Rodenticides Update

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Outline

- Rodenticides Background
- Recap of 2008 Decision
- Current Implementation Status
- Communication Efforts
Decision Timeline

- **Sept. 1998** - Original decisions- more review of commensal use needed
- ‘99-’00 Rodenticide Stakeholder Workgroup (RSW) develops Recommendations for Managing Rodenticide Exposures to Children in the Home
  - ‘99-’01 Comparative Eco Assessment developed
  - 10/01-12/02 “Error only” comments from rodenticide registrants
  - 1/03-9/04 Public comment period on eco assessment and document was revised
- 11/04 WEACT and NRDC sue on the children’s mitigation measures
- 1/07 Mitigation proposal posted for public comment
- **May/June 2008** - Publish Rodenticides Mitigation Decision
- **June 4, 2011** – Last day for complying registrants to release non-conforming product. Non-conforming product released by complying registrants by June 4, 2011 may be sold until stocks are exhausted.
1998 REDs

• Assessed All Rodenticide Uses
  – Commensal & Field

• 1998 Rodenticide Cluster RED
  – Included: Brodifacoum, Bromadiolone, Bromethalin, Chlorophacinone, Diphacinone (& its sodium salt), & Pival (Since Cancelled)
  – Not included but applied to: Difethialone, Cholecalciferol (Vitamin D-3), Red Squill (Since Cancelled), Warfarin (& its sodium salt), & Registrations of New Rodenticide Active Ingredients (i.e. Difenacoum)

• 1998 Zinc Phosphide RED
  – Mitigation mirrored Rodenticide Cluster RED
1998 RED Mitigation Highlights

• Ecological Mitigation
  – Field Use Products RUP
  – Secondary Poisoning Risk Warranted Further Evaluation

• Child Mitigation
  – Bittering Agent Required
  – Indicator Dyes Required
  – Child Risk Reduction Warranted Further Evaluation
Rodenticide Stakeholder Workgroup (RSW) 1999-2000

• Federally Chartered Subcommittee to the Pesticide Program Dialogue Committee (PPDC)

• Purpose:
  – “Provide advice and recommendations to EPA on pesticide exposure issues involving children."

• Recommendations Highlights (Issued November 2000):
  – Rescind indicator dye requirement
  – Rescind bittering agent requirement (remain voluntary)
  – Labeling improvements

• EPA rescinded indicator dye and bittering agent requirements in November 2001
West Harlem Environmental Action & NRDC vs. EPA

- November 2004 – Suit filed in US District Court on decision to rescind bittering agents and dyes
- August 2005 – US District Court agreed with EPA on rescinding of indicator dye, but disagreed with rescinding of bittering agent.  
  - The court set no deadline or specific requirement for EPA to reconsider.
- EPA has since re-examined bittering agents and addressed child exposure concerns in the RMD.
2008 Risk Mitigation Decision

• Assessed Only Commensal Uses
• 1\textsuperscript{st} Generation Anticoagulants
  – chlorophacinone
  – diphacinone (and its sodium salt)
  – warfarin (and its sodium salt)
• 2\textsuperscript{nd} Generation Anticoagulants
  – brodifacoum
  – bromadiolone
  – difenacoum
  – difethialone
• Non-Anticoagulants
  – bromethalin
  – cholecalciferol
  – zinc phosphide
Risk Mitigation – Children & Pets

• Risks Identified:
  – accidental child exposure.  
    Since 1993, 12k-15k cases per year reported.
  – accidental pet exposure.  
    Often result in pet death.

• Mitigation Required:
  – Bait stations mandatory for outdoor, above ground use.
  – Tamper resistant bait stations mandatory if children, pets, non-target mammals, or birds may access the bait.
  – homeowner/retail rodenticide products must be sold with a bait station and may not contain more than 1 lb of bait.
2008 Mitigation Decision

Children’s Risk Mitigation

- Pellets and meal baits prohibited for all “residential consumer” products
  - Other bait forms that are difficult for a rodent to move would be acceptable
  - PCO & Agricultural users will still have access to these bait forms
Risk Mitigation - Ecological

- Risk Identified:
  - direct and secondary poisonings of non-target species.
  - well documented 2\textsuperscript{nd} gen. anticoagulant presence in livers of raptors, foxes, wild cats, deer.

- Mitigation Required:
  - reduce availability of 2\textsuperscript{nd} gen. anticoagulants to homeowners.
  - prohibit sale of 2\textsuperscript{nd} gen. products in retail stores.
  - packaging size requirements for 2\textsuperscript{nd} gen. products
    - 8 lbs for agriculture products / 16 lbs for professionals (PCOs)
  - outdoor (non-field) use must be within 50 ft. of buildings
  - bait stations required outdoor, above ground use
Risk Mitigation – Ecological Package Size Restrictions

Designed to discourage use of these products by “residential consumers”

- 1\textsuperscript{st} Generation Anticoagulants & Non-anticoagulants
  - ≥ 4 lb. for Professional Users (Ag & PCOs)

- 2\textsuperscript{nd} Generation Anticoagulants
  - ≥ 16 lb. for PCOs; ≥ 8 lb. for livestock producers
2008 Mitigation Decision

Ecological Risk Mitigation

- Labeling
  - PCO products: “Intended for use by professional pest control operators”
  - Livestock products: “For use around agricultural buildings” “Not for use in homes”
  - Both types of products: “Do not apply further than 50 feet from buildings”
2008 Mitigation Decision

Ecological Risk Mitigation

• Bait stations required for outdoor above-ground placements of 2nd generation anticoagulants
  
  - “For PCOs and livestock production, the type of bait station for outdoor placements would be left to the discretion of the applicator
June 4, 2011

• Last day for producers to sell or distribute non-compliant products
• Existing stocks may be sold and used as labeled
• Compliant products have been approved and are available
Moving Forward

- EPA is currently preparing a Notice of Intent to Cancel (NOIC)

- Prior to publication of NOIC
  - EPA must notify USDA & HHS
  - EPA must consult FIFRA Scientific Advisory Panel (SAP)

- Following SAP, NOIC is issued to registrant(s) and published in FR.

- Hearing on the NOIC may be requested in accordance with FIFRA Sec. 6(d) & C.F.R. Part 164. The hearing will be chaired by an administrative law judge (ALJ), who makes procedural and substantive decisions.

- ALJ’s decision may be appealed to EPA’s Environmental Appeals Board (EAB).

- Following EAB review, case may be subject to judicial review.
Web Resources

• Rodenticides

• Risk Mitigation Decision for Ten Rodenticides (RMD)

• Web Fact Sheet on RMD
  – [http://www.epa.gov/pesticides/reregistration/rodenticides/finalriskdecision.htm](http://www.epa.gov/pesticides/reregistration/rodenticides/finalriskdecision.htm)

• New More Protective Rodenticide Bait Station Products
Choosing a Bait Station for Household Use

A variety of rodenticide products are available that meet EPA’s new risk reduction goals. These new products offer consumers a range of choices in terms of price and resistance to children, dogs, and weather. Four groups or “tiers” of bait stations offer varying degrees of tamper- and weather-resistance. This approach allows consumers to select rodenticide bait stations that best suit their household needs.

Producers of Tier I - III rodenticide bait stations have submitted test results that demonstrate the bait stations’ level of tamper resistance. As a result, bait station products in tiers I - III are expected to prevent children’s access to bait. For more information on bait station testing protocols, please see Attachments A, B and C of the May 2008 Risk Mitigation Decision for Ten Rodenticides.

- **Four Tiers of Bait Stations**
  - **Tier I - Tamper-Resistant and Weather-Resistant:**
    These bait stations are resistant to weather and to tampering by *children and dogs*. To be used *indoors and outdoors* (within 50 feet of buildings, defined as structures that possess walls and a roof).
  - **Tier II - Tamper-Resistant (but not weather resistant):**
    These bait stations are resistant to tampering by *children and dogs*. To be used *indoors only*.
  - **Tier III – Tamper-Resistant for Children Only:**
    These bait stations are resistant to tampering by *children*. To be used *indoors only*.
  - **Tier IV - Tamper-Resistance Unknown:**
    These bait stations *must not claim to be tamper resistant*. To be used *indoors only* and *only in areas inaccessible to children and pets*.

### Rodenticide Bait Stations and Levels of Tamper- and Weather-Resistance

<table>
<thead>
<tr>
<th></th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistant to Children</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Resistant to Dogs</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
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<tr>
<td>Resistant to Outdoor Weather</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
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<tr>
<td>Resistant to Indoor Conditions</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

Web Resources

• Which Bait Station is Right for You?

1. Do you have pre-school aged children?

If yes, use a rodenticide product that includes a Tier I, Tier II, or Tier III bait station.

For a bait station to claim Tier I, Tier II, or Tier III, the applicant must provide EPA the results of tamper-resistance testing that demonstrate the bait station device is secure enough, when used as labeled, to likely prevent a pre-school aged child’s access to the rodenticide bait. The child tamper resistance testing must follow Agency testing guidelines and results are reviewed for acceptability by Agency staff.

2. Do you have pets?

If yes, use a rodenticide product that includes a Tier I or Tier II bait station.

For a bait station to claim Tier I or Tier II, the manufacturer must provide EPA the results of tamper-resistance testing that demonstrate the bait station device is secure enough, when used as labeled, to likely prevent a dog from accessing the rodenticide bait. While no rodenticide bait is used in the dog testing, the testing must be conducted with dogs that weigh at least 60 pounds. The dog tamper resistance testing must follow Agency testing guidelines. The test results are reviewed for acceptability by Agency staff.

3. Do you need to use the bait station outside (within 50 feet of a building, defined as a structure that possesses walls and a roof)?

If yes, use a rodenticide product that includes a Tier I bait station.

For a bait station to claim Tier I, the applicant must provide EPA the results of weather-resistance testing that demonstrate weather such as rain will not compromise the integrity of the bait station device and the security of the rodenticide bait, when used as labeled. The weather-resistance testing must follow Agency testing guidelines and the results are reviewed for acceptability by Agency staff.

4. Do you need to use the bait station in wet conditions (i.e., basements that flood, greenhouse, and other wet settings)?

If yes, use a rodenticide product that includes a Tier I bait station.

For a bait station to claim Tier I, the applicant must provide EPA the results of weather-resistance testing demonstrating that elements such as water will not compromise the integrity of the bait station device and the security of the rodenticide bait, when used as labeled. The weather resistance testing must follow Agency testing guidelines, and the results are reviewed for acceptability by Agency staff.

• http://www.epa.gov/opp00001/reregistration/rodenticides/consumer-prod.html
Web Resources

New, More Protective Rodenticide Bait Station Products
Current as of May 24, 2011

The rodenticide products listed below meet EPA’s new, more protective risk reduction goals. When used as directed on the label, these products can help consumers control household rodents while greatly reducing accidental exposure to children, pets, and wildlife. EPA will update this list of products as more rodenticide products meeting current risk mitigation goals are approved.

After June 4, 2011, any rodenticide manufacturers who distribute or sell rodenticide products that do not meet the new risk mitigation goals will face EPA actions to remove those products from the market.

Many states require pesticide producers to obtain a state pesticide license before selling a pesticide product in that state. As a result, all the products on this list may not be available in every location. If you have questions, please contact your state pesticide regulatory agency.

EPA-approved labels for these products are available as PDF files in the Agency’s Pesticide Product Label System (PPLS).

Tier I Bait Stations: Tamper-Resistant and Weather-Resistant
These bait stations are resistant to weather and to tampering by children and dogs. To be used indoors and outdoors (within 50 feet of buildings, defined as structures that possess walls and a roof).

<table>
<thead>
<tr>
<th>Product Name</th>
<th>EPA Reg. No.</th>
<th>Active Ingredient</th>
<th>Registration Status</th>
<th>Target Rodent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomcat® Mouse Killer I</td>
<td>12455-120</td>
<td>Bromethalin</td>
<td>Registered 10-13-2010</td>
<td>Yes</td>
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<tr>
<td>Tomcat® Mouse Killer</td>
<td>12455-121</td>
<td>Bromethalin</td>
<td>Registered 4-27-2010</td>
<td>Yes</td>
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<tr>
<td>Tomcat® Rat Killer</td>
<td>12455-122</td>
<td>Bromethalin</td>
<td>Registered 4-27-2010</td>
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<tr>
<td>d-Con® Bait Station XIV</td>
<td>3282-100</td>
<td>Diphacinone</td>
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<tr>
<td>d-Con® Bait Station XIII</td>
<td>3282-101</td>
<td>Diphacinone</td>
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<td>d-Con® Bait Station XI;</td>
<td>3282-102</td>
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<td>d-Con® Bait Station XII</td>
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<td>Diphacinone</td>
<td>Registered 9-3-2010</td>
<td>Yes</td>
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<tr>
<td>Tomcat® Mouse Killer VI</td>
<td>12455-119</td>
<td>Diphacinone</td>
<td>Registered 4-27-2010</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Resources
- Rodenticides Reregistration Web page
- Questions on pesticides?
- National Pesticide Information Center 1-800-858-7378
- American Association of Poison Control Centers (AAPCC) 1-800-222-1222
- AAPCC’s data on poisoning/exposure incidents for pesticides

http://www.epa.gov/opp00001/reregistration/rodenticides/rodent-bait-station.html
Thank You

• For More Information:
  – Rusty Wasem, Chemical Review Manager
  – wasem.russell@epa.gov
  – (703) 305-6979

• EPA Links
  – Rodenticides
    • http://www.epa.gov/pesticides/mice-and-rats/
  – EPA Pesticides
    • http://www.epa.gov/pesticides/
  – Registration Review Status and Contacts
    • http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm