Guidance for Industry and Test Method Developers:

Factors for CPSC Staff Evaluation of Alternative Test Methods and Integrated Testing Approaches to Support FHSA Labeling Requirements

ICCVAM Public Forum

May 27, 2021

Disclaimer

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

Background

- The Federal Hazardous Substances Act (FHSA), 15 U.S.C. §1261-1275, requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazard(s) that the products may present.
  - However, the FHSA does not require manufacturers to perform any specific toxicological tests to assess potential hazards (e.g., toxicity, corrosivity, sensitization, and irritation).

Background

- CPSC's 2012 Animal Testing Policy – Strongly encourages manufacturers to find alternatives to traditional animal testing that replace animals, reduce the number of animals tested, and decrease the pain and suffering in animals associated with testing household products.

- However, CPSC had not issued any guidance describing what factors CPSC will consider in evaluating manufacturer's alternative test methods and resulting data submitted in support of a product's FHSA labeling.

CPSC Proposed Guidance

- CPSC is seeking comments on a draft guidance document describing the factors that staff considers when assessing the scientific validity and defensibility of non-animal alternative toxicology test methods and approaches, as well as data generated from those test methods, to support FHSA labeling.
  - Submit comments to regulations.gov, under Docket No. CPSC-2021-0006.
  - Comments are due by June 14, 2020.

Technical Factors:

1. The test method should have undergone independent scientific peer review by persons with no conflicts of interest.
2. There should be a detailed set of standard operating procedures (SOPs).
3. Data generated by the test method should adequately measure the endpoint of interest.
4. Applicability domain: There should be adequate test method data for chemicals and/or products representative of those administered by CPSC.
5. Limits of use should be specifically identified.
6. The test method should be robust (e.g., false positive and false negative rates).
7. Ideally, all data should be reported in accordance with Good Manufacturing Practices (GMP), Good Laboratory Practices (GLPs) or in the Spirit-of-GLP.

Who Will Use this Guidance Document

- CPSC staff
- Manufacturers
- Test method developers
- Contract laboratories
- ICCVAM
- Other stakeholders, including the public

Purpose of Guidance Document

- Standardize the staff evaluation of alternative toxicological methods, and data generated by such methods, by providing factors staff should consider during technical review.

- Provide greater clarity to manufacturers, in particular, small businesses who lack toxicology expertise and have limited resources for their regulatory testing needs and strategies.

Guiding principles for evaluating methods and data

1. CPSC Staff Considers Scientific Validity and Defensibility of the Submitted Method and Data
   - Ensure that the method has been properly reviewed for accuracy and robustness.
   - Ensure that the data produced and submitted, pertains to CPSC regulatory needs to evaluate FHSA labeling.

2. Data on individual chemicals may not be sufficient for staff to determine FHSA labeling requirements for consumer products containing complex mixtures of chemicals.

Guidance Overview

- Is not mandatory for the public and will not obligate CPSC to accept any particular alternative method.

- Explains that the evaluation of proposed test methods and data will be done on a case-by-case basis, and will require use of expert professional judgment.

- Is not a simple blueprint or checklist of steps for presenting information that leads to a predefined determination by CPSC.

- If accepted, submitted method will be valid and acceptable for a specified purpose.

Comments on CPSC proposed Guidance

- Submit comments to:

  www.regulations.gov

  under Docket No. CPSC-2021-0006

Comments are due by June 14, 2020