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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Proposed Risk Mitigation Decision for Nine Rodenticides
January 17, 2007

I. Proposed Decision and Comment Opportunity

This document describes the Environmental Protection Agency's (EPA's) proposed risk mitigation decision for rodenticide bait products containing the following nine active ingredients: brodifacoum, bromadiolone, difethialone, chlorophacinone, diphacinone, warfarin, zinc phosphide, bromethalin, and cholecalciferol.

Based on an evaluation of the ecological risks associated with the use of rodenticide bait products containing these nine active ingredients, and consideration of the public health and other important benefits of the use of rodenticides, EPA anticipates classifying all bait products containing the active ingredients brodifacoum, bromadiolone, and difethialone as restricted use pesticides. To decrease the possibility of children's exposure to rodenticide products used in homes, EPA also anticipates requiring that all rodenticide bait products available for sale to consumers be sold only in tamper-resistant bait stations with solid bait blocks as the only permissible bait form. Finally, EPA is proposing labeling improvements to mitigate the risks associated with bait products containing any of these nine rodenticides.

The proposed risk mitigation decision would decrease the possibility of unreasonable adverse effects to wildlife and children from the use of rodenticides, but would allow residential and professional users access to a wide variety of effective and appropriate rodenticide products. The Agency anticipates that the requirement for tamper-resistant bait stations may result in a modest price increase for rodenticide products sold on the consumer market, but has concluded that the benefits from a reduction in children's exposure to rodenticide bait products outweighs the estimated cost increase. EPA believes that with the proposed mitigation measures in place, rodenticide products will remain affordable for economically-disadvantaged populations, and also notes that there are other effective and affordable methods of rodent control, such as spring traps and glue boards, in addition to rodenticide products.

The purpose of this document is to outline the Agency's rationale for these proposed decisions and solicit comment. Comments are specifically requested on the Agency's proposed risk mitigation decisions and impact assessment, and the mitigation proposals put forth by various stakeholders. Supporting documents can be found at *www.regulations.gov* under docket number EPA-HQ-OPP-2006-0955 (recent documents)

or EPA-HQ-OPP-2004-0033 / EPA-HQ-OPP-2002-0049 (older documents and previous public comments). Public comments will be accepted for 60-days following publication of a Federal Register Notice of Availability on January 17, 2007. During the comment period, EPA will continue its ongoing consultation with the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), the U.S. Fish and Wildlife Service (FWS), and the Department of Housing and Urban Development (HUD). After the close of the comment period, the Agency will review and consider all comments received and issue its final decision.

II. Ecological Risk Concerns and Proposed Mitigation

For more information about ecological risk concerns, please see EPA's *"Comparative Ecological Risk Assessment for Nine Rodenticides"* (Erickson and Urban, 7/04), located in docket number EPA-HQ-OPP-2006-0955 at *www.regulations.gov*.

Background

In connection with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 4 reregistration requirements, EPA issued Reregistration Eligibility Decisions (REDs) for the Rodenticide Cluster and Zinc Phosphide in 1998. Following the issuance of those REDs, EPA developed a Comparative Ecological Risk Assessment for Nine Rodenticides to further evaluate the potential for rodenticide bait products to pose ecological risks to non-target birds and mammals. The nine rodenticides included in the Comparative Ecological Assessment are brodifacoum, bromadiolone, difethialone, warfarin, chlorophacinone, diphacinone, bromethalin, cholecalciferol and zinc phosphide.

The nine rodenticide active ingredients can be divided into three categories: first-generation anticoagulants, which are warfarin, chlorophacinone, diphacinone; second-generation anticoagulants, which are brodifacoum, bromadiolone, 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.

All nine rodenticides are used in bait products to control rats and mice in and around buildings. Chlorophacinone, diphacinone, and zinc phosphide also have field uses (e.g. in orchards and rangelands). Brodifacoum and diphacinone have island conservation uses that are managed by the FWS.

EPA's comparative ecological risk assessment concludes that all nine rodenticide active ingredients pose 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 the compounds' high toxicity and long persistence in body tissues (liver retention half-lives of greater than 300 days). The second-generation anticoagulants are designed to be toxic in "a single feeding," but since time-to-death is several 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 in the body of second-generation anticoagulants can result in additive adverse effects from multiple feedings that are separated by days to weeks.

EPA's comparative ecological risk assessment followed 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 cases the examining toxicologist concluded that a rodenticide likely caused or contributed to the mortality.

Anticoagulants typically do not cause death until 4 to 10 days or more after a lethal dose is ingested. However, exposed individuals become progressively weaker and lethargic due to blood loss, which may contribute to the animal's death, even where the proximate cause of death may be identified as predation, disease, or automobile collision. Even if a cause-effect relationship with rodenticides has not been determined for many wildlife mortality incidents, the detection of rodenticides in a wide variety of non-target wildlife, both birds and mammals, confirms that exposure to the compounds has occurred. 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.

In the United States, only New York (NY State Department of Environmental Conservation) has been actively tracking wildlife mortality incidents associated with

anticoagulants, but funding limits analysis and reporting (many dead raptors still await necropsy and residue analysis). California (Department of Fish and Game) also has reported numerous incidents, but currently has no monitoring program. Analyses for anticoagulants are expensive and funding availability limits wildlife mortality incident reporting. There is no reason to believe that wildlife mortality incidents associated with second-generation anticoagulants are exclusive to these two states. Therefore, EPA believes that widespread exposures to second-generation anticoagulants are occurring wherever rodenticides are being used. Moreover, 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.

Additionally, second-generation anticoagulants have been identified as an environmental issue in many countries, with Canada, the United Kingdom, France, New Zealand, and the United States focusing on incident monitoring and research results. A recent one-day scientific meeting was held in Montreal, following the November 2006 annual meeting of the Society of Environmental Toxicology and Chemistry (SETAC), to discuss the environmental impacts of the second-generation anticoagulants.

EPA's Risk Mitigation Proposal to Decrease Risks to Wildlife

Based on an evaluation of the ecological risks associated with the use of 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 proposing to classify all bait products containing the active ingredients brodifacoum, bromadiolone, and difethialone as restricted use pesticides pursuant to FIFRA section 3(d).[1] Classifying bait products containing these second-generation anticoagulants as restricted use pesticides would limit their use to certified applicators who have had sufficient training to know when to use the products and how to use them in order to limit risks. This risk mitigation measure would preserve the availability of the second-generation anticoagulants to meet critical public health needs in specific situations, but would result in marked overall reduction in exposure to and adverse effects from those compounds.

In addition, EPA is proposing to require that all outdoor, above-ground placements of bait products containing second-generation anticoagulants be contained in

[1] As an alternative to restricted use classification, the Rodenticide Registrant's Task Force (RRTF) has proposed a label statement restricting to certified applicators (or those working under their supervision) the outdoor use of rodenticide bait products containing the nine active ingredients covered in this proposal. The Agency has concluded that it is not appropriate to include on the label of a non-restricted use product any language suggesting that use is limited to certified applicators. EPA believes that "for use only by" label statements such as the one proposed by the RRTF are not enforceable and create no obligations on sellers or enforcement agencies. For additional information on this issue, please refer to the "For Use Only By" issue paper, prepared by the EPA Office of Pesticide Programs' Labeling Committee, which is available on the EPA website at www.epa.gov/pesticides/regulating/labels/projects.html.

tamper-resistant bait stations, 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. Currently, most rodenticide product labels require that rodenticide baits which are placed outdoors and above ground be contained in a tamper-resistant bait station if the bait placement would be within reach of pets, domestic animals, non-target wildlife, or children under six years-of-age. According to the wildlife mortality incident reports, non-target herbivorous wildlife such as deer and squirrels are in fact being exposed, presumably from unprotected or inadequately protected outdoor above-ground placements of unprotected bait. If these animals are in turn consumed by predators or scavengers prior to elimination of rodenticide residues, additional animals would be exposed beyond those exposed from eating the target species. Therefore, the requirement of a tamper-resistant bait station is expected to reduce overall non-target wildlife exposures and resulting adverse effects.

Why "Indoor Use Only" Would Not Be Sufficiently Effective at Mitigating Risks to Wildlife

EPA is not proposing to limit use of baits containing the second-generation anticoagulants to indoor use even though such a limitation has been suggested by some groups as an alternative mitigation measure to minimize risk to wildlife. EPA has concluded that it is important to allow the use of second-generation anticoagulants in outdoor areas by certified applicators. There are certain public health and sanitation situations such as urban alleys and trash collection areas with many rodent food sources where compounds that can kill as the result of a single feeding are useful for adequate rodent control. Additionally, outdoor use is important in perimeter control in agricultural and food warehouse settings, and in certain wildlife recovery programs where rodent eradication is crucial. An indoor-use-only restriction would preclude adequate control in these situations.

Additionally, an indoor-use-only limitation would reduce primary exposures to non-target animals, but would not decrease secondary exposures. Because rodents move in and out of indoor spaces, a rodent exposed to a rodenticide bait indoors may be preyed upon or die outdoors, which may result in secondary exposures. Since EPA has, for many years, registered rodenticides for use "in and around" human structures, residential users may not consistently comply with an indoor-use only limitation. Since rodents do come in from the outdoors, baiting around the home, garage, patio, woodpile, and other similar outdoor areas is often an effective way to target unwanted rodents. However, baiting "around" structures may result in primary as well as secondary exposures since many non-target animals such as small seed-eating birds, opossums, raccoons, skunks, and deer frequently occur around buildings. By making bait products containing second-generation anticoagulants restricted use pesticides, only certified applicators would be allowed to make outdoor bait placements, which would decrease the likelihood of misapplication. EPA's proposed risk mitigation would still allow residential users to bait "in and around" their structures with rodenticide products containing active ingredients

that are less likely to harm non-target wildlife, and, pursuant to another mitigation measure discussed below, in tamper-resistant bait stations.

Sublethal Effects

There is ongoing research into the effects of sublethal doses of anticoagulants on non-target wildlife and the consequences of the highly persistent second-generation anticoagulants to bioaccumulate from repeat exposures to one or more compounds. Whether single or repeat sublethal exposures cause adverse effects, such as impacts on reproduction or behavior, are questions which are yet to be answered. As EPA's proposed mitigation measures are targeted at reducing non-target wildlife exposures to rodenticides, they are expected to reduce the extent and severity of any sublethal effects in non-target wildlife.

Endangered Species

Several reported incidents have involved endangered species, including San Joaquin kit foxes, Northern spotted owls, and bald eagles.

California incident records contain evidence of exposure and mortality of endangered kit foxes in California. Anticoagulant residues were detected in 27 of 32 kit fox carcasses, and many showed signs of extensive hemorrhage upon necropsy. Brodifacoum was detected in all 27 carcasses, and several had residues of two or more anticoagulants.

The FWS issued a biological opinion on eight of the rodenticides in 1993. The opinion does not include difethialone, which was first registered in 1995. 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.

In 2005, EPA and FWS entered an informal consultation phase for all nine rodenticides. Since rodenticide use is widespread and secondary exposure issues with these compounds are complex and include migratory species, the Federally-defined action area may be extensive. EPA and FWS will be working together to determine an appropriate plan of action for the rodenticides. Meanwhile, the mitigation measures proposed in this document should have the beneficial effect of reducing non-target wildlife exposures to rodenticides, and thus limiting the scope of the endangered species risk assessment work, particularly for the second-generation anticoagulants.

III. Children's Exposure and Proposed Mitigation

Background

EPA issued REDs for the Rodenticide Cluster and Zinc Phosphide in 1998. In those 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, CDC, 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 drop the indicator dye requirement due to the lack of suitable dye, and drop the bittering agent requirement 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 when products without a bittering agent may be required. 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. But the court reversed

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

EPA's decision to rescind the bittering agent requirement, and remanded the decision to EPA "for further consideration consistent with this opinion."

The court's decision in 2005 has given focus to the Agency's ongoing efforts to determine how best to reduce exposure and risks to children from rodenticide products. EPA has observed that since 1993, the American Association of Poison Control Centers (AAPCC) has reported approximately 12,000 to 15,000 annual rodenticide exposures to children 6 years old or younger. The AAPCC data fortunately shows that only a small number of exposed children experience medical symptoms or suffer adverse health effects as a result of their exposure. Nonetheless, the Agency believes that the number of exposure incidents is unacceptably high because of the social costs associated with treating children who might have been exposed, and the emotional toll of suspected exposure incidents. 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); and "Updated Review of Rodenticide Incident Reports Primarily Concerning Children" (Hawkins and Allender, 1/09/07).

EPA is concerned about children's exposures to rodenticides, and believes that a bittering agent is an inadequate means to address the problem because the substance can only be tasted after the bait already is in a child's mouth. The frequency of children's exposure to rodenticides has remained relatively constant over recent years, despite the fact that the percentage of rodenticide bait products on the market containing bittering agents has increased substantially. This result is not surprising given that bittering agents do not prevent the initial exposure, but at most would decrease the amount of rodenticide bait a child would consume by rendering the bait less palatable.

EPA's Risk Mitigation Proposal to Decrease Children's Exposure to Rodenticides

EPA believes that the large number of children exposed to rodenticide bait products is too high, and that more stringent requirements are needed. Rodenticide product labels currently direct users to apply rodenticide bait products in locations inaccessible to 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 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.

For this reason, the Agency is proposing a requirement that any rodenticide bait product available for sale to a consumer must be sold in a tamper-resistant bait station, with solid bait blocks as the only permissible bait. Under this proposal, tamper-resistant

bait stations would be sold pre-loaded with bait blocks, and could be packaged for sale with additional bait block refills.[3] Solid bait blocks would be the only form of rodenticide bait approved for use in tamper-resistant bait stations for the consumer market. Pellets, grain baits, seed baits, and other types of loose rodenticide bait products would not be permissible for consumer products because of the potential for loose bait to be scattered or shaken from a bait station, and the potential for a rodent to move the bait outside of the bait station.

In 1994, EPA articulated the performance features required for indoor and outdoor bait stations to be considered to be "tamper-resistant." The following eight criteria for tamper-resistant bait stations were set forth in Pesticide Registration (PR) Notice 94-7[4]:

1. Resistant to destruction or weakening by elements of typical non-catastrophic weather (e.g., snow, rain, extremes of temperature and humidity, direct sunshine, etc.);

2. Strong enough to prohibit entry or destruction by dogs and by children under six years of age using their hands, their feet, or objects commonly found in the use environment (e.g., sticks, stones, broken glass, etc. – stations stronger than "tamper-resistant" are needed in areas frequented by hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism);

3. Capable of being locked or sealed so that children and non-target animals cannot gain access through the opening or procedures used to fill the bait compartment(s);

4. Equipped with rodent entrances which a) readily allow target animals access to baits, b) deny such access to other animals larger than adults of the target species, and c) discourage entry by birds. Means for achieving these ends might include use of baffles, mazes, or small entrances;

5. Capable of being anchored securely to resist efforts to move the station or to displace its contents, or equipped with a mechanism which virtually prevents bait from being shaken out of the station after it has been moved;

6. Equipped with internal structures for containing baits and minimizing spillage and tracking of bait outside of the station or into readily accessible parts of the station;

7. Made of a design and color that is not especially attractive to children; and

8. Capable of displaying precautionary statements in a prominent location.

[3] Under this mitigation proposal, bait block refills would not be available for sale unless packaged together with at least one bait station.

[4] The criteria in PR Notice 94-7 apply to bait stations that are sold separately from rodenticide bait products and to bait stations that applicators might construct for their personal use so as to make bait placements that are compliant with label requirements.

The Agency believes that the tamper-resistant criteria from PR Notice 94-7 remain appropriate for rodenticide bait products, except that EPA is proposing to make Criterion 5 optional for bait stations designed for use in and around homes. The Agency believes that rodenticide bait stations for use in and around homes would not need to be anchored because, under the mitigation proposal, rodenticide bait stations used by consumers would only be permitted to contain active ingredients formulated in bait blocks that could not be shaken out of the bait station. Loose bait that could be shaken out of a bait station would no longer be permissible for use by consumers in residential settings. Moreover, EPA believes that most consumers would be unlikely to comply with instructions to anchor or affix a bait station to indoor floor surfaces due to the potential for damage to those surfaces.

EPA expects that its proposal to require tamper-resistant bait stations for all consumer rodenticide bait products with uses in and around homes would dramatically decrease the number of children who are exposed to rodenticide products each year. The Agency believes that most exposure incidents are due to inadequate protection of baits applied in areas accessible to children. Non-professional users often apply rodenticide baits in open containers or in ready-to-use, nonprotective cardboard packaging. Most rodenticide bait products currently on the consumer market are packaged in thin cardboard trays with pop-up lids or in "place packs" (plastic, cellophane, or paper packets containing bait). EPA believes that these types of packaging may contribute significantly to the high number of exposures to children reported each year to the AAPCC. By removing these products from the consumer market, EPA's mitigation proposal should significantly decrease the number of rodenticide exposures to children.

IV. Antidote Issue

Vitamin K is an antidote to treat exposure to first-generation or second-generation anticoagulant rodenticides. There are no true antidotes for the non-anticoagulant rodenticides (bromethalin, cholecalciferol, and zinc phosphide), but there are effective medical treatments designed to lessen absorption and/or to address symptoms.

It has been suggested by some groups that the proposed regulatory measures to prohibit the sale of second-generation anticoagulant products on the consumer market in order to mitigate ecological risks would result in greater risks to children because consumers would be forced to buy rodenticides for which there are no antidotes. The Agency disagrees with this assertion for three reasons. First, there are antidotes for the three first-generation anticoagulants (chlorophacinone, diphacinone, and warfarin), and the Agency believes that these active ingredients are appropriate for use in consumer products. Second, if antidote treatment is necessary following exposure to a first-generation anticoagulant, a single dose of Vitamin K is often sufficient, whereas antidote therapy following exposure to a second-generation anticoagulant may require repeated doses of Vitamin K (due to the fact that the second-generation anticoagulants are more toxic and persistent than the first-generation anticoagulants). Third, the Agency believes

that the vast majority of exposures to children will be prevented if the proposed requirement for tamper-resistant bait stations is implemented.

V. Label Improvement Measures

Independent of the mitigation measures discussed above, EPA is currently considering specific labeling improvements to make rodenticide labels clearer and more understandable. In particular, the Agency is focused on labeling changes that would provide clearer direction to consumers on how to use rodenticide products in order to minimize potential exposure to children, wildlife, and pets. The Agency has concluded, however, that labeling enhancements alone would not mitigate the risks to children and wildlife to a sufficient degree.

EPA has received a stewardship proposal from the Rodenticide Registrants Task Force (RRTF), which articulates the industry's suggestions for rodenticide labeling improvements. (The RRTF's stewardship proposal may be found in docket number EPA-HQ-OPP-2006-0955 at *www.regulations.gov*.) After the Agency reviews the public comments received on the proposed risk mitigation measures described in this document and reaches a final decision on those risk mitigation measures, EPA will then complete its evaluation of the proposed label improvement measures and determine the specific labeling changes that will be required.

VI. Impacts of EPA's Mitigation Proposal

For more detailed information about the potential impacts of EPA's proposed risk mitigation for rodenticide bait products, please see EPA's *"Impact Assessment for Proposed Rodenticide Mitigation,"* (Chiri et al., 9/20/06), located in the rodenticide docket (EPA-HQ-OPP-2006-0955) on the internet at www.regulations.gov.

Impacts of Proposed Restricted Use Classification to Address Ecological Risks

As described in Section II of this document, EPA is proposing to classify all rodenticide bait products containing the active ingredients brodifacoum, bromadiolone, and difethialone as restricted use pesticides under FIFRA section 3(d). The intended beneficial impact of the proposed mitigation would be a significant reduction in the risk of secondary exposures to wildlife, a reduction in primary risks to non-target animals (especially small birds) where small amounts of second generation anticoagulants can be lethal, and a decrease in the number of wildlife incidents caused by rodenticide exposure, as described in Section II.

EPA has concluded that requiring rodenticide bait products containing second-generation anticoagulants to be classified as restricted use pesticides should not have an adverse impact on residential users in terms of significantly increased costs or decreased effectiveness. EPA believes costs to residential users will not increase unduly because

such users will still be able to purchase rodenticide baits (in bait stations) containing first-generation anticoagulant and non-anticoagulant active ingredients. The Agency believes that consumers' selection of rodenticide products is primarily driven by trade names and not by the active ingredients contained in the baits. As public health pesticides, all rodenticide products must demonstrate basic efficacy prior to registration. Therefore, EPA further believes that the replacement of second-generation anticoagulants with first-generation anticoagulants will not significantly affect residential users' capability to control commensal rodents because the first-generation anticoagulants are sufficiently efficacious for typical residential settings.

For those residential settings where second-generation anticoagulants provide a distinct advantage, these products would still be available from certified applicators. Although hiring certified applicators is significantly more expensive than purchasing consumer use products, EPA believes that the vast majority of the residential settings that would require the use of second-generation anticoagulants are high-occupancy buildings that are already likely to be relying on professional pest control companies, which can provide certified applicators with little, if any, increase in cost. EPA anticipates that any cost increase that might result from this risk mitigation measure would be outweighed by the anticipated reductions in exposures to non-target animals.

Resistance to the first-generation anticoagulants has been reported in the past, and recently there have been some reports of resistance to the second-generation anticoagulants. Integrated Pest Management (IPM) experts have demonstrated that this resistance can be controlled by withdrawing the rodenticides for at least thirty days, by alternatively using bait and non-bait techniques, or by alternating between rodenticides with different modes of action. EPA's proposed risk mitigation leaves a variety of compounds available for rodent control. The topics of resistance, resistance management, and Integrated Pest Management techniques are discussed in detail in *"Analysis of Rodenticide Bait Use"* (Chiri et al., 1/23/06), which may be found in docket number EPA-HQ-OPP-2006-0955 at *www.regulations.gov*.

Impacts of Proposed Requirement for Tamper-Resistant Bait Stations for All Outdoor, Above-Ground Placements of Bait Products Containing Second-Generation Anticoagulants to Address Ecological Risks

EPA is proposing to require that all outdoor, above-ground placements of bait products containing second-generation anticoagulants be contained in tamper-resistant bait stations, to prevent access to rodenticide bait by non-target animals. The intended beneficial impact of this proposed mitigation measure would be a reduction in primary risks to non-target animals (especially small birds) where small amounts of second generation anticoagulants can be lethal, and a decrease in the number of wildlife incidents caused by rodenticide exposure, as described in Section II.

EPA anticipates that this mitigation measure will not result in an increased cost for rodent control performed by certified applicators (the only permissible applicators of second-generation anticoagulants, under this mitigation proposal) because EPA believes

that certified applicators have, and likely are already using, tamper-resistant bait stations in many situations. Requiring the use of tamper-resistant bait stations in all situations, rather than leaving the decision to the applicator's discretion, should not result in a cost increase to certified applicators or those using the services of a certified applicator.

Impacts of Proposed Requirement for Tamper-Resistant Bait Stations to Address Children's Exposure to Rodenticides

EPA is proposing to require that all consumer-use rodenticide bait products labeled for use in and around residences be available only in tamper-resistant bait stations containing active ingredients formulated in bait blocks.

An anticipated adverse impact of the proposed risk mitigation is increased cost for rodent control for consumers who choose rodenticide baits, because EPA believes that rodenticide manufacturers are likely to pass onto consumers the additional cost to develop and produce tamper-resistant bait stations. The Agency estimates that the increased cost to consumers who continue to use rodenticide products would be between $0.50 and $10.01 per household per year for mouse control, and between $2.34 and $46.84 per household per year for rat control. EPA has concluded that this small potential cost increase will not impede the public's access to rodent control tools because residential users who are unable or unwilling to buy rodenticide baits will be able to use other affordable alternative methods, such as snap traps and glue boards. Below is a table of estimated costs per household for different types of rodent control methods. These cost estimates are discussed in more detail in EPA's *"Impact Assessment for Proposed Rodenticide Mitigation,"* (Chiri et al., 9/20/06), located in the rodenticide docket (EPA-HQ-OPP-2006-0955) on the internet at www.regulations.gov.

Rodent Control Options	**Mice**	**Rats**
	Cost per household per year	**Cost per household per year**
Current cost of rodenticide	$0.60 - $2.40	$1.20 - $4.80
Bait station plus rodenticide bait block *(EPA's current risk mitigation proposal)*	$1.10 - $12.41	$3.54 - $51.64
Snap Trap/Glue Trap	$0.28 - $5.58	$0.56 - $11.24
Pest Control Operator	$254.00 - $254.00	$254.00 - $254.00

The intended beneficial impact of the proposed mitigation would be a significant reduction in the number of incidents of rodenticide exposure to children, which would result in both health and social benefits, as described in Section III.

New York State Health Department data from 1990-1997 show that African-American and Latino children and children living below the poverty level are disproportionately exposed to rodenticides. Fifty-seven percent of children hospitalized for rodenticide exposure in New York during those years were African-American, although only 16% of New York State's population in 1990 was African-American; 26%

of hospitalized children were Latino, while Latinos comprised only 12% of the State's population in 1990; and 17.5% of the children hospitalized for rodenticide exposure were below the poverty level, while children living below the poverty level comprised only 13% of the State's population in 1990. These data are further discussed in EPA's *"Updated Review of Rodenticide Incident Reports Primarily Concerning Children"* (Blondell, 6/3/99), available at *www.regulations.gov* under docket number EPA-HQ-OPP-2006-0955. EPA's proposed risk mitigation measures would significantly reduce the likelihood of rodenticide exposure to children, including those populations of children who may be disproportionately at risk for exposure.

EPA has concluded that the expected reduction in children's exposure to rodenticide bait products outweighs the estimated cost increase due to the requirement for tamper-resistant bait stations.

Integrated Pest Management (IPM) Necessary for Effective Rodent Control

EPA believes that the proposed risk mitigation measures will not affect the ability of residential users or professional pest control operators to control rodents, because fully effective rodent control products would remain available and affordable. In most situations, it is not possible to control commensal rodents with rodenticides alone. In addition to trapping or baiting, rodent control requires sanitation, rodent-proofing, and removal of rodent harborage. Without habitat modification to make areas less attractive to commensal rodents, even eradication will not prevent new populations from recolonizing the habitat. The term Integrated Pest Management (IPM) is used to describe multi-faceted approaches for pest control. For urban pest control, including rodent control, IPM has been defined as "the coordinated use of pest and environmental information with available pest suppression methods to prevent unacceptable levels of pest damage by the most economical means and with the least possible hazard to people, property, and the environment."[5] EPA's document *"Analysis of Rodenticide Bait Use"* (Chiri et al., 1/23/06) details IPM programs in three cities, as well as alternate means of rodent control which may be used in an IPM program. The document may be found in docket number EPA-HQ-OPP-2006-0955 at *www.regulations.gov*. For additional information about IPM, please refer to www.epa.gov/pesticides/factsheets/ipm.htm.

The CDC, as part of the Department of Health and Human Services, monitors diseases and disease-causing agents and advises the public on disease control and prevention. The CDC and EPA's Office of Pesticide Programs work closely to develop risk mitigation measures on public health pesticides. EPA has consulted with CDC on the risk mitigation measures for rodenticides described in this document, and will continue this consultation as EPA develops its final risk mitigation decision on the rodenticides.

[5] Frantz, S.C. 1996. Integrated pest management in New York State. IPM Practitioner. 18(2):8-10.

EPA has developed partnerships with the CDC and the Department of Housing and Urban Development (HUD) to promote IPM in low-income housing and other setting where pest pressures are significant. Activities carried out under these partnerships include:

- issuance of a HUD order that strongly encourages the use of IPM for pest control in low income housing;
- development of HUD guidance and fact sheets on IPM in multi-family housing;
- collaboration with CDC on "Rodent Control Academies" developed to provide basic training on IPM or rodent control and foster greater cooperation among city agencies in strategic approaches to rodent control;
- integration of IPM into training courses offered by federally funded entities including the National Center for Healthy Housing and the National Environmental Health Association;
- funding research for assessing health outcomes associated with IPM interventions; and
- funding IPM demonstration projects in multi-family housing and other sites with significant pest pressures.

The CDC maintains a website to advise the public about rodent control at http://www.cdc.gov/rodents/. This website provides excellent advice about urban and surburban commensal rodent control. The CDC also provides public health continuing education and has a program, titled "*Managing Rodents and Mosquitoes through Integrated Pest Management*," available on webcast at http://www2.cdc.gov/phtn/ipm/default.asp.

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