Testing Methods

Daniel Ma
Director, Business Development

July 29, 2008
The task

Testing methods:
– Lead, Cadmium, Phthalates

• What testing protocols are in use worldwide?
• What is involved with testing in the EU, in different U.S. states, and elsewhere in the world?
• What is the range and extent of testing worldwide?
• What are the pros and cons of different testing methods (costs, feasibility, reliability, etc.)?
• What best management practices to incorporate testing procedures?
Topics in this presentation

• An overview of toy safety testing standards for some major markets
  – Total heavy metals versus soluble heavy metals
  – Phthalates requirements EU versus USA
• Material testing & analytical methods - chemical & XRF
• Best management practices – implementation and demonstration
• Trend of the future
Overview of some major toy safety standards

• North America
  – **USA:**
    – Federal: 16 CFR 1303, lead
    – State Regulations: Lead, Cadmium, Phthalates
    – ASTM F963 Toy Safety Standard
  – **Canada:**
    – Heavy Metals: Hazardous Products Act (Toys)
    – Phthalates: The Phthalate Control Act - DEHP

• Europe
  – Toy Safety Standard EN71
  – Cadmium Directive 91/338/EEC
  – Phthalates Directive 2005/84/EC

• Australia & New Zealand
  – ISO8124 (equivalent to EN71)
### Comparison of heavy metals requirements

<table>
<thead>
<tr>
<th>Elements</th>
<th>Canada Hazardous Products Act (Toys) Chapter H-3 Part 1</th>
<th>Europe/UK/France/Australia/New Zealand EN 71 Part 3 BS 5665 Part 3 NF EN 71-3 AS/NZS ISO 8124 Part 3</th>
<th>U.S. ASTM F963 US CPSC*</th>
</tr>
</thead>
<tbody>
<tr>
<td>(%), (mg/kg), (ppm)</td>
<td>SOL. 0.1, SOL. 60</td>
<td>SOL. 0.1, SOL. 25, SOL. 30, SOL. 1000, SOL. 250, SOL. 1000</td>
<td>SOL. 60, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Antimony (Sb)</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Arsenic (As)</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 1000, SOL. 250, SOL. 1000</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Barium (Ba)</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Cadmium (Cd)</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Chromium (Cr)</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Lead (Pb)</td>
<td>SOL. 0.5</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Mercury (Hg)</td>
<td>TL. N.D.</td>
<td>TL. N.D., SOL. 60, SOL. 25, SOL. 60</td>
<td>TL. N.D., SOL. 60, SOL. 25</td>
</tr>
<tr>
<td>Selenium (Se)</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
<tr>
<td>Others</td>
<td>SOL. 0.1</td>
<td>SOL. 0.1, SOL. 75, SOL. 50, SOL. 75</td>
<td>SOL. 0.1, SOL. 25, SOL. 60</td>
</tr>
</tbody>
</table>

Note: 0.1% = 1000 ppm = 1000 mg/kg

Canada has both total metal requirement for lead and mercury and soluble metal requirement for the others (coating only). Canada revised total lead requirement from 0.5% to 0.06%, effective June 20, 2008.

Europe, Australia, New Zealand and other countries adopting ISO 8124 standard, they only have soluble metals requirements (coating & substrate).

USA has total metal requirement for lead, and soluble metals requirements for lead and other heavy metals (coating only).
Discussion of the heavy metals standards

• Total Metal Content
  – w/w ratio: the weight of metal *digested* to the weight of material tested
  – identical to total metal concentration of the tested material
  – concentration expressed in %, ppm, mg/kg

• Soluble Metal Content
  – w/w ratio: the weight of metal *extracted* by simulated gastric solution to the weight of material tested
  – extraction is done by means of an agitation at a temperature which simulates gastric conditions (EN 71 only)
  – concentration expressed in %, ppm, mg/kg
Relationship between soluble metals and bioavailability – EU Toy Safety Directive 88/378/EEC

Chemical properties
For the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day:

Bioavailability

- 0.2 µg for antimony
- 0.1 µg for arsenic
- 25.0 µg for barium
- 0.6 µg for cadmium
- 0.3 µg for chromium
- 0.7 µg for lead
- 0.5 µg for mercury
- 5.0 µg for selenium

Maximum migration for materials (mg/kg)

- 60 for antimony
- 25 for arsenic
- 1000 for barium
- 75 for cadmium
- 60 for chromium
- 90 for lead
- 60 for mercury
- 500 for selenium

Assumption: average daily intake of toy materials 8 mg per day

The bioavailability of these substances means the soluble extract having toxicological significance.
Definition of Accessibility

Establishing a relationship risk / chemical hazards.

- The design of the probe contains joints in the finger probe simulate the flexibility of a finger. The probe joints are designed to rotate up to 90 degree in one direction.

- Accessibility assessment procedure requires that the articulated probe is maneuvered to the part or component of a toy being tested. If the probe contacts the part or component, that part or component is considered to be accessible.

Note: European toy standard EN 71-3 exempts inaccessible materials from the heavy metals requirements.
## Lead & Cadmium – USA

<table>
<thead>
<tr>
<th>States</th>
<th>Requirement</th>
<th>Enforcement</th>
</tr>
</thead>
</table>
| Illinois    | Product Scope: toys, furniture, clothing, accessories, jewelry, decorative objects, edible items, candy, food, dietary supplements  
Applied age: ≤ 6 years  
Lead content ≤ 0.06%                                                                 | 20 June 2006         |
| Michigan    | Product Scope: Children’s jewelry, toy or child care article  
Applied age: ≤ 7 years  
Lead content ≤ 0.06%                                                                 | 20 March 2008 (Effective date) |
| Maryland    | Product Scope: accessories and jewelry, clothing, decorative objects, furniture, lunch boxes and eating utensils, toys and other item specified by the department in regulation  
Applied age: < 6 years  
Lead content ≤ 0.06%                                                                 | 1 July 2008 (Effective date) |
| Washington  | Product Scope: Toys, children’s cosmetic, children’s jewelry, sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, clothing, child car seats  
Applied age: ≤ 12 years  
Lead content ≤ 0.009%  
Cadmium content ≤ 0.004%                                                                 | 1 July 2009 (Effective date) |
| Federal     | Product Scope: children’s product  
Applied age: < 12 years  
Lead content ≤600 ppm (in 180 days)/300 ppm (in 2 years)/100 (in 4 years) ppm  
Lead in paint ≤ 0.009% from 0.06%                                                                 | 6 Mar 2008 (Proposed) |
| USA Congress| Product Scope: Jewelry and non-jewelry  
Applied age: ≤ 7 years  
Lead content ≤0.02% (Jewelry) / 0.04%(non-jewelry)                                                                                             | 11 Sep 2007 (Not later than 2 years ) |

<table>
<thead>
<tr>
<th>States</th>
<th>Requirement</th>
<th>Enforcement</th>
</tr>
</thead>
</table>
| Nebraska    | Product Scope: Toys and child care article  
Applied age: ≤ 7 years  
Lead content ≤ 0.06%                                                                                              | 10 Jan 2008 (Proposed) |
| Massachusetts| Product Scope: Jewelry  
Applied age: ≤ 14 years  
Lead content ≤ 0.06%                                                                                                  | 30 Jun 2008 (Proposed) |
| California  | Product Scope: clothing, accessory, decorative object, edible item, candy, food, dietary supplement, toy, or item of furniture  
Applied age: ≤ 12 years  
Lead content ≤40 ppm (any substance)/ 0.4% (paint)                                                                    | Not specified (Proposed) |
| Kentucky    | Product Scope: Clothing, accessory, jewelry, decorative objects, edible items, candy, food, dietary supplements, toys, children’s furniture  
Applied age: < 7 years  
Lead content ≤ 0.06%                                                                                                  | 90 days after the day of approval |
| Vermont     | Product Scope: toys, furniture, jewelry, vitamins and other supplements, personal care products, clothing, food, and food containers and packaging.  
Applied age: < 12 years  
Lead content ≤ 0.06% as of October 1, 2008; ≤0.03% as of July 1, 2009; and ≤0.01% as of January 1, 2010.  
Exemption: Inaccessible materials & electronics. However, paint, coatings, and electroplating shall not be considered barriers that would render lead in the substrate inaccessible to a child | 7 June 2008 (Proposed) |
| Alabama     | Product Scope: toys; children’s cosmetics; children's jewelry; products for teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children; or child car seats.  
Applied age: < 12 years  
Lead content ≤ 0.009%  
Cadmium content ≤ 0.004%                                                                                          | 27 May 2008 (Proposed) |
Lead & Cadmium – USA (Summary)

• Most of these state requirements cover ‘lead’ only. Washington and Alabama include ‘cadmium’ as well.

• The highest tolerable limit for lead is 600 ppm. This limit for lead is likely to be reduced over time and the future limit could possibly be down to 40 ppm

• The limit for cadmium is 40 ppm

• These metal requirements apply to children product of a wide variety for different ages.

• Requirements from Vermont specifically exempt inaccessible materials and electronic components. *Paint, coatings, and electroplating shall not be considered barriers that would render lead in the substrate inaccessible to a child.*
Phthalates standards

Development highlights in Europe

- Commission’s first proposal to introduce a ban on the use of six phthalates in toys and childcare articles intended to be put in the mouth by children under the age of three on November 10, 1999.

- Risk assessments revealed DEHP, DBP, and BBP are toxic for reproduction, classified as CMR (carcinogen, mutagen, reprotoxic) substances, category 2 and should therefore be banned in all toys and childcare articles.

- Precautionary principle: DINP, DIDP and DNOP should be banned in toys and childcare articles that can be mouthed by the most vulnerable age group of children, namely those under three years of age.

- Requirements:
  - **DEHP, DBP & BBP** - 0.1% by mass of the plasticized material in **toys and childcare articles**
  - **DINP, DIDP & DNOP** - 0.1% by mass of the plasticized material in **toys and childcare articles which can be placed in the mouth** by children

- Effective January 17, 2007 and guidance document for “can be placed in the mouth by children” created for implementation.
<table>
<thead>
<tr>
<th>States</th>
<th>Requirement</th>
<th>Enforcement</th>
</tr>
</thead>
</table>
| Maryland         | 1) Any Toy or Child Care Article < 6yrs: Bisphenol-A prohibited AND individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 6yrs AND can be placed in mouth: Bisphenol-A prohibited AND individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 1 Jan 2010 (Proposed) |
| Illinois         | 1) Any Toy or Child Care Article: Individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 3yrs AND can be placed in mouth: Individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 1 Jan 2009 (Proposed) |
| San Francisco City | 1) Any Toy or Child Care Article: Individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 3yrs AND can be placed in mouth: Individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 27 May 2007          |
| Hawaii           | 1) Any Toy or Child Care Article: Individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 3yrs AND can be placed in mouth: Bisphenol-A prohibited AND individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 1 Jan 2009 (Proposed) |
| Alabama          | Product Scope: toys; children’s cosmetics; children’s jewelry; products designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children; or child car seats.  
Applied age: < 12 years  
Individual phthalate or combined (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 27 May 2008 (Proposed) |
| Vermont          | 1) Any Toy or Child Care Article: Individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 3yrs AND can be placed in mouth: Individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 1 Jan 2009 (Proposed) |
| Massachusetts    | 1) Any Toy < 3yrs: Bisphenol-A prohibited AND individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Child Care Article < 3yrs AND can be placed in mouth: Bisphenol-A prohibited AND individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 1 Jan 2008 (Proposed) |
| California       | 1) Any Toy or Child Care Article: Individual phthalate (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 3yrs AND can be placed in mouth: Individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1% | 1 Jan 2009 (Effective date) |
| Washington       | Any Toy or Child Care Article (includes clothing) < 12 yrs: DEHP + DBP + BBP + DINP + DIDP + DNOP ≤ 0.1% | 1 Jul 2009 (Effective date) |
| Federal          | 1) Any Toy or Child Care Article: (DEHP, DBP, BBP) ≤ 0.1%  
2) Any Toy or Child Care Article < 3yrs AND can be placed in mouth: DEHP + DBP + BBP + DINP + DIDP + DNOP ≤ 0.1% | 1 Jan 2009 (Proposed) |
# Phthalates requirements comparison

<table>
<thead>
<tr>
<th>Location</th>
<th>EU</th>
<th>US CA &amp; SF</th>
<th>Washington</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>Toys and Child care article</td>
<td>Toys and Child care article</td>
<td>Toys; cosmetics; children's jewelry; child care article; clothing; child car seats for use by children under the age of twelve</td>
</tr>
<tr>
<td><strong>Requirement</strong></td>
<td>1) DEHP, DBP &amp; BBP - 0.1% by mass of the plasticized material in toys and childcare articles 2) DINP, DIDP &amp; DNOP - 0.1% by mass of the plasticized material in toys and childcare articles which can be placed in the mouth* by children*</td>
<td>1) Any Toy or Child Care Article: Individual phthalate (DEHP, DBP, BBP) ≤ 0.1% 2) Any Toy or Child Care Article &lt; 3yrs AND can be placed in mouth: Individual phthalate (DEHP, DBP, BBP, DINP, DIDP, DNOP) ≤ 0.1%</td>
<td>Individually or in combination of phthalates (DEHP, DBP, BBP, DINP, DIDP, DNOP) should be less than 0.1%</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Guidance Document to interpret the concept “which can be placed in the mouth by children” – meaning any one dimension smaller than 5 cm <a href="http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&amp;doc_id=165">http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&amp;doc_id=165</a></td>
<td>Guidance document not yet available</td>
<td>Because of such difference, a PVC toy which complies with EU phthalate requirements may fail the Washington requirements</td>
</tr>
</tbody>
</table>
Some available chemical methods for metal content determination: lead & cadmium

USA

- ASTM E 1645, Dry Paint Samples by Hotplate or Microwave Digestion for Subsequent Lead Analysis
- ASTM E 1613, Determination of Lead by ICP, AA
- ASTM 4004, Determination of Metal Contents for Rubber by AA
- AOAC 974.02, Lead in Paint AA Method
- EPA 3050B, Acid digestion of sediments, sludges, and soils
- EPA 3052, Microwave assisted acid digestion of silicones and organically based matrices

Europe

- EN71-3, Migration of Certain Elements (ISO 8124-3, Migration of Certain Elements)
- EN1122 – Microwave Digestion for halogen containing plastic

Canada

- Health Canada, Laboratory Policies and Procedures:
  - Method C-02 – Determination of Total Lead in Paint and Applied Coating
  - Method C-02.2 – Determination of Total Lead in Surface Coating Materials by Close Vessel Microwave Digestion
  - Method C-07 – Determination of Total Mercury in Paint and Applied Coating

Total Metal group
- Method C-03 – Determination of Leachable Arsenic, Selenium, Cadmium, Antimony, and Barium in Applied Coating

Soluble Metal group
Total Metal Testing

Scrape off coating from sample

Hot plate: acid, heat, agitation

Min. 0.1g sample weight

Digestion

Determine sample weight

Microwave: acid, heat, pressure

Concentration determined by ICP

Analyte solution
Soluble Metals Testing

Coating removal from sample

Concentration determined by ICP

Shaker bath for 1 hour at 37 °C (EN71)

Min. 0.3g sample weight

Sample size specification: 0.5 mm or smaller through 500 μm sieve (EN71)

Sample weight determination

Add of 50 times 0.07N HCl, maintaining pH value within 1.0-1.5 (EN71)
Phthalate testing - USA & Europe

Sample cutting (3 mm x 3 mm)

Extraction: EN 14372
Extract sample with diethyl ether at 50 °C for 6 hrs by Soxhlet apparatus

Extraction: ASTM D 3421
Extract sample with 2:1 Carbon Tetrachloride:Methanol at 80 °C for 16 hrs by Soxhlet apparatus

Solvent evaporation

Dissolved in hexane
Dissolved in chloroform

Determined by GC-MS
XRF methods and instrument

• Merits
  – XRF is a relative quick measuring process. Measurement could be obtained in 5 minutes
  – XRF non-destructive.

• Challenges and cautions
  – XRF detects elements: lead, cadmium in materials but not phthalates in materials
  – Energy dispersive versus wavelength disperse, different detection limit (90 ppm of lead / 40 ppm of cadmium could be below detection limit)
  – XRF is a comparative technique, its performance depends on the quality of calibration, which in turn depends on the accuracy of the standards used to establish instrument calibration. (limited CRM available)
  – XRF is very much matrix sensitive. Spectral and matrix interferences must be taken into account during analysis, especially of such diverse and complex samples as polymers and metal alloys. (absorption of fluorescence radiation)
  – Knowing the capability and limitation of an XRF equipment before measurement is taken and results are accepted
Thickness effect

XRF can penetrate thin layer of material. Measurement of cadmium varies depending on thickness of the sample.
Quantity effect

Measurement varies if quantity falls short of minimum sample quantity requirement prescribed by the XRF instrument.
Matrix effect

When interference element Cl is present, absorption of fluorescence radiation from Pb occurs. Measurement becomes lower than actual value.
Challenges & Cautions - chemical testing

• Heavy Metals
  – Minimum sample weight from surface coating, min 0.1 gm – 0.3 gm could mean destroying many toys
  – Off-the-shelf test kits reliability
    • Not recommend because of reliability problem
    • False positive and false negative
    • http://www.cpsc.gov/cpscpub/prerel/prhtml08/lead.pdf

• Phthalates
  – What types of plastic may contain phthalates?
Phthalates testing experience with Intertek
Reliability of Test Results

Laboratory Accreditation

<table>
<thead>
<tr>
<th>Schedule</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>24-47 High Street, Ltd</td>
</tr>
<tr>
<td>Intertek</td>
<td>Site Address: 18 Shengdian Road, Shezhen, China</td>
</tr>
</tbody>
</table>

This certificate is issued by the United Kingdom Accreditation Service (UKAS) to Intertek Testing Services Shenzhen Ltd for the testing of toys, food, and hard lines division.

The certificate is valid from 09 August 2005 to 31 May 2008, and can be renewed on the same conditions.

The Accreditation Manager is [Name], and the Quality Manager is [Name].

The European Parliament and the Council of the European Union, through their decision No. 2001/144/EC, have established the framework for the recognition of the national bodies responsible for ensuring and controlling the competence of organizations in the fields of calibration, testing, inspection, and certification of systems, products, and processes.
ISO 9001: Quality management systems - Requirements

• Quality management system
  – General requirements
  – **Documentation requirements**

• Management responsibility
  – Management commitment
  – Customer focus
  – Quality policy
  – Planning
  – Responsibility, authority and communication
  – Management review

• Resource management
  – Provision of resources
  – Human resources
  – Infrastructure
  – Work environment

• Product realization
  – Planning of product realization
  – Customer-related processes
  – **Design and development**
  – **Purchasing**
  – Production and service provision
  – **Control of monitoring and measuring devices**

• Measurement, analysis and improvement
  – General
  – Monitoring and measurement
  – Control of nonconforming product
  – **Analysis of data**
  – Improvement

■ Critical elements
ISO 9001: Quality management systems - Requirements

• **Documentation requirements**
  – Obvious need for documented policy, quality manual, procedures and records

• **Design and development**
  – Applicable statutory and regulatory requirements should be determined and reviewed as design input

• **Purchasing**
  – The rule of thumb is that if you do not specify it, it is likely that you do not get it. Therefore it is important that all applicable compliance requirements be specified in purchase order

• **Control of monitoring and measuring devices**
  – All testing and measuring devices used in manufacturing process, have to be calibrated, re-adjusted and protected to maintain accuracy

• **Analysis of data**
  – Data have to be collected, analyzed and verified conformity to the requirements
Certification option to demonstrate best practice management in place

- Intertek toy certification program
  - The Scheme adopts –
  - Product Certification System 7 – batch testing, and
  - Elements of Product Certification System 2
  - As specified in the ISO publication “Certification and related activities – Assessment and Verification of Conformity to Standards and Technical Specification, 1992”.

- The Scheme includes the following elements:
  - Material Sampling
  - Safety Testing
    - both raw materials and finished product
    - design appraisal
  - Quality System Review
  - Granting of Product Certification
  - Compliance Surveillance – testing of samples from the open market
EU REACH – Overview

“There is a general obligation for manufacturers and importers of substances to submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or above per year. Failure to register means that the substance is not allowed to be manufactured or imported.”


• Entry into force June 1, 2007
• Requirements for REACH compliance
  • Pre-registration
  • Registration
  • Notification
  • Evaluation
  • Authorization
  • Restriction
  • CSAs, CSRs, & Technical Dossiers
Notification responsibility under REACH

As part of the REACH regulation requirements, a list of SVHC, Substances of Very High Concern, is required to be published. Under Article 33 of REACH Regulation, the supplier of an article (for example a toy manufacturer) has the following responsibility:

On request by a consumer any supplier of an article containing a substance in a concentration above 0.1% weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.
ECHA published a consultation list recently


<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS number</th>
<th>Reason for proposing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthracene</td>
<td>120-12-7</td>
<td>PBT</td>
</tr>
<tr>
<td>4,4’- Diaminodiphenylmethane</td>
<td>101-77-9</td>
<td>CMR</td>
</tr>
<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>84-74-2</td>
<td>CMR</td>
</tr>
<tr>
<td>Cyclododecane</td>
<td>294-62-2</td>
<td>PBT</td>
</tr>
<tr>
<td>Cobalt dichloride</td>
<td>7646-79-9</td>
<td>CMR</td>
</tr>
<tr>
<td>Diarsenic pentoxide</td>
<td>1303-28-2</td>
<td>CMR</td>
</tr>
<tr>
<td>Diarsenic trioxide</td>
<td>1327-53-3</td>
<td>CMR</td>
</tr>
<tr>
<td>Sodium dichromate, dihydrate</td>
<td>7789-12-0</td>
<td>CMR</td>
</tr>
<tr>
<td>5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)</td>
<td>81-15-2</td>
<td>vPvB</td>
</tr>
<tr>
<td>Bis (2-ethyl(hexyl)phthalate) (DEHP)</td>
<td>117-81-7</td>
<td>CMR</td>
</tr>
<tr>
<td>Hexabromocyclododecane (HBCDD)</td>
<td>25637-99-4</td>
<td>PBT</td>
</tr>
<tr>
<td>Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)</td>
<td>85535-84-8</td>
<td>PBT</td>
</tr>
<tr>
<td>Bis(tributyl)oxide</td>
<td>56-35-9</td>
<td>PBT</td>
</tr>
<tr>
<td>Lead hydrogen arsenate</td>
<td>7784-40-9</td>
<td>CMR</td>
</tr>
<tr>
<td>Triethyl arsenate</td>
<td>15606-95-8</td>
<td>CMR</td>
</tr>
<tr>
<td>Benzyl butyl phthalate (BBP)</td>
<td>85-68-7</td>
<td>CMR</td>
</tr>
</tbody>
</table>

**Substances of Very High Concern (SVHC)**

- **CMR**: Carcinogenic, Mutagenic and toxic for Reproduction
- **PBT**: Persistent, Bioaccumulative and Toxic
- **vPvB**: very Persistent and very Bioaccumulative substances
Challenges and Opportunities

Challenges:

• Different and emerging standards from different markets – US states laws
• Many materials can no longer be used because of new requirements – colorants & phthalates in PVC
• Timely supplies of compliant material and their cost

Opportunities:

• Effective quality management system to assure process control and final product compliance
• Internal production control versus external laboratory testing
• Testing protocols and frequency of testing become important factors in risk management
Questions & Answers