

U.S. Consumer Product Safety Commission



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

Regulatory Authorities

a selection

- Consumer Product Safety Act (CPSA),
15 U.S.C. § 2051-2084
- Federal Hazardous Substances Act (FHSA),
15 U.S.C. § 1261-1278
- Consumer Product Safety Improvement Act of
2008 (CPSIA)
- Labeling of Hazardous Art Materials Act
(LHAMA)
- Poison Prevention Packaging Act (PPPA)

Federal Hazardous Substances Act (FHSA)

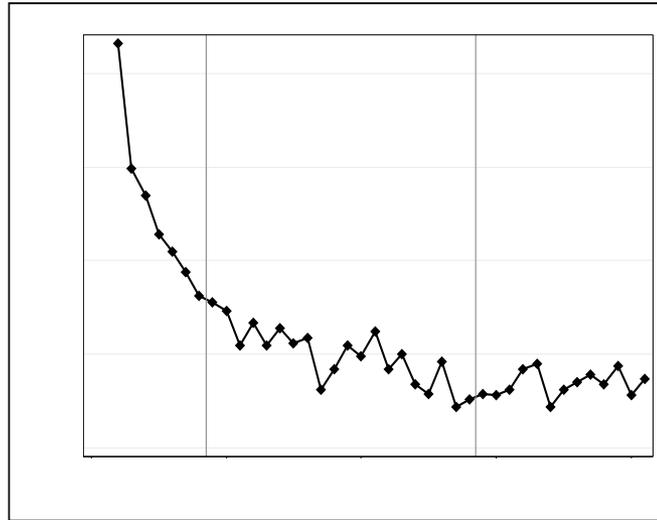
- Authorizes action when a product is or contains a “hazardous substance,” 15 U.S.C. § 1261(f)
 - Any substance or mixture which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture 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.
 - considers exposure
 - requires case-by-case hazard assessment

FHSA (continued)

- Toy or other article intended for children and containing a hazardous substance is a banned hazardous substance, 15 U.S.C. § 1261(q)(1)
- Product not specifically intended for children may require precautionary labeling, 15 U.S.C. § 1261(p)

Poison Prevention Packaging Act

- PPPA requires special (child-resistant & senior-friendly) packaging of hazardous household substances to protect children from serious personal injury or serious illness resulting from handling, using or ingesting hazardous household substances.



Acute Toxicity

- Defined as toxicity occurring from a single event or short-term exposure
- Toxicological assessment is similar to chronic toxicity assessment
 - *i.e.*, hazard identification, dose-response evaluation, exposure assessment, risk characterization
 - Data used: human is preferred, existing data preferred
 - Factors considered: accessibility of the chemical or product component; age and foreseeable behavior of the children exposed to the product, including foreseeable duration of the exposure; marketing, patterns of use, and life cycle of the product

Acute Toxicity

- Evaluate potential exposure vs. a derived exposure limit; a product may be “hazardous substance” if the estimated exposure exceeds the Acceptable Daily Intake (ADI):
 - Based on no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL)
 - Apply uncertainty factors for extrapolation from animal data to human, account for sensitive populations, and cases where NOAEL is not established
 - Also called reference dose (RfD), tolerable daily intake (TDI)

Animal Testing Policy

- <http://www.cpsc.gov/en/business--manufacturing/testing-certification/recommended-procedures-regarding-the-cpsc-policy-on-animal-testing/>
- <http://www.cpsc.gov//PageFiles/134753/animaltestfinalfr.pdf>
- Neither the FHSA nor the regulations issued thereunder require animal testing to determine whether a hazard exists.
- The Commission and CPSC staff strongly encourage the use of scientifically validated alternatives to animal testing and the use of existing information, including expert opinion, prior human experience, and prior animal testing results, in the determination of hazard.

Animal Testing Policy

Acute Toxicity Testing

- For each of three exposure routes (oral, dermal, and inhalation), the FHSA distinguishes two levels of acute toxicity, *highly toxic* and *toxic*, from substances that are not toxic, and therefore, do not require labeling. These terms are defined in [16 CFR § 1500.3](#), along with a description of the traditional method for determining the acute toxicity endpoint, the LD₅₀ or the LC₅₀. Currently, there are no Commission-approved non-animal methods for inhalation and dermal toxicity testing

Acute Oral Toxicity Testing

- CPSC staff recommends the revised oral Up-and-Down Procedure (UDP) for determining acute oral toxicity for the purpose of classification and labeling under the FHSA. The UDP was issued by U.S. Environmental Protection Agency's Office of Prevention, Pesticides and Toxic Substances (OPPTS) as OPPTS Harmonized Test Guideline 870.1100. The scientifically validated test guideline is referenced in CPSC staff's response to ICCVAM on Acute Toxicity Testing, <http://www.cpsc.gov//PageFiles/90415/iccvam1.pdf>
- CPSC staff has determined that *in vitro* basal cytotoxicity tests are appropriate for determining a starting dose for the oral LD₅₀ test. The test guidelines are referenced in CPSC staff's response to ICCVAM on the Use of In Vitro Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing <http://www.cpsc.gov//PageFiles/133387/invitr11.pdf>

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