



United States
Consumer Product Safety Commission

US CPSC progress on Applicability of New Approach Methods (NAMs) for FHSA Labeling Requirements

ICCVAM Public Forum
May 18, 2023

***Disclaimer:** This presentation was prepared by CPSC Staff and may not necessarily reflect the views of the Commission.*



Outline of Efforts

- Guidance for Industry and Test Method Developers:
CPSC Staff Evaluation of Alternative Test Methods and Integrated Testing Approaches and Data Generated from Such Methods to Support FHSA Labeling Requirements
- Web Page Update

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; reduce the number of animals tested; and decrease the pain and suffering in animals associated with testing household products.
- The policy encourages tiered approaches and using a weight-of-evidence analysis evaluating existing information (prior human experience, prior animal testing results), expert judgment, and NAMs, with new animal testing as a last resort.



Guidance for Industry and Test Method Developers:

**CPSC Staff Evaluation of Alternative Test Methods and
Integrated Testing Approaches and Data Generated
from Such Methods to Support FHSA Labeling
Requirements**

Guiding principles for evaluating methods and data



1. CPSC Staff will consider 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 Document Overview



- The guidance is not mandatory for the public and does 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 need the use of expert professional judgment.
- The Guidance Document is not a blueprint or checklist for obtaining CPSC approval.
- If accepted, the submitted method will be valid and acceptable for a specified purpose.
- Optional nomination form.

CPSC Guidance Document



- FR notice on proposed guidance published March 31, 2021
- Public Comment period ended June 14, 2021
 - Received 5 comments which were reviewed and addressed
 - Commission voted April 2022 to approve the final guidance document
- Final version of the guidance document published April 11, 2022
 - <https://www.regulations.gov/document/CPSC-2021-0006-0010>



Web Page Update

<https://www.cpsc.gov/FAQ/CPSC-Policy-on-Animal-Testing>

Web Page Update



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Safety Education

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How may I help you?



CPSC Policy on Animal Testing

+ Recommended Procedures Regarding the CPSC's Policy on Animal Testing

+ Guidance for Industry and Test Method Developers: CPSC Staff's Evaluation of Alternative Test Methods and Integrated Testing Approaches and Data Generated from Such Methods to Support FHSA Labeling Requirements

+ Definitions

+ List of CPSC Approvals Pertinent to the Alternatives to Animal Testing Policy

+ FAQ

Report an unsafe product



List of CPSC Approvals Pertinent to the Alternatives to Animal Testing Policy



- **Bovine corneal opacity and permeability (BCOP)**

Contact the Office of Compliance or the Directorate for Health Sciences for any clarification on use of this assay (AlternativeMethods@cpsc.gov).

- Brief Description:

The BCOP test method is proposed as the initial test in a battery of tests to evaluate the ocular irritancy of substances. The BCOP assay uses isolated bovine cornea to predict irritation, as measured by corneal opacity and permeability. The BCOP test should closely model human response because the corneal tissue of the bovine eye is similar to the corneal tissue of the human eye.

- Staff Recommendations:

The BCOP can be used as a screening test to identify severe ocular irritants and ocular corrosives as a part of a tiered testing strategy. This strategy calls for a follow-up *in vivo* study when a negative result is obtained via the BCOP. A positive result does not require further testing.

The BCOP is not recommended for identifying reversible eye irritants (*i.e.*, EPA Category II and III; GHS Category 2A and 2B), as defined by the EPA and GHS classification systems.

- Documents:

Staff response to the ICCVAM Recommendation on Four Test Method Evaluation Reports Regarding Ocular Toxicity Testing

Thank you

Final version of the guidance document:

<https://www.regulations.gov/document/CPSC-2021-0006-0010>

or e-mail me for the link

jgordon@cpsc.gov

