Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2006-11

Brodifacoum, Bromadiolone, Chlorophacinone, Diphacinone and Warfarin

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the active ingredients brodifacoum, bromadiolone, chlorophacinone, diphacinone and warfarin and their associated uses as rodenticides.

On 14 July 2004, Proposed Acceptability for Continuing Registration document (PACR) PACR2004-27, *Re-evaluation of brodifacoum, bromadiolone, chlorophacinone, diphacinone and warfarin*, was published for consultation. The PMRA has reviewed the comments received and provides a response in Appendix I of this RRD. These comments did not result in substantive changes to the regulatory decision as described in PACR2004-27. However, these external comments have resulted in changes to the label statements, and the PMRA has further revised the proposed label statements found in the PACR.

The PMRA has determined that brodifacoum, bromadiolone, chlorophacinone, diphacinone and warfarin are acceptable for continued registration. Mitigation measures to further protect workers, children, pets and the environment are specified in this RRD (Appendices II and III).

The registrants have been informed by letter of the specific requirements affecting their product registrations and the regulatory options available to comply with this decision. Further mitigation measures may be requested pending the finalization of the United States Environmental Protection Agency (USEPA) comparative ecological assessment and the results of the PMRA stakeholder consultation.

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Appendix I Comments and Responses to PACR2004-27

1.0 General Comments Pertaining to the Re-evaluation Process and Uses of the Rodenticide Cluster

1.1 Comment on the Overall Re-evaluation of the Rodenticide Cluster

PACR2004-27 is based on the United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decisions (REDs) for these chemicals (1991 and 1998). However, the USEPA has not yet finished the reregistration process for the rodenticides; therefore, the PMRA's re-evaluation is premature.

Response
Although the PMRA's decision is based on the RED documents, the PMRA has been monitoring USEPA progress on its re-evaluation of the rodenticide cluster. The PMRA is aware of the steps taken by the USEPA described in the notification for the re-registration of rodenticide cluster, published in the Federal Register on 28 November 2001. The PMRA has already included some of these revised regulatory decisions in the PACR (e.g., rescinding of requirement for bittering agent and dye). The PMRA has also reviewed environmental data generated following the publication of the RED documents and has developed mitigation measures accordingly. The PMRA will monitor and review any new decisions the USEPA makes as additional regulatory measures may be required in the context of Canadian use conditions.

1.2 Comment on the Field Use of the Rodenticides

There was lack of clarity regarding the continued broadcast use of field use rodenticides. Agricultural broadcast uses should not be denied nor be required to be in tamper-resistant bait boxes.

Response
The commercial broadcast field use of rodenticides (e.g., for vole control in orchards, nurseries and ornamentals) is not being denied in PACR2004-27, and the bait for the broadcast uses does not have to be placed in a bait station. Users are requested either to place bait out of the reach of children and pets (i.e., agricultural sites) **or** to place the bait in a tamper-resistant bait station (i.e., only where there is a hazard to children or pets, bait need to be in stations).

1.3 Comments on the Benefits of Rodenticides

The PACR2004-27 does not fully show appreciation for the benefits of rodenticides and focuses on minor child exposures occurring during storage in the home and on minimal non-target bird and mammal exposures. These exposures can be reduced through proper labelling and use. Rodenticides control significant public health pests such as rats and mice, vectors that transmit diseases.

Response
It is the PMRA's practice during re-evaluation to assess continuing acceptability of the existing use patterns according to current health and environmental standards; the benefits are typically not described in detail. Value assessments were done when these products were first registered to show these products had merit and value. These are not repeated during re-evaluation.

1.4 Comment on the Need for These Products

Second-generation single feed rodenticides (see Section 3.5) were introduced to largely combat resistance in rats and mice, yet no evidence has been provided that all these products are needed in Canada. Given the environmental ramifications from using these products, is there any data that show the benefits of these products?

Response
The PMRA has determined that these rodenticides are acceptable for continuing registration provided that the mitigation measures specified in this RRD are adopted. At this time, sales data is not routinely available to the PMRA; however, it is assumed that number of products available does not impact overall volume of use of rodenticides. The PMRA does not reject an application to register a product when the risk to human health and environment is acceptable and the product has merit/value.

1.5 Comment on the Enforcement of the Label Changes

Assuming that enforcing label changes is the solution to reduce the high level of contamination of the Canadian environment, how does the PMRA propose to enforce the new labels when it is not known what is being used and where it is being used?

Response
The approved labels are legal documents, and users must follow the label instructions when applying any registered products. The PMRA as well as other federal and provincial governments enforce compliance with labels according to their specific jurisdictions/responsibilities. Currently, the PMRA is in the process of collecting pesticide use information—including data indicating what is being used and where it is being used—from registrants, federal and provincial governments, academics and user groups, etc. that will assist in making a better informed regulatory decision.

1.6 Comment on the Need of Further Public Consultations

Further dialogue is needed between public health officials, regulatory bodies, registrants, pest management professionals and their associations prior to making a final decision with regards to the proposed mitigation measures outlined in PACR2004-27.

Response
As per normal practice, the PMRA had a 45-day public comment period from the date of publication of PACR2004-27. Comments received during the comment period were

carefully reviewed and responses are provided in this RRD. The PMRA has concluded that these comments did not result in substantive changes to the regulatory decision as described in PACR2004-27. Should an issue arise with implementation of this decision, the PMRA will re-open a focussed discussion with relevant associations.

2.0 Comments Pertaining to Human Health

2.1 Comment on the Requirement for Gloves When Using Place Packs or Wax Baits

In addition to the exemption of those products in pre-packaged bait stations, products packaged in place packs should be exempt from the requirement of gloves because they are not intended to be opened during placement and hence preclude exposure of handlers to loose bait. Similarly, wax bait block products that do not need to be broken apart should be exempt from the requirement of gloves given the minimal dermal toxicity and the formulation of these products.

Response
The PMRA recommended that users of place packs wear gloves because some of these products must be opened and the contents removed to measure out the correct amount to be applied (e.g., for mice). The PMRA agrees that using place packs would result in minimal exposure to the applicator if a place pack is not opened because the packaging prevents direct contact with the end-use product. Therefore, the PMRA will not require applicators of pre-measured place pack products to wear gloves, provided that the registrants of these products add the following label statement to the end-use product label:

> "Do not open pre-measured place packs."

Wax bait block products that do not need to be broken apart will not be exempted from the requirement of wearing gloves because the user is in direct contact with the end-use product. This is consistent with the American decision that does not lessen personal protective equipment for these products. However, registrants have the option of submitting additional data to the PMRA through the regular submission process to support the amended use of this type of product without the glove requirement.

2.2 Comment on the Requirement of Gloves, Respirator and Protective Eyewear When Using Certain Commercial End-use Products

A long-sleeved shirt and long plants, shoes plus socks, chemical-resistant gloves, a NIOSH-approved dust/mist filtering respirator and protective eyewear should not be required for end-use baits.

Response
The PMRA is requiring the personal protective equipment stated above for commercial handlers who load pellet or bait end-use formulations into mechanical ground equipment and for commercial handlers who load and apply pellet or bait formulations with

hand-held or hand-pushed equipment (e.g., such as a push-type or cyclone spreader) based on the USEPA RED recommendation. The PMRA agrees with the USEPA's determination that eyewear and a respirator minimize the possibility of ocular exposure or of inhalation and ingestion of dusts resulting from the pouring and application of these products.

2.3 Comment on Dyes and Bittering Agents

The PMRA should allow incorporation of dyes and bittering agents on a voluntary basis.

Response
As stated in PACR2004-27, the PMRA supports the voluntary incorporation of bittering agents and indicator dyes.

2.4 Comment on Certified Applicator Statement for Commercial Products

The statement in Appendix VII of PACR2004-27 regarding the use only by certified applicators should be reworded to prevent placing the rodenticides discussed in PACR2004-27 out of the reach of farmers in Alberta and Saskatchewan.

Response
The PMRA recommended the statement in Appendix VII of PACR2004-27[1] to ensure that users are educated in the safe and effective use of rodenticides. In Alberta, Saskatchewan and Manitoba, farmers are exempt from mandatory pesticide certification and licensing. However, Alberta Agriculture, Food and Rural Development (AAFRD) and Saskatchewan Agriculture Food and Rural Revitalization (SAFRR) administer provincial rat control programs. It is our understanding that in Saskatchewan and Alberta, farmers have access to these rodenticides, and that provincial officials provide them with necessary instructions on using the products safely. In Manitoba, a pesticide safety course that provides information on the proper use, storage and disposal of pesticides, including rodent baits is available for farmers. In all other provinces, farmers require an applicator certificate to purchase a commercial pesticide product.

Based on this, the PMRA has determined that the above-mentioned statement can be revised to include farmers as potential users:

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

[1] Only to be used by individuals holding an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide regulatory agency where the application occurs.

2.5 Comment on Redundancy of Wording on the Label

To prevent redundancy on the label, include all requirements for wearing gloves in the PRECAUTION section (i.e., handling of the product, disposal of unused bait and dead rodents) rather than separate references in the PRECAUTION and DISPOSAL sections.

Response
The PMRA agrees that all requirements for personal protective equipment should be in the PRECAUTIONS section of the label, not the DIRECTIONS FOR USE section as indicated in PACR2004-27. Refer to Appendices II and III of this RRD for revised labelling instructions.

2.6 Comment on Use of Rodenticides in Food Processing Areas

The label changes proposed in Appendix VII of PACR2004-27[2] regarding use in food/feed processing plants, restaurants and such could have a detrimental effect on rodent control in these settings. Current rodenticide labels allow use in food processing and service areas, but limit use during times when the establishment is not in operation. This use pattern must be retained to ensure proper baiting and effective control of rodents in these establishments.

Response
The PMRA proposed the statement to prevent rodenticide products from contaminating food/feed items in commercial establishments. Taking into consideration the need for effective rodent control in these establishments, the PMRA has determined that the following statement, which is currently on many Canadian labels for anticoagulant rodenticides, provides the same intent and is acceptable in lieu of the statement recommended in PACR2004-27:

"**Food Processing, Food Manufacturing, Food Storage and Food Service Areas:** For areas not directly related to food processing: Use only in non-food or non-feed area where feed, food, packaging and handling equipment are never opened or exposed. For areas where feed or food is processed, served or stored: In meat and food processing plants (processing areas), use only when plant is not in operation. Remove or cover all food, packaging material and utensils before placing bait in baiting stations. Remove all baits and dead rodents before reuse of the plant (processing areas include storage and service)."

[2] Do not use in edible product areas of food or feed processing plants, restaurants or other areas where food or feed is commercially prepared or processed. Do not contaminate food/feed or food/feed handling equipment or place near or inside ventilation duct openings.

3.0 Comments Pertaining to the Environment

3.1 Comment on the Restriction of Indoor Use 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. Brodifacoum should not be restricted to indoor use only. The USEPA has not indicated it will be restricting the use of brodifacoum to indoors only.

Response
The restriction on the placement of rat and mouse baits containing bromadiolone, chlorophacinone, diphacinone and warfarin—by changing the current label statement "in and around buildings" to "indoors and against the outside walls of buildings"—was proposed in order to reduce exposure to predators and scavengers, thereby minimizing non-target effects. The previous label statement was not precise enough and thus allowed for placement of baits at an undefined distance from buildings. At present, the PMRA does not have data to suggest that placing baits adjacent to buildings will significantly impact their effectiveness.

The USEPA review documents indicated that brodifacoum posed the greatest risk to birds and non-target mammals. In addition, Environment Canada's (Canadian Wildlife Service) preliminary surveys of birds of prey also indicated brodifacoum was of the most concern compared to the other rodenticides. Prohibiting outdoor use of brodifacoum can reduce exposure and substantially decrease the risk of primary and secondary non-target effects. Restricting brodifacoum to indoor use only is an acceptable mitigation measure.

Registrants have the option of submitting additional data or a science-based rationale through regular submissions to amend these requirements.

3.2 Comment on the Contamination of Wildlife Species from Second-generation Products

The PACR is based on conclusions reached in 1991. Since then, new evidence has shown that there is contamination of wildlife species from second-generation products. Data from different sources show extensive exposure to rodenticides and contamination of birds prey by rodenticides. One probable consequence is that exposed individuals are made very sensitive to frank anticoagulation upon re-exposure. There is evidence for this in mammals. This point should have been made clear in the PACR document. There is a serious and worrisome level of contamination with unknown consequences. The PMRA should consider this data in the review of rodenticides.

Response
The PMRA's risk assessment of the rodenticides considered data from USEPA RED for Rodenticide Cluster (EPA 738-R-98-007, July 1998), RED for Warfarin (May 1991) and

USEPA document *Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach* (December 2002). The risk assessment also took into consideration the data an Environment Canada (Canadian Wildlife Service) presentation provided to the PMRA in early 2004. All the reviews and available information provided evidence of exposure as well as secondary non-target effects among birds of prey and other wildlife from the current use of the anticoagulants. Re-exposure may be possible, especially if the exposure is to sublethal concentrations. To reduce exposure to non-target species, restrictions on the use of the rodenticides were proposed as follows:

- The placement of rat and mouse baits of bromadiolone, chlorophacinone, diphacinone and warfarin is restricted by the revision of the current label statement “in and around buildings” to “indoors and against the outside walls of buildings”. In addition, use of brodifacoum is restricted to indoor use only.

3.3 Comment on the Responsibility of Registrants to Provide Information

The PMRA must put the onus on the registrants to provide information on the significance of the widespread contamination by rodenticides as a condition of re-registration.

Response
Registrants will be required to amend product labels in accordance with the PMRA’s recommendation on the use of the rodenticides, as described previously. This will reduce environmental contamination as well as exposure of non-target birds and mammals. In the near future, the PMRA will require registrants to report adverse effects on human health and the environment as a result of pesticide use, as required under the new *Pest Control Products Act*.

3.4 Comment on Risk Concerns Posed by Bromadiolone

The PMRA rates bromadiolone as posing less secondary risk than the first generation compounds diphacinone and chlorophacinone. Available monitoring information seems to indicate that bromadiolone is more of a concern than predicted.

Response
A comparative analysis conducted by the USEPA of mean percent mortalities from secondary effects showed higher mortalities for diphacinone (58%) and chlorophacinone (55%) than for bromadiolone (23%). Available monitoring data from Environment Canada (Canadian Wildlife Service) revealed residues of bromadiolone in three species of birds of prey. Although this was an indication of the percentage of exposure rather than the percentage of mortality, the PMRA agrees with Environment Canada that bromadiolone may be more of a concern than was predicted by the laboratory toxicity studies reported by the USEPA.

3.5 Comment on the Primary Exposure to Non-target Species

Why does the PMRA not discuss how to reduce the primary risk from diphacinone and chlorophacinone? The use of scattered grain baits in orchards and other agricultural sites ensures primary exposure to non-target species.

Response

The anticoagulant rodenticides are typically grouped into "first-generation" (chlorophacinone, diphacinone, warfarin) and "second-generation" (brodifacoum, bromadiolone). Second-generation anticoagulants tend to be more acutely toxic than the first-generation and are retained much longer in body tissues of primary consumers mammals. They generally provide a lethal dose after one single feeding, although death is usually delayed 5 to 10 days and animals continue feeding. The first-generation compounds such as chlorophacinone and diphacinone generally must be ingested for several days to provide a dose lethal to most individuals because they are less acutely toxic and more rapidly metabolized and/or excreted.

The PMRA's risk assessment showed that chlorophacinone and diphacinone were of low acute risk and low to moderate dietary risk to birds. Incident reports from the United States revealed that the numbers of birds with residues of chlorophacinone and diphacinone were scarce. Monitoring data from Environment Canada also revealed very limited exposure of these two rodenticides to birds, confirming the risk assessment that chlorophacinone and diphacinone are not of as high concern as brodifacoum.

Consideration of toxicity data and feeding rates indicates that chlorophacinone and diphacinone when used as bait in the form of pellets could pose a potential risk to small mammals such as field mice. Field data on effects on small mammals are not available. Incident reports from the United States with mammals showed that residues of brodifacoum were the predominant anticoagulant found and residues from chlorophacinone and diphacinone were limited.

3.6 Comment on the Physical Chemical Properties

Information in the USEPA RED appears to show some gaps in physical chemical properties. The document also discusses adsorption to soil and leaching properties. It seems difficult to believe there is a 100-fold difference in the vapour pressures and Henry's law constants for chlorophacinone and diphacinone and their melting points are identical. The log K_{ow} for brodifacoum seems suspiciously low.

Based on the available data, there is a possibility that chlorophacinone could have an atmospheric pathway because its vapour pressure is about 7×10^{-3} Pa. That is more volatile than PCB101. Diphacinone would have a vapour pressure of about 2×10^{-5} Pa, which is about the volatility of nonachlorobiphenyl. The other compounds are heavier and, presumably, less volatile.

Response

The physical chemical properties that were taken from the USEPA RED documents were confirmed by checking other available sources and Internet databases, such as:

- *The Pesticide Manual*, 12th edition, published by the British Crop Protection Council; and
- Extoxnet at http://extoxnet.orst.edu/.

The vapour pressure of chlorophacinone is 1×10^{-7} Pa at 20°C and that of diphacinone is 1.37×10^{-8} Pa at 25°C. According to Kennedy and Talbert[3], these vapour pressures indicate low volatility. Furthermore, these rodenticides are formulated as solid bait, e.g., pellets; hence, any potential volatility is further reduced.

[3] Kennedy, J.M., and R.E. Talbert. 1977. Comparative persistence of dinitroaniline type herbicides on the soil surface. *Weed Science*. 25(5): 373–381.

Appendix II Canadian Labelling Requirements for Domestic End-use Products

NOTE: The information in this appendix summarizes required label statements for domestic class products containing warfarin, brodifacoum, bromadiolone, chlorophacinone, or diphacinone or its sodium salt resulting from this re-evaluation. 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.

To protect handlers, and to protect children, pets and livestock from accidental ingestion, all warfarin, brodifacoum, bromadiolone, chlorophacinone, and diphacinone and its sodium salt domestic end-use product labels, with the exception of those products that are packaged in pre-measured place packs (i.e., place pack must not be opened), must be modified to include the following statement:

- In the PRECAUTIONS section of the secondary panel of the label,

  "KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK. May be harmful or fatal if swallowed or absorbed through the skin. Rubber 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."

To protect handlers, and to protect children, pets and livestock from accidental ingestion, warfarin, brodifacoum, bromadiolone, chlorophacinone, and diphacinone and its sodium salt domestic pre-measured place pack (i.e., place pack must not be opened) end-use product labels must be modified to include the following statement:

- In the PRECAUTIONS section of the secondary panel 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. Rubber 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."

The labels of all end-use products must be modified as follows:

- In the USE LIMITATIONS section of the secondary panel of the label,

  "Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock. DO NOT place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food."

- In the TOXICOLOGICAL INFORMATION section, **the intravenous route of administration of the Vitamin K_1 antidote must be removed from the label**.

- 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."

For brodifacoum end-use products, all labels must be amended to include:

"For indoor use only."

For bromadiolone, chlorophacinone, diphacinone and warfarin, to protect non-target wildlife, all domestic end-use product labels that currently allow placement of rat and mouse baits "in and around buildings" must be amended to read:

"indoors and against the outside walls of buildings."

Appendix III Canadian Labelling Requirements for Commercial End-use Products

NOTE: The information in this appendix summarizes required label statements for commercial class products containing warfarin, brodifacoum, bromadiolone, chlorophacinone, or diphacinone or its sodium salt resulting from this re-evaluation. 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.

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

- On the principal panel of the label,

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

To protect handlers, and to protect children, pets, and livestock from accidental ingestion, all warfarin, brodifacoum, bromadiolone, chlorophacinone, and diphacinone and its sodium salt commercial end-use product labels, with the exception of those products that are packaged in pre-measured place packs (i.e., place pack must not be opened), 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. 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."

To protect handlers, and to protect children, pets and livestock from accidental ingestion, warfarin, brodifacoum, bromadiolone, chlorophacinone, and diphacinone and its sodium salt, commercial pre-measured place pack (i.e., place pack must not be opened) end-use product labels 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."

The labels of all end-use products must be modified as follows:

- In the USE LIMITATIONS section of the label,

  "Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock. DO NOT place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food."

  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 that 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".

- In the TOXICOLOGICAL INFORMATION section, **the intravenous route of administration of the Vitamin K_1 antidote must be removed from the label**.

- 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."

All commercial end-use products that are registered for use in indoor commercial establishments must include the following statement:

- On the product label in the DIRECTIONS FOR USE section,

  "Food Processing, Food Manufacturing, Food Storage and Food Service Areas: For areas not directly related to food processing: Use only in non-food or non-feed area where feed, food, packaging and handling equipment are never opened or exposed. For areas where feed or food is processed, served, or stored: In meat and food processing plants (processing areas), use only when plant is not in operation. Remove or cover all food, packaging material and utensils before placing bait in baiting stations. Remove all baits and dead rodents before reuse of the plant (processing areas include storage and service)."

For commercial end-use products that are dust or powder concentrate formulations that must be diluted prior to use, the following statement is required:

- In the PRECAUTIONS section,

  "All handlers must wear long-sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves. Wear a NIOSH-approved particulate-filter respirator and protective eyewear while pouring and mixing the concentrate with bait."

For commercial end-use products that require loading of pellets or bait into mechanical ground equipment or loading/applying with hand-pushed or hand-held equipment, the following statement is required:

- In the PRECAUTIONS section,

  "All handlers must wear long-sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves. In addition, persons loading pellets or bait into mechanical ground equipment, or persons loading/applying with hand-pushed or hand-held equipment, must wear a NIOSH-approved particulate-filter respirator and protective eyewear."

For all other commercial pellet and bait formulations not already contained in place packs, the following statement is required on all commercial end-use products:

- In the PRECAUTIONS section,

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

The following statement is required on labels of warfarin concentrates used to prepare dry baits:

> "Exposure to warfarin during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects."

For brodifacoum end-use products, all labels must be amended to include:

> "For indoor use only."

For bromadiolone, chlorophacinone, diphacinone and warfarin, to protect non-target wildlife, all commercial end-use product labels that currently allow placement of rat and mouse baits "in and around buildings" must be amended to read:

> "indoors and against the outside walls of buildings."