

2025 Current Fiscal Year Report: National Toxicology Program Special Emphasis Panel

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1. Department or Agency

Department of Health and Human
Services

2. Fiscal Year

2025

3. Committee or Subcommittee

National Toxicology Program Special
Emphasis Panel

3b. GSA

Committee No.

5255

4. Is this New During Fiscal Year?

5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
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No 01/07/2025 01/07/2027

8a. Was Terminated During Fiscal Year?

8b. Specific Termination Authority

8c. Actual Term Date

No

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority

42 USC 217a

13. Effective Date

01/07/1997

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee Special Emphasis Panel

16a. Total Number of Reports

No Reports for
this Fiscal Year

17a. Open

0 17b. Closed0 17c. Partially Closed0 Other Activities0 17d. Total0

Meetings and Dates

No Meetings

Current Next
FY 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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	\$0.00	\$0.00
18d. Other (all other funds not captured by any other cost category)	\$0.00	\$0.00
18e. Total Costs	\$0.00	\$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The National Toxicology Program (NTP) convenes ad hoc Special Emphasis Panels (SEPs) to provide independent peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. They help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human health, setting research and testing priorities, and

providing information to regulatory agencies about alternative methods for toxicity screening. The panels provide opinions and recommendations that include, but are not limited to, the strength of the scientific evidence that exposure to an agent is a hazard for human health, the adequacy of new/revised/alternative toxicological test methods relative to current methods for assessing specific toxicities, or the validation status of test methods. They may also advise on the quality, reproducibility, and limitations of scientific findings; identify critical knowledge gaps and data needs; identify areas where improved or new test methods are needed; or advise on the design, conduct, and adequacy of validation studies for proposed test methods. These panels are comprised of members designated to serve for individual meetings based on their expertise, and they are not appointed for fixed terms of service.

20b. How does the Committee balance its membership?

The panels have a fluid membership with members designated to serve for individual meetings rather than formally appointed for fixed terms of service. The panelists for each meeting are selected to address specific issues, such as to evaluate test methods for toxicological assessments, to develop consensus on usefulness of test methods to generate information for specific human health and/or ecological risk assessment purposes, or to evaluate the potential hazard for human health from exposure to a specific environmental substance. Participants on the panel are assembled from experts in the various disciplines and fields relative to the issue under review.

20c. How frequent and relevant are the

Committee Meetings?

Meetings are held approximately 3-4 times each fiscal year. The flexibility in review allows the NTP to hold panel meetings as programmatic needs dictate to ensure efficiency and effectiveness in the review process. There were no meetings in FY2024. NTP has spent the last several months reviewing and formalizing the Peer-Review process including SEPs, in accordance with OMB Guidelines. They are now starting to plan for oxybenzone panel early next year (dates TBD) and also anticipate two others for later in the year.

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

Because of the unique function and objectives of the NTP within the public sector, an independent advisory panel is required that includes a breadth of relevant scientific expertise and a panel that can evaluate and advise on activities ranging from identification of human health hazards to methods for use in regulatory safety testing.

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

N/A

21. Remarks

DFO and Committee Decision Maker positions are held by the same individual based on the assignment of responsibilities within the National Toxicology Program. Reports: This committee did not produce any public reports during the fiscal year. Member(s): No members are being reported due to no meetings occurring in FY 2024. In the years that the committee does meet, the members of this Special Emphasis Panel (SEP) do not have standing appointments and serve on an as needed basis for meetings throughout the fiscal

year. Therefore, when meetings occur, the members list does not reflect appointment start and end dates. As often as possible, instead of appointment start and end dates, each meeting date on which the SEP member served is identified on the Members list. When necessary to protect peer review integrity, a fiscal year start and end date is used as the alternative to appointment start and end dates for some SEP members. As a result, the Members list, including the number of chairs, may not align or directly match to specific meeting dates. Meeting rosters, including members' affiliations and zip codes are available online at <https://public.era.nih.gov/pubroster/>. Since there was no meeting this fiscal year, there are no listed members. Meetings: None at this time. A meeting is tentatively planned for November 2025.

Designated Federal Officer

Mary S. Wolfe Deputy Director for Policy and Communication, Division of Translational Toxicology; Director, Office of Policy, Review, and Outreach

Narrative Description

NTP Special Emphasis Panels are technical, scientific advisory bodies established on an as needed basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening.

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 checked="" type="checkbox"/>
Unable to Determine	<input 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

NIH supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

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

Number of Recommendations Comments

No recommendations were reported in FY25. The National Toxicology Program (NTP) is an interagency program with partners from the National Institutes of Health/National Institute of Environmental Health Sciences, Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health, and Food and Drug Administration/National Center for Toxicological Research. In FY2024 we reviewed and formalized our peer review processes, including Special Emphasis Panels (SEPs), in accordance with Office of Management and Budget Information Quality Guidelines for Peer Review. In 2025 we initiated planning for external peer review of the draft NTP Technical Report on Developmental and Reproductive Toxicity Studies on 2-Hydroxy-4-methoxybenzophenone (oxybenzone), including identifying potential panel members and setting a date for the panel's peer review of the draft report at a public meeting. In March 2025 we learned that in accordance with the administration transition, the NTP SEP charter would move to NIH Center for Scientific Review (CSR). Transition of the charter to CSR occurred in May 2025. We are now working with CSR staff to share information and transition conduct of NTP SEP peer review. External peer review of the draft NTP report on oxybenzone is tentatively planned for November 2025.

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

The results of NTP studies and recommendations can be found at <http://ntp.niehs.nih.gov>.

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

N/A

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 resulting from closed initial peer review meetings is subject to the Freedom of

Information Act. The public can view information on research projects funded by NIH on the RePORT (Research Portfolio Online Reporting Tool) website located at <http://report.nih.gov>.

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. The National Toxicology Program (NTP) convenes Special Emphasis Panels (SEPs) to provide independent peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues.

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

Access Comments

N/A