

Module H.i.

Establishing Legal Limits on Lead in Paint: The European Union Experience



LEAD PAINT ALLIANCE



Establishing Legal Limits on Lead in Paint The European Union Experience

Dr Jutta Emig

German Federal Ministry for the Environment,
Nature Conservation, Building and Nuclear Safety
Division of International Chemical Safety, Sustainable Chemistry

Dr Johanna Rose

German Federal Environment Agency
Division of International Chemicals Management

Workshop on Establishing Legal Limits on Lead in Paint
New-Delhi, India
22nd - 23rd September 2014



- Exposure to lead in paints remains a global public health concern.
- Effective legislation and regulations are needed to achieve the global phasing-out of the manufacture and use of lead in paints.
- The EU experience in regulating lead in paints may be one example of an approach to take.





Legal instruments on lead in paints in the European Union

Regulation (EC) No 1907/2006 (REACH)

Name	Registration, Evaluation, Authorisation and Restriction of Chemicals
Entry into force	2007
Scope	Manufacture, placing on the market or use of substances on their own, in mixtures or in articles
Provisions on the use of some lead compounds in paints	(a) restrictions on the placing on the market or use (b) the authorisation procedure for the use



Other EU legal instruments relevant to lead in paint

Regulation (EC) No 1272/2008	Classification, Labelling and Packaging of substances and mixtures
Directive 2009/48/EC	Safety of toys



REACH¹: a cornerstone of EU legislation on chemicals management

Registration Evaluation Authorisation Restriction of Chemicals

- Entered into force in 2007 to improve the protection of human health and the environment from the risks that can be posed by chemicals
- Applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives
- To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU
- If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

¹) http://ec.europa.eu/environment/chemicals/reach/reach_en.htm





- Procedures for collecting and assessing information on properties of substances in force
- Companies work together on registration of the same substance
- The European Chemicals Agency¹ – ECHA – evaluates individual registrations for their compliance
- National authorities and ECHA's scientific committees assess whether the risks of substances can be managed
- Authorities can restrict or ban hazardous substances
- Obligations for manufacturers, importers and downstream users of chemicals and also for companies outside the EU

¹⁾ <http://echa.europa.eu/regulations/reach/understanding-reach>





REACH: a cornerstone of EU legislation on chemicals management

- REACH: more than 51 681 registration dossiers corresponding to 13 682 substances (05/2015)
- REACH: more than 163 substances of very high concern (SVHCs) on the 'Candidate List' (06/2015)
- CLP Regulation in force (Classification, Labelling and Packaging of Substances and Mixtures)
- renewal legislation process, i.e. for sustainable use of pesticides, authorisation of plant protection products, biocidal products




Registration
Evaluation
Authorisation
Restriction of Chemicals





REACH Regulation¹ (Annex XVII): Restrictions on the placing on the market or use of some lead compounds in paints

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction 
Lead carbonates CAS No 598-63-0 CAS No 1319-46-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for <i>use as paint</i> .
Lead sulphates CAS No 7446-14-2 CAS No 15739-80-7	However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the <i>restoration and maintenance of works of art and historic buildings and their interiors</i> , as well as the <i>placing on the market for such use</i> . Where a Member State makes use of this derogation, it shall inform the Commission thereof.

¹⁾ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140410&qid=1405608384996&from=EN>



REACH Regulation (Annex XVII) : Restrictions on the placing on the market or use of some lead compounds in paints



Designation of the substance, of the group of substances or of the mixture	Conditions of restriction	
<p>Lead compounds when classified in the CLP Regulation¹ as:</p> <ul style="list-style-type: none"> • carcinogen 1A or 1B and/or • toxic to reproduction 1A or 1B <p>e.g. Silicic acid, lead nickel salt (CAS No 68130-19-8), Lead hydrogen arsenate (CAS No 7784-40-9), <i>etc</i></p> <p>Specific <i>concentration limits</i> apply</p>	<p>Shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the <i>general public</i>.</p> <p>The use of those lead compounds by <i>professionals</i> is allowed, and for certain product categories <i>derogations apply</i>, e.g. for artists' paints.</p> <p>Suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: "<i>Restricted to professional users</i>".</p>	
Example	Classification	Specific Conc. Limits
lead alkyls	Reproductive tox. 1A	Reproductive tox. 1A: C ≥ 0.1 %

¹⁾ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20131201&qid=1405674984129&from=EN>



REACH Regulation (Annex XIV): Authorisation procedure for the use of certain lead compounds

Substances subject to authorisation procedure	Conditions of authorisation
<p>Lead compounds that are substances of very high concern (SVHC)</p> <p>Lead chromate (CAS No 7758-97-6)</p> <p>Lead sulfochromate yellow (CAS No 1344-37-2)</p> <p>Lead chromate molybdate sulfate red (CAS No 12656-85-8)</p>	<p>Authorisation can only be granted when:</p> <ul style="list-style-type: none">• the <i>risks to human health</i> and the environment arising from the use of the substance can be adequately controlled.• the <i>socio-economic benefits</i> from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable.



N.B. The use of the above-mentioned substances is not allowed in the EU after 21 May 2015 without authorisation



REACH Regulation (Annex XIV): Authorisation procedure for the use of certain lead compounds

Substances subject to authorisation procedure

**Lead compounds that
are on the candidate list¹
of substances of very
high concern**

Lead di(acetate)
(CAS No 301-04-2)

Conditions of authorisation



When the substances are present in articles:

- Producers or importers of articles must *notify* the European Chemicals Agency if a substance of very high concern on the candidate list is present in those articles in quantities totalling over *one tonne per producer or importer per year* and the substance is present in those articles above a *concentration of 0.1 % weight by weight*, unless exposure to humans or the environment can be excluded under normal or reasonably foreseeable conditions of use including disposal (Article 7(2)).
- Any supplier of an article containing a substance included in the candidate list *above 0.1% weight by weight* must provide to the recipient of the article with *sufficient information*, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. *Consumers have the right to request that information*, which has to be provided within 45 days of the request (Article 33).

¹⁾ <http://echa.europa.eu/web/guest/candidate-list-table>



Directive 2009/48/EC (Safety of toys)

Name	Toy Safety Directive								
Entry into force	2009								
Scope	Products designed or intended, whether or not exclusively, for use in play by children under 14 years of age								
Provisions on the use of lead compounds in toys	<p>Substances that are classified as <i>carcinogenic, mutagenic or toxic for reproduction (CMR)</i> of category 1A, 1B or 2 under the CLP Regulation shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.</p> <p>Specific <i>derogations</i> apply.</p> <p>The following migration limits, from toys or components of toys, shall not be exceeded:</p> <table border="1"><thead><tr><th>Element</th><th>in dry, brittle, powder-like or pliable toy material</th><th>in liquid or sticky toy material</th><th>in scraped-off toy material</th></tr></thead><tbody><tr><td>Lead</td><td>13.5 mg/kg</td><td>3.4 mg/kg</td><td>160 mg/kg</td></tr></tbody></table>	Element	in dry, brittle, powder-like or pliable toy material	in liquid or sticky toy material	in scraped-off toy material	Lead	13.5 mg/kg	3.4 mg/kg	160 mg/kg
Element	in dry, brittle, powder-like or pliable toy material	in liquid or sticky toy material	in scraped-off toy material						
Lead	13.5 mg/kg	3.4 mg/kg	160 mg/kg						

¹⁾ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20130720&from=EN>



Information Exchange: RAPEX¹

- *EU rapid alert system that facilitates the exchange of information on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.*
- It does not cover food, pharmaceuticals and medical devices.
- RAPEX was established by the General Product Safety Directive² (GPSD) in 2004.

Brussels, 25 October 2007

Toy safety – Mattel recall on lead paint toys

Speaking today following the announcement of a recall by Mattel of Go Diego Go (Animal Rescue Boat) toys of their Fisher-Price brand, sold in the UK, Ireland, US and Canada due to excessive levels of lead in paint, EU Consumer Commissioner Meglena Kuneva made it clear that recalling goods from the market is a last resort for industry. With effective controls all along the supply chain, dangerous goods should not be reaching supermarket shelves or arrive in the hands of children at home. Commissioner Kuneva said the fact that the European Commission had, on this occasion, received prior notice before the recall from Mattel is a sign that some of the intensive work with industry in recent months is starting to pay off. In this way, the European Commission is able to provide advice to companies on the recall process if necessary and to circulate to all EU Member States authorities full information through the EU RAPEX (Rapid Alert System) system for dangerous consumer goods. This fourth Mattel recall comes as the European Commission is in the final stages of a 2 month review of the consumer product safety mechanisms in place in Europe. Commissioner Kuneva will present the results of this stocktaking and analysis on the EU China (RAPEX) report on Chinese enforcement actions, on 22 November 2007 in Brussels.

http://europa.eu/rapid/press-release_IP-07-1605_en.htm

1) http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm

2) <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN>



Follow-up to REACH: COM Regulation as regards lead 836/2012¹

Recitals

- Due to their mouthing behaviour, children, especially those under 36 months, can be repeatedly exposed to lead released from jewellery articles. Such repeated exposure to lead can result in severe and irreversible neurobehavioural and neurodevelopmental effects, to which children are particularly sensitive given that their central nervous system is still under development.
- The REACH dossier proposes a prohibition of placing on the market and the use of lead and its compounds in jewellery articles if the lead migration rate is greater than 0.09 $\mu\text{g}/\text{cm}^2/\text{h}$.

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0836&rid=1>





Follow-up to REACH: COM Regulation as regards lead 836/2012

Recitals

- Given the lack of information on the release of lead under mouthing conditions and due to the lack of suitable alternatives for all uses in crystal glass and vitreous enamels, the latter are being exempted from the COM regulation.
- Further exemptions: non-synthetic or reconstructed precious and semiprecious stones, internal components of watch timepieces.
- Moreover: A restriction on the placing on the market of second-hand and antique jewellery would have a significant socioeconomic impact, as such items would lose their marketable value in the Union, and would pose difficulties for enforcement. Therefore, jewellery articles placed on the market for the first time up to 12 months after the entry into force of the restriction as well as imported antique jewellery articles should be exempted from the restriction.





German regulations on management of substances containing lead at workplace

Technical Rules for hazardous substances Nr 505 under
Hazardous Substance Ordinance (GefStoffV)

Scope

- Exposure in 24 types of workplaces (i.e. renovation, construction works)

Requirements

- Identification of substitutes and alternative processes (lead free)
- Organisation measures, i.e. cleaning, protection, safety, information of the personnel
- Management concept for health protection
- Bio-monitoring data



Our commitment to SAICM / emerging policy issue: lead in paint

Strongly supportive of the Strategic Approach to
International Chemicals Management and the work on
lead in paint

Funding of activities since 2009





- The EU has long standing experience in regulating lead in paints.
- Effective legislation and regulations are needed also in developing countries to achieve the global phasing-out of the manufacture and use of lead in paints.
- Reducing exposure to lead in paints remains a global public health priority.





Dr Jutta Emig

German Federal Ministry for the Environment,
Nature Conservation, Building and Nuclear Safety
Division of International Chemicals Safety, Sustainable Chemistry

Dr Johanna Rose

German Federal Environment Agency
Division of International Chemicals Management