Re-evaluation Note

REV2010-17
revised

Risk Mitigation Measures for Eight Rodenticides

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Executive Summary

The purpose of this document is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) is requiring additional risk mitigation measures for rodenticide products containing the active ingredients brodifacoum, bromadiolone, bromethalin, chlorophacinone, difethialone, diphacinone, warfarin or zinc phosphide, as part of an overall risk-reduction strategy for rodenticides in Canada. Furthermore, these measures may be applied to new active ingredients and end-use products when risk mitigation measures are required. The regulatory actions outlined in this document do not apply to rodenticide field uses (for example, in crop land, orchards, nurseries, rangeland, landfills, etc.), with the exception of fields open to the public for "pick your own" activities, or to products registered for use as a tracking powder.

This Re-evaluation Note summarizes comments made to the PMRA in response to the Re-evaluation Note document REV2009-05, *Proposed Risk Mitigation Measures for Eight Rodenticides*, published on 22 June 2009. This document also provides the PMRA's responses to the comments received.

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1.0 Background

As part of an overall risk-reduction strategy for rodenticides in Canada, the PMRA has proposed additional mitigation measures for rodenticide products containing brodifacoum, bromadiolone, bromethalin, chlorophacinone, difethialone, diphacinone, warfarin or zinc phosphide, similar to those required by the United States Environmental Protection Agency (USEPA) in their *Risk Mitigation Decision for Ten Rodenticides* (2008). The proposed mitigation measures for these active ingredients were first presented in Re-evaluation Note REV2009-05, *Proposed Risk Mitigation Measures for Eight Rodenticides*, a consultation document[1].

This Re-evaluation Note summarizes the PMRA's risk mitigation decision and the reasons for it. Comments received during the consultation resulted in some changes to the proposed risk mitigation measures as described in REV2009-05. Appendix I summarizes the comments received during the consultation period and provides the PMRA's response.

2.0 Regulatory Action

The risk mitigation measures for eight rodenticides outlined in this document apply to products registered for use in or around structures, including the following: in and around residential, commercial, agricultural (such as, feed barns, storage sheds, poultry houses), industrial and public buildings; closed structures, such as garbage dumpsters; sewers. It should be noted that these measures do not apply to products registered solely for "field" uses (for example, in crop land, orchards, nurseries, rangeland, landfills, etc.), with the exception of fields open to the public for "pick your own" activities, or to products registered for use as a tracking powder. The PMRA's regulatory actions are summarized in Appendix II and III. Appendix IV and V outline the revised labelling requirements for domestic and commercial class products, respectively.

3.0 Implementation of the Regulatory Action

3.1 Timeline for the Implementation of the Regulatory Action

Appendix VI provides an overview of timelines and requirements for complying with the risk mitigation decision.

3.1.1 Submissions for Amendments Consistent with the Risk Mitigation Decision

For products for which registrants intend to comply, registrants must submit an application to amend the product labels and package (if applicable) within 90 days of publication of the risk mitigation decision.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

3.1.2 Notice of Intent to Discontinue and Last Date of Sale for Products Not Complying with Risk Mitigation Decision

Registrants who do not intend to comply with the risk mitigation decision must notify the PMRA that they intend to discontinue sales of these products. This must be done within 90 days of publication of the risk mitigation decision. The last date of sale by registrants for products not complying with the risk mitigation decision is 31 December 2012.

3.2 Ready-to-Use Bait Stations for Domestic Class Products

The PMRA requires that domestic class products be packaged with one or more tamper-resistant bait stations that meet the conditions of use (indoor versus outdoors), as well as the tamper-resistance indicated by the label:

- The tier 1 to 4 designations are indicators of the resistance of packaging:
    - **Tier 1** bait stations are tamper-resistant for children and dogs, and are weather resistant. They can be used indoors or outdoors.
    - **Tier 2** bait stations are tamper-resistant for children and dogs. They can only be used indoors.
    - **Tier 3** bait stations are tamper-resistant for children only. They can only be used indoors, in locations inaccessible to pets, domestic animals and non-target wildlife.
    - **Tier 4** bait stations are non-refillable (one-time use only). They can only be used indoors, in locations inaccessible to children, pets, domestic animals or non-target wildlife. These bait stations are self-certified by the registrants. Please note that the registrants must certify that the bait station is made of a material of sufficient rigidity such that the station is not easily crushed or opened by children younger than 6 years old, not easily chewed by rats/mice and will not release rodenticide bait except for bait removed by target rodents.
- Tier 1 to 3 bait stations may be non-refillable (disposable, one-time-use stations) or refillable (sold with bait refills); however, it should be noted that the label of domestic class products must indicate that the use of a tamper-resistant bait station is mandatory for each placement of rodenticide baits (see Appendix IV).
- It is the registrant's responsibility to test tier 1, 2 and 3 bait stations that are to be sold with domestic class end-use products in Canada for tamper-resistance according to USEPA protocols.[2]

[2] These protocols are provided in the USEPA's *Risk Mitigation Decision for Ten Rodenticides* available at www. regulations.gov (Docket ID EPA-HQ-OPP-2006-0955).

- For domestic class products sold with tier 4 bait stations, a self-certification statement about packaging must be provided to the PMRA.

- The labels of domestic class end-use products must indicate if the bait station included in the packaging can be used indoors and outdoors (tier 1) or indoors only (tier 2, 3 and 4) and must indicate the bait station's ability to isolate bait from children and/or pets (see Appendix IV).

- Bait stations for mouse control are required to accommodate bait placements of between 7 and 28 g of bait. Bait stations for rat control are required to accommodate bait placements of between 113 and 454 g of bait for warfarin, diphacinone or chlorophacinone baits; between 28 and 170 g of bait for bromethalin baits; and between 4 and 9 g of bait for zinc phosphide baits.

- No more than 454 g of bait can be sold with one bait station.

- All bait stations distributed with domestic class rodenticide products must be clearly labelled "WARNING POISON" and bear the skull and crossbones symbol.

3.3 Bait Stations Sold Without Bait

Bait stations that are sold without bait are considered to be application equipment. Therefore, they are not pest control products and not regulated directly by the *Pest Control Products Act*. However, commercial class rodenticide products registered in Canada must be used in bait stations in certain situations. In such cases, the users of rodenticide baits are responsible for obtaining or constructing bait stations that are appropriate for the use situation (for example, resistant to weather and/or to tampering by children and dogs) and consistent with label requirements. Appendix V lists the required label amendments for commercial class products.

4.0 Additional Information

Any person may file a notice of objection[3] regarding this decision on the eight rodenticide active ingredients within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) at www.healthcanada.gc.ca/pmra or contact the PMRA's Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

PMRA documents can be found on the Pesticides and Pest Management portion of Health Canada's website. PMRA documents are also available through the Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

The USEPA documents for rodenticides are available at www.regulations.gov (Docket ID EPA-HQ-OPP-2006-0955).

Appendix I Comments and Response

1.0 Comments on the Assessment of Exposure and Risk

1.1 Comments on the USEPA Evaluation

1.1.1 The evaluation conducted by the USEPA, on which the PMRA's proposed risk mitigation measures are based, is flawed and should not be relied upon for making risk mitigation decision. The USEPA's decision gives little consideration to the adverse health implications from rodent infestations.

Response

Rodenticides active ingredients have high acute toxicity. Since these chemicals are used in residential and agricultural settings, the PMRA believes that additional risk mitigation measures should be put in place in order to reduce the risks of exposure of children, pets and non-target wildlife to these chemicals. Under the current re-evaluation program, the PMRA has relied on the USEPA's assessments for many active ingredients to make re-evaluation decisions. The PMRA concurs with the risk mitigation strategy adopted by the USEPA, and is requiring similar measures in Canada for rodenticides.

1.1.2 The USEPA's observations and assessments are not representative of Alberta's use of anticoagulants. Second-generation anticoagulants should not be prohibited in Alberta based on the USEPA's findings for rodent control in the United States.

Response

When conducting the re-evaluation of zinc phosphide (RVD2007-01) and the rodenticide cluster (brodifacoum, bromadiolone, chlorophacinone, diphacinone and warfarin) (RRD2006-11), the PMRA identified various levels of risk to non-target terrestrial organisms from primary and secondary exposure to rodenticides. Secondary exposure (consumption by predators or scavengers of prey with rodenticide stored in body tissues) to the second-generation anticoagulants is particularly problematic due to these compounds' high toxicity and long persistence in the body. The PMRA concurs with the risks identified by the USEPA in their *Risk Decision for Ten Rodenticides*.

Commercial class products containing second-generation anticoagulants remain available in Canada for use by certified pest control operators, farmers and persons authorized in government-approved pest control programs.

1.2 Comment on the Status of the USEPA Decision

The USEPA's risk mitigation decision is the subject of current litigation in the United States. The issue of this litigation may substantially alter or negate the mitigation measures required by the USEPA.

Response

Communications with the USEPA have confirmed that the USEPA is moving forward with the implementation of the required risk mitigation measures. The PMRA is aware of activities taking place in other jurisdictions, including the USEPA, and is closely monitoring their decisions, and will determine if further regulatory action in Canada is necessary.

1.3 Comment on Reports of Incidental Exposure

In their evaluation of incidents of human poisoning, the USEPA did not take into consideration the "exposure versus effect" relationship, specifically the severity of adverse effects to children that were exposed to rodenticides. These products have a wide margin of safety and there is typically no need for medical intervention after accidental exposure.

The PMRA should not move forward with any mitigation measures until it has assessed incident data relating to human exposures in Canada. A request for Canadian incident reports sent to the PMRA was also received.

Response

Although registrants have been required by law to report incidents to the PMRA since April 2007, the available information regarding incidents related to the use of rodenticides in Canada is still insufficient to adequately assess accidental exposure of children, pets and non-target wildlife to these chemicals. The PMRA considers the USEPA's observations and assessments as being representative of what is expected to be observed in Canada and; therefore, concurs with the risks identified in the USEPA's decision document.

Incident reports received by the PMRA are available to the public, and can be found in the Pesticide Product Information Database located in the Public Registry of the Pesticides and Pest Management portion of Health Canada's website at www.hc--sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php.

Rodenticides are highly acutely toxic compounds, which are used in residential and agricultural settings. On this basis, the PMRA believes that additional risk mitigation measures must be put in place in order to prevent exposure of children, pets and non-target wildlife to these chemicals.

1.4 Comment on the Assessment of Exposure and Risk in Canada

1.4.1 The PMRA should conduct research in Canada on the effects of rodenticides before implementing any regulatory actions.

Response

The PMRA considers the USEPA's observations and assessments as being representative of what could be expected to be observed in Canada, and concurs with the risks identified as a result of their evaluation. Furthermore, available monitoring data from surveys conducted by Environment Canada's Canadian Wildlife Service shows evidence of secondary exposure of avian predators and scavengers to rodenticides (consumption of prey with rodenticide stored in body tissues). As part of an overall risk-reduction strategy for rodenticides in Canada, the PMRA is requiring additional mitigation measures for eight active ingredients used in rodenticides.

1.4.2 Under Section 4.2 of REV2009-05, it states that residues of second-generation anticoagulants in rodent carcasses "may" be many times the lethal dose for predators or scavengers. The PMRA should verify if this is true before implementing mitigation measures for second-generation anticoagulants.

Response

The challenges with regards to the quantification of risks to birds and mammals from secondary exposure to rodenticides were discussed in PACR2004-27 at the time of the re-evaluation. Risk quotients were not calculated because the levels of toxin in prey are unknown. However, available information from laboratory studies, field studies and rodent control programs have indicated that rodenticides are posing a secondary risk to predators and scavengers that may feed on poisoned prey.

2.0 Comments on the Proposed Mitigation Measures

2.1 General Comments

2.1.1 In 2006, first- and second-generation rodenticides were re-evaluated by the PMRA and found to be acceptable for continued use and registration in Canada without the implementation of drastic mitigation measures.

Response

Rodenticides are compounds that are highly acutely toxic to mammals. As part of an overall risk-reduction strategy for rodenticides, the PMRA is requiring additional protective measures to further protect children, pets and non-target wildlife from the risks associated with the use of rodenticides in Canada.

2.1.2 Based on an examination of the data provided on the USEPA's website, it appears that brodifacoum is involved in the majority of incidental exposures to rodenticides. This chemical is far more toxic than the second-generation anticoagulant bromadiolone. On this basis, the additional mitigation measures should apply to brodifacoum alone.

Response

All rodenticides used in a residential setting constitute a risk for potential exposure for children and pets if they are not placed in a location inaccessible to them. Rodenticides used outdoors and above-ground represent a risk of exposure for children, pets and non-target wildlife if they are not placed in an inaccessible location. Therefore, risk mitigation measures are required for brodifacoum, bromadiolone, bromethalin, chlorophacinone, difethialone, diphacinone, warfarin, and zinc phosphide. Brodifacoum and difethialone were identified as posing a greater potential secondary risk to predators and scavengers than other rodenticides, and thus, were restricted to indoor use only.

2.1.3 A rationale was not provided as to why the mitigation measures pertaining to the protection of non-target species and secondary poisoning required in urban areas are more stringent than the measures required in rural areas. Most urban treatments are indoors and the non-target species are rare in urban areas.

Response

Mitigation measures relating to primary and secondary exposure of non-target species to rodenticides are not specific to urban areas or rural environments but rather the product classification of domestic versus commercial. The PMRA has taken steps to limit the access of general consumers to products which are more of concern for incidental exposures. For example, domestic class products containing second-generation anticoagulants or formulated as loose bait are now prohibited.

2.2 Comments on the Accessibility of Rodent Control Tools for Consumers

2.2.1 The PMRA's current proposal will diminish the ability of consumers to control rodents. A loss of important products (for example, second-generation anticoagulants) will be detrimental to public health and prevent appropriate rodent control in the future during high levels of rodent pressures (for example, garbage strikes).

First-generation products have been shown to be ineffective because of the bait-shyness due to the numerous feedings required. The proposed risk mitigation measures may result in the increase of populations of resistant rodents.

Response

With the additional mitigation measures, consumers continue to have access to a variety of rodent control tools: Products containing first-generation anticoagulants remain available for purchase by the general public. Commercial class products containing second-generation anticoagulants and non-anticoagulants are still available for the control of rodents in residential settings; however, these products need to be applied by commercial pest control operators. Other control methods, such as mechanical traps, are also available for rodent control.

The efficacy of first- generation anticoagulants has been addressed by the USEPA in the *SRRD Response to Public Comments on the Proposed Risk Mitigation Decision for Nine Rodenticides*, and the PMRA concurs with the response provided in that document. In situations where there are limited sources of food for rodents, as in typical residential settings, rodenticide baits that kill after a single night's feeding, such as second-generation anticoagulants, do not offer a significant advantage over rodenticide baits that require multiple feedings. Rodents in these settings are very likely to make repeated feedings on the bait and, therefore, consume a lethal dose, because the bait is the primary source of food.

2.2.2 The removal of second-generation anticoagulants from the domestic class will prevent farmers from using products containing these chemicals.

Response

Commercial class products containing second-generation anticoagulants remain available. These products can be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.

2.3 Comment on the Availability of Commercial Class Products

The general public may have access to the same products as certified applicators by going to agricultural stores.

Response

To ensure that individuals applying commercial class products are educated in the safe and effective use of rodenticide, the following statement was required in 2006 and 2007 for warfarin, chlorophacinone, diphacinone, brodifacoum, bromadiolone and zinc phosphide: ‘‘Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.’’ This statement is now also required for bromethalin and difethialone.

Farmers are required to either obtain a provincial applicator certificate to purchase a commercial pesticide product, or follow other specific provincial regulations. Provinces provide farmers with necessary information on the safe use of rodenticides.

2.4 Comments on the Requirement of Bait Stations

2.4.1 Comment on the Increase in the Cost of Rodenticides

Rodenticide baits packaged in tamper-resistant pre-baited bait stations are currently available on the market for situations where exposure is a concern. Pellets are currently available in weatherproof sachets that are somewhat childproof and not appealing to children. The requirement for all domestic class products to be packaged with at least one bait station places unnecessary costs upon consumers. The current proposal will greatly increase the cost of rodent control efforts and will disproportionately impact minorities, low-income citizens and residents of inner city neighbourhoods of Canada. The proposed mitigation measures have the potential to significantly increase adverse social and public health conditions for financially disadvantaged households.

Response

Our main responsibility is to protect Canadian health and environment from adverse effects related with the use of pesticides in Canada. The requirement for domestic class products to be packaged with at least one bait station will ensure the availability of tamper-resistant bait stations to the general public. Consumers will continue to have access to effective and economical rodent control measures. The “tiered” system for bait stations will enable continued consumer access to rodenticides at different price points, depending on the level of tamper-resistance required for the intended location of use. Other economical methods of control, including mechanical traps, will also remain available.

2.4.2 Comment on the Maximum Amount of Bait Sold with One Bait Station

For domestic class products, it is unclear whether or not there is a maximum number of bait refills that will be allowed to be packaged with a single bait station.

Response

The PMRA will allow up to 454 grams of bait to be packaged with one bait station. The PMRA considers this weight as the maximum amount of bait that can reasonably be expected to be used at each placement site. This requirement is consistent with what will be allowed in the United States.

2.4.3 Comment on the Requirement of Pre-baited Bait Stations

REV2009-05 does not provide a rationale as to why the bait stations packaged with domestic class products need to be pre-baited, when packaged with more than one refill. This is an added cost to registrants which will be passed along to the consumer, with no real benefit to the user.

Response

After further consideration, tier 1, 2 or 3 bait stations sold with domestic class product are not required to be pre-baited.

2.4.4 Comment of the Requirement for Affixed Bait Stations

Bait stations should not be required to be fastened to surfaces, as this may cause damage or mar surfaces.

Response

Based on this consideration, and on the USEPA risk mitigation decision, bait station will not be required to be secured to surfaces, with the exception of bait stations used along the fence line of properties (for more details, see the PMRA's response to comment 2.5).

2.4.5 Comment on the Disposal of Bait Stations

The labels of domestic class rodenticide products should instruct users to dispose of unwanted or used tamper-resistant bait stations in household garbage.

Response

The PMRA agrees with this consideration. Statements with regards to the disposal of unwanted, damaged, or used bait stations are required on domestic class product labels (see Appendix IV).

2.5 Comment on the Restriction of Use Indoors and Against the Outside Walls of Buildings

The PMRA should remove the restriction requiring rodenticides to be placed "indoors and against the outside walls of buildings". Such a restriction would limit the effectiveness of these products in controlling rodents before they get into the building. As the USEPA did in its *Risk Mitigation Decision for Ten Rodenticides*, the PMRA should allow the use of rodenticides within 15 metres of a structure, provided that the bait is placed in a tamper-resistant bait station for all above-ground applications.

Rodents reach buildings by following protected pathways such as fence-lines; thus, the placement of rodenticide baits along fence lines should be allowed. The placement of rodenticide baits is currently allowed only in empty granary bins. Fence-line baiting would allow rodent control around granary bins located in fields, during periods when the bins are not empty.

Response

Based on the comments received, and on input from stakeholders, the PMRA is no longer requiring rodenticides to be placed "indoors and against the outside walls of buildings" and will allow the placement of rodenticides within 15 metres of structures. Outdoor, above-ground placements of rodenticide bait need to be contained in bait stations, with the exception of field uses.

The placement of commercial class rodenticide products along the fence line of properties, outside of the 15-metre limit, but within a 100 metres of buildings, will also be allowed if the bait station is securely fastened (nailed down) to the fence or the ground. Rodents have a relatively small home range, and are not expected to travel great distances to feed. On this basis, the PMRA considers the placement of bait up to 15 metres from structures, or along fence lines within 100 metres of structures, will help reduce the risks of rodents entering these structures. To mitigate risks to non-target animals, fence-line baiting outside of the 100-metre limit is not allowed.

2.6 Comment on the Restrictions in Agricultural Settings

The PMRA should provide rodent control specialists with the necessary manoeuvre margin to adequately control rodents, and in a safe manner. The home range of rodents, especially mice, is extremely limited, and these organisms can hide in small, hard-to-access spaces. On this basis, the use of bait stations in agricultural settings is sometimes impossible. For example, mice can hide in the slotted floors used in swine holding facilities, and rats can dig burrows in proximity of farm buildings to gain access to food supplies. In those situations, rodenticide baits need to be placed directly in the slots or burrows to effectively control rodents. Indoors, rodenticide baits placed in lofts, granaries, or "between walls" are essentially inaccessible to children and non-target animals. Bait stations should not be required for such uses.

Response

The PMRA agrees that farmers and professional applicators need to have access to a wide selection of tools for rodent control. It is expected that these applicators have knowledge of rodent biology and the safe use of rodenticides. On this basis, it is expected that applicators can adequately determine which locations are inaccessible to children and non-target animals, and commercial class products are not required to be packaged with bait stations.

With the new requirements, all outdoors, above-ground placements of rodenticides need to be placed in bait stations, with the exception of field uses for the control of pests such as meadow voles (*Microtus* sp.) and deer mice (*Peromyscus* sp.). Locations such as slotted floors "gaps" and burrows are considered to be "below-ground", out of reach of children, and would not require the use of bait stations. Indoors, placement of rodenticides in bait stations is required in locations accessible to children and non-target animals. In some indoor agricultural settings, where it can be reasonably determined that access to children and non-target animals will not occur (e.g., lofts/granaries, "between walls", etc.) bait stations would not be required.

2.7 Comments on the Product Formulation and Bait Station Requirements

2.7.1 Products formulated as loose bait (for example, pellets, meals and grains) have been reconfirmed by the PMRA as acceptable in RRD2006-11 and should not be prohibited.

Response

Loose bait forms are easily shaken or removed from bait stations, and resemble edible material; thus, they constitute a particular risk for children, pet and non-target wildlife exposures. On this basis, the PMRA is prohibiting the formulation of domestic class products as loose bait. Certified applicators and farmers are expected to be knowledgeable on the safe use of rodenticides; therefore, only commercial class products may be formulated as loose bait.

2.7.2 Loose bait forms should not be allowed, and tamper-resistant bait stations should be mandatory for all placements. Bait stations should be required to be secured (fixed).

Response

Domestic class products must be formulated as solid bait (for example, blocks) and packaged with at least one tamper-resistant bait station. For most use situations, bait stations are not required to be fastened to surfaces, as this may cause damage or mar surfaces.

Farmers and certified applicators are expected to be knowledgeable on the safe use of rodenticides, and need to have access to a wide selection of tools for rodent control. On this basis, commercial class products are not subject to the same restrictions as domestic class products.

2.7.3 Licensed applicators who apply commercial class products in residential settings should be required to provide information to the client about the rodent bait that is used in the bait stations. Information, such as the product name, guarantee, registration number and antidote (if applicable), should be affixed on the bait stations.

Response

The PMRA agrees that such information should be provided to homeowners, and is requiring that information such as the product name, active ingredient, guarantee and registration number must be affixed on the bait stations used for the application of commercial class products in residential settings (see Appendix V).

2.7.4 One-time disposable (tier 4) bait stations are going to be made of non-expensive materials. Consequently, these containers will remain in landfills for a really long time. This alternative can result in adverse effects to the environment, and potentially to non-target birds that visit landfills.

Response

One-time disposable bait stations may result in adverse effects to the environment (namely, an increase in residential waste). However, the PMRA considers that these products should be allowed, as they constitute a less expensive rodent control alternative for low-income households.

2.8 Comment on Additional Risk Mitigation Measures

2.8.1 The PMRA should require the incorporation of bittering agents to all rodenticide products. This measure would limit the duration of children's exposure and reduce the amount of rodenticide bait accidentally ingested.

Response

As stated in RRD2006-11, the PMRA supported the voluntary incorporation of bittering agents to rodenticide baits but it was not intended to be a requirement. Although bittering agents have the potential to reduce the amount of rodenticide bait that an exposed child might consume, the addition of taste deterrent is not expected to reduce the frequency of exposure incidents involving children. Bait stations are being required in order to prevent children's exposure to rodenticides.

2.8.2 The labels of domestic class products should provide basic rodent-proof instructions, as part of an Integrated Pest Management component.

Response

The label of pesticide products registered in Canada is a legal document, which prescribes how the pesticides can be legally used. It also provides information on potential hazards related to the use of the products, and on measures to limit human health and environmental exposures. Integrated Pest Management practices are not required to be included on product labels.

However, as part of a separate initiative, the PMRA is currently working on developing outreach material to raise awareness on the safe use of rodenticides, which will target homeowners and growers. The content of the outreach material will include information on Integrated Pest Management.

3.0 Comments on the Requirements for Difethialone

3.1 Comment on the Similarity between Difethialone and Brodifacoum

The PMRA proposes changes to the registration of difethialone products justified by the similarity of difethialone and brodifacoum and of the risks both chemicals pose. There are significant differences between the toxicological profiles of the two chemicals, as well in their chemical and physical characteristics. It is not appropriate to apply the restrictions placed on brodifacoum to difethialone without any field data or actual testing.

Response

Based on the data available to the PMRA, brodifacoum and difethialone have similar chemical structures, physical and chemical properties, modes of action, and primary toxicity endpoints in the most sensitive bird and mammal species tested. Available data also suggest that, like brodifacoum, difethialone will persist in liver and blood of birds and mammals which have consumed poisoned baits. As no secondary toxicity data were submitted to the PMRA it is not possible to generate endpoints that could be used to assess the potential for effects from secondary exposure of predators and scavengers feeding on animals which have consumed difethialone. However, wildlife mortality incidents reported in the United States Ecological Incident Information System (EIIS) indicate that difethialone was the probable cause of mortality through secondary poisoning in animals such as foxes and hawks. Difethialone has only been registered in Canada since the year 2000, and sales data indicate a lower quantity of difethialone being used compared to other second generation anticoagulant rodenticides (Brimble *et al*., 2005). Despite its more recent registration and its lower use, Canadian field data indicate that non-target predators are exposed to second generation anticoagulant rodenticides, including difethialone as indicated by concentrations in owl livers (Albert *et al.*, 2010).

Given the lack of available secondary toxicity data for difethialone, the similarity of brodifacoum and difethialone with respect to their chemical properties, mode of action and primary toxicity to birds and mammals, available field data indicating exposure and existing incident reports, the PMRA believes that similar mitigation measures for these two chemicals are warranted.

3.2 Comment on the Legality of the Proposed Risk Mitigation Measures

The proposed changes to difethialone products do not comply with the *Pest Control Products Act* and existing regulations. The PMRA is required by law and regulation to conduct a proper, formal re-evaluation of difethialone and presents its findings.

Response

The PMRA has re-evaluated several older rodenticides which were registered before 1995 (RRD2006-11). Difethialone was not included then because it was first registered in Canada in 2000.

In 2008, the USEPA evaluated ten rodenticides concurrently to ensure that human health and ecological risk assessment and risk management approaches were consistent, and published their *Risk Mitigation Decision for Ten Rodenticides*. As an initiative separate from the re-evaluation process, and as part of an overall risk-reduction strategy for rodenticides in Canada, the PMRA is requiring additional risk mitigation measures for eight rodenticides, including difethialone, similar to those required by the USEPA.

4.0 Comments on the Implementation of the Regulatory Action

4.1 Comment on the Timeline for Compliance

The document does not indicate the last day of manufacture/shipping that will be allowed for current registrations (products) that will be prohibited. A timeline similar to what was established by the USEPA should be provided for Canadian registrants. The American timeline provides registrants with a predictable framework in which to determine their courses of action (for example, sourcing, procuring and testing of bait stations, developing acceptable formulations, registering new products).

Response

Appendix VI provides an overview of timelines and requirements for complying with the regulatory decision for these active ingredients and the risk mitigation measures.The last date of sale by registrants of products with current labels was set to 31 December 2012. After that date, all products should bear amended labels and meet the new packaging requirements (if applicable).

4.2 Comment on the Process for Submissions of Amendments Consistent with the Decision

REV2009-05 does not indicate whether registrants will be allowed to amend current registrations (for example, adding a bait station or changing the formulation of products from loose to solid bait) or if these amendments would require a new product registration.

Response

Current registrations will be allowed to be amended by adding a bait station to the package. However, modifications, such as changing the formulation of end-use products (for example, from pellets to blocks) will require a new product registration, as additional data/information may be required to support the application (for example, chemistry or efficacy data).

Appendix II Summary of Additional Risk Mitigation Measures for Domestic Class Products Containing Brodifacoum, Bromadiolone, Chlorophacinone, Difethialone, Diphacinone or Warfarin

Marketing class	Additional risk mitigation measures for domestic class products registered for use in and around structures (in and around buildings, or closed structures, such as garbage dumpsters, etc)	
Domestic	Applicator	Anyone
	Bait form	Block or solid form only. Bait must be in a form that is reasonably expected to remain in bait station, except for bait removed, and crumbs created, by target rodents. Loose bait forms (such as, meal, treated whole-grain, pelleted and liquid) and concentrated products (such as, solution, emulsifiable concentrate, dust, powder) to be diluted into solid or liquid bait are prohibited.
	Packaging	• Products must be sold packaged with a bait station meeting the requirements of tier 1, 2, 3 or 4 (see Section 3.2). No more than 454 g of bait can be sold with one bait station. • Bait stations for mouse control are required to accommodate bait placements of between 7 and 28 g of bait. Bait stations for rat control are required to accommodate bait placements of between 113 and 454 g of bait for warfarin, diphacinone, or chlorophacinone baits. • Bait stations packaged with domestic class products may be non-refillable (disposable, one-time-use stations) or refillable (sold with bait refills). Bait refills cannot be sold individually; they must be sold with at least one bait station.
	Label amendments [1] / mitigation measures	• Labels of domestic class products must be amended to read “Bait MUST be placed in tamper-resistant bait stations.” • Labels of end-use products that allow rat and mouse baits to be placed “in and around buildings”, ‘‘indoors and against the outside walls of buildings” or “inside and in areas adjacent to buildings’’ need to be amended to read ‘‘indoors and within 15 metres of buildings.” • The labels of domestic class end-use products must indicate if the bait station included in the packaging can be used indoors and outdoors (tier 1) or indoors only (tier 2, 3 and 4) and indicate the bait station’s ability to isolate bait from children, and/or pets. • The labels of domestic class end-use products must be amended to indicate that unwanted, damaged or used bait stations must be disposed of in household garbage. • Domestic class products containing second-generation anticoagulants (brodifacoum, bromadiolone and difethialone) are prohibited.

[1] The labelling requirements are detailed in Appendix IV.

Appendix III Summary of Additional Risk Mitigation Measures for Commercial Class Products Containing Brodifacoum, Bromadiolone, Bromethalin, Chlorophacinone, Difethialone, Diphacinone, Warfarin or Zinc Phosphide

Marketing class	Additional risk mitigation measures for commercial class products registered for use in and around structures (for example, in and around residential, commercial, agricultural, industrial and public buildings; closed structures, such as garbage dumpsters, etc.; sewers)	
Commercial	Applicator	Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.
	Bait form	All currently registered bait forms are allowed.
	Packaging	Commercial class products are not required to be sold packaged with bait stations.
	Label amendments [1] / mitigation measures	• Labels of products must be amended to read ''Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets, livestock or non-target wildlife.'' • Labels of end-use products that allow rat and mouse baits to be placed ''in and around buildings'', ''indoors and against the outside walls of buildings'' or ''inside and in areas adjacent to buildings'' must to be amended to read ''indoors and outdoors within 15 metres of buildings.'' Rodenticide bait can be placed in tamper-resistant bait stations along the fence line of properties, outside of the 15-metre limit, but within a 100 metres of buildings, if the station is securely fastened (e.g., nailed down) to the fence or the ground. • All outdoor, above-ground placements of bait products must be contained in bait stations. Tamper-resistant bait stations are required if the bait placement is within reach of pets, domestic animals, non-target wildlife, or children under six years-of-age.[2] • The outdoor use of commercial class, concentrated products (such as, solution, emulsifiable concentrate, dust, powder) to be diluted into solid or liquid bait is prohibited. • The use in residential settings of commercial class, concentrated products (such as, solution, emulsifiable concentrate, dust, powder) to be diluted into solid or liquid bait is prohibited. • The label of commercial class products must be amended to reflect the new requirements for bait stations used for the placement of commercial class bait products.[2] • The use of difethialone is restricted to indoor use only. • Labels of bromethalin and difethialone commercial class products must be amended to include additional precautions/first aid/storage label statements.

[1] The labelling requirements are detailed in Appendix V.

[2] These requirements also apply to products registered for field use sites where Pick-Your-Own activities can occur (including cropland, orchards, nurseries, ornamentals, garden and similar sites).

Appendix IV Revised Label Amendments for Domestic Class End-Use Products Containing Chlorophacinone, Diphacinone or Warfarin Registered for Use In and Around Structures

NOTE: The information in this appendix summarizes required label statements for domestic class products containing chlorophacinone, diphacinone or warfarin. This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary personal protective equipment (PPE) that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

The label of all domestic class products containing chlorophacinone, diphacinone or warfarin must be amended as follows.

- In the **USE LIMITATIONS** section, the following statement must be removed:

  > Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock.

  and must be replaced with the following:

  > Bait MUST be placed in tamper-resistant bait stations.

The label of domestic class end-use products containing chlorophacinone, diphacinone or warfarin that currently allow rat and mouse baits to be placed ‘‘in and around buildings’’, ‘‘indoors and against the outside walls of buildings’’ or ‘‘inside and in areas adjacent to buildings’’ must be amended to read:

> ‘‘indoors and outdoors within 15 metres of buildings’’

The label of domestic class end-use products containing chlorophacinone, diphacinone or warfarin packaged with tier 1, 2 or 3 bait stations must be modified to include:

- In the **DISPOSAL** section,

  > Wrap unwanted or damaged bait stations and discard in household garbage. DO NOT use damaged bait stations.

The label of domestic class end-use products containing chlorophacinone, diphacinone or warfarin packaged with tier 1 bait stations must be modified to include:

- On the primary panel,

  > This bait station is resistant to weather and to tampering by children and pets. For use indoors and outdoors.

- In the **USE LIMITATIONS** section,

  This bait station may be used indoors and outdoors within 15 metres of buildings accessible to children, pets and non-target animals, consistent with all use restrictions and other requirements indicated on this label.

The label of domestic class end-use products containing chlorophacinone, diphacinone or warfarin packaged with tier 2 bait stations must be modified to include:

- On the primary panel,

  This bait station is resistant to tampering by children and pets. Use indoors only.

- In the **USE LIMITATIONS** section,

  This bait station may be used in indoor areas accessible to children and pets, consistent with all use restrictions and other requirements indicated on this label. DO NOT USE THIS PRODUCT OUTDOORS.

- The label must be amended to delete any outdoor sites.

The label of domestic class end-use products containing chlorophacinone, diphacinone or warfarin packaged with tier 3 bait stations must be modified to include:

- On the primary panel,

  This bait station is resistant to tampering by children. Use indoors only.

- In the **USE LIMITATIONS** section,

  This bait station may be used in indoor areas accessible to children, consistent with all use restrictions and other requirements indicated on this label. DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO PETS, DOMESTIC ANIMALS, OR NON-TARGET WILDLIFE.

- The label must be amended to delete any outdoor sites.

The label of domestic class end-use products containing chlorophacinone, diphacinone or warfarin packaged with tier 4 bait stations must be modified to include:

- On the primary panel,

  This bait station is not tamper-resistant. Use indoors only in areas inaccessible to children and pets.

- In the **USE LIMITATIONS** section,

  DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO CHILDREN, PETS, DOMESTIC ANIMALS, OR NON-TARGET WILDLIFE.

- In the **DISPOSAL** section,

  Wrap used or damaged bait stations and discard in household garbage. DO NOT use damaged bait stations.

Appendix V Revised Label Amendments for Commercial Class End-Use Products Containing Brodifacoum, Bromadiolone, Bromethalin, Chlorophacinone, Difethialone, Diphacinone, Warfarin or Zinc Phosphide Registered for Use In and Around Structures

NOTE: The information in this appendix summarizes required label statements for commercial class products containing brodifacoum, bromadiolone, bromethalin, chlorophacinone, difethialone, diphacinone, warfarin or zinc phosphide. This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary personal protective equipment (PPE) that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

I) Commercial class products containing bromethalin and difethialone

To ensure that the use of commercial class end-use products is limited to certified pest control operators, farmers and persons authorized in government-approved pest control programs, product labels must be modified to include the following statement:

- On the primary panel of the label,

  Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.

Product labels must be amended to include:

- In the **FIRST AID** section of the label,

  For all cases of human ingestion, immediately notify a physician or poison control centre.

  If pet or livestock poisoning is suspected, immediately contact a veterinarian.

- In the **STORAGE** section of the label,

  Store in a cool, dry place away from other chemicals and food or feed. Store product not in use, in original container, in a secure location inaccessible to children and non-target animals.

- In the **DIRECTIONS FOR USE** section,

  Users should remove clothing immediately if pesticide gets inside. Then wash skin thoroughly and put on clean clothing.

The label of all commercial class end-use products, with the exception of those products that are packaged in pre-measured place packs, must be modified to include the following statements:

- In the **PRECAUTIONS** section of the label,

  All handlers must wear long-sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves when handling this product.

  KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK. May be harmful or fatal if swallowed or absorbed through the skin. Chemical-resistant gloves must be worn when handling product and when disposing of dead rodents, unconsumed bait and empty containers. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Wash skin thoroughly with soap and water after handling. Wash contaminated clothing, separately from other laundry, with soap and hot water before reuse. KEEP AWAY FROM FEED AND FOODSTUFFS.

The label of products packaged as pre-measured place packs must be modified to include the following statements:

- In the **PRECAUTIONS** section of the label,

  KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK. May be harmful or fatal if swallowed or absorbed through the skin. Do not open pre-measured place packs. Chemical-resistant gloves must be worn when disposing of dead rodents, unconsumed bait and empty containers. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Wash skin thoroughly with soap and water after handling. Wash contaminated clothing, separately from other laundry, with soap and hot water before reuse. KEEP AWAY FROM FEED AND FOODSTUFFS.

II) Commercial class products containing difethialone

- The **USE LIMITATIONS** section must be amended to include:

  For indoor use only.

III) Commercial class products containing chlorophacinone, diphacinone or zinc phosphide

The **DIRECTION FOR USE** section of the label of products registered for field uses (including cropland, orchards, nurseries, ornamentals, garden and similar sites) must be amended to include:

> Baits placed outdoors and above-ground in sites where Pick-Your-Own activities occur MUST be placed in bait stations. The bait stations used MUST meet the characteristics described under **USE LIMITATIONS**.

The **USE LIMITATIONS** section of the label of products registered for field uses (including cropland, orchards, nurseries, ornamentals, garden and similar sites) must be amended as described below under section IV.

IV) Commercial class products containing bromethalin, brodifacoum, bromadiolone, chlorophacinone, difethialone, diphacinone, warfarin or zinc phosphide

Product labels must be amended as follows:

- In the **USE LIMITATIONS** section, the following statement must be removed:

  > Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock.

  and must be replaced with the following:

  > Bait MUST be placed either in tamper-resistant bait stations or in locations not accessible to children, pets, livestock or non-target wildlife.

- In the **USE LIMITATIONS** section, the following statement must be removed:

  > To ensure safe use of this product, tamper-resistant bait stations must have the following characteristics:
  > - constructed of high-strength material (e.g. metal or injection moulded plastic) and resistant to destruction by children and non-target animals;
  > - entrance designed so that children and non-target animals cannot reach the bait;
  > - internal structure that prevents bait from being shaken loose;

- access panel which fastens securely and locks (e.g. metal screw or padlock);
- capable of being securely fastened to a surface (e.g. nailed down); and
- clearly labelled: "WARNING POISON".

- The **USE LIMITATIONS** section must be amended to include:

  Bait stations (**tier 3**) used for the placement of rodenticide bait indoors, in locations not accessible to pets or livestock must have the following characteristics: (1) be constructed of high-strength material (e.g., metal or injection moulded plastic) and resistant to destruction by children; (2) have an entrance designed so that children cannot reach the bait; (3) have an internal structure that prevents bait from being shaken loose; (4) have an access panel that fastens securely and locks (e.g., metal screw or padlock); and (5) bear the product name, active ingredient, guarantee, registration number, "WARNING POISON", and the skull and crossbones symbol.

  Bait stations (t**ier 2**) used for the placement of rodenticide bait indoors, in locations accessible to pets or livestock must have the following characteristics, in addition to those outlined above for tier 3 bait stations: (1) resistant to destruction by non-target animals; and (2) have an entrance designed so that non-target animals cannot reach the bait.

- The **USE LIMITATIONS** section of the label of concentrated products (to be diluted into solid or liquid bait), must be amended to include:

  For indoor use only. Do not use in areas accessible to children, pets and non-target wildlife.

  Do not use in homes or other residential settings.

- and delete any residential sites.

V) Commercial class products containing bromethalin, bromadiolone, chlorophacinone, diphacinone, warfarin or zinc phosphide

- The **USE LIMITATIONS** section must be amended to include:

> Bait applied outdoors and above-ground MUST be placed in bait stations.
>
> Bait stations (**tier 1**) used outdoors, above-ground, in locations accessible to children, pets and non-target wildlife must have the following characteristic, in addition to those outlined above for tier 2 and 3 bait stations: (1) be resistant to destruction or weakening by elements of typical non-catastrophic weather (such as, snow, rain, extremes of temperature and humidity, direct sunshine, etc.).

The label of products that currently allow rat and mouse baits to be placed ‘‘in and around buildings’’, “indoors and against the outside walls of buildings” or ‘‘inside and in areas adjacent to buildings’’ must be amended to read:

> Indoors and outdoors within 15 metres of buildings. Rodenticide bait can be placed in tamper-resistant bait stations along the fence line of properties, outside of the 15-metre limit but within a 100 metres of buildings, if the station is securely fastened (e.g., nailed down) to the fence or the ground.

Appendix VI Timelines and Requirements for Complying with the Risk Mitigation Decision for Eight Rodenticides

Table 1: Steps for Complying with Rodenticide Risk Mitigation Measures	
90 days After Publication of Risk Mitigation Measures for Eight Rodenticides (REV2010-17)	
If Registrant …	**Then it must …**
Intends to revise the labelling and package size (if needed) for a currently registered product, **Note:** The addition of a bait station to a product will <u>not</u> require a new product registration.	1. For commercial Class products, submit an application to revise labels. 2. For domestic class products, submit an application to revise labels. In addition, - submit bait station testing report and raw data, plus bait station drawings, for any Tier 1, 2 or 3 bait station that is to be packaged with a domestic class product (see Table 2), - submit a self-certification statement for any Tier 4 bait station. The last date of sale by Registrants for products with currently registered label is **December 31, 2012**. After this date, all products sold or distributed by Registrants must bear the new label requirements and package (if applicable).
Does not intend to comply with risk mitigation measures	Submit a Notice of Intent to Discontinue. The last date of sale by Registrant is **December 31, 2012**.
At Any Time After Publication of Risk Mitigation Measures for Eight Rodenticides (REV2010-17)	
If Registrant …	**Then it must …**
Intends to replace a non-complying product with one or more new products that comply with the risk mitigation decision, **Note:** A change in bait form (i.e., from pellets to bait blocks) will require a new product registration.	1. Submit a Notice of Intent to discontinue for the current product (within 90 days of the publication of REV2010-17), 2. Apply for new registrations for the replacement products. In addition, for domestic class products, registrants must : - submit bait station testing report and raw data, plus bait station drawings, for any Tier 1, 2 or 3 bait station that is to be packaged with a domestic class product (see Table 2), - submit a self-certification statement for any Tier 4 bait station.

Table 2: Supporting Materials for Application for Bait Stations	
If Registrant is applying for …	**Then it must submit …**
Tier 1 Bait Station	1. Description of weather-resistant properties 2. Reports and raw data from studies conducted according to the USEPA 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 3. Drawings of bait station design

Table 2: Supporting Materials for Application for Bait Stations	
Tier 2 Bait Station	1. Reports and raw data from studies conducted according to the USEPA 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 2. Drawings of bait station design
Tier 3 Bait Station	1. Reports and raw data from studies conducted according to the USEPA 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 2. Drawings of bait station design
Tier 4 Bait Station	1. Self-certification statement about packaging: ''[Insert company name] certifies the bait station [insert model number] sold with [insert product name; insert PMRA registration number] is a sealed, single-use, non-refillable unit, for indoor use only. 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 six 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.''

References

Studies considered for the Response to Comments

ADDITIONAL INFORMATION CONSIDERED

Published Information

PMRA Document Number	Reference
1946126	Albert, C.A., L.K. Wilson, P. Mineau, S. Trudeau, and J.E. Elliott. 2010. Anticoagulant rodenticides in three owl species from Western Canada, 1988-2003. Arch Environ Contam Toxicol 58:451-459.
1946133	Brimble, S., P. Bacchus, P. and P.-Y. Caux. 2005. Pesticide utilization in Canada: A compilation of current sales and use data. Environment Canada, Ottawa.