

**US ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD  
JULY 12-13, 2016 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: 2025642550)

Tuesday, July 12, 2016

**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** – Toby Schonfeld, Ph.D., Human Subjects Research Review Official, OSA, EPA

**1:20 PM Brief Update on Research Discussed at Last HSRB Meeting**, Maureen Lydon (OPP, EPA)

**Topic: Completed Studies and Monograph Report for Agricultural Handler Exposure during Open Pour Mixing/Loading of Wettable Powders (Agricultural Handlers Exposure Task Force)**

**1:25 PM EPA Science Review Highlights** – Matthew Crowley (Health Effects Division, OPP, EPA)

**2:00 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**2:20 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)

**3:05 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**3:20 PM Break**

**3:35 PM Public Comments**

**3:40 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:

- Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph report and associated field study report for AHE80 faithful to the design and objectives of the protocol?
- Did the research generate scientifically reliable data, useful for assessing the exposure of individuals who mix and load conventional pesticides formulated as wettable powders?

**Discussants:** Randy Maddalena, Ph.D. (Ed Gbur, Ph.D., statistics)

Charge to the Board - Ethics:

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

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

**5:15 PM\* Adjourn**

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**1:15 PM Follow-up Discussion from the Previous Day**– Liza Dawson, Ph.D., HSRB Chair

**Topic: Completed Study and Monograph Report for Agricultural Handler Exposure during Mixing/Loading of Pesticide Products in Water Soluble Packets (Agricultural Handlers Exposure Task Force)**

**1:20 PM EPA Science Review Highlights** – Matthew Crowley (Health Effects Division, OPP, EPA)

**1:50 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**2:10 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)

**2:55 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**3:10 PM Public Comments**

**3:15 PM Break**

**3:30 PM Board Discussion**

Charge to the Board - Science:

- Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph report and associated field study report for AHE120 faithful to the design and objectives of the protocol?
- Did the research generate scientifically reliable data, useful for assessing the exposure of individuals who mix and load conventional pesticides formulated in water soluble packets?

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**Discussants:** Kenneth Ramos, Ph.D. (Jun Zhu, Ph.D., statistics)

Charge to the Board - Ethics:

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

**Discussant:** Klye Galbraith, Ph.D.

**4:45 PM\*      Adjourn**

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Thank you for your feedback.

Sincerely,

Office of the Science Advisor  
United States Environmental Protection Agency  
[www.epa.gov/OSA@epa.gov](mailto:www.epa.gov/OSA@epa.gov)