSES ECHA has been in exchange with industry representative – EU Anti-fouling Task Force (AFTF)- working for antifouling industry. In April 2013, EU AFTF provided the data on observed cadmium concentrations in raw materials for the antifouling paints. Furthermore, EU AFTF has provided useful information concerning the use and manufacture of antifouling products. These pieces of information have been essential in establishing the cadmium content of antifouling copper-based paints on the EU market.

In June-July 2013 ECHA has also been in contact with Australian Pesticides and Veterinary Medicines Authority (APVMA) in order to find out any potential background information and/or studies behind the standard setting by APVMA on cadmium levels in marine environment. However, according to the APVMA, no further background information is available. APVMA's website[10] gives limits for a range of impurities in standards for copper hydroxide, copper oxychloride, copper carbonate, copper sulphate pentahydrate and cuprous oxide. APVMA and other Australian Government agencies also conducted enquiries in relation to ECHA's request regarding the calculations on which the

[10] Standard - cuprous oxide For Use in Marine Coatings and Antifouling Paints' (APVMA, 2009) http://apvma.gov.au/products/constituents/standards/standard_cuprous_oxide_marine.php

cadmium limits are based. However, they were unable to ascertain the history of the establishment of the Australian standards for the limits of cadmium impurities in copper-based anti-fouling paints. Therefore they are unable to provide any documentation to justify the limits cited (NICNAS, 2013).

ECHA carried out a consultation of Member States in 2012 as part of the preparation of the report on cadmium in general and copper-based paints in 2012 (ECHA, 2012).

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