

Dated: March 11, 2005.

Cassandra Isom,

Program Administrator, Office of Science
Education, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program; National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Request for Data on Non-Animal Methods and Approaches for Determining Skin and Eye Irritation Potential of Antimicrobial Cleaning Product Formulations; Request for Nominations for an Independent Expert Panel

AGENCY: National Institute of
Environmental Health Sciences
(NIEHS), National Institutes of Health
(NIH).

ACTION: Request for data and nomination
of panelists.

SUMMARY: The Interagency Coordinating
Committee on the Validation of
Alternative Methods (ICCVAM) and
NICEATM are requesting the
submission of data that would assist in
evaluating the validation status of non-
animal methods and approaches used
for determining the skin and eye
irritation potential of antimicrobial
cleaning product formulations to meet
regulatory hazard classification and
labeling purposes. Additionally,
NICEATM is also requesting the
nomination of scientists for
consideration as potential members of
an independent scientific expert panel
("Panel") to evaluate the proposed
methods and approaches. The ICCVAM
will consider the conclusions and
recommendations from the Panel in
developing its recommendations on the
validation status of these methods.

DATES: Nominations and data should be
received by noon on May 5, 2005.

ADDRESSES: Nominations and data
should be sent by mail, fax, or email to
Dr. William S. Stokes, Director of
NICEATM at NICEATM, NIEHS, P.O.
Box 12233, MD EC-17, Research
Triangle Park, NC, 27709, (phone) 919-
541-2384, (fax) 919-541-0947, (e-mail)
niceatm@niehs.nih.gov. Courier address:
NICEATM, 79 T.W. Alexander Drive,
Building 4401, Room 3128, Research
Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr.
William S. Stokes, Director of

NICEATM, (phone) 919-541-2384, (fax)
919-541-0947, (email)
niceatm@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

In June 2004, the Environmental
Protection Agency (EPA) asked ICCVAM
to evaluate the validation status of
proposed non-animal approaches for
determining the skin and eye irritation
potential of antimicrobial cleaning
product formulations for meeting
regulatory hazard classification and
labeling requirements. ICCVAM
considered the EPA's request and
recommended that the evaluation of
these non-animal approaches proceed as
a high priority. ICCVAM agreed to work
with the EPA and representatives of its
Pesticide Program Dialogue Committee
(PPDC) to help assure that the
submission provided to ICCVAM
contains all relevant information, data,
and appropriate analyses as described in
the "ICCVAM Guidelines for the
Nomination and Submission of New,
Revised, and Alternative Test Methods"
(NIH publication 03-4508). The
NICEATM on behalf of ICCVAM plans
to convene an independent scientific
expert panel to review the submission,
develop conclusions on the validation
status of these methods, and make
recommendations about the usefulness
and limitations of these methods for
their intended purpose. The date for the
expert panel meeting has not been
determined but will be announced in a
future **Federal Register** notice.

Request for Data

Data, the nomination of experts, and
other information submitted in response
to this notice should be sent to
NICEATM at the address given above.
Data received by the deadline will be
made available on the ICCVAM/
NICEATM Web site at <http://iccvam.niehs.nih.gov> and considered by
the Panel and ICCVAM.

When submitting data or information
on protocols, please reference this
Federal Register notice and provide
appropriate contact information (name,
affiliation, mailing address, phone, fax,
e-mail, and sponsoring organization, as
applicable). NICEATM prefers the
submission of raw untransformed data
in addition to any summary data
including the submission of copies of
pages from applicable study notebooks
and/or study reports, if available. *In vivo*
and *in vitro* data for each substance are
preferred. Post-marketing surveillance
data, ethical human studies, and
accidental exposure reports also are
sought when available and applicable.

Each submission for a chemical or
product should preferably include the
following information when available:

- Common and trade name.
- Chemical Abstracts Service Registry
Number (CASRN) for each ingredient of
a formulation, and the percent
composition of each ingredient.
- Chemical structure.
- Chemical class.
- Product class.
- Commercial source.
- Test protocol used for either *in vivo*
or *in vitro* testing.
- The extent to which the study
complies with national/international
Good Laboratory Practice (GLP)
guidelines.
- Date and testing organization.

Request for the Nomination of Scientists for the Expert Panel

NICEATM invites the nomination of
scientists with relevant knowledge and
experience that can serve on the Panel
to evaluate *in vitro* dermal and ocular
toxicity test methods. Areas of relevant
expertise include, but are not limited to:
human and animal dermatotoxicology/
ophthalmology with an emphasis on
evaluation and treatment of chemical
injuries, *in vivo* dermal/ocular toxicity
testing, *in vitro* dermal/ocular
toxicology, test method validation, and
biostatistics. Each nomination should
include the person's name, affiliation,
contact information (*i.e.*, mailing
address, e-mail address, telephone and
fax numbers), a brief summary of
relevant experience and qualifications,
and curriculum vitae, if possible.
NICEATM and ICCVAM will also
consider nominations previously
submitted in response to a request for
scientific experts for the evaluation of *in
vitro* ocular test methods (**Federal
Register**, Vol. 69, No. 57, pp. 13859-
13861, March 24, 2004, available at
<http://iccvam.niehs.nih.gov/>) and do not
need to be resubmitted.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee
composed of representatives from 15
Federal regulatory and research agencies
that use or generate toxicological
information. ICCVAM conducts
technical evaluations of new, revised,
and alternative methods with regulatory
applicability and promotes the scientific
validation and regulatory acceptance of
toxicological test methods that more
accurately assess the safety and hazards
of chemicals and products and that
refine, reduce, or replace animal use.
The ICCVAM Authorization Act of 2000
(Pub. L. 106-545, available at <http://iccvam.niehs.nih.gov/about/>)

PL106545.htm) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: <http://iccvam.niehs.nih.gov>.

Dated: March 9, 2005.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program; National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of Expert Panel Report on the Evaluation of the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Availability of report and request for comments.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of a report entitled, "The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Expert Panel Evaluation of the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants." The NICEATM invites public comment on the expert panel report. Copies of the expert panel report may be obtained on the ICCVAM/NICEATM Web site at <http://iccvam.niehs.nih.gov>, or by contacting NICEATM at the address given below.

DATES: Written comments and additional information should be received by noon on May 5, 2005.

ADDRESSES: Comments and additional information should be sent by mail, fax, or e-mail to Dr. William S. Stokes, Director of NICEATM, at NICEATM,

NIEHS, P. O. Box 12233, MD EC-17, Research Triangle Park, NC 27709, (phone) 919-541-2384, (fax) 919-541-0947, (e-mail) niceatm@niehs.nih.gov. Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director of NICEATM, (phone) 919-541-2384, (e-mail) niceatm@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

On January 11 and 12, 2005, NICEATM and ICCVAM held an expert panel meeting to evaluate the validation status for four *in vitro* ocular test methods nominated by the EPA: (1) The Bovine Corneal Opacity and Permeability (BCOP) test; (2) the Hen's Egg Test—Chorion Allantoic Membrane (HET-CAM); (3) the Isolated Rabbit Eye (IRE) test; and (4) the Isolated Chicken Eye (ICE) test. At this meeting, the expert panel reviewed the Background Review Document (BRD) for each method and was asked to:

- Evaluate the extent and adequacy that each method's BRD addresses the applicable ICCVAM validation and acceptance criteria based on available information and data, or will address the criteria in proposed studies, focused on identifying ocular corrosives and severe irritants in a tiered testing strategy.

- Develop conclusions and recommendations on:

- The current usefulness and limitations of each of the four test methods for identifying ocular corrosives and severe/irreversible irritants.
- The test method protocol that should be used for future testing and validation studies.
- The adequacy of proposed optimization and/or validation studies.
- The adequacy of reference substances proposed for future validation studies.

The expert panel's conclusions and recommendations on the four test methods are described in "The ICCVAM Expert Panel Evaluation of the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants".

Prior to the expert panel meeting, NICEATM issued several **Federal Register** notices to (1) request public comment on the EPA nomination of ocular toxicity test methods and related activities and request data on chemicals evaluated by *in vitro* or *in vivo* ocular irritancy test methods (**Federal Register**, Vol. 69, No. 57, pp. 13859-13861,

March 24, 2004, available at <http://iccvam.niehs.nih.gov/>); (2) request the nomination of scientific experts to serve on the expert panel (**Federal Register**, Vol. 69, No. 77, pg. 21565, April 21, 2004, available at <http://iccvam.niehs.nih.gov/>); and (3) request public comments on the BRDs prepared by NICEATM for each of the four test methods (**Federal Register**, Vol. 69, No. 212, pp. 64081-64082, November 3, 2004, and public comments are available at <http://iccvam.niehs.nih.gov/>).

Request for Comments

NICEATM invites the submission of written comments on the expert panel report. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable). All written comments received by the deadline listed above will be posted on the ICCVAM/NICEATM Web site and made available to ICCVAM.

ICCVAM will consider the expert panel report and any written public comments received on that report as it prepares final ICCVAM test method recommendations for the four *in vitro* ocular test methods. An ICCVAM test method evaluation report, which includes the ICCVAM recommendations, will be forwarded to appropriate Federal agencies for their consideration. This report also will be available to the public on the ICCVAM/NICEATM Web site and by request to NICEATM.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability, and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106-545, available at <http://iccvam.niehs.nih.gov/about/PL106545.htm>) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of