UNITED STATES ENVIRONMENTAL PROTECTION AGANCY
HUMAN SUBJECTS REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE/WEBINAR
MEETING AGENDA

Tuesday, May 16, 2023
1:00pm – 5:00pm (Eastern Time*)

Internet Virtual Meeting
The meeting will be conducted at the following website:
Join Zoom Meeting

https://us02web.zoom.us/j/82948106193

Meeting ID: 829 4810 6193

Passcode: 711885

HSRB WEBSITE https://www.epa.gov/osa/human-studies-review-board

12:50 PM HSRB members login online and call in on the phone

1:00 PM Convene Meeting and Introduction of Members – Tom Tracy (Designated Federal Officer, EPA HSRB)

1:05 PM Opening Remarks – Lisa Corey (HSRB Co-Chair)
Julia Sharp (HSRB Co-Chair)

1:10 PM Updates from OPP – Michelle Arling (Office of Pesticide Programs)

Topic

Mueller, J., Bruckner, T., and Triebig, G. Exposure study to examine the chemosensory effects of formaldehyde on hyposensitive and hypersensitive males. Int Arch Occup Environ Health (2013) 86:107–117. DOI 10.1007/s00420-012-0745-9

1:15 PM EPA Science Review Highlights – Deborah Burgin, PhD, DABT (OPP Antimicrobials Division)

1:55 PM Board Questions of Clarification

2:05 PM EPA Ethics Review Highlights – Michelle Arling (Office of Pesticide Programs)

2:25 PM Board Questions of Clarification

2:35 PM Public Comments

3:05 PM Break

3:20 PM Board Discussion

Charge to the Board – Science:

Is the research described in "Exposure study to examine the chemosensory effects of formaldehyde on hyposensitive and hypersensitive males" by Joerg U. Mueller, Thomas Bruckner, and Gerhard Triebig scientifically sound, providing reliable data for use in a weight-of-evidence to determine a point of departure for acute inhalation exposures to formaldehyde?

Discussants

Weiying Jiang, Ph.D. and Srikumaran Melethil, Ph.D. Science Review

George Milliken, Ph.D. Statistics

Charges to the Board – Ethics:

Does available information support a determination that the conduct of the research was not fundamentally unethical?

Does available information support a determination that the research was not deficient relative to the ethical standards prevailing at the time the research was conducted or conducted in a way that placed participants at increased risk of harm or impaired their informed consent?

Discussant

Albert (AJ) Allen, M.D., Ph.D.

5:00 PM **Adjournment – Tom Tracy, DFO**

*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Tom Tracy at tracy.tom@epa.gov

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Julia Sharp (HSRB Co-Chair)

1:10 PM Updates from Day 1 – Michelle Arling (Office of Pesticide Programs)

Topic

Lang, I., Bruckner, T., and Triebig, G. (2007) Formaldehyde and chemosensory irritation in humans: A controlled human exposure study. Regulatory Toxicology and Pharmacology 50:23-26. DOI:10.1016/j.yrtph.2007.08.012

1:15 PM EPA Science Review Highlights – Deborah Burgin, PhD, DABT (OPP Antimicrobials Division)

1:50 PM Board Questions of Clarification

2:00 PM EPA Ethics Review Highlights – Michelle Arling (Office of Pesticide Programs)

2:20 PM Board Questions of Clarification

2:30 PM Public Comments

3:00 PM Break

3:15 PM Board Discussion

Charge to the Board – Science:

Is the research described in "Formaldehyde and chemosensory irritation in humans: A controlled human exposure study" by Isabelle Lang, Thomas Bruckner, and Gerhard Triebig scientifically sound, providing reliable data for use in a weight-of-evidence to determine a point of departure for acute inhalation exposures to formaldehyde?

Discussants

Thomas Lewandowski Ph.D. and David Williams, Ph.D. Science Review
Sinziana Seicean, M.D., MPH, Ph.D. Statistics

Charges to the Board – Ethics:

Does available information support a determination that the conduct of the research was not fundamentally unethical?

Does available information support a determination that the research was not deficient relative to the ethical standards prevailing at the time the research was conducted or conducted in a way that placed participants at increased risk of harm or impaired their informed consent?

Discussant

Philip Day, Ph.D. Ethics Review

5:00 PM **Adjournment – Tom Tracy, DFO**

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UNITED STATES ENVIRONMENTAL PROTECTION AGANCY
HUMAN SUBJECTS REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE/WEBINAR
MEETING AGENDA

Thursday, May 18, 2023
1:00pm – 5:00pm (Eastern Time*)

Internet Virtual Meeting
The meeting will be conducted at the following website:
Join Zoom Meeting

https://us02web.zoom.us/j/82948106193

Meeting ID: 829 4810 6193

Passcode: 711885

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12:50 PM HSRB members login online and call in on the phone

1:00 PM Convene Meeting and Introduction of Members – Tom Tracy (Designated Federal Officer, EPA HSRB)

1:10 PM Opening Remarks – Lisa Corey (HSRB Co-Chair)
Julia Sharp (HSRB Co-Chair)

1:15 PM Updates from OPP – Michelle Arling (Office of Pesticide Programs)

1:20 PM Review and Finalize Report on: **S. Freestone and P. McFarlane (2001) A Single Oral Dose Study with Acephate Technical in Humans; Report Amendment 2**

Lisa Corey (HSRB Co-Chair)
Julia Sharp (HSRB Co-Chair)

Topic

Use of Human Studies for Derivation of an Acute Inhalation Reference Concentration (RfC) for Formaldehyde

1:40 PM EPA Overview of Weight of Evidence - – Deborah Burgin, PhD, DABT (OPP Antimicrobials Division)

2:30 PM Board Questions of Clarification

2:40 PM Public Comments

3:10 PM Break

3:15 PM Board Discussion

Weight of Evidence Charge

OCSPP has developed a weight of evidence for acute inhalation endpoints for formaldehyde that considered multiple studies and proposed acute inhalation PODs for 3 durations (15-min peak, 8-hr, and 24-hr PODs). Please comment on the use of the 4 studies reviewed by the HSRB (Kulle et al., 1987; Andersen and Mølhave, 1983; Lang et al., 2008; Mueller et al., 2013) in OCSPP's weight of evidence for acute inhalation endpoints and the proposed PODs in Table 3.

Discussants

Chad Cross, Ph.D.

Nicole Deming, J.D., Ph.D.

5:00 PM **Adjournment – Tom Tracy, DFO**

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