

2024 Current Fiscal Year Report: Scientific Advisory Committee on Alternative Toxicological Methods

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2024

3b. GSA

Committee

No.

Scientific Advisory Committee on Alternative Toxicological Methods

12153

4. Is this New During Fiscal Year?

No

5. Current Charter

12/18/2021 12/18/2023

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority

42USC 285l-3(d), as amended

13. Effective Date

12/19/2000

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open

0

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$0.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$0.00	\$0.00
18d. Total	\$0.00	\$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The scope and objectives of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) are to advise the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) 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, and national and international harmonization of new, revised, and alternative toxicological test methods. Alternative methods are those that reduce, refine (lessen or avoid pain and/or distress), or replace the use of animals in testing. SACATM also provides input on ways to foster partnerships and communication with interested parties. Meeting information can be found at <http://ntp.niehs.nih.gov/go/32822>.

20b. How does the Committee balance its membership?

The Committee will consist of up to 15 members, including the Chair, selected by the Director, NIEHS and NTP, plus non-voting ex officio members, as described below. Members are selected from recognized authorities knowledgeable in academia, industry, state government, public health, environmental communities or organizations using new or alternative test methods, as appropriate, in accordance with the statutorily mandated requirements for representation on the SACATM. In accordance with 42 U.S.C. 285l-3(c) and 285l-3(d)(2)(B), the membership of SACATM will also include, as nonvoting ex officio members, the agency heads or their designees from the Federal agencies represented on ICCVAM, as follows: (1) Agency for Toxic Substances and Disease Registry; (2) Consumer Product Safety Commission; (3) Department of Agriculture; (4) Department of Defense; (5) Department of Energy; (6) Department of the Interior; (7) Department of Transportation; (8) Environmental Protection Agency; (9) Food and Drug Administration; (10) National Institute for Occupational Safety and Health; (11) National

Institutes of Health; (12) National Cancer Institute; (13) NIEHS; (14) National Library of Medicine; (15) Occupational Safety and Health Administration; and (16) National Institute of Standards and Technology; (17) Department of Veterans Affairs Research and Development Office, and (18) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

20c. How frequent and relevant are the Committee Meetings?

Meetings are held at least once each fiscal year. The NIEHS Director appoints voting members to the SACATM, and membership is defined in the ICCVAM Authorization Act of 2000 to include representatives from academia, state government, industry, and animal protection organizations. There was one FY2023 meeting.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The quality, scope and balance of advice provided cannot be obtained from NIH staff or from other established sources. Membership is constituted to meet the specific requirements of the mandated mission of the committee and the Institute.

20e. Why is it necessary to close and/or partially closed committee meetings?

NA

21. Remarks

The DFO and Committee Decision Maker positions are held by the same individual due to the assignment of responsibilities within this Institute. This committee did not produce any reports this fiscal year. Ex Officio Members:

According to the charter language NIH has determined there are 17 Ex Officio positions associated with this committee and the max number of positions includes these members. Currently, no Ex Officio members have been identified and there are no Ex Officio members in the list of current members in this report. It has been the practice of ICCVAM members to send ad hoc attendees according to the topics being discussed rather than having ex officio members formally identified. Chair: Dr. Kathryn Page was reappointed as Chair for the remainder of her term.

Designated Federal Officer

Milene Brownlow Health Scientist

Committee Members	Start	End	Occupation	Member Designation
Baines, Antonio	12/19/2021	11/30/2025	Associate Professor, North Carolina Central University	Special Government Employee (SGE) Member
Baran, Szczepan	08/29/2021	11/30/2024	Head of Emerging Technologies, Novartis Institute for Biomedical Research	Special Government Employee (SGE) Member
Berg, Ellen	01/30/2022	11/30/2025	Vice President, DISCOVERX CORPORATION	Special Government Employee (SGE) Member
Fourches, Denis	08/29/2021	11/30/2023	Computational Chemist, Oerth Bio	Special Government Employee (SGE) Member
Leary, Sue	08/29/2021	11/30/2024	President, Alternatives Research & Development Foundation	Special Government Employee (SGE) Member
Nanez, Adrian	01/30/2022	11/30/2025	Senior Medical Science Liaison, University of Louisville	Special Government Employee (SGE) Member

Page, Kathryn	09/12/2021	11/30/2024	Product Safety Toxicologist, The Clorox Company	Special Government Employee (SGE) Member
Sura, Priyanka	08/29/2021	11/30/2024	Director, Product Stewardship and Regulatory Compliance, Angus Chemical Company	Special Government Employee (SGE) Member
Tal, Tamara	08/29/2021	11/30/2023	Senior Scientist, Helmholtz Centre for Environmental Research	Special Government Employee (SGE) Member
Ushio, Misti	08/29/2021	11/30/2024	Chief Executive Officer, Tara Biosystems	Special Government Employee (SGE) Member

Number of Committee Members Listed: 10

Narrative Description

This committee advises the NIEHS, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicology Methods (Center) regarding ICCVAM activities. They also advise the NIEHS and the NTP Center on the NTP Center's activities.

What are the most significant program outcomes associated with this committee?

Checked if
Applies

Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

Cost Savings Comments

Many of the alternative test methods promoted by SACATM may in theory reduce the cost of individual toxicity tests, but it is unclear whether reduced cost per agent tested will be offset by increasing number of agents tested.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

130

Number of Recommendations Comments

SACATM met on September 21-22, 2023, in person at the National Institute of Environmental Health Sciences campus, Research Triangle Park, North Carolina. Agenda topics included: (1) Five Years into the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Strategic Roadmap: Full Replacement of the Acute Tox 6-pack, and Evolution of Validation; (2) The Role of New Approach Methods (NAMs) in Improving Environmental Health Protection; and (3) Computational Resources updates. For the topic of Five Years into the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Strategic Roadmap, there were suggestions for continuing to foster engagement with all relevant agencies, better characterizing the need for predictive versus protective applications and four recommendations made by the committee including defining the confidence necessary for different applications, addressing human specific biology, revising criteria for creating reference lists and repository with greater detailed language about reference chemicals and enhancing

communication between methods developers and agency representatives. For the topic of The role of NAMs in improving environmental health protection, there were three recommendations from the committee including the need to improve engagement with susceptible communities and community members by listening to what their needs are and including team members that look like the community itself, prioritizing complex mixtures as contaminants of emerging concern (CEC) and integrating NAMs for PFAS risk assessment with CEC/National Emerging Contaminants Research Initiative (NECRI), in addition to numerous suggestions such as building trust with communities by starting conversation early and increasing confidence in NAMs by focusing of reproducible and consistent results. Finally, for the topic of Computational Resources, there were three recommendations from the committee including adding features to upload user-defined pharmacokinetic properties, considering the need for more data on formulations and mixtures and reporting available user access statistics, and several suggestions such as ensuring that tools are easily re-trainable and simple to maximize update and considering additional needs or data gaps.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

0%

% of Recommendations Fully Implemented Comments

Due to the complexity of the recommendations made by this committee, staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

0%

% of Recommendations Partially Implemented Comments

Due to the complexity of the recommendations made by this committee, staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

Information is provided to the public at each meeting. The public can view information related to the Committee through the committee's official website. Staff identifies key outcomes of the meeting and reports back to SACATM at the next meeting on developments on the recommendations or advice (either by formal presentation or during discussion).

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

The Committee makes recommendations to federal staff regarding the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) 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. Alternative methods are those that reduce, refine (lessen or avoid pain and/or distress), or replace the use of animals in testing. SACATM also provides input on ways to foster partnerships and communication with interested parties.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
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Online Agency Web Site
Online Committee Web Site
Online GSA FACA Web Site
Publications
Other

☒
☒
☒
☐
☐

Access Comments

N/A