



# Lead, Phthalates, and the CPSIA

Staff of the  
U.S. Consumer Product Safety  
Commission

These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

# Lead Section 101

- Lead content limits phased in over 3 yrs  
600 ppm (Feb 10, 2009) to  
300 ppm (Aug 14, 2009) to  
100 ppm, if feasible (Aug 14, 2011)
- Paint and other surface coatings reduced  
from 0.06% (600 ppm) to 0.009%  
(90 ppm) (Aug 14, 2009)
- Study of XRF effectiveness (Aug 14, 2009)

# Lead-Related Actions

## 1. Interpretive Rule on Inaccessible Component Parts

- Allow use of accessibility probes
- Allow use and abuse tests
- Use of tools will not be considered in evaluating accessibility

# Lead-Related Actions

## 2. Exemptions for Certain Electronic Devices

Withdrawal of proposed rule, issuance of Interim Final Rule (Feb 6, 2009)

- List of items unable to meet limits (e.g., lead in cathode ray tubes)
- Removable components if inaccessible in functional form (e.g., battery packs)
- Staff review no less than 5 yrs

# Lead-Related Actions

3. Determinations: materials or products that do not exceed lead content limits (NPR)
  - natural materials (not adulterated, treated, or had lead added in process)
  - precious gemstones
  - semiprecious gemstones if mineral not associated with lead
  - pearls, wood, natural fibers, others

# Ordinary Books

- Ordinary Books
  - Children's books printed after 1985, conventionally printed, intended to be read
  - Limited staff analysis showed the presence of lead in inks in older books
  - Children's books have limited useful life (approx 20 years)

# Textiles

- Dyed or undyed textiles (cotton, wool, hemp, nylon) and non-metallic thread and trim used in children's apparel and fabric products (e.g., blanket)
  - Does not include products that have undergone further treatment that imparts lead
  - Does not include ornamented products
  - Does not include products with plastic or metal fasteners

# Lead-Related Actions

4. Proposed procedures & requirements for Commission determination or exclusion
  - May be evaluated on a case-by-case basis.
  - Does not exceed lead content limits
  - Exceeds lead content limits

# Staff Assessments

- Products that do not exceed lead limits
  - Detailed description of product or material
  - Data on lead content
  - Data or information on manufacturing process
  - Information on test methods used

# Staff Assessments

- Products that exceed lead limits:
  - Normal and reasonably foreseeable use and abuse activity and aging will not result in absorption of any lead into the body.
  - Information about the product
  - Information about child's interaction with the product

# Lead Enforcement Policy

- Issued Feb 6, 2009, addresses:
  - Accessibility
  - Electronics
  - Exclusions
  - Materials consistently below limits
  - Product classes consistently below limits

# Lead Enforcement Policy

- Reporting excess lead content
- Exports of products with excessive lead
- Testing and certification
- Effectiveness

# CPSIA Section 108

## What are Phthalates?

- Family of >50 compounds
- Plasticizer (softener) for PVC & other plastics
- Solvent in paint, adhesives, cosmetics, fragrances

### Found in:

- Toys, action figures, & playground equipment
- Flooring, siding, windows, plumbing, & home furnishings
- Cosmetics, pharmaceuticals, & room fresheners
- Footwear, rainwear, automobiles, & stationery
- Food, water, air, & house dust

# Phthalates in Children's Products

- Di(2-Ethylhexyl) Phthalate (DEHP)
  - Chronic Hazard Advisory Panel (CHAP)
  - Voluntary ban for teethingers, rattles, and pacifiers (1985)
  - ASTM F-963
- Diisononyl Phthalate (DINP)
  - Petition to ban PVC in children's products
  - Voluntarily removed from teethingers, rattles
  - CHAP
  - DINP in toys, teethingers, and rattles not hazardous to children
  - Petition denied (2003)

# Chronic Hazard Advisory Panel (CHAP)

- Consumer Product Safety Act (CPSA)
- Seven independent scientists:
  - Selected by CPSC from a list of  $\geq 21$  nominated by National Academy of Sciences
  - Possess the required expertise
  - Not employed by the federal government, except NIH, NTP, or NCTR
  - Not associated with manufacturers
  - Cleared by the Office of the General Counsel
- Members select a Chair and Vice-Chair

# CHAP's Examination

For all phthalates used in children's products:

- All potential effects on children's health
  - Including endocrine disruption
- Individual and cumulative risks
- Estimate exposure to children, pregnant women, and others
- Total phthalate exposure from:
  - Children's products
  - Personal care products (FDA jurisdiction)
  - All other sources
- All routes of exposure

# CHAP's Examination

- Level of no harm to:
  - Children
  - Pregnant women
  - Other susceptible individuals
  - Offspring
  - Using appropriate safety factors
- Phthalate alternatives used in children's products
- Conducted *de novo* using
  - All available information
  - Objective methods

# CHAP Report

- CHAP Report
  - Includes a recommendation whether to ban any additional phthalates or phthalate alternatives.
- CPSC Staff
  - Evaluate the CHAP report and recommend to the Commission whether to make the interim ban permanent
  - Evaluate CHAP report and recommend whether to ban any additional phthalates or phthalate alternatives

# CHAP Timeline

- Letter requesting nominees to NAS sent February 10, 2009
- First CHAP meeting
  - Could take a year before the first meeting
- The CHAP will have 18 months to complete its examination, and
- 6 months to prepare a final report
- CPSC staff has 6 months to prepare a Commission briefing package
- Entire process could take 3 years or more

# Phthalates Ban

- Permanent Ban—February 10, 2009  
>0.1% DEHP, DBP, BBP in children's toys or child care articles
- Interim Ban—February 10, 2009  
>0.1% DINP, DIDP, DnOP in children's toys that can be placed in a child's mouth or brought to their mouth so they can be sucked or chewed and child care articles
- Based on mass of entire product

# Draft Guidance – Which Products? Comments & Information Needed

- Published in FR February 23, 2009
- Outlines staff approach and requests submission of comments and information by March 25, 2009

# Children's Toy

- Consumer product designed or intended for use by a child 12 years of age or younger during play
  - Factors
  - ASTM F-963 exclusions

# Examples of Toys

Item	Excluded F-963	Section 108
General use Ball		X
Athletic Equip	X	
Plastic Bat		X
Bike	X	
Bath Toy		X
Art Material	X	?
Playground Equip	X	?
Small Ball Promotion		?

# Toys That Can Be Placed in a Child's Mouth

- If any part can be kept in the mouth so that it can be sucked or chewed
- Toys less than 5 cm in any dimension

# Testing of Toys in Inflatable or Deflated State

Item	Inflated by Cons or Manuf	Inflated	Deflated
Pool Toy	C		X
Beach Ball	C		X
Some general use balls	M	X	
Regulation-size athletic equip	Excluded by F-963, not considered toy		

# Child Care Articles

- Designed or intended for children 3 and under to facilitate sleep or feeding or to help such children with sucking or teething
  - Facilitate child versus adult
  - Consider level of involvement or proximity of child and product

# Child Care Articles

- Used directly in mouth: primary function product, subject to law (e.g., pacifier)
- Direct contact w child w/ or w/o direct mouth contact: primary function product, subject to law (e.g., bib)

# Child Care Articles

- Close proximity to child, may or may not be subject to law (e.g., crib mattress)
- Multifunction items: manufacturer stated intent, primary or secondary function, may or may not be subject to law (e.g., strollers)

# Examples of Child Care Articles

Item	Primary Product	Child Care Article
Pacifier	X	X
Bib	X	X
Bottle Warmer		
Crib Teething Rail	?	?
Crib Mattress	?	?
Stroller	?	?
Diaper Pad		

# Practical Guidance for Meeting Phthalates Requirements

- Until finalized, given limited staff resources, staff will focus on:
  - products most likely to pose a risk of phthalate exposure to children, that is, those intended for young children and can be put in the mouth

# Examples of Input Requested by Staff

- Is staff's approach, primary versus secondary child care articles, technically sound?
- Does the staff's approach focus on products with the most potential exposure to children 3 years and under?

# Examples of Input Requested by Staff

- Should these items be subject to section 108 and how should they be classified?  
bib, crib mattress, crib sheet, swing, stroller, wading pool,
- Should some promotional items be regarded as toys? What characteristics make them toys?