

2022 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

2022

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

No 01/07/2021 01/07/2023

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 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

1 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 1

Meetings and Dates

Purpose	Start	End
Scientific and Technical Peer Review	10/14/2021	- 10/14/2021

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$1,750.00	\$3,500.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$46,543.00	\$38,581.00
18a(4). Personnel Pmts to Non-Member Consultants	\$200.00	\$200.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$8,298.00
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.)	\$11,678.00	\$11,912.00
18d. Total	\$60,171.00	\$62,491.00
19. Federal Staff Support Years (FTE)	0.20	0.30

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. In FY2022, there was one meeting held on 10/14/2021. While the charter states there will be approximately 3-4 meetings per year, the pandemic impacted NTP's ability to complete draft reports and schedule peer reviews; therefore, there was only 1 SEP meeting in FY 2022.

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): Dr. Rebecca Fry was the designated Chair for the October 2021 meeting. Meetings: While the charter states there will be approximately 3-4 meetings per year, the

pandemic impacted NTP's ability to complete draft reports and schedule peer reviews; therefore, there was only 1 SEP meeting in FY 2022.

Designated Federal Officer

Mary S Wolfe Acting Deputy Director for Policy and Communication, Division of NTP

Committee Members	Start	End	Occupation	Member Designation
Enright, Brian	10/14/2021	10/14/2021	Research Fellow, AbbVie, Inc.	Peer Review Consultant Member
Fry, Rebecca	10/14/2021	10/14/2021	Professor, University of North Carolina at Chapel Hill	Peer Review Consultant Member
Hannas, Bethany	10/14/2021	10/14/2021	Team Leader, Corteva Agriscience	Peer Review Consultant Member
Roberts, Linda	10/14/2021	10/14/2021	Principal, NapaTox Consulting LLC	Peer Review Consultant Member
Smith, Mary	10/14/2021	10/14/2021	Professor Emeritus, University of Georgia	Peer Review Consultant Member
Tilton, Susan	10/14/2021	10/14/2021	Associate Professor, Oregon State University	Peer Review Consultant Member

Number of Committee Members Listed: 6

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
- Trust in government
- Major policy changes
- Advance in scientific research
- Effective grant making
- Improved service delivery
- Increased customer satisfaction
- Implementation of laws or regulatory requirements
- Other

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

- None
- Unable to Determine
- Under \$100,000
- \$100,000 - \$500,000
- \$500,001 - \$1,000,000
- \$1,000,001 - \$5,000,000
- \$5,000,001 - \$10,000,000
- Over \$10,000,000
- Cost Savings Other

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?

137

Number of Recommendations Comments

The NTP Developmental and Reproductive Toxicity (DART) Reports Peer Review Panel was held on October 14, 2021, via webcast, to review the Draft NTP DART Reports on 2-Hydroxy-4-Methoxybenzophenone and 2-Ethylhexyl p-Methoxycinnamate.

2-Hydroxy-4-methoxybenzophenone (2H4MBP) is a common synthetic ultraviolet (UV) filtering ingredient in sunscreens. It was nominated for study due to concerns about potential widespread human exposure via dermal application of sunscreen products and possible endocrine activity. Diet was selected as a sustained route of exposure, since dermal exposure was not feasible given group housing and grooming behaviors of the animals. The panel agreed with NTP's three draft conclusions, which included three recommendations regarding the level of evidence of reproductive toxicity, developmental toxicity and other effects of 2H4MBP in Hsd:Sprague Dawley® rats. 2-Ethylhexyl p-methoxycinnamate (EHMC) is a synthetic UV filtering ingredient in sunscreens. It was nominated for study due to concerns about potential widespread human exposure via dermal application of sunscreen products and possible endocrine activity. Diet was selected as a sustained route of exposure, since dermal exposure was not feasible given group housing and grooming behaviors of the animals. The panel agreed with NTP's three draft conclusions, which included three recommendations regarding the level of evidence of reproductive toxicity, developmental toxicity and other effects of EHMC on Hsd:Sprague® Dawley rats.

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

The NTP sends a copy of the NTP DART Report containing the NTP opinion to the Panel.

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

Checked if Applies

- Reorganized Priorities
- Reallocated resources
- Issued new regulation
- Proposed legislation
- Approved grants or other payments
- Other

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
- Online Agency Web Site
- Online Committee Web Site
- Online GSA FACA Web Site
- Publications
- Other

Access Comments

N/A