Assessing Potential Health Risks of Chemicals in Consumer Products

MASOT Webinar: Safety Assessment of Consumer Products
May 8, 2018

Michael A. Babich
U.S. Consumer Product Safety Commission
Rockville, MD

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.
U.S. Consumer Product Safety Commission (CPSC)

• Independent regulatory agency founded in 1973
• 5 Commissioners appointed by the President
• Jurisdiction: Products in and around the home, schools, and recreational settings
  – Generally, products such as food, drugs, cosmetics, medical devices, pesticides, and automobiles not included
  – Does include child-resistant packaging for household chemicals, drugs, and cosmetics
• Budget of $126 M; staff 545 (FY 2018)
FHSA Definition of “Hazardous Substance”

"Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children."
The FHSA is...

- Risk-based—Considers both toxicity and exposure
- Self-enabling—Manufacturers must determine if their products are hazardous substances and if so are properly labeled
- If the product is a “hazardous substance” it must describe the hazard and list the hazardous ingredient
- Other regulatory options available if labeling does not adequately address the hazard
- Children’s products that are or contain “hazardous substances” accessible to a child are banned by statute
- Includes acute and chronic effects
- FHSA regulations give preference to reliable human data
- FHSA regulations regard consumer products as mixtures
The FHSA does not...

- Does not require pre-market approval
- Manufacturers not required to perform toxicity tests
- CPSC cannot require any specific toxicity tests
- Manufacturers are not required to provide ingredients to CPSC
- Manufacturers are not required to list ingredients on the label, except “hazardous” ingredients
- Does not define “non-toxic” or “non-hazardous.” (Defines “toxic” and “hazardous.”)
Risk Management Options

• Information and education
• Voluntary labeling or performance standard
• Mandatory labeling or other standard
• Recall
• Ban
  – Must apply the least burdensome requirement that adequately addresses the hazard
  – Costs and benefits must be in reasonable balance
  – Convene a Chronic Hazard Advisory Panel (CHAP) for carcinogens, teratogens, or mutagens
There are millions of consumer products. The number is unknown.
Products may be made from any of the 86,000 chemicals in commerce.
About 3,000 chemicals are high production volume (HPV).
About 40% of HPV chemicals have no toxicity data; 7% have only basic data.
CPSC Activities

- Phthalates and phthalate substitutes in children’s toys and child care articles
- Organohalogen flame retardants in consumer products
- Crumb rubber in athletic fields and playground surfaces
- Nanomaterials in consumer products
- Methylene chloride in paint strippers
- 3D Printer emissions
- Wearable technology
- Lead and other metals in children’s products
Phthalates—Consumer Product Safety Improvement Act of 2008 (CPSIA)

- Permanently prohibited children’s toys & child care articles containing >0.1% BBP, DBP, or DEHP
- On an interim basis, prohibited children’s toys that can be placed in a child’s mouth & child care articles with >0.1% DINP, DIDP, or DNOP
- Required CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects on children’s health of all phthalates and “phthalate alternatives” as used in children’s toys and child care articles.

https://www.cpsc.gov/chap
CHAP’s Charge

For all phthalates used in children’s products consider:

i. All potential effects on children’s health, including endocrine disruption

ii. Effects of phthalates both in isolation and in combination with other phthalates

iii. Likely levels of exposures to children, pregnant women, and other susceptible individuals, and their offspring

iv. Cumulative effect of total exposure to phthalates from children’s products & other sources such as personal care products, and other sources

v. Review all relevant data
CHAP’s Charge (continued)

vi. Health effects not only from ingestion, but also as a result of dermal, hand-to-mouth, or other exposure

vii. Consider the level at which there is a reasonable certainty of no harm, using appropriate safety factors, to children, pregnant women, other susceptible individuals, and their offspring

viii. Consider possible similar health effects of phthalate alternatives used in children's toys and child care articles

The panel’s examination is to be conducted *de novo*

Recommend to CPSC whether to ban any additional phthalates or phthalate alternatives
Male Reproductive Development

After considering all health effects of phthalates, the CHAP decided to focus on male developmental effects (NRC 2008)

• Phthalate syndrome in rats:
  – Reduced AGD, retained areola/nipples, cryptorchidism, hypospadias...
  – Phthalate syndrome is due, in large part, to inhibition of testosterone synthesis, i.e., anti-androgenicity
  – Fetus > juvenile > adult

• Most sensitive and most studied endpoint

• Mixtures of anti-androgenic phthalates and other antiandrogens are dose additive (Howdeshell et al. 2008)

https://www.cpsc.gov/chap
Lioy et al. (2015) JESEE 25: 343-353
Epidemiology

• Phthalate syndrome resembles testicular dysgenesis syndrome (TDS) in humans
  – Cryptorchidism, hypospadias, poor sperm quality, and testicular cancer
• Prenatal phthalate exposure in humans associated with:
  – Reduced AGD in neonates
  – Cognitive and behavioral effects in children
• Phthalate exposure in adult males is associated with reduced fertility
• Epidemiology studies are limited by study design and concomitant exposure to multiple phthalates
Exposure Assessment

The CHAP assessed exposure by two approaches:

• Human biomonitoring—total exposure
  – NHANES—pregnant women (n ≈ 1200)
  – Study for Future Families (SFF)—mothers (pre- & postnatal) and infants (n ≈ 300)

• Modeling—exposure by source
  – Diet
  – Consumer products
  – Cosmetics
  – Environment
  – Etc.
Cumulative Risk Assessment (CRA)

• Hazard Index Approach
• Biomonitoring data for five antiandrogenic phthalates
  – DEHP, DBP, DIBP, BBP, & DINP
• Populations:
  – Pregnant women (NHANES & SFF) (surrogate for the fetus)
  – Infants (SFF)
• Dose response assessment
  – Based on animal data
  – RfDs specific for male reproductive toxicity
  – 3 sets of RfDs, or potency estimates for anitandrogenicity (PEAA)
Cumulative Risk Assessment Process

• For each individual in a population
  – Calculate daily intake for each of 5 phthalates (DEHP, DBP, DIBP, BBP, & DINP)
  – Calculate hazard quotients (HQs) and hazard index (HI)
• Generate distribution of HI values
  – Accounts for varying proportions of phthalates in individuals
  – Accounts for differences in pharmacokinetics and potency among phthalates
  – Avoids summing 95\textsuperscript{th} percentile exposures or risks
Distribution of the Hazard Index
Case 3 PEAAs

Pregnant Women (NHANES data)  Infants (SFF data)

Line indicates HI = 1

https://www.cpsc.gov/chap
Key CHAP Findings—Hazard Index

• Pregnant women
  – ≤ 10 % have HI > 1
• Infants: ≤ 5 % have HI > 1
• HI primarily due to DEHP:
  – Cases 1 & 3 > 75 % from DEHP
  – Case 2 > 50 % from DEHP
• Median hazard quotients generally ≤ 0.02, except DEHP
Sources of Exposure to Selected Phthalates

CHAP 2014, Figure E1-2
Key CHAP Findings—Exposure Modeling

Women
• Most exposure from diet
• Cosmetics/personal care products (DEP & DBP)

Infants & Toddlers
• Most exposure from diet
• Cosmetics/personal care products (DEP)
• Mouthing teethers and toys (if phthalates allowed)

Data Gaps
• Data availability/quality varies across scenarios and phthalates
Trends in Phthalate Exposure—Women of Reproductive Age (WORA)

Total = sum of BBP, DEHP, DINP, DBP, DIBP

CPSC 2015, 2017
Trends in Hazard Index—Women of Reproductive Age (WORA)

CPSC 2015, 2017
Final Rule—October 2017

• Made the interim prohibition of DINP permanent and expanded the scope from children’s toys that can be placed in a child’s mouth to all children’s toys
• Lifted the interim prohibitions regarding DIDP and DNOP
• Prohibited children’s toys and child care articles with >0.1 percent of DPENP, DHEXP, DCHP, or DIBP
Flame Retardant (FR) Chemicals

• Used in home furnishings, building materials and consumer products to reduce ignition propensity and flame spread
• Typically used to meet voluntary or mandatory flammability standards
• CPSC activities include assessing the potential risks of FRs in upholstered furniture, mattresses, and children’s products
• Many FRs are semi-volatile compounds (SVOCs), which makes exposure assessment more difficult
Estimated Exposure to FRs in Dust and Indoor Air In the Home, Child Care Centers, Auto, and Office

- Modeled distribution of cumulative exposure by age group
- Combines exposures from the home, day care (children), auto, and office (adults)
- TDCPP, tris (1,3-dichloropropyl-2) phosphate; TCPP, tris (chloropropyl) phosphate

Patterson et al. 2016, 2017
Organohalogen Flame Retardants

• In September 2017, in response to a petition, the Commission directed the staff to assess the risks from OFRs, as a class, in:
  – Children’s products
  – Upholstered furniture
  – Mattresses and mattress pads
  – Plastic casings surrounding electronics

• Working with NAS to consider whether OFRs can be treated as a class and, if so, how
Nanotechnology

• Nanotechnology is an emerging area with many applications in consumer products
  – Sports equipment, wearing apparel, coatings, cleaners, appliances, electronics, toys, children’s products

• CPSC is supporting research assessing potential human exposure and risks associated with consumer products
Nanotechnology Research

- **NIOSH/Harvard University**
  - Characterization and toxicity of emissions from nano-enabled laser printers

- **NIST**
  - Exposure to nanomaterials from consumer products and household dust
  - Development of methods to characterize and quantify carbon nanotubes
  - Characterization methods for nanomaterial release during 3D printing

- **University of Cincinnati/Department of Defense**
  - Nano-prioritization tool & database
  - Systematic literature reviews

- **EPA/NIOSH**
  - Characterizing dust from sawing preservative-treated wood
  - Evaluation of CPSC wipe method and exposure estimates to nanomaterials in surface coatings

- **National Nanotechnology Initiative**
  - Workshops on Quantifying Exposure to Engineered Nanomaterials (QEEN) from Manufactured Products

- **University of Florida/SIINN**
  - NanoWIR$^2$ES: NanoWire intelligent re-design and recycling for environmental safety
Crumb Rubber

• Crumb rubber is made from recycled tires
• Used as infill in athletic fields, mulch, and playground surfaces
• Contains multiple compounds of potential concern: PAHs, VOCs, SVOCs, metals
• Interagency group with CDC and EPA
• CPSC focusing on playground surfaces
• See CPSC Crumb Rubber Information Center for additional information
Consumer products present unique challenges to toxicologists

- Multitude of products with unknown and constantly changing formulations
- New chemicals and emerging technology
  - Nanomaterials; 3D printing
- Alternative test methods
  - In vitro and high throughput methods
- Exposure assessment challenges
  - SVOCs, consumer use scenarios, human biomonitoring
- Risk assessment methods
  - Cumulative risk assessment; mixtures; in vitro data
Additional Information

• Phthalates  [https://www.cpsc.gov/chap](https://www.cpsc.gov/chap)
• CPSC  [https://www.cpsc.gov](https://www.cpsc.gov)
• Or Contact  mbabich@cpsc.gov
Extra Slides
CPSC Statutes Relevant to Chemical Hazards

• Consumer Product Safety Act (CPSA)
  – Establishes the Agency and general procedures

• Federal Hazardous Substances Act (FHSA)
  – Chemical hazards are often addressed under the FHSA
  – FHSA also addresses mechanical and other hazards

• Labeling of Hazardous Art Materials Act (LHAMA)
  – Special requirements for art materials
  – Addresses chronic hazards

• Poison Prevention Packaging Act (PPPA)
  – Child-resistant packaging
Chronic Hazard Guidelines

• Carcinogenicity
• Neurotoxicity
• Reproductive/developmental toxicity
• Exposure
• Bioavailability
• Risk assessment
• Acceptable risk

Plastics in Children’s Toys & Child Care Articles

- PVC
- Polypropylene
- Polyethylene
- Unknown
- Polyurethane
- Silicone
- Rubber
- Polyester
- ABS
- Polystyrene

*Dreyfus 2010*
*Dreyfus & Babich 2011*
Plasticizers in PVC Children’s Toys & Child Care Articles

- ATBC
- DEHT
- TPIB
- DINX
- DINP
- DEHP
- Benzoate

Dreyfus 2010
Dreyfus & Babich 2011
Plasticizer Migration from PVC Children’s Teethers & Toys

Migration Rate – μg/10 cm²/minute

Mass Percent

- TPIB
- ATBC
- DINX
- DINP
- DEHT

Dreyfus 2010
Dreyfus & Babich 2011
CHAP 2014, Appendix E-2
Comparison of Exposures from Modeling and Biomonitoring

NHANES, National Health and Nutrition Examination Survey, CDC
SFF, Study for Future Families, Sathyanarayana et al. 2008a,b

CHAP 2014, Figure E1-2