

Estimated Average Burden Hours per Respondent: 1,148.5 hours.

Estimated Total Annual Burden Hours: 122,889.5 hours.

Frequency of Collection: As applicable.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: March 25, 2022.

Robert Sidman,

Deputy Secretary of the Commission.

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CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2021-0006]

Notice of Availability: Final Guidance on Alternative Test Methods and Integrated Testing Approaches

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of availability.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is announcing the availability of a document titled, “Final 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.”

FOR FURTHER INFORMATION CONTACT: John Gordon, Toxicologist, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2025; email: jgordon@cpsc.gov.

SUPPLEMENTARY INFORMATION: The Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1275, requires that hazardous substances bear certain cautionary statements on their labels. Manufacturers may perform toxicological tests to determine whether such products require cautionary labeling addressing the hazard. Although animals are still used in toxicological testing, most governmental agencies support reduced use of animals in testing, by promoting the acceptance of data from alternative test methods.

In 1997, the National Institute of Environmental Health Sciences (NIEHS), the National Toxicology Program (NTP), and 13 federal agencies (including CPSC) joined to form the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM). ICCVAM sponsors scientific

review of non-animal tests (known as New Approach Methodologies or NAMs) that may reduce, refine, or replace animal tests in evaluating potential hazards. Reviews from ICCVAM and other federal agencies can provide a basis for regulatory agencies, such as CPSC, to consider non-animal testing alternatives for use in regulatory decision making. In the past, CPSC staff relied upon ICCVAM’s validation of new alternative testing methods, as reliable test methods to determine compliance with the labeling requirements of the FHSA. However, ICCVAM no longer validates test methods.

In 2012, CPSC issued a policy on non-animal or alternative testing methods to support labeling requirements under the FHSA, as codified under 16 CFR 1500.232 (Animal Testing Policy). CPSC’s website lists current CPSC-accepted alternative test methods and their conditions of use.¹ Since 2012, new advancements in toxicological testing, and in particular with NAMs, have occurred. NAMs include *in vitro* (in test tube), *in chemico* (all chemical test, no biological material), or *in silico* (computer models) methods and approaches used to test for toxicological effects in place of animal testing. In some cases, NAMs are combined with other NAMs or existing *in vivo* (animal) data to form an “integrated approach to testing and assessment” (IATAs).

The Commission reaffirms its policy 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. As such, the Commission strongly encourages all agency stakeholders to submit for evaluation by CPSC staff any scientifically validated alternative test methods that do not require animal testing for determining compliance with the labeling requirements under the FHSA.

Because ICCVAM no longer validates test methods, to assist stakeholders, including the public, manufacturers, test method developers, and test laboratories in determining what test methods are deemed reliable for determining compliance with the labeling requirements under the FHSA, on March 31, 2021, the Commission published a Notice of Availability in the **Federal Register** and requested comments on “Proposed 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” 86 FR 16704. CPSC received five comments that are addressed in the staff’s briefing package on the final guidance. The staff’s briefing package is available on CPSC’s website at NAM Final Guidance BVS (cpsc.gov).

The CPSC has finalized its guidance for industry and test method developers.² The final guidance informs the public of staff’s informational requirements and process for evaluating NAMs and IATAs. The final guidance does not prescribe a specific form of validation and explains that validation can be accomplished via several different processes. A method’s reliability includes reproducibility, repeatability, and robustness. In addition to the performance and applicability of the NAM/IATA, good scientific, technical, and quality practices will ensure that the overall process is more efficient and effective and leads to increased confidence in the proposed method. The final guidance also includes an optional NAM nomination form that can be used to organize information about a NAM or IATA for evaluation by CPSC staff. Such non-animal alternative test methods, if accepted by CPSC, would be considered reliable test methods for determining compliance with the labeling requirements under the FHSA. Additionally, CPSC would continue to list CPSC-accepted alternative test methods on CPSC’s website.

The final guidance will be available at: <https://www.regulations.gov> under docket number, CPSC-2021-0006, under “Supporting and Related Material,” and on the Commission’s website at: <https://www.cpsc.gov/Business-Manufacturing/Testing-Certification/Recommended-Procedures-Regarding-the-CPSCs-Policy-on-Animal-Testing>.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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¹ <https://www.cpsc.gov/Business-Manufacturing/Testing-Certification/Recommended-Procedures-Regarding-the-CPSCs-Policy-on-Animal-Testing/>.

² The Commission voted 4-0 to approve this notice.