US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
JANUARY 25-26, 2017 PUBLIC MEETING AGENDA

Internet Virtual Meeting
The meeting will be conducted at the following website:
https://epawebconferencing.acms.com/hsrb

And on the phone: 866-299-3188 (access code: 2025646493)

Wednesday, January 25, 2017

HSRB WEB SITE http://www.epa.gov/osa/human-studies-review-board

12:50 PM **HSRB members login online**

1:00 PM* **Convene Public Meeting –** Jim Downing, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor
Virtual Meeting Operations – Liza Dawson, Ph.D., HSRB Chair
Introduction of Board Members – Liza Dawson, Ph.D., HSRB Chair
Opening Remarks – Tom Sinks, Ph.D., Director, Office of the Science Advisor, EPA

1:20 PM **Brief Update on Topics Discussed at Last HSRB Meeting,** Michelle Arling (OPP, EPA)

1:30 PM **Topic 1: Follow-on Discussion on Mosquito Repellency Testing**– Liza Dawson, Ph.D., HSRB Chair

2:00 PM **EPA Overview of Physiologically-based Pharmacokinetic (PBPK) Modeling –** Sarah Gallagher, Ph.D., Cecilia Tan, Ph.D., (Health Effects Division, OPP, EPA)

Topic 2: **Published article: Cimetidine-Carbaryl Interaction in Humans: Evidence for an Active Metabolite of Carbaryl, authored by D. Gail May, Rebecca J. Naukam, J. Reddy Kambam, and Robert A. Branch. Journal of Pharmacology Exposure Therapy (1992) 262(3), 1057-1061.**

2:15 PM **EPA Science Review Highlights –** Sarah Gallagher, Ph.D., (Health Effects Division, OPP, EPA)
2:30 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
2:45 PM **EPA Ethics Review Highlights –** Michelle Arling (OPP, EPA)
3:00 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
3:15 PM **Public Comments**
3:20 PM **Break**
3:30 PM **Board Discussion**

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

Charge to the Board - Science:

- Is the research described in the published article "Cimetidine-Carbaryl Interaction in Humans: Evidence for an Active Metabolite of Carbaryl" scientifically sound, providing reliable data?

Discussants: Walter Klimecki, D.V.M., Ph.D. and Jennifer Cavallari, Sc.D. (Statistics, Jun Zhu, Ph.D.)

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: Jewel Halanych, M.D., M.Sc.

Topic 3: Unpublished study: A randomized double blind study with malathion to determine the residues of malathion dicarboxylic acid (DCA), malathion monocarboxylic acid (MCA), dimethyl phosphate (DMP), dimethyl thiophosphate (DMTP), and dimethyl dithiophosphate (DMDTP) in human urine.

4:00 PM **EPA Science Review Highlights –** Yung Yang, Ph.D., (Health Effects Division, OPP, EPA)
4:20 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
4:35 PM **EPA Ethics Review Highlights –** Michelle Arling (OPP, EPA)
4:55 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
5:10 PM **Public Comments**
5:15 PM **Board Discussion**

Charge to the Board - Science:

- Did the research on plasma levels of malathion and malaoxon, and urinary metabolites of malathion, as described in the study reports "A randomized double blind ascending single oral dose study with malathion to determine the No Effect Level on plasma and RBC cholinesterase activity" and "Determination of residues of malathion dicarboxylic acid (DCA), malathion monocarboxylic acid (MCA), dimethyl phosphate (DMP), dimethyl thiophosphate (DMTP), and dimethyl dithiophosphate (DMDTP) in human urine," generate scientifically sound, reliable data?

Discussants: Walter Klimecki, D.V.M., Ph.D. and Jennifer Cavallari, Sc.D. (Statistics, Jun Zhu, Ph.D.)

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?

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

Discussant: Jewel Halanych, M.D., M.Sc.

5:45 PM* Adjourn

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
JANUARY 25-26, 2017 PUBLIC MEETING AGENDA

Internet Virtual Meeting
The meeting will be conducted at the following website:
https://epawebconferencing.acms.com/hsrb

And on the phone: 866-299-3188 (access code: 2025646493)

Thursday, January 26, 2017

HSRB WEB SITE http://www.epa.gov/osa/human-studies-review-board

12:50 PM **HSRB members login online**

1:00 PM* **Convene Public Meeting –** Jim Downing, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor
Virtual Meeting Operations – Liza Dawson, Ph.D., HSRB Chair
Introduction of Board Members – Liza Dawson, Ph.D., HSRB Chair

1:20 PM **Follow-up Discussion from the Previous Day– Liza Dawson, Ph.D., HSRB Chair**

1:25 PM **EPA Overview of ROAT Studies –** Timothy McMahon, Ph.D., (Antimicrobials Division, OPP, EPA)
1:35 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

Topic 4: **Methylisothiazolinone contact allergy and dose-response relationships, authored by Michael D. Lundov, Claus Zachariae, and Jeanne D. Johansen. Contact Dermatitis (2011) 64, 330-336.**

1:40 PM **EPA Science Review Highlights –** Timothy McMahon, Ph.D., (Antimicrobials Division, OPP, EPA)
2:00 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
2:15 PM **EPA Ethics Review Highlights –** Michelle Arling (OPP, EPA)
2:35 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
2:50 PM **Public Comments -** American Chemistry Council
3:10 PM **Board Discussion**

Charge to the Board – Science:

- Is the research described in the published article "Methylisothiazolinone contact allergy and dose-response relationships" scientifically sound, providing reliable data?

Discussants: Alesia Ferguson, MS., MPH., PhD. and Randy Maddalena, Ph.D. (Statistics, George Fernandez, Ph.D.)

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

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: Gary Chadwick, Pharm.D., M.P.H, C.I.P.

3:40 PM Break

Topic 5: Methylisothiazolinone in rinse-off products causes allergic contact dermatitis: a repeated open-application study, authored by K. Yazar, M. D. Lundov, A. Faurschou, M. Matura, A. Boman, J. D. Johansen, and C. Lidén. British Journal of Dermatology (2015) 173, 115-122.

3:50 PM EPA Science Review Highlights – Timothy McMahon, Ph.D., (Antimicrobials Division, OPP, EPA)
4:10 PM Board Questions of Clarification – Liza Dawson, Ph.D., HSRB Chair, EPA staff
4:25 PM EPA Ethics Review Highlights – Michelle Arling (OPP, EPA)
4:45 PM Board Questions of Clarification – Liza Dawson, Ph.D., HSRB Chair, EPA staff
4:55 PM Public Comments - American Chemistry Council
5:00 PM Board Discussion

Charge to the Board - Science:

- Is the research described in the published article "Methylisothiazolinone in rinse-off products causes allergic contact dermatitis: a repeated open-application study" scientifically sound, providing reliable data?

Discussants: Alesia Ferguson, MS., MPH., PhD. and Randy Maddalena, Ph.D. (Statistics, Edward Gbur, Jr., Ph.D.)

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: Gary Chadwick, Pharm.D., M.P.H, C.I.P.

Topic 6: An evaluation of dose/unit area and time as key factors influencing the elicitation capacity of methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) in MCI/MI-allergic patients, authored by Claus Zachariae, Anne Lerbaek, Pauline M. McNamee, John E. Gray, Mike Wooder, and Torkil Menné. Contact Dermatitis (2006) 55, 160-166.

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

5:20 PM **EPA Science Review Highlights –** Timothy McMahon, Ph.D., (Antimicrobials Division, OPP, EPA)
5:30 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
5:35 PM **EPA Ethics Review Highlights –** Michelle Arling (OPP, EPA)
5:45 PM **Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
5:50 PM **Public Comments -** American Chemistry Council
5:55 PM **Board Discussion**

Charge to the Board - Science:

- Is the research described in the published article "An evaluation of dose/unit area and time as key factors influencing the elicitation capacity of methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) in MCI/MI-allergic patients" scientifically sound, providing reliable data?

Discussants: Alesia Ferguson, MS., MPH., PhD. and Randy Maddalena, Ph.D. (Statistics, Edward Gbur, Jr., Ph.D.)

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: Kyle Galbraith, Ph.D.

ROAT Studies Overall Question

When considered together, do the three studies described in Lundov et al., Yazar et al., and Zachariae et al., provide a scientific weight of evidence in support of the establishing a point of departure for determination of an elicitation threshold for methylisothiazolinone (as identified in Lundov et al.) for use in dermal risk assessments?

6:20 PM* **Adjourn**

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]