Risk Mitigation Decision for Ten Rodenticides

May 28, 2008

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Approved by: **/s/**
Steven Bradbury, Ph.D.
Director
Special Review and Reregistration Division

Date: **May 28, 2008**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 24, 2008

Certified Mail

Dear Registrant:

The *Risk Mitigation Decision for Ten Rodenticides* was signed on May 28, 2008. A Federal Register Notice announcing its availability was published on June 4, 2008. Since that time, the Agency has determined that some revisions are necessary to the document. These revisions do not affect the risk conclusions, the risk management decision, or the rationale behind the decision, and the requirements imposed by the decision are unchanged. However, there have been some changes to the implementation timeline, to ensure consistency with the required timelines in the Pesticide Registration Improvement Renewal Act of 2007 (PRIA2). In addition, some other minor corrections have been made. The specific changes that have been made to the document are listed below.

1) In Section V.A.2, fourth bullet, the phrase "…but labels of meal, treated whole-grain, or pelleted forms of bait must prohibit use where children, domesticated animals, or non-target wildlife may be exposed" has been deleted.

2) In Section V.A.3, third bullet, the phrase "…but labels of meal, treated whole-grain, or pelleted forms of bait must prohibit use where children, domesticated animals, or non-target wildlife may be exposed" has been deleted.

3) In Section V.A.4, fifth bullet, the phrase "…but labels of meal, treated whole-grain, or pelleted forms of bait must prohibit use where children, domesticated animals, or non-target wildlife may be exposed" has been deleted.

4) In Section VII, the first sentence in the first paragraph now reads "Currently registered rodenticide bait products containing one of the **ten** active ingredients…" ("ten" not "nine")

5) In Section VII, the next-to-last sentence in the second paragraph now reads "If all measures outlined in this document are adopted, then current risks for rodenticide bait products will be adequately mitigated for the purposes of this FIFRA **re**registration determination." ("**re**registration" not "registration")

6) In Section VII.A.1, in the first paragraph, the second sentence now reads "This 90-day response letter must indicate, for each of the registrants' registered **rodenticide** products, whether the registrant intends to amend the registration to conform to this risk mitigation decision." ("rodenticide" not "pesticide")

7) Section VII.A.2 has been rewritten as follows:

2. Applications for Amendment (Deadline: December 4, 2009; 1.5 years from issuance of decision)

Applications for amended registration consistent with the risk mitigation decision are due on or before December 4, 2009. The Agency intends to issue decisions on amendments submitted without supporting data within 3 months. The Agency intends to issue decisions on amendments submitted with supporting data within 4 months. Amendment applications will not be subject to registration service fees required under the Pesticide Registration Improvement Renewal Act of 2007 (PRIA2).

8) Section VII.A.3 has been deleted.

9) Section VII.A.4 has been renumbered to Section VII.A.3.

10) Section VII.B.2 has been revised to include the word "difenacoum".

11) Table 1 has been revised (new text is highlighted).

12) Table 3 has been revised as follows (new text is highlighted):
- The word "non-residential" has been deleted from the "sites" identified for the 1st Generation Anticoagulants (Warfarin, Diphacinone, Chlorophacinone) and Non-Anticoagulants (Zinc Phosphide, Bromethalin, Cholecalciferol) (Products containing ≥4 pounds of bait)
- Under "labeling," for 2nd Generation Anticoagulants (Brodifacoum, Bromadiolone, Difenacoum, Difethialone) (8 pounds and greater) (Agricultural Buildings Only Use) – the prohibition "Do not use in homes or other human residences" has been added.

The revised version of the document is now available on the EPA website at www.epa.gov/pesticides/reregistration/rodenticides. It also is available in docket number EPA-HQ-OPP-2006-0955 through www.regulations.gov. The revised version of the document supercedes the previous versions.

If you have any questions on the rodenticide risk mitigation decision or any of the revisions listed above, please contact Laura Parsons at parsons.laura@epa.gov or (703) 305-5776.

Sincerely,

Steven Bradbury, Ph.D., Director
Special Review and Reregistration Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Risk Mitigation Decision for Ten Rodenticides
May 28, 2008
(revised June 24, 2008)

I. Summary and Background

A. Final Decision

1. Summary of Decision

This document describes the Environmental Protection Agency's (EPA's or Agency's) risk mitigation decision for rodenticide bait products containing one or more of the following ten active ingredients: brodifacoum, bromadiolone, bromethalin, chlorophacinone, cholecalciferol, difenacoum,[1] difethialone, diphacinone (and its sodium salt), warfarin (and its sodium salt), and zinc phosphide. This final risk mitigation decision represents the Agency's final decision on the reregistration eligibility of rodenticide products containing brodifacoum, bromadiolone, bromethalin, chlorophacinone, cholecalciferol, difethialone, diphacinone (and its sodium salt), warfarin (and its sodium salt), and zinc phosphide.. It also constitutes the Agency's final action in response to the remand order in *West Harlem Environmental Action and Natural Resources Defense Council v. U.S. Environmental Protection Agency*, 380 F.Supp.2d 289 (S.D.N.Y. 2005).

EPA's decision includes two major components.

- To minimize children's exposure to rodenticide products used in homes, EPA is requiring that all rodenticide bait products marketed to general and residential consumers be sold only with bait stations, with loose bait (e.g., pellets and meal) as a prohibited bait form. EPA expects that a range of different types of bait stations will meet the new requirements, providing a variety of cost and protection options.

[1] Difenacoum, a second-generation anticoagulant rodenticide, was conditionally registered in September 2007 in accordance with FIFRA section 3(c)(7)(C) provided that all difenacoum products are amended to comply with EPA's Final Risk Mitigation Measures for registered products containing the other second-generation anticoagulants, on the same time schedule as those similar rodenticides.

- To reduce wildlife exposures and ecological risks, the Agency will require sale and distribution limits intended to prevent general consumers from purchasing residential use bait products containing four of the ten rodenticides that pose the greatest risk to wildlife (the second generation anticoagulants – brodifacoum, bromadiolone, difenacoum, and difethialone). Moreover, bait stations will be required for all outdoor, above-ground uses of these second generation-anticoagulants.

EPA expects that the measures described in this risk mitigation document will allow effective and affordable rodenticide products to remain available without causing unreasonable adverse effects to children or wildlife. The Agency has conducted human health and environmental fate and effects risk assessments and has determined that currently registered rodenticide bait products are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and the product registrations are amended to reflect these measures.

The purpose of this document is to describe the Agency's decision and the underlying rationale, and outline what registrants need to do to comply with the decision. All supporting documents, including the comparative ecological risk assessment, the mitigation impact assessment, incident reports, and EPA's response to comments can be found at: http://www.regulations.gov under docket number EPA-HQ-OPP-2006-0955.

2. Scope

The risk mitigation decision described in this document applies to rodenticide bait products containing any of the following ten active ingredients: brodifacoum, bromadiolone, bromethalin, chlorophacinone, cholecalciferol, difenacoum, difethialone, diphacinone (and its sodium salt), warfarin (and its sodium salt), and zinc phosphide. These ten rodenticides can be divided into three categories: first-generation anticoagulants, which are warfarin, chlorophacinone, diphacinone; second-generation anticoagulants, which are brodifacoum, bromadiolone, difenacoum, and difethialone; and non-anticoagulants, which are bromethalin, cholecalciferol and zinc phosphide. The anticoagulants interfere with blood clotting and death results from hemorrhage. Bromethalin is a nerve toxicant that causes respiratory distress; cholecalciferol causes hypercalcemia (excessive calcium) in the blood and other body tissues; and zinc phosphide causes liberation of phosphine gas in the stomach. The first-generation anticoagulants require several days of consecutive feedings to deliver a lethal dose, whereas the second-generation anticoagulants can deliver a lethal dose in only one night of feeding, although with either type of anticoagulant, death does not occur until 5-7 days after the feeding.

Products covered by the risk mitigation measures discussed in this document may be used in and around buildings and in alleys, transport vehicles, and sewers. Rodenticides are used in urban, suburban, and rural areas to control a variety of pest mammals including house mice, Norway rats, roof rats, moles, voles, pocket gophers, prairie dogs, ground squirrels, and chipmunks. Chlorophacinone, diphacinone, and zinc

phosphide also have field uses (e.g. in crop land, non-crop areas, ditch banks, river banks, gullies, irrigation ditches, railroad tracks, fence lines, buffer strips, garbage dumps, landfills, orchards, and rangelands). Brodifacoum and diphacinone also have island conservation uses that are managed by the U.S. Fish and Wildlife Service (FWS).

The risk mitigation decision described in this document does not apply to rodenticide field uses or to tracking powder products. Risks associated with field uses and tracking powder products were addressed in the 1998 Zinc Phosphide and Rodenticide Cluster Reregistration Eligibility Decision (RED) documents. In those REDs, the Agency required restricted use classification for all field use products (except those limited to manual underground baiting) and for all tracking powder products.

The decision described in this document also does not impact island conservation uses of rodenticides. These uses are managed by the FWS and applications are performed by certified pesticide applicators. These uses are important in preventing the extinction of native plant and animal species due to rat predation, and in restoring larger and more diverse island ecosystems.

B. Regulatory History

EPA has been working aggressively to apply the best available information and scientific methods in understanding the human health and environmental risks posed by rodenticides, and to weigh those risks against the important public health and other benefits associated with their use. As part of its ongoing work to reassess the safety of older pesticides, EPA issued REDs for Zinc Phosphide and the Rodenticide Cluster in 1998. These documents required further evaluation of several issues, including potential risks to children and potential effects on non-target mammals and birds.

1. Risks to Children

In the Zinc Phosphide and Rodenticide Cluster REDs, the Agency expressed concern about reported exposures of children to rodenticides. The REDs articulated the Agency's determination that rodenticide bait products (other than those used exclusively at agricultural sites) were eligible for reregistration only if certain measures were adopted to reduce risks of harm to children. Among these mitigation measures, EPA specified two interim measures: changing product formulations to incorporate a bittering agent and an indicator dye. The bittering agents were expected to make the baits less palatable to children, and the indicator dyes were expected to show whether a child had come into contact with a rodenticide product by leaving a stain on a child's mouth or hands. These interim measures were intended to reduce risks while new technologies for preventing exposure were assessed by a stakeholder group.

In 1999, EPA formed the Rodenticide Stakeholders Workgroup (RSW) as a subcommittee under the federally-chartered advisory body, the Pesticide Program Dialogue Committee (PPDC), to consider the risks to children of accidental rodenticide exposure and potential measures to reduce such exposures. The RSW membership was

drawn from a broad range of stakeholders and government representatives, including EPA, the Centers for Disease Control (CDC), the U.S. Department of Agriculture (USDA), the medical community, the rodenticide industry, public interest groups, and members of the general public. The RSW met five times in 1999, and ultimately issued a report recommending that EPA not require the indicator dye due to the lack of suitable dye, and not require the bittering agent due to its potential adverse effect on the efficacy of rodenticide baits. The report recommended that EPA allow manufacturers to include the bittering agents on a voluntary basis.[2] The Agency adopted the RSW's recommendations, and in November 2001, EPA issued a Federal Register notice announcing that it was amending the two rodenticide REDs to allow reregistration of rodenticide bait products without requiring the incorporation of a bittering agent and indicator dye.

Since 2001, many rodenticide registrants have voluntarily incorporated a bittering agent into rodenticide products. The Agency maintains, however, that there are some situations involving severe pest pressure and/or substantial competing food sources where a bittering agent may decrease efficacy to an unacceptable degree. EPA's decision not to require inclusion of bittering agents in all rodenticides provides flexibility for such situations.

In November 2004, West Harlem Environmental Action and the Natural Resources Defense Council filed suit in the District Court for the Southern District of New York, challenging EPA's 2001 reversal of its 1998 determination that rodenticide bait products posed an unreasonable risk of harm to children unless they contained a bittering agent and an indicator dye. In August 2005, the District Court upheld EPA's 2001 determination that an indicator dye should not be required. (380 F.Supp.2d 289 (S.D.N.Y. 2005)) But the court reversed EPA's decision to rescind the bittering agent requirement, and remanded the decision to EPA for further consideration. The court's decision gave focus to EPA's ongoing efforts to determine how best to reduce exposure and risks to children from rodenticide products. This final risk mitigation decision constitutes the Agency's final action in response to the remand order.

2. Ecological Risks

In the Zinc Phosphide and Rodenticide Cluster REDs, the Agency concluded that further evaluation of the ecological risks of rodenticides was necessary. As part of this work, the Agency developed a comparative ecological assessment in which nine rodenticide active ingredients were evaluated, compared, and ranked among one another in terms of potential primary and secondary risks to birds and non-target mammals. The risk conclusions from the comparative ecological assessment are based on comparative analysis modeling and multiple lines of evidence including acute toxicity, persistence of compounds in body tissues of primary consumers (i.e., bait eaters), information from laboratory and pen studies in which poisoned prey are fed to predators or scavengers in

[2] The RSW also considered tamper-resistant bait stations, but because at that time there were no ready-to-use bait stations on the market that appeared to meet EPA's criteria for tamper-resistance, the RSW recommended against requiring tamper-resistant bait stations.

various amounts for one or more days, data from field trials and operational control programs, and wildlife mortality incidents.

Due to the public interest in rodenticides, the Agency elected to employ the full six-phase public participation process for the comparative ecological risk assessment. (The public participation process that EPA applies to its reregistration eligibility decisions is described in a May 14, 2004 Federal Register Notice, which is available at http://www.epa.gov/EPA-PEST/2004/May/Day-14/p10985.htm.) Between October 1999 and September 2001, the comparative risk assessment was drafted by Agency scientists and it underwent internal and external peer review. During the Phase 1 comment period that closed in December 2001, the Rodenticide Registrant Task Force raised some issues that required additional technical work by EPA scientists. After that work was completed, the preliminary risk assessment was made available for public comment in January 2003. EPA accepted public comment on the document through May 30, 2003. Then, the Agency reviewed and responded to the public comments and revised the risk assessment based upon those comments.

In September 2004, the Agency opened Phase 5 of the public participation process by publishing the revised comparative ecological risk assessment, which incorporated new ecological incident data and reflected revisions made in response to public comments on the preliminary version of the assessment. Along with the revised ecological assessment, EPA also published a document discussing the benefits associated with rodenticide products and EPA's preliminary position on appropriate risk reduction options. EPA accepted public comments on those documents through January 2005.

In March 2005, EPA initiated informal consultation for the nine rodenticides registered at that time. Several reported incidents have involved Federally listed threatened and endangered species, for example the San Joaquin kit fox and Northern spotted owl, in addition to the Bald eagle, which is protected under the Bald and Golden Eagle Act. The FWS issued a biological opinion on eight of the rodenticides in 1993.[3] The jeopardy determinations for the individual compounds primarily recommend prohibiting use in habitat occupied by listed species and requiring tamper-resistant bait stations for outdoor placements for some uses. The jeopardy determinations can be found in EPA's *"Comparative Ecological Risk Assessment for Nine Rodenticides"* (Erickson and Urban, 7/2004), available under docket number EPA-HQ-OPP-2006-0955 at www.regulations.gov.

Since rodenticide use is widespread and secondary exposure issues with these compounds are complex and may include listed species that migrate, the Federally-defined action area may be extensive. Through informal consultation, EPA and FWS are working together to determine an appropriate plan of action for the rodenticides. Meanwhile, the mitigation measures set forth in this document should have the beneficial effect of reducing non-target wildlife exposures to rodenticides, and thus refining the

[3] The biological opinion does not include difethialone, which was first registered in 1995, or difenacoum, which was first registered in 2007.

scope of the endangered species risk assessment work remaining to be completed, particularly for the second-generation anticoagulants.

C. January 2007 Proposed Risk Mitigation Decision

On January 17, 2007, EPA published a Proposed Risk Mitigation Decision for the nine rodenticides registered at that time.[4] To minimize children's exposure to rodenticide products used in homes, EPA proposed requiring that all rodenticide bait products available for sale to consumers be marketed only in tamper-resistant bait stations with solid bait blocks as the only permissible bait form. To mitigate ecological risks, the January 2007 proposal included a requirement to classify all bait products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone as restricted use pesticides, thus making them available for purchase and use only by trained, certified pesticide applicators or persons under their direct supervision. These three rodenticides pose particularly significant risks to non-target wildlife.

D. Comments Received on the January 2007 Proposed Risk Mitigation Decision

EPA received more than 700 individual written comments on the January 2007 Proposed Risk Mitigation Decision, plus a letter from an advocacy group that was signed by more than 6,000 of the group's members. Individual comments were received from a diverse range of stakeholders, including government agencies, city governments, non-governmental organizations (NGOs), wildlife rehabilitators, professional pest control operators, livestock producers, rodenticide registrants, and interested citizens.[5]

Many comments, including those received from the U.S. Department of Housing and Urban Development (HUD), the Centers for Disease Control and Prevention (CDC), several non-governmental organizations (NGOs), and some citizens, articulated support for EPA's proposal. Other comments, particularly those received from citizens or NGOs who work with or advocate for wildlife, argued that the Agency's risk mitigation proposal does not provide for sufficient protection for children and/or wildlife. Other comments, mainly those received from rodenticide registrants and livestock producers, claimed that the risks do not warrant the proposed mitigation or that the proposed mitigation is overreaching.

The Agency's responses to the comments received on the Proposed Risk Mitigation Decision can be found at: http://www.regulations.gov under docket number EPA-HQ-OPP-2006-0955. Responses to comments related to ecological risk, human health, economic analyses, and risk mitigation are addressed in separate documents prepared by the Environmental Fate and Effects Division (EFED), the Health Effects Division (HED), the

[4] Difenacoum was not included in the Proposed Risk Mitigation Decision because it was not registered at the time that the proposed decision was issued.

[5] EPA initially provided for a 60-day comment period for the Proposed Risk Mitigation Decision. But after receiving several requests for a comment period extension, the Agency extended the comment period by 60 days. The comment period closed on May 18, 2007.

Biological and Economic Analysis Division (BEAD), and the Special Review and Reregistration Division (SRRD). These documents provide additional detail on the Agency's rationale for this mitigation decision.

II. Summary of Risks

A. Children's Risks

EPA has observed that since 1993, the American Association of Poison Control Centers (AAPCC) annually has received reports of approximately 12,000 to 15,000 rodenticide exposures to children less than 6 years of age. The AAPCC data show that relatively few of the exposed children experienced medical symptoms or suffered adverse health effects as a result of their exposure. However, for the years 1999 through 2003, an average of 115 cases per year were symptomatic, an average of 3,617 cases per year were treated in a health care facility, and an average of 17 cases per year required treatment in an Intensive Care Unit. The Agency believes that the number of exposure incidents resulting in symptomatic diagnoses and/or requiring treatment is unacceptably high given that feasible measures for reducing exposure are available. The Agency also believes that the number of non-symptomatic exposure incidents is unacceptably high because of the social costs associated with evaluating and treating children who might have been exposed.

For more information about human incident data, please refer to the following EPA documents, available at www.regulations.gov under docket number EPA-HQ-OPP-2006-0955: *"Updated Review of Poison Control Center Data for Residential Exposures to Rodenticides"* (Blondell, 3/22/99); *"Updated Review of Rodenticide Incident Reports Primarily Concerning Children"* (Blondell, 6/3/99); *"Updated Review of Rodenticide Incident Reports Primarily Concerning Children"* (Hawkins and Allender, 1/09/07); and *"Addendum to "Updated Review of Rodenticide Incident Reports Primarily Concerning Children""* (Winfield, 5/08/08).

B. Ecological Risks

EPA's comparative ecological risk assessment concludes that each of the rodenticide active ingredients poses significant risks to non-target wildlife when applied as grain-based bait products. The risks to wildlife are from primary exposure (direct consumption of rodenticide bait) for all compounds and secondary exposure (consumption of prey by predators or scavengers with rodenticide stored in body tissues) from the anticoagulants. Secondary exposure to the second-generation anticoagulants is particularly problematic due to these compounds' high toxicity and long persistence in body tissues (e.g., liver retention half-lives of greater than 300 days). The second-generation anticoagulants are designed to be toxic in "a single night's feeding," but since time to death is 5-7 days, the target rodent can feed multiple times before death, leading to a carcass containing residues that may be many times the lethal dose. Additionally, the extended persistence of second-generation anticoagulants in the body of a predator or

scavenger can result in adverse effects from additive exposures through multiple feedings that are separated by days or weeks.

EPA's comparative ecological risk assessment evaluated multiple lines of evidence and concluded that the second-generation anticoagulants have greater potential to adversely affect non-target wildlife, especially birds, than the first-generation anticoagulants. These lines of evidence include acute toxicity, persistence of compounds in body tissues of primary consumers (i.e., bait eaters), information from laboratory and pen studies in which poisoned prey are fed to predators or scavengers in various amounts for one or more days, data from field trials and operational control programs, and wildlife mortality incidents.

In some wildlife mortality incident reports, the relationship between rodenticide exposure and incident outcome is not established, although in many of the cases the examining toxicologist or pathologist concluded that a rodenticide likely caused or contributed to the mortality. Anticoagulants typically do not cause death until 5-7 days or more after a lethal dose is ingested, and exposed individuals become progressively weaker and lethargic due to blood loss. Thus even in incident cases where rodenticide exposure was established but the proximate cause of death may be identified as predation, disease, or automobile collision, a toxicologist or pathologist may be able to conclude that rodenticide-induced blood loss increased the vulnerability of the animals. Even if a cause-effect relationship with rodenticides has not been determined for some of the wildlife mortality incidents reported to the Agency, the routine detection of rodenticides in a wide variety of non-target wildlife, both birds and mammals, confirms that rodenticide exposure routinely occurs.

As discussed in EPA's updated ecological incident report, several monitoring programs have found that major portions of some non-target animal populations are being exposed to second-generation anticoagulant rodenticides. The updated ecological incident report, "*Rodenticide Incidents Update"* (Erickson, 11/15/06), may be obtained at *www.regulations.gov* under docket number EPA-HQ-OPP-2006-0955. Incident reports have identified many taxa of non-target animals exposed to rodenticides, including strict carnivores such as mountain lions, bobcats, hawks and owls; omnivores such as coyotes, foxes, skunks and raccoons; and granivores and herbivores such as squirrels and deer. EPA's updated rodenticide ecological incident report documents anticoagulant residues in 27 avian species and 17 mammalian species. For some species (e.g. bobcats, foxes, great horned owls), carcasses frequently contain residue of two or more anticoagulants, usually second generation compounds. In approximately 50% of those incidents, necropsy results indicate that it is highly probable that a second-generation anticoagulant was the cause of the death. The frequency with which second-generation anticoagulants are found is highly significant.

EPA believes that widespread exposures to second-generation anticoagulants are occurring wherever those rodenticides are being used. Residue analyses indicate that exposure is widespread in non-target populations. In New York, second-generation anticoagulants were detected in 48% of 265 (15 species) diurnal raptors and owls

analyzed, including 81% of 53 great horned owls, 58% of 78 red-tailed hawks, and 45% of 22 Eastern screech-owls. In California, second-generation anticoagulants were detected in 71 to 84% of the 106 bobcats, mountain lions, and San Joaquin kit foxes analyzed. Although comparable data from other states are lacking, EPA suspects that the results from New York and California are representative of non-target wildlife exposures nationwide.

Additionally, second-generation anticoagulants have been identified as an environmental issue in many countries, including Canada, the United Kingdom, France, and New Zealand, through incident monitoring and research.

III. Summary of Benefits of Rodenticides

For more detailed information about the benefits associated with the use of rodenticides, please see EPA's "Analysis of Rodenticide Bait Use" (Chiri et al., 1/23/06).

A. Pest Significance of Rodents

Rodents are among the most significant of all pests on the earth. "Rats and mice take advantage of our food and shelter, multiply into populations of millions, and attempt to co-exist with us in nearly every building we live, eat, or work in." [6] They may be carriers or reservoirs for infectious diseases, and may cause economic damage to crops; consume and contaminate stored food supplies; disturb soil through burrowing activities; damage houses, other types of buildings and man-made structures; and prey on native species, notably birds that nest on oceanic islands. It is generally estimated that commensal rats cause between $0.5 and $1.0 billion of economic losses in the United States annually. This estimate is based on the assumption that there is one commensal rat per every two people in the country, at a time when the population of the United States numbered approximately 200 million, and that each rat consumes or damages between $1 and $10 worth of food and other materials, while contaminating 5 to 10 times more of it.[7] It is estimated that a typical large city in the United States annually receives more than 10,000 complaints about commensal rodent problems and performs tens of thousands of rodent control inspections and baiting services.[8]

In houses and buildings, commensal rodents can gnaw through gas pipes, electric wiring and its insulation, and building insulation, thereby creating a fire risk. They can also damage electronic and computer equipment. White-footed and deer mice often enter cabins and other buildings, where they may build nests and raise their young, causing damage to furniture, clothing, books, paper files, and other belongings. Damage from

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[6] Corrigan, R.M. (2001) *Rodent Control. A Practical Guide for Pest Management Professionals.*

[7] Pratt, H.D., B.F. Bjornson, and K.S. Litting. 1976. Control of domestic rats & mice. U.S. Department of Health and Human Services, Public Health Services, Center for Disease Control, Atlanta, Georgia, HHS Publication No. (CDC) 81-8141. Although these figures are dated, there is no indication that the frequency of rodent damage has significantly changed.

[8] Illinois Department of Public Health, 2004.

commensal rodents to farm buildings and equipment through gnawing, burrowing, and nest-building activities has been estimated at $8.0 million per year.[9] Voles can damage or kill young trees and shrubs by feeding on the inner bark layer of the trunks near the base, both above and below ground. Voles also feed on flower bulbs, on many types of garden plants and vegetables, and on various field and forage crops. Deer mice may cause economic damage to Douglas fir and Ponderosa pine seeds in the West and Northwest, which is of concern in reforesting logged areas by direct seeding. Voles and commensal rodents, if unchecked, will often eat, damage, or contaminate (with urine, droppings, and hair) tons of stored food items, including grain, flour, cereals, sugar, vegetables, fruit, nuts, meat, animal feed, pet food, and any existing kind of stored edible material. Rodents typically contaminate far more stored grain than they consume. Rodents also cause economic losses to livestock and poultry production operations by consuming feed, by causing structural damage to facilities, and by vectoring pathogens. Pocket gophers often damage lawns, golf courses, parks, and other noncrop areas through their burrowing activities. Ground squirrels and other rodents may damage levees, ditch banks, and culverts in agricultural areas.

B. Benefits of Rodenticide Bait Products

Rodenticide baits, along with a variety of habitat modification and other pest management techniques, are used to reduce the damage caused by rodents. Rodenticide baits are especially useful for rapidly reducing rodent numbers in cases of major infestations. For commensal rodent control, rodenticide baits are best used within the context of an integrated pest management (IPM) approach that emphasizes measures such as sanitation, exclusion, habitat modification, trapping, coordination at the community level, public health education, and legal measures such as the enforcement of sanitation codes. IPM approaches are discussed in more detail in Section VI.A of this document.

Rodenticide baits are used, sometimes as part of community rodent-control programs, in situations where major commensal rodent infestations must be reduced rapidly. The baits often are used to control rodents which have entered homes and other buildings. They are also used to eliminate rodents that remain after buildings have been rodent-proofed. Rodenticide baits are commonly used to manage both indigenous and introduced rodents that feed on, contaminate, or cause various types of damage to a wide range of crops and farm infrastructure and equipment, as well as to grain and other stored food. In homes, using rodenticide baits rather than traps may be preferred by those who would rather not deal with dead rodents in traps. When using bait, however, disposing of dead rodents may still be unavoidable. Rodents dying inside a home after eating rodenticide bait may remain undiscovered until the smell of decay becomes noticeable.

[9] Hygnstrom, S.E. 1995. Vertebrate pest damage in grain storage facilities. Pp. 227-238 *In* Stored Product Management, Oklahoma Cooperative Extension Service, U.S. Deportment of Agriculture, Federal Grain Inspection Service, Animal and Plant Health Inspection Service, Circular No. E-912.

IV. Final Decision on Risk Mitigation

A. Children's Exposure Risk Mitigation

1. Summary of Mitigation Measures

The labels for rodenticide bait product labels currently registered in the U.S. instruct users to apply rodenticide bait products in locations out of reach of children, and if that is not possible, to place bait in a tamper-resistant bait station. However, the high number of children exposed to rodenticide bait products indicates that these label instructions are not always being followed and have not been sufficiently effective in keeping rodenticide bait products inaccessible to children. Because a large portion of the rodenticide baits used in the home environment are consumer products applied by residential users, EPA believes that a major cause of the child exposure incidents is residential users' failure to adequately comply with label directions to apply rodenticide bait products in locations inaccessible to children or in tamper-resistant bait stations. The fact that tamper-resistant bait stations are rarely available for sale in retail stores likely contributes to the problem.[10]

For these reasons, the Agency is requiring the following changes to "consumer size" rodenticide products, which are defined as those products containing less than or equal to one pound of bait and available for sale in typical retail outlets (e.g., hardware and home improvement stores, grocery stores, convenience stores, drug stores, club stores, big box stores).

- All "consumer size" rodenticide bait products must be sold packaged together with a ready-to-use (pre-baited) bait station. Bait station design and testing requirements are outlined in Section V.C of this document.

- Bait stations may be 1) non-refillable (disposable, one-time-use stations), or 2) refillable (sold with bait refills). The total amount of bait that may be contained in a "consumer size" product (including the initial bait placement in the bait station, plus any refills) must not exceed one pound. Bait refills may not be sold individually; they must be sold with at least one bait station.

- Meal, treated whole-grain, pelleted, and liquid forms of bait (whether packaged in placepacks or not) are prohibited. Bait must be in a form that is reasonably expected to remain in the bait station, except for bait removed by target rodents and minor quantities of crumbs created by target rodents. Bait blocks (and other solid baits that achieve the safety goal, such as paste forms)

[10] Rodenticide manufacturers that have attempted to market "empty" bait stations (i.e., bait stations sold without bait in them) have commented to the Agency that there is little consumer interest in purchasing bait stations and that stores, therefore, do not want to stock them because of sluggish sales and the fact that bait stations occupy a large amount of shelf space.

are the only forms of rodenticide bait that will be approved for use in "consumer size" products.

2. Below-Ground Uses Excluded from the Requirement for Bait Stations

"Consumer size" products that are labeled solely for use outdoors, below-ground for control of moles and pocket gophers are exempt from the requirement for bait stations and the prohibition on pelleted, meal, and treated whole-grain forms of bait because below-ground baiting of moles and pocket gophers can only be effectively accomplished through the application of bait directly into the underground burrow systems. If below-ground application of bait is performed properly according to product labels, no bait should be available above-ground for exposure to children or non-target animals.

In the case of "consumer size" products that are currently labeled for both below-ground use against moles and pocket gophers, and above-ground use (indoors or outdoors) against other pests, the registrants must either cancel the above-ground uses, or must comply with the requirements for bait stations, solid bait forms, and bait placement amounts discussed above.

3. Comparison with January 2007 Proposed Risk Mitigation Measures

In January 2007, EPA proposed a requirement for tamper-resistant bait stations for all rodenticide bait products marketed to general and residential consumers. In response to the proposal, EPA received comments from a diverse range of stakeholders, including some groups advocating on behalf of minority and low-income communities, expressing concerns about the potential for increased costs of "consumer use" rodenticide products due to the proposed requirement for tamper-resistant bait stations. In response to these comments, the Agency has decided to allow a range of different bait stations, providing a variety of cost and protection options, all of which are expected to meet the EPA's goal of preventing children's access to bait. Specific bait station requirements are detailed in Section V.C of this document.

B. Mitigation for Ecological Risks to Non-Target Birds and Mammals

1. Discussion

Based on an evaluation of the ecological risks associated with the use of rodenticide bait products containing any of the nine rodenticide active ingredients, and consideration of the public health and other important benefits of the use of rodenticide baits, EPA is imposing new requirements on bait products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone (the second-generation anticoagulants). These requirements further EPA's goal of minimizing the availability of the second generation anticoagulants on the consumer market, and hence the overall amount of use of the second generation anticoagulants, but will not change

how the products are used in livestock production or other professional use settings, where important public health and other benefits may require the use of the second-generation anticoagulants. The new requirements are listed and described below.

- Minimum package size requirements
- Use site restrictions
- Sale and distribution restrictions
- Bait stations required for all outdoor above-ground placements

Minimum Package Size Requirements. The Agency has determined that product size is a significant factor in determining where and to what type of customer a product is sold. Large-size products are generally not sold in grocery stores, drug stores, and hardware stores because shelf space is too limited to accommodate large boxes and because larger products generally carry a price that is too high for typical residential consumers. The Agency generally considers "consumer size" products for rodenticides to be those containing ≤ 1 pound of bait. Larger packages are typically sold in farm stores or through direct sale to professional pest control operators, livestock producers, and other professional users.

In order to minimize the availability of second-generation anticoagulant products on the general consumer market, EPA is imposing minimum package size requirements. Permitting the sale of only large-size packages will minimize the availability of the second-generation products to residential consumers. The Agency is requiring second-generation bait products to be sold in packages that contain ≥ 8 pounds of bait for products that are labeled for use only inside of and within 50 feet of agricultural buildings and not for use in and around homes. For products intended for use by professional applicators, the minimum permissible amount of bait per package is 16 pounds.

The 8-pound and 16-pound size thresholds were selected based on sales information received from several rodenticide registrants, and purchasing and use information received from some livestock groups and professional applicators.

Use Site Restriction. Consistent with EPA's goal of minimizing the availability of the second-generation anticoagulant products on the general consumer market, the Agency is requiring the following use site restriction on all products containing brodifacoum, difethialone, difenacoum, or bromadiolone.

- For products in packages with at least 8 but not more than 16 pounds of bait, labels must state that products may only be used in and around (within 50 feet) of agricultural buildings (e.g., barns, hen houses), and bear the statement "Do not use this product in homes or other human residences."

Sale and Distribution Restrictions. The terms and conditions of registration for products containing brodifacoum, bromadiolone, difenacoum, and difethialone must be amended to specify that the registrants will control distribution of the products so that they shall only be distributed to or sold in agricultural, farm and tractor stores or directly to PCOs and other professional applicators, and that registrants will not sell or distribute products containing brodifacoum, bromadiolone, difenacoum, and difethialone in channels of trade likely to result in retail sale in hardware and home improvement stores, grocery stores, convenience stores, drug stores, club stores, big box stores, and other general retailers.

Bait Stations Required for Outdoor Above-Ground Placements. EPA is also requiring that all outdoor, above-ground placements of bait products containing second-generation anticoagulants be contained in bait stations, in order to deny non-target animals ready access to rodenticide bait. Most baits are grain-based and are therefore attractive to many birds and non-target mammals; those baits with flavor enhancers (e.g. fish flavors) might also attract carnivores. Tamper-resistant bait stations are required if the bait placement would be within reach of pets, domestic animals, non-target wildlife, or children under six years-of-age. Other types of bait stations may be constructed and used in settings, such as around livestock production buildings, where exposure to children and non-target wildlife is unlikely.

2. Comparison with January 2007 Proposed Risk Mitigation Measures

In January 2007, EPA proposed requiring restricted use classification for the second-generation anticoagulants in order to mitigate ecological risks. During the public comment period on the proposal, the Agency received comments and heard concerns from poultry and livestock producer groups indicating that the proposed requirement would place a significant burden on the poultry and livestock industries because most producers do not currently use restricted use pesticides and therefore would either have to stop using second-generation anticoagulants or arrange for employees to become certified pesticide applicators.[11] The poultry and livestock groups stressed the importance of rodent control for their particular industries in terms of productivity since rodents consume and ruin a significant quantity of animal feed. In addition, they indicated that rodent control is critical to biosecurity and the overall health of livestock animals because rodents can carry diseases which can be transmitted to animals.

[11] USDA reports on agricultural chemical usage confirm that swine facilities use a relatively small amount of restricted use pesticides, and that poultry and dairy or cattle facilities do not appear to use restricted use pesticides at all. (U.S. Department of Agriculture – National Agricultural Statistics Service. Agricultural Chemical Usage 2006 Restricted Use Summary. October 2007. Accessible online at: http://usda.mannlib.cornell.edu/usda/current/AgriChemUsRestricted/AgriChemUsRestricted-10-03-2007.pdf. U.S. Department of Agriculture – National Agricultural Statistics Service. Agricultural Chemical Usage Swine and Swine Facilities. December 2006. Accessible online at: http://usda.mannlib.cornell.edu/usda/current/AgChemUseSwine/AgChemUseSwine-12-20-2006.pdf).

The Agency has determined that the benefits of the use of the second-generation anticoagulants by poultry and livestock producers outweigh the risks. Second-generation anticoagulants, which provide a lethal dose to a rodent in a single night's feeding, are critical in livestock settings because the availability of other food sources besides the rodenticide bait reduces the likelihood of rodents consuming bait a sufficient number of times to achieve a lethal dose from first-generation anticoagulants. Also, poultry and livestock producers need to rotate different active ingredients in order to limit the possibility of resistance, since rodents may be a constant problem for livestock facilities and baiting may need to be continuous. This makes it particularly important for these producers to have access to a wide range of products, including in this case second generation anticoagulants.

Based on concerns about the burden on the poultry and livestock industries posed by the proposed decision, and recognizing the importance of second-generation anticoagulants to these industries, EPA has decided to use sale and distribution limitations – rather than restricted use classification – to minimize the use of second generation anticoagulants in settings where the risks outweigh the benefits (i.e., most residential settings). The sale and distribution restrictions (discussed above in Section IV.B.1) will minimize the availability of second-generation anticoagulants on the general retail market, but will not change the availability of these products for poultry and livestock producers, and other professional applicators.

The new packaging and sale and distribution restrictions for the second-generation anticoagulants should allow agricultural and other professional users to maintain unrestricted access to the second-generation anticoagulant rodenticides, and is expected to be nearly as effective as the proposed requirement of restricted use classification in achieving EPA's goal of dramatically reducing the overall use of second generation anticoagulants by limiting the availability of those products on the general consumer market.

By preventing or substantially limiting general consumer access to second generation anticoagulants, EPA expects to substantially reduce the number of rodents bearing "super-lethal" doses of rodenticides, and thereby reduce adverse effects to non-target animals. Because rodents get a lethal dose from a single feeding on a second-generation anticoagulant bait, yet do not die for 5-7 days, super-lethal doses occur where rodents repeatedly feed on second generation anticoagulant baits. Such repeat feeding is unlikely to occur in agricultural and food handling facilities, because there are usually many food sources available despite best management efforts. EPA believes that the majority of super-lethal dosings occur where relatively few food sources are available, as is typical of residential scenarios. EPA expects that shifting residential use away from second-generation anticoagulants (except in circumstances where professional applicators consider them necessary) will substantially reduce the number of rodents bearing super-lethal doses, and will also significantly reduce the total amount of second-generation anticoagulants affecting rodent predators and scavengers.

EPA believes that misuse and overuse of rodenticides is more common among general consumers than occupational users. General consumers are less likely to accurately understand rodenticide risks, rodent behavior, the manner in which particular rodenticides work, and are less likely to read and follow label instructions correctly. Occupational users (including persons who routinely apply pesticides as a minor part of their job, as well as full-time professional pesticide applicators) are more likely to choose a method of pest control appropriate for the specific circumstances, more likely to appreciate the consequences of pesticide misuse, and are in most cases acutely sensitive to the economic consequences of overuse. For these reasons, EPA believes that pesticides generally pose less risk when applied by occupational users than when applied by the general public. In the case of second generation anticoagulants, EPA believes that this difference is significant enough to warrant taking steps to limit access to these products to occupational users.

Although EPA believes that second generation anticoagulants should be applied by occupational users rather than general consumers, EPA has concluded that in this instance this can be accomplished to a satisfactory degree by means other than classifying these products for restricted use. Classifying second generation anticoagulants for restricted use would impose substantial costs on agricultural and commercial enterprises that are major users of rodenticides, and EPA believes that these costs can be avoided by taking advantage of existing natural divisions in the rodenticide market. Pesticide registrants have demonstrated that the agricultural and professional use products are distributed through channels that are distinctly different from those typical of the consumer use products. Rodenticide products intended for consumer residential use generally contain one pound or less of rodenticide bait. Products intended for agricultural use generally are packaged in larger quantities, usually eight pounds of more. Products marketed to pest control operators generally are in larger quantities, 16 pounds or more. In order to limit general consumer access to second generation anticoagulants, EPA intends to approve these products only where packaged in quantities of 8 pounds or more when labeled for agricultural use, and 16 pounds or more when labeled for other uses. EPA believes that these size limits will effectively discourage residential users from obtaining second generation anticoagulants for their own use. In order to promote market segregation, EPA will not register second-generation anticoagulant products in packages containing less than eight pounds of bait, or other agricultural and professional use rodenticides in packages containing less than 4 pounds of bait. Although this approach will not absolutely prevent members of the general public from obtaining and applying second-generation anticoagulants, EPA believes that such use will be uncommon and that the consequences of such incidental use would not rise to a level warranting restricted use classification.

In deciding not to classify second-generation anticoagulants for restricted use at this time, EPA has also taken into account the low applicator risks and relatively simple use instructions. Most pesticides classified for restricted use present substantial risk to applicators or require training for proper use. These factors are absent from the second generation anticoagulant bait products. Although the risks of misuse by general consumers are of concern to the Agency, EPA expects the limitations on sale and

distribution to make adverse effects infrequent. However, if these mitigation measures fail to achieve the intended risk reductions, EPA will reconsider classification for restricted use.

V. Implementation of Risk Mitigation Measures

The Agency has structured the rodenticide mitigation measures to take advantage of existing natural distinctions in the rodenticide market. Rodenticide products intended for consumer residential use generally contain one pound or less of rodenticide bait. Products intended for agricultural use generally are sold in larger quantities, usually eight pounds or more. Products marketed to pest control operators generally are sold in larger quantities, 16 pounds or more. EPA has identified mitigation measures specific to each of these classes of products as discussed below, and intends to approve agricultural and professional use products only for sale in quantities of at least 8 pounds of bait and of at least 16 pounds of bait, respectively. EPA believes that these size limits will effectively discourage residential users from obtaining rodenticides that are not appropriate for residential use or that should be applied only by professionals. In order to promote market segregation, EPA does not intend to approve agricultural and professional use second-generation anticoagulant products that contain less than 8 pounds of bait, and EPA does not intend to approve rodenticide bait products containing any of the six other active ingredients covered by this decision that contain more than one but less than four pounds of bait.

A. Summary of Restrictions

1. "Consumer Size" Products (Containing First-Generation Anticoagulants and Non-Anticoagulants Only)

For the purposes of this risk mitigation decision, the Agency has determined that rodenticide products containing ≤ 1 pound of bait are to be considered "consumer size" products. The following restrictions apply to "consumer size" rodenticide bait products.

- "Consumer size" bait products must be sold with ready-to-use (one-time use or refillable) bait stations, except for products that are labeled solely for use outdoors, below-ground for control of moles and pocket gophers.
- "Consumer size" bait products may contain one or more of the following active ingredients: chlorophacinone, diphacinone, warfarin, bromethalin, cholecalciferol, and zinc phosphide.
- "Consumer size" products may not contain the following active ingredients: brodifacoum, difethialone, bromadiolone, or difenacoum.
- Meal, treated whole-grain, or pelleted forms of bait (whether packaged in placepacks or not) are prohibited, except for products that are labeled solely for use outdoors, below-ground for control of moles and pocket gophers. Bait must be in a form that is reasonably expected to remain in

the bait station, except for bait removed by target rodents and minor quantities of crumbs created by target rodents.
- Bait stations must meet the standards set forth in Section V.C, below, for ability to isolate bait from children.
- Bait stations for mouse control must accommodate bait placements of between 0.25 and 1 ounce of bait.
- Bait stations for rat control must accommodate bait placements of between 4 and 16 ounces of bait for warfarin, diphacinone, or chlorophacinone baits; between 2 and 8 ounces of bait for cholecalciferol baits; between 1 and 6 ounces of bait for bromethalin baits; and between 0.15 and 0.3 ounces of bait for zinc phosphide.
- A retail package containing a bait station may contain up to a maximum of 1 pound of bait for either mouse or rat control (the 1 pound limit includes the initial bait placement inside the bait station, plus any bait refills).

2. First-Generation Anticoagulant and Non-Anticoagulant Products for Agricultural Use and Professional Applicators (Pest Control Operators)

The following restrictions apply to first-generation anticoagulants or non-anticoagulant rodenticide products intended for agricultural use or for use by professional applicators (pest control operators).

- Bait need not be *sold* in or with bait stations, but labels must require use of bait stations where children, domesticated animals, or non-target wildlife may be exposed (this is not a new requirement).
- Products may contain the following active ingredients: warfarin, diphacinone, chlorophacinone, zinc phosphide, bromethalin, and cholecalciferol.
- Products may <u>not</u> contain the following active ingredients: brodifacoum, difethialone, bromadiolone, or difenacoum.
- Any form of bait is acceptable, including meal, pelleted, or block forms.
- Products must contain at least 4 pounds of bait.

3. Second-Generation Anticoagulant Products for Agricultural Use

The following restrictions apply to rodenticide products intended for agricultural use other than field use and containing any of the second-generation anticoagulants (brodifacoum, difethialone, bromadiolone, and difenacoum):

- Bait need not be *sold* in bait stations, but labels must require use of bait stations for indoor applications where children, domesticated animals, or non-target wildlife may be exposed (this is not a new requirement).
- Product labels must require use of bait stations for all outdoor, above-ground placements.

- Any form of bait is acceptable, including meal, pelleted, and block forms.
- Product labels must state, "For use in and around agricultural buildings only. Do not apply further than 50 feet from agricultural buildings.**"**
- Product labels must state, "Do not use in homes or other human residences."
- Products must be labeled specifically for use in and around agricultural buildings.
- Products must contain at least 8 pounds of bait.
- Registrants must agree to terms and conditions of registration specifying that the registrants will control distribution of the products so that they only be distributed to or sold in agricultural, farm and tractor stores or directly to PCOs and other professional applicators, and that registrants will not sell or distribute the product in channels of trade likely to result in retail sale in hardware and home improvement stores, grocery stores, convenience stores, drug stores, club stores, big box stores, and other general retailers.

4. Second-Generation Anticoagulant Products for Professional Applicators (Pest Control Operators)

The following restrictions apply to rodenticide products intended for the professional market (commercial pest control operators (PCOs), public health officials, Federal, State, or municipal employees charged with rodent control, etc.) other than field use and containing any of the second-generation anticoagulants (brodifacoum, difethialone, bromadiolone, and difenacoum).

- Bait need not be *sold* in bait stations, but labels must require use of bait stations for indoor applications where children, domesticated animals, or non-target wildlife may be exposed (this is not a new requirement).
- Product labels must require the use of bait stations for all outdoor, above-ground placements.
- Product labels must state "Do not apply further than 50 feet from buildings.**"**
- Bait stations used in residential and institutional settings must meet the standards set forth in Section V.C, below, for ability to isolate bait from children.
- Any form of bait except liquid is acceptable, including meal, pelleted, block, and paste forms.
- Products must contain at least 16 pounds of bait.
- Registrants must agree to terms and conditions of registration specifying that the registrants will control distribution of the products so that they only be distributed to or sold in agricultural, farm and tractor stores or directly to PCOs and other professional applicators, and that registrants will not sell or distribute the product in channels of trade likely to result in retail sale in hardware and home improvement stores, grocery stores, convenience stores, drug stores, club stores, big box stores, and other general retailers.

B. Exclusions

The risk mitigation decision discussed in this document does not affect products that are labeled only for field (non-structural) uses (e.g., agricultural crops, orchards, groves, non-crop sites, ditch banks, gullies, irrigation ditches, garbage dumps, landfills, etc.). Persons holding registrations for field use products must list the products in their 90-day response letter, but indicate that the risk mitigation measures are inapplicable. The risk mitigation measures set forth in the Rodenticide Cluster and Zinc Phosphide REDs remain requirements for the field (non-structural) use products. Products that are labeled for both structural and field (non-structural) uses are subject to the new requirements discussed in this document for structural use products, as well as the requirements imposed in the Rodenticide Cluster and Zinc Phosphide REDs.

C. Bait Stations

1. Ready-to-Use Bait Stations

Rodenticide bait products containing ≤ 1 pound of bait (i.e., the "consumer size" products discussed in Section V.A.1, above) may only be sold packaged with bait stations meeting one of the following four categories of specifications.

Tier 1. Tier 1 bait stations meet the revised criteria for tamper-resistant bait stations that are set forth in Pesticide Registration (PR) Notice 94-7. They have demonstrated the performance features for weather resistance set out in PR Notice 94-7, namely that the station is resistant to destruction or weakening by typical non-catastrophic weather (rain, snow, sunlight). They have also demonstrated an ability to isolate bait from children and dogs, based on successful laboratory testing according to the following three EPA protocols, which are provided as attachments to this document (Attachments A, B, C). Rodenticide bait products that include Tier 1 bait stations may be labeled for indoor and outdoor use, subject to other restrictions regarding use sites and other aspects of product use that appear on the registered label.

- Method for Testing Ready-to-Use Bait Stations with Young Children
- Method for Testing Ready-to-Use Bait Stations with Dogs
- Method for Testing Ready-to-Use Bait Stations with Adults for Facility of Opening, Reclosing, and Securing

Tier 2. Tier 2 bait stations have demonstrated an ability to isolate bait from children and dogs, based on successful laboratory testing according to the following three EPA protocols, which are provided as attachments to this document (Attachments A, B, C). Tier 2 bait stations do not meet the performance standards for weather resistance. Therefore, rodenticide bait products that include Tier 2 bait stations must be labeled for indoor use only.

- Method for Testing Ready-to-Use Bait Stations with Young Children
- Method for Testing Ready-to-Use Bait Stations with Dogs

- Method for Testing Ready-to-Use Bait Stations with Adults for Facility of Opening, Reclosing, and Securing

Tier 3. Tier 3 bait stations have demonstrated an ability to isolate bait from children, based on successful laboratory testing according to the following two EPA protocols, which are provided as attachments to this document (Attachments A and C). Tier 3 bait stations do not meet the performance standards for weather resistance, and either have not been tested or did not meet the standards for ability to isolate bait from dogs. Rodenticide bait products that include Tier 3 bait stations are permitted for indoor use only, and may be applied only in locations inaccessible to pets, domesticated animals, or non-target wildlife.

- Method for Testing Ready-to-Use Bait Stations with Young Children
- Method for Testing Ready-to-Use Bait Stations with Adults for Facility of Opening, Reclosing, and Securing

Tier 4. Tier 4 bait stations have either not been tested or did not meet the standards for ability to isolate bait from children and dogs. Registrants submitting applications for rodenticide bait products that include a Tier 4 bait station must certify that the station meets the following performance standard. Rodenticide bait products that include Tier 4 bait stations are permitted for indoor use only, and may be applied only in locations inaccessible to children, pets, domestic animals, and non-target wildlife.

Tier 4 Bait Station Self-Certification Statement:

> "[Insert company name] certifies that the bait station [insert model number] sold with [insert product name; insert EPA registration number or File Symbol] is a sealed, single-use, non-refillable unit, for indoor use only, containing no more than 1 oz of bait [if for mouse control] or no more than 4 oz of bait [if for rat control]. The bait station is made of a material of sufficient rigidity such that the station is not easily crushed or opened by a child less than 6 years of age, not easily chewed by mice [or rats], and not reasonably anticipated to release rodenticide bait except for bait removed by target rodents and minor quantities of crumbs created by target rodents."

2. Bait Stations Sold Without Bait

Bait stations that are sold without bait are not pesticide products. Such bait stations are considered to be application equipment, and therefore are not regulated directly under the Federal Insecticide, Fungicide and Rodenticide Act. However, labels of registered rodenticide baits require that bait stations be used in certain use situations. In such cases, users of rodenticide baits are required to obtain or construct bait stations that are appropriate for the use situation and consistent with label requirements.

Since 1983, EPA has provided assistance to companies and individuals who seek to design bait stations that conform to the degree of protection that users of rodenticide baits are expected to provide for controlling rats or mice in structural situations. EPA maintains a list of "adequately protective" stations that have been concluded to conform to the criteria for tamper-resistant bait stations that are delineated in PR Notice 94-7.[12] During the assessment process, bait station manufacturers are given the option of testing their products in cases where compliance with one or more of the criteria is not obvious from examination of the unit. Depending upon the specific issue, manufacturers may avail themselves of protocols that EPA has developed for assessing the ability of the stations to deny access to dogs and children under six years of age. A protocol for testing empty bait stations for utility by adults also is available upon request.

It is not mandatory that empty bait station designs be submitted to EPA, that they be listed by EPA as "adequately protective", or that they be tested according to EPA's protocols for bait stations or any other procedures. In situations in which the product's label requires use of bait stations, it is the responsibility of the user to obtain or construct bait stations that conform to the label's requirements. If the label requires use of a "tamper-resistant bait station", the stations used must conform to the criteria for "tamper-resistant bait stations" that appear in PR Notice 94-7.

D. Labeling Changes

Please refer to the label tables in section VII.D of this document regarding the labeling changes required for rodenticide products containing any of the ten active ingredients covered by the risk mitigation decision described herein.

VI. Controlling Rodents

A. IPM Principles

Long-term rodent control, like control of other types of pests, is best achieved through the use of various complementary chemical and non-chemical control techniques. This approach, first articulated for agricultural insect pests by Stern *et al.*

[12] From 1983 until PR Notice 94-7 was issued, bait stations were assessed according to the criteria for "tamper-proof bait boxes" that were listed in PR Notice 83-5.

(1959)[13], is known as integrated pest management (IPM). The selection of methods to use for managing rodent infestations varies according to the nature of the situation, the knowledge and abilities of the applicator, and the tools and approaches available to that person. For example, Timm (1994)[14] outlines factors and control options that may be considered in dealing with an infestation of house mice. If there are no rodents present, rodent-proofing and habitat modification should be implemented to decrease the likelihood that rodents will enter a home. Planning to incorporate rodent stoppage into building designs, seeing to it that stoppage is affected during construction, and regularly maintaining stoppage and sanitation on the premises may prevent rodent infestations from occurring at a site (Frantz and Davis, 1991)[15]. It is clear that sanitation, rodent-proofing, and other non-chemical, non-lethal approaches are important aspects in limiting the conditions that are favorable to the presence of rodents. Where infestations occur, mechanical and adhesive traps may be used to remove some or all individuals, depending on the size and nature of the infestations. However, there are also situations that require the use of rodenticide baits, alone or in combination with non-chemical control methods, to ensure satisfactory rodent control levels.

B. Impact of Risk Mitigation Measures on Resistance

There is no recent information on status of resistance to first-generation anticoagulants in commensal rodents in the United States, as no systematic studies or surveys of resistance have been undertaken for nearly 30 years (Kaukeinen and Prescott, 2007)[16]. However, during 1977-79, a nationwide testing program that focused primarily on Norway rats documented some level of resistance to warfarin in 45 of 98 sites sampled, mainly in urban centers in the eastern half of the country. In most cases, the prevalence of resistant individuals within a given sample was less than 20% of the rats tested, the exception being Chicago, where resistance exceeded 50% (Jackson, et al., 1985).[17] Although that study focused on Norway rats (*Rattus norwegicus*), small samples of house mice (*Mus musculus*) were also tested, revealing that about 50% of house mice from 14 sites tested were resistant to warfarin. Resistance to warfarin and other anticoagulant rodenticides has been also documented in several European countries. To date, warfarin resistance has been found only in commensal rodents in the United States. Warfarin resistance has not been reported for indigenous rodent species.

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[13] Stern, V. M., R.F. Smith, R. van den Bosch, and K. S. Hagen. 1959. The integrated control concept. Hilgardia 29: 81-101.

[14] Timm, R.M. 1994a. House mice. Pages B-31 - B-46 In: Hyngstrom, S.E., Timm, R.M., and Larson, G.E. (Eds.) Prevention and Control of Wildlife Damage, University of Nebraska Cooperative Extension, Institute of Agriculture and Natural Resources, University of Nebraska, Lincoln, NE; and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Damage Control, Riverdale, MD.

[15] Frantz, S.C. and D.E. Davis. 1991. Bionomics and integrated pest management of commensal rodents. In: Gorham, J.R. (ed.) Ecology and Management of Food-Industry Pests, FDA Technical Bulletin 4, Association of Official Analytical Chemists, Arlington, VA, 243-313.

[16] Kaukeinen, D. and C. Prescott. 2007. Warfarin Revisited: New Information on an Old Rodenticide. Pest Control Web Exclusive, 3/21/2007.

[17] Jackson, W.B., A.D. Ashton, S.C. Frantz, and C. Padula. 1985. Present status of rodent resistance to warfarin in the United States. Acta Zool. Fennica 173:163-165.

The earliest instance of rodent resistance to warfarin was first documented from a hog farm in England. In the United States, resistance to warfarin in Norway rats was first found in a sample of 25 rats trapped alive at six farms and two rural stores in North Carolina (Jackson and Kaukeinen, 1972),[18] where the abundance of grain and other dry goods likely provided conditions favorable to rat survival. Over-reliance on warfarin as a primary means of rodent control in those localities may have, in turn, resulted in localized warfarin resistance. Similar selection pressures were probably also present in the urban centers where warfarin was used as the main rodenticide during the rat control campaigns that took place in the United States in the 1970s.

Although EPA's risk mitigation decision is expected to result in increased consumer use of first generation anticoagulants, the Agency believes that it is unlikely that any existing warfarin resistance problems in commensal rodents will be exacerbated by the proposed action. Residential users' reliance on first-generation anticoagulants would have little effect on rat populations because rat control is typically carried out by pest control operators (PCOs) and municipal personnel who would continue to have access to second-generation anticoagulant baits. Thus, unlike the over-dependence on warfarin that was the norm during the 1960s and 1970s, rat control will include the use of both first- and second-generation anticoagulants, as well as non-anticoagulant rodenticides and non-chemical control options.

The Agency acknowledges that it is possible that in localized mouse populations that include warfarin-resistant individuals, the prevalence of resistance could increase if a residential user persists in using only first-generation anticoagulant baits, with no other form of control. Under such a scenario, susceptible individuals would die while resistant individuals would survive and reproduce. However, results of the consumer survey submitted by Reckitt Benckiser[19] suggest that this scenario would be unlikely. This is because only 35% of consumers use rodenticides as their first means of controlling rodents, while 42% choose to start with traps. According to the survey, when consumers use a rodenticide that proves to be ineffective, 50% switch to a different control method, whereas 49% switch to another type or brand of bait. Of the 50% who switch to an alternative control method, 44% switch to traps, while the other 6% hire a PCO. Switching from bait to traps or hiring a PCO (who would likely use a second-generation anticoagulant bait) would result in resistant individuals being controlled in localized populations. Therefore, under this scenario, it is unlikely that localized resistant populations will spread. If localized pockets of warfarin resistance do occur, relief could be obtained using other control methods available to consumers. In cases where severe mouse infestations exist (with or without resistance), second-generation anticoagulants could be applied by commercial pest control operators and/or government agencies.

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[18] Jackson, W.B. and D. Kaukeinen. 1972. Resistance of wild wild Norway rats in North Carolina to warfarin rodenticide. Science 176(4041):1343-1344.

[19] Heiden, E.J. and S. McGonegal. 2007. Economic Assessment of EPA Proposed Rodenticide Risk Mitigation Decision. Document submitted to EPA Docket No. EPA.HQ-OPP-2006-0955-0644(1)5.

VII. What Do Registrants Need to Do?

Currently registered rodenticide bait products containing one of the ten active ingredients covered by this risk mitigation decision (bromadiolone, bromethalin, chlorophacinone, cholecalciferol, difenacoum, difethialone, diphacinone (and its sodium salt), warfarin (and its sodium salt), and zinc phosphide) will meet the FIFRA section 3(c)(5) registration criteria if: (i) the risk mitigation measures outlined in this document are adopted; (ii) risk mitigation measures identified in the 1998 Zinc Phosphide and Rodenticide Cluster Reregistration Eligibility Decisions are adopted, except as modified by this document; and, (iii) applications for amended registration to implement these measures are submitted as provided below.

Based on its evaluation of the rodenticide bait products containing one of the active ingredients covered by this risk mitigation decision (brodifacoum, bromadiolone, bromethalin, chlorophacinone, cholecalciferol, difenacoum, difethialone, diphacinone (and its sodium salt), warfarin (and its sodium salt), and zinc phosphide), the Agency has determined that these products, unless labeled and used as specified in this document, would present unreasonable risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of the affected products. If all measures outlined in this document are adopted, then current risks for rodenticide bait products will be adequately mitigated for the purposes of this FIFRA reregistration determination. Once a comprehensive endangered species assessment is completed, further changes to these registrations may be necessary.

A. Timeline for Compliance

1. 90-Day Response (Deadline: September 2, 2008)

Persons holding a manufacturing-use or end-use registration for a rodenticide product containing one of the active ingredients covered by this risk mitigation decision (brodifacoum, bromadiolone, difethialone, difenacoum, chlorophacinone, diphacinone (and its sodium salt), warfarin (and its sodium salt), zinc phosphide, bromethalin, cholecalciferol) must provide a letter to the Agency on or before September 2, 2008, declaring an intent to comply or not comply with the risk mitigation measures described in this document. This 90-day response letter must indicate, for each of the registrants' registered rodenticide products, whether the registrant intends to amend the registration to conform to this risk mitigation decision. The Agency may initiate cancellation actions against products for which it does not receive notification of the registrant's intent to comply with the risk mitigation measures described in this document.

For each registered product for which a registrant declares its intent not to comply (i.e., not to amend labeling and/or packaging and not to develop a replacement bait station product), the company needs to include a request to cancel that product

voluntarily under FIFRA Section 6(f)(1). Failure to make such a voluntary cancellation request will result in additional regulatory action.

Persons holding registrations for products labeled solely for field uses (for which the risk mitigation measures described in this document do not apply) should list the products in their 90-day response letter, but indicate that the risk mitigation measures are inapplicable. Products that are labeled for both structural and field (non-structural) uses are subject to the new requirements discussed in this document for structural use products, as well as the requirements imposed in the Rodenticide Cluster and Zinc Phosphide REDs.

2. Applications for Amendments and Cancellations (Deadline: December 4, 2009; 1.5 years from issuance of decision)

Applications for amended registration consistent with the risk mitigation decision are due on or before December 4, 2009. The Agency intends to issue decisions on amendments submitted without supporting data within 3 months. The Agency intends to issue decisions on amendments submitted with supporting data within 4 months. Amendment applications will not be subject to registration service fees required under the Pesticide Registration Improvement Renewal Act of 2007 (PRIA2).

3. Last Day for "Release for Shipment" of Product Not Complying with Risk Mitigation Decision (Deadline: June 4, 2011; 3 years from issuance of decision)

Pursuant to the terms of the voluntary cancellations, June 4, 2011 would be the last day for registrants to "release for shipment" (sell or distribute) rodenticide products not complying with the Risk Mitigation Decision. This limitation would apply to those registered both on and after the publication of the Federal Register announcing availability of the decision (June 4, 2008). Rodenticide products that do not comply with this Risk Mitigation Decision that a registrant releases for shipment after June 4, 2011, would be considered misbranded.

B. Product Efficacy Issues for Compliance with this Decision

Existing registered bait formulations that have met the applicable efficacy criteria for the claims made for them will not have to be retested for efficacy if they are to be:

1. packaged in and/or with a bait station;

2. registered as the formulation for a new bait product that is labeled for use only in or within 50 feet of agricultural buildings (≥ 8 pound products containing brodifacoum, bromadiolone, difenacoum, or difethialone); or

3. registered as the formulation for a new bait product intended for professional use (≥ 16 pound products containing containing brodifacoum, bromadiolone, difenacoum, or difethialone).

Applicants for registration of such products must cite all of the efficacy reports that apply to the new product as it is proposed to be labeled. If the new product is claimed to control only one species of commensal rodent (e.g., the house mouse), only the efficacy data pertaining to that species will be required.

Submission of efficacy data will be required for new bait formulations that are proposed for registration.

C. Steps to Comply with Rodenticide Risk Reduction Measures

Please see Table 1 (pages 28-30) and Table 2 (page 31-32).

D. Label Tables

Please see Table 3 (pages 33-36) and Table 4 (page 37).

Table 1

Steps for Complying with Rodenticide Risk Reduction Measures [Response Needed for Each Product]	
90 Days after Publication of the *Federal Register* Notice Announcing the Availability of the Decision (September 2, 2008)	
If company …	**Then it must …**
intends to comply with risk mitigation measures,	inform EPA, in writing, if and how it will comply within the 1.5 years deadline. Options for compliance include: 1. certifying that the product is a technical grade or manufacturing use product that currently complies with the risk mitigation decision; 2. certifying that the requirements of the May 2008 risk mitigation decision do not apply because the product is: a. labeled solely for outdoor, below-ground control of moles and pocket gophers; b. labeled solely for outdoor, field use; or c. a tracking powder product; 3. certifying that, on or before December 4, 2009, you will submit an application for amended registration consistent with the risk mitigation decision; or 4. submitting a request for voluntary cancellation (cancellation must be effective on or before June 4, 2011).
does not intend to comply with risk mitigation measures,	request a voluntary cancellation (cancellation must be effective on or before June 4, 2011).
Note: Failure to make a timely, complete 90 Day Response for a product will result in EPA issuing a Notice of Intent to Cancel (NOIC) the registration.	

Table 1

Steps for Complying with Rodenticide Risk Reduction Measures [Response Needed for Each Product]	
1.5 Years after Publication of the *Federal Register* Notice Announcing the Availability of the Decision (December 4, 2009)	
If company …	**Then it must …**
intends to revise the labeling and package size (if needed) for a currently registered product,	submit an amended application with proposed, revised labeling.
Note: Failure to make a timely, complete 1.5 Year Response for a product will result in EPA issuing a Notice of Intent to Cancel (NOIC) the registration. **Note:** PRIA does not apply to applications to amend registrations in order to comply with the rodenticide risk mitigation decision. **Note:** EPA intends to issue decisions on amendments not involving the submission of supporting data within 3 months. The Agency intends to issue decisions on amendments submitted with supporting data within 4 months.	
At Any Time	
If company …	**Then it must …**
intends to replace a non-complying product with one or more new products that comply with the risk mitigation decision, **Note:** The addition of a bait station to a product will require a new product registration. **Note:** A change in bait form (i.e., from pellets to bait blocks) will require a new product registration.	1. request a voluntary cancellation of the old product (voluntary cancellations are due on or before September 2, 2008), 2. apply for new registrations for the replacement products, 3. submit bait station testing report and raw data, plus bait station drawings, for any Tier 1, 2, 3 bait station, 4. submit a self-certification statement for any Tier 4 bait station.

3 Years after Publication of the *Federal Register* Notice Announcing the Availability of the Decision (June 4, 2011)	
If company …	**Then it must …**
has a product for which it requested voluntary cancellation effective on or before June 4, 2011,	cease production of the product and use up existing stocks as required under the cancellation order.
has a product for which EPA issued a registration after June 4, 2008 (the date of the publication of the Federal Register Notice announcing the availability of the decision),	cease production of the product and use up existing stocks as required under the time-limited registration.
has a product for which it requested revised labeling on or before December 4, 2009,	cease production of product with the old labeling and use up existing stocks of product with old labeling within six (6) months.
Note: Failure to cease sale and distribution of existing stocks of product on this date would be unlawful acts under FIFRA subject to civil and/or criminal penalties.	

Table 2

Supporting Materials for Applications for Bait Stations	
If company is applying for …	**then it must submit …**
Tier 1 Bait Station	Description of weather-resistant properties consistent with PR Notice 94-7 Reports and raw data from studies conducted according to the following protocols: - Method for Testing Ready-to-Use Bait Stations with Young Children - Method for Testing Ready-to-Use Bait Stations with Dogs - Method for Testing Ready-to-Use Bait Stations with Adults for Facility of Opening, Reclosing, and Securing Drawings of bait station design **Note:** Submit all test data in PR 86-5 format.
Tier 2 Bait Station	Reports and raw data from studies conducted according to the following protocols: - Method for Testing Ready-to-Use Bait Stations with Young Children - Method for Testing Ready-to-Use Bait Stations with Dogs - Method for Testing Ready-to-Use Bait Stations with Adults for Facility of Opening, Reclosing, and Securing Drawings of bait station design **Note:** Submit all test data in PR 86-5 format.
Tier 3 Bait Station	Reports and raw data from studies conducted according to the following protocols: - Method for Testing Ready-to-Use Bait Stations with Young Children - Method for Testing Ready-to-Use Bait Stations with Adults for Facility of Opening, Reclosing, and Securing Drawings of bait station design **Note:** Submit all test data in PR 86-5 format.

Table 2

Supporting Materials for Applications for Bait Stations	
If company is applying for …	**then it must submit …**
Tier 4 Bait Station	1. self-certification statement about packaging: "[Insert company name] certifies that the bait station [insert model number] sold with [insert product name; insert EPA registration number or file symbol] is a sealed, single-use unit, for indoor use only, containing no more than 1 oz of bait [if for mouse control] or no more than 4 oz of bait [if for rat control]. The bait station is made of a material of sufficient rigidity such that the station is not easily crushed or opened by children < 6 years old, not easily chewed by rats/mice, and not reasonably anticipated to release rodenticide bait except for bait removed by target rodents and minor quantities of crumbs created by target rodents."

Table 3

Label Table
Summary of Labeling, Packaging, and Size Requirements and Terms/Conditions of Sale/Distribution for Rodenticides Used in and Around Structures (Buildings) and Inside of Transport Vehicles

Description	Amended Labeling and Other Requirements	Label Location
Manufacturing Use Products		
All Manufacturing Use products	Add "A Rodenticide for Formulating Other Registered Products for the following sites: [list]."	Front Panel under Product Name
All Manufacturing Use products	Add "Only for formulation into a rodenticide for the following uses(s) [Fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
All Manufacturing Use products (optional statement) One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such uses(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such uses(s)."	Directions for Use

Label Table **Summary of Labeling, Packaging, and Size Requirements and Terms/Conditions of Sale/Distribution for Rodenticides used in and Around Structures (Buildings) and Inside of Transport Vehicles**		
Solid Baits Applied in and around Structural Sites (Buildings) and Inside Transport Vehicles		
"Consumer Size" Products 1st Generation Anticoagulants (Warfarin, Diphacinone, Chlorophacinone) and Non-Anticoagulants (Zinc Phosphide, Bromethalin, Cholecalciferol) Products containing ≤1 pound of bait	**Applicator:** Anyone **Bait Form:** Block or other solid form only. Meal, treated whole-grain, or pelleted forms of bait are prohibited. The Agency will consider another bait form, like a paste, if the registrant shows that it has the same protective features as the block form. **Packaging:** Contains 1 pound of bait or less. **Bait Stations:** Bait must be sold packaged in a bait station meeting the requirements of Tiers 1, 2, 3, or 4. Bait stations for mouse control must accommodate bait placements of between 0.25 and 1 ounce of bait. Bait stations for rat control must accommodate bait placements of between 4 and 16 ounces of bait for warfarin, diphacinone, or chlorophacinone baits; between 2 and 8 ounces of bait for cholecalciferol baits; or between 1 and 6 ounces of bait for bromethalin baits. **Refills:** Products for either mouse or rat control may not contain more than 1 pound of bait. The one pound limit includes the initial bait placement in the bait station, plus any refills. Tier 4 bait stations are not refillable. **Labeling:** Include additional mandatory text found in next table, **"Mandatory Labeling Requirements to Distinguish Residential, Preloaded, Refillable Bait Stations, Tier 1, Tier 2, Tier 3, and Tier 4."** **Sites:** Residential use sites (e.g., inside homes). **Labeling:** For products with outdoor use sites (Tier 1 bait stations only), add: "Do not apply further than 50 feet from home or building."	Front Panel and Use Restrictions
1st Generation Anticoagulants (Warfarin, Diphacinone, Chlorophacinone) and Non-Anticoagulants (Zinc Phosphide, Bromethalin, Cholecalciferol) Products containing ≥4 pounds of bait	**Applicator:** Professional applicators **Bait Form:** Meal, pellet, block, paste **Packaging:** Contains greater than four pounds of bait. **Sites:** In and Around Buildings and Inside of Transport Vehicles **Bait Stations:** Mandatory for outdoor, above-ground use **Labeling:** 1. Add "This product may only be used inside and within 50 feet of buildings or inside of transport vehicles (ships, trains, or aircraft)." 2. Add "Do not sell this product in individual containers holding less than 4 pounds of bait." **Terms/Conditions of Sale/Distribution:** 3. Product may not be sold in packaging that holds less than 4 pounds of bait.	1. Front Panel immediately under Product Name 2. Use Restrictions in Directions for Use 3. Notice of Registration or Amendment Approval

Label Table **Summary of Labeling, Packaging, and Size Requirements and Terms/Conditions of Sale/Distribution for Rodenticides used in and Around Structures (Buildings) and Inside of Transport Vehicles**		
Solid Baits Applied in and around Structural Sites (Buildings) and Inside Transport Vehicles		
2nd Generation Anticoagulants (Brodifacoum, Bromadiolone, Difenacoum, Difethialone) 8 pounds and Greater (Agricultural Buildings Only Use)	**Applicator:** Professional user working in livestock production. **Form:** Meal, pellet, block, paste **Packaging:** Must contain at least 8 pounds of bait **Sites:** In and\ Around Agricultural Buildings Only. (Not for Use in and around Residential sites) **Bait Stations:** Bait stations are mandatory for outdoor use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait. **Labeling:** 1. Add "For Use In and Around Agricultural Buildings Only." 2. Add "Do not use in homes or other human residences." 3. Delete any non-agricultural use sites (e.g. homes, schools, childcare centers, or any other location where children or pets may be exposed). 4. Add "Do not apply further than 50 feet from agricultural buildings." 5. Add "Do not sell this product in individual containers holding less than 8 pounds of bait." **Terms/Conditions of Sale/Distribution:** 6. Prohibited for Sale in Stores Oriented towards Residential Consumers: Grocery, Drug, Hardware and Home Improvement. Acceptable for Sale in Stores Oriented toward Agricultural Consumers: Farm, Agricultural, Tractor Stores. 7. Product may not be sold in packaging that holds less than 8 pounds of bait.	1. Front Panel immediately under Product Name 2. and 3. Use Restrictions in Directions for Use 4. and 5. Use Restrictions in Directions for Use 6. and 7. Notice of Registration or Amendment Approval
2nd Generation Anticoagulants (Brodifacoum, Bromadiolone, Difenacoum, Difethialone) 16 pounds and Greater (PCO Use)	**Applicator:** For use by professional applicators only. **Form:** Granular, pellet, block, paste **Packaging:** Must contain at least 16 pounds of bait **Sites:** In /Around Buildings and Inside Transport Vehicles; In sewers (select products) **Bait Stations:** Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait. **Labeling:** 1. Add "Do not apply further than 50 feet from buildings." 2. Add "Do not sell this product in individual containers holding less than 16 pounds of bait." **Terms/Conditions of Sale/Distribution:** 3. Prohibited for Sale in Stores Oriented towards Residential Consumers: Grocery, Drug, Hardware and Home Improvement. Acceptable for Sale in Stores Oriented toward Agricultural Consumers: Farm, Agricultural, Tractor Stores. 4. Product may not be sold in packaging that holds less than 16 pounds of bait.	1 and 2. Use Restrictions in Directions for Use 3 and 4. Notice of Registration or Amendment Approval

Label Table **Summary of Labeling, Packaging, and Size Requirements and Terms/Conditions of Sale/Distribution for Rodenticides used in and Around Structures (Buildings) and Inside of Transport Vehicles**		
Non-Restricted Use (Unclassified) Products Used to Control Pocket Gophers and Moles Around Residential Sites by Underground, Hand Application		
1st Generation Anticoagulants, Zinc Phosphide, Bromethalin	"This product may only be used to control [moles and/or pocket gophers] in manual, below-ground applications."	Immediately under Product Name
	"This product may only be applied at the use sites and by the application methods indicated on this label."	Use Restrictions in Directions for Use
	"Bait must be applied directly into [moles' and/or pocket gophers'] burrow systems."	Use Restrictions in Directions for Use
	Note: If products contain uses for species requiring bait application above ground, delete such uses and apply for a new registration for these uses.	
Concentrated Products to be Diluted into Solid or Liquid Baits and Applied in and around Structural Sites (Buildings)		
Diphacinone, Sodium Salt Warfarin, Sodium Salt Products containing ≥4 pounds of bait	**Applicator:** Professional applicators **Form:** Concentrate to be diluted **Packaging:** Must contain at least 4 pounds of concentrate **Sites:** In Agricultural or Non-Residential Buildings and Inside Transport Vehicles **Bait Stations:** Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait. **Labeling:** 1. Add "Do not use in homes or other human residences. Do not use outdoors." 2. Delete any residential sites (e.g., "homes"). 3. Add "For indoor use only. Do not use in areas accessible to children, pets and nontarget wildlife." **Terms/Conditions of Sale/Distribution:** 4. Prohibited for Sale in Stores Oriented towards Residential Consumers: Grocery, Drug, Hardware and Home Improvement. Acceptable for Sale in Stores Oriented toward Agricultural or Professional Consumers: Farm, Agricultural, Tractor Stores.	
	Add "Do not use in homes or other residential settings. Do not use outdoors."	Immediately under Product Name
	Delete any residential sites (e.g., "homes"). Add "For indoor use only. Do not use in areas accessible to children, pets and nontarget wildlife."	Use Restrictions in Directions for Use

Table 4

Mandatory Labeling Requirements to Distinguish Residential, Preloaded, Refillable Bait Stations (Tier 1, Tier 2, Tier 3, and Tier 4)

Tier	This Unit is:	May Use:	Front Panel Text:[20]	Use Restriction Text:
1	Tamper-resistant and Weather-resistant	Indoors and Outdoors (within 50 feet of buildings)	**This Bait Station is Resistant to Weather and to Tampering by Children and Dogs. For Use Indoors and Outdoors.**	This bait station may be used in and around (within 50 feet of) buildings accessible to children and pets, consistent with all use restrictions and other requirements indicated on this label.
2	Tamper-resistant (but not weather-resistant)	Indoors	**This Bait Station is Resistant to Tampering by Children and Dogs. Use Indoors Only.**	This bait station may be used in indoor areas accessible to children and pets, consistent with all use restrictions and other requirements indicated in this label. **DO NOT USE THIS PRODUCT OUTDOORS.**
3	Tamper-resistant for young children (only)	Indoors	**This Bait Station is Resistant to Tampering by Children. Use Indoors Only.**	This bait station may be used in indoor areas accessible to children, consistent with all use restrictions and other requirements indicated in this label. **DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO PETS.**
4	Untested or tested without meeting any criteria for tamper-resistance	Indoors	**THIS BAIT STATION IS NOT TAMPER-RESISTANT. Use Indoors Only in Areas Inaccessible to Children and Pets.**	**DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO CHILDREN, PETS, DOMESTIC ANIMALS, OR NONTAGET WILDLIFE.**

[20] Place required text, 1) **bolded** 2) on Front Panel 3) immediately under product name, 4) in a box, 5) in type size equal to "Keep Out of Reach of Children" or 8 Point Type (which ever is larger), 6) on contrasting background, and 7) clearly readable by average person at the point of sale.

Attachment A:

READY-TO-USE BAIT STATION PROTOCOLS

METHOD FOR TESTING READY-TO-USE BAIT STATIONS
WITH YOUNG CHILDREN

METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH YOUNG CHILDREN[1]

OPP Designation: 1.229 (10-29-87)

1. Purpose

1.1 This protocol is designed to test the abilities of ready-to-use bait stations to isolate bait from children of pre-school age.

2. Rationale

2.1 Thousands of incidents of known or suspected rodenticide exposures to children under six years of age are reported each year (e.g., Litovitz and Veltri, 1985; Litovitz, *et al*, 1987). It is suspected that many more exposure incidents are not reported. This protocol has been developed to test the extent to which ready-to-use bait station designs prevent young children from being exposed to rodenticide baits.

2.2 While many reported incidents involve children under two years of age, older pre-school age children are better equipped mentally and physically to attack and compromise bait stations. Subject test ages and many other aspects of this protocol are adapted from the methods used for evaluating Child-Resistant Packaging (CRP). CRP performance standards and procedures (16 CFR §1700.15 and §1700.20) have been in use for many years. EPA has applied these methods and criteria to Child-Resistant Packaging for certain pesticides (40 CFR §157) and believes that CRP methods can be adapted for evaluating protective qualities of bait stations with children.

2.3 This protocol has been adapted from Child-Resistant Packaging test protocols developed by the Consumer Product Safety Commission (CPSC) and described in 16 CFR §1700.15 and §1700.20. The procedures described in this protocol may be modified in the future based upon knowledge gained through testing, comments from concerned parties, changes in EPA's policies, changes to CPSC methods which are appropriate for inclusion in this protocol, and other factors. If EPA determines that changes in procedures are sufficient to call into question the results of tests conducted under earlier versions of this protocol, the Agency may require the stations affected to be retested.

2.4 This protocol describes test methods that can be used with bait stations that are secured to the substrate, a wall, or other virtually immovable object and with stations that are not secured. Because young children may encounter ready-to-use bait stations in situations such as store displays, in shopping bags, in improper storage, or in improper use in which units are not secured, groups of children must be tested with units that are not secured. Testing children with secured stations also is necessary because it is possible that some designs could be more vulnerable to children's attacks when secured. Child-testing secured stations also provides a means for determining whether there are weaknesses in the securing features for a station which enable children to remove "properly secured" stations from their moorings.

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[1] William W. Jacobs and Rosalind Gross, Registration Division (7505P), Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460

2.5 EPA will consider sequential testing of groups of 50 children as an alternative to the 200-child test. (See Federal Register, 48:13, 2389-2392.) Because the performance standards of this protocol are higher than those currently used for CRP, fewer failures can be tolerated for passing or continuing in sequential tests with ready-to-use bait stations. (See 6.3.)

3. Subjects

3.1 Use 200 healthy children, 42-51 months of age, inclusive, for the test with secured stations and 200 healthy children, 42-51 months of age, inclusive, for the test with unsecured stations. Do not use children who have had more than one previous experience in testing bait stations. Do not use the same subjects for testing secured and unsecured stations of the same design. Follow procedures outlined in 16 CFR §1700.20(a)(2) for age and sex distribution requirements for test subjects.

4. Procedures

4.1 Use production models of ready-to-use bait stations or models from early runs on preproduction molds. Do not use toxic bait in stations that are to be tested with children. Instead, use a placebo bait identical in composition and physical form to the toxic bait except for the absence of the toxicant. If the toxic bait contains a dye, the dye may also be omitted from the placebo bait formulation. To help determine whether children have contacted the bait, coat bait with a nontoxic material that will adhere to the child's skin and that will wash off easily. This material may be a visible agent or an agent that can only be detected by use of special equipment such as an ultraviolet light. Take care to apply the material only to the bait and not to areas of the bait station that are more accessible than the bait area. Inspect children's hands prior to the test to determine whether there are any materials present which could affect the reliability of the method used to determine whether the bait has been contacted. If the bait in the station is enclosed in a chamber or pouch through which rodents must chew to gain access to bait, coat the outside of the chamber or pouch with the indicator substance.

4.2 If the bait station is of a refillable design, each station tested must be subjected to simulated repeated use before it is tested with children. Prior to testing with children, each station must be opened and closed (as necessary for refilling) ten times, or more if a larger number of openings and closings would be more representative of use in the normal life of the product.

4.3 Use at least five different test sites and at least four different interviewers. Do not test more than 20% of test subjects at any one test site. No interviewer should test more than 30% of all subjects used.[2] Test children in circumstances in which they feel at ease. Do not use "hostile" or imposing test environments.

4.4 Test children in pairs. Allow each child to challenge only the station presented to him (her). Children should be on the floor or seated at a table so that the interviewer can observe them simultaneously.

[2] These stipulations regarding sites, subjects, and interviewer also hold for sequential tests.

4.5 Beginning Tests

4.5.1 For tests with unsecured stations, hand a station, free from its box or other outer packaging, to each child. A test begins when both children have been presented with stations and have been given the appropriate verbal instructions such as

> "I have just given you a box that has something in it. When I say 'Start', I want you to try to get something out of the box."

4.5.2 For tests with secured stations, present each child with a station secured using the securing method of first choice (as discussed in paragraph 4.1.2 of Protocol 1.228). A test begins when both children have been presented with stations and have been given the appropriate verbal instructions such as

> "I have just given you a box that has something in it. When I say 'Start', I want you to try to get something out of the box."

4.6 Do not encourage or discourage any specific approach by children to compromising the station unless their activities endanger themselves or each other, or involve trading stations or working together on one station. Prohibit such activities. Interviewers may gently encourage children who seem to be reluctant to participate in the test. Children may talk to each other about the stations.

4.7 Test Duration

4.7.1 If the ready-to-use station is not of a refillable design, continue the test for ten minutes. After five minutes, interviewer may remind children that they may use their feet or their teeth.

4.7.2 If the ready-to-use station is of a refillable design, suspend the test after five minutes and give the pair of subjects a demonstration, without explanation, of how to open the station. (If a special tool designed to be used with the bait station is required to open it, do not demonstrate how to open it or give the children access to the tool.) Use a separate, identical station for the demonstration. Conduct this demonstration at normal speed for opening the unit under use conditions. Do not exaggerate or protract movements. At this time, the interviewer also may remind children that they may use their feet or their teeth. After the demonstration, give subjects five more minutes to try to compromise the station.

4.8 At the conclusions of each trial, inspect child's hands, feet, mouth, clothing, and the immediate test environment for evidence of the placebo bait. Examine station carefully to determine existence and nature of any damage sustained by the unit and to assess whether bait was contacted or moved within the station by the child. If placepacks are in station, look for evidence that placepacks have been broken. Look for the marker substance (described in paragraph 4.1) on each subject's fingers, feet, mouth, and clothing.

5. Reporting Results

5.1 Report the age, sex, height, and weight of each test subject. Describe test environment and exact test procedures followed. Provide raw data sheets which indicate the performance of each test subject. Summarize the means used by children to attack stations. Describe the techniques used by each child who succeeded in compromising the station.

5.2 Report the total numbers of station failures, numbers of instances in which stations did not fail, and the percent of child-resistant effectiveness.[3] Report test results for each individual subject including whether there was a failure and the time that elapsed from the start of the test until the time, if any, that failure occurred. For refillable units, report the numbers of failures which occurred before or following the demonstration. A failure occurs when any child compromises the bait station or gains access to its contents. Examples of failures include (but are not limited to) instances in which:

a. Subject touches bait or gains access to bait in bait compartment.

b. Through any action, subject is able to move bait to an area of the station where bait can be touched by subject.

c. Subject removes bait from station.

d. Subject opens station or pulls it apart.

e. Subject cracks or breaks station with the result that the placebo bait is moved to more accessible areas or that the bait in any other way becomes more accessible to the subject.[4]

6. Performance Standards

6.1 Non-refillable Stations: Stations pass if child-resistant effectiveness is 85% or greater for the entire 10-minute test.

6.2 Refillable Stations: Stations pass if child-resistant effectiveness is 90% or greater before the demonstration and 85% or greater for the entire 10-minute period.

6.3 If sequential testing of units of 50 subjects is done, use the table below for making decisions regarding whether the station has passed or failed, or whether testing must be continued.

Sample	Sample Size	Cumulative Sample Size	Acceptance and Rejection Criteria (based upon number of failures) PASS	CONTINUE	FAIL
First	50	50	0 to 2	3 to 13	$\geq$ 14
Second	50	100	3 to 7	8 to 22	$\geq$ 23
Third	50	150	8 to 13	14 to 30	$\geq$ 31
Fourth	50	200	14 to 30	---	$\geq$ 31

[3] For a 200-subject test, percent child-resistance effectiveness is calculated as "the number of children tested, less the test failures, divided by two."

[4] For this type of failure, it is not necessary that the subject touch or remove bait. For example, if the subject put a big hole in the unit, the station would fail, even if the subject did not reach in for the bait immediately or at all.

7. References

Litovitz, T.L., Martin, T.G., and Schmitz, B. (1987) 1986 annual report of the American Association of Poison Control Centers National Data Collection System. American Journal of Emergency Medicine, 5, 405-445.

Litovitz, T.L. and Veltri, J.C. (1985) 1984 annual report of the American Association of Poison Control Centers National Data Collection System. American Journal of Emergency Medicine, 3, 423-450.

Attachment B:

READY-TO-USE BAIT STATION PROTOCOLS

METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH DOGS

METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH DOGS[1]

OPP Designation: 1.230 (10-29-87)

1. Purpose

1.1 This protocol is designed to assess the abilities of ready-to-use bait stations to isolate bait from dogs.

2. Rationale

2.1 Thousands of incidents of known or suspected exposures of dogs to commensal rodenticides are reported each year (e.g., Buck, *et al*, 1985). It is suspected that many more exposure incidents are not reported. This protocol has been developed to test the extent to which bait station designs prevent dogs from being exposed to rodenticide baits.

2.2 Dogs' chief weapons for attacking bait stations are their teeth. While dogs of all breeds and sizes may be exposed to rodenticides, larger dogs have greater capacities for damaging bait stations. Consequently, this protocol requires use of relatively large dogs. Subjects should be relatively hungry and otherwise strongly motivated to attack the test station. Dogs used in tests under this protocol should be accustomed to being fed once a day at the same time every day. Each test dog shall be exposed to stations at its normal feeding time, before being fed its daily ration.

2.3 This protocol has been adapted from methods used by manufacturers of bait stations which are sold without bait in them to test their products with dogs. The procedures used by these manufacturers were developed through dialogue with OPP staff. The procedures described in this protocol may be modified in the future based upon knowledge gained through testing, comments from concerned parties, changes in EPA's policies, and other sources. If EPA determines that changes in procedures are sufficient to call into question the results of tests conducted under earlier versions of this protocol, the Agency may require the affected stations to be retested.

3. Subjects

3.1 Use at least six adult dogs weighing at least 60 lbs for each test. Select healthy dogs 1-6 years of age. Do not use excessively fat dogs. Each group of six subjects shall include at least two females and at least two males. Use mongrels or dogs of any breed as long as size and age requirements are met. Do not use dogs with small or weak mouths or dogs which have misaligned jaws, or misaligned, missing, or small canine or molar teeth. The group of dogs tested must include at least two different breeds. Mongrels count as one "breed". At least two different breeds should be represented for each sex. It is not necessary that male and female subjects tested include examples of the same breed. For purposes of this protocol, a dog shall be considered to be of a particular breed if its characteristics are consistent with those generally

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recognized for the breed. It is not necessary that the subjects have "papers". Use each subject only once with a specific bait station design. Do not use the same subjects for testing more than two different bait station designs.

3.2 Test dogs may wear flea collars. If other ectoparasite control (e.g., dusting, spraying, dipping, bathing) is needed, wait at least seven days from the conclusion of the treatment before starting the test.

4. Procedures

4.1 Test two groups of six dogs. For one group, use bait stations that are secured to an immobile substrate or object by use of the securing method of first choice for the station. (See paragraph 4.1.2 of Protocol 1.228.) For the other group, use stations that are not secured.

4.2 Test dogs in surroundings that are familiar to them. Dogs may be tested on their owners' premises if the conditions of this protocol can be met and its procedures can be followed. If dogs are kenneled, use enclosures that are at least 40 square feet in area. Larger areas are preferred.

4.3 Condition each dog to being fed once a day at a fixed time every day. Exclude dogs that do not feed vigorously and rapidly when food is presented. Persons handling bait stations and feeding and exercising dogs should be familiar to the animals. Dog owners may perform these tasks if they can do so in accordance with the requirements of this protocol. A tester must be present on test day to instruct owner on the method of presenting the station. The tester must record all observations during the test period.

4.4 On the day before test with bait station, remove food dish 30-60 minutes after it has been offered. Remove bones or any other possible sources of food. Instruct others likely to encounter the subject that it is not to be fed. If this condition is violated, do not test the subject. Do not remove water source.

4.5 At normal feeding time on test day, present station to dog at or near location where dog normally is fed. At the time that station is to be presented, the dog will have been without food for 23-23.5 hr. The ready-to-use bait station must contain non-toxic bait otherwise identical in composition to the toxic bait offered in the ready-to-use station.[2] For the test with secured units, build a structure, if necessary, that will permit securing the station according to the method of first choice and otherwise presenting it to the dog in the manner prescribed for baiting rodents by the product label. This structure must be sturdy and heavy enough to prevent the dog from tearing it apart or lifting it along with the station.

4.6 After presenting the station to the dog, withdraw from area to place from which observations are to be made. Avoid actions that might distract the dog. Do not interfere with or encourage dog’s efforts to reach bait in the station. Observe the dog continuously for 60

[2] If the toxic bait contains a dye, this dye also may be omitted from the placebo bait used in the dog test.

minutes. For the next hour, check the dog and the condition of the station at 10-minute intervals.[3] Terminate the test after two hours and provide dog with its normal food ration.

4.7 Photograph top, sides, and bottom of each station tested, paying particular attention to any areas where there is visible evidence (scratches, holes, saliva, etc.) that the station has been attacked.

4.8 Record number and nature of attempts to gain access to material in the station. Determine and record the amount of time spent by the dog in attacking the station and in attempting to get at its contents.

5. Reporting Results

5.1 Report breed, age, weight, and general health of all test subjects. Describe holding and test areas, and general procedures used in handling and maintaining animals. Describe animals' feeding schedules, foods normally fed, and general temperament. Describe each test subject's reactions to station and report number and nature of attempts to gain access to material in the station. Report lengths of time that each dog interacted with the station and techniques used to attempt to get at bait. Describe conditions and provide photographs of stations at start and at conclusion of test. (See paragraph 4.7.) Provide photographs of each test subject. Submit copies of all raw data sheets. If trials are videotaped or otherwise visually recorded, submit copies of such videotapes or discs.

5.2 Report and describe all failures that occur in this test. Failures occur when the station fails to isolate the bait from the dog or when the dog compromises the protective features of the unit. Examples of failures include (but are not limited to) instances in which the dog:

a. contacts or eats the placebo bait;

b. cracks or breaks the station;

c. punctures the station;[4]

d. pulls the station off of its moorings (secured unit tests only); or

e. pulls the station apart (e.g., by defeating tabs or other locking mechanisms).

5.3 Report results and retain records as prescribed by EPA's Good Laboratory Practice (GLP) regulations (40 CFR §160.185, §160.190, §160.195) and by paragraph 5.1 (above).

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[3] If trial is video-recorded, observer should remain on site for the 2-hr period as indicated here (i.e., observing dog continuously for 1 hr and at 10-minute intervals for second hour).

[4] Scratches and holes that do not go all the way through the surface contacted are not considered to be punctures. All dog-caused scratches and partial punctures of stations must be noted in reports.

6. Performance Standard

6.1 To pass this test, stations must completely deny access or potential access to bait for 100% of test subjects. There may be no failures.

7. Reference

Buck, W.B., Beasley, V.R., Trammel, J.L., and Carlson-Stark, C. (1985) National Animal Poison Control Center annual progress report 1984. College of Veterinary Medicine, University of Illinois, Urbana, IL, 181 pp.

Attachment C:

READY-TO-USE BAIT STATION PROTOCOLS

METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH ADULTS FOR FACILITY OF OPENING, RECLOSING, AND SECURING

METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH ADULTS FOR FACILITY OF OPENING, RECLOSING, AND SECURING[1]

OPP Designation: 1.228 (10-29-87)

1. Purpose

1.1 This protocol is designed to assess the reliability with which untrained adults can perform tasks necessary for proper use of ready-to-use bait stations.

2. Rationale

2.1 Thousands of incidents of known or suspected exposures of nontarget organisms to commensal rodenticides are reported each year. It is suspected that many more exposure incidents are not reported. Most known nontarget rodenticide exposures involve children under six years of age and dogs (c.f., Buck, et al, 1985; Litovitz, et al, 1987; Frantz, *et al*, 1984). Most exposures appear to result from use of rodenticide products that are bought almost exclusively by persons who are not professional pest control operators (NCPCC, 1970-1982). Data developed in a survey of "private" pesticide users indicate that many people do not read pesticide labels for information related to how products should be used in pest control and steps to be followed to limit hazards associated with using pesticides (Savage, et al, 1980). Whether consumers read use directions is beyond the control of the registrant and the EPA, but whether persons who read directions can and will follow them could be related to the clarity of the directions and the complexities of the tasks required.

2.2 Ready-to-use bait stations have been developed to provide homeowners and other private users of rodenticides with products that can be applied without touching or measuring bait. Whether use of such stations will lead to a safer use environment when bait is applied in areas accessible to children or nontarget animals depends upon the protective qualities of the stations and the likelihood that applicators will use the stations properly. Nearly all of the bait stations developed to date could have bait shaken out of them if they were lifted. This problem exists even for ready-to-use bait stations designed to hold paraffinized blocks because these blocks tend to crumble or break somewhat after rodents have begun to feed on them. The shake-out problem can be avoided if the bait station is secured, or otherwise immobilized, while in use. If users do not secure stations adequately or ignore directions to do so, bait shake-out could occur.

2.3 Some ready-to-use bait station designs cannot be refilled and must be discarded after the initial quantity of bait contained in them has been eaten. Other ready-to-use bait stations are refillable. Whether a refillable unit will remain as protective as it was when first packaged depends upon the durability of the unit and on the likelihood that users will reclose it properly.

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2.4 This protocol consists of two different methodologies: a test to be used for non-refillable ready-to-use bait stations and a test to be used for ready-to-use bait stations that are designed to be refillable. Select the methodology appropriate for the type of station to be tested. These procedures should be used for testing ready-to-use bait stations with "parent-aged" adults (18-45 years) and "grandparent-aged" adults (60-75 years). Adult effectiveness requirements are similar for both age groups. (See 4.3 and 5.3.)

2.5 This protocol has been developed from child-resistant packaging test protocols developed by the Consumer Product Safety Commission (CPSC) and described in 16 CFR 1700.15 and 1700.20. The procedures described in this protocol may be modified in the future based upon knowledge gained through testing, comments from concerned parties, changes to CPSC methods which are appropriate for inclusion in this protocol, and other factors. If EPA determines that changes in procedures are sufficient to call into question the results of tests conducted under earlier versions of this protocol, the Agency may require the stations affected to be retested.

3. Subjects

3.1 For the "parent-aged" tests, use 100 healthy adults, 18-45 years of age, who have no obvious physical or mental handicaps. Seventy percent of the test subjects shall be females. Within each gender, numbers of subjects used shall be approximately equal for the age ranges 18-27 years, 28-36 years, and 37-45 years.

3.2 For the "grandparent-aged" tests, use 100 healthy adults, 60-75 years of age, who have no obvious physical or mental handicaps. Seventy percent of the test subjects shall be females. Within each gender, numbers of subjects used shall be approximately equal for the age ranges 60-64 years, 65-69 years, and 70-75 years.

4. Test for Non-Refillable Stations

4.1 Procedures

4.1.1 Use at least three different test locations and at least three different interviewers.

4.1.2 Direct subjects to use the method of first choice for securing stations. The method of first choice must be one of the securing methods mentioned in the product literature. If all materials needed to secure a station by a particular method are shipped in the box with the station, that method shall be considered to be the method of first choice and shall be the method tested. If all necessary materials are not shipped in the box for any of the securing methods mentioned on the label, the manufacturer shall select the method of first choice. Provide subjects with all items (tools, nails, screws, etc.) needed for securing station by the method of first choice, if these materials are not provided with the product.

4.1.3 Test subjects individually. Give subjects the printed instructions for putting the bait station into use that are intended to appear on the package to be delivered to the consumer. If available, use the printed product label. Give subjects limited instructions such as

"When I say 'Begin', you will have 30 minutes to place this station into use and secure it according to the instructions for (the method of first choice) on the package. Indicate when you have completed the job by saying 'Done.'"

4.1.4 Allow each trial to continue for 30 minutes unless subject indicates that she or he is finished at an earlier time.[2] Record the amount of time taken from the start until
subject is finished, the amount of time that the subject appears to spend reading directions, and what the subject does with the unit.

4.1.5 After the subject is finished, determine whether the unit has been secured properly (i.e., that the method of first choice for securing the station has been executed in accordance with label directions). Note any shortcomings (e.g., failure to use the required number of screws, failure to apply tape at the required number of locations, failure to move tabs to the point where they "catch", etc.). Determine whether tasks necessary for proper use, aside from those associated with securing the unit, have been performed properly.

4.2 Reporting Results

4.2.1 Report number of persons tested, the gender and age of each subject, the securing method of first choice (and the rationale for selecting it), the time taken for each individual to secure the unit and put it into use, the amount of time that the person appeared to devote to reading directions, and what the subject did with the unit. Summarize results for the entire group and for each sex. Provide tables summarizing results and copies of all original raw data sheets.

4.2.2 Report adult failures for each sex and for all subjects together. Describe each adult failure in detail. Examples of failures include, but are not limited to, the following events:

a. The subject makes no attempt to secure the station.

b. The subject "gives up" after failing to secure the station.

c. The subject does not secure the station properly or completely.

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[2] Although 30 minutes are allowed for this test, the time required to secure stations could vary greatly depending upon the tasks that subjects are required to perform. Experimenters desiring to fix test durations to facilitate the scheduling of subjects may employ a pilot test to estimate the longest time that subjects will require before they either have secured the station of have abandoned efforts to do so. A pilot test shall include 20 "grandparent-aged" subjects, 13-15 of which shall be female. Run the subjects through the procedures prescribed in the protocol for this test. Record times, in seconds, to completion or resignation for each subject. Calculate the mean and standard deviation for test durations for the group. The duration of the main test may be limited to the nearest (or most convenient) whole number of minutes that is more than two standard deviation units beyond the mean time, in seconds, for completing the pilot test and more than 60 seconds beyond the longest test duration observed in the pilot test. Report results of pilot test separately from the results of the main 100-subject tests.

d. The subject damages the station while attempting to secure it, making securing impossible or making the bait potentially more accessible to children or nontarget animals.

e. The subject does not put the station into proper use (i.e., fails to perform acts, apart from securing, that are required for proper use).

4.2.3 Calculate and report the level of effectiveness for the test and for each sex. The level of adult effectiveness is the percent of adults who successfully secure the bait station and put it into proper use.

4.3 Performance Standards

4.3.1 90% or more of "parent-aged" test subjects must secure stations adequately as defined in paragraph 4.1.5 and put them into use properly.

4.3.2 90% or more of "grandparent-aged" test subjects must secure stations adequately as defined in paragraph 4.1.5 and put them into use properly.

5. Test for Refillable Bait Stations

5.1 Procedures

5.1.1 Use at least three different test locations and at least three different interviewers.

5.1.2 Test subjects individually.

5.1.3 Use placebo bait instead of the toxic bait. The placebo shall be identical to the toxic bait except for the absence of the toxicant. If the toxic bait contains a dye, the dye may also be omitted from the placebo bait formulation.

5.1.4 To test subjects' abilities to secure stations and put them into use, follow procedures outlined under 4., the test for Non-Refillable Stations. Follow all procedures in that method including determining time required to compete the test, evaluating the quality of the job performed, determining whether the subject has passed of failed, and completing all data recording requirements associated with the individual subjects.

5.1.5 Evaluate the quality of the securing and putting into use. (See 4.1.5 and 4.2.2.) If station has been secured and deployed properly, the same station may be used for the "refilling" portion of the test. If station has not been secured and put into use properly, the subject has failed already and does not have to be tested further. Provide tools (if any) needed to open, refill, reclose, and/or resecure (using the method of first choice as described in paragraph 4.1.2) the station in accordance with the product label. (Note: It may be possible to refill some stations without removing them from the "secured" condition.) Provide safety gloves if required by the label.

5.1.6 Give subjects the printed instructions for opening, refilling, reclosing, and resecuring bait station that are to appear on the package when delivered to the consumer. If available, use printed product label. Subjects may be given limited verbal instructions such as

"When I say 'Begin', you will have 30 minutes to open this station, remove bait, replace the old bait with new bait, reclose station, and resecure it (if necessary). Indicate when you have completed the job by saying 'Done.'"

5.1.7 Allow each trial to continue until the subject indicates that she or he is finished or until 30 minutes have passed (whichever comes first).[3] For each subject, record the time taken from the start of the refilling phase of the test until the subject is finished, the time spent in reading (or appearing to read) use directions, the time taken to open the station, the time taken to remove the old bait and to refill the station, the time taken to reclose the station, and the time taken to resecure the station (if necessary). Describe the general methods used by each subject while attempting to refill the unit.

5.1.8 After the subject is finished, evaluate the quality of the refilling, reclosing, and resecuring. Examine the unit and determine whether it has been closed properly (e.g., with all tabs in proper slots), it has been locked properly, and all bait added is confined to the appropriate places (e.g., bait hoppers) within the station. If resecuring is necessary, assess the quality of the effort at resecuring the station. (See 4.1.5 and 4.2.2.) Note any failures to execute the required activities properly and completely.

5.2 Reporting Results

5.2.1 Report number of persons tested, the gender and age of each subject, and the time taken for each individual to secure and put the station into use. Report the times taken by each individual to complete the entire refilling and resecuring job, and the times taken by each individual to do each of the following activities: to open the unit, to remove the old bait, to refill the unit, to reclose the station, and to resecure it (if necessary). Report the amount of time that the person appeared to devote to reading directions for the securing and for the refilling phases of the test. Report the methods used by each subject while attempting to refill the unit. Summarize results for the entire group and for each sex. Provide tables summarizing results and copies of al original raw data sheets.

5.2.2 Report all failures for each sex and for all subjects together. Describe each adult failure in detail. Examples of failures include, but are not limited to, the following events:

a. The subject fails to secure the station or to put it into use properly. (See 4.2.2.)

[3] Experimenters desiring to fix test durations to facilitate the scheduling of subjects may employ a pilot test to estimate the longest time that subjects will require before they either have refilled and resecured the station of have abandoned efforts to do so. A pilot test shall include 20 "grandparent-aged" subjects, 13-15 of which shall be female. Run the subjects through the procedures prescribed in this protocol for the "Refill" test. Record times, in seconds, to completion or resignation for each subject. Calculate the mean and standard deviation for test durations for the group. The duration of the main test may be limited to the nearest (or most convenient) whole number of minutes that is more than two standard deviation units beyond the mean time, in seconds, for completing the test and more than 60 seconds beyond the longest test duration observed in the pilot test. Report results of pilot test separately from the results of the main 100-subject tests.

b. The subject is not able to open the station.

c. The subject damages station while attempting to open, empty, refill, reclose, or resecure it.

d. The subject spills bait while refilling station and fails to clean it up.

e. The subject puts bait in areas other than the bait hoppers.

f. The subject fails to reclose bait station completely (including locking, if necessary).

g. The subject fails to resecure station (if necessary).

h. The subject abandons efforts before entire job is completed.

i. The subject does not complete all required tasks within allotted period of time.

5.2.3 Calculate and report the level of effectiveness for the test and for each sex. The level of adult effectiveness is the percent of adults tested who successfully and properly complete all of the tasks associated with refilling the bait station and returning it to proper use.

5.3 Performance Standards

5.3.1 90% or more of "parent-aged" test subjects must secure, put into use, refill, reclose, and resecure stations adequately and return them to use.

5.3.2 90% or more of "grandparent-aged" test subjects must secure, put into use, refill, reclose, and resecure stations adequately and return them to use.

6. Post-Test Interviews (Optional)

6.1 After the test period is over, the interviewer may ask the subjects questions concerning the ease or difficulty of the tasks that they were required to perform. The post-test interview should be structured so that the subjects give these opinions first, before they are asked more "loaded" questions such as whether they would take as much time with the units if they were not being tested or whether they would buy the product if they had a rodent problem.

7. References

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