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

Module F-1
General Remarks

• 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

<table>
<thead>
<tr>
<th>Regulation (EC) No 1907/2006 (REACH)</th>
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<tbody>
<tr>
<td><strong>Name</strong></td>
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<tr>
<td><strong>Entry into force</strong></td>
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<tr>
<td><strong>Scope</strong></td>
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</table>
| **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**

<table>
<thead>
<tr>
<th>Regulation (EC) No 1272/2008</th>
<th>Classification, Labelling and Packaging of substances and mixtures</th>
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</table>
REACH\textsuperscript{1}: 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.

\textsuperscript{1} http://ec.europa.eu/environment/chemicals/reach/reach_en.htm
REACH: Basic Works

Registration Evaluation Authorisation Restriction of Chemicals

- Procedures for collecting and assessing information on properties of substances in force
- Companies work together on registration of the same substance
- The European Chemicals Agency\(^1\) – 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

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
**REACH Regulation\(^1\) (Annex XVII):**
Restrictions on the Placing on the Market or Use of Some Lead Compounds in Paints

<table>
<thead>
<tr>
<th>Designation of the substance, of the group of substances or of the mixture</th>
<th>Conditions of restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lead carbonates</strong></td>
<td>Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for <em>use as paint</em>.</td>
</tr>
<tr>
<td>CAS No 598-63-0</td>
<td></td>
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<tr>
<td>CAS No 1319-46-6</td>
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<tr>
<td><strong>Lead sulphates</strong></td>
<td>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 <em>restoration and maintenance of works of art and historic buildings and their interiors</em>, as well as the <em>placing on the market for such use</em>. Where a Member State makes use of this derogation, it shall inform the Commission thereof.</td>
</tr>
<tr>
<td>CAS No 7446-14-2</td>
<td></td>
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<tr>
<td>CAS No 15739-80-7</td>
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| **Lead compounds** when classified in the CLP Regulation¹ as:  
  • carcinogen 1A or 1B  
  and/or  
  • toxic to reproduction 1A or 1B  
  e.g. Silicic acid, lead nickel salt (CAS No 68130-19-8), Lead hydrogen arsenate (CAS No 7784-40-9), *etc*  
Specific concentration limits apply | Shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public.  
The use of those lead compounds by *professionals* is allowed, and for certain product categories *derogations apply*, e.g. for artists’ paints.  
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: *"Restricted to professional users".*  

<table>
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<tr>
<th>Example</th>
<th>Classification</th>
<th>Specific Conc. Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>lead alkyls</td>
<td>Reproductive tox. 1A</td>
<td>Reproductive tox. 1A: C ≥ 0.1 %</td>
</tr>
</tbody>
</table>

**REACH Regulation (Annex XIV):**

**Authorisation Procedure for the Use of Certain Lead Compounds**

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<tr>
<th>Substances subject to authorisation procedure</th>
<th>Conditions of authorisation</th>
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<tr>
<td><strong>Lead compounds that are substances of very high concern (SVHC)</strong></td>
<td>Authorisation can only be granted when:</td>
</tr>
<tr>
<td>Lead chromate (CAS No 7758-97-6)</td>
<td>• the <em>risks to human health</em> and the environment arising from the use of the substance can be adequately controlled.</td>
</tr>
<tr>
<td>Lead sulfochromate yellow (CAS No 1344-37-2)</td>
<td>• the <em>socio-economic benefits</em> 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.</td>
</tr>
<tr>
<td>Lead chromate molybdate sulfate red (CAS No 12656-85-8)</td>
<td></td>
</tr>
</tbody>
</table>

*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

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<tr>
<td>Lead compounds that are on the candidate list(^1) of substances of very high concern</td>
<td>When the substances are present in articles:</td>
</tr>
<tr>
<td>Lead di(acetate) (CAS No 301-04-2)</td>
<td>• Producers or importers of articles must <em>notify</em> the European Chemicals Agency if a substance of very high concern on the candidate list is present in those articles in quantities totalling <em>one tonne per producer or importer per year</em> and the substance is present in those articles above a concentration of <em>0.1% weight by weight</em>, unless exposure to humans or the environment can be excluded under normal or reasonably foreseeable conditions of use including disposal (Article 7(2)).</td>
</tr>
<tr>
<td></td>
<td>• Any supplier of an article containing a substance included in the candidate list <em>above 0.1% weight by weight</em> must provide to the recipient of the article with <em>sufficient information</em>, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. <em>Consumers have the right to request that information</em>, which has to be provided within 45 days of the request (Article 33).</td>
</tr>
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</table>

# Toy Safety Directive

**Directive 2009/48/EC (Safety of toys)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Toy Safety Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entry into force</td>
<td>2009</td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td>Products designed or intended, whether or not exclusively, for use in play by children under 14 years of age</td>
</tr>
<tr>
<td><strong>Provisions on the use of lead compounds in toys</strong></td>
<td>Substances that are classified as <strong>carcinogenic, mutagenic or toxic for reproduction (CMR)</strong> 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. Specific <strong>derogations</strong> apply. The following migration limits, from toys or components of toys, shall not be exceeded:</td>
</tr>
</tbody>
</table>

<table>
<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>
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<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>

Information Exchange: RAPEX

- *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 Directive\(^2\) (GPSD) in 2004.


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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 Sates 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.

Follow-up to REACH: COM Regulation as Regards Lead 836/2012

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 μg/cm²/h.

Follow-up to REACH:
COM Regulation as Regards Lead 836/2012

• 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
Conclusion

- 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.
For more information, visit the European Chemicals Agency (ECHA) website at: 
https://echa.europa.eu/de/home

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