

US EPA ARCHIVE DOCUMENT

Need for New Research on Occupational Handler Exposure

CHARGE QUESTIONS

April 20, 2007 HSRB Meeting

- ✓ Do the materials provided by EPA regarding the quality of the scientific data currently available for assessing exposures for handlers contain useful information to establish the societal value of proposed new handler exposure research, assuming individual protocols would generate scientifically valid information?
- ✓ What additional information, if any, would the Board want with respect to handler research in general or to individual protocols?

Occupational Handler Exposure AGENDA

Current Agenda

1. EPA presentations on need for new research -- 130 min
2. Summary of FIFRA SAP report -- 30 min
3. Public comments -- 30 min
4. Board discussion -- 60 min

Proposed Agenda

1. HSRB initial response to charge questions -- 30 min
2. Summary of FIFRA SAP report -- 60 min
3. Public comments -- 30 min
4. Board discussion -- 90 min

Occupational Handler Exposure

✓ EPA Charge Question #1

- ✓ Do the materials provided by EPA regarding the quality of the scientific data currently available for assessing exposures for handlers contain useful information to establish the societal value of proposed new handler exposure research, assuming individual protocols would generate scientifically valid information?

✓ Proposed Board Response

- ✓ Yes. The report from the January 2007 meeting of the FIFRA Scientific Advisory Panel (SAP) provides an excellent rationale for the collection of new occupational handler exposure data for use by EPA and other regulatory agencies in pesticide risk assessments for agricultural workers.

Occupational Handler Exposure

✓ EPA Charge Question #2

- ✓ What additional information, if any, would the Board want with respect either to handler research in general or to individual protocols?

✓ Proposed Board Response #1

- ✓ EPA's "Draft Framework for Developing Best Practices . . ." applies to all human subjects of occupational exposure studies with pesticides
- ✓ Discussion today should be broadened to include all occupational exposure studies with pesticides, including the Agricultural Reentry Task Force (ARTF) study
- ✓ The ARTF study should be discussed at the Board's next meeting, if possible, to inform discussion of the AHETF study

Intentional vs. Observational Exposure

✓ Proposed HSRB Policy

- ✓ Occupational pesticide exposure studies are intentional exposure studies unless demonstrated otherwise

✓ Rationale

- ✓ Special attention needed for ethical aspects due to employer--employee relationship
- ✓ Incentives may be provided by registrants to employers
- ✓ Current lack of clarity regarding consequence of workers “opting out” of study
- ✓ Complexities of recruitment of agricultural workers: language barriers, comprehension of risks, true informed consent

Agricultural Reentry Task Force Study

✓ Response to 1994 EPA Data Call-in

- ✓ EPA requests exposure data on workers who entered fields after pesticide treatments
- ✓ Data needed on multiple pesticide/crop/activity (“scenarios”)

✓ Task Force Response

- ✓ Pool industry resources to develop ARTF database
- ✓ Data collection 1996-2001
- ✓ Task Force sponsored Peer Review: Sep-Nov 2000
- ✓ EPA use of ARTF data for risk assessment: 1999--

Agricultural Reentry Task Force Study

✓ Key Elements

- ✓ Grower survey to develop estimates of worker contact with treated foliage
- ✓ Collect personal exposure data via passive dosimetry
- ✓ Measure pesticide residues on leaf surfaces as an estimate of hazard potential (“dislodgeable foliar residue” -- DFR)
- ✓ Calculate contact rate for various scenarios (“transfer coefficient” -- TC)
- ✓ Transfer coefficient is ratio of exposure/DFR (cm²/hr)

$$TC = \text{Exposure (ug/hr)} / \text{DFR (ug/cm}^2\text{)}$$

Occupational Handler Exposure

✓ EPA Charge Question #2

- ✓ What additional information, if any, would the Board want with respect either to handler research in general or to individual protocols?

✓ Overarching June 2006 Meeting Requests

- ✓ A separate and new “governing document” that is not simply a generic description of the planned activities
- ✓ A clear and appropriate plan for the handling of the data, including its statistical analysis
- ✓ An explanation of the uses to which the data will be put

Occupational Handler Exposure

- ✓ **Additional June 2006 Meeting Requests**
 - ✓ Plans, if any for additional validation studies to determine the extent to which dermal exposure measurements may underestimate true exposure, as recommended by the Board
 - ✓ Plans, if any, to broaden participation of the scientific community and of parties with a direct interest in the database project, such as the labor community, as recommended by the Board
 - ✓ Plans, if any, to meet the requirements established in the 40CFR26, as recommended by the Board