

Testing Methods

Daniel Ma

Director, Business Development

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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 Directive 88/378/EEC
 - Toy Safety Standard EN71
 - Cadmium Directive 91/338/EEC
 - Phthalates Directive 2005/84/EC
 - Nickel Directive 94/27/EC, amended by 2004/96/EC
 - Azocolourants Directive 2002/61/EC, amended by 2004/21/EC
- Australia & New Zealand
 - ISO8124 (equivalent to EN71)

Comparison of heavy metals requirements

Elements	Canada	Europe/UK/France/Australia/New Zealand		U.S.
	Hazardous Products Act (Toys) Chapter H-3 Part 1	EN 71 Part 3 BS 5665 Part 3 NF EN 71-3 AS/NZS ISO 8124 Part 3		ASTM F963 US CPSC*
	Paint & Surface Coating	Paint & Surface Coating, Plastic, Paper & Board, Textiles, Mass Coloured Materials, Gel, Graphic Instrument Glass, Ceramic, Metallic Materials	Modelling Materials	Paint & Surface Coating
	(%)	(mg/kg)		(ppm)
Antimony (Sb)	SOL 0.1	SOL 60	SOL 60	SOL 60
Arsenic (As)	SOL 0.1	SOL 25	SOL 25	SOL 25
Barium (Ba)	SOL 0.1	SOL 1000	SOL 250	SOL 1000
Cadmium (Cd)	SOL 0.1	SOL 75	SOL 50	SOL 75
Chromium (Cr)	-	SOL 60	SOL 25	SOL 60
Lead (Pb)	TL 0.5	SOL 90	SOL 90	TL 600 SOL 90
Mercury (Hg)	TL N.D.	SOL 60	SOL 25	SOL 60
Selenium (Se)	SOL 0.1	SOL 500	SOL 500	SOL 500
Others	-	-	-	-

ppm - PARTS PER MILLION
 mg/kg - MILLIGRAM PER KILOGRAM
 SOL - SOLUBLE
 TL - TOTAL
 * - US CPSC REQUIREMENT (16 CFR 1303) IS 0.06% FOR LEAD CONTENT ONLY
 N.D. - NOT DETECTED

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 metal 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

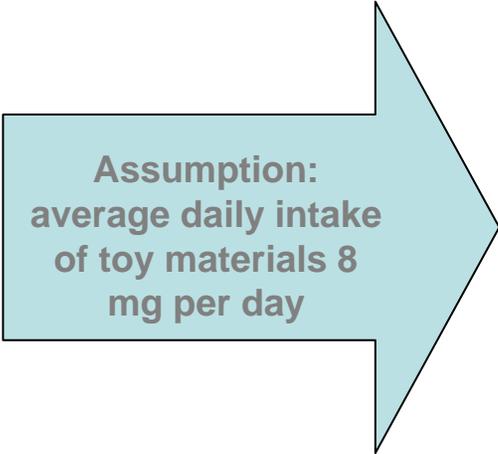
Relationship between soluble metals and bioavailability – EU Toy Safety Directive 88/378/EEC

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



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

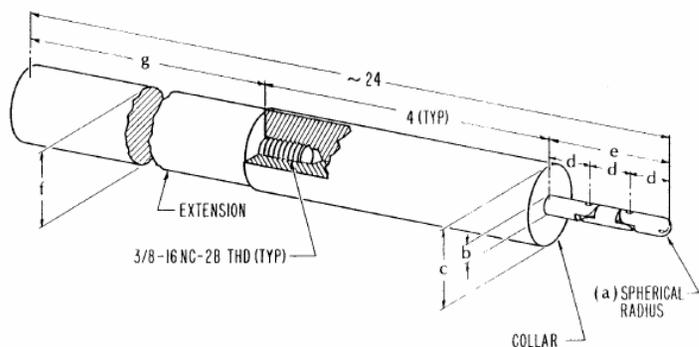
Maximum migration for
materials (mg/kg)

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

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

Definition of Accessibility

Establishing a relationship risk / chemical hazards.



	a	b	c	d	e	f	g
(CHILDREN 0-36 MONTHS INCL.)	PROBE A	110	220	1020	577	1.731	1 1/8 9/32
(* 37-96 * *)	PROBE B	170	340	1510	760	2.280	1 1/2 17 25/32

ALL DIMENSIONS IN INCHES

FIG. 1 Accessibility Probes

- 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.

States	Requirement	Enforcement
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)

States	Requirement	Enforcement
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

States	Requirement	Enforcement
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)

States	Requirement	Enforcement
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

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

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

■ Total Metal group

■ Soluble Metal group

Total Metal Testing

Scrape off coating from sample

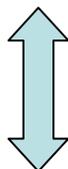


Min. 0.1g sample weight



Determine sample weight

Hot plate: acid, heat, agitation



Digestion



Microwave: acid, heat, pressure

Concentration determined by ICP



Analyte solution

Soluble Metals Testing

Coating removal from sample



Min. 0.3g sample weight



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

Concentration determined
by ICP



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



Extraction



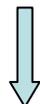
Add of 50 times 0.07N HCl,
maintaining pH value within
1.0-1.5 (EN71)



Sample weight
determination

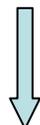
Phthalate testing - USA & Europe

**Sample cutting
(3 mm x 3 mm)**

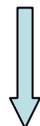


Extraction: EN 14372
Extract sample with diethyl ether at 50 °C for 6 hrs by Soxhlet apparatus

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

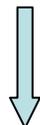


Solvent evaporation



Dissolved in hexane

Dissolved in chloroform



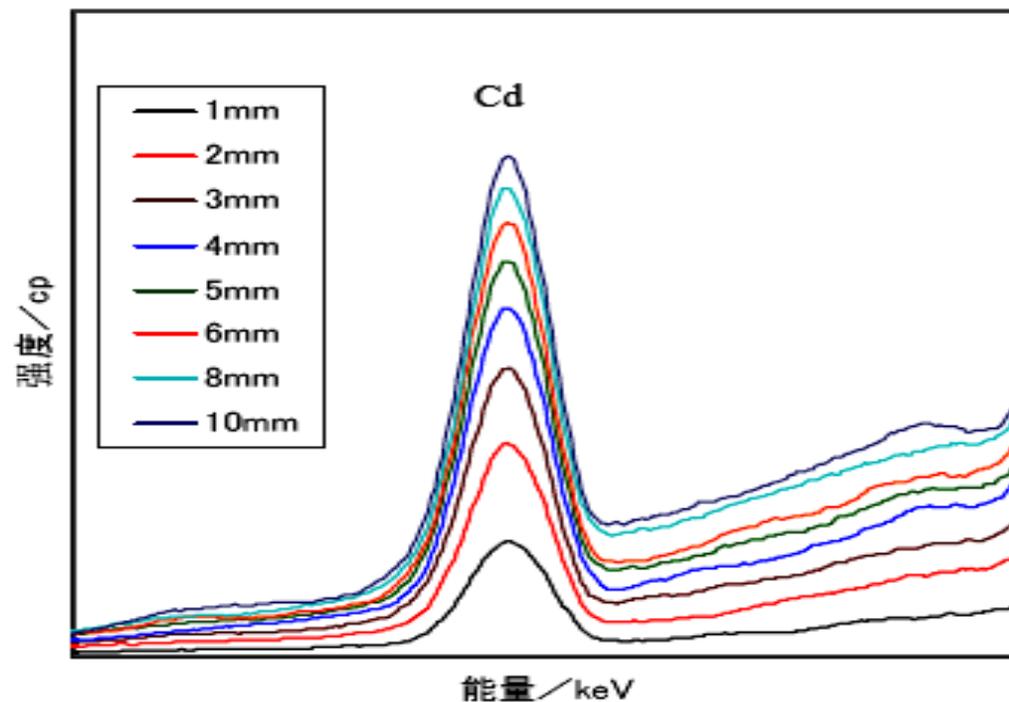
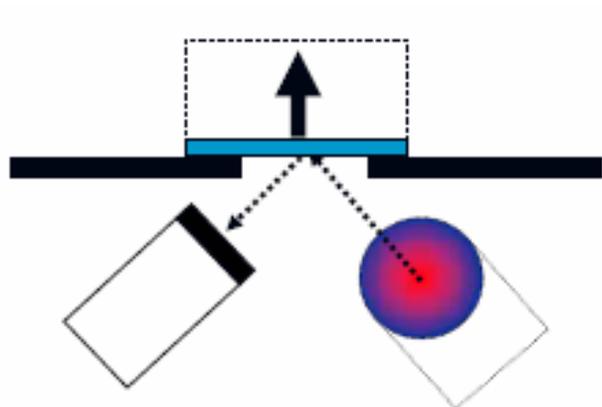
Determined by GC-MS



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

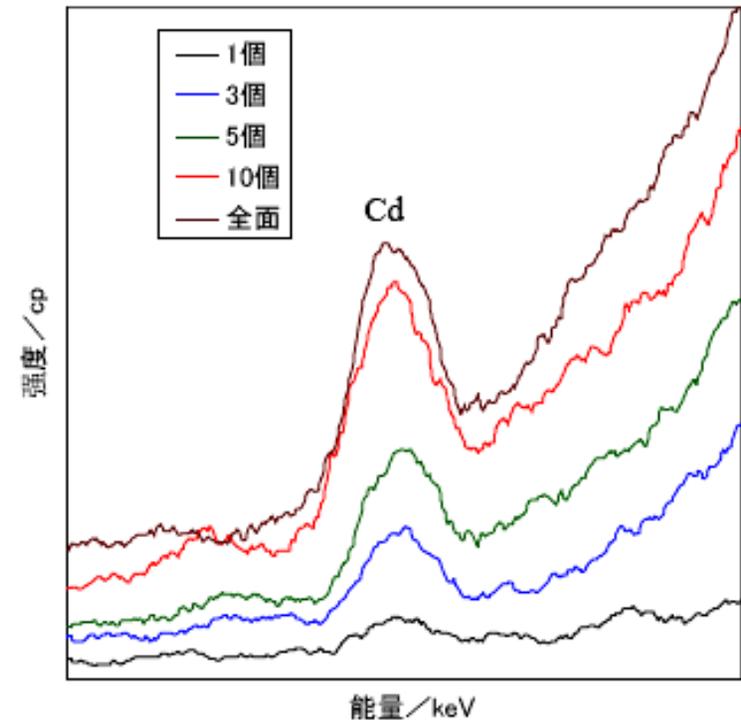
Thickness effect

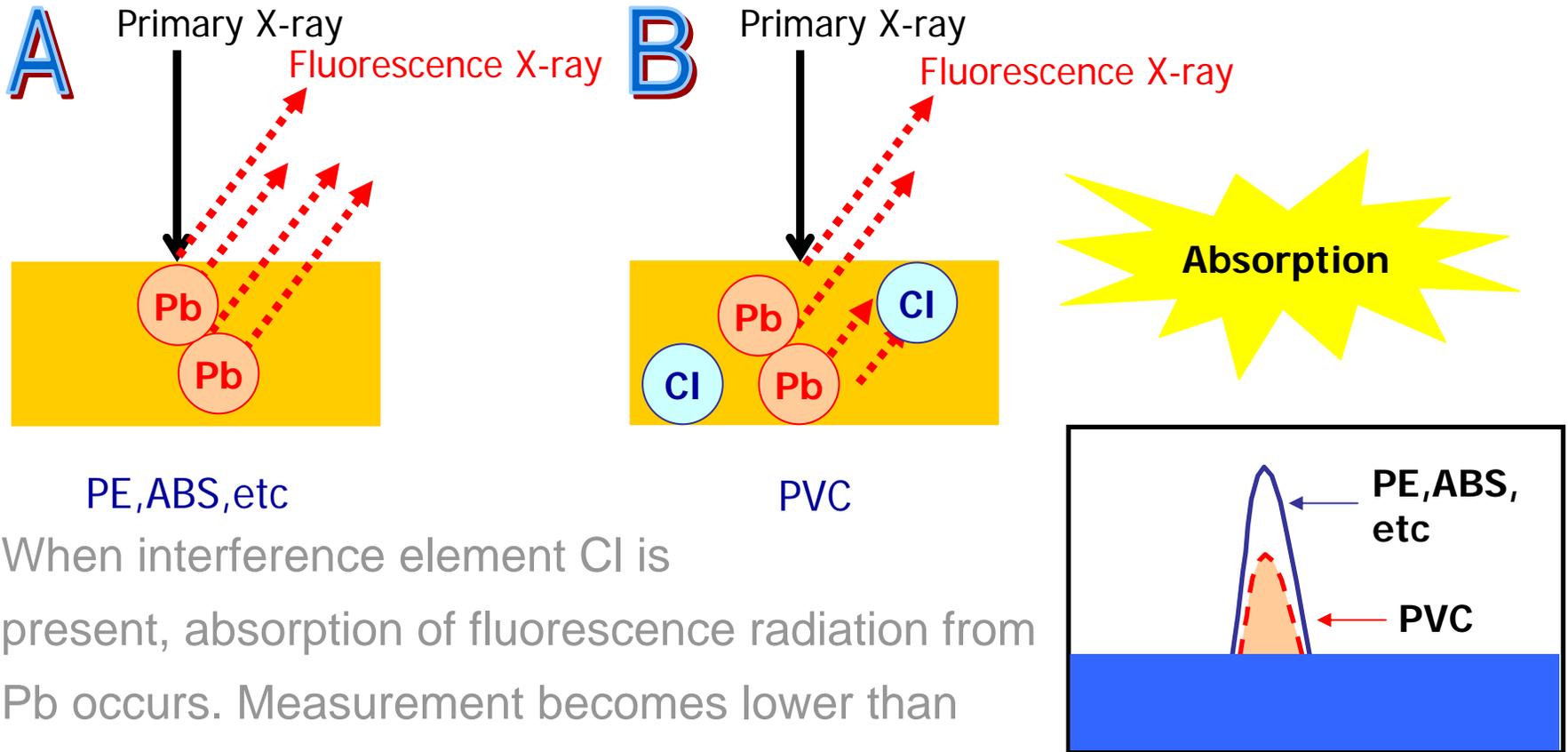


XRF can penetrate thin layer of material. Measurement of cadmium varies depending on thickness of the sample.

Quantity effect

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



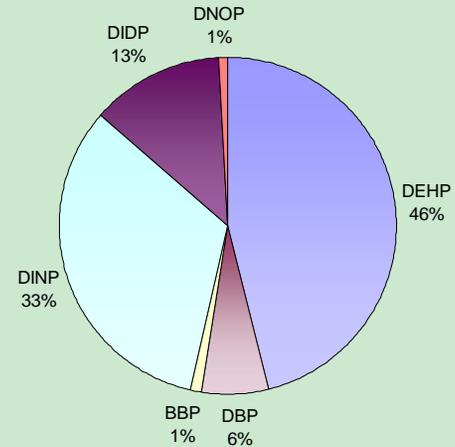


Challenges & Cautions - chemical testing

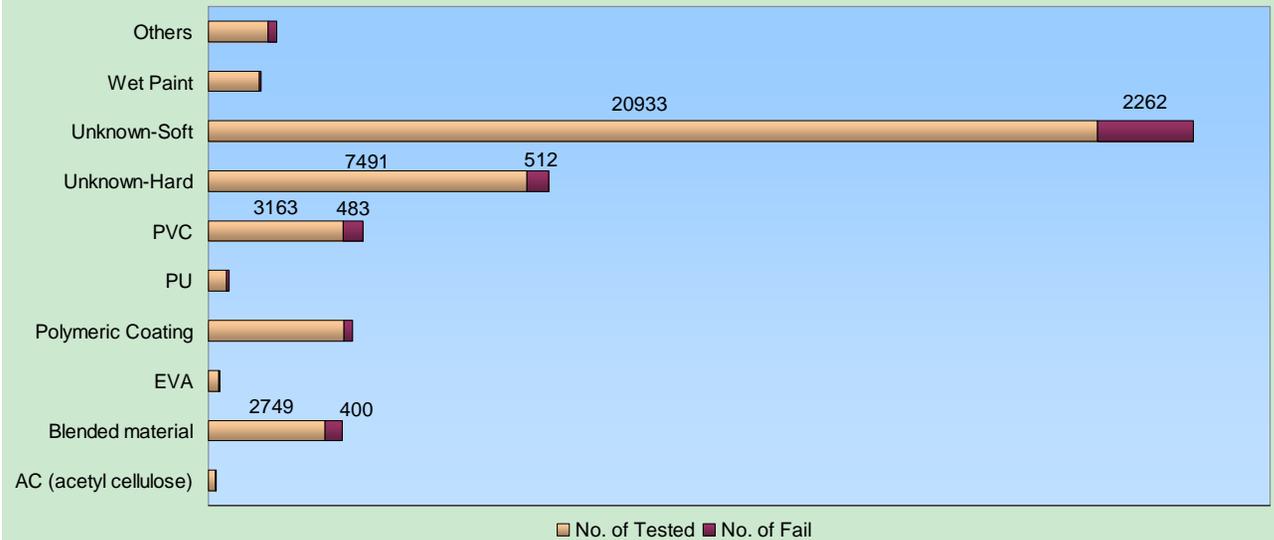
- Heavy Metals
 - Minimum sample weight from surface coating, min 0.1 gm – 0.3 gm could mean destroying many toys
 - Off-the-shelf test kits reliability
 - Not recommend because of reliability problem
 - False positive and false negative
 - <http://www.cpsc.gov/cpsc/pub/prerel/prhtml08/lead.pdf>
- Phthalates
 - What types of plastic may contain phthalates?

Phthalates testing experience with Intertek

Proportion of Different Fail Items



Proportion of Fail and Tested Case in Most Tested Materials



Reliability of Test Results

Laboratory Accreditation

United Kingdom Accreditation Service

ACCREDITATION CERTIFICATE



TESTING LABORATORY
No. 2691

Intertek Testing Services Shenzhen Ltd
Toys, Food & Hard Lines Division
7/F Shekou Technology Main Building
Industrial 7th Road
Shekou
Shenzhen
China

is accredited to BS/EN/ISO/IEC 17025 General Requirements for the competence of testing and calibration laboratories to undertake tests as detailed in the schedule bearing the above accreditation number.

From time to time the schedule to this certificate may be revised and issued by the United Kingdom Accreditation Service.

This Accreditation shall remain in force until the expiry date printed below, subject to continuing conformity with United Kingdom Accreditation Service requirements.

Initial Accreditation: 27 May 2005

[Signature]
Accreditation Manager, United Kingdom Accreditation Service

This certificate issued on 09 August 2005

Expiry date: 31 May 2009

The Department of Trade and Industry (DTI) has entered into a memorandum of understanding with the United Kingdom Accreditation Service (UKAS) through which UKAS is recognised as the national body responsible for assessing and accrediting the competence of organisations in the fields of calibration, testing, inspection and certification of systems, products and personnel.

Schedule United Kingdom 21 - 47 High Street, Fell

	Intertek
	Issue No: 2691 Accredited to: ISO/IEC 17025:2006
Toys, Food & Hard Lines Division 7/F Shekou Technology Main Building Industrial 7th Road Shekou Shenzhen China	
Testing performed	

Materials/Products tested	Type measured	Standard specifications/ Equipment/Techniques used
TOYS AND TOY PACKAGING	Physical and	
	Flammability	EN 71-2:2006 + A1:2007 BS EN 71-2:2005 + A1:2007 Ph023 TP EN 71-2:2003 (Withdrawn) Ph014 TP EN 71-2:1993 (Withdrawn) BS EN 71-2:1994 (Withdrawn) BS 6858:Part 2:1994 Ph026 TP ISO 8124-2:2007 ISO 8124-2:1994 (Withdrawn) Ph019 TP AS/NZS ISO 8124-2:2003

	Schedule of Accreditation Issued by United Kingdom Accreditation Service 21 - 47 High Street, Fellon, Millisay, W11 4JN, UK
	Intertek Testing Services Shenzhen Ltd Issue No: 026 Issue date: 13 November 2007
Testing performed at main address only	

	U# 21:
	Tests

Materials/Products tested	Type measured	Standard specifications/ Equipment/Techniques used
TOYS AND TOY PACKAGING (cont'd)	Chem	
	Chem	
	Physi	
	Electr	
STROLLERS	Physi	
TEXTILES	Formaldehyde	ISO 14184-1:1998 JIS L1041:2000 CE013 TP

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
LEATHER	Forbidden amine (Azo dye) in leather products Chromium (VI)	ISO 17234:2003 CE017 TP In-house Method CE033 TP (additional amines) using HPLC (DAD) and GC (MS) DIN 53314:1995 CH012 TP
METALLIC MATERIALS	Chromium (VI) content	ISO 3613:2003, cl 5.6 Using XRF/UV
POLYESTER FIBRES	Forbidden amine (Azo dye) in polyester products	German Ordinance on Commodities Annex I, No 7, 35 LMBG B62.02-4 1993 In-house Method CE031 TP (additional amines) In-house Method CE032 TP (additional amines) European Council Directive 2002/61/EC EN 14362-2:2003 CE016 TP Using HPLC (DAD) and GC (MS)
PRODUCTS INTENDED TO COME INTO CONTACT WITH SKIN	Release of nickel from products (intended to come into contact with skin)	Statutory instrument 2000 No 1669 The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000 on release of nickel The European Parliament and of the Council Directive 94/27/EC on Release of Nickel Consumer Article Regulation (EC) on Release of Nickel using AAS

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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

“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.”

– European Commission Guidance Document of February 2007

- 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

http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp

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

■ phthalates covered by US State Laws and EU Phthalates Directive

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