CADMIUM IN SPECTACLE FRAMES

REPORT

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1. INTRODUCTION

According to paragraph 10 of Entry 23 of Annex XVII of REACH:

"Cadmium and its compounds shall not be used or placed on the market if the concentration is equal to or greater than 0.01% by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories including: bracelets, necklaces and rings, piercing jewellery, wrist-watches and wrist-wear, brooches and cufflinks."

On 25 July 2011, the Commission was informed by the Helpdesk Unit of ECHA of the possible risk from cadmium contained in spectacle frames, which are currently not included in paragraph 10 on jewellery articles and hair accessories of the amended restriction on cadmium. This information emerged from a question to ECHA from a non-EU company as to whether use of cadmium is currently restricted under the REACH provisions for jewellery articles and hair accessories.

In response to that question, the Commission has expressed the opinion (August 2011[1]) that "Metallic parts of eyeglass frames are not considered as jewellery items and therefore do not currently fall under the scope of the restriction in paragraph 10 of entry 23 of Annex XVII of REACH".

The Commission services requested ECHA on 28 September 2011 to investigate the issue of cadmium in spectacle frames, as follows:

- To collect the available technical and socio-economic information on the issue of cadmium in spectacle frames.
- Based on the outcome of this investigation, [to] give advice to the Commission on whether these articles should be included in the restriction provision of the Annex XVII of entry 23 of REACH.

Spectacle frames refer to frames designed for use with all types of lenses (including both medical glasses and sunglasses) no matter what material they are made of (e.g. plastic or metal). Generally, an eyeglass frame includes a pair of lens holders in which plastic or glass lenses are mounted. A bridge joins the lens holders in a fixed relation with each other.

2. SCOPE

The presence of cadmium in any plastic parts of spectacle frames (as with all such articles) is currently restricted according to paragraph 1 of Entry 23 of Annex XVII of REACH: *"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".*

Similarly the presence of cadmium in any painted parts of a spectacle frame (case mainly applicable for sun protection or decorative type of glasses) is restricted according to the paragraph 2 of the Entry 23: *"Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.1 % by weight of the paint on the painted article".*

[1] ECHA Helpdesk question, incident number INC000000053539, 2011.

Therefore, this investigation has focussed on any potential existence (intended or otherwise) of cadmium or its compounds in the metal part of the frame, which is not currently restricted under the REACH provisions.[2]

ECHA has been informed by the European Federation of Optical Industries (EUROM1) that in some Member States, such as the UK, spectacle frames are classified as medical devices. If a company intends to use the CE mark (voluntary action but essential in order to circulate their spectacle frames in the EU market) they should comply with the ISO standard that applies for these products in all EU countries (as indicated in the Medical Devices Directive (MDD)). Although the MDD (2007/47/EC) does not make direct reference to spectacle frames, it seems that these articles may be covered by the definition of medical devices as given in Article 1 of the Directive. Annex I of MDD contains information on the CE mark, according to which, "*The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances*".

The Commission (communication of August 2011) has also expressed the opinion that medical devices legislation could apply to these types of products. It should be noted that defining a given product as a medical device falls within the competence of the Competent Authorities of the Member States where the product is on the market. According to EUROM1, the obligation to check for the conformity of frames is part of the post market surveillance, which each manufacturer has to undergo under the MDD (e.g. the RAPEX system at the European level, or similar notification systems at the national level).

However, even though medical devices legislation can be applied to spectacle frames, restrictions may also be posed for these articles under the REACH Regulation as they are not exempted from title VIII of REACH (Restrictions).

Some information about non-EU legislation was requested via contact with Environment Canada and Health Canada. The Canadian Consumer Product Safety Directorate (CPSD) reported that the Canada Consumer Product Safety Act, which came into effect in June 2011, includes general prohibitions on the manufacture, import, advertising or sale in Canada of consumer products that pose an unreasonable risk to human health or safety (http://laws-lois.justice.gc.ca/eng/acts/C-1.68/page-2.html#h-5). CPSD has no information suggesting that cadmium is used in Canada in either metallic or plastic components of either medical or non-medical glasses such as sunglasses. The Therapeutic Products Directorate of Health Canada is responsible for the regulation of medical glasses under the Food and Drugs Act and its Medical Devices Regulations, but does not collect information on the composition of frames.

[2] Paragraph 5 of Entry 23 restricts the use of cadmium in metallic plating of a number of sectors and articles, in particular (but not exclusively) relating to food production, household goods and furniture. Spectacle frames (and other small consumer articles) are not specified in this restriction.

3. METHODOLOGY

For the purposes of this investigation, ECHA has carried out (i) a consultation with Member States and relevant industrial stakeholders asking them to share with ECHA any available data of a technical or socioeconomic nature on the issue of cadmium in spectacle frames; (ii) a screening of all available REACH sources (e.g. registration dossiers) and relevant scientific literature.

More specifically, ECHA established contacts with: (a) industry stakeholders, both leading companies in the EU market (e.g. Euro-optics, Polaroid) and relevant European industry associations (e.g. European Council of Optometry and Optics (ECOO), European Federation of Optical Industries (EUROM1) or other associations that could possess relevant information due to the nature of their activities (e.g. International Association of Cadmium manufacturers (ICdA)); (b) Member States competent authorities via a CIRCABC consultation launched in May 2012; (c) Health Canada and Environment Canada who provided information on their existing legislative provisions and scientific studies concerning cadmium.

ECHA invited the identified stakeholders to contribute with any available socio-economic data and/or technical evidence of relevance to the following main questions (adapted according to the organisation):

> (a) Have cadmium or its compounds been intentionally used at the national or EU levels, or outside the EU, in the production of the metal parts of spectacle frames (either intended for medical glasses or sun protection and any other type of glasses) and for which function?
>
> (b) Has cadmium or its compounds been found in imported spectacle frames (from third countries)? Is any testing applied?
>
> (c) If cadmium or its compounds are used in the metal parts of spectacle frames (either produced in the EU or imported), would a potential restriction on the placing on the EU market of such cadmium containing articles cause any technical or socio-economic consequences to the associated industry (e.g. availability of alternatives to cadmium and its compounds, cost impacts?)

An overview of the stakeholder's responses to the ECHA questions concerning cadmium in spectacle frames is given in the Annex table (section A-4). The main findings are discussed in the next section.

4. FINDINGS

4.1 Exposure related to cadmium in spectacle frames

Only a limited amount of information was obtained from the relevant literature and the stakeholder consultation about hazards and exposure related to the presence of cadmium in spectacle frames. A review article (Walsh et al, 2006) considered the presence of heavy metals and other potential allergens in spectacle frames, and briefly mentioned cadmium as being present historically in paints, plastic and solder used in spectacle frames, but to a very limited extent now. However, the focus of this article was skin sensitisation, which is likely to make cadmium, whose primary hazards are toxicity and carcinogenicity, of minor investigatory interest.

The impact assessment undertaken previously on cadmium in jewellery (RPA, 2010) could be used as a starting point for assessing the health concerns related to cadmium in spectacle frames. In that study, exposure to cadmium in jewellery was generally assumed to be through mouthing and skin contact, with the possibility of direct migration from metal alloys, solders and platings all of which might contain cadmium. In the case of spectacle frames, migration will be mitigated in many cases by plastic and paint coatings (in which cadmium is already restricted), and mouthing and (possibly) direct skin contact might be considered to be relatively reduced sources of exposure. Nevertheless, the RPA study is clearly of relevance in terms of the nature of the impacts potentially associated with cadmium in spectacle frames.

4.2 Information from the literature on the technical uses of cadmium in spectacle frames

The available international literature was reviewed for information about: (a) The function of cadmium containing alloys in the metal part of spectacle frames; (b) The current use of cadmium-free alloys which are widely available on the market for use in spectacle frames.

The results of this search are presented in Section A-1 of the Annex. Two specific uses can be identified: (a) As a pigment additive to precious and other metals which are used to construct frames or to plate base metal frames; (b) As a component in memory alloys. In addition, cadmium could be used as a minor component of any base metal which is used to produce the structure of the frames and which is then coated, painted or encased in plastic. Cadmium can also be used as a pigment in the plastic part of frames, in paints used for coating, and in solders. The first two of these are already subject to restriction through Entry 23 of Annex XVII, which limits the cadmium content of plastic articles (0.01% by weight of the plastic) and painted articles (0.1% by weight of the paint).

It should be noted that the information presented in A-1 mainly refers to some technical functions of cadmium alloys in metal spectacle frames worldwide (e.g. US patent, 2012) but does not indicate any use in the EU area.

In addition, ECHA undertook a screening of information available from REACH registration/notification dossier on cadmium alloys, with the results presented in section A-2 of the Annex. There is some general information in these reports about the use of cadmium in alloys for plating, pigmentation and so on, but no registered or notified use in spectacle frames.

4.3 Cadmium in the metal parts of spectacle frames manufactured in or imported into the EU

4.3.1. Articles manufactured in the EU area

As part of the ECHA consultation, EUROM1 (which represents around 700 companies, making up about 85% of European manufacturers of optical lenses and frames) replied that there is neither intentional use nor identified presence of cadmium in spectacle frames, either in plating, colouring or brazing/soldering materials. Similar information has been received by ECOO, which represents the interests of more than 75,000 optometrists and opticians ('downstream users') from 31 European countries. Following consultation with its national members, ECOO confirmed that their EU manufacturers do not use cadmium in the production of metal, plating and painting frames. No use of cadmium in spectacle frames has been identified by the International Association of Cadmium manufacturers (ICdA).

ECHA also received input from two major EU companies in the spectacle frames market, Euro Optics (a manufacturer, importer and distributor of sun- and reading glasses and optical frames), and Polaroid (a global eyewear manufacturer, distributor and direct importer, principally of sunglasses frames rather than medical glasses). Both Euro Optics and Polaroid confirmed that cadmium is not used in the production of either the plastic or metal part of spectacle frames in the EU area.

A summary of the responses received from industry stakeholders is given in the Annex table (A-4). Overall, the consultation with industrial stakeholders concluded that there is no identified use of cadmium (or its compounds) in the metal (and any other) part of spectacle frames in the EU area.

4.3.2 Articles imported into the EU area

ECHA also consulted stakeholders on the issue of the potential presence of cadmium in spectacle frames imported into the EU and on the existence of testing regimes inside or outside the EU.

According to ECOO, which also represents a number of companies which import and label own-brand products, the potential for spectacle frames imported from outside of the EU to contain cadmium could not be excluded, although there had been no report so far of articles which do not comply with existing REACH restrictions on cadmium in plastic and painted articles. Furthermore, Euro Optics, which imports sunglasses and reading glasses from China and Taiwan, reported that some Asian companies might still use cadmium in products destined for local markets, which could theoretically result in traces of the waste material in spectacle frames exported to Europe if machines and tools were not cleaned sufficiently.

Information was received from Euro Optics, ECOO and the UK Optical Confederation (member of ECOO) concerning testing applied to their or their members' imported spectacle frames to check for compliance with REACH restriction provisions on cadmium in the plastic and painted parts of the articles (see section A-3 of the Annex). No cases of non-compliant samples were reported. However, because there are currently no restrictions in Entry 23 relating to the cadmium content of metal parts of metal frames (or any provisions which would imply such a restriction), no specific testing for cadmium in metal parts is currently undertaken.

10 Member States responded to ECHA's cadmium consultation. No specific information was received concerning the presence of cadmium in the metal part of imported articles. Only Norway reported any information relating to testing for cadmium in imported or domestically produced spectacle frames. This was that their enforcement unit has performed (non-routine) screening analysis of spectacle frames, in relation to the REACH restriction on cadmium in plastic and painted articles, but no cadmium presence was reported – more information is provided in section A-3 of the Annex.

4.3.3 Information on the potential impacts on industry of a future restriction

EUROM1 expected no significant socio-economic implications from a potential cadmium restriction in spectacle frames, but this conclusion was not based on a consideration of the increased costs of more specific and systematic testing, exceeding current REACH restrictions (i.e. of the metal part of the frame). Limited or no socio-economic implications were also reported by Polaroid, some ECOO national members (Italy, Switzerland) and Member States through the CIRCABC consultation, but it is not clear to what extent these respondents had considered the possible costs of additional testing. Europtics and various ECOO members reported that current testing is limited because of the high cost of testing – a figure of $850 per article for a full test report

was mentioned. Respondents did not report by how much costs would increase per complete test if testing requirements were extended to cover cadmium in metal parts, and what the total aggregate increase in costs of such a change would be.

The UK Optical Confederation (representing optometrists, dispensing opticians, manufacturers and distributors of frames and contact lenses in the UK) argued that imposing further limits on cadmium in spectacle frames would increase the price of frames in middle markets. This was based on qualitative arguments that greater numbers of spectacle frames would need to be tested for cadmium content and that more costly alternative materials and processes might need to be used. These comments were made in the context of a presumed complete ban on cadmium, but they are still indicative of the potential impacts of a new limit value on the presence of cadmium in the metal parts of spectacle frames.

However, according to EUROM1, if spectacles are already classed as medical devices in the UK, frames manufactured in or imported into the UK might already comply with the relevant "CE marked" requirements to reduce to a minimum the risks posed by dangerous substances (such as CMRs) leaking from the device. This would imply that it might be mainly firms importing frames into countries which do not classify them as medical devices which would be affected.

5. CONCLUSIONS

The conclusions of this consultation with Member States and industry are as follows:

- Cadmium is not currently used intentionally in the EU for the manufacture of the metal parts of spectacle frames.

- No evidence was found to indicate that cadmium is present in the metal parts of imported spectacle frames. As there is no systematic testing for cadmium in these parts, there is a possibility that cadmium might be present, for instance as an impurity.

- The use of cadmium in plastic and painted parts of spectacle frames is already restricted. Testing for the presence of cadmium in these restricted parts of spectacle frames imported into the EU is carried out by industry and enforcement authorities. No evidence was found to indicate non-compliance with existing REACH restrictions.

- Industry stakeholders generally reported that they did not expect significant adverse socioeconomic effects for them if cadmium content were to be restricted in the metal parts of spectacle frames (e.g. at 0.01% cadmium by weight of the metal, in line with paragraph 10 of Entry 23 of Annex XVII for restriction in jewellery). However, it is not clear to what extent stakeholders took account of the potential additional costs of testing should a restriction be adopted.

In sum, the stakeholder consultation and literature review did not demonstrate that there would be a risk related to cadmium in the metal parts of frames, as the (limited) evidence available indicates that cadmium is not present in these parts of spectacle frames. Furthermore, the preparation and opinion making of a restriction proposal would in itself create an administrative cost that would seem to be disproportionate given that there is no indication of risk. Also, any restriction could generate enforcement and implementation (testing) costs.

It is concluded that a restriction of cadmium in the metal part of spectacle frames (under paragraph 10 of Entry 23) would not be proportionate based on current evidence.

REFERENCES

Health and Environment Canada (2011) Consumer Product Safety Act (S.C. 2010,c.21) last amended 2011-06-20, available at http://laws-lois.justice.gc.ca/eng/acts/C1.68/page-2.html#h-5.

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Weldmaxx (2012) available at www.udomsawat.com, searched February 2012.

ANNEX

A-1 Literature information on the use of cadmium containing and cadmium free alloys in the spectacle frames

According to the Kirk-Othmer Encyclopaedia (2010), cadmium metal is utilized commercially as a corrosion-resistant coating on steel, aluminium, and other nonferrous alloys. It is also added in small quantities to some nonferrous alloys to improve strength, hardness, and wear resistance while maintaining thermal and electrical conductivity and other properties. This capacity to improve the quality of certain alloys made it suitable for use in spectacle frames, although its hazard properties forced the opticians to look for alternatives.

The flexible spectacle frames use the so called shape (or smart) memory alloys (SMA). Shape memory alloys are special alloys allowing to any deformation and being able to return to their original shape after an external stimulus, as they would have memory. Due to its properties, like excellent lubricity, softness and malleability (Weldmaxx (2012)), Cd may be used in metal spectacle frames either in the spectacles joints or in flexible spectacle frames (Weldmaxx (2012), Memory alloys (2012), US Patent (2012).

For use in spectacle frames, there are cadmium free alloys widely available on the market.
As indicated in the literature (Welsh et al (2006):
Nickel alloys were by far the commonest metal frame materials (hidden by alloy names such as 'nickel–silver' and 'Monel'.) but their use in the last years has been declined.
Cobalt and cobalt alloy frames have been marketed as 'hypoallergenic' in recent years, and the metal's use appears to be on the increase.
Palladium is used relatively frequently in the spectacle industry for plating metal frames and has been reported as a cause of allergy in this context (Finishing.com, (2012), US Patent (2012)). It is also sometimes used as an underlying plating to improve the adherence of other metal over it.

Perret Opticians (2012) inform on their website of the following cadmium free alloys circulated in the market for use in spectacle frames:
TITANflex a super elastic titanium alloy, ten times more elastic than the conventional spring steel, used for spectacle frames, to allow them reverting to the original shape even after extreme distortions.
Genium, a special alloy used for spectacle frames thanks to its nickel-free composition and skin compatibility and tolerance.
Ticral (Perret Opticians (2012)), an alloy of titanium, copper and chrome. It is nickel-free (and also cadmium-free) and thus hypoallergenic. It is also very lightweight and offers titanium features at lower cost.

A-2 Screening of information on Cadmium from REACH registration/notification reports

Registrations and Downstream User reports

Companies manufacturing/importing the substance at tonnages of more than 1 t/year had to register cadmium by 1 December 2010. From the ECHA investigation of registered data, a number of 22 companies (manufacturers, importers and only representatives) jointly registered cadmium at tonnages above 100 ton/year and only two for 10 to 100ton/year. The identified uses reported in some of the registrations

dossiers include PC7: Base metals and alloys; PC38: Welding and soldering products (with flux coatings or fluxes cores), flux products; SU14: Manufacture of basic metals, including alloys; SU0: Other: Nace C25.6.1: Treatment and coating of metals. The reported tonnages are not detailed on type of uses (REACH IT search 2012).

Classification and labelling notifications

64 classification and labelling notifications have been submitted to ECHA for cadmium (REACH-IT search July/2012, 45 individual notifications and 19 bulk notifications). These companies are manufacturers/importers of cadmium (or of products and mixtures containing it), which put their products in the EU market. The notifications do not contain any information on the uses of the substance on its own or in mixtures.

Pre-registrations

No additional registrations might be expected for the following two registration deadlines. Approximately 500 pre-registrations have been received for all tonnage bands.
The information provided in the submitted CSRs refers to "small amounts of cadmium metal added to copper-cadmium alloys to improve the mechanical properties e.g. contact wires in railways, overhead power lines etc. In the very limited other applications cadmium alloys are used basically in the industrial environment (as special fusible and joining alloys, in nuclear power plants). In these limited applications, it is expected that the potential for consumer exposure to cadmium in alloys is very low.

A-3 Testing on imported spectacle frames for compliance to the REACH restriction provisions on cadmium.

Eurooptics informed that they test group of glasses per different supplier rather than all the imported articles due to the high cost of testing ($850 per article/per colour for a complete test report). On average, they test about 200 models sunglasses (imported from Far East) per year in different colours, all of which so far have passed the tests on cadmium. Eurooptics provided ECHA with reports of recent testing applied to parts of imported spectacle frames in order to measure cadmium concentration in the plastic arms (*plastic part of the frame*) and on the purple coating of the arm (*painted part of the frame*). The used testing method is the European Standard EN 1836:2005. The described tested articles meet the requirements of the allowed % Cadmium ≤ 10ppm (Maximum allowable limit 100ppm or 0.01% set up by REACH) and non-conformity has not been reported so far.
Similarly, the various ECOO members informed of test regimes in place to which all frame batches are subject to ensure compliance with REACH regulations. Due to significant cost of testing, though, not all but a selected number of articles are tested for cadmium as well as for other heavy metals (test reports were also provided). According the UK Optical Confederation, the testing regime is applied to samples from batches of spectacle frames to ensure they do not exceed current safety limits. The manufacturing and testing process happens in the supply chain, usually in the Far East (as articles are mainly manufactured in China and often supplied through Hong Kong). IND is importing these articles to satisfy consumer demand i.e. to ensure that a cheaper alternative frame is available to provide a choice for patients with low to middle incomes. However, they require certification from suppliers that their frames conform to the REACH requirements, including that cadmium is not used in concentrations exceeding the REACH limits.
Among the responded Competent Authorities, only Norway presented some relevant information on testing. The Norwegian CA, although their enforcement unit does not perform analysis on Cd in spectacle frames on a regular basis, informed about a

reported measurement of Cd at 0.019% Cd (> than the 0,01% REACH limit for Cd in plastic articles) in the elastic straps of a pair of swimming spectacles (goggles). No other information about testing of spectacle articles has been reported by the rest of responded national authorities. Member States, though, are expected to test imported spectacle frames within their monitoring activities for the implementation of the REACH relevant provisions for the restriction of cadmium (in the painted or plastic articles according to the provisions of Entry 23 of Annex XVII).

A-4 Overview of IND responses to the ECHA questions concerning cadmium in spectacle frame

	EUROM 1 (European Federation of Optical industries)	**Euro-optics**	**Polaroid eyewear**	**ECOO (European Council of Optometry and Optics)**
Organisation / **Question**	Represents the European manufacturers of optical lenses and frames.	Manufactures, imports, designs and distributes sun-/reading glasses and optical frames.	Global eyewear manufacturer and distributor (and direct importer).	Represents optometrists and opticians from 31 European countries. Does not directly represent the manufacturers of spectacles.
(1) Is there any use of Cd (or its compounds) in the EU area in the production of spectacle frames?	No intentional use in neither plating, coloration, or in brazing or soldering materials.	No.	No use in products sold by Polaroid.	No use in frames, plating, painting and soldering (SZ, IT). A very small percentage may contain Cd (UK) in levels ranging between 5ppm to 100ppm.
(2) Is there any import of Cd containing spectacle frames in the EU area?	Imported parts or completed spectacle frames should comply with REACH restrictions.	In principle, no. However, Cd may still be used in spectacles destined for local Asian market and traces of Cd due to waste may be found in spectacle frames in Europe.	----------	Potential importation from non-EU countries containing Cd cannot be excluded (IT). A very small percentage contains Cd (UK).
(3) Test methods to ensure no Cd in imported products.	Manufacturers /importers test products on a regular basis. Children frames are frequently subject to test according to CPSIA.	Test rapports with European Standard EN 1836:2005 A1:2007. Test series of glasses per supplier.	Regular testing. The testing is done in accordance with the procedure of the independent testing laboratory commissioned.	Imported sunglasses are checked (SZ). All batches are subject to a test regime (UK). Governmental institution tests exist (TR).
(4) Would a potential restriction of such Cd containing articles cause any socio-economic implications to the industry?	No cost impact and/or socio-economic implication. Possible additional socio-economic implication if more specific/systematic testing.	----------	Limited socio-economic implications.	No socio-economic implications (SZ, IT). Increased costs related to removing Cd based spectacle frames from the market, in case of a ban (UK).