DEPARTMENT OF HEALTH AND HUMAN SERVICES

Availability of Draft ICCVAM Recommendations on Using Fewer Animals to Identify Chemical Eye Hazards: Revised Criteria Necessary to Maintain Equivalent Hazard Classification; Request for Comments

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, HHS.

ACTION: Availability of Recommendations; Request for Comments.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), conducted an analysis to determine classification criteria using results from 3-animal tests that would provide eye hazard classification equivalent to testing conducted in accordance with current U.S. Federal Hazardous Substances Act (FHSA) regulations, which require the use of 6 to 18 animals. The results showed that using a classification criterion of at least 1 positive animal in a 3-animal test to identify eye hazards will provide the same or greater level of eye hazard classification as current FHSA requirements, while using 50% to 83% fewer animals. ICCVAM developed draft recommendations based on the results of this analysis. NICEATM invites public comments on these draft ICCVAM recommendations.

DATES: Written comments on the draft recommendations should be received by September 26, 2011.

ADDRESSES: NICEATM prefers that comments be submitted electronically via the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm*) or via e-mail to *niceatm@niehs.nih.gov.* Written comments may also be sent by mail or fax to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709; (fax) 919–541–0947. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes: (telephone) 919–541–2384, (fax) 919–541–0947, or (e-mail) *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Testing requirements necessary to determine the eye hazard potential for substances regulated under the FHSA (FHSA, 2008) are provided in 16 CFR 1500.42 (U.S. Consumer Product Safety Commission [CPSC], 2010). Current FHSA regulations provide procedures to determine the eye hazard classification and labeling requirements for chemicals and products to which consumers may be exposed. The current procedure requires a minimum of 6 animals per test and may require up to 3 sequential tests for each substance, thus requiring 6, 12, or 18 animals to reach a hazard classification decision. The requirement for second and third sequential tests is based on the number of positive responses in the previous test.

In 2002, the Organisation for Economic Co-operation and Development (OECD) Test Guidelines Program adopted U.S. proposed revisions to Test Guideline 405: Acute Eye Irritation/Corrosion (OECD, 2002) that reduce the maximum number of required animals per test from 6 to 3. The Animal Welfare Act (7 U.S.C. 2131 *et seq*) and the Public Health Service (PHS) Policy (PHS, 2002) similarly require that only the minimum number of animals necessary to obtain scientifically valid results should be used and that a rationale for the appropriateness of the number of animals used be provided to and approved by the Institutional Animal Care and Use Committee. In light of this policy and regulations, most *in vivo* ocular safety testing is expected to adhere to the 3-animal procedure described in OECD Test Guideline 405 (OECD, 2002) and in a test guideline issued by the U.S. Environmental Protection Agency (EPA, 1998). However, current FHSA regulations do not provide criteria to classify results from a 3-animal test. Therefore, an analysis was conducted to determine classification criteria based on results from a 3-animal test that would provide eye hazard classification equivalent to procedures in current FHSA regulations (Haseman *et al.,* 2011). The results showed that using a classification criterion of at least 1 positive in a 3-animal test to identify eye hazards will provide the same or greater level of eye hazard classification as current FHSA requirements, while using 50% to 83% fewer animals. Based on these results, ICCVAM developed draft recommendations to use this classification criterion for ocular safety testing procedures that use only a maximum of 3 animals per test substance.

Availability of the Documents

The draft ICCVAM recommendations and the supporting publication describing the results of the analysis are available on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/methods/ocutox/reducenum.htm*), and may also be obtained by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT**).

Request for Public Comments

NICEATM invites the submission of written comments on the draft ICCVAM recommendations and the extent to which the NICEATM analysis supports the recommendations by September 26, 2011. When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). NICEATM will post all comments on the NICEATM–ICCVAM Web site (*http://ntp-apps.niehs.nih.gov/iccvampb/searchPubCom.cfm*) identified by the individual's name and affiliation or sponsoring organization (if applicable). ICCVAM will consider all public comments and comments made by the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) at the June 17–18, 2010 meeting (75 FR 26757) when finalizing its recommendations. Final ICCVAM recommendations will be forwarded to relevant Federal agencies for their consideration. These recommendations will also be available to the public on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/methods/ocutox/reducenum.htm*).

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

SACATM was established in response to the ICCVAM Authorization Act [Section 285*l*–3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

References

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CPSC. 2010. Hazardous Substances and Articles; Administration and Enforcement Regulations. 16 CFR part 1500. Available: *http://www.gpo.gov/fdsys/pkg/CFR-2010-title16-vol2/xml/CFR-2010-title16-vol2-part1500.xml.*

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Haseman JK, Allen DG, Lipscomb EA, Truax JF, Stokes WS. 2011. Using fewer animals to identify chemical eye hazards: Revised criteria necessary to maintain equivalent hazard classification [published online ahead of print]. Regul Toxicol Pharmacol. Available: *http://dx.doi.org/10.1016/j.yrtph.2011.06.006.*

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