

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

Tuesday, April 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/83523186544>

Meeting ID: 835 2318 6544

Passcode: 477495

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

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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) |
| 1:05 PM | Welcome and Updates – Monique Tadeo (HSRB Official and Director) |
| 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) |
| | Topic: S. Freestone and P. McFarlane (2001) A Single Oral Dose Study with Acephate Technical in Humans; Report Amendment 2. Inveresk Research, Elphinstone Research Centre, Tranent Scotland. March 23, 2001 |
| 1:20 PM | EPA Science Review Highlights – Ruthanne Loudon, OPP Health Effects Division |
| 2:00 PM | Board Questions of Clarification |
| 2:10 PM | EPA Ethics Review Highlights – Michelle Arling, OPP |
| 2:30 PM | Board Questions of Clarification |
| 2:40 PM | Public Comments |
| 2:50 PM | Break |

3:05 PM **Board Discussion**

Charge to the Board – Science:

Is the plasma and urine concentration data for acephate and methamidophos, as described in the study “A single dose study with acephate technical in humans (Freestone, S. and McFarlane, P. (2002)” considered scientifically sound for the purposes of validating a PBPK model?

Discussants

Weiyang Jiang, Ph.D. and Thomas Lewandowski, Science Review
Chad Cross, Ph.D. Statistics

Charge to the Board – Ethics:

Does available information support a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR part 26?

Discussant

Joseph Tuminello, Ph.D. Ethics Review

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

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Wednesday, April 19, 2023
1:00pm – 5:00pm (Eastern Time*)

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Julia Sharp (HSRB Co-Chair) |
| 1:15 PM | Updates from OPP – Michelle Arling (Office of Pesticide Programs) |
| | Topic: Efficacy Testing of SCJ Personal Repellents Products against Mosquitos in a Field Study. Protocol ID: 90020741/ February 2022. Submitted by S.C. Johnson & Sons, Inc. |
| 1:20 PM | EPA Science Review Highlights – Robert D. Mitchell, III, Ph.D., OPP Registration Division |
| 2:10 PM | Board Questions of Clarification |
| 2:20 PM | EPA Ethics Review Highlights – Michelle Arling, OPP |
| 2:40 PM | Board Questions of Clarification |
| 2:50 PM | Public Comments |
| 3:00 PM | Break |

3:15 PM Board Discussion

Charge to the Board – Science:

Is the protocol “Efficacy Testing of SCJ Personal Repellent Products against Mosquitoes in a Field Study” likely to generate scientifically reliable data, useful for estimating the amount of time each of the product tested repels mosquitoes, if modified as recommended by the EPA?

Discussants

David Williams, Ph.D. Science Review

Srikumaran Melethil, Ph.D. Science Review

Sinziana Seicean, M.D., MPH, Ph.D, Statistics

Kendra L. Lawrence, Ph.D., BCE, PMP Consultant

Charge to the Board – Ethics:

Is the research likely to meet the applicable requirements of 40 CFR part 26, sub parts K and L, if the protocol and additional materials are modified as recommended by the EPA?

Discussant

Nicole Deming, Ethics Review

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

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