ANNEX XV REPORT

ASSESSMENT WHETHER THE USE OF CADMIUM AND ITS COMPOUNDS IN PLASTIC MATERIALS NOT COVERED BY ENTRY 23 OF REACH ANNEX XVII SHOULD BE RESTRICTED

SUBSTANCE NAMES: CADMIUM AND ITS COMPOUNDS

IUPAC NAME: Cadmium

EC NUMBER: 231-152-8 (Cadmium)

CAS NUMBER: 7440-43-9 (Cadmium)

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EUROPEAN CHEMICALS AGENCY

About this report

Since 1988, the EU has shared a common aim to control and reduce cadmium pollution in order to increase the protection of human health and the environment. The Council Resolution of the 25th of January 1988[1] calls for an overall strategy to combat environmental pollution by cadmium and outlined that a major element of the strategy should limit the uses of cadmium to cases where suitable alternatives do not exist.

The Council Resolution was followed by Directive 91/338/EEC[2] (the 'Cadmium Directive') which limited the following uses of cadmium:

- to give colour (i.e. use as a pigment) to finished products manufactured from certain types of plastic materials[3],
- in paints,
- as a stabilizer in finished products manufactured from polymer and copolymers of vinyl chloride and
- in cadmium plating in certain sectors/applications (where plating was defined as deposition of cadmium metal onto a metallic surface).

Certain derogations to these limitations were established where e.g. cadmium was used in plastic materials coloured for safety reasons. In 2006, the requirements of Directive 91/338/EEC were carried forward to the REACH Regulation as a Restriction (entry 23 of REACH Annex XVII). Uses of cadmium and its compounds in plastic materials not specifically identified in Directive 91/338/EEC or in REACH Annex XVII are subsequently termed within this Annex XV report as "non-restricted" uses, and are the focus of this Annex XV report. Many widely used plastic materials are not included in the list of plastic materials to which the existing restriction applies e.g. high-density polyethylene (HDPE) and ABS (acrylonitrile, butadiene, styrene).

In 2012, by means of Regulation (EU) No 835/2012, the Commission (in accordance with Article 69 of REACH) asked the European Chemicals Agency (ECHA) to assess whether the "non-restricted" uses of cadmium and its compounds in plastic material should also be

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[1] OJ C 30, 4.2.1988, p.1

[2] Council Directive 91/338/EEC of 18 June 1991 amending for the 10th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

[3] The specific plastic materials listed in Council Directive 91/338/EEC & REACH Annex XVII entry 23 are: polyvinyl chloride (PVC), polyurethane (PUR), low-density polyethylene (ld PE), with the exception of low-density polyethylene used for the production of coloured masterbatch, cellulose acetate (CA), cellulose acetate butyrate (CAB), epoxy resins, melamine-formaldehyde (MF) resins, urea-formaldehyde (UF) resins, unsaturated polyesters (UP), polyethylene terephthalate (PET), polybutylene terephthalate (PBT), transparent/general-purpose polystyrene, acrylonitrile methylmethacrylate (AMMA), cross-linked polyethylene (VPE), high-impact polystyrene and polypropylene (PP).

restricted and to prepare a dossier according to the requirements of Annex XV of REACH detailing the results of its assessment.

This Annex XV report is intended to fulfil the obligations of ECHA under Regulation (EU) No 835/2012 and focuses on:

1. the identification of uses/applications of cadmium and its compounds in plastic materials and articles (mainly cadmium pigments);

2. a review of the current knowledge of the health hazards of cadmium; and,

3. an assessment of the human health hazards related to cadmium pigments.

This Annex XV report also provides some information on exposure to cadmium pigments in relation to risk assessment; classification and labelling of cadmium pigments; technical and economic feasibility of possible alternatives to cadmium containing pigments in plastics; and risk assessment of alternatives to cadmium pigments in plastics.

ECHA and consultants carried out investigations from 2012 to 2013. The approach for the preparation of this Annex XV report has been to collate information from four main sources:

1. readily available published information such as previous reports on the uses of cadmium and the associated risks;

2. internet searches for specific companies which may supply/use cadmium pigments and their alternatives and any additional applications;

3. information held by ECHA including registration dossiers, in the classification and labelling inventory, and responses received by ECHA to its calls for evidence; and

4. direct consultation with stakeholders by questionnaire, email and telephone.

ECHA sent a draft of this Annex XV report to the Commission, Member State Competent Authorities and stakeholders for discussions at the 15th Meeting of Competent Authorities for REACH and CLP (CARACAL) in 8-9 July 2014. The MSCAs were requested to provide their views on the proposed ways forward and in particular on the specific questions posed in a document CA/63/2014 'Commission's request to ECHA to prepare a restriction proposal on cadmium and its compounds in plastics'. ECHA received comments from several MSCAs on the ways forward. In addition, ECHA received feedback from the International Cadmium Association. This information is included in this final report.

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A. Conclusions

A.1 Conclusions based on the assessment

By means of Regulation (EU) No 835/2012, the European Commission requested ECHA to assess whether the use of cadmium and its compounds in plastic material, other than that listed in the first subparagraph of paragraph 1 of entry 23 of Annex XVII, should be restricted.

Industry has reported (including within registration dossiers) that certain cadmium-based pigments (i.e. cadmium sulphoselenide orange, cadmium sulphoselenide red and cadmium zinc sulphide) are used to manufacture non-restricted plastic articles, although ECHA was unable to identify individual downstream users or specific applications. Only generic claims that uses in articles were for safety applications were received.

ECHA submitted a draft Annex XV report to the CARACAL-15 in July 2014. In August 2014 the International Cadmium Association provided comments that the remaining uses of cadmium pigments in non-restricted plastics are in articles that are already regulated by toys directive, RoHS directive and End-of Life Vehicles directive. Based on this it can be interpreted that a possible restriction with the exemptions to the above uses would not have major impacts to human health or economic impacts. In other words, only uses in imported articles – if any - would be affected.

Two cadmium pigments have been registered under REACH and neither has been classified as hazardous by the registrant. There are many uncertainties in the assessment of the human health hazards of these pigments.

After initial information gathering, ECHA considered that because of significant uncertainties in exposure and hazard information it was not possible to prepare a restriction proposal for cadmium in plastic material that would conform to the requirements of Annex XV. Therefore, ECHA developed a series of hypothetical (tentative) exposure scenarios for consumers (dermal exposure from tablet computer covers, oral exposure from consumption of soup prepared using a plastic spoon and oral exposure from consumption of crops watered via a plastic nozzle).

Furthermore, an estimation of cadmium exposure to humans via the environment was carried out using the EUSES model. However, because of the uncertainties in the input assumptions the results were not considered to be sufficiently reliable for reaching conclusions.

In addition, it is possible that the registration dossiers of two of these three pigments do not comply with the (hazard) information requirements of REACH. For example, the studies provided for higher tier endpoints do not seem to provide equivalent information to standard studies for those endpoints. ECHA is thus considering further assessment of the compliance of these two registered pigments according to title VI of the REACH regulation.

On the basis of the information gathered on the use of cadmium and its compounds in plastic material, in combination with uncertainties with respect to the human health hazard of cadmium pigments, ECHA concludes that it is not in a position to prepare a restriction dossier that would conform to the requirements of Annex XV of the REACH Regulation. Further information on hazard properties of cadmium pigments are required before an adequate risk assessment or further risk management, including the preparation of a restriction proposal, can be undertaken.

It is noted that Sweden has submitted a restriction proposal for cadmium and its compounds in artists' paints to ECHA. Which is currently being considered by and the Committee for Socio-Economic Analysis (SEAC). According to this proposal, insoluble cadmium pigments, given sufficient time, have similar potential to dissolve in soils as soluble cadmium salts. In its opinion adopted in November 2014 the Committee for Risk Assessment (RAC) supported this aspect of the restriction proposal. In addition, a stakeholder observer representative at RAC supports this aspect of the Swedish restriction proposal based on the findings of ongoing research into the fate and behaviour of cadmium pigments in soils supported by the International Cadmium Association (ICdA). The ICdA, in correspondence with ECHA, stressed that the influence of the plastic material matrix within which the cadmium pigment was contained is also likely to strongly influence the fate and behaviour of cadmium pigments in soils and further work to investigate this is underway.

A.2 Targeting

This report is targeted to assess whether the use of cadmium and its compounds in non-restricted plastic materials should be restricted.

This targeting is based on the request of the Commission to ECHA. The report concentrates of describing the uses and human health hazards of cadmium pigments in plastic materials and provides information on hypothetical consumer risk assessment and estimation of exposure to humans via the environment using EUSES. The report also provides some information on worker exposure e.g. in the production of cadmium pigments and in production of polymer compounds.

A.3 Summary of the justification

A.3.1 Identification of hazard and risk

Information on uses

Cadmium and its compounds, mainly as pigments, are reported by manufacturers to be used in non-restricted plastic materials. A new use of cadmium selenide in electronic devices was reported by an US producer and an application for RoHS exemption was submitted to the EU in 2013.

Cadmium pigments are manufactured in and imported into the EU. According to Eurocolour (2012), and supported by information from pigment manufacturers (2013), three cadmium pigments are used in plastics: cadmium sulphoselenide red, cadmium sulphoselenide orange and cadmium zinc sulphide yellow. No articles containing cadmium pigments have been reported. It was noted by some consultees that some plastics (such as nylon) required high processing temperatures, which made it difficult to use organic pigments instead of cadmium pigments. ECHA (through a stakeholder consultation in 2013) did not identify any reliable information on the cadmium pigments required for non-restricted plastic materials used in specific applications. No downstream users of cadmium pigments in non-restricted plastics were identified.

Manufacturers of cadmium pigments in the EU, supported by the International Cadmium Association, claimed that 30 tonnes of cadmium in cadmium pigments are used in non-restricted plastics each year (direct contact, 2013) In August 2014, the International Cadmium Association provided information based on sales figures from 2012-2013. According to this four tonnes of cadmium pigments (equal to 2.6 tonnes of cadmium) per year is used in the non-restricted plastics. However, these manufacturers have not provided further details of the downstream users of these pigments in plastics. As such these users could not be contacted to provide information. Information from the EU RAR (2007) indicateed that the amount of cadmium used in pigments in plastics (restricted but taking advantage of the derogations and non-restricted) was nearly 10 times higher (270 tonnes) than the amount reported to be used in non-restricted plastics by manufacturers.

One manufacturer of masterbatches (used to colour plastics) reported to supply masterbatches containing cadmium-based pigments. This manufacturer reported that downstream users of these masterbatches claim that they are used in plastics with safety applications, such as in safety helmets, safety chains, security tags and roofing parts. However, no direct information on these applications was obtained from downstream users. In August 2014, the International Cadmium Association stated that the remaining uses of cadmium pigments in non-restricted plastics are in articles that are already regulated by toys directive, RoHS directive and End-of Life Vehicles directive.

The registration dossiers for two cadmium pigments (cadmium sulphoselenide red and cadmium zinc sulphide yellow) report that cadmium pigments are used for colouring polymers or similar matrices. However no further details about which polymers the pigments are used in, in what quantities or the associated applications are provided.

Highly coloured plastics are reported to contain cadmium in the range of 0.3 % to 0.6 % (0.5 % - 1 % as cadmium pigments). It is estimated that 5,000 – 90,000 tonnes of highly coloured (cadmium containing) plastics are produced per year, equivalent to 30 - 270 tonnes of cadmium as metal annually. However, as less-highly coloured plastics may also be coloured with cadmium pigments the total annual tonnage of cadmium containing plastics may be higher than this estimate. In August 2014 the International Cadmium Association stated the estimated figures would be lower.

Information on hazards to human health

The hazardous properties of cadmium are well known. Cadmium and cadmium oxide are classified on the basis of their CMR properties. Cadmium is also linked to many other adverse health effects, such as osteoporosis and non-cancer kidney effects. Ionic cadmium is considered to be the most hazardous form of cadmium. There are indications that the current DNEL values used for long term non-carcinogenic effects might not be sufficiently protective. Information provided in the Swedish Annex XV SVHC dossier on cadmium supports this view. The support document of the Member State Committee for identifying cadmium as an SVHC[4] states that *"…new findings on hazards and risks connected with cadmium and its compounds continuously appear. As an example, effects on bone tissue have recently been shown at exposure levels previously considered without effects."*

The three cadmium pigments mentioned above are exempted from the generic cadmium compounds classification entry and thus industry has to self-classify these pigments. In the dossiers of the two registered cadmium pigments (manufactured between 100 – 1000 tonnes annually) information requirements according to Annex IX to REACH have been adapted. Instead of studies with registered substances according to standard information requirements, an approach combining weight of evidence considerations (results from bio-elution tests) with the read-across information from cadmium telluride has been used. The approach is based on the hypothesis that any hazard associated with cadmium pigments is linked to the release of cadmium ion from the pigment molecules. The registrants conclude that because the release is very low, the cadmium pigments are not hazardous and therefore do not need to be classified. OEL/DNELs, as derived for the soluble cadmium compounds, were used to some extent in the cadmium pigments chemical safety assessment (CSA).

However, the approach taken has several shortcomings and the dossiers may not be compliant with REACH information requirements. The studies used to fulfil higher tier endpoints for cadmium pigments (90-day study and prenatal development toxicity study(ies) are read-across from cadmium telluride and do not provide an equivalent level of information compared to standard studies for those endpoints. In addition, no NOEAC/NOAEL could be derived based on the 28-day studies provided. Cadmium telluride meets classification criteria for a STOT RE 1 classification. However, the classification or the LOAEC value for cadmium telluride were not read-across to cadmium pigments. Similarly the classification of Acute tox 4 for cadmium telluride was not read-across to cadmium pigments. Other toxicological endpoints also have limited read-across justification.

In terms of the potential carcinogenicity of cadmium pigments, registrants refer to the non-genotoxic properties of cadmium telluride. The registrants claim that cadmium pigments are less hazardous than cadmium telluride. This conclusion is based on the results of bio-elution tests that indicate that cadmium ions are released from cadmium pigments to a lesser extent than from cadmium telluride.

Although the bio-elution tests may provide important information on cadmium release in an artificial environment, the method, especially for inhalation and dermal absorption endpoints has not been widely accepted to predict toxicokinetics. In addition, the registrants

[4] http://echa.europa.eu/documents/10162/b876c789-8fa0-4cf6-88c1-7bfeb027348d

have not provided information/justification substantiated with data on the relevance and validity of these methods to assess absorption, especially the potential long-term effects (e.g., in lung) have not been assessed and justified. In addition, the assessment provided by the registrants regarding to the role of the other components in cadmium pigments on the toxicity of cadmium pigments is based only on a statement on DNEL values for zinc and selenium and does not provide information on the hazardous properties of all the components present individually and in combination in registered substances.

The results from bio-elution testing have also been used as argumentation in cases where exposure is reported to be above the DNEL value. In these instances it is argued that the DNEL values used are overly conservative for cadmium pigments due to the lower bioavailability of the cadmium ion in pigments relative to other soluble forms of cadmium.

In conclusion, information requirements for cadmium pigments in registration dossiers have been adapted by registrants based on the hypothesis that hazard is based on the release of cadmium ions, a weight of evidence approach using information from bio-elution tests and read-across from cadmium telluride. However, considering the information available and the justifications provided, the dossiers may not be fully compliant with the information requirements. Although there is evidence to suggest that cadmium pigments are less soluble than other cadmium compounds, there is insufficient data to show that this reduced solubility corresponds to reduced toxicity, especially with long-term (inhalation) exposure. The hazardous properties of cadmium pigments used in Europe are therefore still unclear. In order to get more clarity on the hazardous properties, ECHA intends to further assess the compliance of the two registered pigment according to the title VI of the REACH Regulation. Based on the assessment the substances might be considered for substance evaluation.

Information on exposure

As the specific uses of cadmium pigments in non-restricted plastics are not known, only some hypothetical assumptions could be made to estimate any potential exposure.

The rate of leaching of cadmium pigments from plastics has not been extensively studied but some studies indicate that leaching might occur. Hypothetical exposure scenarios (oral and dermal) developed for consumers from generic assumptions of use during the development of this dossier are uncertain and are not considered sufficiently robust to make conclusions on potential risks from use of non-restricted plastics containing cadmium pigments.

An estimation of exposure to humans via the environment has been done using the EUSES 2.1.2 model. The calculated total daily intake of cadmium modelled for man via the environment from use in plastics increased slightly. However, the results were not considered to be sufficiently reliable to make conclusions on risk due to many uncertainties in the use of the model.

The inhalation route of exposure to cadmium pigments from plastics seems to be non-relevant to consumers. This is based on an observation that no statistically significant increase in exposure to cadmium was shown in people living in vicinity of incinerators.

There are few data on exposure of workers producing or handling pigments. The few publications available are old[5] and report values that are, in several cases, much higher than levels that are currently under discussion as being relevant to human health. The registration dossiers from 2013 report that exposure levels for workers in cadmium pigment manufacture are strictly controlled and routinely monitored to ensure a safe working environment.

Characterisation of risk

The key elements for carrying out a risk characterisation are still unclear. There is lack of clarity about in which plastics and plastic articles the cadmium pigments are used. There is also no information on the potential exposure to cadmium and cadmium pigments in plastics during uses. The exposure to cadmium from plastics via the environment has been modelled.

Based on the information presented in registration dossiers, the hazardous properties of cadmium pigments are not clear and do not allow a comprehensive evaluation. In particular, the long-term effects of exposure to cadmium pigments should be clarified. However, the hazardous properties of the cadmium ion are well known, even though there are indications that the current DNEL values used for long term non-carcinogenic effects might not be sufficiently protective.

The DNELs used for risk characterisation in this report and in the registration dossiers are those for cadmium. The conclusion for consumers, based on hypothetical (tentative) modelling, was that several plastic articles containing cadmium pigments would need to be used per day before the DNEL is reached. For toddlers, exposure to only a few articles might be enough to reach the DNEL. However, the results are hampered due to lack of reliable information on leaching of cadmium from plastics. Moreover, the exposure scenarios were hypothetical and no consumer uses of non-restricted plastics containing cadmium pigments were identified.[6] Therefore, the results are not considered sufficiently robust to make firm conclusions on potential risks from use of non-restricted plastics containing cadmium pigments.

The model used for estimating cadmium exposure to humans via the environment was considered to have many uncertainties. For example, the partition-coefficients for cadmium pigments were not available. Equally, available models may not be suitable to estimate the exposure to cadmium ions released from pigments contained in a matrix. Therefore, the modelled results are also not considered sufficiently reliable to conclude on potential risks.

[5] Referred to in the EU RAR (ECB, 2007) on cadmium.

[6] The information from August 2014 indicated the consumer uses.

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

Non-restricted uses of cadmium and cadmium compounds in plastic materials were not specifically identified, although were reported generically. Combined with uncertainty with respect to the hazardous properties of cadmium pigments, ECHA concludes that it is not in a position to prepare a restriction dossier that would conform to the requirements of Annex XV of the REACH Regulation.

If unacceptable risks are shown, any further action on cadmium and its compounds in plastic materials is assumed to be of concern to the whole Union, as plastic materials are assumed to be used in all EU Member States.

B. Information on hazard and risk

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

B.1.1 Identity

Cadmium (CAS No 744-43-9, EC No 231-152-8) and all its compounds are within the scope of the current restriction entry 23 of Annex XVII to REACH. As the request from the Commission is to establish if the scope of the restriction in the first subparagraph of paragraph 1 of entry 23 should be increased to cover all plastic materials, the designation of the substance, of the group of substances or of the mixture will not be affected. However, as the main function of cadmium and its compounds in plastics that has been identified is their use as pigments, the identification of the cadmium containing pigments has been described here.

Cadmium pigments are best known for their ability to be yellow, orange and especially, red colorants. The intensity of the colour is dependent on the amount of the cadmium in these pigments. The typical concentration of cadmium in the pigments is 65 %. Some examples of cadmium pigments are presented in Table 1.

Table 1

EXAMPLES OF CADMIUM PIGMENTS USED IN CERAMICS, GLASS, ENAMELS, PLASTICS OR ARTISTS COLOURS			
Compound (IUPAC Name)	**Colour**	**EC Number**	**CAS Number**
Cadmium sulphoselenide*	Red	261-218-1	58339-34-7
Cadmium mercury sulphide**	Red	215-717-6	1345-09-1
Cadmium sulphoselenide orange*	Orange	235-758-3	12656-57-4

Cadmium sulphide***	Yellow	215-147-8	1306-23-6
Cadmium zinc sulphide yellow*	Yellow	232-466-8	8048-07-5

* These three pigments are used in the polymers (Eurocolour, 2012).

** It is unlikely that "cadmium mercury sulphide" is manufactured or imported in EU as there is no entry for this substance in the classification and labelling inventory database published on ECHA website. It has not been identified by the Cadmium REACH Consortium as a substance for REACH registration (see: http://www.reach-cadmium.eu/pg_n.php?id_menu=37). The substance in in the list of pre-registered substance with the envisaged deadline of registration 30 November 2010, but no registrations were received.

*** The joint registration of cadmium sulphide does not have the use of pigment as identified use in EU, but the substance is used as a component for production of inorganic pigments.

Based on information from registration dossiers and from consultation with industry, it appears that only two cadmium pigments are currently used in significant quantities: **cadmium sulphoselenide red** (EC No: 261-218-1) and **cadmium zinc sulphide yellow** (EC No: 232-466-8). These cadmium pigments have been registered under REACH in the tonnage band of 100-1000 tonnes per year. It is not known if there will be registrations for potential further cadmium pigments with lower annual tonnage levels before the next registration deadline i.e. for substances that are manufactures/imported 10-100 tonnes annually. The current registrations of two pigments refer to families of pigments where the relative ratio of elements is not fixed.

It should be noted that even though cadmium sulphide is used as pigment, it has not been reported to be used in plastics (Eurocolour, 2012). According to information received during the public consultation on the Annex XV SVHC dossier on cadmium sulphide (ECHA website, 2013)[7], cadmium sulphide is used as a pigment in EU but only in the coloration of glass, as an intermediate, in quantities of less than 1 tonnes per year. In principal, the possibility remains that plastic articles imported from outside the EU may contain cadmium sulphide as a pigment. However, no information is available on imported articles containing cadmium sulphide as a pigment.

B.1.2 Physical and chemical properties

Certain physicochemical properties of cadmium pigments used in plastics and which are registered are shown in Table 2. Information on cadmium telluride is provided as for comparison. Information is taken from the ECHA dissemination website.

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[7] Comments on an Annex XV dossier for identification of a substance as SVHC and responses to these comments. Cadmium sulphide, 2013. (http://echa.europa.eu/candidate-list-table/-/substance/1508/search/+/term)

Table 2

SELECTED PHYSICOCHEMICAL PROPERTIES OF CADMIUM SULPHOSELENIDE RED, CADMIUM ZINC SULPHIDE YELLOW AND CADMIUM TELLURIDE (information provided by the registrants)			
Property	**Cd red** **cadmium sulphoselenide**	**Cd yellow** **cadmium zinc sulphide**	**CdTe** **cadmium telluride**
Generic formula	CdSe(x)S(1-x)	(Cdx.Zn1-x)S	CdTe
Relative density (g/cm3) at 22 °C	5.15	4.7	5.83
Granulometry (by volumetric distribution (the concentration of cadmium in pigments tested is not provided)	D10 = 1.153 µm D50 = 2.846 µm D90 = 5.91 µm	D50 = 338 µm D80 = 831 µm (supporting study D50 = 2.525 µm)	D50 = 1286 µm D80 = 3204 µm
Water solubility (µg/L) 7 day (transformation/dissolution test (on pigments, the test is done twice, the concentration of cadmium in pigments tested is not provided)	0.24 (0.036% of Cd content) <0.1 (<0.015% of Cd content)	0.18* (0.028% of Cd content) 0.61* (0.09% of Cd content)	15 (Cd) (3% of Cd content)
Water solubility (µg/L) 28 day (transformation/dissolution test) (on pigments, the test is done twice, the concentration of cadmium in pigments tested is not provided)	0.23 (0.035% of Cd content) 0.14 (0.02% Cd content)	0.98* (0.15% of Cd content) 1.97* (0.3% of Cd content)	19 (Cd) (4% of Cd content)
*Done with cadmium sulphoselenide.			

The concentration of cadmium in pigments tested for their water solubility is not provided. However, in the calculation of cadmium content (percentage) the concentration of cadmium in cadmium sulphoselenide is stated to be 66.3 % and the concentration of cadmium in cadmium zinc sulphide is stated to be 65 %. The degree of purity is reported to be high for the both of the cadmium pigments.

Transformation/dissolution tests at environmentally relevant conditions indicate lower dissolution of cadmium ions from cadmium pigments compared to cadmium telluride. However, cadmium release from cadmium zinc sulphide increased with time reaching 0.3% within a month. This is around 10 times lower than cadmium release from cadmium telluride within the same time period. Recent information on the fate and behaviour of cadmium pigments in soil is discussed in section B.4.

B.1.3 Conclusion

Based on the information available, the main function of cadmium and its compounds in plastics is as pigments. For this purpose, two cadmium pigments seem to be used in significant quantities: cadmium sulphoselenide red and cadmium zinc sulphide. According to registration dossiers, both of these cadmium pigments have very low water solubility in transformation/dissolution test at environmentally relevant conditions. Recent information on the fate and behaviour of cadmium pigments in soil is discussed in section B.4.

B.2 Manufacture and uses

The information given in this chapter focuses on cadmium pigments. This is because they are currently the only cadmium compounds that companies claim to be used in plastics in EU.

B.2.1 Manufacture, import and export of cadmium pigments

According to the EU RAR of cadmium (2007), three companies produce cadmium pigments in the EU[8]. Data from Eurostat indicate that these are located in the UK, Spain and Portugal. Data on the most active markets within the EU were derived by identifying those member states with the largest amounts of imports and exports for 2006 and 2007 as shown in Table 3.

[8] By the May 2013 deadline, two UK companies submitted registration dossiers on cadmium pigments. Information from these registration dossiers shows that two pigments were registered for the tonnage band of 100 – 1,000 t/year. According to the International Cadmium Association there were only two manufacturers of cadmium pigments in the EU (August 2014).

Table 3

MOST ACTIVE MEMBER STATES FOR IMPORTS/EXPORTS OF CADMIUM PIGMENTS AND PREPARATIONS BASED ON CADMIUM COMPOUNDS		
Parameter	**2006**	**2007**
Imports	Austria, France, Italy, Spain, United Kingdom	Austria, Denmark, France, Italy, United Kingdom
Approximate import value	€ 9000/tonne	€ 4500/tonne
Exports	Belgium, Italy, Poland, Spain, United Kingdom	Austria, Denmark, Italy Poland, United Kingdom
Approximate export value	€ 9500/tonne	€ 3000/tonne
Source: Prodcom data from Eurostat for NACE 1 code: 24122450		

As is often the case with Eurostat trade data on specialist products, the data must be viewed with caution. For example, the data suggest a price collapse from 2006 to 2007. However, there could well be another explanation for this change in price.

Some countries with exports have no production (such as Belgium, Denmark, Italy and Poland). It is assumed that these countries are importing pigments and then producing 'added-value' preparations. For example, the exports may include the export of concentrated coloured plastic (known as 'masterbatch' - see below) based on imported cadmium pigments[9].

B.2.1.1 Consumption of cadmium pigments

The EU Risk Assessment Report (RAR) of 2007 on cadmium[10] reported that the EU-16 consumption of **cadmium compounds in pigments** was about 500 tonnes per year in 2003 (equivalent to about 300 tonnes of cadmium metal). Eurostat data on *pigments and preparations based on cadmium compounds* for the later years of 2006 and 2007 is presented in Table 4.

[9] This was confirmed with the leading producer of cadmium pigment masterbatches in Poland (by telephone April 2013)

[10] ECB (2007): European Risk Assessment Report – Cadmium Metal

Table 4

EUROSTAT DATA* FOR PIGMENTS AND PREPARATIONS BASED ON CADMIUM COMPOUNDS		
Parameter	**2006**	**2007**
Production	1731	1872
Imports (extra-EU)	213	194
Exports (extra-EU)	645	981
Consumption* *	**1299**	**1085**
Approximate trade value	€5,000 to €10,000 per tonne	
Notes: * *Values expressed in tonnes per year* *** Derived from Consumption = (Production + Imports) - Exports* *Source: Prodcom data from Eurostat for NACE[11] 1 code: 24122450*		

The data presented in Table 4 are based on quantities of 'pigments and preparations' and, as such, the figures will be significantly higher than the equivalent amount of the pure cadmium compounds used in the pigments. It should be noted that pigments may be used for other purposes than in plastics, such as in artistic paints, glass, ceramics and enamel production.

From 2008 onwards, the NACE 1 code of 24122450 was merged with the NACE 1 code of 24122430 - *Pigments and preparations based on chromium compounds* to form the NACE 2 code 20122440 - *Pigments and preparations based on chromium or cadmium compounds*.

Unfortunately, the corresponding figures for chromium compounds are about an order of magnitude greater than those for cadmium. As such the Eurostat trade figures for NACE 2 code 20122440 provide no useful data on cadmium pigments from 2008 onwards.

The interpretation of the figures in Table 4 is difficult since the figures are comprised of obviously different preparations, such as the previously mentioned 'masterbatches', but also artists paints, pigments for glass production etc. The average percentage of cadmium pigment content varies being approximately 10-15 % in paints and 25 % in masterbatches.

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[11] NACE (Nomenclature des Activités Économiques dans la Communauté Européenne) is a European industry standard classification for classifying business activities

In the stakeholder consultation undertaken during the development of this Annex XV dossier, the cadmium industry advised a total EU consumption of about 5,400 tonnes cadmium in 2010. According to consultees, of the total tonnage, 300 tonnes (5.5%) were associated with pigments, which is the same as the tonnage for pigments presented in the RAR (for 2003). According to Environment Canada (direct contact, 2012) 90% of the cadmium pigments are used in plastics. The basis for this estimation is unclear. However, it is supported by the International Cadmium Association which states that most cadmium pigments are used in plastics[12] and the Annex XV SVHC report on cadmium sulphide, which states that 90 % of pigments are used in polymers (Smith, 2002, as referred in AXV SVHC dossier on cadmium. (Swedish Competent Authority, 2013)). Using this information it can therefore be assumed that based on data provided in the stakeholder consultation approximately 270 tonnes of cadmium is used as a pigment in plastic materials (i.e. in non-restricted plastic materials and restricted plastic materials taking advantage of the derogation for safety reasons).

In a subsequent submission to ECHA by an industry representative (direct contact, 2013), a lower estimate was provided (200-250 tonnes of pigments were placed on the EU market in 2012 which is equivalent to about 150 tonnes of cadmium, assuming 65% cadmium content in pigments).

In addition, the 2013 estimate provided by industry, and supported by the International Cadmium Association, states that in the EU only 20 % of cadmium pigments are used in non-restricted plastics, which is significantly lower than the 90 % of pigments used in plastics assumed above. A value of 20 % of total pigment tonnage is equivalent to approximately 30 tonnes of cadmium per annum in plastic materials. The explanation provided by industry for this lower percentage was the existing restrictions implemented in EU.

The remaining volumes of cadmium pigments, 80 %, i.e. 120 tonnes of cadmium (equivalent to about 200 tonnes of pigments), are used in non-plastic applications and a minor amount (not quantified) in restricted plastics but using the derogation for safety reasons. A recent Annex XV restriction report on cadmium in artists' paints prepared by Sweden (2013)[13] states that around 8.6 tonnes of cadmium (5.7 % of cadmium pigments) is used in artists' paints in EU. Therefore it can be estimated that in EU around 110 tonnes of cadmium (73 % of cadmium pigments) is used for other purposes such as in the production of glass, ceramics and in enamels.

In August 2014, the International Cadmium Association stated that 'Sales figures in 2012-2013 and interviews indicate a maximum use of 20 t/y of cadmium pigments for incorporation in plastics'. This is equivalent to about 16 tonnes of cadmium, assuming 65% cadmium content in pigments. Furthermore the information received provides the following figures

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[12] http://www.cadmium.org/pg_n.php?id_menu=13
[13] http://echa.europa.eu/documents/10162/04846943-29dc-40c0-9bc5-0116d3757e83

- "about 10 t/y for applications in the 16-restricted resins, under derogation of entry-23 for "safety, aerospace and defence applications"
- about 6 t/y are incorporated in plastic 'master-batches' exported outside Europe
- about 4 t/y are incorporated in master-batches and further used in Europe for niche applications where the unmatched colouring and resistance characteristics of the Cd-pigments are required. It is to be noted that those niche applications are already regulated under the "Toys, ROHS and ELV" legislation".

B.2.1.2 Conclusion

Cadmium pigment consumption is estimated to be between 200 (estimate from 2013) to 500 tonnes (information from EU RAR, 2007) per annum, which corresponds to 150-300 tonnes of cadmium metal per annum. Based on the most recent data received from industry, only 20% of the total annual cadmium pigment consumption is used in non-restricted plastic materials, corresponding to 30 tonnes per annum as cadmium metal. The previous assumption was that 90 % (worldwide assumption) of EU cadmium pigments tonnage, corresponding to 270 tonnes per annum as cadmium metal, was used in non-restricted and restricted plastic materials.

Uncertainties in the information
There is uncertainty related to annual consumption of cadmium pigments in plastics within a range of 30 – 270 tonnes (as cadmium metal). The most recent information supports lower consumption due to existing restrictions on the use of cadmium in plastics in Europe since 1991. In the exposure scenario for humans via the environment, the recent consumption is used even though it does not take into account that imported articles may also contain cadmium pigments. The information submitted by the International Cadmium Association in August 2014 on sales figures indicated even lower use of cadmium pigments for incorporation in plastics.

B.2.2 Uses of cadmium pigments in plastics

B.2.2.1 Incorporation into plastics

According to the latest information from cadmium pigment manufacturers, around 20 % of cadmium pigment tonnage in the EU is used in plastic materials. In registration dossiers the environmental release categories (ERC) of the article service life are: 1) ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release and 2) ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release. No information on imported articles containing cadmium pigments is available.

Cadmium pigments may be incorporated into plastics by three routes[14]:

- dry colouring, involving the mixing of pigment powder with polymer nibs, granules or powder. This mix is then injection moulded. This process is increasingly rare within the EU;

- a pre-dispersion of pigment in polymer compound, at a concentration required for the end use. It is estimated that between 5-10% of cadmium pigments are used in this way. Typically, this method is used for high melting point engineering polymers such as polyamide and nylon); and

- a pre-dispersion pigment at a concentration higher than that for the end-use ('masterbatch' - typically about 25% pigment by weight). Most usage of cadmium pigments in the EU is via masterbatch. Masterbatch is supplied to a moulder, who will add additional non-pigmented polymer to achieve the required concentration of pigment in the final application.

Cadmium pigments are known for colour-fastness, durability and resilience to temperature. Although available for a wide range of yellows, oranges and reds, they are particularly useful where bright reds are required. The colours and properties of cadmium pigments lend themselves to safety applications, which was the key reason for the derogations under Directive 91/338/EEC and REACH Annex XVII (current entry 23).

Typically, the concentration of cadmium pigments in plastic material end applications will be 0.5% to 1% for highly coloured plastics[15], but much lower than 0.5% in other applications where cadmium pigments are used in conjunction with other pigments (especially white pigments) to give less highly coloured (pastel) plastic[16]. Between 5,000 – 90,000 tonnes of highly coloured plastics may be produced per year using cadmium pigments. As a proportion of the cadmium-containing plastic materials produced may be coloured with lighter colours, the total tonnage of cadmium containing plastic materials may be considerably higher than 5,000 – 90,000. With the tonnage information by the International Cadmium Association stated from August 2014 these estimates would be lower.

B.2.2.2 Use of cadmium pigments in plastics

Cadmium pigment usage in the EU may be divided into two categories:

- <u>usage in plastics on the restricted list</u> (from entry 23 paragraph 1 of Annex XVII to REACH) which takes advantage of the derogation for safety applications; and

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[14] RPA (2000): The Risks to Health and Environment by Cadmium used as a Colouring Agent or a Stabiliser in Polymers and for Metal Plating, report for DG Enterprise, dated December 2000

[15] As a typical concentration of cadmium in the pigments is around 60%, the concentration of cadmium in highly coloured plastics can be estimated to be in the range 0.3% to 0.6%.

[16] RPA (2000): The Risks to Health and Environment by Cadmium used as a Colouring Agent or a Stabiliser in Polymers and for Metal Plating, report for DG Enterprise, dated December 2000

- usage in other plastics not on the restricted list but which may be subject to other legislation.

It is important to remember that there are many widely-used plastics which are not on the list of plastic materials that cannot contain cadmium. Although no detailed data are available, it would be expected that the majority of cadmium pigment tonnage used in the production of plastic materials will be used in plastics which are not currently restricted[17][18]. The leading cadmium pigment manufacturer has indicated that the generic use cadmium pigments in non-restricted plastic materials is in engineering plastics.

Cadmium is used in manufacturing pigments which are used for their:

- colouring properties (ability to perform identical colours of different pieces, ability to maintain this identity in colour under a variety of lighting, ability to create opaque colours of quality;
- stability (at the temperature, UV rays, moisture as well as enabling high processing temperatures in the production phase);
- broad spectrum of use (neutral towards the substrate, no change in mechanical properties of the substrate, no migration or release of pigment).

One manufacturer of cadmium pigments provided a list of non-restricted plastic materials which could potentially be coloured with cadmium pigments:

PTFE	polytetrafluoroethylene (teflon)
ETFE	polyethylene tetrafluoroethylene (tefzel)
PA	Polyamide
ABS	poly acrylonitrile butadiene styrene
SI	silicone
PVR	Poly vinyl acetal resin
Nylon	Polyamide
PFA	perfluoroalkoxy acrylate
FEP	fluorinated ethylene propylene

[17] And this was confirmed by one of the leading cadmium pigment manufacturers in consultation for this study (February 2013).

[18] In August 2014 International Cadmium Association informed that 50 % is used in plastics that are listed in the entry 23 but which are using the derogation for 'safety, aerospace and defence application', 30 % is incorporated in plastic masterbatches exported outside Europe and 20 % is incorporated in other masterbatches used in Europe.

PVDF	poly vinylidene fluoride (kymar, symalite)
PEEK	poly etheretherketone
PPS	polyphenylenesulfide (techtron, ryton)
PEI	polyetherimide (ulten)
PAI	poly amide-imide
POM	polyoxymetylene (acetal)
SAN	poly styrene acrylonitrile
PMMA	polymetyl methacrylate
EVA	Ethylene vinyl acetate
ASA	polyacrylic styrene acrylonitrile
HDPE	high density polyethylene

It should be noted that the registration dossiers on both cadmium sulphoselenide red and cadmium zinc sulphide yellow report that their industrial uses include:

- use of cadmium pigments for coloration of polymers or similar matrices by extrusion or similar processes; and
- use of cadmium pigments for coloration of polymers or similar matrices by high temperature processing

However, it is important to note that registration dossiers provide no further detail on:

- which 'polymers or similar matrices' (i.e. plastics) are being referred to
- the (relative) quantities used in each use
- the associated applications.

The International Cadmium Association (ICdA) describes, on its website, that "*nowadays the greatest application of plastic products which contain cadmium pigments is in complex polymers which are processed at high temperatures and require the unique durability and technical performance of a cadmium pigment*". In addition, e.g. pigmented engineering polymers such as ABS are widely used in products which include telephones, gas pipes and fittings, electricity cables, beverage crates and motor vehicle radiator fans.

Uncertainties in the information
One of the key difficulties encountered in the research for this report is that detailed information does not seem to flow up the supply chain. Information on types of plastics where the manufactured/imported pigments are used was provided by the manufacturers/importers in registration dossiers or during the consultation. However information on cadmium pigment uses in articles from downstream users was not received during the consultation.

Use in non-restricted plastics

Cadmium pigments may be used in any non-restricted plastic material. However, for the purposes of this assessment particular attention was given to the three groups of plastics that were specifically identified in the Regulation 494/2011 (later amended by Regulation 835/2012), i.e. HDPE, ABS and PMMA.

For these three groups of plastics, searches were made to determine the prevalence of yellow/red products and further research and/or consultation with relevant manufacturers was used to determine whether cadmium pigment were likely to have been used. A brief summary of the findings for each group is presented below:

High-density polyethylene (HDPE) is easy to manufacture and process and provides flexible, weatherproof, low temperature toughness. The area of application is very diverse and ranges from household and kitchenware, food wrapping material to uses in which a high environmental resilience is of importance. This means that HDPE is often used for construction/building materials such as pipes and cable insulation and also for transport products such as pallets and crates. As already noted, a derogation (under the Packaging Directive 94/62/EC) was granted to allow the continuing circulation and recycling of plastic (usually HDPE) crates/pallets (such as beer crates) with (relatively) significant levels of heavy metals – including cadmium, which may originate from the use of cadmium pigment in the past, but also from the use of other cadmium compounds (e.g. used as stabiliser), in order to prevent such items entering landfill or being incinerated.

ABS plastics are composed of acrylonitrile, butadiene, and styrene in varying proportions. ABS plastics provide a balanced combination of mechanical toughness, wide temperature range, good dimensional stability, chemical resistance, electrical insulating properties, and ease of fabrication. ABS plastics are available as compounds for injection moulding, blow moulding, extrusion, and calendaring, as sheet for thermoforming or cold forming, and in expandable grades for foam moulding. It is worth noting that internet searches for 'red ABS' quickly reveal that a major product is filament for 3D printers. However, no information has been found to suggest that ABS filaments for 3D printers are coloured with cadmium pigments.

Polymethyl methacrylate (PMMA), a hard, rigid, and transparent plastic, is the most widely used member of the acrylic family. Trade names include Plexiglass and Altuglas. Cast PMMA sheet has excellent optical properties (it transmits more than 90% total light) and is more resistant to impact than glass. In addition to excellent optical properties, acrylics have low water absorption, good electrical resistivity, and fair tensile strength. Acrylic plastics are available as compounds for extrusion, injection moulding, blow moulding and casting. Extruded or cast sheet and film also are marketed. Coloured Plexiglass has been observed to be supplied with a cadmium-free guarantee[19].

Examples of other groups of plastics which could potentially be affected by further restrictions on cadmium pigments are listed in Table 5.

[19] http://www.plexiglas.de/product/plexiglas/en/about/downloads/guarantees/pages/default.asp

Table 5

FURTHER EXAMPLES OF PLASTICS NOT COVERED BY ENTRY 23 WHICH WERE TAKEN INTO ACCOUNT IN SEARCHES AND CONSULTATIONS	
Plastic	**Comment**
PA Polyamide (Nylon)	Widely used in clothing/shoes but also widely used as an engineering plastic
Acetal (Polyoxymethylene)	Used as an engineering plastic
Fluorocarbons (including PTFE, ETFE, etc.)	Fluorocarbons have a wide range of uses from tubing (PTFE) through to construction materials (ETFE)
Polycarbonates	Noted for their strength, polycarbonates are widely used to provide a protective shell

One manufacturer reported that they had substituted cadmium pigments in their fluorocarbon products (wire insulation products) as their customers were seeking 'cadmium-free' products. Similarly, one of the major chemical companies which produces polycarbonates now provides a standard 'statement of compliance' for the RoHS Directive and other legislation which confirms a cadmium content of less than 100 ppm across its polycarbonate range. ECHA did not receive confirmation that the polycarbonates in question previously contained cadmium pigments.

It was noted by some consultees that some plastics (such as nylon) required high processing temperatures (300°C or more) which made it difficult to use organic pigments instead of cadmium pigments – as they tend to decompose at such temperatures. However, the articles produced from these plastics containing cadmium and its compounds were not identified during this study.

In August 2014, the ICdA submitted information that four tonnes of cadmium pigments was incorporated in masterbatches (non-restricted plastics, information based on sales figures from 2012-2013) and further used in Europe for niche applications, which are already regulated by the toys directive (Directive 2012/7/EU), RoHS directive (Directive 2011/65/EU) and End-of Life Vehicles (ELV) directive (Directive 2000/53/EC).

Use in plastics for safety applications

Examples of 'articles coloured with mixtures containing cadmium for safety reasons' which have been identified during consultation (including pigment/masterbatch/plastics manufacturers and downstream users) include:

- marine buoys

- road cones
- safety barriers/chains
- fire extinguisher cabinets on trucks
- roadside bins for salt
- wiring for aircraft
- safety helmets

This list contains similar items as identified by ECHA as being eligible for derogation on safety grounds[20].

International Cadmium Association stated in August 2014 that 10 tonnes of cadmium pigments per year was used in the 16-restricted resins, using the derogation of the entry.

However, during the consultation for this report, these uses could not be verified (only information on wiring for aircraft was received). Moreover, as an example one of the UK's leading manufacturers of safety helmets produces a wide range of brightly coloured HDPE safety helmets (including red, orange and yellow) to the highest safety standards. However, discussion with the manufacturers indicated that cadmium pigments are not used in their production.

B.2.3 Other uses than in pigments

Vinyl 2010 is a voluntary initiative from the PVC Industry to phase out cadmium containing stabilisers. The Voluntary Commitment was signed in 2000. The use of cadmium-based stabilisers in PVC applications made of virgin PVC has therefore completely stopped in the EU-15 since March 2001. This commitment was extended to the EU-25 as from the end of 2006 and to EU-27 in 2007. Before this phasing out, the use of cadmium-containing stabilisers, which in recent years were used only in construction profiles, had already been decreasing steadily (VITO NV, Study commissioned by Vinyl2010, 2009). Launched in 2011, VinylPlus is the renewed ten-year Voluntary Commitment to Sustainable Development by the European PVC industry. Currently the regional scope of the programme is the EU-27 plus Norway and Switzerland (VinylPlus. Progress Report 2014).[21]

According to ICdA (2012) there is no use of cadmium compounds as stabilisers in plastics other than PVC. However, it should be noted that in EU PVC is among the 16 plastics for which restriction of cadmium and its compounds apply, only by way of derogation recovered PVC can be used with specific conditions. None of the consultees had any information on cadmium containing stabilisers in imported articles.

During the call for evidence a new technology was reported where cadmium selenide is used in quantum dot light control films that are used in liquid crystal displays (LCD) for television, monitors, tablets, phones etc. An application for RoHS exemption was submitted to the EU in May 2013 by the producer in USA. The exemption is not in the consolidated

[20] ECHA Q&As No 825 accessible from: http://echa.europa.eu/support/qas-support/search-qas
[21] http://www.vinylplus.eu/uploads/Progress_Report_2014/VinylPlus_Progress_Report_2014_pbp_small.pdf

version of the RoHS directive 2011/65/EU (dated 29.01.2014). These types of new products are not yet imported into the EU. The producer reported that the concentration in an article intended to be imported to the EU is below the limit 0.01% that is provided in entry 23 paragraph 2.

Another information received during the call for evidence is from one consultant about the potential presence of cadmium in plastics (impurity) produced from recycled plastic materials (other than PVC) already containing cadmium compounds. However, according to the consultant this relates to high-density polyethylene (HPDE) in plastic crates/pallets such as beer crates, for which a derogation in entry 23 paragraph 1 (reference to Council Directive 94/62/EC and acts adopted on its basis) apply.

No other cadmium or cadmium compounds have been reported to be used in plastics.

B.2.4 Uses advised against by the registrants

No advice beyond legal compliance has been identified.

B.2.5 Conclusion on uses

Cadmium pigments are estimated to be used in plastics in tonnages of between 30 (based on recent information from industry and using 20 % use in plastics) and 270 tonnes (based on information from EU RAR and using estimation of 90 % use in plastics) cadmium annually. The assumption is that major part is used in plastics that are not covered by the entry 23. According to industry, brightly coloured plastics contain cadmium in the range 0.3% to 0.6% (0.5 – 1% as cadmium pigments). Therefore, it is estimated that between 5, 000 – 90,000 tonnes of brightly coloured plastics produced in the EU per annum contain cadmium. The information submitted in August 2014 by the International Cadmium Association indicated even lower figures.

Cadmium pigments may be used in restricted plastics as there is as existing derogation for safety applications. The pigment manufacturers have provided information that cadmium pigments can also be used in non-restricted plastics. Masterbatch producers have reported that clients have claimed that their particular uses are for safety applications, but this has not been verified by ECHA. Even though further information on uses has been requested, the registrants of the cadmium pigments (i.e. James M. Brown Limited and Rockwood Pigment Ltd) have not provided further information to ECHA. The masterbatch producer who provided information during the call for evidence did not subsequently respond after contacting them to follow-up their evidence. Other consultees, such as Eurocolour, European Plastic Converters, PlasticsEurope and several national plastic associations either did not respond to the call for evidence or did not provide information on uses. Some plastic producers using plastics which might contain cadmium pigments (specific coloured products) were contacted as part of this assessment but responded that cadmium pigments were not used in their products. The International Cadmium Association (ICdA) and pigment manufacturing industry requested that any unacceptable risks were specifically identified in order that the restriction process was appropriately targeted.

Due to lack of information on specific uses[22], the exposure scenarios have been developed based on a series of hypothetical uses.

The information provided by the International Cadmium Association in August 2014 (Annex 6) suggested that the remaining uses of cadmium pigments in non-restricted plastics are in articles which are regulated by the Toys directive, RoHS directive and End-of Life Vehicles directive. The hypothetical exposure scenarios were prepared before receiving this information and they are kept in this report for information purposes.

B.3 Classification and labelling

Cadmium and certain cadmium compounds have harmonised classification as separate entries in Annex VI to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures, part 3, table 3.1. The currently registered two cadmium pigments, cadmium sulphoselenide red and cadmium zinc sulphide, have no harmonised classification and are exempted from the group entry for harmonised classification of cadmium compounds. Hence, they are subject to self-classification by industry.

Information on harmonised classification of selected cadmium substances and self-classification of registered cadmium pigments (based on registration dossiers and classification and labelling inventory) is provided below.

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

Cadmium and cadmium oxide are classified as carcinogenic category 1B, mutagenic category 2 and reprotoxic category 2. In addition they have the following hazard class and category: Acute Tox. 2 *, STOT RE 1, Aquatic Acute 1 and Aquatic Chronic 1.

Of the five cadmium pigments listed in Table 1, only one, cadmium sulphide, has received harmonised classification as listed in Table 6.

[22] The only other function of cadmium and its compounds than the use as pigments was a new technology in USA, where cadmium selenide is used. For this use an application of a RoHS exemption is submitted to the EU. The exemption is not in the consolidated version of the RoHS directive 2011/65/EU (dated 29.01.2014).

Table 6

HARMONISED CLASSIFICATION OF CADMIUM PIGMENT COMPOUNDS				
Compound	**EC Number**	**CLP Hazard Class**	**CLP Hazard Code**	**Number of Notifiers**
Cadmium sulphide	215-147-8	Acute Tox. 4 Muta. 2 Carc. 1B Repr. 2 STOT RE 1 Aquatic Chronic 4*	H302 H341 H350 H361fd H372 H413	152
Note: As of 1 November 2013, there are 143 notifiers with the harmonised hazard profile shown above and also 9 more (including the Lead Registrant) who have submitted a more strict environmental classification (Aquatic Chronic 2 instead of 4).				

The harmonised classification for cadmium sulphide follows that of cadmium and cadmium oxide in CMR and specific organ toxicity. Cadmium sulphide is classified for carcinogenic category 1B, mutagenic category 2, reprotoxic category 2, STOT RE 1, Acute Tox. 4 * and Aquatic Chronic 4.

There is a less severe harmonised classification for cadmium compounds not elsewhere specified (n.e.s.) as shown in Table 7. This entry was added to Annex 1 of Directive 67/548/EEC with the second Adaptation to Technical Progress (Directive 79/370/EEC[23]). This category specifically exempts those substances which have been identified as (possible) cadmium pigments; cadmium sulphoselenide (xCdS.yCdSe), reaction mass of cadmium sulphide with zinc sulphide (xCdS.yZnS), reaction mass of cadmium sulphide with mercury sulphide (xCdS.yHgS).

Also cadmium compounds specified elsewhere in the Annex VI of the CLP Regulation are exempted. Cadmium compounds not elsewhere specified have a harmonised hazard class and category: Acute Tox. 4 *, Aquatic Acute 1 and Aquatic Chronic 1.

[23] Commission Directive of 30 January 1979 on the second adaptation to technical progress of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (79/370/EEC)

The registration dossiers for several cadmium compounds covered by this general entry include data indicating further health and environmental effects above and beyond those set out in the harmonised classification and accordingly the registrants have applied self-classification to address hazards. E.g. for cadmium carbonate (EC Number 208-168-9, CAS Number 513-78-0), the registrants have assessed the available information as justifying Acute Tox. 2 H330; Repr. 2 H361; Muta. 2 H341; Carc. 1B H350; STOT Rep. Exp. 1 H372).

Table 7

HARMONISED CLASSIFICATION OF CADMIUM COMPOUNDS – NOT ELSEWHERE SPECIFIED			
Compound	**EC Number**	**CLP Hazard Class**	**CLP Hazard Code**
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 this Annex	n/a	Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H332 H400 H410
Source: http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database *(accessed 01.11.13)*			

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

The reported cadmium pigments in the EU (Eurocolour, 2012) do not have a harmonised classification and labelling according to the CLP Regulation. The industry self-classifications for these pigments (available in the Classification and Labelling inventory) are summarised in Table 8.

Table 8

CLASSIFICATION OF IDENTIFIED PIGMENTS ACCORDING TO INDUSTRY'S SELF CLASSIFICATION (C&L INVENTORY SEARCH (12 June 2013))								
Identification	**Classification**		**Labelling**					
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 statement Code(s)	Specific Conc. Limits, M- factors	Notes	No of notifiers
261-218-1 58339-34-7 Cadmium sulfoselenide Red	AcuteTox. 4 AcuteTox. 4 AcuteTox. 4	H302 H312 H332	GHS07 Wng	H302 H312 H332				93
	AcuteTox. 4 Skin Irrit. 2 AcuteTox. 4 STOT SE 3	H302 H315 H332 H335		H302 H315 H332 H335				19
	Not classified							17 (joint)
235-758-3 12656-57-4 Cadmium sulfoselenide orange	Not classified							11
232-466-8 8048-07-5 Cadmium zinc sulfide yellow	Not classified							14 (joint)

Many of the notifiers have not self-classified cadmium pigments. Cadmium sulphoselenide orange and cadmium zinc sulphide yellow are not classified by any of the notifiers. Cadmium sulfoselenide red has a self-classification for acute toxicity by 93 of notifiers, self-classification for acute toxicity, skin irritation and specific organ toxicity after a single exposure by 19 notifiers. In the joint submission, 17 notifiers have not self-classified cadmium sulphoselenide red.

For cadmium mercury sulphide red (EC number 215-717-6, CAS number 1345-09-1) there is no notification in the classification and labelling inventory (search date 12 June 2013).

B.3.3 IARC review on carcinogenicity of cadmium and cadmium compounds

The carcinogenicity of cadmium and its compounds has recently been re-affirmed by the WHO International Agency for Research on Cancer (IARC) which has concluded[24]:

There is <u>sufficient evidence</u> in humans for the carcinogenicity of cadmium and cadmium compounds. Cadmium and cadmium compounds cause cancer of the lung. Also, positive associations have been observed between exposure to cadmium and cadmium compounds and cancer of the kidney and of the prostate.

There is <u>sufficient evidence</u> in experimental animals for the carcinogenicity of cadmium compounds.

There is <u>limited evidence</u> in experimental animals for the carcinogenicity of cadmium metal.

Cadmium and cadmium compounds are <u>carcinogenic to humans</u> (Group 1).

The report by the WHO-IARC neither includes, nor excludes specific cadmium compounds, such as pigments in relation to these conclusions. However, in the 'Identification of the agents' the monograph presents a table of cadmium compounds for which data on carcinogenicity or mutagenicity were available or which are commercially important. The cadmium pigments that are the focus of this Annex XV report are not included in this table.

B.3.4. Registered cadmium pigments

The registrants for cadmium sulphoselenide red and cadmium zinc sulphide propose no-classification for either human health or environmental endpoints. From the chemical safety report (CSR) of cadmium sulphoselenide red: "*Under index number 048-001-00-5 of Annex I of Directive 67/548/EEC, the cadmium sulphoselenide is specifically exempted from classification (updated ATP 29)*." In addition, they specifically remark "*Specifically exempted from classification under Annex VI of CLP*" in their CSR. The registrants seem to interpret that the exemption means that no classification is needed. However, the registrants of cadmium pigments should apply self-classification and not no-classification by default.

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[24] WHO-IARC (2012): A Review of Human Carcinogens: Arsenic, Metals, Fibres, and Dusts, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 100C (2012)

It is also important to note that although the registrants use the justification "*Specifically exempted from classification under Annex VI of CLP*" they also provide justifications on why cadmium sulphoselenide red and cadmium zinc sulphide should be 'not classified' at all. The justifications are based on read-across from information from another cadmium substance with low solubility, cadmium telluride (CdTe), *in vitro* bio-elution tests, and toxicokinetic studies on registered substances. Results from studies with cadmium telluride are not used as originally reported but are further modified with the information from bio-elution tests in a weight of evidence approach. The non-classification is based on hypothesis that (very low) release of cadmium from cadmium pigments is the driver for classification, and that other components in the substances have no role. However, justification on the role and the non-classification of the other components is not provided. Key elements of these justifications are the adequacy and reliability of the conducted toxicokinetic studies and *in vitro* bio-elution tests and acceptability of the read across from cadmium telluride, including compliance with REACH information requirements. A short discussion on these elements is provided in the context of each endpoint.

In their comments on a draft of this Annex XV report dated 29 August 2014, the International Cadmium Association provided information from registration dossiers on the reasons why cadmium sulphoselenide and cadmium zinc sulphide have not been classified for acute or chronic aquatic effects (Annex 6).

B.4 Environmental fate properties

Below is the summary of the assessment. ECHA has prepared a separate document on sections B.4-B.5 which contains confidential information from the registration dossiers.

There is no substance-specific information on the environmental distribution of cadmium containing pigments cadmium zinc sulphide yellow and cadmium sulphoselenide red in registration dossiers. Instead the registrants present general cadmium-related information. The only additional study on environmental fate and behaviour done with these cadmium pigments is a transformation/dissolution test.

The registrants of cadmium pigments state that due to the insoluble nature of the cadmium pigments, their potential to release cadmium ion in the environment is very limited and the information presented on cadmium is less relevant for the cadmium pigments.

For cadmium sulphoselenide red the acute (7d) transformation/dissolution test in a standard aqueous medium at pH 6 and with a 1 mg/L loading resulted in an average dissolved cadmium concentration of 0.24 +/- 0.09 µg/L Cd (0.036 %). The chronic (28d) transformation/dissolution test on cadmium sulphoselenide red in a standard aqueous medium at pH 6 and with a 1 mg/L loading resulted in an average dissolved cadmium concentration of 0.23 +/- 0.13 µg/L Cd (0.035 %). For cadmium zinc sulphide yellow the corresponding values were 0.18 +/- 0.13 µg/L Cd (0.028 %) and 0.98 +/- 0.95 µg/L Cd (0.15 %), respectively. Compared to the cadmium telluride (read across/reference compound) the dissolved cadmium concentration was higher i.e. 3 % of cadmium content with the similar test. The percentage is calculated using specific concentration of cadmium in pigments (for cadmium sulphoselenide red 66.3 % and for cadmium zinc sulphide yellow 65 %). In the description of the tests, the concentration of cadmium is not mentioned.

Uncertainties in the information
The recent information on solubility contradicts the information provided by the registrant. The RAC opinion adopted in November 2014 on the Swedish proposal to restrict cadmium and its compounds in artists' paints supports the findings of the study prepared for the Swedish authority (Gustafsson, 2013). In this study the cadmium pigments in concern have – over a number of years – similar possibility to dissolve in soils leading to similar availability of cadmium ions as for more soluble cadmium salts when released to the environment. Industry association (Eurometaux) as a stakeholder observer confirmed the Gustafsson results and reported that the ICdA were carrying out 'field trials' on pigments themselves, which have shown that the cadmium in the pigments become available in a similar time-scale. Further field trials with pigments encapsulated within a plastic material matrix are ongoing (direct contact, ICdA 2014).

B.5 Human health hazard assessment

Below is the summary of the assessment. ECHA has prepared a separate document on sections B.4-B.5 which contains confidential information from the registration dossiers.

Very limited substance-specific information on the properties of the cadmium containing pigments cadmium sulphoselenide red and cadmium zinc sulphide yellow is available. Registrants have adapted the information requirements in REACH for cadmium pigments with an approach including the hypothesis that the cadmium ion is the most hazardous component of the pigment. This hypothesis is supported with a weight of evidence approach using information from bio-elution tests and read-across from cadmium telluride. As general background, they refer to the information from cadmium and cadmium oxide.

Cadmium and cadmium oxide are classified on the basis of their CMR properties. Cadmium is also linked to many other adverse health effects, such as osteoporosis and non-cancer kidney effects. Ionic cadmium is considered to be the most hazardous form of the various soluble cadmium compounds. The hazardous properties of cadmium are well known. For workers the registrants use as a DNEL the Occupational Exposure Level (OEL) of 4 µg Cd/m³ for long-term local effects of cadmium (non-cancerous respiratory effects) recommended by SCOEL (2010)[25]. For the general population a DNEL value of 1 µg/kg bw/day is used. There are indications that the current DNEL values used for long term non-carcinogenic effects might not be sufficiently protective. Information provided in the

[25] SCOEL. Recommendation from the Scientific Committee on Occupational Exposure Limits for cadmium and its compounds. SCOEL/SUM/136, February 2010.

Swedish Annex XV SVHC dossier on cadmium[26] supports this view. The support document of the Member State Committee for identifying cadmium as SVHC[27] states that "*…new findings on hazards and risks connected with cadmium and its compounds continuously appear. As an example, effects on bone tissue have recently been shown at exposure levels previously considered without effects*."

The three cadmium pigments are exempted from the generic cadmium compounds classification entry and therefore industry has to self-classify them. The registrants conclude that because the release of cadmium from the pigments cadmium zinc sulphide yellow and cadmium sulphoselenide red is very low based on the results from bio-elution tests, the cadmium pigments are not hazardous and therefore do not need to be classified.

The bio-elution tests may provide useful information on cadmium release from pigments in an artificial environment. However, the methods are not internationally accepted and validated (i.e. equivalent to OECD test methods). In addition, the registrants have not provided any justification, substantiated with data, on the relevance and validity of these results to oral, dermal and inhalation absorption.

There are also limitations with respect to the read-across justifications presented and the use of the information of the "reference substance" cadmium telluride. For example, the classification of Acute tox 4 (Harmful if inhaled) was not read-across to the pigments from cadmium telluride. The 90-day inhalation toxicity and prenatal developmental toxicity information requirement for the cadmium pigments is read-across from a 28-day dose range finding study with cadmium telluride. The results meet the classification criteria for STOT RE 1. However, results from a 28-day study do not provide equivalent information to a 90-day toxicity and prenatal developmental toxicity information requirement. In addition, no NOEAC/NOAEL could be derived from this study. The lowest exposure concentration of 0.01 mg/L for 2 hours was considered to have had an adverse effect on the respiratory tract. However, the classification or the LOAEC value was not read-across from cadmium telluride to cadmium pigments.

Also, other toxicological endpoints suffer from limited read-across/weight of evidence justifications. Regarding potential carcinogenic properties, registrants refer to the non-genotoxic properties of cadmium telluride. The registrants claim, based on the hypothesis of the cadmium ion being the relevant component in cadmium pigments and results from bio-elution tests, that cadmium pigments in question are not similarly hazardous as cadmium substances that release more cadmium ions in bio-elution tests.

OEL/DNELs, as derived for the soluble cadmium substances, were used to some extent for the cadmium pigments in risk characterisation. However, the results from the bio-elution

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[26] http://echa.europa.eu/documents/10162/6c43dd5c-0803-4247-8f1f-74fd49085c65

[27] http://echa.europa.eu/documents/10162/b876c789-8fa0-4cf6-88c1-7bfeb027348d

test have also been used as an explanation in cases where exposure seems to be above the DNEL values, to argue that the DNEL values used are not actually valid for the cadmium pigments due to lower availability of the cadmium ion.

In conclusion, information requirements for cadmium pigments have been adapted in the registration dossiers with an approach based on the hypothesis that the cadmium ion is the most hazardous component of the pigments combined with a weight of evidence approach using information from bio-elution testing and read-across from cadmium telluride. However, there is insufficient data to conclude with confidence that the results from the bio-elution test adequately predict the toxicity of cadmium sulphoselenide red and cadmium zinc sulphide yellow. Therefore, the hazardous properties of cadmium pigments remain unclear. In order to get more clarity on the hazardous properties, ECHA intends to further assess the compliance of the two registered pigment according to the title VI of the REACH Regulation. Based on the assessment the substances might be considered for substance evaluation.

Uncertainties
Data in the registration dossiers of two cadmium pigments is insufficient to show and conclude with confidence that the results from the bio-elution test adequately predict the toxicity of cadmium sulphoselenide red and cadmium zinc sulphide yellow.

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

Not relevant as the pigments do not present any physic-chemical hazardous properties (e.g. flammability).

B.7 Environmental hazard assessment

This is not relevant for the current report, which focuses mainly on the hazards to human health. According to the harmonised classification of cadmium and its compounds there is potential risk of cadmium to the environment (see Section B.3). According to the registration information of the two cadmium pigments and based on transformation / dissolution test results, no need for classification for aquatic toxicity hazards was identified by the registrants. The registrants of cadmium pigments have used read-across approach for the assessment of environmental hazards of cadmium pigments (read-across to cadmium telluride). This aspect will not be further discussed in this report.

Annex 6 provides information submitted by the International Cadmium Association in August 2014.

B.8 PBT and vPvB assessment

PBT and vPvB assessment is not relevant for inorganic substances, hence it was not considered in this report.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

The exposure assessment proposed by the registrants relies on the hypothesis that the exposure to the cadmium ion is the determining factor linked to the potential hazards. Therefore, the results from *in vitro* bio-elution tests reflect human exposure, and results from transformation/dissolution testing in environmentally relevant conditions determine the environmental fate.

Therefore, the results from the bio-elution tests reported by the registrants, show that relatively low oral and dermal exposures, e.g. those in the order of the oral DNEL of 1 µg Cd/kg bw/day set by the registrants for consumers, can generally be considered of protective for potential risks of cadmium. The potential oral or dermal amounts absorbed will clearly be lower than the exposure that is considered to be relevant in the Swedish Annex XV SVHC dossier on cadmium (see footnote 24) and support document of the Member State Committee for identifying cadmium as SVHC (see footnote 25) (*i.e.* 0.5 µg Cd/g creatinine) after taking into account the results from the bio-elution test. For example, an oral exposure of pigments equivalent to 10 µg Cd/kg bw/day will lead to an uptake of less than 0.1 µg Cd/kg bw/day (based on the gastric bio-elution tests) and this would correlate to approximately 0.2 µg Cd/g creatinine. Cadmium excretion of 0.2 µg Cd/g creatinine is below the value of 0.5 µg Cd/g creatinine, whose causal relation with effects in humans is proposed in the Swedish Annex XV SVHC dossier on cadmium. However, the proposal is based on associations only and still needs further information for confirmation.

Keeping the oral (and dermal) exposure to pigments below 1 µg Cd/kg bw/day (the oral DNEL by the registrants) can therefore probably be considered to be safe. However, the oral DNEL proposed by the registrant is above the mean and 95th percentile of the dietary exposure of toddlers and adults (respectively around 0.93 µg Cd/kg bw/day and around 0.45 µg Cd/kg bw/day; EFSA, 2012[28]).

For consumers, direct exposure to cadmium pigments is not expected. Instead exposure would probably be caused by leaching of cadmium from plastics and subsequent exposure to cadmium. Some leaching studies have been done in the past with cadmium pigmented plastics. However, the results of these studies may not be relevant for the registered cadmium pigments, because it is not always known which cadmium pigments have been used in those leaching studies. Some cadmium pigments may be more soluble than the pigments considered in this Annex XV report.

Some of the leaching studies, e.g. Valadez-Vega *et al* (2011[29]) and Guo *et al* (2011[30]), are recent. However, they are not per se on plastics and not per se on products coloured with

[28] EFSA (2012): Cadmium dietary exposure in the European population, EFSA Journal;10(1):255
[29] Valadaz-Vega C*et al* (2011): Lead, Cadmium and Cobalt (Pb, Cd, and Co) Leaching of Glass-Clay Containers by pH Effect of Food, Int. J. Mol. Sci. 2011, 12, 2336-2350
[30] Guo J. *et al* (2012): Volatile Organic Compounds and Metal Leaching from Composite Products Made from Fiberglass-Resin Portion of Printed Circuit Board Waste, Environ. Sci. Technol. 2012; 46: 1028−1034

cadmium zinc sulphide yellow or cadmium sulfoselenide red. It is to be expected that the leaching from plastics with common household liquids (washing liquids, food) will not be much more than the leaching with gastric fluid, which is very acidic. Furthermore, when washing plastic material, large parts of the potential leached material will not lead to exposure of the consumers. Food contact with plastic tends to be of short duration, unless perhaps the contact is of food packaged in plastics for freezing. The effect of freezing on the possible leaching is unknown.

B.9.1.1 Summary of the existing legal requirements

Information on existing legal requirements is available in Annex 1.

B.9.2 Potentially relevant exposure scenario

B.9.2.1 Workers

Workers exposure to cadmium pigments in plastics and also to cadmium pigments as such are described in Annex 2.

B.9.2.2 Consumers / general population

Use of plastics

Although consumer plastics may be coloured using cadmium pigments, no specific evidence on the use of cadmium pigments in consumer articles was identified.[31] In the registration dossiers of cadmium pigments the environmental release category (ERC) is for the wide dispersive indoor use of long-life articles and materials with low release, which might suggest the consumer use of these plastic articles. Some of these plastics may be handled relatively intensively by consumers, e.g. pens. Some of the pigments may migrate in the plastic and leach from the plastic to the skin. If consumer products are used to contain foods or drinks or if they are directly mouthed (e.g. pens), oral exposure may also occur.

Other uses may indirectly lead to exposure, e.g. watering food crops via nozzles with cadmium pigments. Due to lack of information on the real consumer uses of plastics containing cadmium, hypothetical consumer exposure scenarios were developed which are described in the Annex 3.

Man exposed via the local environment

Some people may be exposed via the local environment. In theory, this could be relevant for potential exposure via inhalation of exhaust of incinerators in which plastic products are incinerated. However, studies did not find evidence for this hypothesis. This is further discussed in an Annex 3.

Man exposed via the wider environment

[31] The information from August 2014 indicated the consumer uses.

According to the registration dossiers of cadmium pigments the environmental release category (ERC) is for the wide dispersive outdoor use of long–life articles and materials with low release. The exposure to humans via the environment was calculated using the EUSES 2.1.2 model. The model describes the exposure during the service life of articles. However, it is recognised that there are many uncertainties of using the model. This is further discussed in Annex 4.

B.9.3 Exposure assessment for workers

Exposure assessment for worker prepared by the consultant is presented in Annex 2.

B.9.4 Exposure assessment for consumers

Even though no information was available on consumer applications of cadmium containing plastics, the available information on leaching of cadmium from plastics and other materials was reviewed and exposure assessment for consumers was evaluated using hypothetical exposure scenarios. This information is available in Annex 3.

In summary, the estimate of dermal exposure, recalculated to internal exposure, caused by handling a hard cover or a tablet computer for 4 hours per day is to 0.009 µg/kg bw/day for a 60 kg person (default bodyweight of females). This exposure is very far below the DNEL of 1 µg/kg bw/day*.* Even if this DNEL is (intended to be) an external value, calculated with a low oral absorption of 6%, the estimated value is still much lower.

The estimate of oral exposure caused by leaching of cadmium (pigment) into soup from a cooking spoon is 5.4 µg per day (for a 60 kg person this is 5.4/60 = 0.09 µg/kg bw/day), which is around 10% of the consumer oral DNEL. The corresponding value for a 12 kg toddler is 0.45 µg/kg bw/day which would equate to 45% of the consumer oral DNEL. Adding this value to the daily mean dietary exposure (0.69 µg/kg bw/day), the figure is 1.14 µg/kg bw/day which is above the DNEL of 1 µg/kg bw/day set by the registrants and 4-fold higher than DNEL of 0.25 µg/kg bw/day, corresponding to excretions of 0.5 µg Cd/g creatinine as proposed by Sweden. Thus, the exposure would increase by 65%.

During this study no evidence was found that cadmium pigments are used in in consumer articles. If this would be the case, the above examples show that for adults there need to be several plastic consumer articles containing cadmium pigments used per day before the DNEL set by the registrant is reached. However, for toddlers only exposure to a few articles might be enough to reach the DNEL.

The exposure due to leaching of cadmium pigments from nozzles of irrigation systems, leading to contamination of self-produced food, is probably much lower than the values mentioned above.

Uncertainties
The estimated leaching value used in calculations includes various uncertainties including

high variation. However, the value selected is considered to reflect the information available. However, as the exposure scenarios were hypothetical and no consumer uses of non-restricted plastics containing cadmium pigments were established, the conclusion cannot be considered to be equivalent to a conclusion following a conventional consumer exposure assessment.

B.9.5 Indirect exposure of humans via the environment

Indirect exposure of humans via the environment may occur due to the use of plastics containing cadmium pigments and their release during service life. Examples of potentially releasing 'sources' are underground cables with plastic coating containing pigments.

Separate calculation of the contribution of these materials to human exposures is too complex and too uncertain. Therefore, only a general calculation of exposure of humans via the environment can be done. This model describes the exposure from article service life and does not cover the manufacture of the article or the waste phase.

The calculations were done with EUSES 2.1.2 model, but due to many uncertainties the results are not regarded to be reliable. Information on the calculations can be found in Annex 4.

Uncertainties
The model results are highly uncertain. E.g. partition-coefficient values for the cadmium pigments are not available and it is uncertain if the values from cadmium used in the model adequately represents the pigments. Furthermore, even though the environmental release category (ERC) is, according to the registrants for wide dispersive outdoor use of long-life articles and materials with low release, it is uncertain how representative the model is for the pigments incorporated into the plastic materials.

B.10 Risk characterisation

One of the goals of the assessment presented in this document is to indicate whether there is increased exposure to cadmium and a significant risk for humans due to exposure to cadmium, in whatever form, as a result of use of cadmium pigments in plastics.

The risk can be assessed by comparing the potential exposure levels to the hazard limits. For the risks to workers, the potential inhalation exposure will be compared to the DNEL of 4 µg Cd/m^3 as used by industry and recommended by the Scientific Committee on Occupational Exposure Limits (SCOEL). The portion of increased exposure due to cadmium pigments used in plastics others than safety applications is challenging to estimate because those uses were not identified. However, to get a view of the size of the potentially increase in exposure, the whole amount of cadmium pigments used in plastics may be taken up for calculations.

For the general population, the potential exposures are compared to the oral DNEL of 1 µg Cd/kg bw/day. For the general population inhalation exposure of the pigments is rather unlikely and in the hazard assessment it was concluded by the registrant that this DNEL for these pigments could be considered a safe level, due to the very low bio-accessibility of cadmium from pigments via the oral and dermal routes. The dermal and oral absorption assumptions in the exposure estimations presented earlier do not yet account for this very low bio-accessibility.

B.10.1 Workers

The characterisation of risk to workers is included in Annex 2. The summary is presented below.

Based on the limited, and often rather old (referred to in the EU RAR, 2007), measured exposure levels, it can be concluded that workers in the production of cadmium pigments and those handling cadmium pigments in powder forms may be / have been exposed to levels above the inhalation DNEL of 4 µg Cd/m^3 and the recommended BLV of 2 µg Cd/g creatinine. In other work situations exposures are expected to be lower and are probably below the DNEL and the recommended BLV.

Based on these data, it cannot be excluded that there is a health risk for workers producing or handling cadmium pigments. However, the new information in the registration dossiers indicates that exposure to cadmium pigments during manufacture is carefully monitored to ensure minimal risk.

However, it should be noted that if workers were to be exposed to the DNEL of 4 µg Cd/m^3, this would equate to a daily intake of 0.57 µg/kg bw/day[32] which is comparable to the 95th percentile of the daily dietary intake of 0.45 µg/kg bw/day (see below). The total exposure of such workers would then be about 1.0 µg/kg bw/day, which is equal to the oral DNEL set by the registrants for the general population. Since this level, according to the registrants of the cadmium pigments, equates to about 2 µg/g creatinine, it would be about 4 times the level of 0.5 µg/g creatinine that according to the Swedish authorities (in the Annex XV SVHC dossier on cadmium) can be considered to be relevant as a potential basis for a limit value. This may challenge the DNEL of 1.0 µg/kg bw/day set by the registrant for consumers and suggests that the DNEL could be set at four-fold lower level, to 0.25 µg/kg bw/day in which would be the same as the mean daily intake of adults.

However, considering the 95th percentile of the daily dietary intake (0.45 µg/kg bw/day) the workers exposed to the DNEL of 4 µg Cd/m^3, corresponding to 0.57 µg/kg bw/day, would increase the daily exposure to cadmium by 100%, and is at the level of DNEL set by the

[32] Based on a typical inhalation rate of 1.25 m3/hour (default for light activity) for an 8 hour shift (default) and a body weight of a worker of 70 kg (default).

registrants but is higher than DNEL derived from proposal by Swedish authorities systemic effects such as osteoporosis and kidney effects.

B.10.2 Consumers and general population

There is no information available on consumer uses of cadmium pigments in plastics and consequently on exposure. Due to this lack of information, hypothetical exposure estimations were prepared. The model calculations are further hampered by the lack of reliable studies on the leaching of cadmium pigments from plastic materials, which is needed to give input parameters for the exposure estimations. The details of the hypothetical exposure estimations are presented in Annex 3 and the results are summarised below.

Consumers are generally not exposed to cadmium pigments, but may be exposed to cadmium leached from the pigments through handling of plastics. The general population may be exposed via the environment, either more or less directly, from the emissions of municipal waste incinerators, or indirectly, via various routes. It is to be noted that exposure of general population via municipal waste incinerators has not been verified in new studies.

The exposure can be compared to the DNEL of 1 µg/kg bw/day and/or the air quality standard target value of 0.005 $\mu g/m^3$. No biological limit values for general population are available. However, it can be assumed that the biological values in urine should at least stay clearly below the (worker) BLV of 2 µg Cd/g creatinine and preferably below the level of 0.5 µg/g creatinine that according to the Swedish authorities (in the Annex XV SVHC dossier on cadmium) can be considered to be relevant as a potential basis for a limit value.

The hypothetical estimate of dermal exposure to cadmium from cadmium pigments, recalculated to internal exposure, caused by handling a hard cover of a tablet computer for 4 hours per day is to 0.009 µg/kg bw/day for a 60 kg person (default bodyweight of females). This value is very far below the DNEL of 1 µg/kg bw/day. Even if this DNEL is (intended to be) an external value, calculated with a low oral absorption of 6%, the estimated value is still much lower.

The estimate of hypothetical oral exposure caused by leaching of cadmium from a cooking spoon coloured with cadmium pigment into soup from a cooking spoon is 5.4 µg per day is 5.4/60 = 0.09 µg/kg bw/day), which is around 10% of the consumer oral DNEL. The corresponding value for a 12kg toddler is 0.45 µg/kg bw/day which would equate to 45% of the consumer oral DNEL. Adding this value to the daily mean dietary exposure (0.69 µg/kg bw/day), the figure is 1.14 µg/kg bw/day which is above the DNEL of 1 µg/kg bw/day set by the registrants and 4-fold higher than DNEL of 0.25 µg/kg bw/day, corresponding to excretions of 0.5 µg Cd/g creatinine as proposed by Sweden. Thus, the exposure would increase by 65%.

The leaching of cadmium from cadmium pigments in plastics is variable. Leaching experiments carried out with plastic material ground to particles with different sizes showed variations in leaching of a factor of plus-minus 5. It may be estimated that leaching of cadmium may be 5 times higher or lower than the value used in calculations above.

During this study no evidence was found that cadmium pigments are used in consumer articles. If consumers did use cadmium pigmented plastics, the hypothetical examples above suggest that for adults there would need to be several plastic consumer articles containing cadmium pigments used per day before the DNEL set by the registrant would be reached. However, for toddlers only exposure to few articles might be enough to reach the DNEL.

The hypothetical exposure due to leaching of cadmium pigments from nozzles of irrigation systems, leading to contamination of self-produced food, is probably much lower than the values mentioned above.

A rough estimation of exposure to humans via the environment with the EUSES 2.1.2 model was used. However, due to many uncertainties in using the model, the results, which show an increase in the total daily intake of cadmium due to the use of these cadmium pigments in plastics, were not considered reliable enough.

B.10.3 Dietary exposure to cadmium in Europe

To put the estimates of human exposure potentially caused by use of cadmium pigments into perspective, the values can be compared to those of dietary exposure to cadmium in Europe. EFSA has made an assessment of dietary exposure to cadmium (EFSA, 2012[33]).

The medians of the 'middle bound means' and 'middle bound 95th percentile' of dietary cadmium exposure were estimated to be highest for toddlers (1-2 year olds with a mean weight of 12kg), with a 'mean' of 4.80 µg/kg bw/week and a 95th percentile of 6.50 µg/kg bw/week (or around 0.69 and 0.93 µg/kg bw/day) and the values for adults were respectively 1.77 and 3.13 µg/kg bw/week (or around 0.25 and 0.45 µg/kg bw/day).

The (very) conservative estimates of hypothetical direct consumer exposure to cadmium via handling of plastics containing cadmium pigments are less than half of the values for adults (with two examples the 'mean' daily exposure level increases up to 0.35 µg/kg bw/day) and for toddlers with one example the 'mean daily exposure level increases up to 1.14 µg/kg bw/day. The estimated leaching value used in calculations includes various uncertainties including high variation. However, the value selected is considered to reflect the information available. These estimates do not account for the very low leaching of cadmium expected from these particular pigments, which is suggested by the very low bio-accessibility of cadmium from the pigments via gastric fluid and sweat. Real internal exposures to cadmium caused by use of these pigments in plastics are expected to be much lower than the calculated values, because the assumptions on leaching are conservative. Furthermore, as the bio-accessibility of the cadmium in pigments in plastics are much lower than other more

[33] EFSA (2012): Cadmium dietary exposure in the European population, EFSA Journal;10(1):255.

common and more soluble cadmium compounds based on the bio-elution tests, the actual effects are likely to be lower than those predicted for other cadmium compounds.

The value for indirect exposure to cadmium via the environment caused by plastics containing cadmium pigments showed also increase of daily exposure but due to many uncertainties in using the model, the result was considered to be unreliable.

Uptake of cadmium can occur in humans via the inhalation of polluted air, the ingestion of contaminated food or drinking water and, to a minor extent, through exposure of the skin to dusts or liquids contaminated by the element (ECB, 2008; SCOEL, 2010).

In occupational settings, mainly inhalation exposure occurs although the dermal route may also play a role when metal, powder or dust is handled or during maintenance of machinery. Additional uptake is possible through food and tobacco (for example in workers who eat or smoke at the workplace).

For the general population, uptake of cadmium occurs principally via the ingestion of food or, to a lesser extent, of contaminated drinking water. In industrial sites polluted by cadmium, inhalation of air and/or ingestion of soil or dusts may contribute to significant exposure. Tobacco is an important additional source of cadmium uptake in smokers. Finally, the consumer could be exposed (skin, inhalation or oral) through the use of consumer products.

B.11 Summary on hazard and risk

The use of cadmium and its compounds in pigments probably accounts for less than 10% of the cadmium used (whether manufactured, imported, processed or used) within the EU.

Cadmium and some cadmium compounds, including cadmium sulphide, are considered to be carcinogens and toxic to the reproduction. The REACH registration dossiers of cadmium, cadmium oxide and cadmium sulphide contain DNELs of 4 µg/m³ (long-term inhalation workers for non-cancer effects) and 1 µg/kg bw/day (long-term oral general population). The same DNELs are used by the registrants for the cadmium pigments. According to the Swedish Annex XV SVHC dossier on cadmium, there are indications that the current DNEL values used for long term non-carcinogenic effects might not be sufficiently protective. The support document of the Member State Committee for identifying cadmium as SVHC[34] states that "*…new findings on hazards and risks connected with cadmium and its compounds continuously appear. As an example, effects on bone tissue have recently been shown at exposure levels previously considered without effects.*"

Cadmium pigments are exempted from the generic cadmium compounds classification entry and therefore industry has to self-classify these pigments.

[34] http://echa.europa.eu/documents/10162/b876c789-8fa0-4cf6-88c1-7bfeb027348d

The chemical safety assessment was performed for the registration of two cadmium pigments. That assessment concluded that the pigments are not hazardous and that there are no risks during the production and use of these substances. However, the approach used by the registrants combining weight of evidence considerations (results from bio-elution tests) with the read-across information from cadmium telluride is questionable and the hazardous properties (especially with long term inhalation) of cadmium pigments are thus still unclear. In order to get more clarity on the hazardous properties, ECHA intends to further assess the compliance of the two registered pigment according to the title VI of the REACH Regulation. Based on the assessment the substances might be considered for substance evaluation.

Exposure of workers to cadmium can occur in the production of cadmium pigments and in the use of those pigments as well as in the service life, recycling, disposal or incineration of the plastics. Very limited actual information on the exposure levels for workers could be found in open literature sources. The measured data found is in general rather old (at least 10 years old or much older) and may not be relevant for present practice. However, the registration dossiers of cadmium pigments state that exposure levels for workers in cadmium pigment manufacture are strictly controlled and routinely monitored to ensure a safe working environment. The probability of a risk for workers further down the supply chain is considered to be much smaller, due to the expected much lower exposure to pigment dust. Relatively recent data of workers in municipal incinerators do not show that these workers have relevant exposure to cadmium.

Actual information on uses of cadmium pigments in plastic materials (other than claims for safety reasons) and therefore consumer exposure due to handling of plastics as well as actual information on indirect exposure via the environment is not available, except some data on biological monitoring of people in the vicinity of municipal waste incinerators. Their uptake of cadmium does not appear to be substantially increased due to living in the vicinity of the incinerators.

Hypothetical estimations of consumer exposure due to handling of plastics have been made. For this purpose, information on leaching of cadmium (from pigments or in some cases potentially from stabilisers) from plastics as well as some other materials has been studied. Many factors influence leaching, but the pH of the leachate appears to be a very important factor. There are therefore indications that the ingestion of plastic particles leads to higher leaching (and potentially absorption) than leaching due to contact with water or sweat and subsequent dermal or oral exposure.

Estimates with conservative to very conservative assumptions (largely based on expert judgement) have been made. The highest estimates of consumer exposure due to more or less direct contact with a number of probably 'worst case' plastic articles, such as a cover of a tablet computer and a cooking spoon, are around 10% of the oral DNEL for adults (1 μg/kg bw/day set by the registrants) and 45% for toddlers. These estimates were also compared to estimates of dietary intake of cadmium in Europe and equate to about 35% and 65% of the mean dietary intakes for adults and toddlers respectively. When adding these examples of exposure to the mean dietary intakes, the levels increase up to 0.35 μg/kg bw/day (adults) and up to 1.14 μg/kg bw/day (toddlers). The estimated leaching value used in calculations includes various uncertainties including high variation. The value selected is considered to reflect the information available. However, as the exposure scenarios were hypothetical and no consumer uses of non-restricted plastics containing cadmium pigments were identified, the conclusion cannot be drawn for the real examples of consumer uses.

The value for exposure to cadmium via the environment caused by plastics containing cadmium pigments showed also increase of daily exposure but due to many uncertainties in using the model, the result was considered to be unreliable.

Cadmium in urine levels in people living in the vicinity of a municipal waste incinerator were relatively close to the Biological Limit Value for workers recommended by the EU SCOEL. However, since their exposure does not appear to be caused by the incinerator and also waste can contain several other cadmium sources, this does not imply that incinerating plastics containing cadmium pigments increases the potential risks of cadmium exposure.

The key elements for risk characterisation are still unclear. There is lack of clarity about in which plastics and plastic articles the cadmium pigments are used. The hazards of the cadmium pigments are not clear and the information in the registration dossiers of cadmium pigments does not allow a comprehensive evaluation. There is also no information on the potential exposure to cadmium and cadmium pigments in plastics during uses. The exposure to cadmium from plastics via the environment has been modelled, but the calculations contain many uncertainties and the results were considered to be unreliable. Based on the above it has not been possible to conclude unequivocally that cadmium and cadmium compounds in plastic materials not covered by the entry 23 to REACH Annex XVII do not pose a risk to human health or the environment.

The information provided by the International Cadmium Association in August 2014 (Annex 6) on the draft Annex XV report submitted to the CARACAL-15 stated that the remaining uses of cadmium pigments in non-restricted plastics are in articles which are regulated by the Toys directive, RoHS directive and End-of Life Vehicles directive.

It should be noted that ECHA was unable to obtain any information on the users of cadmium pigments, only from the International Cadmium Association. In other words, ECHA was unable to verify or corroborate the information that it has received during consultations. However,

i) given the hazard related to these cadmium compounds has not been established and

ii) given that ECHA has not been able to obtain satisfactory information of the uses of cadmium in plastics,

ECHA is unable to conclude whether an unacceptable risk exists to human health or the environment exists on cadmium, which would need to be addressed on a Union wide basis.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

There have been restrictions on the use of cadmium pigments in many plastic materials for over 20 years. This has given the affected industries many years to develop and use alternative pigments, which most industries appear to have done.

In respect of the plastics newly specified in Regulation 494/2011, it is possible that the affected industries may have experienced some difficulties finding alternatives. However, based on the consultant consultation, it suggests that alternatives are readily available – even in areas where it was possible that derogations for safety reasons could be considered (see Box below).

Safety Derogation Not Required
One of the UK's leading manufacturers of safety helmets produces a wide range of brightly coloured HDPE safety helmets including red, orange and yellow ones to the highest safety standards. Discussion with the manufacturers indicated that cadmium pigments are not used.
Source: Internet search and follow-up telephone discussion (4 April 2013)

Interestingly, for those producing coloured plastics which could be associated with electric and electrical equipment, many companies have switched to 'cadmium-free' pigments due to customer demands in respect of ensuring compliance with RoHS requirements.

The information provided in the following sections on alternatives is of general nature and does not take into account the possible demands of individual plastics.

Moreover as a potential alternative the article producers could consider the use of totally different colours.

C.2 Assessment of alternatives

Alternatives are readily available and some examples are presented in Table 9.

Table 9

Examples of Alternatives to Cadmium Pigments for Use in Plastics			
Name	**Colour**	**EC Number**	**CAS Number**
Lead sulphochromate	Yellow/Orange	215-693-7	1344-37-2
Lead chromate molybdate sulphate red	Red	235-759-9	12656-85-8
Perinone orange	Orange	224-597-4	4424-06-0
Quinophthalone yellow	Yellow	250-063-5	30125-47-4
Antimony nickel titanium oxide yellow	Yellow	232-353-3	8007-18-9
Bismuth vanadate	Yellow	237-898-0	14059-33-7
Quinacridone	Red	213-561-3	980-26-7
Sources: *1) Discussions with plastics manufacturers, internet searches, etc.* *A comprehensive introduction to potential alternatives by colour is provided by SpecialChem, http://www.specialchem4coatings.com/tc/color-handbook/index.aspx*			

Clearly, given the very wide range of plastics and associated uses under consideration, it is not feasible to identify the 'best' candidates for alternatives to cadmium pigments for each and every plastic/application. Rather, the intention is to demonstrate that there is a range of alternatives available.

As can be seen from Table 9, there is a mixture of inorganic and organic pigments. The list includes two lead chromates but these are unlikely to be considered attractive alternatives due to their inherent toxicity and because they have been identified as SVHC and may potentially be recommended in future inclusion in the authorisation list under REACH.

C.2.1 Human health risks

Lead sulphochromate

Lead sulphochromate has been registered under REACH. It also has a harmonised classification in Annex VI of Regulation (EC) No 1272/2008 with the following human health effects:

Carc. 1B, H350
Repr. 1A, H360fd
STOT RE 2, H373

The long term worker inhalation DMEL that the registrants have derived is 6 µg/m³. No DNELs have been derived for the general population.

Lead chromate molybdate sulphate red

This substance has the same harmonized classification as lead sulphochromate, so it is also considered to be a carcinogen and reprotoxic agent. It is also registered under REACH and the same DNEL has been derived as for lead sulphochromate: 6 µg/m³ (inhalation, long-term, workers).

Perinone orange

According to self-classification by 301 notifiers, perinone orange (bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione) is not classified. No toxicity data is available at the Hazardous Substance Database (HSDB) . There are a few reports of contact dermatitis caused by a perinone-type dye in plastics (Shono & Kaniwa, 1999[35]; Yeo *et al*, 2011[36]). This substance is not in the database of registered substances at ECHA.

Quinophthalone yellow

Quinophthalone yellow (3,4,5,6-tetrachloro-N-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolyl]phthalimide) has been registered under REACH. Only a long-term worker DNEL via the dermal route of 3.33 mg/kg bw/day and a long-term general population DNEL via the dermal route of 1.67 mg/kg bw/day have been derived for this substance. According to self-classification of a large number of notifiers, this substance is not classified for human health hazards. There are a few reports of contact dermatitis caused by a quinophthalone-type dye in plastics (Komamura *et al*, 1989[37]; Noster and Hausen, 1978[38]).

Antimony nickel titanium oxide yellow

Self classification of antimony nickel titanium oxide yellow by the majority of notifiers indicates that the substance is not classified. A relatively large group of notifiers reported

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[35] Shono M & Kaniwa MA (1999): Allergic contact dermatitis from a perinone-type dye C.I. Solvent Orange 60 in spectacle frames, Contact Dermatitis, 41(4): 181-4
[36] Yeo L *et al* (2011): Allergic contact dermatitis caused by Solvent Orange 60 dye, Contact Dermatitis, 4(6):354-6.
[37] Komamura H *et al* (1989): Allergic contact sensitivity to quinophthalone, Contact Dermatitis, 20(3): 177-81
[38] Noster U & Hausen BM (1978): Occupational dermatitis due to a yellow quinophthalone dye (solvent yellow 33: C.I. 47 000), Hautarzt; 29(3): 153-7

acute toxicity (Acute Tox. 4). Some notifiers only mention skin and eye irritation, but some others notify skin and respiratory sensitization and carcinogenicity (Carc. 1A). However it should be noted that a major study into 'titanium yellow' has concluded that it is effectively inert with virtually no indications of toxicity[39].

The substance has also been registered under REACH. In the registration dossier, the substance is reported to be not classified. The worker inhalation long-term DNEL has been set at 4 mg/m3.

Bismuth vanadate

Bismuth vanadate or bismuth vanadium tetraoxide is registered under REACH. The worker inhalation long-term DNEL has been set at 0.02 mg/m3 and the long term inhalation general population DNEL at 0.005 mg/m3. A hazard via the oral route for the general population is covered by a DNEL of 20 mg/kg bw/day. The majority of notifiers in the C&L notification database reports a classification of STOT RE 2, H373.

Quinacridone

Quinacridone or 5,12-dihydro-2,9-dimethylquino[2,3-b]acridine-7,14-dione, according to the majority of notifiers in the C&L notification database, is not classified. Some notifiers mention skin irritation, eye irritation or eye damage. The substance has also been registered under REACH. The long term DNEL via inhalation for workers is set at 147 mg/m3 and the long term DNEL via dermal for workers at 42 mg/kg bw/day. For the general population there is a dermal and an oral long term DNEL of (both) 25 mg/kg bw/day.

The human health risks associated with alternative pigments will vary depending on the nature of the particular pigment. As has already been mentioned, some chromate pigments may be considered as alternatives to cadmium pigments but these may also be considered to present significant risks to human health.

C.2.2.1 Overview of possible risks of alternatives

Regarding the risks of alternative substances, the most relevant part for comparison with the cadmium pigments is the hazard, because all of these substances are solids and for handling in worker exposure situations the expected exposures will be similar as for the cadmium pigments.

For exposure via leaching from plastics no information has been gathered on the alternatives (yet). Information on leaching of lead from plastics and other materials does exist, but for the other substances this is not yet studied.

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[39] OECD-SIDS (2002): SIDS Initial Assessment Report on CI Pigment Yellow 53 (CAS 8007-18-9), report presented by Japan to SIAM 15 as part of OECD HPV Chemicals Programme

The two lead substances are classified as carcinogens and substances toxic to reproduction. They also have a DNEL in the same order of magnitude of that of cadmium sulphide. Therefore, they do not appear to be attractive alternatives when considering a need to reduce the risks.

Bismuth vanadate has a relatively 'severe' classification (STOT RE 2) and inhalation DNELs that are somewhat higher than those of cadmium sulphide. However, the DNELs are still rather low and therefore this substance might not be the most logical alternative from a human health risk point of view.

The other substances are, according to the majority of notifiers, not classified and where there is a REACH registration, the relevant DNELs are relatively high or very high. From a human health risk perspective, based on the very limited information available, these substances could be very relevant alternatives to cadmium pigments.

When looking at alternatives, based on DNELs and classification, it has to be considered that the two cadmium pigments under specific consideration are also not classified (self-classification).

C.2.3 Environment risks

As for the human health risks, the risks to the environment associated with alternative pigments will vary depending on the nature of the particular pigment. However, it is important to note that, by definition, pigments are essentially insoluble in water and organic solvents. As such, extensive dispersion through the environment would not generally be expected.

C.2.4 Technical and economic feasibility of alternatives

There is a broad consensus that cadmium pigments offer intense colours, excellent durability and heat resistance. The importance of these particular attributes will vary by plastic and by application. In some cases, the heat resistance may be a key feature as the plastic processing may take place at high temperatures. In other cases, the colour brightness and/or its resistance to fading may also be important.

In some cases, changing to alternatives may lead to other unexpected consequences. By way of example, during consultation for this study, one plastics manufacturer noted that the switch from cadmium to organic pigments had led to increased quantities of residue on the process plant equipment which required additional time and resources for cleaning after production runs. Similarly, another plastics manufacturer noted that the effectiveness of rotational moulding for HDPE tanks had been impaired when moving from the use of cadmium pigments to alternatives.

Overall, responses to consultation for this study suggest that replacing red cadmium pigments is not only the most difficult from a technical point of view but is also the most expensive with cost estimates of a 40-50% increase in pigment costs. Alternatives to yellow (and orange) cadmium pigments were also found to be more expensive with estimates of 10-20% increase in pigment costs.

C.2.5 Other information on alternatives

Although alternatives to cadmium pigments may not be quite so intense and durable, it is important to note that the colour itself does not enhance the durability or performance of the associated plastic.

However, several respondents to the consultation undertaken by both ECHA and the consultant have highlighted concerns from the aviation industry as illustrated in Box below.

Safety Derogation for Aviation
The colour of wire/cables is regulated by industry standards. Colours are required to have a high thermal stability and durability as the wire/cable are often used in high temperature applications and over a timeline of several decades. Due to their physical properties the use of cadmium based pigments in such applications has been essential to ensure easy visual identification of the wires/cables within the aircraft and to ensure safe identification and handling of wires/cables during maintenance.
Source: Quote taken from response to ECHA's 'Call for Evidence' (February 2013)

It should be noted that 'cadmium-free' cabling and wiring is required under the RoHS Directive and that many manufactures appear to be moving towards cadmium-free plastics to ensure compliance with the RoHS Directive and other legislation. Furthermore, no exemptions have been granted under the RoHS Directive on the grounds of colour for wiring or other electrical components. However, the use of wiring in aviation is exempt from the RoHS Directive as it does not apply to transport in general.

Aviation wiring has been granted an exemption[40] from the proposed restriction on safety grounds.

D. Justification for action on a Union-wide basis

Because non-regulated uses of cadmium and cadmium compounds in plastics were not identified and hazardous properties of cadmium pigments (the only identified function of cadmium compounds in plastics) are unclear, it is not possible to propose a restriction.

If unacceptable risks are shown, any further action on cadmium and its compounds in plastics is of concern in the whole Union as the plastics are assumed to be used in all EU Member States.

[40] Aviation wiring is exempt from the current restrictions on safety grounds as indicated in ECHA Q&As No 825 accessible from: http://echa.europa.eu/support/qas-support/search-qas

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

Not applicable for the report.

F. Socio-economic Assessment of Proposed Restriction

Not applicable for this report.

G. Stakeholder consultation

During the preparation of this report, there have been several rounds of consultation and inputs from stakeholders.

Under the first round of REACH registration (which formally closed on 30 November 2010), ECHA received over 90 registration dossiers for cadmium and nine of its compounds (cadmium carbonate, cadmium oxide, cadmium hydroxide, cadmium sulphide, cadmium chloride, cadmium sulphate, cadmium nitrate, cadmium tin oxide and dicadmium tin tetraoxide). ECHA and, subsequently, its consultants have screened the IUCLID database for these dossiers and found that most dossiers have not identified uses of cadmium compounds in polymers/plastics.

ECHA contacted all Member State Competent Authorities in May 2012 and asked for information on any current uses of cadmium or of its compounds in plastic materials other than the 16 already regulated. ECHA received only eight replies and the replies did not generally provide any significant information. ECHA also sent questions to eight industry associations, four or which replied.

An on-line questionnaire was launched in January 2013 and e-mail invitations were sent out to eight associations and 29 companies. This was followed up by reminders as well as contacts with other relevant organisations. In total, about 20 responses were received.

A 'Call for Evidence' was also made on the ECHA website in January 2013, which produced six responses.

To provide additional information on the use of cadmium pigments in plastics, over 40 plastics companies were approached by email and phone in April 2013 to try and elicit further information on the use and non-use of cadmium pigments in plastics. A further 12 responses were received.

Further information on two cadmium pigments (cadmium sulphoselenide red and cadmium zinc sulphide yellow) were provided in six registration dossiers submitted in May 2013. ECHA launched a final 'Call for Further Evidence' on its website in July 2013, which produced four responses but did not provide any significant new information.

ECHA forwarded the draft Annex XV report (dated 30 June 2014) to the Commission, Member State Competent Authorities and stakeholders for discussions at the 15th Meeting of

Competent Authorities for REACH and CLP (CARACAL) in 8-9 July 2014. The MSCAs were requested to provide their views on the proposed ways forward and in particular on the specific questions posed in a document CA/63/2014 'Commission's request to ECHA to prepare a restriction proposal on cadmium and its compounds in plastics'. ECHA received comments from several MSCAs on the ways forward; however this information is not included in this report. In addition, ECHA received comments from the International Cadmium Association on the Annex XV report. This comment is annexed (Annex 6) to this report and information is referenced in the relevant parts of the report.

H. Other information

No other information included.

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This reference list includes also studies referred to in the confidential document on sections B.4-B.5.

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Annex 1 - Summary of existing legal requirements

Council Resolution

Before the legislative actions on cadmium, in 1988, a Council Resolution[41] created a common aim and strategy in the EU regarding cadmium control in the interests of the protection of human health and the environment. Part of this strategy was the "*limitation of the uses of cadmium to cases where suitable alternatives do not exist*".

Directive 91/338/EEC

In 1991, the Resolution was followed by Directive 91/338/EEC[42] (the 'Cadmium Directive') which limits the use of cadmium as a pigment in a range of plastics, as a stabiliser in polymers or co-polymers of vinylchloride in certain finished products and in cadmium plating with derogations where cadmium was being used for safety reasons. For pigments, the restrictions are listed in Table 2-1.

Table 1-1

RESTRICTION ON CADMIUM PIGMETNS IN PLASTICS FROM DIRECTIVE 91/338/EEC **Cadmium (CAS No 7440-43-9) and its compounds may not be used to give colour to finished products manufactured from the substances and preparations listed below**	
from 31 December 1992: - polyvinyl chloride (PVC) [3904 10] [3904 21] [3904 22]* - polyurethane (PUR) [3909 50] - low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] - cellulose acetate (CA) [3912 11] [3912 12] - cellulose acetate butyrate (CAB) [3912 11] [3912 12] - epoxy resins [3907 30]	*from 31 December 1995:* - melamine-formaldehyde (MF) resins [3909 20] - urea-formaldehyde (UF) resins [3909 10] - unsaturated polyesters (UP) [3907 91] - polyethylene terephthalate (PET) [3907 60] - polybutylene terephthalate (PBT) - transparent/general-purpose polystyrene [3903 11] [3903 19] - acrylonitrile methylmethacrylate (AMMA) - cross-linked polyethylene (VPE)

[41] Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium (88/C30/01)
[42] Council Directive 91/338/EEC of 18 June 1991 amending for the 10th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

	- high-impact polystyrene - polypropylene (PP) [3902 10]
In any case, whatever their use or intended final purpose, finished products or components of products manufactured from the substances and preparations listed above coloured with cadmium may not be placed on the market if their cadmium content (expressed as Cd metal) exceeds 0.01% by mass** of the plastic material	
These restrictions do not apply to products to be coloured for safety reasons	
*Note: * Tariff codes as in Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Tariff (OJ No L 256, 7.9.1987)* *** 0.01% is equivalent to a concentration of 100 mg/kg or 100 parts per million (by weight)* *Source: Annex to Directive 91/338/EEC*	

It is important to note that the list of plastics presented in Table 2-1 is by no means an exhaustive list of the range of plastics on the EU market.

Directives 2002/95/EC and 2011/65/EU

The Restriction of Hazardous Substances (RoHS) Directive[43] took effect from July 2006 and required Member States to ban the presence of six substances (lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE) and cadmium) in new electrical and electronic equipment. A Commission Decision of 2005[44] clarified that the associated concentration limits would be 0.01% by weight for cadmium (i.e. the same limit as introduced Directive 91/338/EEC) and 0.1% for the other substances.

Directive 2002/95/EC has been updated and has now been replaced by Directive 2011/65/EU[45]. The recast Directive includes several exemptions also for cadmium and its compounds relating to specialist applications.

However, it is also important to note that the RoHS Directive does not apply to some significant areas of electrical equipment including military, space, transport, large-scale

[43] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
[44] Commission Decision of 18 August 2005 amending Directive 2002/95/EC of the European Parliament and of the Council for the purpose of establishing the maximum concentration values for certain hazardous substances in electrical and electronic equipment
[45] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)

stationary industry tools, large-scale fixed installations and equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive.

Regulation 1907/2006

Directive 76/769/EEC and its amendments were repealed and replaced by the REACH Regulation of 2006[46]. Annex XVII of the REACH Regulation lists the *Restrictions on the Manufacture, Placing on the Market and use of Certain Dangerous Substances, Preparations and Articles*. Entry 23 for cadmium and its compounds reproduces the restrictions from Directive 91/338/EEC as presented in Table 2-1.

Directive 94/62/EC and Decision 2009/292/EC

The Packaging Directive (94/62/EC[47]) introduced concentration limits of heavy metals (including cadmium) present in packaging. However, derogation was granted to allow the continuing circulation and recycling of plastic crates/pallets (such as beer crates) with (relatively) significant levels of heavy metals – including cadmium, in order to prevent such items entering landfill or being incinerated. It should be noted that these are typically made out of HDPE.

Following a detailed analysis for DG Environment[48], the derogation was extended by Decision 2009/292/EC[49] which states that:

> *The sum of concentration levels of heavy metals in plastic crates and plastic pallets may exceed the applicable limit laid down in Article 11(1) of Directive 94/62/EC provided that those crates and pallets are introduced and kept in product loops which are in a closed and controlled chain under the conditions set out in Articles 3, 4 and 5.*

The current concentration limit imposed by Directive 94/62/EC is that the sum of the concentrations of four heavy metals (lead, cadmium, mercury and hexavalent chromium) must not exceed 100 ppm (as from July 2001). Thus, in presence of the other heavy metals, the limit for packaging material other than the exempted plastic crates and pallets is stricter than the 100 ppm for cadmium alone set by Directive 91/338/EEC.

Directive 2009/48/EC

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[46] 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

[47] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

[48] Bio Intelligence Services (2008): Study to Analyse the Derogation Request on the use of Heavy Metals in Plastic Crates and Plastic Pallets, report for DG Environment, dated September 2008

[49] Decision 2009/292/EC: Commission Decision of 24 March 2009 establishing the conditions for a derogation for plastic crates and plastic pallets in relation to the heavy metal concentration levels established in Directive 94/62/EC on packaging and packaging waste

Toys have been subject to strict EU regulation for many years. The original Toy Safety Directive 88/378/EEC[50] introduced specified bioavailability limits for eight heavy metals including cadmium. After 20 years, the Directive was overhauled and replaced by Directive 2009/48/EC[51] which came into force in July 2011.

The new Toy Safety Directive now specifies migration limits for 19 different metals including cadmium. The migration limits for cadmium were subsequently reduced by Directive 2012/7/EU[52] as shown in Table 2-2.

Table 1-2

RESTRICTION ON CADMIUM MIGRATION (in mg/kg) FROM TOYS AND THEIR COMPONENTS			
Directive	**in dry, brittle, powder-like or pliable toy material**	**in liquid or sticky toy material**	**in scrapped-off toy material**
2009/48/EC	1.9	0.5	23
2012/7/EU	1.3	0.3	17

The migration is measured using procedures set out in a new (draft) standard[53] in which toy material is immersed in hydrochloric acid (to simulate gastric juices) and the resultant concentration of cadmium (and the other restricted metals) is then measured. Cadmium pigments could be used in plastics which are used in toys if they pass the migration test.

Directive 2000/53/EC

The objective of the Directive 2000/53/EC[54] on end-of life vehicles (ELVs) is to prevent waste from vehicles and reduce the disposal of waste by encouraging reuse, recycling and other forms of recovery of end-of life vehicles and their components. The aim is also to improve the environmental performance of operators involved in the life cycle of vehicles and especially those involved in the treatment of ELVs. A definition of 'vehicle' falling within the scope of the directive is given in the article 2(1). According to recital (8), spare parts and replacement parts, without prejudice to safety standards, air emissions and noise control are also covered by the directive. Recital (10) states that vintage vehicles, meaning

[50] Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys
[51] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys
[52] Commission Directive 2012/7/EU of 2 March 2012 amending, for the purpose of adaptation to technical progress, part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council relating to toy safety
[53] CEN (2012): Safety of toys - Part 3: Migration of certain elements, currently in Draft (prEN 71-3 rev)
[54] Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (consolidated version, dated 11.06.2013)

historic vehicles or vehicles of value to collectors or intended for museums are not covered by the definition of waste and are thus outside the scope of the directive.

Article 4 relates to prevention of waste and article 4(2)(a) states that Member States shall ensure that materials and components of vehicles put on the market after 1 July 2003 do not contain lead, mercury, cadmium or hexavalent chromium other than in cases listed in Annex II. Annex II exempts cadmium in batteries for electrical vehicles as spare parts for vehicles put on the market before 31 December 2008. Spare parts put on the market after 1 July 2003 which are used for vehicles put on the market before 1 July 2003 are also exempted. A maximum concentration of cadmium of up to 0,01 % by weight of homogenous material is tolerated. The intention of the Directive is to cover cadmium and its compounds (as is clear from the treatment of lead in Annex II where exemptions are granted not only for lead but also for lead compounds). Thus cadmium pigments may be used in materials and components of vehicles only when there are specific exemptions (e.g. spare parts, concentration limit).

Regulation 494/2011

Entry 23 to Annex XVII of the REACH Regulation was modified by Regulation 494/2011[55]. The modifications to Entry 23 relating to cadmium pigments are summarised in Table 1-3 (overleaf).

Apart from minor word changes, the three key changes are:

- the merging of the restrictions of cadmium and its compounds as a pigment and as a stabiliser (and including any other function) into a single set of restrictions;
- the extension of the list of plastics to include three new specified groups (HDPE, ABS and PMMA) as highlighted in bold in Table 2-3 as well as, apparently, other plastics; and
- the exemptions granted to recovered PVC (due to the extensive historic use of cadmium as a stabiliser in PVC).

Table 1-3

RESTRICTIONS ON CADMIUM AND ITS COMPOUNDS IN PLASTICS FROM REGULATION 494/2011 **Cadmium (CAS No 7440-43-9; EC No 231-152-8) and its compounds shall not be used in mixtures and articles produced from synthetic organic polymers (hereafter referred to as plastic material) such as:**

[55] Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium)

RESTRICTIONS ON CADMIUM AND ITS COMPOUNDS IN PLASTICS FROM REGULATION 494/2011 **Cadmium (CAS No 7440-43-9; EC No 231-152-8) and its compounds shall not be used in mixtures and articles produced from synthetic organic polymers (hereafter referred to as plastic material) such as:**	
- polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]* - polyurethane (PUR) [3909 50] - low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] - cellulose acetate (CA) [3912 11] - cellulose acetate butyrate (CAB) [3912 11] - epoxy resins [3907 30] - melamine-formaldehyde (MF) resins [3909 20] - urea-formaldehyde (UF) resins [3909 10] - unsaturated polyesters (UP) [3907 91]	- polyethylene terephthalate (PET) [3907 60] - polybutylene terephthalate (PBT) - transparent/general-purpose polystyrene [3903 11] - acrylonitrile methylmethacrylate (AMMA) - cross-linked polyethylene (VPE) - high-impact polystyrene - polypropylene (PP) [3902 10] - **high-density polyethylene (HDPE) [3901 20]** - **acrylonitrile butadiene styrene (ABS) [3903 30]** - **poly(methyl methacrylate) (PMMA) [3906 10]**
Mixtures and articles produced from plastic material shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.01 % by weight of the plastic material**	
These restrictions shall not apply to articles coloured with mixtures containing cadmium for safety reasons	
The cadmium concentration limit of 0.01% shall not apply to: - mixtures produced from PVC waste, hereinafter referred to as "recovered PVC", mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0.1 % by weight of the plastic material in a range of specified rigid PVC applications (mostly related to building materials)	

RESTRICTIONS ON CADMIUM AND ITS COMPOUNDS IN PLASTICS FROM REGULATION 494/2011

Cadmium (CAS No 7440-43-9; EC No 231-152-8) and its compounds shall not be used in mixtures and articles produced from synthetic organic polymers (hereafter referred to as plastic material) such as:

*Note: Tariff codes as in Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Tariff (OJ No L 256, 7.9.1987,** 0.01% is equivalent to a concentration of 100 mg/kg or 100 parts per million (by weight)*

Source: Annex to Regulation 494/2011

Regulation 835/2012

Following the Regulation 494/2011, the Commission was informed of uses of cadmium pigments in certain types of plastic materials, restricted for the first time by this regulation, where suitable alternatives to the use of cadmium compounds appear not to be available. Furthermore, it became apparent that an assessment of the risks according to Regulation (EC) No 1907/2006 for cadmium and its compounds in plastic materials not listed in entry 23 before amending it by Regulation 494/2011 was not available.

In response, the Commission reversed the extension of the restriction to cover all plastics into the previous list of plastic materials through Regulation 835/2012[56]. In addition, Regulation 835/2012 inserted the following into Entry 23:

> *By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted.*

As a direct consequence of this, the Commission asked ECHA to prepare an Annex XV Restrictions Dossier on the use of cadmium and its compounds in plastics which, in turn, led to this report of its findings.

[56] Commission Regulation (EU) No 835/2012 of 18 September 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium)

Annex 2 - Exposure assessment – workers

Potentially relevant exposure scenario

Cadmium pigment production

Workers can be exposed to cadmium pigments in the production of such pigments, specifically towards the end of the process. Relevant exposure situations may e.g. be packaging of the final product, logistics and cleaning and maintenance of installations. However, workers in the production of cadmium pigments may also be exposed to other cadmium compounds used as basic chemical in that production. For example cadmium (metal) powder and cadmium oxide are used as starting material in the pigment production. It can be very difficult or impossible to assess the specific exposure to cadmium pigments in these facilities.

Production of polymer compounds and plastic articles

In the production of coloured plastics, the cadmium pigment can first be mixed with other components in a compounding facility (producing a coloured compound) or in the plastic production facility itself. Workers in these kinds of facilities can also be exposed to cadmium pigments. Their exposure to cadmium is probably mostly due to the pigments. Exposure may occur due to transfer of pigments, but also due to activities such as moulding and extrusion.

Handling of plastics

Worker exposure due to the handling of plastics will generally be limited. The finishing of plastic articles is considered to be part of the production of plastic articles. Manual handling may lead to some dermal exposure if some of the pigment leaches from the plastic.

Recycling plastic materials

Plastics may be recycled and plastics containing cadmium pigments have been reported as being recycled[57]. Usually plastic recycling consists of activities such as sorting (often automated), shredding, elimination of impurities (e.g. paper), melting and extruding. Plastic dust and in some cases fumes may occur during operation of granulators and agglomerators and fumes may be emitted when extruders are overheated (HSE, 1998).

Disposal of plastics

Disposal of plastics at the end of their service life in landfills is not expected to lead to significant exposure of the workers that are involved, because not granulation or heat treatment generally occurs.

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[57] Such a response was received by ECHA in response to its first *Call for Evidence* (see Section 4.8 for further detail)

Incineration of plastic waste

The incineration of plastic waste may partly lead to the breaking up of the pigment and formation of CdO, $CdCl_2$ or $Cd(OH)_2$. It is reported that cadmium and its salts are vaporised during waste incineration and emitted to the air as chlorides, oxides or in elemental form (CHEWI, 2000[58]). These are rather soluble cadmium compounds. However, in proper incinerators, workers should not be exposed to the emissions of the incineration directly.

Cadmium pigments in registration dossiers

Although the substances are not classified by the registrants, an exposure and risk assessment is performed in the CSRs for the two pigments (CdSSe and CdZnS). This includes two worker exposure scenarios for the use of cadmium pigments in polymers. In the exposure estimates, modelling with MEASE is done (a model containing, for the relevant PROCs, the same options as version 2.0 of ECETOC TRA[59]). No risk is predicted based on the estimates and comparing to the DNEL of 4 µg Cd/m^3 for non-cancer respiratory effects.

Exposure assessment for workers

Cadmium pigment production

A publication by Miksche (1981[60]) describes cadmium in blood and urine in 36 workers in cadmium pigment production, where exposure levels in air in the preceding years were in the range of 30-50 µg/m^3. The range of cadmium in blood was between 0.2 and 3.6 µg/100 ml and in cadmium in urine was 0.5-38 µg/g creatinine.

The EU RAR reports exposure levels, measured as total cadmium in respirable dust, for parts of the process where exposure will be mainly to pigments, as 8-35 µg/m^3. This refers to 15 personal exposure measurements from 2 companies in 1994-1996 in areas called 'pigment processing' (company A) of 'presses', 'driers', 'kilns', 'wet milling' and 'milling and packing' (company B).

A Japanese study from 2004[61] reports higher values for these parts of the process: 151-1151 µg/m^3. These refer to ambient (stationary measured) concentrations in tasks/areas called 'pouring into grinder' and 'removing from grinder'.

The few data mentioned in the EU RAR do not allow a conclusion on the exposure levels related to cadmium pigments in the production of these pigments. Furthermore, the Japanese study may not be very relevant to Europe, because the conditions in Japan may be rather different from those in Europe. However, the CSRs for the two cadmium pigments indicate that extensive measures are taken to minimise worker exposure to cadmium

[58] CHEWI (2000): Waste Incineration & Public Health, Committee on Health Effects of Waste Incineration, Board on Environmental Studies and Toxicology, Commission on Life Sciences, Division on Earth and Life Studies, US National Research Council. National Academies Press, dated 21 September 2000
[59] ECETOC Targeted Risk Assessment (TRA) tool - http://www.ecetoc.org/tra
[60] Miksche LW (1981): Cadmium exposure and health of workers in cadmium pigment production and cadmium pigment application. Cadmium 81 : 3rd International Conference, Miami, pp. 177-178
[61] Kawasaki T *et al* (2004): Markers of cadmium exposure in workers in a cadmium pigment factory after changes in the exposure conditions, Toxicol. Industrial. Health, 20: 51-56.

pigments and cadmium levels in the air, urine and blood are routinely monitored. Indeed, the CSRs report that over 90% of workers (exposed to manufacture of cadmium pigments) show lower levels of Cd in the blood than the action levels that are used. They also state that, if the recommended measures are in place in the workplace, the risk to workers is negligible.

Production of polymer compounds and plastic articles

Some data are presented in the EU RAR on cadmium metal on the exposure to cadmium caused by processing of cadmium pigments. The 95th percentile of 64 samples taken in Germany between 1991 and 1996 during weighing and mixing of cadmium pigments in the plastic industry was 66 µg/m^3 (expressed as cadmium). Exposure in the UK in 24 measurements taken between 1987 and 1988 due to blending, bagging, mixing and weighing in the plastic industry was between 0.1 and 310 µg/m^3 (expressed as cadmium). The values for similar activities in the paint manufacture and the ceramics and glass industry were up to 20 µg/m^3 (cadmium), respectively a 95th percentile of 30 µg/m^3 (cadmium, based on 83 measurements).

In the study by Miksche (1981), next to workers in cadmium pigment production also 21 workers in application of pigments in the compounding of acrylonitrile-butadiene styrene plastics were studied. No air concentrations had been measured. Cadmium in blood ranged from 0.04 to 0.30 µg/l and cadmium in urine from 0.4-3.1 µg/g creatinine. These values were in the same range as those found by Miksche in the literature for not occupationally exposed workers.

Bonilla and Milbrath (1994[62]) measured local concentrations of cadmium caused by moulding of different plastics: poly(bisphenol A-carbonate), poly(butelene terephthalate), polyeterimide, acrylonitrile-butadiene-styrene terpolymer and polyphenylene oxide / high impact polystyrene polymer blend. The plastics had a cadmium content of 1.38 to 1.82%. Three locations in or at the moulding machine were sampled and one location typical of where a worker would be present: at about a meter from the machine. At different locations concentrations between 0.27 and 1 µg/m^3 cadmium were measured. This would lead to an exposure an around 0.04-0.14 µg/kg bw/day, assuming a typical inhalation rate of 1.25 m^3/hour (default for light activity), 8 hour shift (default) and a body weight of a worker of 70 kg (default), which is up to about 60% of the mean daily dietary exposure of adults (discussed further in Section 4.3.10) giving maximum exposure values of 0.39 (mean) or 0.57 µg/kg bw/day (95th percentile), both below DNELs set by the registrant (oral DNEL 1 µg/kg bw/day for consumer).

Older measurements in the UK showed higher inhalation cadmium exposures at transfer tasks in the plastic industry than newer (but still old) measurements in Germany. The exposure in these tasks will be caused by dust. Assuming that the data from Germany on transfer tasks may be from relevant conditions, a reasonable worst case (inhalation) exposure level to cadmium, due to cadmium pigment dust, is around 66 µg/m^3. This would

[62] Bonilla JV & Milbrath RA (1994): Cadmium in plastic processing fumes from injection molding. AIHA Journal, 55 (11): 1069-1071.

be around 9.4 µg/kg bw/day, using the same assumptions as above. This would be more than 20 times the 95th percentile of the daily dietary exposure. Inhalation exposures due to moulding of plastics appear to be much lower.

Dermal exposures have not been measured. In transfer tasks a relatively high dermal exposure to powders may occur, but in moulding no dermal contact is expected. A quantification of dermal exposure is not possible.

Handling of plastics

Workers may handle coloured plastics that contain cadmium pigments, e.g. workers in logistics departments of facilities that produce plastic articles or workers laying cables in the ground. No exposure data exist for these workers. It is highly probable that any emissions into the air of cadmium pigment that is bound in plastics, without extensive comminuting activities, will be very low. Inhalation exposures are expected to be lower than those measured during moulding of plastics containing cadmium pigments.

Dermal exposure may also occur. No data on dermal exposure are available and quantification is not possible.

Recycling plastic materials

Plastic recycling consists of sorting several steps, including sorting, shredding, washing and extruding. Most processes either do not lead to emission into the workroom air or direct skin contact other than in other situations. The most special activity for this situation is shredding. In this task plastics are ripped into small pellets. This may lead to some dust formation, though the activity is not intended to produce very small particles. Some producers of plastic shredders do warn against dust exposure in their product description, but no relevant data on real exposure levels have been found in a quick literature search.

Disposal of plastics

Disposal of plastics on landfills may, just like recycling, involve some exposure to plastic dust. However, no information on this type of exposure is available.

Incineration of plastic waste

Incineration of waste leads to the breaking down by burning of the waste materials and also to reaction of substances within those materials to a more oxidised state. Cadmium pigments may be transformed to cadmium oxide or cadmium hydroxide in the process. Workers in the incinerator facilities may be exposed. Maître *et al* (2003[63]) measured air concentrations of several substances, including cadmium, in two French municipal waste incinerators and at a supermarket near the same town (that acted as a control site). Static sampling was done at various locations on the sites. Cadmium concentrations were between 0.03 and 0.98 µg/m^3 at one incinerator and between 0.01 and 3.56 µg/m^3 at the other

[63] Maître A *et al* (2003): Municipal waste incinerators: air and biological monitoring of workers for exposure to particles, metals, and organic compounds. Occup Environ Med, 60:563–569

incinerator. These concentrations were significantly increased compared to the values at the supermarket (0.0004-0.003 µg/m^3). Workers in the incinerators also were monitored for urine concentrations of cadmium, both before a shift and after a shift. There was no significant difference between the before and after shift measurements. The values were between 0.05 and 2.63 µg/g creatinine. Supermarket workers had similar biological monitoring values (0.08-1.34 µg/g creatinine) but with lower maximum values.

Agramunt *et al* (2003[64]) also measured several contaminants via biological monitoring in incinerator workers. The workers worked in a rather new incinerator (active for around 3 years) in Spain. Cadmium levels were determined in urine samples before the start of the incinerator and in the following three calendar years. The values for plant workers were between 0.03 and 1.5 µg/g creatinine. The values for laboratory workers were between 0.03 and 0.8 µg/g creatinine and for administrative workers between 0.1 and 0.5 µg/g creatinine. The cadmium concentrations in urine of workers in the active period of the plant were actually statistically significantly reduced from the baseline. The conclusion of the authors was that there is no relevant uptake of cadmium caused by working in the incinerator.

Summary for workers

Workers can be exposed when handling the powdered pigments, but some exposure due to e.g. moulding and handling pigmented plastics (e.g. via the skin) cannot be fully excluded. Workers in municipal incinerators may also be exposed to cadmium.

There are few data on exposure of workers producing or handling cadmium pigments. The few publications are already old and they show values that are, in several cases, much higher than the levels that are under discussion for being relevant for human health. Workers handling pigments in the past had cadmium exposures far above the 95th percentile of the daily dietary intake. However, the CSRs report that exposure levels for workers in cadmium pigment manufacture are strictly controlled and routinely monitored to ensure a safe working environment. In moulding of plastics the exposures were up to around one-third of this value. Relatively recent data of workers in municipal incinerators do not show that these workers have a relevant exposure to cadmium.

Risk characterisation for workers

There are few data on exposure of workers producing or handling cadmium pigments. The few publications (in the open literature) are already old and they show values that are, in several cases, much higher than the levels that are under discussion for being relevant for human health.

The values reported for inhalation exposure in the EU RAR on cadmium exposure in parts of the process for cadmium pigment production that will mostly be related to exposure to cadmium pigments (and much less to other cadmium compounds, such as cadmium dust or

[64] Agramunt MC *et al* (2003): Monitoring internal exposure to metals and organic substances in workers at a hazardous waste incinerator after 3 years of operation. Toxicology Letters 146 (2003) 83–91

cadmium oxide) are clearly above the DNEL of 4 µg Cd/m^3 (ECB, 2007). The data on cadmium in urine in the old publication by Miksche (1981) are also clearly above the recommended BLV of 2 µg Cd/g creatinine. However, the CSRs (submitted in May 2013) report that exposure levels for workers in cadmium pigment manufacture are strictly controlled and routinely monitored to ensure a safe working environment.

Transfer and weighing of cadmium pigments in the production of polymer compounds and plastic articles in the past, according to relatively old publications (largely summarised in the EU RAR), clearly led to exposures of workers above the DNEL of 4 µg Cd/m^3. Cadmium in blood and urine for workers in similar tasks were not increased compared to non-exposed workers, according to Miksche (1981). A study on moulding of plastics did find worker exposures below the DNEL of 4 µg Cd/m^3 (Bonilla and Milbrath, 1994).

Some worker exposure, e.g. via the skin, but also via inhalation of dust, may occur due to handling, recycling and disposal of plastic articles or materials. No data are available on exposure levels, but the inhalation exposure levels are considered to be much lower than for production of cadmium pigments and production of polymer compounds and plastic articles.

Cadmium concentrations at incinerators have been found to be below or up to the DNEL of 4 µg Cd/m^3 or the BLV of 2 µg Cd/g creatinine. Workers at incinerators might be exposed above background values from populations used in those studies, but the data found in literature do not show increased uptake of cadmium by workers in incinerators. If there would be increased exposure for workers in incinerators, certainly not all cadmium concentrations at incinerators would be caused by cadmium pigments in plastics (Agramunt *et al*, 2003, Maître *et al*, 2003).

Based on the limited, and often rather old, measured exposure levels, it can be concluded that workers in the production of cadmium pigments and those handling cadmium pigments in powder forms may be / have been exposed to levels above the inhalation DNEL of 4 µg Cd/m^3 and the recommended BLV of 2 µg Cd/g creatinine. In other work situations exposures are expected to be lower and are probably below the DNEL and the recommended BLV.

Based on these data, it cannot be excluded that there is a health risk for workers producing or handling cadmium pigments. However, the new information in the registration dossiers indicates that exposure to cadmium pigments during manufacture is carefully monitored to ensure minimal risk.

However, it should be noted that if workers were to be exposed to the DNEL of 4 µg Cd/m^3, this would equate to a daily intake of 0.57 µg/kg bw/day[65] which is comparable to the 95th percentile of the daily dietary intake of 0.45 µg/kg bw/day (see below). The total exposure of such workers would then be about 1.0 µg/kg bw/day, which is equal to the oral DNEL set by the registrants for the general population. Since this level, according to the registrants

[65] Based on a typical inhalation rate of 1.25 m3/hour (default for light activity) for an 8 hour shift (default) and a body weight of a worker of 70 kg (default).

of the cadmium pigments, equates to about 2 µg/g creatinine, it would be about 4 times the level of 0.5 µg/g creatinine that according to the Swedish authorities (in the Annex XV SVHC dossier) can be considered to be relevant as a potential basis for a limit value. This may challenge the DNEL of 1.0 µg/kg bw/day set by the registrant for consumers and suggests that the DNEL could be set at four-fold lower level, to 0.25 µg/kg bw/day in which would be the same as the mean daily intake of adults.

However, considering the 95th percentile of the daily dietary intake (0.45 µg/kg bw/day) the workers exposed to the DNEL of 4 µg Cd/m^3, corresponding to 0.57 µg/kg bw/day, would increase the daily exposure to cadmium by 100%, and is at the level of DNEL set by the registrants but is higher than DNEL derived from proposal by Swedish authorities systemic effects such as osteoporosis and kidney effects.

Annex 3 - Exposure assessment – consumers

Potentially relevant exposure scenario

Hypothetical exposure scenarios

Research and stakeholder consultation did not result in concrete information on the combination of specific cadmium pigments being used in specific plastics for specific purposes. It was concluded that cadmium pigments are used in some plastics, but the exact combinations could not be established. Neither could it be confirmed if the uses are safety applications or other uses.

However, based on the available information, a number of hypothetical use scenarios have been described. These use scenarios can be used as the basis for the risk assessment as they are considered representative for the variety of potential exposure situations, specifically related to service life of the cadmium pigments.

The type of situations that together may represent the various potential routes of risk for cadmium pigments were chosen to account for:

- Frequent and extensive dermal contact
- Direct oral contact
- Potentially extensive leaching in the environment

The following hypothetical examples of types of products, coloured with red or orange pigments, were chosen.

1. Hard EVA (Ethylene Vinyl Acetate) Case Skin Cover for a 7.0 inch tablet. This is actually a kind of case around the tablet. The case allows the use of the tablet while it is in the case and therefore leads to a rather high potential of dermal contact.
2. A silicone spoon. The spoon is heat resistant up to 260 °C. It is a relatively large spoon intended for cooking. As a worst case it will also be assumed to be used for eating (though not daily).
3. Acetal (Polyoxymethylene) Flat Fan Nozzle Tips designed for 2 litres per min at 4 bars. These nozzles can be used in an irrigation water system in gardens, e.g. vegetable gardens. Leaching may occur due to the long duration and frequent water contact.
4. Protective double-walled corrugated HDPE tubes protecting electrical cables directly into the soil through water obstacles as well as in pipes, blocks, bridges and viaducts. These tubes may reside in contact with soil for long periods (years) and during those periods leaching may occur. Via groundwater and other compartments the contamination might reach people.
5. Plastic may also reach the landfills. Via leaching and other compartments part of the contamination might reach people. This scenario should not occur if the landfill is operated according to the legal requirements.

Incineration of plastic waste

Some information on cadmium concentrations in the neighbourhood of municipal incinerators is also presented, but no attempt is made to calculate the actual contribution of the cadmium pigments to these concentrations, because this cannot be realistically calculated with reasonable certainty.

The percentage of cadmium pigment in a plastic material is often less than 0.5% and can be much less if the cadmium pigment is mixed with other pigments (e.g. whites). However, a percentage of 0.5-1% is possible for highly coloured plastics. Therefore, in the assessments it will be assumed conservatively that the plastic consists of 1% of cadmium pigment.

Cadmium pigments in registration dossiers

Furthermore, there are two descriptions of consumer use of cadmium pigments. These descriptions are related to consumer use of solid preparations containing the pigments in plastics, rubber, metal coatings, glass and ceramics and related to consumer use of paste or solid preparations containing the pigments in artists' colours. In relation to plastics, the registrants conclude that there is no release of cadmium pigments from the articles and therefore no risk to consumers. The consumer exposure from plastics, etc. is considered, by the registrants, to be effectively prevented by their encapsulation in a solid matrix. Specific mention of safety uses was not made in either of the dossiers and it is unclear what the uses are.

Exposure assessment for consumers

Leaching of cadmium (from pigments) from plastic and other materials

The rate of leaching of cadmium pigments from plastic materials has not been extensively studied. Since both direct and indirect exposure of consumers/the general population will largely be caused by leaching of cadmium from products or waste, the literature on leaching of cadmium has been studied.

The EU RAR on cadmium metal describes some results of chemical analyses and wiping and extraction tests reported in 1997 on a number of plastic articles made of PVC that may be handled by children. In this study, wiping with moist filters was used to simulate handling and skin contact, while extraction with saline was used to simulate leaching while mouthing and extraction with mild acid to simulate chewing/ingestion. In general, wiping or extraction was reported not to be done when the content of cadmium in the products was less than 100 ppm (0.01% or 100 mg/kg). Cadmium levels in the reported products ranged from 10 ppm (0.001% or 10 mg/kg product) to 510 ppm (510 mg/kg). Wiping resulted in 0.4 µg from the material containing the highest level of cadmium and 5.93 µg from materials containing only 30 or 10 ppm of cadmium. A material containing 160 ppm cadmium gave non-detectable wiping results (< 50 ppm). The extraction of a material with 290 ppm cadmium also led to non-detectable extraction results (< 50 ppm). The extraction with saline of the material containing 510 ppm cadmium gave 0.72 µg/g material, while acid extraction gave 18.6 µg/g material.

In the USA, decorated dinnerware samples and melamine plastic dinnerware were tested for leaching of lead and cadmium by different methods (Sheets, 1999[66]). No cadmium was found to be extracted by either 4% acetic acid or 0.1 M nitric acid from 18 melamine plastic dishes (12 older used dishes and 6 new dishes). The publication does not indicate whether or not any cadmium pigments or stabilisers were used in these dishes.

Leaching of cadmium from plastic is very much dependent on many factors. Fowles (1977 – see Footnote 45) studied the amount leaching from plastic used for toys containing cadmium compounds relation to several parameters. The focus was on parameters that may be relevant for leaching of cadmium in the stomach, from plastic dust resulting from e.g. abrasion of the toys or chewing. Several parameters that influenced the leaching are presented:

- more cadmium is extracted with lower particle sizes. The extraction from particles < 0.1 mm was about ten times that of particles > 1 mm. However, this is also determined by the smoothness and surface area of the particles;
- the amount extracted increased threefold with a tenfold increase of acidity (from 0.046 M HCl to 0.47 M HCl);
- under light conditions, around 10 times more was extracted than under dark conditions for red material and around 3 threefold for yellow material;
- the extracted amount increased with duration of extraction, with an approximate tenfold increase for 24 hour extraction compared to 1 hour extraction; and
- higher temperatures lead to higher extraction, with an increase of three to four times from 19 to 42.5 °C.

The results of all tests indicate that the amount of cadmium extracted per gram of sample is less than 100 µg in reasonable worst case conditions, i.e. around 4 hours extraction of not too small particles without light and in approximately 0.1 M HCl. The study results include several uncertainties and the results are not used in further estimations except for the information that the release of cadmium is increased with increasing temperature. This piece of information may not have been substantially affected by the identified uncertainty sources in the study.

Cheng *et al* (2010[67]) studied the leaching under varied conditions of a large number of metals from plastic bottles made from recycled plastics. All used bottles were crystal clear, so no cadmium pigments were used. The conditions included boiling water, ice-cold water, low pH (acetic acid in water, pH = 4), outdoor sunlight and storage in a car. The cadmium amounts leaching from the different types of bottles ranged from 0.002 to 0.123 ppb.

[66] Sheets RW (1999): Acid extraction of lead and cadmium from newly-purchased ceramic and melamine dinnerware. The Science of the Total Environment 233 (1999): 233-237
[67] Cheng X *et al* (2010): Assessment of metal contaminations leaching out from recycling plastic bottles upon treatments. Environ Sci Pollut Res (2010) 17:1323–1330

Wilson *et al* (1982[68]) conducted two types of leaching tests: laboratory extraction with either distilled water or 5000 ppm acetic acid (pH = 5), both with granulated material, and long term leach testing in columns filled with several combinations of granulated plastic and granulated refuse to simulate leaching in landfill situations. The plastic contained up to 1% of the cadmium pigment (mainly cadmium sulphide) with the highest relative cadmium concentration. Acid-washed cadmium sulphide was selected as an example of cadmium pigments as "*it has a typical solubility and the highest cadmium concentration of all commercial pigments*" as stated by Wilson et al., (1982). Pigment concentration, particle size and plastic type were varied in the laboratory extraction experiments, while pelletized ABS plastic with 1% of pigment was used in the column experiments. In the laboratory extraction experiments 0.2-8 mg cadmium/kg plastic was extracted in water and 0.2-5.6 mg/kg in acidic acid from plastics containing 0.1, 0.33 or 1% pigment. The highest cadmium removal value was measured for polystyrene with 1% pigment and water (8.0 mg Cd/kg plastic) and the next highest value with ABS and 1% pigment in acetic acid (5.6 mg Cd/kg plastic). Most values were between 0.2 and 1 mg Cd/kg plastic. This latter value was used in the hypothetical exposure scenarios.

In most cases the pigment was cadmium sulphide, in one case a lemon yellow mixed cadmium-zinc sulphide pigment and in one case red-purple mixed cadmium sulphide-selenide pigment. The particle size was either granulated, 1-cm square, cryogenically ground or pelletized. The calculations are made by using a leaching value of 1 mg Cd/kg plastic. The variation, as mentioned, was between 0.2 – 8.0 mg Cd/kg plastic in distilled water and between 0.2 - 5.6 mg Cd/kg plastic in pH 5 with the peak removal of cadmium per bed volume with the range of 0.06 – 2.1 mg Cd/kg. By taking the lowest and highest total cadmium removal in distilled water, it may be considered that the leaching could be 5 times lower or 8 times higher than estimated in the calculations above. For pH 5 values may be 5 times lower or 5.5. times higher. For the lemon yellow mixed cadmium-zinc sulphide pigment the leaching values were 0.3 and 0.6 mg Cd/kg plastic in distilled water and 0.8 and 2.1 mg Cd/kg plastic in pH 5 acetic acid. For red-purple mixed cadmium sulphide-selenide pigment the leaching values are 1.0 and 2.5 mg Cd/kg plastic in distilled water and pH 5 acetic acid, respectively. It is considered that the value used in calculations (1 mg Cd/kg plastic) is a good estimate for leaching cadmium from plastics coloured with 1% of cadmium pigments. However, it is not clear if other cadmium compounds in the plastics were evaluated, e.g. as stabilisers or if there is cadmium contamination of plastics during manufacturing. Unpigmented plastic (ABS) also showed cadmium releases between 0.6-1.0 mg Cd/kg plastic in water and 0.9-1.5 mg Cd/kg plastic in pH 5. In spite of these uncertainties, it is considered that the estimate of 1 mg Cd/kg plastic can be used because for several cases higher than "base line" values were measured, including for plastics coloured with lemon yellow mixed cadmium-zinc sulphide pigment or red-purple mixed cadmium sulphide-selenide pigment. However, acknowledging the uncertainties included to the release value of cadmium estimated and used in the hypothetical estimations and

[68] Wilson DC *et al* (1982): Leaching of Cadmium from Pigmented Plastics in a Landfill Site. Environ. Sci. Technol. 16: 560-566

models, and which based on the results from the Wilson study, it is highly recommended that new measurements for cadmium releases from plastics coloured with cadmium pigments should be conducted. Table 1 of the Wilson study summarising the results is copied in an Annex 5.

Leaching of cadmium from other types of products has also been studied, from ceramic dinnerware by Sheets (1997[69]; 1998[70]), Dessuy *et al* (2011), Valadez-Vega *et al* (2011 – see Footnote 56) and from electronic waste by Keith *et al* (2008[71]) and Guo *et al* (2011 - see Footnote 57) showing low values.

Direct or indirect exposure via plastic articles

Although cadmium pigments are incorporated in a fixed polymer matrix when the consumer handles them, there is a (at least theoretical) possibility of exposure. The inhalation route does not appear to be relevant. Even if the substances would migrate to the surface of the plastic articles, the way people use these articles will not lead to substantial emission into the air of non-volatile substances. The dermal route may be more relevant. Substances in solid matrices may migrate through the matrix and leach from the matrix to the skin of consumers. Leaching will probably occur relatively more when there is a liquid 'film', such as water or sweat between the skin and the matrix. The oral route may be most important, specifically for children that may chew on plastic toys and absorb some plastic parts/dust orally.

According to a study by Patterson *et al* (2000[72]), sweat is slightly acidic, pH around 5 to 6, with possibly some variation over the body area. For leaching due to skin contact, leached amounts from slightly acidic experiments are to be preferred, since the acidity has a clear effect on extractability of cadmium from plastics (Fowles, 1977).

Skin exposure via a tablet cover/case

The potential exposure of the skin to cadmium via cadmium pigments is assessed with the following assumptions:

- Concentration of cadmium pigment in the plastic is 1% (10 g/kg);
- Weight of a cover/case for a tablet: 350 g (similar cases for tablets appear to have around this weight);
- Contact area (skin-article contact): 35.7 cm^2 (from ECETOC TRA v3.0 consumer model default for small plastic articles);

[69] Sheets RW (1997): Extraction of lead, cadmium and zinc from overglaze decorations on ceramic dinnerware by acidic and basic food substances. The Science of the Total Environment 197 (1997) 167-175
[70] Sheets RW (1998) Release of heavy metals from European and Asian porcelain dinnerware. The Science of the Total Environment 212 (1998): 107-113
[71] Keith A *et al* (2008): Assessment of Pb, Cd, Cr and Ag leaching from electronics waste using four extraction methods, J. Environ. Science Health Part A; 43: 1717-1724
[72] Patterson MJ *et al* (2000): Variations in regional sweat composition in normal human males, Exp. Physiol.; 85(6): 869—875

Contact duration: 4 hours (ECETOC TRA v3.0 consumer model assumes 8 hours, but that appears to be a very conservative value);
Extraction: 1 mg cadmium / kg plastic (based on Wilson *et al* (1982))

The estimation of leached amount of cadmium (1 mg Cd/kg plastic) is based on information on cadmium leach from plastics coloured mainly with acid-washed cadmium sulphide as reported in Wilson et al., 1982. They justified the use of acid-washed cadmium sulphide as an example pigment as "*it has a typical solubility and the highest cadmium concentration of all commercial pigments.*" Cadmium sulphide is considered as practically insoluble in water but soluble in acids. For determining the leaching both distilled water and pH 5 acetic acid solutions were used leading to a mean value of cadmium removal of 1 mg Cd/kg plastics. The article contains also information from leaching values of cadmium from plastics coloured with lemon yellow mixed cadmium-zinc sulphide pigment or red-purple mixed cadmium sulphide-selenide pigment. These values are in line with the information from cadmium sulphide. Thus, it is considered that leaching information from also cadmium sulphide can be is used in the following estimations.

No direct data are available to estimate the leaching into a sweat solution with a pH around 5 or 6. Fowles (1977) gives a concentration of 10.6 µg cadmium in 25 ml HCL (0.046 M; pH ≈ 1.3), extracted from finely grounded (0.106-0.5 mm) 1 g of plastic. Wilson *et al* (1982) found around 1 mg Cd/kg plastics for water and acetic acid solutions with a pH of 5 when extracting with a solid/liquid ratio of 1 and 4 hours of vigorous shaking. The values of Wilson *et al* (1982) appear more relevant than those by Fowles (1977), because the high acidity in the study of Fowles (1977), the extraction of finely grounded particles and the high volume of extraction liquid) may lead to much more leaching than expected under the conditions of handling a plastic cover.

The outside of the case is approximately 20 x 14 cm = 280 cm^2 for both sides, so 560 cm^2 total (inside given as 200 x 133 mm). Thus, contact with 35.7 cm^2 involves approximately 15.6% of the case and approximately 55 g. The leaching value of 1 mg Cd/kg plastic from Wilson *et al* (1982) will therefore be a conservative estimate. As noted above the variation of cadmium removal from plastics varies a lot depending on the plastic material, the size of plastic particles, amount of pigments used and potentially other properties of the pigments, such as cadmium content. More precise information is not available from cadmium releases from plastics coloured with cadmium pigments and, thus, this is considered to be an usable estimate, although including uncertainties.

The skin exposure based on the assumptions given above is estimated as follows: contact with 55 g plastic, in 4 hours 1 mg cadmium/kg plastic is extracted → total extracted amount = 0.055 mg = 55 µg.

The value of 1 mg/kg plastic probably also is very conservative, because it is based on pelletized plastic, with a much higher surface-to-volume ratio than an article, and because it is extracted using vigorous shaking. Furthermore, sweat production (including transepidermal water loss) of the palms of the hand in rest is around 0.7 mg/cm^2/min, which is the 95th percentile from data summarised by Taylor & Machado-Moreira (2013[73]). This is a limited amount of liquid for extraction, further increasing the conservative nature of the estimate.

The EU RAR assumes that dermal absorption must be below 1%, however, in calculations a value of 1% is used. Using this assumption, the uptake of cadmium via contact with a tablet cover coloured with cadmium pigments for 4 hours is very conservatively estimated to be 0.55 µg/day, which recalculates to 0.009 µg/kg bw/day for a 60 kg person (default bodyweight of females). This is less than 4% of the mean daily dietary intake of adults. Due to the variation of leaching values measured by Wilson et al., (1982) and other uncertainties this estimation is considered as conservative. However, due to lack of more precise information on leaching of cadmium from plastics, more realistic calculations are difficult to conduct.

Oral absorption via eating a soup cooked with a plastic spoon coloured with cadmium pigments

The example spoon coloured with a cadmium pigment and releasing cadmium 1 mg Cd/kg plastic is used in the estimations. It is not intended for eating, but for cooking. It may sometimes be used for tasting, but it is not expected to be used by small children that chew on their spoons.

Leaching may occur due to stirring the hot soup, that may be a bit acidic too. Fowles (1977) noticed a rather substantial effect of temperature on leaching (in 0.1 M HCl). Therefore, the estimated leaching from the plastic given by the values measured by Wilson *et al* (1982) of 1 mg/kg material will be increased by a factor of 4 to account for the high temperature. However, the duration of stirring (and keeping the spoon in the soup) per day is assumed to be no more than half an hour, while the tests had a duration of 4 hours. Assuming that the leaching is continuous, the low duration will lower the leached amount by a factor of 8 (4/0.5). In total, the effect of high temperature and low duration lead to a decreased leaching by a factor of 2: 0.5 mg/kg material.

A silicone spoon has a weight of approximately 65 g[74]*.* Not more than two-thirds of the spoon is expected to be in contact with the soup: approximately 43.4 g*.* The potential leaching of cadmium therefore is 0.5 * 0.0434 = 0.0217 mg = 21.7 µg*.* This amount will be diluted in approximately a litre of soup*.* Assuming the soup is eaten by 4 people (250 ml each), the exposure via the oral route will be estimated around 5.4 µg per day*.* This would lead to an intake of 0.09 µg/kg bw/day for a 60 kg person (default bodyweight of females), which is nearly 40% of the mean daily dietary intake of adults and could increase the exposure to 0.34 µg/kg bw/day which is below the oral DNEL of 1 µg/kg bw/day for

[73] Taylor NAS & Machado-Moreira CA (2013): Regional variations in transepidermal water loss, eccrine sweat gland density, sweat secretion rates and electrolyte composition in resting and exercising humans, Extreme Physiology & Medicine 2013; 2:4

consumer. The calculations are made by using a leaching value of 1 mg Cd/kg plastic. The variation was dependent on plastic, pigment, particle size etc. and varied between 0.2 – 8.0 mg Cd/kg plastic in distilled water and from 0.2 to 5.6 mg Cd/kg plastic in pH 5 from plastics coloured with cadmium pigments. The peak removal of cadmium per bed volume with the range of 0.06 – 2.1 mg Cd/kg. The variation, as mentioned, was between 0.2 - 5.6 mg Cd/kg plastic in pH 5. By taking the lowest and highest total cadmium removal in pH 5, it may be considered that the leaching could be 5 times lower or 5.6 times higher than estimated in the calculations above. For the lemon yellow mixed cadmium-zinc sulphide pigment the leaching values were 0.8 and 2.1 mg Cd/kg plastic in pH 5 acetic acid. For red-purple mixed cadmium sulphide-selenide pigment the leaching value was 2.5 mg Cd/kg plastic in pH 5 acetic acid. It is considered that the value used in calculations (1 mg Cd/kg plastic) is a good estimate for leaching cadmium from plastics coloured with 1% of cadmium pigments. However, as mentioned above it is not clear if other cadmium compounds in the plastics were evaluated. In spite of the uncertainties, it is considered that the estimate of 1 mg Cd/kg plastic can be used because for several cases higher than "base line" values were measured, including for plastics coloured with lemon yellow mixed cadmium-zinc sulphide pigment or red-purple mixed cadmium sulphide-selenide pigment.

Leaching from water nozzles and subsequent exposure via eating watered crops

Theoretically, the cadmium pigments may leach from nozzles used for watering plants in irrigation systems and may be transferred onto the crops watered by this system. However, no estimation of exposure due to eating such crops is considered to be necessary. The nozzles used are only very small and therefore the amount of cadmium pigment potentially leaching from the nozzles is also small. Assuming irrigation of an area of 20 m^2 with nozzles every 0.5 m would result in 80 nozzles. Such a nozzle is very lightweight (no more than 2 g per nozzle)[75], so the total nozzle weight would be 160 g. Assuming 4 hours irrigation per day with a leaching of 1 mg cadmium per kg of plastic (Wilson *et al* 1982) would lead to a total emission from the nozzles of 0.16 mg per day. Most of this amount will not actually be taken up by, or deposited on crops and part will be removed by washing or cutting of certain parts of the crops. Therefore, no further estimation of exposure via eating of the crops will be done.

Inhalation exposure near incinerators

Incinerators (of municipal wastes) may burn several cadmium containing products, including plastics containing cadmium pigments. It is expected that this will lead to the reaction of these pigments into other forms of cadmium, e.g. cadmium oxide. Some studies on concentrations or human exposure near incinerators are available.

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[74] See, for example, http://www.globalreap.com/index.php/product-center/silicone-series/silicone-kitchen-utensils/solid-red-silicone-mixing-spoon-detail
[75] See, for example, http://www.antelco.com/usa/pdfs/2012%20Antelco%20USA%20Catalog.pdf

Reis *et al* (2007[76]) published biological monitoring results of people living close to or further away from municipal waste incinerators in Lisbon and Madeira*.* There were no differences in cadmium in blood levels between 'exposed' individuals (living close to incinerators) and controls (living further away)*.* The average values ranged from 0.1 to 0.7 µg/dl blood*.* Values in the first (baseline) measurement period were higher than in the next measurement period(s)*.* There appeared to be higher blood cadmium levels in Lisbon than on Madeira, which the authors assume to be due to other sources*.*

Another study was done for people living close to or further away from a new incinerator, commissioned in 2005 (Zubero *et al*, 2010[77])*.* Cadmium in urine was measured for people in 2006 and in 2008. In both years, people living far from the incinerator had a mean Cd-U of 0.23 µg/g creatinine, while people living near the incinerator had a mean Cd-U of 0.37 µg/g creatinine. There was no increase from 2006 to 2008. A figure in the publication suggests a 90th percentile of the cadmium in urine levels around 0.8-1.3 µg/g creatinine for the different subgroups (combination of close/further and 2006/2008). The authors also show figures from a Belgian study of 2007, where one population near an incinerator had a 14% lower mean Cd-U than the population far from the incinerator, while another population near the incinerator had a 21% higher mean Cd-U.

Based on the available information, it cannot be concluded that people living closer to a modern municipal incinerator are exposed to higher cadmium levels than people living further away from such incinerators. The calculation of potential exposure to cadmium via incinerators due to the cadmium pigments is not reasonably possible, due to the very large uncertainties and the high variabilities in amounts of material (with pigments) incinerated, the fate of the cadmium pigments in the different resulting streams of the incinerator, effectiveness of emission reduction methods, effects of stack height and effects of climate on these concentrations and drifting and landing of emissions.

Risk characterisation for consumers

Hardly any real exposure data for consumers or the general population related to the use of cadmium pigments in plastics are available*.* Some estimates have been made and there are some data on the cadmium exposure (via biological monitoring) of the general population living more or less close to municipal waste incinerators*.*

The estimate of dermal exposure, recalculated to internal exposure, caused by handling a hard cover or a tablet computer if coloured with cadmium pigments releasing 1 mg Cd/kg plastic, for 4 hours per day is very conservatively estimated to 0.009 µg/kg bw/day for a 60 kg person (default bodyweight of females)*.* This value is very far below the DNEL of 1 µg/kg bw/day*.* Even if this DNEL is (intended to be) an external value, calculated with a low oral absorption of 6%, the estimated value is still much lower.

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[76] Reis MF *et al* (2007): Human exposure to heavy metals in the vicinity of Portuguese solid waste incinerators – Part 1: Biomonitoring of Pb, Cd and Hg in blood of the general population, Int. J. Hyg. Environ.-Health 210 (2007) 439–446

[77] Zubero MB *et al* (2010): Heavy metal levels (Pb, Cd, Cr and Hg) in the adult general population near an urban solid waste incinerator, Science of the Total Environment 408 (2010) 4468–4474

The estimate of oral exposure caused by leaching of cadmium into soup from a cooking spoon leaching 1 mg Cd/kg plastic is 5.4 µg per day is 5.4/60 = 0.09 µg/kg bw/day), which is around 10% of the consumer oral DNEL. The corresponding value for a 12kg toddler is 0.45 µg/kg bw/day which would equate to 45% of the consumer oral DNEL. Adding this value to the daily mean dietary exposure (0.69 µg/kg bw/day), the figure is 1.14 µg/kg bw/day which is above the DNEL of 1 µg/kg bw/day set by the registrants and 4-fold higher than DNEL of 0.25 µg/kg bw/day, corresponding to excretions of 0.5 µg Cd/g creatinine as proposed by Sweden. Thus, the exposure would increase by 65%. This estimation is based on information on cadmium leach from a plastic coloured with cadmium pigments as reported in Wilson et al., 1982. They justified the use of acid-washed cadmium sulphide as an example pigment as "*it has a typical solubility and the highest cadmium concentration of all commercial pigments*". However, one sample of plastic coloured with lemon yellow mixed cadmium-zinc sulphide pigment and oen sample containing red-purple mixed cadmium sulphide-selenide pigment were also included. For determining the leaching both distilled water and pH 5 acetic acid solutions were used leading to an estimation used in calculations (total cadmium removals from plastics of 1 mg Cd/kg plastics). The variation of data indicated that 5 time lower or 5 times higher values may be measured at pH 5.

During the preparation of this report no evidence was found that cadmium pigments are used in non-restricted plastics, that are used in consumer articles. If this would be the case, the above examples show that for adults there need to be several plastic consumer articles containing cadmium pigments used per day before the DNEL set by the registrant is reached. For toddlers only exposure to few articles might be enough to reach the DNEL. However, as no evidence on the use in non-restricted plastics was identified, these considerations are speculative.

The exposure due to leaching of cadmium pigments from nozzles of irrigation systems, leading to contamination of self-produced food, is probably much lower than the values mentioned above.

It is expected that the very low bioaccessibility results in gastric fluid and sweat also indicate very low leaching of these pigments from plastics in e.g. dish washing fluid, irrigation water, food and saliva. The conditions of the liquids (lower acidity) and the material (plastic articles instead of pigment powder) in almost all cases indicate lower leaching than those measured for gastric fluid. A possible exception is the higher temperature during cooking.

There does not appear to be a clear increase of uptake of cadmium in people living close to municipal waste incinerators that can be considered caused by such incinerators. Exposure does appear to be increased in urban areas compared to rural areas, but that cannot be considered to be caused by the use of cadmium pigments in plastics. Values from one study (0.8-1.3 µg/g creatinine) were below the recommended worker BLV (2 µg/g creatinine) - but above the value of 0.5 µg/g creatinine assumed to be relevant for setting a limit in the Annex XV dossier prepared by Sweden. There was no clear relation with the emission from the incinerator and these levels can be caused by other sources. Results from a study by Reis *et al* (2007) near Lisbon and on Madeira Island showed no significant difference in levels of metals (including cadmium) in blood in people living close to an incinerator in comparison to people living further away from an incinerator. In a study on blood levels of metals in an area close to a Spanish incinerator, multiple linear regression models did not show increases over time of the levels of the metals in the areas close to the SWI compared to those of areas located further away, after adjusting for confounding variables (Zubero *et al*, 2010).

Considering all estimated exposure levels, and assuming that the DNEL for consumers is sufficiently protective, because of the expected very low leaching of cadmium from the two pigments from plastics (as indicated by the very low bioaccessibility in gastric fluid and sweat), it can be considered that there is probably no significant increase in exposure to cadmium and risk for consumers via more or less direct contact with plastics containing cadmium pigments and also for indirect exposure for the general population via the environment. The biological levels of people living close to municipal waste incinerators do not appear to be clearly increased because of those incinerators. Clearly, the contribution to the total load (of exposure to cadmium) will be influenced by the extent to which cadmium pigments are used in plastics although substantial increases will be required for the associate exposures to exceed the associated DNELs.

Annex 4 - Indirect exposure of humans via the environment

Indirect exposure of humans via the environment may occur due to the use of plastics containing cadmium pigments and their release during service life. Examples of potentially releasing 'sources' are underground cables with plastic coating containing pigments.

Separate calculation of the contribution of these materials to human exposures is too complex and too uncertain. Therefore, only a general calculation of exposure of humans via the environment can be done. However, it has to be pointed out, that the model results are highly uncertain. Furthermore, even though the environmental release category (ERC) is for wide dispersive outdoor use of long-life articles and materials with low release, it is uncertain how representative it is for the pigments incorporated into the plastic materials. This model describes the exposure from article service life and does not cover the manufacture of the article or the waste phase.

The most recent information (2013) from the companies is that 200-250 tonnes of pigments containing cadmium are used annually in EU of which 20 % is used in non-restricted plastics. In pigments there are around 60-65 % cadmium. Thus the amount of pigment based on cadmium compounds in plastics is around 50 tonnes (30 tonnes of cadmium). An appropriate estimation of potential exposure of humans via the environment can be made with EUSES 2.1.2 model. The simulation has been done largely using data from cadmium zinc sulphide[78]. In case no information is available on this specific substance, information from the EU RAR, 2007 (Cadmium oxide and cadmium metal) is used. Input data for the model are summarised here below:

- Tonnage: 50 tonnes/year (as cadmium zinc sulphide)
- Fraction of tonnage to region: 10%
- Calculation of releases via ERC
    - ERC: 10a (Wide dispersive outdoor use of long-life articles and materials with low release)
- STP: yes (default assumption for EUSES regional scenario: 80% of releases passing STP, 20% direct release to surface water)
- Molecular weight: 170 g/mol
- Vapour pressure: 1×10^{-6} Pa (vapour pressure is very low, a very low value has been entered in EUSES)
- Water solubility: 1.48 μg/L (average value from 28 day tests, see section B.1)
- Partition coefficient octanol-water (logKow): -1[79] (minimum value suggested by EUSES)
- Biodegradability: not biodegradable

[78] Values taken from registration dossier on Cadmium zinc sulphide, unless otherwise stated
[79] Log Kow is not available for metals. However, it is an important parameter to calculate concentration in the items forming food basket (leaves and root crops, meat, dairy products). See sensitivity analysis on this particular parameter.

- Partition coefficient solid-water in suspended matter (Kpsusp) = 130.000 l/kg dw (dry weight) (taken from EU RAR, 2007)
- Partition coefficient solid-water in sediments (Kpsed) = 10.000 l/kg dw (taken from EU RAR, 2007)
- Partition coefficient solid-porewater in soil (Kpsoil) = 280 l/kg dw (taken from EU RAR, 2007)
- Bioconcentration Factor (BCFfish) = 233 l/kg (taken from EU RAR, 2007)
- Fraction of cadmium releases from STP = 40% (taken from EU RAR, 2007). It has been assumed that 60% of cadmium ends up in the STP sludge.

The calculated total daily intake of man via the environment regional is about 4.25×10^{-4} μg/kg bw/day which equates to about 2.55×10^{-4} μg Cd/kg bw/day (as the pigments are approximately 60% cadmium) or about 0.1% of the mean daily dietary intake (0.25 μg/kg bw/day, adults).

There are uncertainties in calculating the indirect exposure of humans via environment related to the following parameters:

- Log Kow, which is not available for metals and
- BCF, for which higher values (median value of 5.000 l/kg dw) are reported for invertebrates

A sensitivity analysis has been performed on those parameters.

The log kow does not show significant variation in daily intake for men via the environment even when values ranging from -3 to 2 are used as input parameter (which means a variation of 6 order of magnitude for the parameter Kow). Only 10% of increase of daily intake has been estimated when using the extreme Log Kow = 2. However it has to be mentioned that the model used might not be suitable for metals in relation to biotransfer to crops, since other mechanisms than those simulated play a role in the cadmium uptake by plants.

On contrary, BCF has a high impact on the daily intake of men via environment, in relation to fish intake. In the calculation, if the median value of BCF for invertebrates aquatic organisms (5.000) are used instead of the median values of BCFs reported for fish (233), the daily intake would increase by one order of magnitude, which would mean a daily intake of cadmium equal to 2.6×10^{-3} μg Cd/kg bw/day or about 1% of the mean daily dietary intake.

Moreover, other uncertainties are related to the parameters taken from the EU RAR, 2007 i.e. partition coefficient values, bioconcentration factor as well fraction of cadmium releases from STP. For instance, the partition coefficient values are dependent on the water solubility of the compound. Since the pigments have a much lower solubility than cadmium, the values for cadmium are probably not suitable for the pigments. How representative they are for the service life of plastics that contains cadmium pigments in concern can be questioned.

Other uncertainties relate to how cadmium in pigments behave. It is to be noted that in its opinion the Committee for Risk Assessment (RAC) in November 2014, and also stakeholder representative from industry provided support to the findings from Gustafsson (2013) indicating that the cadmium is released within several years from the cadmium pigments. This information could support the use of parameters for cadmium. It should also be noted that the tonnage used in the calculation represents the consumption of cadmium pigments in plastics in the EU and does not consider the import or export of articles containing cadmium pigments.

As a conclusion, ECHA considers that currently there are too many uncertainties with using the modelled data, so that the results cannot be used as a basis for a restriction.

Annex 5 - Results from the Wilson DC et al (1982) study (copy of table 1)

Table I. Total and Peak Cadmium Removals from the Plastics Examined by Laboratory Leaching Tests

sample no.	description	particle size description	comments	peak removal per bed volume, mg/kg	total Cd removal, mg/kg: distilled water	total Cd removal, mg/kg: 5000-ppm acetic acid (pH 5)
1	P.3680 pigment	powder	base line for comparison; golden-yellow cadmium sulfide pigment	13.3	210[a]	120[a]
2	unpigmented ABS	granulated	base line for comparison	0.5	(a) 0.6 (b) 1.0 (c) 0.8	(a) 1.5 (b) 0.9
3	ABS containing 1% P.3680 pigment	granulated	basic pigmented plastic tested	0.2	0.5	0.6
4	ABS containing 0.33% P.3680 pigment	granulated	chosen to study effect of pigment concentration	0.3	(a) 0.4 (b) 0.5	(a) 0.5 (b) 1.1
5	ABS containing 0.1% P.3680 pigment	granulated		0.3	(a) 0.3 (b) 0.5	(a) 0.6 (b) 0.9
6	ABS containing 1% P.3680 pigment	1-cm squares	chosen to study effect of particle size	0.3	0.5	0.7
6A	ABS containing 1% P.3680 pigment	cryogenically ground		2.1	1.3	5.6
7	ABS containing 1% P.3681 pigment	granulated	lemon yellow mixed cadmium-zinc sulfide pigment	0.3	(a) 0.3 (b) 0.6	(a) 0.8 (b) 2.1
8	ABS containing 1% P.4707 pigment	granulated	red-purple mixed cadmium sulfide-selenide pigment	0.3	1.0	2.5
9	polystyrene containing 1% P.3680 pigment	granulated	chosen to study effect of varying the plastic	1.9	8.0	2.3
10	polypropylene containing 1% P.3680 pigment	granulated		0.2	0.9	0.4
11	HD polyethylene containing 1% P.3680 pigment	granulated		0.4	1.6	0.2
12	ABS containing 1% P.3680 pigment	pelletized	sample of basic material used in column experiments	0.06	0.2	0.4
13	PVC containing tin-based stabilizer	1-cm squares	included to study leaching from a cadmium-stabilized plastic	0.06	<0.03	0.07
14	PVC containing cadmium-zinc-based stabilizer	1-cm squares		0.7	0.4	1.0

[a] Calculated figure.

Annex 6 - International Cadmium Association (ICdA) comments on the Annex XV report – 30 June 2014 – ECHA/Comments sent on 29 August 2014

<u>Questions raised about cadmium pigments and their uses in plastics</u>

(ref. to Annex XV report – 30 June 2014 – ECHA)

International Cadmium Association (ICdA) comments

1. <u>Introduction</u>

In 2012, the Commission asked ECHA (reg.835/2012) to assess whether the "non-restricted" uses of cadmium and its compounds in plastic material should also be restricted.

The Annex XV report, in question here (June 2014), was intended to fulfill the obligations of ECHA under Regulation EU 835/2012 and to focus on:

- The identification of uses of cadmium and its compounds in plastic materials and articles (other than in 16-restricted resins)
- The identification of risks of those uses, needing an EU-wide answer through amended/expanded Restriction

It was obvious, from the very beginning of the work of the Annex XV, that the targeted uses in plastics were not uses of cadmium metal nor of the compounds used in the past e.g. as stabilizer (already restricted in all plastics in EU – entry 23 /Annex XVII REACH), but, specifically, uses of cadmium pigments in plastics other than the 16-restricted resins.

This summary document provides specific information on the 2 main questions that have been raised during discussions: a) the classification of Cd-pigments , and b) the current uses of Cd-pigments in plastics.

2. <u>Current uses in plastics</u>

Gaining detailed information on the uses of Cd-pigments proved to be difficult to organize so far, despite the repeated „call for evidence" launched by ECHA in 2012-2013 and despite several industrial initiatives in the frame of the REACH registration files of those Cd-pigments. The main difficulty when approaching the supply chain from manufacturers to downstream users, is that there are only two manufacturers of Cd-pigments left in the EU and all attempts to aggregate market figures –even through a third party- conflict immediately with 'Competition law requirements'.

It is also quite understandable, when looking at the niche-applications type, that downstream-users do not like to disclose the non-restricted niche-markets where they believe to have a business-advantage.

The most recent industrial initiative to approach mass-flow of Cd-pigments in plastics applications shows definitively much lower figures than those reported earlier.

Sales figures in 2012-2013 and interviews indicate a maximum use of 20 t/y of cadmium pigments for incorporation in plastics:

- about 10 t/y for applications in the 16-restricted resins, under derogation of entry-23 for "safety, aerospace and defence applications"
- about 6 t/y are incorporated in plastic 'master-batches' exported outside Europe
- about 4 t/y are incorporated in master-batches and further used in Europe for niche applications where the unmatched colouring and resistance characteristics of the Cd-pigments are required. It is to be noted that those niche applications are already regulated under the "Toys, ROHS and ELV" legislation

As stated in the Annex XV (June 2014), releases from Cd-pigments out of plastic matrices (appendix 5 – Results from Wilson DC study 1982) are very low; even when modelled, and cautious consideration of all uncertainties is provided (the EUSES-model with e.g. as assumption 50 t/y application in plastics vs. 4 t/y currently),the calculated daily intake of man via the environment would represent no more than 0,1% of the allowed mean daily dietary intake (same Annex XV document – appendix 4).

3. Classification of Cd-pigments

As indicated in their REACH registration files, submitted in 2013, the Cd-pigments CdZnS ("cadmium yellow") and CdSSe ("cadmium red") were excepted from group-classification, carrying forward the same exception which had existed for many years under the previous EU classification and labelling scheme, e.g. under EU-CLP regulation EC 1272/2008 (Annex VI) which adopted the identical wording from the earlier Annex I lists of Directive 67/548/EEC (classification and labelling of substances).

For registration, Transformation-Dissolution (TD) data generated for both substances were checked against the CLP rules. To this end, TD data on the Cd-pigments were compared with TD data obtained on another sparingly soluble Cd-compound, i. e. CdTe. By this comparison, and by referring to aquatic effect levels observed for CdTe, the aquatic hazard of the Cd-pigments was assessed as follows:

Acute aquatic classification CdZnS

Standard ecotoxicity testing on CdTe revealed a lowest EC50 value of 1.14 mg CdTe/L observed for Daphnia magna (resulting in no acute classification of CdTe; Cadmium consortium 2013, Chemical safety report CdTe). The ecotoxicity of Cd-compounds is related to the amount of Cd ions, released in aqueous medium. TD testing on CdTe demonstrated the sparingly soluble character of this substance: 3.2% of Cd was solubilised after 7days (pH 6). The solubility of Cd from CdZnS is however proven to be even much lower than the solubility of Cd in CdTe: after 7 days only 0.06 % of the Cd was solubilised from CdZnS at pH 6. Considering a) the lowest EC50 value of CdTe of 1.14mg/l, and b) the 50x lower solubility of Cd in CdZnS, as compared to CdTe, CdZnS was not classified for acute aquatic effect.

Chronic aquatic classification CdZnS

Standard ecotoxicity testing on CdTe revealed a lowest NOEC value of 0.2 mg CdTe/L observed for

Daphnia magna, resulting in classification as "chronic 3" of CdTe - in this respect it is noted that Cadmium compounds are considered as being "equivalent to rapidly degradable" based on their rapid removal from the water column, ref Mutch Ass, 2013). TD testing on CdTe demonstrated the sparingly soluble character of this substance (3.8% of Cd solubilised after 28 days in pH 6 medium, which is maximising Cd-solubilisation in the relevant pH range 6 -8.5).

From TD tests, it was shown that the solubility of Cd from CdZnS was however proven to be even much lower than the solubility of Cd in CdTe: after 28 days only 0.23 % of the Cd was solubilised from CdZnS at pH 6. Considering a) the lowest NOEC value of CdTe of 0.2mg/l, and b) the fact that >16 x less Cd solubilizes from the CdZnS as compared to CdTe (in other words, 16x more CdZnS loading (~=0.2 x 16 ~= 3.3 mg/l - would be needed to reach the lowest NOEC value), CdZnS was not classified for chronic aquatic effect.

Acute aquatic classification CdSSe

Also for CdSSe, reference was made to the lowest EC50 value of CdTe (1.14 mg CdTe/L) observed for Daphnia magna (resulting in no acute classification of CdTe). The solubility of Cd from CdTe (3.2% of Cd solubilised after 7days in pH 6) was again compared to the one of Cd from CdSSe; the latter was proven to be even lower than the solubility of Cd in CdTe: after 7 days only 0.026 % of the Cd was solubilised from CdSSe at pH 6. Considering a) the lowest EC50 value of CdTe of 1.14mg/l, and b) the >100x lower solubility of Cd in CdSSe, as compared to CdTe, CdSSe was not classified for acute aquatic effect.

Chronic aquatic classification CdSSe

Likewise, the lowest NOEC value of 0.2 mg CdTe/L observed for Daphnia magna was used a reference point for the classification of CdSSe. In this respect it is noted that Cadmium compounds are considered as being "equivalent to rapidly degradable" based on their rapid removal from the water column (Mutch Ass 2013).

The TD data on CdTe, demonstrating 3.8% of Cd solubilised after 28 days in pH 6, were compared with the TD data on CdSSe. From TD tests, it was shown that the solubility of Cd from CdSSe was proven to be even much lower than the solubility of Cd in CdTe: after 28 days only 0.028 % of the Cd was solubilised from CdSSe. Considering a) the lowest NOEC value of CdTe of 0.2mg/l, and b) the >100x lower solubility of Cd in CdSSe, as compared to CdTe, CdSSe was not classified for chronic aquatic effect.

Conclusion :

We strongly believe that the insignificant potential release from 4 t/y of non-hazardous Cd-pigments in plastics does not represent a risk for workers or the general population and does not justify a Restriction action at EU-level. This is particularly true when there is clear and definite evidence of the sources (>120 T/y) of the vast majority of cadmium exposure to the general population: use of cadmium-containing fertilisers, metal refining and the burning of fossil fuels. On top of that, smokers also have significant exposure from tobacco combustion (+50%).