AGENDA
FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING
November 29 - December 1, 2011

FIFRA SAP WEB SITE http://www.epa.gov/scipoly/sap/
OPP Docket Telephone: (703) 305-5805
Docket Number: EPA-HQ-OPP-2011-0718

U.S. Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive, Arlington, VA 22202

Scientific Conclusions Supporting EPA's FIFRA Section 6(b) Notice of Intent to Cancel Twenty Homeowner Rodenticide Bait Products

Please note that all times are approximate (see note at end of Agenda).

Day 1
Tuesday, November 29, 2011

8:30 a.m. **Opening of Meeting and Administrative Procedures** - Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA

8:35 a.m. **Welcome and Introduction of Panel Members** - Kenneth Portier, Ph.D., FIFRA Scientific Advisory Panel Chair

8:45 a.m. **Opening Remarks** - Steven Bradbury, Ph.D., Director, Office of Pesticide Programs (OPP), EPA

9:00 a.m. **Regulatory History** - Russell Wasem, M.S., Pesticide Re-evaluation Division, OPP, EPA

9:15 a.m. **Commensal Rodenticides: Pesticides and Pesticide Products Used to Control Norway Rats, Roof Rats and/or House Mice** - William Jacobs, Ph.D., Registration Division, OPP, EPA

9:45 a.m. **The Rodenticides NOIC - A Toxicological Overview -** Ray Kent, Ph.D., Health Effects Division (HED), OPP, EPA

10:00 a.m. **Rodenticides: Human Incident Analysis** - Shanna Recore**,** HED, OPP, EPA

10:30 a.m. **Break**

10:45 a.m. **Rodenticides: Pet Incident Analysis** - Sarah Winfield, HED, OPP, EPA

11:15 a.m. **Ecological Risk Assessment of Rodenticides** - **Introduction and Overview -** Edward Odenkirchen, Ph.D., Environmental Fate and Effects Division (EFED), OPP, EPA

11:30 a.m. **Toxicity and Elimination: Primary Exposure and Risk Characterization** - Christine Hartless, M.Stat., Ph.D., EFED, OPP

12:30 p.m. **Lunch**

1:30 p.m. **Rodenticide Secondary Exposure and Risk Characterization** - Elizabeth Riley, M.S., EFED, OPP, EPA

2:30 p.m. **Reported Wildlife Incidents for Rodenticides** - Justin Housenger, M.S., EFED, OPP, EPA

3:15 p.m. **Break**

3:30 p.m. **Conclusions from Ecological Risk Assessment for Rodenticides** - Edward Odenkirchen, Ph.D., EFED, OPP, EPA

4:00 p.m. **Public Comments**

5:30 p.m. **Meeting Adjourns**

Day 2
Wednesday, November 30, 2011

8:30 a.m. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA

8:35 a.m. **Introduction of Panel Members** – Kenneth Portier, Ph.D., FIFRA Scientific Advisory Panel Chair

8:45 a.m. **Public Comments Continued**

10:15 a.m. **Follow-up from Previous Day's Presentations**

10:30 a.m. **Break**

10:45 a.m. **Charge to Panel - Charge Question 1:** Does the Agency's analysis of the mammalian toxicity studies and human incident reports provide a reasonable basis for concluding that exposure to warfarin, brodifacoum, difethialone and/or bromethalin can cause health effects in individuals who ingest these rodenticides? Are the adverse effects described in the children's incident reports [e.g., anemia, melena (bloody stool), hematemesis (vomiting of blood)], credible consequences of exposure to these active ingredients? Please provide the basis for your conclusions.

11:15 a.m. **Charge to Panel - Charge Question 2:** The human incident report summarizes a number of data and information sources used in the analyses and reviews conducted. Based on the incident report analysis, EPA has concluded that there are a large number of rodenticide exposure incidents that involve children less than 6 years old. While exposure generally results in no clinical harm to children, the exposures to rodenticides have the potential to result in severe outcomes and/or require medical care or follow-up. Does the SAP concur with the EPA's conclusions regarding the extent of exposures, potential severity of effects, and degree of risks posed to humans? Are the conclusions reached reasonably supported by the data analysis? Please explain the basis of your position.

11:45 a.m. **Charge to Panel - Charge Question 3:** Based on the human incident report, EPA concludes that the use of conforming rodenticide products will reduce the risk rodenticides pose to humans by reducing the opportunity for exposure. Is it reasonable to expect that limiting consumer use to conforming rodenticide products will generally reduce the opportunity for exposure of humans to commensal rodenticide products? Please provide the basis for your conclusions.

12:15 p.m. **Lunch**

1:15 p.m. **Charge to Panel - Charge Question 4:** The pet incident report summarizes a number of data and information sources used in the analyses and reviews conducted. The EPA concludes that there is a high frequency of reported pet incidents involving rodenticides, many of which result in severe outcomes; this conclusion is further supported by the information reported in the open literature as well as the characterization of primary acute risk. Does the SAP concur with EPA's conclusions of the risks posed to pets by non-conforming rodenticide products? Are the conclusions reached reasonably supported by the data analysis? Please explain the basis of your position.

2:00 p.m. **Charge to Panel - Charge Question 5:** The pet analysis has relied on the assessment of risks to wildlife from primary exposure as one line of evidence to characterize primary acute risk to pets from non-conforming rodenticide products. Is it reasonable to conclude that risks to pets are similar to risks to non-target mammalian wildlife, assuming comparable exposures? Please explain the basis of your conclusions.

2:30 p.m. **Charge to Panel - Charge Question 6:** Based on the pet incident report, EPA concludes that the use of conforming rodenticide products will reduce the opportunity for exposure of pets to rodenticides. Is it reasonable to expect that limiting consumer use to conforming rodenticide products will generally reduce the opportunity for exposure of pets to commensal rodenticide products? Please provide the basis for your conclusions.

3:00 p.m. **Break**

3:15 p.m. **Charge to Panel - Charge Question 7a:** The EPA has conducted a deterministic risk assessment to evaluate the risks of acute toxicity to non-target mammals and birds from primary exposure to non-conforming rodenticide products. In its assessment, EPA calculated risk quotients on an acute oral dose and acute dietary exposure basis for birds and mammals and further characterized the opportunity for exposure at lethal levels based on factors including the number of days required to feed and the mass of pesticide required to be consumed to reach lethal thresholds. Using the best available data, EPA made assumptions relative to toxicity, accumulation, and clearance of the pesticides that are material to the exposure and effects modeling in the deterministic primary risk assessment.

Please comment on the reasonableness of the following aspects of EPA's primary exposure deterministic risk assessment:

- Selection of toxicity endpoints for species common to all assessed chemicals in light of the incomplete overlap across available data sets;
- The use of allometric toxicity scaling approaches for birds;
- The reliance on mammalian first order liver or plasma elimination half lives to estimate whole body wildlife (birds and mammals) elimination rates for anticoagulants and bromethalin, respectively;
- The use of the time required and the consumption of rodenticide mass required to reach lethal thresholds as a means of comparing the relative risks of acute mortality following consumption of rodenticide bait.

4:15 p.m. **Charge to Panel - Charge Question 7b:** In addition, does the Panel concur with EPA's analysis and conclusion that use of non-conforming rodenticide products (i.e., not in bait stations) can cause adverse effects to non-target wildlife? Please provide a basis for your conclusions.

5:00 p.m. **Meeting Adjourns**

Day 3
Thursday, December 1, 2011

8:30 a.m. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA

8:35 a.m. **Introduction of Panel Members** – Kenneth Portier, Ph.D., FIFRA Scientific Advisory Panel Chair

8:45 a.m. **Follow-up from Previous Day Discussions**

9:00 a.m. **Charge to Panel - Charge Question 7c:** Is it reasonable to expect that placing rodenticide products in tamper resistant bait stations with formulations expected to remain in the bait station will generally reduce the opportunity for primary exposure of wildlife to commensal rodent control products? Please provide a basis for your conclusions.

9:45 a.m. **Charge to Panel - Charge Question 8a:** The EPA has conducted a deterministic risk assessment to evaluate risks of acute toxicity to non-target mammals and birds from secondary exposure to non-conforming rodenticide products. In its exposure estimate, EPA used both calculated theoretical contamination levels in prey and available empirical data. EPA also characterized the secondary exposure risk using secondary feeding studies and factors including the number of contaminated animals required to be consumed to reach lethal exposure thresholds. For these analyses, using the best available data, EPA made assumptions relative to toxicity, accumulation, and clearance of the pesticide that are material to the exposure and effects modeling in the deterministic secondary exposure risk assessment.

Please comment on the reasonableness of the following aspects of EPA's secondary exposure deterministic risk assessment:

- The use of theoretical body burden calculation together with empirical whole body residue data to produce a reasonable range of estimated exposures for secondary exposure pathways;
- The use of the number of prey items required to reach lethal thresholds as a means of comparing the relative risks across the assessed rodenticides of acute mortality following consumption of contaminated prey;
- The conclusion that the results of predator / scavenger feeding studies are consistent with the findings of the deterministic secondary risk assessment;
- The use of a standardized set of avian toxicity endpoints (i.e., species tested across all the assessed chemicals) in light of information on diphacinone suggesting that raptors may be more sensitive than the surrogate avian species used in the risk assessment.

10:30 a.m. **Break**

10:45 a.m. **Charge to Panel - Charge Question 8b:** Does the Panel concur with EPA's analysis and conclusion that consumption of living or dead rodents poisoned by brodifacoum or difethialone presents a greater opportunity for adverse effects to non-target wildlife compared with the rodenticides warfarin, diphacinone, chlorophacinone, or bromethalin? Please provide a basis for your conclusions. Does the Panel concur that cancellation of products containing brodifacoum and difethialone sold to residential consumers will reduce the opportunity for secondary exposure for wildlife to rodenticides? Please provide a basis for your conclusions.

11:30 a.m. **Charge to Panel - Charge Question 9a:** Incident data demonstrate that rodenticide use can result in wildlife mortality, and that such wildlife mortalities occur in urban and suburban areas. Based on this incident data, EPA has concluded that consumer use of rodenticides in urban and suburban areas may be a significant contributor to the wildlife mortalities attributable to rodenticides. The EPA also determined that both primary and secondary poisonings have been documented.

As part of its analysis of incidents, EPA analyzed the available incident data in order to associate incidents with specific land use categories, i.e., agricultural, urban, suburban areas. In performing this analysis, EPA relied on the information in incident reports identifying associated habitat or on the address reported for the incident and then used remote sensing information to assign a land use category with the incident. Please comment on the reasonableness of this approach to using location information to support the conclusion that use of the commensal rodenticides addressed in the draft NOIC causes wildlife mortalities in urban and suburban areas, as well as rural areas.

12:15 p.m. **Lunch**

1:15 p.m. **Charge to Panel - Charge Question 9b:** EPA analyzed the available incident data in order to differentiate primary and secondary wildlife mortality. For this analysis, EPA relied on information on the dietary requirements of the moribund species and any identified gut contents when available. Does the Panel find this approach a reasonable way to evaluate the occurrence of primary and secondary toxicity as causes of wildlife mortality? Please provide the basis for your conclusions.

2:00 p.m. **Charge to Panel - Charge Question 10:** EPA requires registrants of commensal rodent control products to demonstrate that their products meet criteria for efficacy. The registrants of conforming rodenticide products have submitted such data to EPA, and EPA has determined that their products meet these criteria. Do the meeting of these efficacy performance criteria and EPA's analysis of the effectiveness of conforming rodenticide products reasonably support conclusions that conforming rodenticide products provide effective options for chemical control of commensal rodents by nonprofessional users? If you conclude that conforming rodenticide products do not provide effective options for chemical control of commensal rodents by nonprofessional users, please discuss to what extent the following requirements affect the availability to consumers of effective options for control of commensal rodents:

- The requirement that rodenticides sold to residential consumers must include tamper-resistant bait stations;
- The requirement that rodenticides sold to residential consumers must be in forms (e.g. bait blocks) which are reasonably expected to remain within the bait station; and
- The requirement that rodenticides sold to residential consumers not contain the active ingredients brodifacoum, difethialone, bromadiolone, or difenacoum.

Please provide the basis for your conclusions.

2:45 p.m. **Break**

3:00 p.m. **Charge to Panel - Charge Question 11:** Are conforming rodenticide products containing the active ingredients warfarin, diphacinone, chlorophacinone, or bromethalin, along with non-chemical rodent control methods available to consumers and other options, capable of providing effective control of commensal rodents? Please provide the basis for your conclusions.

3:45 p.m. **Charge to Panel (continued as needed)**

4:30 p.m. **Meeting Wrap-up and Final Panel Comments**

5:00 p.m. **Meeting Adjourns**

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, Joseph Bailey, via telephone: (202) 564-2045; fax: (202) 564-8382; or email: bailey.joseph@epa.gov