AGENDA
U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)
FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN
MEETING
April 19-21,
2016
FIFRA SAP WEB SITE
http://www.epa.gov/scipoly/sap/ DOCKET NUMBER: EPA–HQ–OPP–2016–0062
U.S. ENVIRONMENTAL PROTECTION AGENCY CONFERENCE CENTER LOBBY LEVEL ONE POTOMAC YARD (SOUTH BLDG.) 2777 S. CRYSTAL DRIVE, ARLINGTON, VA 22202

Chlorpyrifos: Analysis of Biomonitoring Data. Please note that all times are approximate (see note at end of Agenda).

Day 1
Tuesday, April 19, 2016

9:00 A.M. Opening of Meeting and Administrative Procedures – Fred Jenkins, Ph.D., Designated Federal Official, Office of Science Coordination and Policy (OSCP), EPA

9:05 A.M. Introduction and Identification of Panel Members – James McManaman, Ph.D., FIFRA Scientific Advisory Panel Session Chair

9:10 A.M. Welcome and Opening Remarks –
Jack Housenger, Director, Office of Pesticides Programs (OPP), EPA

9:25 A.M. Chlorpyrifos: Background and Overview – Dana Vogel, Division Director, Health Effects Division (HED), OPP, EPA

9:40 A.M. Chlorpyrifos: Overview of EPA Epidemiological Literature Review – Elizabeth Holman, DrPH, HED, OPP

10:40 A.M. Break

10:55 A.M. Interpreting Biomarker Data in the CCCEH Cohort Using a Physiologically Based Pharmacokinetic (PBPK) Model – Cecilia Tan, Ph.D., HED, OPP

12:00 A.M. Lunch

1:00 P.M. Chlorpyrifos: Evaluation of CCCEH Blood Data and Predicted Exposures –
Wade Britton, MPH, HED, OPP; Rochelle Bohaty, PhD, Environmental Fate and Effects Division (EFED), OPP; Danette Drew, HED, OPP

3:00 P.M. Break

3:15 P.M. **Point of Departure, Intra-species Extrapolation, the FQPA 10X Safety Factor, and Case Studies: Linking Exposure Assessment with PBPK Modeling to Derive Predicted Internal Doses** – Anna Lowit, PhD, HED, OPP, EPA

5:00 PM Adjourn

Day 2
Wednesday, April 20, 2016

9:00 A.M. Opening of Meeting and Administrative Procedures – Fred Jenkins, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA

9:05 A.M. Introduction and Identification of Panel Members – James McManaman, Ph.D., FIFRA Scientific Advisory Panel Session Chair

9:10 A.M. Public Comments

10:30 A.M. Break

10:45 A.M. Public Comments (Cont'd)

12:00 P.M. Lunch

1:00 P.M. Public Comments (Cont'd)

2:00 P.M. Charge to Panel

List Stages for Consideration

Question 1.a. Fetal exposure – Please comment on the agency's proposal to use female blood levels as a surrogate for fetal exposure**.**

2:45 P.M. Break

3:00 P.M.

Question 1.b. Infant (<1 year old) exposure. Please comment on the agency's proposal to use cord blood data as a surrogate for assessing infant exposure.

3:45 P.M.

Question 1.c. Children (ages 1<2 years old) exposure – Please comment on the strength and uncertainties of using the CCCEH cord blood data as a surrogate for assessing (children ages 1<2 years old) exposure to chlorpyrifos**.**

Charge Question Assignments
4:30 P.M.

Charge to Panel - Uncertainties with Using Biomarker Data from CCCEH for the PoD

Question 2: Please comment on the agency's characterization of the uncertainty associated with using the CCCEH blood data in quantitative risk assessment.

5:15 PM Adjourn

Day 3
Thursday, April 21, 2016

9:00 A.M. Opening of Meeting and Administrative Procedures – Fred Jenkins, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA

9:05 A.M. Introduction and Identification of Panel Members – James McManaman, Ph.D., FIFRA Scientific Advisory Panel Session Chair

9:10 A.M. Charge to Panel (Cont'd)

9:55 A.M.

Pharmacokinetic (PK) Time Course: Considerations for Labor & Delivery

Question 3. Please comment on the agency's characterization of the PK profile and interpretation of the CCCEH biomonitoring data. Please include in your comments the agency's proposal to use the 10 hour and 24 hour post-peak time points on the PK profiles for assessing risk to chlorpyrifos**.**

10:40 Break

10:55 AM Charge to Panel

Evaluation of CCCEH Cord Blood Data & Predicted Exposures to the Cohort

Question 4. Please comment on the agency's conclusions that these scenarios adequately capture the range of exposure. Please also comment on the agency's simulations from residential and food exposures and the degree to which the estimates of internal blood levels do or do not match the CCCEH cohort results before and after the cancellation of indoor products in 2000**.**

Charge to Panel

Options for Deriving a PoD for Neurodevelopmental Outcomes Based on the CCCEH Biomonitoring Data

Question 5a. Approach to Using the Cord Blood. Please comment on the agency proposal to use cord blood directly as the PoD.

12:00 P.M. Lunch

1:00 P.M. Charge to Panel

Question 5.b. PoD Options. Please comment on the PoD options considered by Agency.

1:45 P.M. Charge to Panel

5.c. Agency's Proposal for PoD – Please comment on the analysis/calculations used to derive these estimates as described in Appendix 6 and the selection of a 2% response level.

2:30 P.M. Break

2:45 P.M. Charge to Panel

Assessing Extrapolation/Uncertainty

Question 6.a. Intra-species extrapolation – Please comment on the agency's scientific rationale of the proposed use of a 10X intraspecies extrapolation factor**.**

3:30 P.M.

Question 6.b. Pre- vs. Post-natal Exposure Please comment on the agency's conclusion that the lack of postnatal exposure assessment in the CCCEH study is a source of uncertainty in the epidemiology database.

4:15 P.M.

Question 6.c. Impact of Sample Size on CCCEH Findings Please comment on the agency's conclusion that the moderate sample size of the CCCEH study is a source of uncertainty, given that the agency is proposing to use the CCCEH study data directly for setting a PoD.

5:00 P.M. Charge to Panel

Proposed Approach to Deriving Internal Dose Estimates: Integration of Exposure Assessment & PBPK Modeling

Question 7. Please comment on the implementation of the PBPK model using such exposure inputs and interpretation of respective simulated blood levels.

5:45 P.M. Closing Remarks –
James McManaman, Ph.D., FIFRA Scientific Advisory Panel Session Chair;
Fred Jenkins, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA

6:00 P.M. Adjourn

Please be advised that agenda times are approximate; when the discussion for one topic is completed, discussions for the next topic will begin. For further information, please contact the Designated Federal Official for this meeting, Dr. Fred Jenkins, via telephone: (202) 564- 3327; fax: (202) 564-8382; or email: jenkins.fred@epa.gov.