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**Australian Pesticides and
Veterinary Medicines Authority**



Anticoagulant Rodenticides

Review Technical Report

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority that administers the National Registration Scheme for Agricultural and Veterinary Chemicals. The APVMA evaluates, registers and regulates agricultural and veterinary (agvet) chemicals up to the point of sale. The states and territories are responsible for control of use. Its statutory powers are provided in the Agricultural and Veterinary Chemicals Code (the Agvet Code), which is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in sections 29 to 34 of Part 2, Division 4 of the Agvet Codes. The Code provides for the suspension and cancellation of approvals and registrations if it appears to the APVMA that the criteria for approval or registration are not, or are no longer, satisfied (s 41 and s 44 of Part 2, Division 5).

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label. The scope of each reconsideration can cover a range of areas including human health (toxicology, public health, work health and safety), the environment (environmental fate and ecotoxicology), residues and trade, chemistry, efficacy or target crop or animal safety. However, the scope of each reconsideration is determined on a case-by-case basis reflecting the specific issues raised by the new research or evidence.

The reconsideration process includes a call for data from a variety of sources, a scientific evaluation of that data and, following public consultation, a regulatory decision about the ongoing use of the chemical or product. The data required by the APVMA must be generated according to scientific principles. The APVMA conducts scientific and evidence-based risk analysis with respect to the matters of concern by analysing all the relevant information and data available.

About this document

This Technical Report is intended to provide an overview of the assessments that have been conducted by the APVMA and of the specialist advice received from its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience, thereby encouraging public comment.

This document contains a summary of the assessment reports generated in the course of the chemical review of an active ingredient, including the registered product and approved labels. The document provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Executive Summary

History of Anticoagulant Rodenticides in Australia

What are anticoagulant rodenticides and how do they work?

The anticoagulant rodenticides are a class of chemicals that are used in Australia as poison baits to kill non-native rats and mice. Anticoagulant rodenticides disrupt normal blood-clotting mechanisms, resulting in capillary damage leading to uncontrolled bleeding and death. Rats and mice typically die 5 to 10 days after a lethal dose has been consumed. Anticoagulant rodenticides baits are available in various forms, ready-to-use baits such as including blocks, pellets and treated grains and pastes, and as liquids and powder concentrates for preparing baits by mixing with water, or fruit or grain and/or as high concentration contact baits. There are two classes of anticoagulant rodenticides, which are grouped into so-called first- and second-generation anticoagulant rodenticides based on when they were developed.

The first-generation anticoagulant rodenticides (FGARs) were developed earlier, with the first report of warfarin in 1944. FGARs typically require multiple feeds by the target rodent over several days to deliver a lethal dose. The FGAR active constituents approved by the APVMA are:

- Coumatetralyl
- Diphacinone
- Warfarin

Second-generation anticoagulant rodenticides (SGARs) were developed more recently than FGARs, partly in response to the development of resistance to the FGARs by rats and mice. SGARs differ from FGARs in that they have a higher toxicity, particularly to rats and mice, and can deliver a lethal dose to the target rodent in a single feed. The SGAR active constituents approved by the APVMA are:

- Brodifacoum
- Bromadiolone
- Difenacoum
- Ditethialone
- Flocoumafen

Although these chemicals have some differences in their properties, they act via a common mechanism by binding to the enzyme vitamin K 2,3-epoxide reductase. This interrupts the normal recycling of vitamin K within cells.

Vitamin K is essential for cells to make prothrombin and other blood-clotting factors. Interrupting the recycling of vitamin K prevents blood clotting and eventually leads to death from internal or external bleeding, typically several days after consumption of a lethal dose.

Administration of Vitamin K is an effective antidote to poisoning by anticoagulant rodenticides.

Where and how are anticoagulant rodenticides currently used in Australia?

Ready-to-use baits and concentrates containing FGARs and SGARs are registered for use in a limited range of situations to control rats and mice. Apart from a few products containing coumatetralyl that have approved in-crop uses, and a limited number of products with instructions for use in sewers, products containing FGARs and SGARs are registered for use in and around buildings only. The types of buildings where these products may be used include domestic properties, commercial premises, industrial buildings, agricultural/farm buildings, storehouses, warehouses, grain stores, public service buildings such as schools, hospitals and offices, animal husbandry facilities such as stables, milking parlours, cow sheds, poultry sheds, pig arks, any building concerned in the storage, preparation, distribution, sale or consumption of food, and inside any mode of transport including aeroplanes, trains, ships, commercial and private transport vehicles.

Anticoagulant rodenticide products registered by the APVMA are divided into two groups: the first carry instructions for use that are suited to a domestic user while the second are intended for use by a commercial/professional user. The instructions for domestic users are presented in an easier to understand format and reflect the type of use that is expected in and around the home. For commercial products, the instructions are more detailed and offer a wider range of situations where the products can be used. There is an assumption that products registered with commercial instructions for use are mainly used by professionals with a level of training in pesticide application, but this is not currently a requirement. A key difference between domestic and commercial pest-control products is the amount of bait in a single container. Domestic products are typically limited to less than 1kg of product. Commercial products are available in quantities of up to 140 kg per pack but are more typically registered with pack sizes up to 10 or 20kg.

It is best practice to place the baits in a tamper-resistant (and weather-resistant if outdoors) bait station; however, many products do not explicitly require this in their approved instructions for use. A range of currently registered products are intended to be thrown into hard-to-reach spaces, such as wall or ceiling cavities, or placed directly in rat burrows. A limited number of products that are formulated as loose pellets also include instructions to place small heaps of bait where rodents are a pest, and concentrate powder products can also be used as a 'tracking powder' that relies on the rodent walking in the powder and then grooming it off their fur.

The amount of bait required to control a rodent infestation is dependent on the pests to be controlled and the extent of the infestation. Therefore, instructions on the labels for the products typically indicate a maximum distance between baits/bait stations for rats or mice, but do not specify a maximum number of baits points or duration of treatment. This means there is no specified limit on how much bait may be applied. Although the instructions indicate that the anticoagulant rodenticides (except coumatetralyl) are to be used in and around buildings, many products also do not include specific limits on how far from a building the bait may be placed – in particular, if the bait is placed in an enclosed space around buildings.

Instructions for how place of baits to prevent access by non-target animals and children; to manage/monitor baits during the baiting program; and to clean up used baits and rodent carcasses after use are also inconsistent between different products. Products registered recently by the APVMA tend to have more thorough instructions than older products but, to date, no standardised instructions have been developed and implemented.

How are anticoagulant rodenticides used around the world?

Anticoagulant rodenticides are registered for use in similar situations in many countries around the world. Countries in the European Union, as well as the United Kingdom, the United States of America, and Canada all have products containing FGARs and SGARs available for use. A key difference between Australian products and those used overseas is that products registered for use in Australia are only for use to control rats and mice (specifically black rat; *Rattus rattus*, Norway rat; *Rattus norvegicus*, and house mouse; *Mus musculus*), while products available in other countries are also approved for control of other rodents in their burrows such as moles, gophers and ground squirrels.

Restrictions put in place in the countries mentioned above following regulatory decisions over recent years have included limiting the types of products available or the situations where the products can be used, and the people who are able to access and use each type of product, to different degrees in each country. Generally, SGARs have more restrictions on their use, in some cases with only professional users authorised to use the baits, while FGARs remain more widely available but with restrictions related to the amount of product in each package and limitations on where and how they may be used.

Timeline of the reconsideration

Initially only second-generation anticoagulant rodenticides were nominated for reconsideration due to their higher toxicity and the potential for secondary poisoning caused by predatory animals eating poisoned rodents.

The APVMA conducted a consultation on how all anticoagulant rodenticides are used and the adequacy of the instructions to prevent unintentional exposure to the products between April and July 2020.

Following this consultation, a formal reconsideration on both first- and second-generation anticoagulant rodenticides was commenced by issuing a Notice of Reconsideration to holders of product registration and publishing the notice in the [APVMA Gazette](#) on 2 November 2021. The Notice of Reconsideration described the matters the APVMA intended to reconsider which included:

- a. environmental safety, including primary and secondary poisoning of non-target domestic animals and
- b. human health, including worker exposure and public health; and,
- c. residues, including livestock and edible wildlife exposure, consumer safety, and trade.

The APVMA invited submissions on the matters it proposed to reconsider between 2 November 2021 and 2 February 2022.

Risk assessments completed, information considered and key findings

The APVMA has completed risk assessments related to four key aspects of the anticoagulant rodenticides: Chemistry and Manufacture, Environment, Toxicology and Human Health, and Residues and Trade.

In total over 1,700 studies and published scientific articles have been considered during this reconsideration. These studies were submitted in response to the notice of reconsideration or were supplied in support of the original applications for product registration or active constituent approval. Further, a large number of studies were

sourced independently by the APVMA from the published scientific literature or provided by interested stakeholders during the reconsideration.

Chemistry and Manufacture

The chemistry and manufacture assessment involved a review of the information submitted in support of the approval of each active constituent or registration of each chemical product, and other information submitted during the reconsideration or sourced by the APVMA, against the matters the APVMA must consider when determining if an active constituent or chemical product meets the safety criteria.

The APVMA considered information relation to the composition of the active constituents, where some are supplied as manufacturing concentrates while others are supplied as technical concentrates, and considered whether there are potential risks related to this when the active constituent is formulated into an end-use product. The APVMA also considered whether there is evidence that products contained suitable dyes and bittering agents, which was identified as an important risk mitigation measure by the human health and environment risk assessments.

A number of product and active constituents were identified with inconsistencies in the APVMA record that require rectification, however these are not expected to significantly affect the safety of products or products formulated using the active constituents. The chemistry assessment recommended a conditional continuation of these approvals and registrations, requiring the holders to provide any necessary information within a set time from the completion of the reconsideration.

Numerous chemical products lacking either a dye or bittering agent, or both, were identified. The human health and environment risk assessments recommended that the inclusion of these is essential to minimise the likelihood and/or extent of unintentional exposure, particularly to children and non-target animals. Noting that the APVMA cannot vary the formulation or manufacturing process of a chemical product, we are proposing to cancel the registration of products lacking either a dye or bittering agent.

Environment

The APVMA's environment risk assessment covers three key areas in relation to chemical products:

- Fate and behaviour in the environment, including air, soil and water
- Effects of the products on non-target species
- Risks to non-target species

Although a substantial body of data exists relating to the environmental fate and behaviour of anticoagulant rodenticides, assessment of the risks associated with their use presents unique challenges. This is because they are poisons intended to kill rats and mice and therefore are also moderately to highly toxic to other non-target animals including mammals, birds, reptiles, and fish. The use of these products in and around buildings should result in limited opportunities for non-target animals to be exposed to anticoagulant rodenticides, but evidence shows that exposure is occurring. The risk mitigations recommended as a result of these assessments focus on reducing the likelihood of exposure of non-target animals, through either direct exposure to anticoagulant

rodenticide baits (i.e., primary poisoning) or indirect exposure of predators and scavengers who may eat poisoned animals (i.e., secondary exposure).

Fate and behaviour of in the environment

The anticoagulant rodenticides share similar properties in relation to the air, soil and water. They have low volatility and are not expected to be present as vapour in air, they have low to moderate solubility in water and slight to moderate potential for mobility in soil (through movement of groundwater). The available information indicates that the anticoagulants rodenticides are not biodegradable (that is, degradable by plants, animals, insects, bacteria or fungi) but can be broken down by exposure to sunlight (photolysis).

A key difference between the FGARs and SGARs becomes clear when considering their fate in relation to non-target animals. The FGARs are mostly readily absorbed by rats and mice after eating a bait, (except for diphacinone which is rapidly excreted) and residues accumulate in the liver of poisoned animals. The FGARs are broken down in the liver of affected animals with a half-life¹ ranging from 3 days for diphacinone to a maximum of 67 days for warfarin.

The SGARs are similarly readily absorbed once rats or mice eat a bait but have significantly longer half-lives in the liver of poisoned animals, ranging from 29 days for difethialone to 307 days for brodifacoum or 318 days for bromadiolone.

Wildlife monitoring studies conducted in Australia, and internationally, frequently detect anticoagulant rodenticides in non-target animals in the wider environment. In Australia, this includes wildlife that are suspected of eating baits directly, including insects, slugs, possums and bandicoots, as well as wildlife that are expected to eat rats and mice, including snakes, lizards, quolls, Tasmanian devils, and many birds of prey, and wildlife that may eat other poisons animals, such as frogs with poisoned insect and slugs, carnivorous animals and scavenging birds.

The most likely route of exposure of carnivorous animals to anticoagulant rodenticides is through secondary exposure (i.e., when the carnivorous animal consumes poisoned prey). The data indicate that risk of secondary exposure is correlated with the half-life of the chemical. In some cases, though, such as with scavenging birds including ravens, crows and magpies, it is not clear whether the detection of anticoagulant rodenticides is the result of primary or secondary exposure, or a combination of both.

Effects of the products on non-target species

Although FGARs and SGARs all have high acute toxicity to rats and mice, the FGARs require on the order of 10 times more of the active constituent to reach a lethal dose in rats and mice than the SGARs. For example, rat LD₅₀² values for FGARs range from 1.9 milligrams per kilogram of bodyweight (mg/kg bw) for diphacinone to 15 mg/kg bw for coumatetralyl. In contrast LD₅₀ values for SGARs range between 0.13 mg/kg bw for difethialone and floucoumafen and 1.3 mg/kg bw for bromadiolone.

¹ Half-life: the time taken for half of the chemical to be broken down, metabolised or excreted by the animal

² Lethal dose for half of the study subjects

The toxicity of the anticoagulant rodenticides to non-target species varies considerably but, as with rats and mice, the toxicity of SGARs to birds and non-rodent mammals is substantially higher than the FGARs. Importantly, studies indicate secondary exposure of birds (owls) to mice or rats poisoned by FGARs is not likely to result in death, while all SGARs have the potential to lead to lethal secondary poisoning.

It was also noted that — although a number of studies reported residues of anticoagulant rodenticides in snakes and lizards — reptiles generally appear to have a high tolerance to the effects of these chemicals and are unlikely to suffer lethal effects due to secondary poisoning.

Risks to non-target species

The risks posed to non-target species by the anticoagulant rodenticide arise from the combination of the way that they are used and the impact of the toxic effects outlined above. As noted previously, with a small number of exceptions, most products containing FGARs and SGARs are registered for use in and around buildings only.

It is widely accepted that the consumption of anticoagulant baits (i.e., primary exposure) or the consumption of animals poisoned by those chemicals (i.e., secondary exposure) can result in death. As a result, risk assessment calculations to determine acceptable levels of exposure for non-target animals were not undertaken.

In short, the risks to non-target animals arise from both primary and exposures. Risks are lower when baits are secured in tamper-resistance bait stations that are placed indoors or in close proximity to buildings.

To effectively mitigate the risks to non-target species, a comprehensive risk mitigation strategy is recommended, which encompasses all products to avoid transfer of risk between different anticoagulant rodenticide products. This risk mitigation strategy includes, but is not limited to:

- Restricting use of products to indoors only for the control of mice and to indoors and within 2 meters from buildings for the control of rats
- Prohibiting burrow baiting for the control of rats
- Mandating the use of tamper-resistant bait stations in certain situations
- Limiting supply and use of commercial anticoagulant rodenticide products to trained professionals only and limiting the pack sizes of domestic anticoagulant rodenticide products.
- Updated instructions relating to the placement of baits, management/monitoring of bait stations during treatment, management of dead rodents and other potential poisoned animals during treatment, the expected duration of treatment, and clean-up of bait/bait stations at the end of treatment.
- Cancellation of products that do not contain both a bittering agent and a dye, and cancellation of all liquid and powder bait concentrate products.

Toxicology and Human Health

The APVMA's toxicology and human health risk assessment includes consideration of:

- The hazard associated with each of the active constituents is established by considered the available information relating to the toxicity of the anticoagulant rodenticides.

- The risks to people using the product in commercial or domestic situations (including the risks to bystanders) and recommendations to mitigate these risks.

The human health risk assessment also considered relevant tolerable levels for exposure to anticoagulant rodenticides residues through diet, noting that although these products are not intended to be used in crops or on food-producing animals the potential for accidental contamination remains.

It was noted that the database for assessment of the toxicity of the anticoagulant rodenticides is limited – in particular, for chronic toxicity. However, due to the expected use patterns and limited exposure pathways for humans there were sufficient studies to complete risk assessments for each of the active constituents.

In studies that were considered relevant to human health risk assessments, the FGARs as a group have high acute oral toxicity with acute oral LD₅₀ of the active constituents ranging between 2.1 to 30 mg/kg bw in rats and mice. However, because FGAR products are formulated containing between 0.05 to 0.075% of active constituents, the overall toxicity of the end-use products is considered to be low (LD₅₀ over 5000 mg/kg bw).

The SGARs as a group also have high acute oral toxicity, with the acute oral LD₅₀ of the active constituents ranging between 0.25 mg/kg bw to 2.6 mg/kg bw. Similarly to the FGARs, products containing SGARs are formulated containing 0.0025 to 0.005% of active constituent and have low toxicity.

The human health risk assessment also considered information relating to reported unintentional exposure the anticoagulant rodenticides, primarily from published data by the New South Wales Poisons Information Centre hotline relating to calls over the period from 2004 to 2015 and a second analysis of brodifacoum specific data between 2014 and 2016. Overall, these data indicate that there is the potential for exposure of people, particularly children, to these baits; however the vast majority of incidents require no medical treatment, and the overall risk remains low. This can be partly attributed to the low toxicity of the end-use products noted above.

Occupational and residential exposure assessments performed in this review revealed that the health risks to users when products are used as directed are very low. Updated safety directions and clearer instructions regarding how to handle the baits, as well as requirements to use a tamper resistant bait station in all areas accessible to children and for all baits to contain bittering agent and dye, effectively mitigate the risks to human health posed by the use of these products.

Residues and Trade

Anticoagulant rodenticides are not registered for use in any food producing crop or animal, meaning that any residues present are the result of unintentional contamination, or other off-label use. The APVMA residues risk assessment therefore considered the potential for unintentional contamination of food commodities from all current uses of anticoagulant rodenticides, and if there were any potential associated dietary exposure risks. In particular, it is acknowledged that there have been historical, low-level, detections of residues in farmed pork, and in non-target wild animals that may form part of traditional diets of Australia's indigenous peoples.

The APVMA did not complete a dietary exposure risk assessment for the use of anticoagulant rodenticides due to lack of necessary data, such as levels of wildlife contamination or the quantity of wild game consumed in traditional diets. Therefore, a comprehensive risk mitigation strategy is recommended to prevent unintentional contamination. This risk mitigation strategy includes, but is not limited to:

- Prohibiting the use of certain anticoagulant rodenticide products in and around animal, livestock, and poultry houses, associated equipment, and food and feed processing areas.
- Updated instructions related the use of products in certain situations where livestock, feed or other food commodities may be vulnerable to contamination, the management of poisoned rodents, the use of products in areas where wildlife may be hunted, and the mandatory use of tamper-resistant and weather-resistant bait stations in certain situations.

The risks to international trade were not assessed because the instructions for use relate to non-food uses only and as such there should not be residues detected in food commodities.

1 Introduction

Anticoagulant rodenticides are vertebrate poisons designed to kill rodents by inhibiting blood clotting mechanisms. These vitamin K antagonists used for rodent control in and around homes, animal and agricultural premises, and commercial and industrial sites. They act by binding to the enzyme vitamin K 2,3-epoxide reductase, interrupting the cellular recycling of vitamin K.

Vitamin K in its hydroquinone form is an essential cofactor for the synthesis of functional prothrombin and related blood-clotting factors. Preventing the recycling of vitamin K will prevent blood clotting and lead to death from internal or external bleeding, typically several days after consuming a lethal dose. There are two types of anticoagulant rodenticides as described below.

First-generation anticoagulant rodenticides (FGARs) include products with the active constituents coumatetralyl, diphacinone, or warfarin. Repeated bait feedings are required by rodents to reach fatal levels and require a relatively long time from first feeding to target death. Second-generation anticoagulant rodenticides (SGARs) were formulated to address these concerns and designed to cause death in rodents following a single feeding.

SGARs include products with the active constituents brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen. SGARs were developed to kill rodents more rapidly than the FGARs, and are capable of and designed to cause the death of rodents following a single feeding, meaning they are considered significantly more toxic than FGARs.

1.1 Purpose of review

The APVMA commenced a reconsideration of anticoagulant rodenticide approvals and registrations under Part 2, Division 4 of the Agvet Code in November 2021 because of concerns about potential for unacceptable risks in the following areas:

- Environmental safety, including primary and secondary poisoning of non-target domestic animals and wildlife
- Human health, including worker exposure and public health
- Residues, including livestock and edible wildlife exposure, consumer safety, and trade

The APVMA has assessed the following aspects of active constituent approvals, product registrations and label approvals for the specified anticoagulant rodenticides:

Chemistry

- The establishment of appropriate standards for manufacturing concentrates

Toxicology and worker health and safety

- The safe level of exposure of humans via the oral, dermal and inhalational routes
- Risks to worker and public exposure
- Risks arising from exposure during handling and bait applications

- Re-entry exposure risks including exposure in domestic situations

Residues

- Potential for residues in foods through primary and secondary exposure

Environmental safety

- Risks of off-target primary poisoning
- Risks of off-target secondary poisoning

The APVMA has also considered whether product labels carry adequate instructions and warning statements.

2 Chemistry and Manufacture

The nomenclature, structural formula and physicochemical properties for each of the FGAR active constituents coumatetralyl, diphacinone, or warfarin and SGAR active constituents brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen are described in the tables below, followed by discussion of the approved active constituents and formulated chemical products.

2.1 Chemistry and Manufacture – Active Constituents

The Chemistry and Manufacture assessment for reconsideration of active constituent approvals involves review of the information submitted in support of the approval of each active constituent, and other information submitted during the reconsideration or sourced by the APVMA, against the matters the APVMA must consider when determining if an active constituent meets the safety criteria, including:

(ii) the method by which the constituent is, or is proposed to be, manufactured;

(iii) the extent to which the constituent will contain impurities;

(iv) whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis; and

(via) whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection (1).

Active constituent specific confidential commercial information is not included in this report, but relevant recommendations are provided in the following sections.

2.1.1 Active constituent - Brodifacoum

Brodifacoum is a hydroxycoumarin second generation anticoagulant rodenticide, which acts through inhibition of the vitamin K-dependent steps in the synthesis of the clotting factors II, VII, IX and X (reviewed in British Crop Production Council [BCPC], 2016). It was first reported in 1976 (Redfern R., *et al*, 1976).

Table 1: Nomenclature and structural formula of the active constituent brodifacoum

Common Name	Brodifacoum (ISO 1750)
IUPAC Name	3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-2H-chromen-2-one
CAS Name	3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one
CAS Registry Number	56073-10-0
EC Number	259-980-5
Molecular Formula	C ₃₁ H ₂₃ BrO ₃

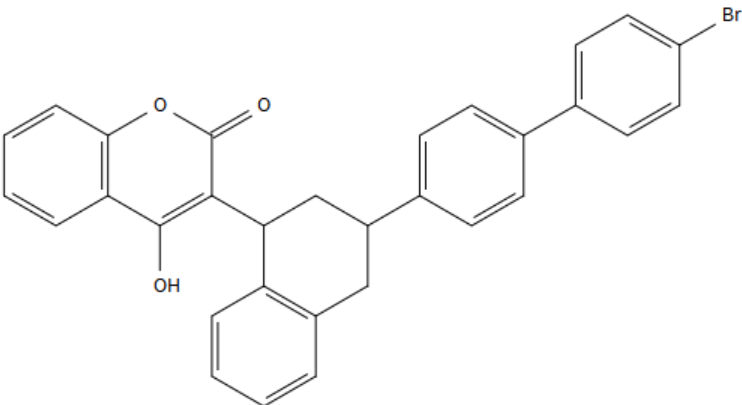
Molecular Weight	523.4 gmol ⁻¹
Structure	
Chemical Family	hydroxycoumarin

Table 2 Key physicochemical properties of the active constituent brodifacoum

Parameters	Properties	Data source
Appearance	White powder (purified active ingredient) Off-white to buff powder (technical active ingredient)	BCPC, 2016
Melting point	228-232 °C (technical active ingredient)	BCPC, 2016
Density	1.42 (25 °C, technical active ingredient)	BCPC, 2016
Octanol-water partition coefficient (log K _{ow})	8.5	BCPC, 2016
Vapour pressure	<0.001 mPa (20 °C, using gas saturation method)	BCPC, 2016
Henry's Law Constant	pH 5.2: <0.1 Pa.m ³ .mol ⁻¹ pH 7.4: <0.001 Pa.m ³ .mol ⁻¹ pH 9.3: <1 × 10 ⁻⁵ Pa.m ³ .mol ⁻¹	BCPC, 2016
Water solubility	pH 5.2: 3.8 × 10 ⁻³ mg/L pH 7.4: 0.24 mg/L pH 9.3: 10 mg/L (all at 20 °C)	BCPC, 2016

Organic solvent solubility	Acetone: 23 g/L Dichloromethane: 50 g/L Toluene: 72. g/L (all at 20 °C)	BCPC, 2016
Hydrolysis	pH 5: DT ₅₀ approximately 173 days pH 7: DT ₅₀ approximately 300 days Stable to hydrolysis at pH 9	Mathis, S.M.G., <i>et al</i> , 1995

Brodifacoum may be supplied to end-use product manufacturers in the form of the technical active constituent (TC), with a purity at or above 90%, or as a technical concentrate (manufacturing concentrate) (TK).

Manufacturing concentrates are generally prepared using a glycol solvent, such as propylene glycol, and typically contain 0.25-2.5% w/w brodifacoum. The manufacturing concentrates facilitate the even distribution of the active constituent during the manufacture of the end use products — which have a relatively low active constituent loading, typically 0.05 g/kg (50 mg/kg or 0.005% w/w) — as well as posing a lower risk to workers. Denatonium benzoate is commonly included in manufacturing concentrates as a bittering agent, typically at 20% of the brodifacoum content, along with a dye to aid in colouring the end use product.

The APVMA Record lists 8 approved sources of brodifacoum active constituent, with 3 sources specifying they are a manufacturing concentrate. A summary of the current brodifacoum active constituent approvals and recommendations, based on review of the information entered in the APVMA's Record of active constituent approvals, is provided in Table 3. Conditional approval, requiring confirmation of the composition and purity of the active constituent and the provision of adequate supporting information, is recommended in instances where potential inconsistencies in the APVMA Record have been identified with respect to whether the active constituent is manufactured and supplied as a technical material or manufacturing concentrate.

Table 3 Current active approvals for brodifacoum

Approval number	Name	Approval holder	Recommendation
44191	Brodifacoum manufacturing concentrate	Syngenta Australia Pty Ltd	Affirm approval
44192	Brodifacoum	Syngenta Australia Pty Ltd	Conditional approval – confirm composition and purity of the active constituent
44522	Brodifacoum	Bell Laboratories, Inc	Affirm approval
48319	Brodifacoum manufacturing concentrate	Helidon Tech Pty Ltd	Affirm approval
62292	Brodifacoum	4 Farmers Australia Pty Ltd	Affirm approval
67386	Brodifacoum	Pelgar International (Aus) Pty Ltd	Affirm approval
85489	Brodifacoum	Activa Srl	Affirm approval
92406	Brodifacoum manufacturing concentrate	Animal Control Products Pty Ltd	Affirm approval

The *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022* (the Active Constituent Standards)³ specification for the standard for brodifacoum active constituents is provided in Table 4. There is also an [FAO specification for brodifacoum Technical Concentrate](#) provided in Table 5.

Table 4: The Active Constituent Standards specification for brodifacoum

Active constituent	Minimum purity
Brodifacoum	900 g/kg

Table 5: FAO specification for brodifacoum Technical Concentrate

Active constituent	Minimum purity
Brodifacoum	950 g/kg

It is noted that the minimum purity for brodifacoum in the APVMA active constituent standard differs from the FAO specification. The amendment of the Active Constituent Standards to align with the FAO specification (i.e., a minimum purity of 950 g/kg) would ensure the provision of higher quality, higher purity technical active constituent to the Australian market and maintain consistency with international standards. However, this has not been considered as part of this reconsideration as variation to the Active Constituent Standards is a separate legislative

³ <https://www.legislation.gov.au/F2022L00137/latest/text>.

process and there have been no safety implications identified with respect to use of a brodifacoum technical active constituent with a purity in the range of 900 g/kg to 950 g/kg.

It is also noted that the Active Constituent Standards does not currently include an entry for brodifacoum manufacturing concentrates and appropriate proposed specifications for such an entry are included below in Table 6. It is anticipated that the APVMA will propose to vary the Active Constituent Standards in future to include an entry for brodifacoum manufacturing concentrates. However, this has not been considered as part of this reconsideration, as variation to the Active Constituent Standards is a separate legislative process and there have been no safety implications identified with respect to use of a brodifacoum manufacturing concentrate listed in Table 3 that has a composition and purity aligning with the Declaration of Composition in the APVMA Record.

Table 6: Proposed APVMA Specification for Brodifacoum Manufacturing Concentrates

Common name	Description	Purity						
Brodifacoum manufacturing concentrate	The material shall consist of a solution of technical brodifacoum in a suitable solvent, typically a glycol solvent such as propylene glycol. The manufacturing concentrate may also contain related manufacturing impurities, as well as denatonium benzoate as a bittering agent, amine and/or polyglycol solubilising agents and a suitable dye as a visual marker but is otherwise free from visible extraneous matter and adding modifying agents.	<p>Minimum purity on a solvent and additive (dye and bittering agent) free basis: 950 g/kg</p> <p>Brodifacoum manufacturing concentrate is typically supplied with a concentration in the range 2.5-25 g/kg. The content must be declared, and when measured, shall not differ from the declared amount by more than the amount specified in the table below:</p> <table border="1"> <thead> <tr> <th>Declared content (g/kg)</th> <th>Allowable deviation from declared content</th> </tr> </thead> <tbody> <tr> <td>Up to 25</td> <td>± 15%</td> </tr> <tr> <td>More than 25, up to 100</td> <td>± 10%</td> </tr> </tbody> </table>	Declared content (g/kg)	Allowable deviation from declared content	Up to 25	± 15%	More than 25, up to 100	± 10%
Declared content (g/kg)	Allowable deviation from declared content							
Up to 25	± 15%							
More than 25, up to 100	± 10%							

The continued approval of the current brodifacoum active constituents listed in Table 3 is supported in this chemistry and manufacture risk assessment, subject to:

- The composition and purity of the relevant active constituent is confirmed by the holders, as noted in Table 3 above, and appropriate supporting information is provided as required.
- The APVMA Record for brodifacoum active constituents are updated as required.

2.1.2 Active constituent - Bromadiolone

Bromadiolone is a hydroxycoumarin second generation anticoagulant rodenticide, which blocks formation of prothrombin (reviewed in BCPC, 2016). It was first reported in 1976 (Redfern R., *et al*, 1976).

Table 7: Nomenclature and structural formula of the active constituent bromadiolone

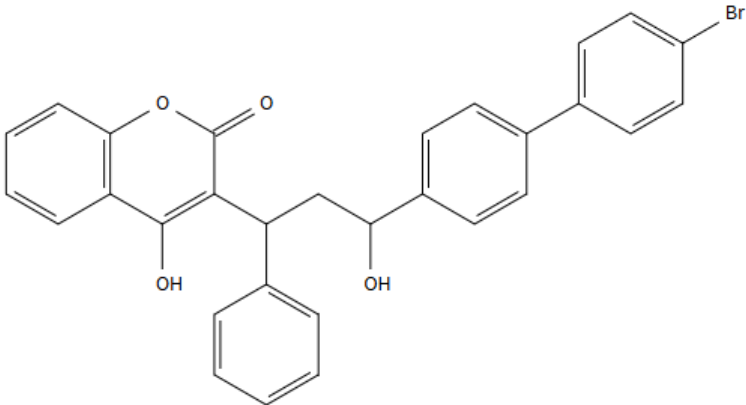
Common Name	Bromadiolone (ISO 1750)
IUPAC Name	Mixture of 80–100% 3-[(1 <i>RS</i> ,3 <i>SR</i>)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2 <i>H</i> -chromen-2-one and 20–0% 3-[(1 <i>RS</i> ,3 <i>RS</i>)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2 <i>H</i> -chromen-2-one
CAS Name	3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2 <i>H</i> -1-benzopyran-2-one
CAS Registry Number	28772-56-7
EC Number	249-205-9
Molecular Formula	C ₃₀ H ₂₃ BrO ₄
Molecular Weight	527.4 gmol ⁻¹
Structure	 <p>The chemical structure of Bromadiolone is a hydroxycoumarin derivative. It features a coumarin core with a hydroxyl group at the 4-position and a 3-hydroxy-1-phenylpropyl group at the 3-position. The propyl chain is further substituted with a 4'-bromobiphenyl-4-yl group at the terminal carbon.</p>
Chemical Family	hydroxycoumarin

Table 8: Key physicochemical properties of the active constituent bromadiolone

Parameters	Properties	Data source
Appearance	White odourless powder (technical active ingredient)	Farrell M.S., 2002(a,b), Pesselman R., 1990(a,b,c)
Melting point	203 – 205 °C	Sarff P, 2002(a)
	198.3 - 199.8 °C	Pesselman R., 1990(d)
Boiling point	Decomposes without boiling above the melting point	Jackson W.A., 2002
Density	1.464 (20 °C)	Sarff P. and Locke J., 2002

Parameters	Properties	Data source
	1.5164	Pesselman, R., 1990(e)
Octanol-water partition coefficient (log K_{ow})	pH 4: >5.71 pH 7: 4.07 pH 10: 3.16 (all at 20 °C using the shake flask method)	Sarff P., 2002(b)
	Deionised water: 4.27 (23 °C, shake flask method)	Pesselman R., 1990(f)
	pH 6: 3.9 (20 °C using the shake flask method)	Ricau H., 2008,
Vapour pressure	2.1×10^{-5} mPa (25 °C), gas saturation method	Pesselman R., 1990(g)
Henry's Law Constant	8.99×10^{-7} Pa.m ³ .mol ⁻¹ (25 °C), calculated	Curl M.G., 2003
Water solubility	pH 4: 0.0994 mg/L pH 7: 18.4 mg/L pH 10: 1230 mg/L (all at 20 °C, using column elution method at pH 4 and 7 and shake flask method for pH 10)	Hahn J.A., 2002
	Deionised water: 12.5 mg/L (column elution method)	Pesselman R., 1990(h)
Organic solvent solubility	Hexane: 7.15 mg/L (25 °C, shake flask method) Methanol: 6.93 g/L (25 °C, shake flask method)	Pesselman R., 1990(h)
Surface tension	71.2 mN/m (17.4 mg/L solution, 20 °C)	De Campos L.F.J., 2007
Hydrolysis	pH 5: half-life 392 days No hydrolysis observed at pH 7 or 9	Spare W., 1992
Photolysis	Rapidly photolysed in aqueous solution, with aa half-life of 28 minutes under summer sunlight at 30-40° N.	Phaff R., 2004
Atmospheric lifetime	Half-life for hydroxyl reaction estimated at 2.09 hours for a 12-hour day Half-life for ozone reaction estimated at 2.015 hours for a 24-hour day	Curl M.G., 2004

Parameters	Properties	Data source
Thermal stability	No decomposition occurred up to 150 °C	Woolley A.J. and Mullee D.M, 2003
Safety properties	Not highly flammable, not explosive, does not self-ignite, not oxidising	Tremain S.P., 2003

Bromadiolone may be supplied to end use product manufacturers in the form of the technical active constituent (TC), with a purity at or above 93%, or as a technical concentrate (manufacturing concentrate)(TK).

Manufacturing concentrates are generally prepared using a glycol solvent such as propylene glycol and typically contain 0.25-2.5% w/w bromadiolone. The manufacturing concentrates facilitate the even distribution of the active constituent during the manufacture of the end use products — which have a relatively low active constituent loading, typically 0.05 g/kg (50 mg/kg or 0.005% w/w) — as well as posing a lower risk to workers. Denatonium benzoate is commonly included in manufacturing concentrates as a bittering agent, typically at 20% of the bromadiolone content, along with a dye to aid in colouring the end-use product.

The APVMA Record lists 8 approved sources of bromadiolone active constituent, with 3 sources specifying they are a manufacturing concentrate. A summary of the current brodifacoum active constituent approvals and recommendations, based on review of the information entered in the APVMA's Record of active constituent approvals, is provided in Table 9. Conditional approval, requiring confirmation of the composition and purity of the active constituent and the provision of adequate supporting information, is recommended in instances where potential inconsistencies in the APVMA Record have been identified with respect to whether the active constituent is manufactured and supplied as a technical material or manufacturing concentrate.

Table 9: Current active constituent approvals for bromadiolone

Approval number	Name	Approval holder	Recommendation
44475	Bromadiolone	Liphatech S.A.S.	Affirm approval
47758	Bromadiolone Manufacturing Concentrate	Animal Control Technologies (Australia) Pty Ltd	Affirm approval
47789	Bromadiolone Manufacturing Concentrate	Liphatech S.A.S.	Affirm approval
47790	Bromadiolone Manufacturing Concentrate	Liphatech S.A.S.	Affirm approval
49195	Bromadiolone	Bell Laboratories, Inc.	Affirm approval
51576	Bromadiolone	Animal Control Technologies (Australia) Pty Ltd	Affirm approval
59135	Bromadiolone	Babolna Bioenvironmental Centre Private Limited Company	Affirm approval
67898	Bromadiolone	Activa S.R.L.	Conditional approval – confirm composition and purity of the active constituent

The Active Constituent Standards specification for the standard for bromadiolone active constituent is provided in Table 10 below. There is no FAO specification for bromadiolone.

Table 10: The Active Constituent Standards specification for bromadiolone

Active constituent	Minimum purity
Bromadiolone	930 g/kg

It is noted that the Active Constituent Standards does not currently include an entry for bromadiolone manufacturing concentrates and appropriate proposed specifications for such an entry are included below in Table 11. It is anticipated that the APVMA will propose to vary the Active Constituent Standards in future to include an entry for brodifacoum manufacturing concentrates. However, this has not been considered as part of this reconsideration as variation to the Active Constituent Standards is a separate legislative process and there have been no safety implications identified with respect to use of a bromadiolone manufacturing concentrate listed in Table 9 that has a composition and purity aligning with the Declaration of Composition in the APVMA Record.

Table 11: Proposed APVMA Specification for Bromadiolone Manufacturing Concentrate

Common name	Description	Purity						
Bromadiolone manufacturing concentrate	The material shall consist of a solution of technical bromadiolone in a suitable solvent, typically a glycol solvent such as propylene glycol. The manufacturing concentrate may also contain related manufacturing impurities, as well as denatonium benzoate as a bittering agent and a suitable dye but is otherwise free from visible extraneous matter and adding modifying agents.	<p>Minimum purity on a solvent and additive (dye and bittering agent) free basis: 930 g/kg</p> <p>Bromadiolone manufacturing concentrate is typically supplied with a concentration in the range 2.5-25 g/kg. The content must be declared, and when measured, shall not differ from the declared amount by more than the amount specified in the table below:</p> <table border="1"> <thead> <tr> <th>Declared content (g/kg)</th> <th>Allowable deviation from declared content</th> </tr> </thead> <tbody> <tr> <td>Up to 25</td> <td>± 15%</td> </tr> <tr> <td>More than 25, up to 100</td> <td>± 10%</td> </tr> </tbody> </table>	Declared content (g/kg)	Allowable deviation from declared content	Up to 25	± 15%	More than 25, up to 100	± 10%
Declared content (g/kg)	Allowable deviation from declared content							
Up to 25	± 15%							
More than 25, up to 100	± 10%							

The continued approval of the current brodifacoum active constituents listed in Table 9 is supported in this chemistry and manufacture risk assessment, subject to:

- The composition and purity of the relevant active constituent is confirmed by the holders, as noted in Table 9 above, and appropriate supporting information is provided as required. The APVMA Record for bromadiolone active constituents are updated as required.

2.1.3 Active constituent - Coumatetralyl

Coumatetralyl is a hydroxycoumarin first generation anticoagulant rodenticide that blocks formation of prothrombin (reviewed in BCPC, 2016). It was first reported in 1962 (Redfern R., *et al*, 1976).

Table 12: Nomenclature and structural formula of the active constituent coumatetralyl

Common Name	Coumatetralyl (ISO 1750)
IUPAC Name	4-hydroxy-3-[(1R)-1,2,3,4-tetrahydro-1-naphthyl]-2H-chromen-2-one

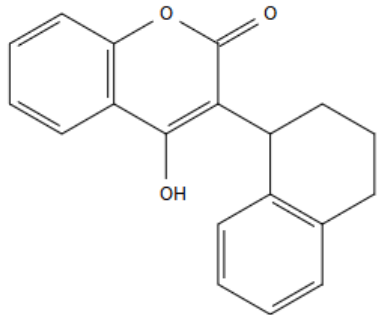
CAS Name	4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthalenyl)-2H-1-benzopyran-2-one
CAS Registry Number	5836-29-3
EC Number	227-424-0
Molecular Formula	C ₁₉ H ₁₆ O ₃
Molecular Weight	292.3 gmol ⁻¹
Structure	
Chemical Family	hydroxycoumarin

Table 13: Key physicochemical properties of the active constituent coumatetralyl

Parameters	Properties	Data source
Appearance	Colourless crystals (purified active ingredient), yellowish crystals (technical active ingredient)	BCPC, 2016
Melting point	172-176 °C (purified active ingredient) 166-172 °C (technical active ingredient)	BCPC, 2016
Octanol-water partition coefficient (log K _{ow})	3.46	BCPC, 2016
pKa	4.5-5.0	BCPC, 2016
Vapour pressure	8.5 × 10 ⁻⁶ mPa (20 °C)	BCPC, 2016
	20 °C: 4 × 10 ⁻⁵ mPa 25 °C: 1.1 × 10 ⁻⁴ mPa 50 °C: 6.2 × 10 ⁻³ mPa	Kuchta C., 2024
Henry's Law Constant	1 × 10 ⁻⁷ Pa.m ³ .mol ⁻¹ (pH 5, 20 °C)	BCPC, 2016
Water solubility	pH 4.2: 4 mg/L pH 5: 20 mg/L	BCPC, 2016

Parameters	Properties	Data source
	pH 7: 425 mg/L pH 9: 100-200 g/L (all at 20 °C)	
Organic solvent solubility	Readily soluble in dimethylformamide, soluble in alcohols and acetone, slightly soluble in benzene, toluene and diethyl ether Dichloromethane 50-100 g/L (20 °C) Isopropanol 20-50 g/L (20 °C)	BCPC, 2016
	Ethyl acetate: <11 g/L (at 10, 20 and 30 °C) Isopropanol: <12 g/L (at 10, 20 and 30 °C) p-Xylene: <12 g/L (at 10, 20 and 30 °C) n-Heptane: <12 g/L (at 10, 20 and 30 °C)	Kuchta C., 2024
Hydrolysis	DT ₅₀ > 1 year, not hydrolysed by water over 5 days at 25 °C	BCPC, 2016
Photolysis	Rapidly degraded on exposure to sunlight or UV light when in solution, DT ₅₀ approximately 1 hour	BCPC, 2016
Safety properties	Not flammable or oxidizing, not self-eating, dust combustible and can ignite and potentially explode	Kuchta C., 2024

Coumatetralyl is generally supplied in the market to end-use product manufacturers as the technical active constituent (TC) with a minimum purity of 98%.

There are currently two active constituent approvals for coumatetralyl that fall within the scope of this reconsideration (note that approvals issued after completion of the risk assessment will be dealt with through a separate regulatory process if necessary).

Table 14: Current active constituent active constituent approvals for coumatetralyl

Approval number	Active name	Approval holder	Recommendation
44211	Coumatetralyl	2022 Environmental Science Au Pty Ltd	Affirm approval
64241	Coumatetralyl	2022 Environmental Science Au Pty Ltd	Affirm approval

The Active Constituent Standards specification for the standard for coumatetralyl active constituent is provided in Table 15. No changes are proposed to this standard. There is no FAO specification for coumatetralyl.

Table 15: The Active Constituent Standards specification for coumatetralyl

Active constituent	Minimum purity
Coumatetralyl	980 g/kg

The continued approval of the current brodifacoum active constituents listed in Table 14 is supported in this chemistry and manufacture risk assessment

2.1.4 Active constituent - Difenacoum

Difenacoum is a hydroxycoumarin second generation anticoagulant rodenticide that inhibits the vitamin K-dependent steps in the synthesis of clotting factors II, VII, IX and X (reviewed in BCPC, 2016). It was first reported in 1975 (Redfern R., *et al*, 1976) and first marketed in 1976.

Table 16: Nomenclature and structural formula of the active constituent difenacoum

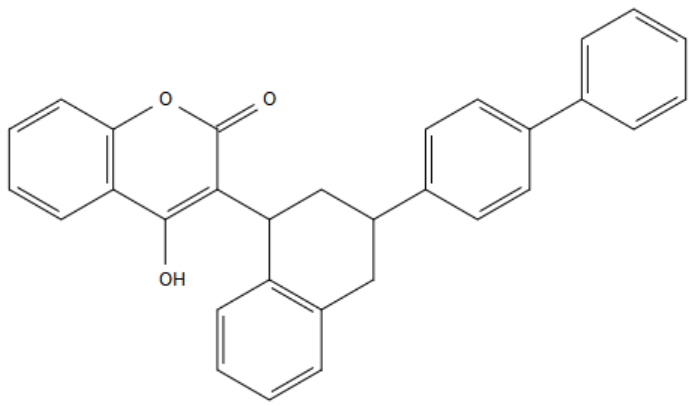
Common Name	Difenacoum (ISO 1750)
IUPAC Name	3-[(1 <i>RS</i> ,3 <i>RS</i> ;1 <i>RS</i> ,3 <i>SR</i>)-3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-2 <i>H</i> -chromen-2-one
CAS Name	3-[3-(1,1'-biphenyl)-4-yl-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2 <i>H</i> -1-benzopyran-2-one
CAS Registry Number	56073-07-5
EC Number	259-978-4
Molecular Formula	C ₃₁ H ₂₄ O ₃
Molecular Weight	444.5 gmol ⁻¹
Structure	
Chemical Family	hydroxycoumarin

Table 17: Key physicochemical properties of the active constituent difenacoum⁴

Parameters	Properties
Appearance	White to tan fine powder
Melting point	211-215 °C
Density	1.2717
Octanol-water partition coefficient (log K _{ow})	7.6
Vapour pressure	5.4 × 10 ⁻¹⁴ – 6.7 × 10 ⁻⁹ Pa (25 °C)
Water solubility	pH 4: <0.05 mg/L pH 7: 1.7 mg/L pH 9: 61.0 mg/L
Organic solvent solubility	Acetone: 7.6 g/L Propan-2-ol (isopropanol): 1.5 g/L Ethyl acetate: 3.7 g/L Toluene: 1.2 g/L Methanol: 1.2 g/L Hexane: 0.01 g/L Dichloromethane: 19.6 g/L

Difenacoum may be supplied to end-use product manufacturers in the form of the technical active constituent (TC), with a purity at or above 96%.

The APVMA Record currently lists 2 approved sources of difenacoum active constituent. A summary of the current difenacoum active constituent approvals and recommendations, based on review of the information entered in the APVMA's Record of active constituent approvals, is provided in Table 18. Conditional approval, requiring confirmation of the composition and purity of the active constituent and the provision of adequate supporting information, is recommended in instances where potential inconsistencies in the APVMA Record have been identified with respect to whether the active constituent is manufactured and supplied as a technical material or manufacturing concentrate.

Table 18: Current active constituent approvals for difenacoum

Approval number	Name	Approval holder	Recommendation
63286	Difenacoum	Pelgar International (Aus) Pty Ltd	Affirm approval

⁴ Supplied by applicant for original approval for difenacoum, Sorex Ltd (approval and data later transferred to BASF Australia Ltd).

Approval number	Name	Approval holder	Recommendation
67881	Difenacoum	Endura S.P.A	Conditional approval – confirm concentration and formulation of the active constituent

The Active Constituent Standards specification for the standard for difenacoum active constituent is provided in Table 19. No changes are proposed to this standard. There is no FAO specification for difenacoum.

Table 19: The Active Constituent Standards specification for difenacoum

Active constituent	Minimum purity
Difenacoum	960 g/kg

It is noted that the Active Constituent Standards does not currently include an entry for difenacoum manufacturing concentrates and appropriate proposed specifications for such an entry are included below in Table 20. It is anticipated that the APVMA will propose to vary the Active Constituent Standards in future to include an entry for difenacoum manufacturing concentrates. However, this has not been considered as part of reconsideration, as it is a separate legislative process.

Table 20: Proposed APVMA specification for difenacoum manufacturing concentrates

Common name	Description	Purity						
Difenacoum manufacturing concentrate	The material shall consist of a solution of technical difenacoum in a suitable solvent, typically a glycol solvent such as propylene glycol. The manufacturing concentrate may also contain related manufacturing impurities, as well as denatonium benzoate as a bittering agent and a suitable dye but is otherwise free from visible extraneous matter and adding modifying agents.	<p>Minimum purity on a solvent and additive (dye and bittering agent) free basis: 930 g/kg</p> <p>Difenacoum manufacturing concentrate is typically supplied with a concentration in the range 2.5-50 g/kg. The content must be declared, and when measured, shall not differ from the declared amount by more than the amount specified in the table below:</p> <table border="1"> <thead> <tr> <th>Declared content (g/kg)</th> <th>Allowable deviation from declared content</th> </tr> </thead> <tbody> <tr> <td>Up to 25</td> <td>± 15%</td> </tr> <tr> <td>More than 25, up to 100</td> <td>± 10%</td> </tr> </tbody> </table>	Declared content (g/kg)	Allowable deviation from declared content	Up to 25	± 15%	More than 25, up to 100	± 10%
Declared content (g/kg)	Allowable deviation from declared content							
Up to 25	± 15%							
More than 25, up to 100	± 10%							

The continued approval of the current difenacoum active constituents listed in Table 18 is supported in this chemistry and manufacture risk assessment, subject to:

- The composition and purity of the relevant active constituent is confirmed by the holders, as noted in Table 18 above, and appropriate supporting information is provided as required. The APVMA Record for difenacoum active constituents are updated as required.

2.1.5 Active constituent - Difethialone

Difethialone is a benzothiazinone analogue of a hydroxycoumarin second generation anticoagulant rodenticide (reviewed in BCPC, 2016). It was first reported in 1986 (Redfern R., *et al.*, 1976).

Table 21: Nomenclature and structural formula of the active constituent difethialone

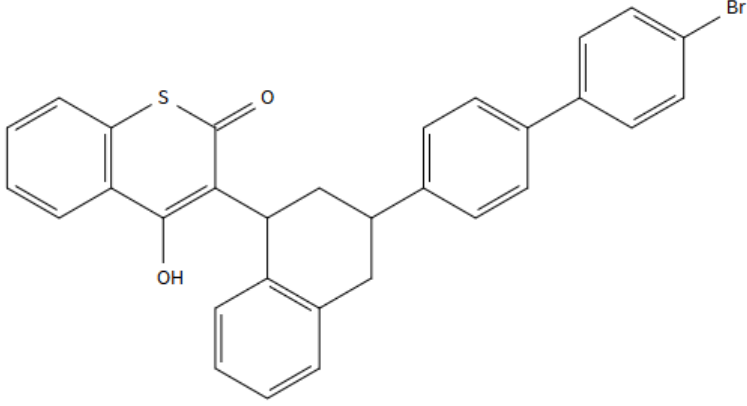
Common Name	Difethialone (ISO 1750)
IUPAC Name	3-[(1 <i>RS</i> ,3 <i>RS</i> ;1 <i>RS</i> ,3 <i>SR</i>)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-1-benzothiazin-2-one containing 0–15% of the (1 <i>RS</i> ,3 <i>RS</i>)-racemate and 85–100% of the (1 <i>RS</i> ,3 <i>SR</i>)-racemate
CAS Name	3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2 <i>H</i> -1-benzothiazopyran-2-one
CAS Registry Number	104653-34-1
EC Number	600-594-7
Molecular Formula	C ₃₁ H ₂₃ BrO ₂ S
Molecular Weight	539.5 gmol ⁻¹
Structure	 <p>The chemical structure of Difethialone is a hydroxycoumarin derivative. It features a benzothiazinone core with a 4-hydroxy group at position 4 and a 3-substituent at position 3. The 3-substituent is a 1,2,3,4-tetrahydro-1-naphthyl group, which is further substituted at the 3-position with a 4'-bromobiphenyl-4-yl group. The bromine atom is attached to the para position of the second phenyl ring of the biphenyl system.</p>
Chemical Family	hydroxycoumarin

Table 22: Key physicochemical properties of the active constituent difethialone

Parameters	Properties	Data source
Appearance	White to slightly yellowish powder	BCPC, 2016
Melting point	233-236 °C	BCPC, 2016
Specific gravity	1.2614 (25 °C)	BCPC, 2016
Octanol-water partition coefficient (log K _{ow})	5.17	BCPC, 2016
Vapour pressure	0.074 mPa (25 °C)	BCPC, 2016
Henry's Law Constant	0.102 (25 °C, calculated)	BCPC, 2016
Water solubility	0.39 mg/L (25 °C)	BCPC, 2016
Organic solvent solubility (purified active ingredient)	Ethanol: 0.7 g/L Methanol: 0.47 g/L Hexane: 0.2 g/L Chloroform: 40.8 g/L Dimethyl formamide: 332.7 g/L Acetone: 4.3 g/L All at 20-25 °C)	BCPC, 2016

Difethialone is generally supplied in to end use product manufacturers as the technical active constituent (TC).

The APVMA Record lists one source of difethialone active constituent. A summary of the current difethialone active constituent approval and recommendations based on review of the information entered in the APVMA's Record of active constituent approvals is provided in Table 23.

Table 23: Current active constituent active constituent approval for difethialone

Approval number	Active constituent name	Approval holder	Recommendation
45234	Difethialone	Liphatech SAS	Affirm approval

The Active Constituent Standards specification for the standard for difethialone active constituent is provided in Table 24. No changes are proposed to this standard. There is no FAO specification for difethialone.

Table 24: The Active Constituent Standards specification for difethialone

Active constituent	Minimum purity
Difethialone	980 g/kg The ratio of (1RS,3RS) isomers to (1RS,3SR) isomers shall be in the range 0-15 to 85-100.

The continued approval of the current difethialone active constituent listed in Table 23 is supported in this chemistry and manufacture risk assessment.

2.1.6 Active constituent - Diphacinone

Diphacinone is an indandione first generation anticoagulant rodenticide, which inhibits the vitamin K dependent steps in the formation synthesis of the clotting factors II, VII and X and was first reported in 1952 (reviewed in BCPC, 2016).

Table 25: Nomenclature and structural formula of the active constituent diphacinone

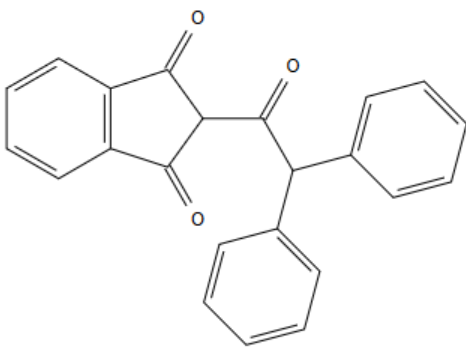
Common Name	Diphacinone (ISO 1750)
IUPAC Name	2-(diphenylacetyl)indane-1,3-dione
CAS Name	2-(2,2-diphenylacetyl)-1 <i>H</i> -indene-1,3(2 <i>H</i>)-dione
CAS Registry Number	82-66-6
EC Number	201-434-5
Molecular Formula	C ₂₃ H ₁₆ O ₃
Molecular Weight	340.4 gmol ⁻¹
Structure	 The chemical structure of Diphacinone is shown. It consists of an indane-1,3-dione core. The 2-position of the indane ring is substituted with a diphenylacetyl group, which is a central carbon atom bonded to two phenyl rings and an acetyl group (-C(=O)-). The indane ring has a benzene ring fused to a five-membered ring containing two carbonyl groups at the 1 and 3 positions.
Chemical Family	indandione

Table 26: Key physicochemical properties of the active constituent diphacinone⁵

Parameters	Properties
Appearance	Light yellow free flowing powder with a slight earthy odour (purified and technical active ingredient)
Melting point	143-146 °C (purified active ingredient) 144-147 °C (technical active ingredient, 98.6%)
Density	1.32 g/mL (20 °C)
Octanol-water partition coefficient (log K _{ow}) – purified active ingredient (20 °C)	pH 4: 3.62 pH 7: 1.36 pH 10: 1.25
pKa	2.7 (20 °C, purified active ingredient)
Vapour pressure	1.5 × 10 ⁻⁵ Pa (25 °C, purified active ingredient)
Henry's Law Constant	2.6 × 10 ⁻¹⁴ (25 °C)
Water solubility	0.00968 g/L (20 °C, purified active ingredient)
Organic solvent solubility (purified active ingredient)	Heptane: 0.82 g/L (20 °C) Xylene: 39.7 g/L (20 °C) 1,2-dichloroethane: 131 g/L (20 °C) Methanol: 0.99 g/L (20 °C) Acetone: 23.2 g/L (20 °C) Ethyl acetate: 27.2 g/L (20 °C) Chloroform: 204 g/L (25 °C) Toluene: 73 g/L (25 °C) Xylene: 50 g/L (25 °C) Acetone 29 g/L (25 °C) Ethanol: 2.1 g/L (25 °C) Heptane: 1.8 g/L (25 °C)
Hydrolysis	Does not readily hydrolyze, but decomposes in water at pH 5
Photolysis	Rapidly decomposes under sunlight in water
Safety properties	Not highly flammable, not self-igniting, not explosive, not oxidizing

⁵ Supplied by applicant for original approval for diphacinone, United Agri Products Pty Ltd (approval later transferred to Neogen Australasia Pty Ltd).

Diphacinone is generally supplied in the market to end-use product manufacturers as the technical active constituent (TC) with a minimum purity of 98.3%.

The APVMA Record lists one source of diphacinone active constituent. A summary of the active constituent approval and recommendations based on review of the information entered in the APVMA's Record of active constituent approvals is provided in Table 27.

Table 27: Current active constituent active constituent approval for diphacinone

Approval number	Active name	Approval holder	Recommendation
54768	Diphacinone	Neogen Australasia Pty Ltd	Affirm approval

The Active Constituent Standards specification for the standard for diphacinone active constituent is provided in Table 28. No changes are proposed to this standard. There is no FAO specification for diphacinone.

Table 28: The Active Constituent Standard for diphacinone active constituent

Active constituent	Minimum purity
Diphacinone	983 g/kg

The continued approval of the current diphacinone active constituent listed in Table 27 is supported in this chemistry and manufacture risk assessment.

2.1.7 Active constituent - Flocoumafen

Flocoumafen is a hydroxycoumarin second generation anticoagulant rodenticide, which acts through inhibition in the metabolism of vitamin K, thus reducing the formation of vitamin K dependent clotting factors and blocking the formation of prothrombin and was first reported in 1984 (reviewed in BCPC, 2016).

Table 29: Nomenclature and structural formula of the active constituent flocoumafen

Common Name	Flocoumafen (ISO 1750)
IUPAC Name	mixture of 50–80% <i>cis</i> -isomers 4-hydroxy-3-[(1 <i>RS</i> ,3 <i>SR</i>)-3-(4-[[4-(trifluoromethyl)phenyl]methoxy]phenyl)-1,2,3,4-tetrahydro-1-naphthyl]-2 <i>H</i> -chromen-2-one and 50–20% <i>trans</i> -isomers 4-hydroxy-3-[(1 <i>RS</i> ,3 <i>RS</i>)-3-(4-[[4-(trifluoromethyl)phenyl]methoxy]phenyl)-1,2,3,4-tetrahydro-1-naphthyl]-2 <i>H</i> -chromen-2-one
CAS Name	4-hydroxy-3-[1,2,3,4-tetrahydro-3-[4-[[4-(trifluoromethyl)phenyl]methoxy]phenyl]-1-naphthalenyl]-2 <i>H</i> -1-benzopyran-2-one
CAS Registry Number	90035-08-8
EC Number	421-960-0
Molecular Formula	C ₃₃ H ₂₅ F ₃ O ₄

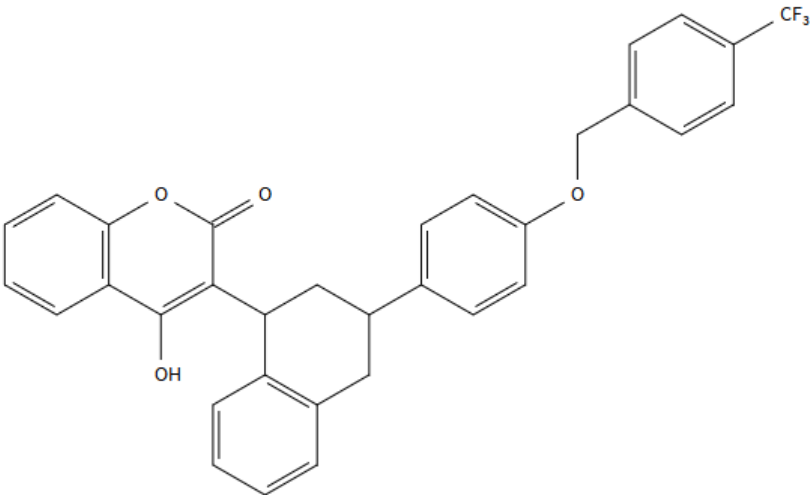
Molecular Weight	542.6 gmol ⁻¹
Structure	
Chemical Family	hydroxycoumarin

Table 30: Key physicochemical properties of the active constituent floccumafen

Parameters	Properties	Data source
Appearance	Off-white solid	BCPC, 2016
Melting point	166.1-168.3 °C	BCPC, 2016
Density	1.40	BCPC, 2016
Octanol-water partition coefficient (log K _{ow})	Deionised water: 4.51 pH 7: 6.12 pH 9: 5.11 (all at 20 °C, using purified active ingredient and the shaken flask method)	Daum A., 2002(a)
pKa	4.5 (solubility method using purified active ingredient)	Daum A., 2002(b)
Vapour pressure	<1 mPa (20-50 °C, using purified active ingredient and the vapour pressure balance method)	Franke J., 2001
Henry's Law Constant	<3.8 Pam ³ mol ⁻¹ (calculated)	BCPC, 2016

Parameters	Properties	Data source
Water solubility	Deionised water: 0.14 mg/L pH 4: 0.0024 mg/L pH 7: 0.114 mg/L pH 9: 14.0 mg/L (all at 20 °C, using purified active ingredient and the column elution method)	Daum A., 2002(c)
Organic solvent solubility	n-Heptane: 0.3 g/L Acetonitrile: 13.7 g/L Methanol: 14.1 g/L n-Octanol: 17.4 g/L Toluene: 31.3 g/L Ethyl acetate: 59.8 g/L Dichloromethane: 146 g/L Acetone: 350 g/L (all at 20 °C)	BCPC, 2016
Hydrolysis	Hydrolytically stable for at least 5 days at 50 °C in pH 4, 7 and 9 buffer	Singh M. and Trollinger J., 2003
Atmospheric fate	Half-life for reaction with OH radicals, 1.479 hours, based on a 12 hour day (calculated) Half life for reaction with ozone, 2.015 hours, based on a 24 hour day (calculated)	Martin C.A., 2002

Flocoumafen is generally supplied in the market to end use product manufacturers as the technical active constituent (TC) with a minimum purity of 95%.

The APVMA Record lists three sources of flocoumafen active constituent. A summary of the current flocoumafen active constituent approvals and recommendations, based on review of the information entered in the APVMA's Record of active constituent approvals, is provided in Table 31.

Table 31: Current active constituent approvals for flocoumafen

Approval number	Active name	Approval holder	Recommendation
44267	Flocoumafen	BASF Australia Ltd	Affirm approval
49436	Flocoumafen	BASF Australia Ltd	Affirm approval
65328	Flocoumafen	BASF Australia Ltd	Affirm approval

The Active Constituent Standards specifications for the standard for flocoumafen active constituent is provided in Table 32 below. No changes are proposed to this standard. There is no FAO specification for flocoumafen.

Table 32: The Active Constituent Standards specification for flocoumafen

Active constituent	Minimum purity
Flocoumafen	950 g/kg

The continued approval of the current flocoumafen active constituent listed in Table 31 is supported in this chemistry and manufacture risk assessment.

2.1.8 Active constituent - Warfarin

Warfarin is a hydroxycoumarin first generation anticoagulant rodenticide, which acts through inhibition of the formation of prothrombin (reviewed in BCPC, 2016). Repeated ingestion is needed to give toxic effects. It was first reported in 1944.

Table 33: Nomenclature and structural formula of the active constituent warfarin

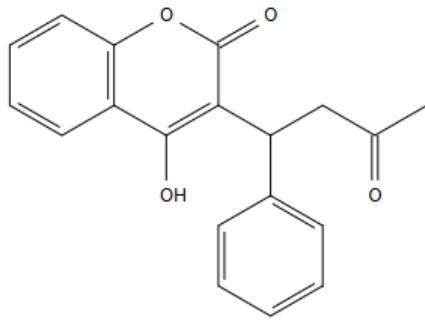
Common Name	Warfarin (ISO 1750)
IUPAC Name	4-hydroxy-3-[(1 <i>RS</i>)-3-oxo-1-phenylbutyl]-2 <i>H</i> -chromen-2-one
CAS Name	4-hydroxy-3-(3-oxo-1-phenylbutyl)-2 <i>H</i> -1-benzopyran-2-one
CAS Registry Number	81-81-2
EC Number	201-377-6
Molecular Formula	C ₁₉ H ₁₆ O ₄
Molecular Weight	308.3 gmol ⁻¹
Structure	
Chemical Family	hydroxycoumarin

Table 34: Key physicochemical properties of the active constituent warfarin

Parameters	Properties	Information source
Appearance	White or light tan crystalline powder, free from lumps	Technical active ingredient (98-102%), information supplied by Ruth Consolidated Industries
	Colourless crystals	Pure active ingredient, BCPC, 2016
Melting point	159-164 °C	Technical active ingredient (98-102%), information supplied by Ruth Consolidated Industries
	161-162 °C	Pure active ingredient, BCPC, 2016
Vapour pressure	1.5×10^{-3} mPa (unspecified temperature)	BCPC, 2016
Water solubility	17 mg/L (20 °C)	BCPC, 2016
Organic solvent solubility (purified active ingredient)	Very slightly soluble in benzene, diethyl ether and cyclohexane. Moderately soluble in methanol, ethanol and isopropanol. Acetone: 65 g/L (20 °C) Chloroform: 56 g/L (20 °C) Dioxane: 100 g/L (20 °C)	BCPC, 2016
Hydrolysis	Stable to hydrolysis, even under strong acidic conditions	BCPC, 2016

Warfarin is generally supplied in the market to end use product manufacturers as the technical active constituent (TC) with a minimum purity of 99%.

The APVMA Record lists one source of warfarin active constituent. A summary of the active constituent approval and recommendations based on review of the information entered in the APVMA's Record of active constituent approvals is provided in Table 35.

Table 35: Current active constituent active constituent approval for warfarin

Approval number	Active name	Approval holder	Recommendation
46121	Warfarin	Ruth Consolidated Industries Pty Ltd	Affirm approval

The Active Constituent Standards specification for the standard for warfarin active constituent is provided in Table 36 below. No changes are proposed to this standard. There is no FAO specification for warfarin.

Table 36: The Active Constituent Standards specification for warfarin active constituent

Active constituent	Minimum purity
Warfarin	990 g/kg

The continued approval of the current warfarin active constituent listed in Table 35 is supported in this chemistry and manufacture risk assessment.

2.2 Chemistry and Manufacture – Chemical Products

The Chemistry and Manufacture assessment for reconsideration of registration of chemical products involves review of the information submitted in support of the registration of each product, and other information submitted during the reconsideration or sourced by the APVMA, against the relevant matters the APVMA must or may consider when determining if a chemical product meets the safety criteria, including:

(iii) how the product is formulated;

(iv) the composition and form of the constituents of the product;

(v) any conditions to which its registration is, or would be, subject;

(via) whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);

(iv) the stability of the product;

(v) the specifications for containers for the product;

Chemical product-specific confidential commercial information is not included in this report, unless material to the proposed decision, but relevant recommendations arising from the risk assessments are provided in the following sections.

2.2.1 Formulated products - Brodifacoum

A summary of the current registered chemical products containing brodifacoum and recommendations based on review of the information entered in the APVMA's Register is provided in Table 37. The registered products are ready-to-use bait formulations containing either 0.025 or 0.05 g/kg of brodifacoum.

It is noted that the human health and environment risk assessments recommend that inclusion of a distinctive dye and bittering agent in the formulated bait is necessary to mitigate risks to people and non-target animals (see sections **3.4.1 Products and uses not supported** and **4.9.4 Formulation recommendations** below). Conditional registration is recommended if minor potential inconsistencies have been identified in the APVMA Register with respect to the concentration and/or purity of the active constituent used in a chemical product formulation, requiring confirmation of the manufacturing source(s) of active constituent used and the formulation details of the chemical product, in addition to the provision of adequate supporting information.

Table 37: Current registered products containing brodifacoum

Product number	Product name	Active content	Registrant	Recommendation
33896	Talon Rat & Mouse Killer Pellets	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
48332	Oztec Ratal Rodenticide Pellets	0.05 g/kg	Oztec Rural Pty Limited	Cancel – does not contain bittering agent
49867	Ditrac All Weather Blox Rodenticide	0.05 g/kg	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
49868	Ditrac Rodenticide	0.05 g/kg	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
50697	Tomcat II All Weather Blox Rodenticide	0.05 g/kg	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
51181	Pestmaster Mouse & Rat Bait	0.05 g/kg	Triox Pty. Ltd.	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
51280	Tomcat II Rodenticide	0.05 g/kg	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
52675	Talon Rat & Mouse Killer All Weather Wax Blocks	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
54836	Fast Action Ratsak Bait Station Kills Rats and Mice	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
54839	Rentokil Brodifacoum Paste	0.05 g/kg	Rentokil Initial Pty Ltd	Vary formulation type to RB – ready-to-use bait
56632	Fast Action Ratsak Throwpacks Kills Rats & Mice	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
57805	Raticide Mouse And Rat Bait	0.05 g/kg	Parafarm Pty Ltd	Cancel – does not contain dye or bittering agent
58301	Talon Rat & Mouse Killer Ezy Throw Pellets	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait

Product number	Product name	Active content	Registrant	Recommendation
58338	Talon Rat & Mouse Killer Pellet Trays	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
58339	Talon Rat & Mouse Killer Wax Blocks	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
58661	Mortein Kills Rats & Mice and the Fleas They Carry Dual Action Bait	0.05 g/kg brodifacoum plus 0.04 g/kg fipronil to control fleas carried by rats	Rb (Hygiene Home) Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
59323	Talon XT Pro Rodenticide Wax Blocks	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
59875	All Weather Pct First Formula Blocks Rodenticide	0.05 g/kg	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
59876	Surefire All Weather Blocks Rodenticide	0.05 g/kg	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
62635	Talon Mouse Bait Station	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
63624	X-Verminator Single Feed Lethal Dose Rodent Blocks	0.05 g/kg	Animal Control Products Ltd	Vary formulation type to RB – ready-to-use bait Vary formulation: remove formulation that does not contain a bittering agent Conditional registration: confirm source of active and formulation details of product
63625	X-Verminator Single Feed, Lethal Dose Rodent Pellets	0.05 g/kg	Animal Control Products Ltd	Cancel – does not contain bittering agent
63867	Surefire Pellets Rodenticide	0.05 g/kg	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product

Product number	Product name	Active content	Registrant	Recommendation
63885	Mortein Kills Rats & Mice and the Fleas They Carry Dual Action Throwpack	0.05 g/kg brodifacoum plus 0.04 g/kg fipronil for control of fleas carried by rats	RB (Hygiene Home) Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
65423	4Farmers Rat and Mouse Bait Pellets	0.05 g/kg	4 Farmers Australia Pty Ltd	Cancel – does not contain dye
65597	Imtrade Top Cat Rodenticide Wax Blocks	0.05 g/kg	Imtrade Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
66235	Rodenthor Block Rodenticide	0.05 g/kg	Zapi S.P.A	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
66331	Rodenthor Soft Bait Rodenticide	0.05 g/kg	Zapi S.P.A	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
67610	Ratsak Professional Pellets	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
67611	Ratsak Professional All Weather Wax Blocks	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
67652	Fast Action Ratsak Waxblocks	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
68021	Brigand Rodenticide Paste	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
68025	Brigand Rodenticide Blocks	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
68028	Brigand Rodenticide Pellets	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

Product number	Product name	Active content	Registrant	Recommendation
68122	Pestmaster Rat & Mouse Killer Wax Blocks	0.05 g/kg	Triox Pty. Ltd.	Vary formulation type to RB – ready-to-use bait
69017	Fast Action Ratsak Reusable Mouse Bait Station with Wax Blocks	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
69119	Fast Action Ratsak Reusable Rodent Bait Station with Wax Blocks	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
69158	Fast Action Ratsak Disposable Mouse Bait Station with Wax Block	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
69209	Ratshot Rapidkill Rodenticide Blocks	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
69210	Ratshot Final Kill Paste Rodenticide	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
69643	Ratal B Rat Blocks	0.05 g/kg	Oztec Rural Pty Limited	Vary formulation type to RB – ready-to-use bait
69867	Klerat XT Pro Rodenticide Wax Blocks	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
69942	Farmalinx Rodi Wax Blocks	0.05 g/kg	Farmalinx Pty Ltd	Cancel – does not contain bittering agent
80029	Ratshot One Shot Rodenticide Pellets	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
80059	Farmalinx RoDi Pellets	0.05 g/kg	Farmalinx Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
81663	The Big Cheese Ultra Power Fast Action Bait Blocks	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
81664	The Big Cheese Ultra Power Rat Kill Bait Station	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

Product number	Product name	Active content	Registrant	Recommendation
81665	The Big Cheese Ultra Power Mouse Kill Bait Station	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
81666	The Big Cheese Ultra Power Fast Action Bait Packs	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
82233	Time's Up Fast Action Baited Mouse Station	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
82234	The Big Cheese Ultra Power Fast Action Disposable Mouse Kill Bait Station	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
83673	Fast Action Ratsak Multi Pack	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
84215	Freezone Ratshot G QuickShot Rodenticide	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
85522	Time's Up Fast Action Throw Pack	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
85523	Time's Up Fast Action Block Bait	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
86214	The Big Cheese Ultra Power Fast Action Block Bait Rodenticide	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
87657	Bainbridge Bait Blocks Rodenticide	0.05 g/kg	Bainbridge Pty Ltd	Cancel – does not contain bittering agent
87659	Bainbridge Bait Pellets Rodenticide	0.05 g/kg	Bainbridge Pty Ltd	Cancel – does not contain bittering agent
87706	Rodenthor Gel Rodenticide	0.05 g/kg	Zapi S.P.A	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
88845	The Big Cheese Ultra Power Block Bait Rodenticide	0.025 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

Product number	Product name	Active content	Registrant	Recommendation
88846	The Big Cheese Ultra Power All Weather Block Bait	0.025 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
88847	The Big Cheese Ultra Power Rat and Mouse Kill Throw Packs	0.025 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
89039	Solo 25 Blox Rodenticide	0.025 g/kg	Bell Laboratories, Inc.	Conditional registration: confirm source of active and formulation details of product
89557	Raticate all-weather block - Brodifacoum	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
90982	ADAMA Brodifacoum Soft Bait	0.05 g/kg	Adama Australia Pty Limited	Conditional registration: confirm source of active and formulation details of product
91393	The Big Cheese Ultra Power Disposable Mouse Kill Bait Station	0.025 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
91394	The Big Cheese Ultra Power Mouse Kill Bait Station Kit	0.025 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
91401	The Big Cheese Ultra Power Rat Kill Bait Station Kit	0.025 g/kg	Pelgar International (Aus) Pty Ltd	N/A
91553	Titan Onza Red Rodenticide Paste	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
91554	Titan Onza Red Rodenticide Blocks	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
91653	Pestmaster Brodifacoum Rat & Mouse Killer Blocks	0.05 g/kg	Triox Pty. Ltd.	Vary formulation type to RB – ready-to-use bait
91708	Titan Onza Red Grain Bait	0.05 g/kg	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
92319	TALON GT Pro Rodenticide Grain Bait Block	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
92320	TALON Rat & Mouse Killer Grain Bait Block	0.05 g/kg	Syngenta Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait

Product number	Product name	Active content	Registrant	Recommendation
				Conditional registration: confirm source of active and formulation details of product
94213	4Farmers Rat and Mouse Blocks	0.05 g/kg	4 Farmers Australia Pty Ltd	Cancel – does not contain bittering agent
94339	Ratsak 50 Waxblocks Kills Rats & Mice	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait
94350	Ratsak 50 Soft Bait Kills Rats & Mice	0.05 g/kg	Duluxgroup (Australia) Pty Ltd	Vary formulation type to RB – ready-to-use bait
94918	No Rats & Mice One Feed Rodenticide Blocks	0.05 g/kg	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

The current registrations for brodifacoum chemical products listed in Table 37:

- Are **not supported** if the formulation in the APVMA Register does not contain the requisite bittering agent and/or dye as constituents.
- Are supported in this chemistry and manufacture risk assessment in all other instances, subject to:
 - Update of the formulation types recorded for in the APVMA Register to the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)';
 - The manufacturing source(s) of active constituent used and the formulation details of relevant chemical products being confirmed by the holders, and appropriate supporting information is provided as required. The APVMA Register for brodifacoum products is updated as required.
 - Variation of the formulation details recorded in the APVMA Register for the relevant chemical product in order to remove subsidiary formulation(s) that do not contain a bittering agent.

2.2.2 Formulated products - Bromadiolone

A summary of the current registered chemical products containing bromadiolone, and both bromadiolone and difenacoum, and recommendations based on review of the information entered in the APVMA's Register are provided in Table 38 and Table 39 respectively. The registered products are ready-to-use bait formulations containing either 0.05 or 0.1 g/kg of bromadiolone, liquid bait concentrates containing 0.5 g/L bromadiolone, or ready-to-use bait formulations containing 0.025 g/kg bromadiolone plus 0.025 g/kg difenacoum.

It is noted that the human health and environment risk assessments recommend that inclusion of a distinctive dye and bittering agent in the formulated bait is necessary to mitigate risks to people and non-target animals (see sections **3.4.1 Products and uses not supported** and **4.9.4 Formulation recommendations** below). It is also noted that the environment risk assessments recommend that the risks posed to non-target animals by use of products formulated as bait concentrates (powders and liquids) cannot be adequately mitigated (see section **3.4.1 Products and uses not supported**).

Conditional registration is recommended if minor potential inconsistencies have been identified in the APVMA Register with respect to the concentration and/or purity of the active constituent used in a chemical product formulation, requiring confirmation of the manufacturing source(s) of active constituent used and the formulation details of the chemical product, in addition to the provision of adequate supporting information.

Table 38: Current registered products containing bromadiolone

Product number	Product name	Active content	Holder	Recommendation
33908	Bromakil Block Bait for Rats and Mice	0.05 g/kg bromadiolone	De Sangosse Australia Pty. Ltd.	Cancel – does not contain bittering agent
33911	Bromakil Pellet Bait for Rats and Mice	0.05 g/kg bromadiolone	De Sangosse Australia Pty. Ltd.	Cancel – does not contain bittering agent
39461	Rentokil Bromard	0.1 g/kg bromadiolone	Rentokil Initial Pty Ltd	Vary formulation type to RB – ready-to-use bait
47484	Bromakil Super Rat Drink	0.5 g/L bromadiolone	De Sangosse Australia Pty. Ltd.	Cancel – does not contain a bittering agent and liquid (bait concentrate) formulation not supported
48145	Bromakil Grain Bait for Rats and Mice	0.05 g/kg bromadiolone	De Sangosse Australia Pty. Ltd.	Cancel – does not contain bittering agent
48372	Contrac Blox	0.05 g/kg bromadiolone	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
48373	Contrac Rat And Mouse Bait	0.05 g/kg bromadiolone	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
48374	Contrac Rodenticide	0.05 g/kg bromadiolone	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
49776	Tomcat All-Weather Blox	0.05 g/kg bromadiolone	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
49782	Tomcat Rat and Mouse Bait	0.05 g/kg bromadiolone	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
51245	Mouseoff Bromadiolone Rodent Bait	0.05 g/kg bromadiolone	Animal Control Technologies (Australia) Pty Ltd	Cancel – does not contain bittering agent
61668	Bromakil Kills Rats and Mice!	0.05 g/kg bromadiolone	De Sangosse Australia Pty. Ltd.	Cancel – does not contain bittering agent
62180	Maki Block Weather - Proof Rodenticide	0.05 g/kg bromadiolone	Liphatech S.A.S.	Vary formulation type to RB – ready-to-use bait
64849	Surefire Broma Blocks Rodenticide	0.05 g/kg bromadiolone	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait

64850	Surefire Broma Pellets Rodenticide	0.05 g/kg bromadiolone	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait
64931	Rodemise Bromadiolone Rodent Block	0.05 g/kg bromadiolone	Animal Control Technologies (Australia) Pty Ltd	Cancel – does not contain bittering agent
65675	Imtrade Alley Cat Rodenticide Wax Blocks	0.05 g/kg bromadiolone	Imtrade Australia Pty Ltd	Cancel – does not contain bittering agent
67142	Surefire Broma Grain Bait Rodenticide	0.05 g/kg bromadiolone	Pct Holdings Pty Ltd	Cancel – does not contain bittering agent
67578	Rodemise Super Bromadiolone Rodent Block	0.05 g/kg bromadiolone	Animal Control Technologies (Australia) Pty Ltd	Cancel – does not contain bittering agent
69641	Rat Stop Grain Bait	0.05 g/kg bromadiolone	Oztec Rural Pty Limited	Cancel – does not contain bittering agent
80379	Generation Green Rodenticide Pellet	0.05 g/kg bromadiolone	Liphatech S.A.S.	Vary formulation type to RB – ready-to-use bait
80388	Bromakil Power Block for Rats and Mice	0.05 g/kg bromadiolone	Liphatech S.A.S.	Vary formulation type to RB – ready-to-use bait
81205	Tomcat Bait Packs	0.05 g/kg bromadiolone	Evergreen Garden Care Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
81206	Tomcat All-Weather Rat & Mouse Block Baits	0.05 g/kg bromadiolone	Evergreen Garden Care Australia Pty Ltd	Vary formulation type to RB – ready-to-use bait
86179	Resolv Soft Bait Rodenticide	0.05 g/kg bromadiolone	Liphatech S.A.S.	Vary formulation type to RB – ready-to-use bait
86331	Contrac Soft Bait	0.05 g/kg bromadiolone	Bell Laboratories, Inc.	Vary formulation type to RB – ready-to-use bait
93518	Surefire Broma Liquid Rodenticide	0.5 g/L bromadiolone	Pct Holdings Pty Ltd	Cancel – liquid (bait concentrate) formulation not supported

Table 39: Current registered products containing both bromadiolone and difenacoum

Product number	Product name	Active content	Registrant	Recommendation
69994	Muskil Dual Active Rodenticide Blocks with Fluo-NP Technology	0.025 g/kg bromadiolone + 0.025 g/kg difenacoum	Zapi SpA	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
82450	Muskil Soft Bait with Two Actives for Faster Kill of Rats & Mice	0.025 g/kg bromadiolone + 0.025 g/kg difenacoum	Zapi SpA	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
84831	Ratsak Rapid Strike Dual Active Waxblocks	0.025 g/kg bromadiolone + 0.025 g/kg difenacoum	Zapi SpA	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product
84832	Ratsak Rapid Strike Advanced Dual Active Soft Bait	0.025 g/kg bromadiolone + 0.025 g/kg difenacoum	Zapi SpA	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product

The current registrations for bromadiolone and bromadiolone/difenacoum chemical products listed respectively in Table 38 and Table 39:

- Are **not supported** if the formulation in the APVMA Register does not contain the requisite bittering agent and/or dye as constituents or if the chemical product is formulated as a liquid bait concentrate.
- Are supported in this chemistry and manufacture risk assessment in all other instances, subject to:
 - Updates to the formulation types recorded in the APVMA Register to reflect the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)'
 - The manufacturing source(s) of active constituent used and the formulation details of relevant brodifacoum/difenacoum chemical products being confirmed by the holders, and appropriate supporting information is provided as required. The APVMA Register for brodifacoum/difenacoum chemical products is updated as required.

2.2.3 Formulated products - Coumatetralyl

A summary of the current registered chemical products containing coumatetralyl and recommendations based on review of the information entered in the APVMA's Register is provided in Table 40. The registered products are ready-to-use bait formulations containing 0.37, 0.38 or 0.4 g/kg coumatetralyl, or bait concentrates containing 7.5 or 8 g/kg coumatetralyl.

It is noted that the human health and environment risk assessments recommend that inclusion of a distinctive dye and bittering agent in the formulated bait is necessary to mitigate risks to people and non-target animals (see sections 3.4.1 **Products and uses not supported** and 4.9.4 **Formulation recommendations** below). It is also noted that the environment risk assessments recommend that the risks posed to non-target animal by use of products formulated as bait concentrates (powders and liquids) cannot be adequately mitigated (see section 3.4.1 **Products and uses not supported**).

Table 40: Current registered products containing coumatetralyl

Product number	Product name	Active content	Holder	Recommendation
42040	Readi Rac Rat & Mouse Killer	0.4 g/kg coumatetralyl	David Gray & Co. Pty Limited	Cancel – does not contain bittering agent
49256	Ratex Mouse and Rat Bait	0.38 g/kg coumatetralyl	Parafarm Pty Ltd	Cancel – does not contain bittering agent
51508	Racumin Rat and Mouse Paste	0.37 g/kg coumatetralyl	2022 Environmental Science Au Pty Ltd	Vary formulation type to RB – ready-to-use bait
52098	Racumin Rat And Mouse Blocks	0.37 g/kg coumatetralyl	2022 Environmental Science Au Pty Ltd	Vary formulation type to RB – ready-to-use bait Vary formulation: remove formulation that does not contain a bittering agent
52182	Racumin 8 Rat and Mouse Rodenticide	8 g/kg coumatetralyl	2022 Environmental Science Au Pty Ltd	Cancel – does not contain bittering agent and powder (bait concentrate) formulation not supported
59284	Bayer Racumin Rat & Mouse Killer	0.37 g/kg coumatetralyl	Bayer Cropscience Pty Ltd	Vary formulation type to RB – ready-to-use bait
82217	Surefire Couma All Weather Blocks Rodenticide	0.37 g/kg coumatetralyl	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait
86417	Racumin Tp Rat And Mouse Rodenticide	7.5 g/kg coumatetralyl	2022 Environmental Science Au Pty Ltd	Cancel – does not contain bittering agent and powder (bait concentrate) formulation not supported

The current registrations for coumatetralyl chemical products listed in Table 40:

- Are **not supported** if the formulation in the APVMA Register does not contain the requisite bittering agent and/or dye as constituents or if the chemical product is formulated as a powder bait concentrate.
- Are supported in this chemistry and manufacture risk assessment in all other instances, subject to:
 - Updates to the formulation types recorded in the APVMA Register to reflect the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)'

- Variation of the formulation details recorded in the APVMA Register for the relevant chemical product in order to remove the formulation that does not contain a bittering agent.

2.2.4 Formulated products - Difenacoum

A summary of the current registered chemical products containing difenacoum and recommendations based on review of the information entered in the APVMA's Register is provided in Table 41. The registered products are ready-to-use bait formulations containing either 0.025 or 0.05 g/kg of difenacoum, or 0.025 g/kg difenacoum plus 0.025 g/kg bromadiolone.

It is noted that the human health and environment risk assessments recommend that inclusion of a distinctive dye and bittering agent in the formulated bait is necessary to mitigate risks to people and non-target animals (see sections 3.4.1 **Products and uses not supported** and 4.9.4 **Formulation recommendations** below). Conditional registration is recommended if minor potential inconsistencies have been identified in the APVMA Register with respect to the concentration and/or purity of the active constituent used in a chemical product formulation, requiring confirmation of the manufacturing source(s) of active constituent used and the formulation details of the chemical product, in addition to the provision of adequate supporting information.

Table 41: Current registered products containing difenacoum

Product number	Product name	Active content	Holder	Recommendation
65339	Roban Rodenticide Blocks	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
65358	Roban Rodenticide Paste	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
65528	Roban Rodenticide Pellets	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
65672	Rodemise Difenacoum Rodent Bait Blocks	0.05 g/kg difenacoum	Animal Control Technologies (Australia) Pty Ltd	Cancel – does not contain bittering agent
66399	Roban Rodenticide Placepacks	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
66587	Cougar Rodenticide Paste Sachets	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
66588	Cougar Rodenticide Wax Blocks	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
67484	Roban Rat And Mouse Killer Paste	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
67644	Time's Up Rat & Mouse Killer Ready to Use Bait Packs	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

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67647	Time's Up All-Weather Block Bait Rodenticide	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
67681	Time's Up Baited Mouse Kill Station	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
68759	Ratshot Rodenticide Paste	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
68760	Ratshot Reusable Baited Rat Kill Station	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
68762	Ratshot Rodenticide Blocks	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
68763	Ratshot Rat And Mouse Killer Paste	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
69347	Roban Rodenticide Grain Bait	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
69911	Surefire Difenate All Weather Blocks Rodenticide	0.05 g/kg difenacoum	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait
80124	All Weather PCT Pro Formula Blocks Rodenticide	0.05 g/kg difenacoum	PCT Holdings Pty Ltd	Vary formulation type to RB – ready-to-use bait
80667	Ratshot-G Rodenticide Grain Bait	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
85512	Amgrow Patrol All Weather Blocks Rodenticide	0.05 g/kg difenacoum	Amgrow Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product.
85513	Amgrow Patrol Rat & Mouse Soft Bait Rodenticide	0.05 g/kg difenacoum	Amgrow Pty Ltd	Cancel – does not contain dye
87869	The Big Cheese Home Choice All Weather Block Bait	0.025 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait Conditional registration: confirm source of active and formulation details of product.
87870	The Big Cheese Home Choice Rat & Mouse Kill Throw Packs	0.025 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

				Conditional registration: confirm source of active and formulation details of product.
89203	The Big Cheese Home Choice Rat & Mouse Killer Ready to Use Bait Station	0.025 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Conditional registration: confirm source of active and formulation details of product.
89204	The Big Cheese Home Choice Mouse Killer Bait Station	0.025 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Conditional registration: confirm source of active and formulation details of product.
89206	The Big Cheese Home Choice Rat Killer Bait Station	0.025 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Conditional registration: confirm source of active and formulation details of product.
89510	Surefire Difenate Paste Bait Rodenticide	0.05 g/kg difenacoum	PCT Holdings Pty Ltd	Conditional registration: confirm source of active and formulation details of product.
89556	Raticate all-weather block - Difenacoum	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
91552	Titan Onza Blue Rodenticide Grain Bait	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
91555	Titan Onza Blue Rodenticide Paste	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
91556	Titan Onza Blue Rodenticide Blocks	0.05 g/kg difenacoum	Freezone Public Health Pty Ltd	Vary formulation type to RB – ready-to-use bait
91657	Pestmaster Difenacoum Rat & Mouse Killer Blocks	0.05 g/kg difenacoum	Triox Pty. Ltd.	Vary formulation type to RB – ready-to-use bait
92812	Roban 25 All Weather Block Bait	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait
94917	No Mice Difend Rodenticide Blocks	0.05 g/kg difenacoum	Pelgar International (Aus) Pty Ltd	Vary formulation type to RB – ready-to-use bait

The current registrations for difenacoum chemical products listed in Table 41:

- Are **not supported** if the formulation in the APVMA Register does not contain the requisite bittering agent and/or dye as constituents.
- Are supported in this chemistry and manufacture risk assessment in all other instances, subject to:
 - Update of the formulation types recorded for in the APVMA Register to the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)';

- The manufacturing source(s) of active constituent used and the formulation details of relevant chemical products being confirmed by the holders, and appropriate supporting information is provided as required. The APVMA Register for difenacoum products is updated as required.

2.2.5 Formulated products - Difethialone

A summary of the current registered chemical products containing difethialone and recommendations based on review of the information entered in the APVMA's Register is provided in Table 42. The registered ready-to-use bait formulations containing 0.025 g/kg difethialone.

Table 42: Current registered products containing difethialone

Product number	Product name	Active content	Holder	Recommendation
62178	Generation Blue Max Block Single-Feed Rodenticide	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait
62694	Generation Block Single-Feed Rodenticide	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait
66889	Generation Firststrike Single-Feed Rodenticide	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait
69086	Rodilon Pro Rodenticide	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait
80381	Generation Blue Rodenticide Block	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait
80382	Generation Blue Rodenticide Pellet	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait
80386	Generation Blue Rodenticide Soft Bait	0.025 g/kg difethialone	Liphatech SAS	Vary formulation type to RB – ready-to-use bait

The current registrations for difethialone chemical products listed in Table 42 are supported in this chemistry and manufacture risk assessment, subject to:

- Update of the formulation type recorded for in the APVMA Register to the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)'.

2.2.6 Formulated products - Diphacinone

A summary of the current registered chemical products containing difethialone and recommendations based on review of the information entered in the APVMA's Register is provided in Table 43. These products are ready-to-use baits containing 0.05 g/kg diphacinone as the active constituent.

It is noted that the human health and environment risk assessments recommend that inclusion of a distinctive dye and bittering agent in the formulated bait is necessary to mitigate risks to people and non-target animals (see sections 3.4.1 **Products and uses not supported** and 4.9.4 **Formulation recommendations** below).

Table 43: Current registered products containing diphacinone

Product number	Product name	Active content	Holder	Recommendation
54756	Ramik Green Bait Bits Rodenticide	0.05 g/kg diphacinone	Neogen Australasia Pty Ltd	Cancel – does not contain bittering agent
89433	Ramik Bars Rodenticide	0.05 g/kg diphacinone	Neogen Australasia Pty Ltd	Vary formulation type to RB – ready-to-use bait

The current registrations for diphacinone chemical products listed in Table 43:

- Are **not supported** if the formulation in the APVMA Register does not contain the requisite bittering agent and/or dye as constituents.
- Are supported in this chemistry and manufacture risk assessment in all other instances, subject to:
 - Update of the formulation types recorded for in the APVMA Register to the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)';

2.2.7 Formulated products - Flocoumafen

A summary of the current registered chemical products containing flocoumafen and recommendations based on review of the information entered in the APVMA's Register is provided in Table 44. All products are ready-to-use baits containing 0.05 g/kg flocoumafen.

Table 44: Current registered products containing flocoumafen

Product number	Product name	Active content	Holder	Recommendation
47768	Storm Wax Block Rodenticide	0.05 g/kg flocoumafen	BASF Australia Ltd	Vary formulation type to RB – ready-to-use bait
54191	Storm Secure Wax Block Rodenticide	0.05 g/kg flocoumafen	BASF Australia Ltd	Vary formulation type to RB – ready-to-use bait
80663	Storm Soft Bait Rodenticide	0.05 g/kg flocoumafen	BASF Australia Ltd	Vary formulation type to RB – ready-to-use bait
90839	Stratagem Soft Bait Rodenticide	0.05 g/kg flocoumafen	BASF Australia Ltd	Vary formulation type to RB – ready-to-use bait
90840	Stratagem Wax Block Rodenticide	0.05 g/kg flocoumafen	BASF Australia Ltd	Vary formulation type to RB – ready-to-use bait

The current registrations for flocoumafen chemical products listed in Table 44 are supported in this chemistry and manufacture risk assessment, subject to:

- Update of the formulation type recorded for in the APVMA Register to the contemporary designation of 'ready-to-use bait (RB)', in place of the more common currently used 'bait (BA)'.

2.2.8 Formulated products - Warfarin

A summary of the current registered chemical products containing warfarin and recommendations based on review of the information entered in the APVMA's Register is provided in Table 45. All products are ready-to-use baits containing 0.25 or 0.5 g/kg of warfarin.

It is noted that the human health and environment risk assessments recommend that inclusion of a distinctive dye and bittering agent in the formulated bait is necessary to mitigate risks to people and non-target animals (see sections **3.4.1 Products and uses not supported** and **4.9.4 Formulation recommendations** below).

Table 45 Current registered products containing warfarin

Product number	Product name	Active content	Registrant	Recommendation
33942	David Grays Rat 'N' Mouse Killer	0.25 g/kg warfarin	David Gray & Co Pty Ltd	Cancel – does not contain dye or bittering agent
33945	RCI Ratblitz Bait	0.25 g/kg warfarin	Ruth Consolidated Industries Pty Ltd	Cancel – does not contain dye or bittering agent
42368	Rat Kill	0.25 g/kg warfarin	Omega Pest Control Pty Ltd	Cancel – does not contain dye or bittering agent
60285	Double Strength Ratsak Kills Rats & Mice	0.5 g/kg warfarin	Duluxgroup (Australia) Ltd	Cancel – does not contain bittering agent

The current registrations for warfarin chemical products listed in Table 45 are **not supported as** the formulation in the APVMA Register does not contain the requisite bittering agent and/or dye as constituents.

3 Environment

3.1 Fate and behaviour in the environment

3.1.1 Fate and behaviour in air, soil and water

A precis of the relevant findings on the fate and behaviour of each chemical in environmental media for each of the chemicals under reconsideration is presented below. A full list of available data on the fate and behaviour of each chemical in environmental media, including relevant references, is tabulated in Appendix A.

Coumatetralyl is not expected to volatilise into the air based on its low vapour pressure ($<1.0 \times 10^{-3}$ Pa at 20°C) and Henry's law constant ($<6.6 \times 10^{-2}$ Pa m³ mol⁻¹). The pKa of coumatetralyl is 3.9, indicating that it will partially exist in anion form in the environment; anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. At neutral pH, coumatetralyl has moderate solubility in water and based on its log P_{OW} 1.5, has low potential for bioaccumulation. Coumatetralyl contains chromophores that absorb at wavelengths >290 nm and, therefore, may be susceptible to direct photolysis by sunlight. Coumatetralyl is non-persistent in soil under aerobic conditions (geomean DT₅₀ 7.5 days), but no degradation is observed under anaerobic conditions. It is moderately mobile with lower sorption to soils observed at neutral pH (mean Koc 125 mL/g at pH ≥ 6.5) than to more acidic soils (mean Koc 404 mL/g at pH <6.5). Coumatetralyl is stable to hydrolysis but is susceptible to aqueous photolysis. It is not readily or inherently biodegradable. Long-range transport of coumatetralyl through the air is not expected based on low volatility, susceptibility to direct photolysis by sunlight, and predicted rapid reaction with hydroxyl radicals and ozone.

Diphacinone is not expected to volatilise into the air based on its low vapour pressure (1.5×10^{-5} Pa at 20°C) and Henry's law constant (2.6×10^{-9} Pa m³ mol⁻¹). The pKa of diphacinone is 2.7, indicating that it will partially exist in anion form in the environment; anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Diphacinone has low solubility in water and based on its log P_{OW} 1.4 at neutral pH, has low potential for bioaccumulation. The UV-VIS absorption maxima of diphacinone do not exceed 290 nm for a range of pH; however, this does not preclude the possibility of photodegradation. Diphacinone is moderately persistent in soil (DT₅₀ 30 days) and is slightly mobile (mean Koc 2955 mL/g). No leaching of diphacinone was observed in four aged soils; negligible leaching was observed in an unaged sand soil. Diphacinone is stable to hydrolysis under neutral and alkaline conditions but may slowly hydrolyse under acidic conditions. Diphacinone entry into the air is expected to be negligible based on its low volatility. If particulate phase diphacinone occurs in the ambient atmosphere, it would be removed by wet or dry deposition. Therefore, long-range transport of diphacinone through the air is not expected.

Warfarin is non-persistent in soils covered by turfgrass or other groundcover (geomean DT₅₀ 4.9 days). Warfarin is not readily biodegradable.

Brodifacoum is not expected to volatilise into the air based on its low vapour pressure (2.6×10^{-22} Pa at 20°C) and Henry's law constant (2.4×10^{-18} Pa m³ mol⁻¹). Brodifacoum has low solubility in water and based on its log P_{OW} 4.9 at neutral pH, has high potential for bioaccumulation. The UV-VIS absorption spectra of brodifacoum have peaks >290 nm and, therefore, it may be susceptible to direct photolysis by sunlight. Brodifacoum is moderately persistent in soil (geomean DT₅₀ 95 days) and is slightly mobile (Koc 525 mL/g). No leaching of brodifacoum was observed in four aged soils. Brodifacoum is stable to hydrolysis but is susceptible to aqueous photolysis. It is not

readily, inherently, or anaerobically biodegradable. Long-range transport of brodifacoum through the air is not expected based on low volatility, susceptibility to direct photolysis by sunlight, and predicted rapid reaction with hydroxyl radicals and ozone.

Bromadiolone is not expected to volatilise into the air based on its low vapour pressure ($<0.05 \times 10^{-3}$ Pa at 45°C) and Henry's law constant (9.0×10^{-7} Pa m³ mol⁻¹). The pKa values of bromadiolone range 3.6 to 6.8, indicating that it will partially exist in anion form in the environment; anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. At neutral pH, bromadiolone has low solubility in water and, based on its log P_{ow} ~4.0, high potential for bioaccumulation. The UV-VIS absorption spectra of bromadiolone have peaks >290 nm and, therefore, it may be susceptible to direct photolysis by sunlight. Bromadiolone is non-persistent in soil (geomean DT₅₀ 14 days) and is immobile (mean Koc 14770 mL/g). Negligible leaching of bromadiolone was observed in aged and non-aged soil column studies. Bromadiolone is stable to hydrolysis but is susceptible to aqueous photolysis. It is not readily, inherently, or anaerobically biodegradable. Long-range transport of bromadiolone through the air is not expected based on low volatility, susceptibility to direct photolysis by sunlight, and predicted rapid reaction with hydroxyl radicals and ozone.

Difenacoum is not expected to volatilise into the air based on its low vapour pressure ($<0.05 \times 10^{-3}$ Pa at 45°C) and Henry's law constant (<0.046 Pa m³ mol⁻¹). The pKa of difenacoum is 4.5, indicating that it will partially exist in anion form in the environment; anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Difenacoum has low solubility in water and based on its estimated log P_{ow} 7.6, has high potential for bioaccumulation. The UV-VIS absorption spectra of difenacoum have peaks >290 nm and, therefore, it may be susceptible to direct photolysis by sunlight. Difenacoum is classified as mobile in soil based on its Koc of 67 mL/g; however, no leaching of difenacoum was observed in three unaged soils. Difenacoum is stable to hydrolysis but is susceptible to aqueous photolysis. It is not readily, inherently, or anaerobically biodegradable.

Difethialone is persistent in soil (geomean DT₅₀ 317 days) and is immobile (Koc $\geq 1.0 \times 10^8$ mL/g). Difethialone is stable to hydrolysis under acidic conditions but may slowly hydrolyse under neutral and alkaline conditions. It is susceptible to aqueous photolysis but is not readily or anaerobically biodegradable. Long-range transport of difethialone through the air is not expected based on predicted rapid reaction with hydroxyl radicals and ozone.

Flocoumafen is not expected to volatilise into the air based on its low vapour pressure ($<2.7 \times 10^{-7}$ Pa at 55-77°C). The pKa of flocoumafen is 4.5, indicating that it will partially exist in anion form in the environment; anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Flocoumafen has low solubility in water and based on its log P_{ow} 6.1 at neutral pH, has high potential for bioaccumulation. The UV-VIS absorption spectra of flocoumafen have peaks >290 nm and, therefore, it may be susceptible to direct photolysis by sunlight. Flocoumafen is persistent in soil (geomean DT₅₀ 256 days) and is immobile (Koc 101684 mL/g). Negligible leaching of flocoumafen was observed in four unaged soils. Flocoumafen is stable to hydrolysis but is susceptible to aqueous photolysis. It is not readily or anaerobically biodegradable. Long-range transport of flocoumafen through the air is not expected based on low volatility, susceptibility to direct photolysis by sunlight, and predicted rapid reaction with hydroxyl radicals and ozone.

Some monitoring studies have investigated the presence of anticoagulant rodenticides in aquatic systems. Based on the available fate information, any residues would be expected to be associated with particulate matter. One study had reported up to 7.6 µg/kg (bromadiolone) in the suspended particulate matter of German rivers, but no other anticoagulant rodenticides were present in aquatic systems in quantifiable amounts (Kotthoff *et al.* 2019).

3.1.2 Fate and behaviour in biota

A precis of the relevant findings on the fate and behaviour of each chemical in biota (i.e., living organisms including plants, animals and insects) for each of the chemicals under reconsideration is presented below. A full list of available data on the fate and behaviour of each chemical in biota (including additional relevant references) is tabulated in Appendix A.

Secondary oral exposure to anticoagulant rodenticides can occur via ingestion of animal tissues that contain residues; this exposure pathway is a particular concern for wildlife species that prey on rodents or scavenge the carcasses of poisoned animals. Long half-lives of anticoagulant rodenticides in the liver suggest limited ability of non-target animals to detoxify the poison.

Coumatetralyl is efficiently absorbed by rodents following oral exposure, with accumulation of residues in the liver. Residues are excreted slowly, primarily via the urine and to a smaller extent via faeces. The half-lives of residues in the liver of rodents ranged from 16-55 days. A similar rate of metabolism was observed in red deer (liver DT₅₀ 19 days). Total residue Bioconcentration Factor (BCF) for coumatetralyl in whole fish was 11x. Residues are depurated quickly with a half-life of approximately 15 hours (Grau 1992c).

Diphacinone is not readily absorbed by rodents following oral exposure with relatively rapid excretion of residues, primarily via the faeces and to a smaller extent via urine. The half-life of diphacinone in the liver of rats was 3.0 days. Slower metabolism was observed in other mammals with liver half-lives ranging from 6.0 days in red deer to >90 days in cattle. Metabolism rates in birds varied with liver half-lives ranging 2.5 days in kestrels to 29 days in screech owls. The BCF values of diphacinone in fish were 10x in the muscle and 80x in the viscera; some 70% of the muscle residues and 80% of the visceral residues were eliminated during 14 days of depuration (Ells 1976).

Warfarin is efficiently absorbed by rodents following oral exposure with wide distribution of residues, the liver being the organ with greatest affinity. The half-lives of warfarin in the liver of rodents ranged from 26-67 days. Metabolism rates in birds varied with owls having the lowest rates of metabolism (Watanabe *et al.* 2010).

Brodifacoum is efficiently absorbed by rodents following oral exposure with wide distribution of residues, the liver being the organ with greatest affinity. The half-lives of brodifacoum in the liver of rodents ranged from 114-307 days. Rates of metabolism were similarly long in other animals such as possums and sheep (liver DT₅₀ >250 days) and kestrels (liver DT₅₀ >50 days). Bait-eating slugs also accumulated brodifacoum residues which were rapidly eliminated post exposure (DT₅₀ 2.5 days).

Bromadiolone is efficiently absorbed by rodents following oral exposure with the potential for bioaccumulation in the liver. The half-lives of bromadiolone in the livers of rodents ranged from 28 days (mouse) to 318 days (rat). Rates of metabolism were similarly long in other animals such as sheep (liver DT₅₀ 256 days). Bait-eating slugs also accumulated bromadiolone residues which were rapidly eliminated post exposure (DT₅₀ 1.9 days). In a translocation study, plant uptake of bromadiolone from the soil was negligible (Askham 1986).

Difenacoum is efficiently absorbed by rodents following oral exposure with wide distribution of residues, the liver being the organ with greatest affinity. The half-lives of difenacoum in the livers of rodents ranged from 62-120 days. The whole-carcass residue concentrations of difenacoum in highly resistant rats are not considerably higher than those in susceptible rats (Atterby *et al.* 2005). The quantitative structure–activity relationship (QSAR) estimation of the fish BCF for difenacoum was 9010 L/kg based on the estimated log P_{ow} of 7.6 (Anon 2004). The experimentally derived growth corrected kinetic BCF of 1100 L/kg in fish was significantly lower than the QSAR

estimated value (Sacker 2004). The growth-corrected elimination half-life was 5 days. The QSAR estimation of the BCF for difenacoum in earthworms was 477729 L/kg based on the estimated log Pow of 7.6 (Anon 2004), which indicates a high potential for bioconcentration in soil macro-organisms.

The half-life of difethialone in the liver of the mouse was 29 days.

Flocoumafen is efficiently absorbed by rodents following oral exposure with wide distribution of residues, the liver being the organ with greatest affinity. The half-life of flocoumafen in the livers of rodents ranged from 94-220 days. Slower metabolism was observed in other animals with liver half-lives ranging >100 days in quail to >300 days in dogs. The experimentally derived steady state BCF of flocoumafen in fish was 9000 L/kg, while the kinetic BCF was 24300 L/kg (Wenzel 2011). The estimated depuration half-life was 38 days.

Monitoring data on anticoagulant rodenticide residues are available from Australia and overseas, all of which have been considered in a weight-of-evidence assessment (see Appendix A for a full listing of available data on each chemical). Use patterns and bait concentrations are broadly similar worldwide, and several overseas studies have examined the effectiveness of protective measures designed to reduce exposure in non-target species. Misuse of anticoagulant rodenticides is commonly suspected (see consideration of adverse incidents in section 3.2.1), making it difficult to determine whether residues detected in non-target species arise from use in accordance with the approved label directions or otherwise. Nevertheless, the frequent detection of residues in the wider environment underscores the need for stronger control measures to limit wildlife exposure. Evidence suggests that restricting user access to one SGAR for outdoor use reduced wildlife exposure; however, these gains appeared to be negated by the availability of another SGAR chemical used for the same purpose (e.g., Elliott *et al.* 2022).

Few monitoring studies have investigated the presence of anticoagulant rodenticides in fish. Concentrations of FGAR liver residues in fish in bioaccumulation ponds of municipal wastewater treatment plants reached up to 1.6 µg/kg (coumatetralyl) (Regnery *et al.* 2019). SGAR exposure of fish reached the wider environment with residues detected in livers of fish at relatively high frequencies in receiving streams of municipal wastewater treatment plants with concentrations up to 30 µg/kg (brodifacoum) (Regnery *et al.* 2020).

Some studies have reported residues in terrestrial invertebrates (such as insects and slugs) collected from baited areas (up to 390 µg/kg diphacinone and 860 µg/kg brodifacoum). A relatively high frequency (17%) of amphibians collected from mortality events in the northeast coast of NSW and around the Sydney region had detectable levels of brodifacoum, with liver concentrations reaching up to 1000 µg/kg (Rowley *et al.* 2024). These observations support the conclusion that terrestrial invertebrates provide a viable secondary exposure pathway for terrestrial wildlife.

Residue burdens in rodents increase with the amount of anticoagulant eaten, and rodents with constant access to bait tend to consume an amount greater than the effective lethal dose (Fisher *et al.* 2004). Concentrations of FGAR residues in rodents from baited areas (up to 640 µg/kg diphacinone) tended to be lower than SGAR residues (up to 4260 µg/kg bromadiolone).

Among potential rodent-eating species in Australia, snakes, lizards, quolls, Tasmanian devils, and many raptors show evidence of secondary exposure to anticoagulant rodenticides in urban and agricultural areas. Detections of SGAR liver residues were relatively frequent with concentrations up to 655 µg/kg (brodifacoum) in quolls; 162 µg/kg (brodifacoum) in Tasmanian devils; 8114 µg/kg (bromadiolone) in raptors; and 700 µg/kg (bromadiolone) in reptiles. The proportion of animals containing anticoagulant residues correlates positively with usage (e.g., Newton

et al. 1997). Given these detections were from individuals collected opportunistically (e.g., as roadkill or in tissues donated by park rangers/wildlife care centres), it is evident that some wildlife carry a residue burden of anticoagulant rodenticides that could accumulate to levels sufficient to cause morbidity or directly contribute to mortality, either alone or in combination with other factors.

In Australia, primary exposure to SGAR baits is also evident in possums, with liver concentrations up to 186,038 µg/kg (bromadiolone), while FGARs have been infrequently detected in possums (Scammell *et al.* 2024, WHA 2022). Scavenging birds such as ravens, crows and magpies, or bandicoots in sugarcane also show evidence of anticoagulant rodenticide exposure, however, the exposure pathways are not certain (may be primary or secondary pathways or a combination of these). There are a few confirmed cases of primary exposure of birds via approved use of anticoagulant rodenticides globally; however, these appear to be relatively infrequent incidents.

3.2 Effects on non-target species

3.2.1 Effects on terrestrial vertebrates

The use of rodenticides is a potential general hazard to non-target mammals and birds. Since birds, mammals and other vertebrates (e.g., reptiles, amphibians and fish) share the same blood clotting mechanism as rodents, they are all vulnerable to the toxic effects of anticoagulants (Smith & Shore 2015).

Coumatetralyl has high toxicity to rodents by gavage administration (rat LD₅₀ 15 mg/kg bw) and dietary exposure (lowest LDD₅₀ 0.53 mg/kg bw/d). No behavioural avoidance was observed in the available studies. Secondary poisoning studies on rats, cats and ferrets suggest that mortality is possible if they consume prey with high body burdens. Coumatetralyl had low toxicity by gavage administration to birds at the highest tested doses (lowest LD₅₀ >37 mg/kg bw in chickens and doves) but had high toxicity by dietary exposure to a passerine species (lowest LDD₅₀ 38 mg/kg bw/d in sparrows). A 0.375 g/kg paste formulation of coumatetralyl was not palatable to chickens and was avoided. Following long-term exposure to coumatetralyl in reproductive toxicity tests, parental mortality due to internal bleeding was observed in birds at dietary concentrations as low as 60 mg/kg feed (NOEC 20 mg/kg food in quail). Secondary poisoning studies on hawks, owls, and woodhens suggest that mortality is unlikely if they consume poisoned animals.

Diphacinone has high toxicity by gavage administration to rodents (rat LD₅₀ 1.9 mg/kg bw) and non-rodents (ferret LD₅₀ 11 mg/kg bw). Diphacinone has low toxicity to birds by gavage administration (lowest LD₅₀ 3158 mg/kg bw in mallard) and moderate toxicity by dietary administration (lowest LC₅₀ 905 mg/kg food in mallard). A secondary poisoning study on owls suggests that mortality is unlikely if they consume poisoned animals.

Warfarin has high toxicity to rodents (lowest LD₅₀ 3.0 mg/kg bw in rats) and moderate toxicity to non-rodents (lowest LD₅₀ 200 mg/kg bw in dogs) by gavage administration. Warfarin had high toxicity to mink by dietary exposure (LC₅₀ 12 mg/kg food). Secondary poisoning studies on minks and weasels suggest that mortality is possible if they consume animals with high body burdens. Warfarin has low toxicity to birds by gavage administration (chicken LD₅₀ >1000 mg/kg bw). A secondary poisoning study on owls suggests that mortality is unlikely if they consume poisoned animals.

Brodifacoum has high toxicity by gavage administration to rodents (rat LD₅₀ 0.27 mg/kg bw) and non-rodents (lowest LD₅₀ 0.20 mg/kg in rabbits). Brodifacoum has high toxicity to birds by gavage administration (lowest LD₅₀ 0.31 mg/kg bw in mallard) and by dietary exposure (lowest LC₅₀ 1.6 mg/kg food in gulls). Brodifacoum can take a

few days to cause death in birds (Godfrey 1986). Sequential exposures may increase the toxicity of subsequent anticoagulant exposures (Rattner *et al.* 2020). Secondary poisoning studies on owls suggest that mortality is possible if they consume animals with high body burdens.

Bromadiolone has high toxicity by gavage administration to rodents (rat LD₅₀ 1.3 mg/kg bw) and non-rodents (lowest dog LD₅₀ 8.1 mg/kg bw), and by dietary exposure of ferrets (LC₅₀ 9.8 mg/kg food). Following oral administration of bromadiolone to rabbits for 21 days in a teratology study, maternal bleeding was recorded around body orifices in the lowest dose group of 2.0 µg/kg bw/d (Druga 2004). An earlier study noted metrorrhagia at 8.0 µg/kg bw/d following 12 days of oral administration but not at the lower dose (NOAEL 4.0 µg/kg bw/d, Virat 1981). Bromadiolone has moderate toxicity to birds by gavage administration (lowest LD₅₀ 134 mg/kg bw in quail), but it had high toxicity by dietary exposure (quail LDD₅₀ 8.3 mg/kg bw/d). Following long-term exposure to bromadiolone in reproductive toxicity tests, decreased numbers of 14-day-old surviving chicks was observed in birds at drinking water concentrations as low as 0.55 mg/L (NOEC 0.26 mg/L in quail). Secondary poisoning studies on owls suggest that mortality is possible if they consume animals with high body burdens.

Difenacoum has high toxicity by gavage administration to rodents (lowest LD₅₀ 0.70 mg/kg bw) and non-rodents (lowest LD₅₀ 50 mg/kg bw in dogs). Following long-term exposure to difenacoum in reproductive toxicity tests, some indications of possible effects on ovarian function of rats were observed in the lowest dose group of 10 µg/kg bw/d (Szakonyi 2004b). Difenacoum has high toxicity to birds by gavage administration (lowest LD₅₀ 50 mg/kg bw in chickens) and by dietary exposure (lowest LC₅₀ 1.4 mg/kg food in quail). Following long-term exposure to difenacoum in reproductive toxicity tests, no adverse effects were observed in birds at the highest tested dietary concentration (NOEL 0.011 mg/kg bw/d in quail). Decreased numbers of 14-day-old surviving chicks were observed in birds exposed to drinking water concentrations as low as 0.63 mg/L (NOEC 0.31 mg/L in quail). Secondary poisoning studies on owls suggest that mortality is possible if they consume animals with high body burdens.

Difethialone has high toxicity to rodents by gavage administration (rat LD₅₀ >0.13 mg/kg bw) and low toxicity to ferrets by dietary exposure (LDD₅₀ 760 mg/kg bw/d). Difethialone has high toxicity to birds by gavage administration (lowest LD₅₀ 0.26 mg/kg bw in quail) and by dietary exposure (lowest LC₅₀ 0.56 mg/kg food in quail). Secondary poisoning studies on owls suggest that mortality is possible if they consume animals with high body burdens.

Floucoumafen has high toxicity to rodents by gavage administration (rat LD₅₀ 0.13 mg/kg bw). Flocoumafen has high toxicity to birds by gavage administration (mallard LD₅₀ 24 mg/kg bw) and by dietary exposure (lowest LDD₅₀ 2.7 mg/kg bw/d in mallards). Secondary poisoning studies on owls suggest that mortality is possible if they consume animals with high body burdens.

Joermann (1998) completed an extensive review of secondary poisoning studies and noted mortality of mammals occurred after feeding periods of 3 days onwards, with no clear distinction between first and second-generation substances. In birds, it was noted that FGARs caused the death of an experimental animal only in one instance (barn owl feeding on coumatetrayl-poisoned rats). Nevertheless, several authors reported effects on blood clotting and internal hematomas. In contrast, SGARs caused mortality in birds after just a few days of feeding and in extreme cases even after 1 day. Within the SGARs, the hazard potential could be differentiated further with bromadiolone and difenacoum showing a lower secondary poisoning potential than brodifacoum and flocoumafen.

Expected toxicity thresholds at 20% probability of coagulopathy for raptors with exposure to total SGAR were estimated to be 8.2 µg/kg for accipiters, 7.9 µg/kg for falcons, 14 µg/kg for true owls, and 0.32 µg/kg for barn owls (Elliott *et al.* 2024; including data from Stone *et al.* 1999, Thomas *et al.* 2011). Compound-specific values for the four raptor families combined were 6.6 µg/kg for brodifacoum, 11 µg/kg for bromadiolone, and 5.3 µg/kg for difethialone.

Reptiles are generally thought to have a high tolerance to anticoagulant rodenticides (Lohr & Davis 2018, Mauldin *et al.* 2020). Geckos were found to contain brodifacoum residues after rat control operations and several anecdotal reports have reported lethal poisoning of geckos from use of anticoagulant rodenticides (Lohr & Davis 2018). Turtles and boas exhibited a relative insensitivity to diphacinone and brodifacoum, while lizards appeared to be somewhat more sensitive to these compounds (Mauldin *et al.* 2020). Coumatetralyl, diphacinone, and brodifacoum had low toxicity to fence lizards (Weir *et al.* 2016). The lowest lethal doses of diphacinone and warfarin to the brown tree snake were 10 and 40 mg/kg bw, respectively (Brookes *et al.* 1998). A secondary poisoning study on rattlesnakes suggests that mortality is unlikely if they consume poisoned animals.

Many accounts of non-target anticoagulant rodenticide toxicity in Australian wildlife appear in the published literature and have been summarised by Lohr & Davis (2018). All reports available to the APVMA that are attributed to approved uses or unspecified exposures worldwide are summarised in Appendix A (Table 90, Table 100, Table 106, Table 112, Table 122, Table 131 and Table 147). Confirmed cases of misuse and abuse are excluded from this table, noting misuse or abuse may still be a contributor to observed incidents of unspecified exposures. Several adverse incidents in wildlife have been documented following rodent eradication and ecological restoration programmes on islands or National Parks in Australia and overseas. (reports summarised in Appendix A, Table 113) While consideration of off-label uses are outside of the scope of this reconsideration they do provide some insight into the movement of anticoagulant rodenticides through the trophic levels.

Various wild raptors (5 grey goshawk, 2 brown goshawk, 1 collared sparrowhawk, 1 brown falcon, 12 masked owl, 6 Tasmanian boobook) were found with classic symptoms of anticoagulant rodenticide poisoning around Hobart, Tasmania between 2004 and 2016 (Mooney 2017).

Primary poisoning from the use of anticoagulant rodenticides was suspected in several ringtail and brushtail possum events in various regions across Australia spanning 2016 to 2020 (Grillo *et al.* 2016, WHA 2022a). Events attributed to anticoagulant poisoning were also recorded in 8 other mammalian species (antechinus, bandicoots, gliders, native rats), 25 species of birds (including raptors, songbirds, parrots, gulls, ibis, kookaburra, frogmouths), 3 species of reptiles (carpet python, brown snake, shingleback lizard), and 1 amphibian (WHA 2022a, 2022b).

While most of the primary poisoning events with birds are likely attributed to misuse (e.g., corellas, gulls, starlings, galahs), given the use restrictions currently in place to mitigate primary poisoning risks to birds, secondary poisoning events from on-label uses of anticoagulant rodenticides cannot be ruled out. In all cases, brodifacoum was the most common anticoagulant detected when liver samples were analysed.

Secondary poisoning from the use of brodifacoum baits was determined to be a possible contributor to the severe population declines of owls that commonly feed on rodent pests in sugarcane growing regions of Queensland over a 10-year period (Thomas & Kutt 1997, Young & de Lai 1997). Although brodifacoum is no longer registered for use in sugarcane, this research demonstrates a clear exposure pathway for raptors when rodenticides are used in open field situations in Australia.

Anticoagulants act slowly, with the onset of symptoms delayed, to prevent target rodents from becoming bait shy. This delayed action, combined with the wide hunting ranges of predators, makes it difficult to identify the precise source(s) of rodenticide exposure. Based on the species involved and the level of residues present, Barrett *et al.* (2003) concluded that rodent control operations were the most likely cause of incidents involving anticoagulant rodenticides in 2002 in the UK. Similar conclusions were made in subsequent years (e.g., Barrett *et al.* 2007). Although the number of poisonings reported globally per year may appear low, these figures represent only detected and confirmed cases. The true number of poisonings and their impact on wildlife populations are not known. Accordingly, regardless of the uncertainties surrounding incidents, strengthening control measures to reduce exposure of Australian wildlife is a prudent course of action.

No data are available on the effects of anticoagulant rodenticides on non-target terrestrial plants.

A listing of available data on the effects of each chemical on terrestrial vertebrates is tabulated in Appendix A.

3.2.2 Effects on other non-target species

Coumatetralyl has moderate toxicity to fish (LC₅₀ 53 mg/L) and low toxicity to aquatic invertebrates and algae at the highest tested concentrations (EC₅₀ >14 mg/L and E_rC₅₀ >18 mg/L, respectively). Following long-term exposure to coumatetralyl, the lowest lethal concentration to fish was 0.016 mg/L, with no dose-response relationship or other adverse effect observed (NOEC 0.0050 mg/L), while reduced reproduction of aquatic invertebrates was observed at concentrations as low as 0.32 mg/L (NOEC 0.10 mg/L). Coumatetralyl has high toxicity to bees by contact exposure (LD₅₀ 0.63 µg/bee, *Apis mellifera*). Coumatetralyl has low toxicity to soil macro-organisms such as earthworms (lowest LC₅₀ 225 mg/kg dry soil, *Eisenia fetida*). Coumatetralyl was shown to inhibit bacterial activity in an activated sludge inhibition test at relatively high concentrations (EC₅₀ 4210 mg/L).

Diphacinone has moderate toxicity to fish (lowest LC₅₀ 2.1 mg/L).

Brodifacoum has high toxicity to fish (lowest LC₅₀ 0.026 mg/L), aquatic invertebrates (lowest EC₅₀ 0.25 mg/L, water flea), and algae (E_rC₅₀ 0.040 mg/L, green algae). In the published literature, observations during laboratory studies and baiting programs with brodifacoum noted that terrestrial arthropods (e.g., cockroaches, woodlice, ants, etc.) feed on bait pellets with no apparent effect (Brooke *et al.* 2013, Masuda *et al.* 2014, Pitt *et al.* 2015). Brodifacoum has low toxicity to earthworms (LC_{50corr} >497 mg/kg dry soil, *Eisenia fetida*). Brodifacoum did not inhibit bacterial activity at the highest tested concentration, which was limited by the solubility of the test substance.

Bromadiolone has moderate toxicity to fish (lowest LC₅₀ 2.9 mg/L), aquatic invertebrates (lowest EC₅₀ 2.0 mg/L, water flea), and algae (lowest E_rC₅₀ 1.1 mg/L). Bromadiolone has low toxicity to earthworms (LC_{50corr} >665 mg/kg dry soil, *Eisenia fetida*). Bromadiolone was shown to inhibit bacterial activity in activated sludge inhibition tests at relatively high concentrations (lowest EC₅₀ 32 mg/L).

Difenacoum has high toxicity to fish (lowest LC₅₀ 0.064 mg/L), aquatic invertebrates (lowest EC₅₀ 0.52 mg/L), and algae (lowest E_rC₅₀ 0.51 mg/L). Difenacoum has low toxicity to earthworms (LC_{50corr} >497 mg/kg dry soil, *Eisenia fetida*). Difenacoum did not inhibit bacterial activity at the highest tested concentration, which was limited by the solubility of the test substance.

Difethialone has high toxicity to fish (lowest LC₅₀ 0.051 mg/L) and aquatic invertebrates (EC₅₀ 0.0044 mg/L), and low toxicity to algae at the highest tested concentration (E_rC₅₀ >0.18 mg/L). Difethialone has low toxicity to

earthworms ($LC_{50corr} > 500$ mg/kg dry soil, *Eisenia fetida*). Difethialone did not inhibit bacterial activity at the highest tested concentration, which was limited by the solubility of the test substance.

Flocoumafen has high toxicity to fish (lowest LC_{50} 0.070 mg/L) and aquatic invertebrates (EC_{50} 0.18 mg/L), and low toxicity to algae at the highest tested concentration ($E_rC_{50} > 18$ mg/L). Following long-term exposure to flocoumafen, the reproduction of earthworms was inhibited in a dose-dependent manner (EC_{10corr} 2.8 mg/kg dry soil, *Eisenia fetida*). Flocoumafen did not inhibit bacterial activity at the highest tested concentration, which was limited by the solubility of the test substance.

A listing of available data on the effects of each chemical on terrestrial vertebrates is tabulated in Appendix A.

3.3 Risks to non-target species

3.3.1 Use patterns

In and around buildings

Anticoagulant rodenticides are commonly used to control commensal rodents (i.e. rats and mice) that are, by definition, found in association with people.⁶ Accordingly, all registered products containing anticoagulant rodenticides are approved for use in and around buildings.

'In and around buildings' may capture numerous use scenarios including domestic properties, commercial premises, industrial buildings, agricultural/farm buildings, storehouses, warehouses, grain stores, public service buildings such as schools, hospitals and offices, animal husbandry facilities such as stables, milking parlours, cow sheds, poultry sheds, pig arks, and any building concerned in the storage, preparation, distribution, sale or consumption of food etc. This use situation may also include inside any mode of transport including aeroplanes, trains, ships, commercial and private transport vehicles.

Solid bait formulations (blocks, pastes, pellets, treated grain, and dry bait prepared from powder and a cereal or fruit bait matrix), contact formulations (powder) and liquid formulations of anticoagulant rodenticides are registered for use in and around buildings.

The application rates for the use of solid baits containing the FGARs coumatetralyl, diphacinone and warfarin, and the SGARs brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen, in and around buildings are summarised in Table 46 below. The continued registration of products based on contact formulations (powder) and liquid formulations is not supported in this environment risk assessment; therefore, these products are not considered further (see recommendations under section 3.4.1).

Agricultural crops

Rodent infestations, in particular infestations of rats, may become established away from buildings when food and cover is available (Berny *et al.* 2014). A sub-set of product registrations containing the FGAR coumatetralyl are approved for use in agricultural crops (specifically sugarcane, macadamias, and pineapples) where rats can

⁶ Commensal means 'sharing the table'

become a problem. The associated labels indicate that baits must be placed in bait stations and used as part of a comprehensive rodent control program, which includes encouragement of natural predatory wildlife (e.g., owls), annual field clean-up, weed control, clearance of adjacent scrubland, and strategically timed baiting. Bait stations in these contexts include car tyres covered by corrugated iron; PVC plumbing pipes with a screw topped "T"-piece in the centre; or dishes covered by 4-litre ice-cream containers (with tops secured by wire and pegs, where applicable).

The use of anticoagulant rodenticides in agricultural crops is considered an 'open area' situation. In contrast to uses in and around buildings, open air situations present a considerably higher risk of primary and secondary exposure for non-target wildlife. The reasons for this are multifarious, including, for example, that some non-target species are small enough to gain access to the baits (for example, antechinus, or finches), and collection of poisoned rodents may not be feasible to mitigate exposure of rodent-eating species. Furthermore, invertebrates (i.e., slugs, snails, cockroaches and ants) are known to feed on anticoagulant rodenticides, which further increases the potential for secondary poisoning of invertebrate-eating species.

The application rates of registered coumatetralyl products with approved uses in agricultural crops are summarised in Table 47. The formulations of these products are limited to solid bait formulations (blocks and dry bait prepared from powder and a cereal or fruit bait matrix).

Sewers

A sub-set of product registrations containing the SGARs difethialone and flocoumafen are registered for use in sewers. A sewer system is mainly an underground carriage system of pipes, chambers, and manholes that convey water from the point of production to the point of treatment or discharge. Several types of sewer systems exist in Australia. Sanitary sewers transport sewage from houses and commercial buildings, mainly to sewage treatment plants (STPs). In addition, separate storm drains may be constructed to transport rainwater directly into surface water bodies. Mixed water sewers combine sewage water and storm water in the same pipe/system. Mixed water is generally discharged to STPs, however, in case of heavy weather situations, the combination of both waste- and rainwater can be discharged directly into surface water bodies (i.e. bypassing the STP).

The use of rodenticides in sewer systems can result in significant unintended releases, through spillage during rodenticide application, spillage by rodents during baiting period and disintegration of remaining baits at the end of use phase. There can also be indirect emissions of rodenticides into the sewer system through rat carcasses, urine and faeces.

The labels of difethialone products approved for use in sewer systems specify that, for sewers and storm water drains, baits should be suspended from manholes in a manner that prevents baits from being washed into the water supply. However, no specific critical comments are currently included on the labels of flocoumafen products.

Only solid bait formulations (pastes contained in sachets) containing difethialone and flocoumafen are registered for use in sewers. The application rates of registered products with approved uses in sewers are summarised in Table 47.

Table 46: Use rates in and around buildings

Group	Active constituent	Bait type	Bait concentration (mg a.c./kg)	mg a.c./station for rat control	mg a.c./station for mouse control
FGAR	Coumatetralyl	Sachet/ block/ paste	370	from 11 to 22	from 11 to 22
			400	40	40
		Loose grain/ fruit	357	21	21
			380	23	23
	Diphacinone	Sachet/ block/ paste	50	23	3.0
		Loose grain/ pellets	50	23	3.0
Warfarin	Loose grain/ pellets	250	25	13	
		500	63	13	
SGAR	Brodifacoum	Sachet/ block/ paste	25	from 1.0 to 5.6	from 1.0 to 5.6
			50	from 0.50 to 6.0	from 0.20 to 6.0
		Loose grain/ pellets	50	from 2.0 to 10	from 1.5 to 3.0
	Bromadiolone	Sachet/ block/ paste	25	from 0.75 to 1.1	from 0.25 to 0.38
			50	from 6.0 to 23	from 2.0 to 23
		100	0.40	0.40	
Difenacoum	Sachet/ block/ paste	25	from 0.75 to 5.0	from 0.75 to 1.3	
		50	from 5.0 to 20	from 1.0 to 20	
	Loose grain/ pellets	50	10	1.5	
Difethialone	Sachet/ block/ paste	25	from 1.5 to 4.1	from 1.3 to 1.5	
	Loose grain/ pellets	25	3.8	1.3	

Group	Active constituent	Bait type	Bait concentration (mg a.c./kg)	mg a.c./station for rat control	mg a.c./station for mouse control
	Flocoumafen	Sachet/ block/ paste	50	from 3.8 to 4.0	from 2.0 to 2.3
		Loose grain/ pellets	50	2.3	0.76

Table 47: Use rates in agricultural crops

Group	Active constituent	Bait type	Bait concentration (mg a.c./kg)	mg a.c./station
FGAR	Coumatetralyl	Block	370	22
		Loose grain/ fruit	357	36
			381	38

Table 48: Use rates in sewers

Group	Active constituent	Bait concentration (mg a.c./kg)	mg a.c./station
SGAR	Difethialone	25	2.5
	Flocoumafen	50	3.8

3.3.2 Risks to terrestrial vertebrates

Exposure scenarios

Although outdoor baiting involves protected baiting points (around buildings and in open areas), primary exposure of terrestrial vertebrates cannot be excluded. Species of the same size or smaller than the target rodents may be able to enter the bait stations. Some species may be drawn to the baits and motivated to access the bait station. Furthermore, spilled or expelled baits may be directly consumed. Even if exposed to the elements, baits may retain their activity for an extended period. For instance, field tests conducted over 21 days showed that bromadiolone degraded by 45% in pelleted form and 78% in grain form, under average weather conditions (Poché 1988).

Secondary poisoning via consumption of contaminated rodents can only be ruled out when the rodenticide is used in fully enclosed spaces where poisoned rodents are prevented from moving to outdoor areas or to (parts of) buildings accessible to predators. Furthermore, predatory mammals and birds may enter open buildings, and may hunt in the immediate vicinity of buildings (e.g., parks and gardens). Scavengers may search for food close to buildings. Baiting in open areas greatly expands the exposure potential of non-target species, including to those that are not inclined to hunt or scavenge near humans (Brakes & Smith 2005). Accordingly, it is reasonable to assume that non-target predators may be affected by both indoor or outdoor application of rodenticides.

Even for SGARs, there is a delay between consumption of bait and death of rodents (Lund 1981). This creates that possibility that rodents may consume multiple doses, resulting in even greater accumulation of residues (Littin *et al.* 2000). Poisoned rodents may exhibit behaviours that may make them more susceptible to predation (e.g., slower reaction times, changes in activity patterns) thereby resulting in secondary exposure of predatory animals (Cox & Smith 1992). There is also some evidence that the survival period of rodents may increase following years of continued anticoagulant rodenticide use (Lin *et al.* 2022).

Exposure of owls is of particular concern, as rodents can make up a key component of their diet. House mice comprised the majority of the diet of the barn owl in NSW (Rose 1996) and 41% of biomass of the diet of southern boobook in ACT (Trost *et al.* 2008), while rats comprised at least one-third of the diet of the Norfolk Island morepork (Sperring *et al.* 2024) and were found to constitute a major part of the diet of mainland masked owl at some sites in NSW (Debus 1993; Kavanagh & Murray 1996; Kavanagh 2002). Additionally, other predatory and scavenger vertebrates may also be susceptible to anticoagulant poisoning via consumption of contaminated rodent and non-rodent prey or carcasses.

Incidences of terrestrial invertebrates such as millipedes, slugs and snails consuming anticoagulant baits have also been reported (Alomar *et al.* 2018, Hernandez-Moreno *et al.* 2013, Johnston *et al.* 2005, Pitt *et al.* 2015, Thorsen *et al.* 2000), thereby confirming a secondary exposure pathway for invertebrate-eating wildlife (Dowding *et al.* 2010). Crabs were also observed to consume baits when applied near intertidal areas (Thorsen *et al.* 2000).

Since consumption of baits or poisoned animals can result in death, a quantitative risk assessment for non-target terrestrial vertebrates was not undertaken.

While a definitive causal link between anticoagulant rodenticides and population-level effects in non-target wildlife has not been established, (Rattner *et al.* 2014), the weight of evidence supports the need for risk mitigation measures to reduce exposure to non-target wildlife. For example, of 696 animal adverse incidents recorded by the Australian national electronic Wildlife Health Information System (eWHIS) between 2006 to 2021, 77 (11%) involved suspected anticoagulant poisonings. Further, appreciable mortality even without population level consequences can be unacceptable.

Table 49: Relevant scenarios for assessing non-target primary and secondary poisoning

Scenario	Primary poisoning	Secondary poisoning
In buildings	Not relevant	Relevant only to rodent-eating species
Around buildings	Relevant	Relevant
Bait stations in open areas (agricultural crops)	Relevant	Relevant
Sewers	Not relevant	Relevant only to rodent-eating species

Primary poisoning

Baits are mostly based on cereals, thus granivorous and omnivorous mammals are the potentially affected non-target species. Dogs and possums are omnivorous animals and often become victims of primary poisoning (ECHA 2018, Grillo *et al.* 2016, WHA 2022a). Pigs may gain access to bait stations containing anticoagulant rodenticides (Eason *et al.* 1999). Additional omnivorous species that have been identified in anticoagulant rodenticide poisonings include bandicoots, antechinus and gliders (see section **3.2.1 Effects of terrestrial vertebrates**).

In literature reviews of the toxicity and impacts of brodifacoum on non-target wildlife in New Zealand, authors have noted that birds most at risk from eating cereal-based baits are herbivorous and omnivorous species (e.g., weka, pukeko and saddleback) (Eason & Spurr 1995a, Eason *et al.* 2002). Emerald doves, currawongs, silvereyes and a magpie-lark showed no signs of exposure in non-toxic baiting trials (Wilkinson & Priddel 2007). In contrast, buff-banded rails, blackbirds, mallards, and woodhens showed signs of exposure. Several observations were made of wild birds accessing bait from bait stations during a rodent eradication program on Lord Howe Island (O'Dwyer *et al.* 2024). Buff-banded rails and some of the few remaining free-living woodhens were observed accessing bait by inserting their head into the access tunnel and removing bait from internal bait trays. These two species were also seen eating bait off the ground outside bait stations.

Direct consumption of cereal-based baits by lizards has been observed in island eradication programs (Hoare & Hare 2006a, 2006b, Merton 1987, Wedding *et al.* 2010) and palatability trials (Freeman *et al.* 1996). Bennison *et al.* (2016) used dye tracers to prove that the large carnivorous King's Skink (*Egernia kingii*) had ingested non-toxic baits laid out on islands off the West Australian coast. King's Skinks were subsequently observed consuming toxic baits during a rat eradication program on Penguin Island in Western Australia, despite the use of specially designed bait containers intended to exclude the skinks (Bettink 2015). Others have observed bobtails (*Tiliqua rugosa*) – another large omnivorous skink – inside bait boxes in urban areas (Lohr & Davis 2018). It is also possible the skinks are feeding on the invertebrates within the bait boxes rather than the baits themselves (.e., establishing a potential secondary exposure route). Smaller skinks appear to be at much lower risk of exposure, noting a single delicate skink (*Lampropholis delicata*) showed no evidence of exposure in a non-toxic baiting trial on Lord Howe Island (Wilkinson & Priddel 2007).

It is widely accepted that use of anticoagulant rodenticides poses low risk to the environment when used indoors (e.g., for control of house mice in the home) (Berny *et al.* 2014). When bait was used indoors only, the percentage of trapped non-target small mammals with brodifacoum residues was about 50% lower in comparison to bait application in and around buildings (Walther *et al.* 2021a). Given the natural behaviour of house mice (being closely associated with humans), it is considered that a restriction to 'indoor use only' is reasonable for domestic product uses of anticoagulant rodenticides to mitigate risks of primary poisoning of wildlife. Anticoagulant residues were detected in several ground feeding songbird species when bait was used in and around farm buildings (Walther *et al.* 2021b); however, exposure of songbirds appeared spatially-focused and mostly restricted to the immediate surroundings where the bait was used (less than 20 m distance to the closest bait station), which might limit the transfer to the wider environment (Walther *et al.* 2021b).

Berny *et al.* (2014) also provide recommendations on risk mitigation measures addressing primary poisoning: (1) add a specific dye in baits; (2) add a bittering agent at a standard concentration (e.g., 0.001% denatonium benzoate); (3) survey sites before rodenticide use; and (4) avoid posting information on baiting areas⁷.

With respect to inclusion of a specific dye in baits, Moran (1999) found that pigeons and partridges preferred undyed grains of their favoured seeds (whole-grain oat and sorghum, respectively), but pigeons showed no colour discrimination when only the seeds of a species normally avoided were available. Similarly, the buff-banded rails

⁷ To avoid drawing unwanted attention to the presence of baits and of rodents and potentially increasing the risk of illicit use, the authors advised against posting information / warnings on the presence of toxic substances (Berny *et al.* 2014).

readily consumed un-dyed bait (beige in colour) and red-dyed bait but showed no interest in green-dyed bait (Wilkinson & Priddel 2007). Although species, sex and even individual preferences will modulate the response of birds to colour, there is evidence from the literature that colours in the middle of the visible colour spectrum range are generally better deterrents than other colours. For example, green and yellow are particularly effective colours for discouraging intake of rodenticidal baits and the deterrent effect of the colorant may in some cases be a visual cue coupled with taste-conditioned aversion (Brunner & Coman 1983, Kalmbach & Welch 1946, Marsh 1985, Pank 1976). Conversely, Hartley *et al.* (1999) noted robins, when presented with novel food (cake) showed preference for red, yellow or green food over blue or brown food.

Since visual recognition plays the dominant role for birds in locating food items, the risk of unintended primary exposure of granivorous birds is further mitigated when baits are placed in small quantities directly inside the burrows, bait stations, or bait points covered with objects such as roofing tiles that provide protection. Furthermore, bait point location should be marked for the benefit of the rodent control operative and permit regular monitoring of bait consumption. In all cases, it is imperative that baits are hidden from view and do not attract the attention of seed-eating birds. There remains a possibility that bait grains may become exposed in the open if they are moved or carried out by target rodents. Therefore, baiting should be done at times of year when natural food sources are relatively scarce, which makes it more likely that baits will be either consumed quickly by the target animals or cached more secretly.

With respect to bittering agents, denatonium benzoate is a well-known repellent to cats, dogs, horses and birds and does not change the efficacy of baits against rodents when used at 10 ppm (Kaukeinen & Buckle 1992).

Based on the available information and overseas experiences, it is expected that risks to Australian wildlife can be mitigated in most cases by implementing various best practice strategies to minimise primary (direct) exposure, as well as limiting access to authorised persons or limiting pack sizes available to the general public (see recommendations in section **3.4.2 Supported products and uses**).

Secondary poisoning

A secondary exposure pathway to quolls and Tasmanian devils is clearly demonstrated by available monitoring data (see section **3.1.2 Fate and behaviour in biota**). Pigs may also consume rodents poisoned with anticoagulant rodenticides (Eason *et al.* 1999). In literature reviews of the toxicity and impacts of brodifacoum on non-target wildlife in New Zealand, authors have noted that insectivorous mammal species such as bats were probably least at risk of secondary poisoning relative to predatory and scavenging birds (Eason & Spurr 1995a, Eason *et al.* 2002). In a non-toxic baiting trial on Lord Howe Island (Wilkinson & Priddel 2007), a harp trap was set for five nights on the golf course, and for three in the bait zone to the east of Transit Hill, to catch large forest bats (*Vespadelus darlingtoni*) after baiting. All 21 large forest bats captured showed no signs of exposure to the fluorescent biomarker within the baits.

In literature reviews of the toxicity and impacts of brodifacoum on non-target wildlife in New Zealand, authors have noted that birds most at risk from secondary poisoning are predatory and scavenging species such as wekas, harriers, gulls and morepork (Eason & Spurr 1995a, Eason *et al.* 2002). Insectivorous species were considered least at risk. Kingfishers showed no signs of exposure in non-toxic baiting trials (Wilkinson & Priddel 2007). In contrast, a masked owl (*Tyto novaehollandiae*) showed signs of exposure. Wiens *et al.* (2019) noted anticoagulant exposure of barred owls in California was ubiquitous and did not correlate with proximity to developed or agricultural areas; however, illegal use in older forests was not discounted.

Barn owls (*Tyto alba*) are bird species that almost exclusively prey on rodents. They often nest in houses and artificial nest boxes and hunt close to human settlements or in areas where rodents may be controlled.

Anticoagulant rodenticides were found in more than 50% of the investigated barn owls across Western Germany and the UK (Geduhn *et al.* 2016, Walker *et al.* 2010) and the amount of detected anticoagulant residues rose steadily in the UK from 1980 to 2011 (Walker *et al.* 2013). The barn owl is considered a long-term sentinel in the UK's Predatory Bird Monitoring Scheme (PBMS) (Walker *et al.* 2010). Thus, the barn owl is considered to function as a generic focal species for secondary poisoning of Australian owl species. Food-chain transfer was also clearly demonstrated for sparrowhawks (Walker *et al.* 2015).

Australian kestrels (*Falco cenchroides*) also prey on rodents. They often hunt close to human settlements or in areas where rodents may be controlled. Kestrels are highly affected by anticoagulant rodenticides (Martínez-Padilla *et al.* 2017). Referring to the UK's PBMS (Walker *et al.* 2010), kestrels are considered as species of concern, with a similar diet as the barn owl but, for unknown reasons, with a greater assimilation of residues.

Crows and ravens often nest close to human settlements or in areas where rodents may be controlled. They are scavenging birds that often feed on carrion and are therefore potentially at risk of being poisoned secondarily with rodenticides. In France, researchers killed unpoisoned water voles and showed that carrion crows took two thirds of all the carcasses (Montaz *et al.* 2014).

The house mouse was found to be an important component of the diet of letter-winged and black-shouldered kites, and their numbers were positively correlated with house mouse abundance in cropland and pasture in Queensland (Mathieson *et al.* 1997). House mice comprised 92% of prey items consumed by the black-shouldered kite in the ACT, and was ranked as the most important prey item overall in its diet (Tsang *et al.* 2017). Two kite species in France (including black kite) were also shown to scavenge on carrion given the opportunity (Montaz *et al.* 2014).

A secondary exposure pathway to reptiles has been demonstrated by the available monitoring data (see section **3.1.2 Fate and behaviour in biota**). A small number of suspected anticoagulant rodenticide poisonings have been reported in snakes (carpet python and brown snake) and shingleback lizard in Australia (WHA 2022b). In one off-label island baiting program, sand goanna were observed eating dead or dying rats with evidence of green dye from the bait in their droppings following brodifacoum baiting on the Montebello Islands, WA; however, no dead or moribund goannas were observed (Burbridge 2004). In literature reviews of the toxicity and impacts of brodifacoum on non-target wildlife in New Zealand, authors have noted that insectivorous reptile species such as lizards were least at risk of secondary poisoning relative to predatory and scavenging birds, for example (Eason & Spurr 1995a, Eason *et al.* 2002).

A secondary exposure pathway to amphibians has also been demonstrated by the available monitoring data (see section **3.1.2 Fate and behaviour in biota**). In literature reviews of the toxicity and impacts of brodifacoum on non-target wildlife in New Zealand, authors have noted that amphibian species were probably least at risk of secondary poisoning relative to predatory and scavenging birds (Eason & Spurr 1995a, Eason *et al.* 2002). Anticoagulant poisoning was suspected in one amphibian in Australia (WHA 2022a); however, this appears to be an uncommon occurrence.

Berny *et al.* (2014) provide recommendations on risk mitigation measures addressing secondary poisoning: (1) limit treatment application to 35 days in a first step; (2) provide indicative recommendations for regular visits – to be adapted with local risk assessment; (3) search for and remove dead bodies based on local risk assessment; (4) and remove uneaten baits at the end of the baiting period. However, a number of these risk mitigation measures

had been implemented in Finland since 2011 without success in reducing wide scale secondary exposure of wildlife (Koivisto *et al.* 2018).

The changes in authorisations for anticoagulant rodenticides in the UK commenced in mid-2016 and were accompanied by the development and implementation of an industry-led stewardship scheme in early 2018. The scheme includes⁸ monitoring rodenticide residues in wildlife using barn owls as a sentinel species. Alongside the stewardship scheme, the restriction on indoor use only for brodifacoum, flocoumafen and difethialone was relaxed, allowing their use both indoors and outdoors around buildings. Difenacoum and bromadiolone formulations were the only SGARs with approved uses in open areas and waste dumps.

Relative to baseline levels (Walker *et al.* 2010, 2012, 2013, 2014), there was no detectable general reduction in exposure of barn owls to SGARs one year after full implementation of the scheme (Shore *et al.* 2018). In subsequent years, potential reductions of bromadiolone and difenacoum residues were observed, but not for brodifacoum or total SGARs (Ozaki *et al.* 2022). A similar trend was observed in monitoring of residues in the scavenger species, Red Kite (Ozaki *et al.* 2024). As of January 1, 2025, the use of SGARs will no longer be approved in open areas and waste dumps in the UK.

In Canada, risk mitigation measures for rodenticides have been introduced, prohibiting outdoor use of brodifacoum and difethialone and requiring tamper-resistant bait stations for all outdoor above-ground uses of anticoagulant rodenticides within reach of wildlife (PMRA 2009, 2010). The only anticoagulant rodenticides approved for outdoor use around buildings and structures⁹ were bromadiolone, warfarin, chlorophacinone and diphacinone. Chlorophacinone and diphacinone were also approved for use in landfills and other outdoor areas such as cropland, fields and nurseries. Following full implementation of these measures in 2013 accompanied by strong enforcement action, Elliott *et al.* (2022) reported a decrease in mean concentrations of brodifacoum and difethialone in barred and great horned owls but an increase in bromodialone.

Based on the available information and overseas experiences, a comprehensive and integrated management strategy is necessary to reduce entry of anticoagulant rodenticides into the environment. This strategy must be consistent across the different chemical groups to prevent simply shifting the problem from one type of anticoagulant to another. It is anticipated that risks to Australian wildlife can be mitigated in most cases by implementing various best practice strategies to minimise secondary (indirect) exposure, as well as by limiting access to authorised persons or limiting pack sizes available to the general public (see recommendations in section **3.4.2 Supported products and uses**).

3.3.3 Risks to other non-target species

Exposure of natural aquatic areas due to use of rodenticides in and around buildings and in agricultural crops is considered negligible on the basis that bait is contained in stations and only a small amount of spot contamination around the bait station itself is likely to occur (see also section **3.4 Recommendations**). Aquatic life can be contaminated if baits are applied in intertidal areas (Primus *et al.* 2005) or when baits are placed in areas liable to flooding. For these use patterns, risks of anticoagulant rodenticides to aquatic species are considered acceptable,

⁸ <https://www.thinkwildlife.org/>

⁹ Within 15 meters of buildings/structures, or up to 100 meters from buildings/structures if bait is placed along fence lines in a secured, tamper-resistant bait station.

provided precautionary measures are observed when placing baits to avoid accidental entry into natural aquatic areas and drainage systems.

The use of anticoagulant rodenticides in sewer systems can result in significant releases to surface waters via sewage treatment plants (STPs), through spillage during rodenticide application, spillage by rodents during baiting period and disintegration of remaining baits at the end of use phase. There can also be indirect emissions via the sewer through rat carcasses, urine and faeces. Three difethialone products (66889, 69086, 80386) and 2 flocoumafen products (80663, 90839) have registered uses in sewers, for which risks to aquatic species are determined to be acceptable (Table 53).

Risks of anticoagulant rodenticides to bees are considered acceptable based on the lack of direct and indirect exposure pathways. Risks to other terrestrial arthropods that might feed directly on the baits (e.g., cockroaches, woodlice, ants, etc.) are considered acceptable based on the mode of action and no adverse effects observed in the available studies (see section **3.2.2 Effects on other non-target species**).

For bait stations around buildings or in open areas, direct exposure of soil can occur by spillage during application, refill and disposal processes, as well as transport by rodents. Indirect exposure occurs by rodent carcasses, urine, and faeces. Indirect exposure of soil is also considered possible for indoor bait stations; however, indirect exposure in the open area scenario is considered negligible since the area inhabited by rodents is too large to cause significant indirect emissions.

Risks of coumatetralyl and the SGARs to soil organisms were determined to be acceptable for worst-case scenarios resulting in the highest localised soil concentrations (Table 57). No data are available on the toxicity of diphacinone and warfarin to soil organisms; however, since only spot contamination is likely to occur in each case (i.e., only a small soil volume around a bait box is likely to be contaminated), overall exposure of soil may be considered insignificant. Therefore, risks of diphacinone and warfarin to soil organisms are also considered to be acceptable.

Risks of anticoagulant rodenticides to terrestrial plants are considered acceptable based on the mode of action, method of application, low bioavailability in soil, and a lack of a similar blood-clotting mechanism in plants.

Only use of difethialone and flocoumafen in sewers are considered to result in potential exposure of STPs. Risks to biological methods of sewage treatment for this use pattern were determined to be acceptable (Table 59). For uses in and around buildings and in agricultural crops, risks of anticoagulant rodenticides are considered acceptable provided precautionary measures are observed in the placement of baits to avoid accidental entry into drainage systems.

Table 50: Relevant scenarios for exposure of aquatic species

Scenario	Surface water exposure
In buildings	Not relevant
Around buildings	Not relevant
Bait stations in open areas (agricultural crops)	Not relevant

Scenario	Surface water exposure
Sewers	Relevant

Table 51: Default input parameters for predicting surface water concentrations (use in sewers)¹⁰

Parameter		Value	Note
Fraction of product replenished		[-] 0.33	
Number of cesspools treated	$N_{\text{cesspools}}$	[-] 200	
Number of emission days	T_{emission}	[-] 7	
Fraction released directly	$F_{\text{released-D,sewer}}$	[-] 0.4	
Fraction released indirectly	$F_{\text{released-ID,sewer}}$	[-] 0.6	Assumes no rat metabolism
Effluent discharge rate of sewer	$\text{EFFLUENT}_{\text{water}}$	L/d 2.0×10 ⁶ 0.6×10 ⁶	Mixed water sewer Rainwater sewer
Concentration of suspended matter in surface water	$\text{SUSP}_{\text{water}}$	mg/L 15	
Weight fraction organic carbon in suspended matter	Foc_{susp}	kg/kg 0.1	
Dilution factor	DILUTION	[-] 10	

Table 52: Predicted surface water concentrations (use in sewers)

Active constituent	Parameter		Mixed water sewer	Rainwater sewer
Difethialone	Amount applied in one cesspool	Q_{ac} kg a.c.	2.5×10 ⁻⁶	2.5×10 ⁻⁶
	Organic-carbon normalised partition coefficient	K_{oc} L/kg	1.6×10 ⁹	1.6×10 ⁹
	Local water concentration	PEC µg/L	4.9×10 ⁻⁷	1.6×10 ⁻⁶
Flocoumafen	Amount applied in one cesspool	Q_{ac} g a.c.	3.8×10 ⁻⁶	3.8×10 ⁻⁶

¹⁰ According to ECHA (European Chemicals Agency) 2018. PT 14 - Rodenticides

Active constituent	Parameter		Mixed water sewer	Rainwater sewer
	Organic-carbon normalised partition coefficient	Koc L/kg	101684	101684
	Local water concentration	PEC µg/L	0.0016	0.0052

Q_{ac} values from Table 48; Koc from Table 135 (difethialone) and Table 143 (flocoumafen) in Appendix A

$$PEC = Q_{ac} * F_{rep} * N_{cesspools} * (F_{released-D,sewer} + F_{released-ID,sewer}) * 10^9 / (T_{emission} * EFFLUENT_{water} * (1 + (Koc * Foc_{susp}) * SUSP_{water} * 10^{-6}) * DILUTION)$$

Table 53: Risks of anticoagulant rodenticides to aquatic species

Group	Active constituent	Worst-case scenario	PEC (mg/L)	RAL (mg/L)	RQ
FGAR	Coumatetralyl	In and around buildings; agricultural crops	Acceptable risk due to negligible exposure		
	Diphacinone	In and around buildings	Acceptable risk due to negligible exposure		
	Warfarin	In and around buildings	Acceptable risk due to negligible exposure		
SGAR	Brodifacoum	In and around buildings	Acceptable risk due to negligible exposure		
	Bromadiolone	In and around buildings	Acceptable risk due to negligible exposure		
	Difenacoum	In and around buildings	Acceptable risk due to negligible exposure		
	Difethialone	Rainwater sewer systems	1.6×10^{-6}	0.00044	<0.01
	Flocoumafen	Rainwater sewer systems	0.0052	0.0070	0.74

PEC (predicted environmental concentration) in water for worst-case sewer scenario (rainwater sewer) from Table 52

RAL (regulatory acceptable level) based on

Daphnid EC_{50} 0.044 mg/L / assessment factor 10 for difethialone (Table 139 in Appendix A)

Fish LC_{50} 0.070 mg/L / assessment factor 10 for flocoumafen (Table 148 in Appendix A)

RQ (risk quotient) = PEC / RAL, where acceptable RQ ≤ 1

Table 54: Relevant scenarios for exposure of soil organisms

Scenario	Soil exposure
In buildings	Relevant (indirect pathway via rodent carcasses, urine and faeces)
Around buildings	Relevant (direct and indirect pathways; unpaved ground assumed)
Bait stations in open areas (agricultural crops)	Relevant (direct pathway via spillage and rodent transport)
Sewers	Not relevant

Table 55: Default input parameters for predicting soil concentrations¹¹

Parameter		Value	Note
Use in buildings			
Number of application sites	N_{sites}	[-]	22
Number of applications (initial baiting + refillings)	N_{appl}	[-]	5
Fraction released indirectly to soil	$F_{\text{released-ID,soil}}$	[-]	0.5 Assumes no rat metabolism
Soil area exposed indirectly	$AREA_{\text{exposed-ID}}$	m ²	1800
Depth of exposed soil	$DEPTH_{\text{soil}}$	m	0.05
Bulk density of dry soil	RHO_{soil}	kg _{ww} /m ³	1500
Use around buildings on unpaved ground			
Number of application sites	N_{sites}	[-]	10 Rat control
			20 Mouse control
Number of applications (initial baiting + refillings)	N_{appl}	[-]	5
Fraction released directly to soil	$F_{\text{released-D,soil}}$	[-]	0.01 Sachet/block/paste
			0.05 Loose grain/fruit/pellets
Fraction released indirectly to soil	$F_{\text{released-ID,soil}}$	[-]	0.9 Assumes no rat metabolism

¹¹ According to ECHA (European Chemicals Agency) 2018. PT 14 - Rodenticides

Parameter		Value	Note
Soil area exposed directly	$AREA_{\text{exposed-D}}$ m ²	0.09	
Soil area exposed indirectly	$AREA_{\text{exposed-ID}}$ m ²	550	
Depth of exposed soil	$DEPTH_{\text{soil}}$ m	0.05	
Bulk density of dry soil	RHO_{soil} kg _{ww} /m ³	1500	
Use in open areas (agricultural crops)			
Number of applications (initial baiting + refilling's)	N_{appl} [-]	5	
Fraction released directly to soil	$F_{\text{released-D,soil}}$ [-]	0.01	Block
		0.05	Loose grain/fruit
Soil area exposed directly	$AREA_{\text{exposed-D}}$ m ²	0.14	
Depth of exposed soil	$DEPTH_{\text{soil}}$ m	0.05	
Bulk density of dry soil	RHO_{soil} kg _{ww} /m ³	1500	

Table 56: Predicted soil concentrations

Active constituent	Scenario	Parameter		Rat control	Mouse control	Bait type
Coumatetralyl	In and around buildings	Amount used at each refill for one bait station	Q_{ac} g a.c.	0.074	0.040	Sachet/block/paste
				0.023	0.023	Loose grain/fruit
		Local soil concentration (in buildings)	PEC mg/kg ds	0.016	0.016	Sachet/block/paste
			0.0094	0.0094	Loose grain/fruit	
	Open areas (agricultural crops)	Amount used at each refill for one bait station	Q_{ac} g a.c.	0.022	n/a	Block
				0.038	n/a	Loose grain/fruit
Local soil concentration		PEC mg/kg ds	0.11	n/a	Block	
	0.90		n/a	Loose grain/fruit		

Active constituent	Scenario	Parameter		Rat control	Mouse control	Bait type
Diphacinone	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.023	0.003	Sachet/block/paste
				0.023	0.003	Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.0094	0.0012	Sachet/block/paste
			0.0094	0.0012	Loose grain/pellets	
		Local soil concentration (around buildings)	PEC mg/kg ds	0.20	0.029	Sachet/block/paste
				0.88	0.12	Loose grain/pellets
Warfarin	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.063	0.013	Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.026	0.0053	Loose grain/pellets
		Local soil concentration (around buildings)	PEC mg/kg ds	2.4	0.51	Loose grain/pellets
Brodifacoum	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.006	0.006	Sachet/block/paste
				0.010	0.003	Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.0024	0.0024	Sachet/block/paste
			0.0041	0.0012	Loose grain/pellets	
		Local soil concentration (around buildings)	PEC mg/kg ds	0.051	0.058	Sachet/block/paste
				0.38	0.12	Loose grain/pellets
Bromadiolone	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.023	0.023	Sachet/block/paste
				0.025	0.025	Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.0094	0.0094	Sachet/block/paste
			0.010	0.010	Loose grain/pellets	
		Local soil concentration (around buildings)	PEC mg/kg ds	0.20	0.22	Sachet/block/paste
				0.95	0.98	Loose grain/pellets

Active constituent	Scenario	Parameter		Rat control	Mouse control	Bait type
Difenacoum	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.02 0.01	0.02 0.0015	Sachet/block/paste Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.0082 0.0041	0.0082 0.00061	Sachet/block/paste Loose grain/pellets
		Local soil concentration (around buildings)	PEC mg/kg ds	0.17 0.38	0.19 0.059	Sachet/block/paste Loose grain/pellets
Difethialone	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.0041 0.0038	0.0015 0.0015	Sachet/block/paste Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.0017 0.0016	0.00061 0.00061	Sachet/block/paste Loose grain/pellets
		Local soil concentration (around buildings)	PEC mg/kg ds	0.035 0.15	0.014 0.059	Sachet/block/paste Loose grain/pellets
Flocoumafen	In and around buildings	Amount used at each refill for one bait station	Q _{ac} g a.c.	0.0040 0.0023	0.0023 0.00076	Sachet/block/paste Loose grain/pellets
		Local soil concentration (in buildings)	PEC mg/kg ds	0.0016 0.00094	0.00094 0.00031	Sachet/block/paste Loose grain/pellets
		Local soil concentration (around buildings)	PEC mg/kg ds	0.034 0.088	0.022 0.030	Sachet/block/paste Loose grain/pellets

Q_{ac} values from Table 46 and Table 47

Use in buildings PEC = $Q_{ac} * N_{sites} * N_{appl} * F_{released-ID,soil} * 10^3 / (AREA_{exposed-ID} * DEPTH_{soil} * RHO_{soil})$

Around buildings PEC = $(Q_{ac} * N_{appl} * F_{released-D,soil} * 10^3 / (AREA_{exposed-D} * DEPTH_{soil} * RHO_{soil})) + (Q_{ac} * N_{sites} * N_{appl} * F_{released-ID,soil} * 10^3 / (AREA_{exposed-ID} * DEPTH_{soil} * RHO_{soil}))$

Open areas PEC = $Q_{ac} * N_{appl} * F_{released-D,soil} * 10^3 / (AREA_{exposed-D} * DEPTH_{soil} * RHO_{soil})$

Table 57: Risks of anticoagulant rodenticides to soil organisms

Group	Active constituent	Worst-case scenario	PEC (mg/kg dry soil)	RAL (mg/kg dry soil)	RQ
FGAR	Coumatetralyl	Mouse control using loose grain/fruit bait in stations around buildings	0.90	23	0.04
	Diphacinone	Rat control using loose grain/pellet bait in stations around buildings	0.88	No effects data	
	Warfarin	Rat control using loose grain/pellet bait in stations around buildings	2.4	No effects data	
SGAR	Brodifacoum	Rat control using loose grain/pellet bait in stations around buildings	0.38	50	<0.01
	Bromadiolone	Mouse control using loose grain/pellet bait in stations around buildings	0.98	67	0.01
	Difenacoum	Rat control using loose grain/pellet bait in stations around buildings	0.38	50	<0.01
	Difethialone	Rat control using loose grain/pellet bait in stations around buildings	0.15	50	<0.01
	Flocoumafen	Rat control using loose grain/pellet bait in stations around buildings	0.088	2.8	0.03

PEC (predicted environmental concentration) in soil for each worst-case scenario from Table 57

RAL (regulatory acceptable level) based on earthworm LC₅₀ / assessment factor 10, where LC₅₀ values from Table 93 (coumatetralyl), Table 115 (brodifacoum), Table 124 (bromadiolone), Table 133 (difenacoum), Table 140 (difethialone), and Table 149 (flocoumafen) in Appendix A

RQ (risk quotient) = PEC / RAL, where acceptable RQ ≤ 1

Table 58: Relevant scenarios for exposure of sewage treatment plant (STP)¹²

Scenario	STP exposure
In buildings	Not relevant
Around buildings	Not relevant

¹² According to ECHA (European Chemicals Agency) 2018. PT 14 - Rodenticides emission estimations

Scenario	STP exposure
Bait stations in open areas (agricultural crops)	Not relevant
Sewers	Relevant

Table 59: Risks of anticoagulant rodenticides to biological methods of sewage treatment

Group	Active constituent	Worst-case scenario	PEC (mg/L)	RAL (mg/L)	RQ
FGAR	Coumatetralyl	In and around buildings; agricultural crops	Acceptable risk due to negligible exposure		
	Diphacinone	In and around buildings	Acceptable risk due to negligible exposure		
	Warfarin	In and around buildings	Acceptable risk due to negligible exposure		
SGAR	Brodifacoum	In and around buildings	Acceptable risk due to negligible exposure		
	Bromadiolone	In and around buildings	Acceptable risk due to negligible exposure		
	Difenacoum	In and around buildings	Acceptable risk due to negligible exposure		
	Difethialone	Rainwater sewer systems	1.6×10 ⁻⁵	10	<0.01
	Flocoumafen	Rainwater sewer systems	0.052	0.40	0.13

PEC (predicted environmental concentration) in STP = worst-case surface water PEC from Table 52 * DILUTION 10

RAL (regulatory acceptable level) based on activated sludge EC50 / assessment factor 10, where EC50 values from Table 141 (difethialone) and Table 150 (flocoumafen) in Appendix A

RQ (risk quotient) = PEC / RAL, where acceptable RQ ≤1

3.4 Recommendations

3.4.1 Products and uses not supported

To mitigate risks of primary poisoning, products that do not contain a bittering agent (e.g., denatonium benzoate, bitrix) or a dye are not supported.

Four flocoumafen products (54191, 80663, 90839, 90840) have directions for burrow baiting around buildings, which involves the direct placement of baits in rodent burrows (described as 'rat holes' on some labels). Burrow baiting may result in spillage of baits outside the treated burrow, because baits may be ejected by rodents from the

baited burrow, leading to an enhanced risk of primary poisoning of non-target species. Burrow baiting is not appropriate around buildings, where risk of primary poisoning of livestock or pets (particularly dogs) is of concern.

Tracking powders (contact dusts) have high concentrations of active constituents and have the potential to become airborne. Furthermore, tracking powders, liquids, and products that are not ready-to-use are considered to have high risk of unintentional exposure and misuse; therefore, continued registration and use of these types of products are not supported. For the same reasons, large pack sizes are not recommended for supply as domestic pest control products. In addition, high bait concentrations pose greater risk of primary poisoning of terrestrial vertebrates and subsequently, secondary poisoning of their predators. The following sections detail the recommended limits and conditions on the use of anticoagulant rodenticide products.

3.4.2 Supported products and uses

With the exceptions described in the previous section, the use of anticoagulant rodenticide products is supported in and around buildings, in agricultural crops, and in sewers only if additional restrictions are applied to minimise the risk of exposure to non-target species. The recommended restrictions are as follows:

Based on the intrinsic toxicity (EC_{50} or LC_{50}) of the active constituents to aquatic species (see section **3.2.2 Effects on other non-target species**), the following hazard statements are required on the labels of products containing these substances.

EC_{50} or LC_{50} >10 mg/L: (No hazard statement)	(coumatetralyl, warfarin)
EC_{50} or LC_{50} 1-10 mg/L: Toxic to aquatic life.	(diphacinone, bromadiolone)
EC_{50} or LC_{50} <1 mg/L: Very toxic to aquatic life.	(brodifacoum, difenacoum, difethialone, flocoumafen)

The following standard protection measure is also required for all agricultural chemical products.

DO NOT contaminate wetlands or watercourses with this product or used containers.

In addition, the following precautionary measure is required for bait products in and around buildings and in agricultural crops (but not required for use in sewers).

Place the bait stations in areas not liable to flooding. When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

Several mitigation measures are proposed to mitigate risks of primary and secondary poisoning of wildlife. Berny *et al.* (2014) provide recommendations on conditions that will reduce the overall risks of anticoagulant rodenticides including: (1) restrictions on pack size for domestic pest control products; (2) mandatory use of tamper-resistant bait boxes for domestic pest control products, and recommended (covered) bait points for commercial products; (3) development of non-commercial website to provide adequate information on anticoagulant rodenticides. These recommendations have been reiterated in the UK Code of Pest Practice (CRRU 2015). Restricting pack sizes and requiring the use of tamper-resistant bait boxes for domestic uses are reasonable and feasible in the Australian market.

Continued rodent activity after 35 days of treatment could indicate that the rodents are resistant to the rodenticide, or that a significant proportion of the infestation is not being treated and that unexposed rodents are continually

moving into the treated area. Labels should advise the domestic user to contact a professional if rodent activity is still observed after 35 days.

The primary purpose of the pulsed baiting technique is to permit effective rodent control while reducing the quantities of rodenticide used and, thereby, the quantity of the active substance released into the environment. This application technique is applicable for the most potent, single-feed second-generation anticoagulant rodenticides (i.e., brodifacoum, difethialone, difenacoum, flocoumafen). It has been observed that dominant or less neophobic rodents consume the baits completely when they are first put out. These animals die before the next pulse of baits is applied where more neophobic or less dominant rodents encounter and consume the baits (Buckle & Eason 2015). Considering the advanced knowledge required, the pulsed baiting technique should only be applied by trained professionals. The pulsed baiting technique is also not appropriate for use with FGARs due to the increased risk of rodents receiving a non-lethal dose of the bait, given that an FGAR requires multiple feeds for a rodent to receive a lethal dose.

The use of commercial products by trained professional users is supported without limits on pack sizes and with placement in tamper-resistant bait stations (or covered and protected bait points as long as they provide the same level of protection for non-target species as tamper-resistant bait stations). Trained professionals are expected to have advanced knowledge in rodent behaviour and risks to local non-target species; however, currently there is no restriction on whether untrained persons are able to commercial products. Therefore, it is the recommendation on this environment risk assessment that all commercial products containing anticoagulant rodenticides should be declared as RESTRICTED CHEMICAL PRODUCTS.

In summary, to mitigate risks to non-target wildlife, the following labelling is advised for all products containing anticoagulant rodenticides.

DO NOT place bait stations outdoors around buildings for control of mice.

Outdoor bait stations for control of rats must be placed within 2 metres of buildings.¹³ DO NOT apply this product directly into burrows.

Hazardous to wildlife. Search for and dispose of dead rodents and slugs/snails in the infested area at each visit to prevent secondary poisoning. In case slugs/snails are present, move bait station to another location within the rodent infested site, away from slugs/snails. Dispose of slugs/snails in a way that non-target animals are not exposed. Dispose of dead rodents and uneaten bait in compliance with local, state or territory government regulations.

To align with overseas (European) restrictions to limit exposure of non-target wildlife, the following limits on pack sizes for domestic products (i.e., non-commercial products that are available to the general public) are advised for products containing anticoagulant rodenticides.

¹³ This statement does not apply to the use of coumatetralyl in agricultural crops

FGARs	Mice only	250 g (grain, pellet or paste), 500 g (wax block)
	Rats only or mice & rats	750 g (grain, pellet or paste), 1500 g (wax block)
SGARs	Mice only	50 g (grain, pellet or paste), 100 g (wax block)
	Rats only or mice & rats	150 g (grain, pellet or paste), 300 g (wax block)

In addition, the following labelling is advised for all domestic products containing anticoagulant rodenticides:

Use in tamper resistant bait stations only. Where possible, fix tamper-resistant bait stations to the ground or other structures.

DO NOT use the product in pulsed baiting treatments.

DO NOT use the product continuously for more than 35 days. If rodent activity is still observed after 35 days, seek advice from the product supplier or call a pest control service.

The following labelling is advised for all commercial products containing anticoagulant rodenticides.

RESTRICTED CHEMICAL PRODUCT – ONLY TO BE SUPPLIED TO OR USED BY AN AUTHORISED PERSON

Where possible, bait stations must be fixed to the ground or other structures. Covered or protected bait points may be used as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.

DO NOT use the product continuously for more than 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

The following labelling is also advised for all commercial products containing the FGARs coumatetralyl, diphacinone, warfarin.

DO NOT use the product in pulsed baiting treatments.

4 Toxicology and Human Health

4.1 Introduction

The APVMA has reviewed the human health risks posed by currently registered first-generation anticoagulant rodenticides (coumatetralyl, diphacinone and warfarin), and second-generation anticoagulant rodenticides (brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen). The review includes a reconsideration of the toxicology of the various active constituents, and relevant new information. Contemporary exposure and risk assessments for all uses of registered anticoagulant rodenticides were also performed.

4.2 Summary of available toxicological studies

A precis of the relevant findings on the toxicology for each of the chemicals under reconsideration is presented below. A full list of available data on the toxicology of each chemical, including relevant references, is tabulated in Appendix B.

4.2.1 Coumatetralyl

Coumatetralyl has high acute oral toxicity in rats (LD_{50} 30 mg/kg bw in males and 15 mg/kg bw in females) but low acute oral toxicity in rabbits (LD_{50} >500 mg/kg bw in males and 750 mg/kg bw in females). The acute dermal toxicity in rats is moderate (LD_{50} 100-500 mg/kg bw in males and 258 mg/kg in females). The inhalation toxicity in rats (LC_{50} 39-63 mg/m³) and mice (LC_{50} 54 mg/m³) is moderate. Coumatetralyl is neither a skin nor eye irritant in rabbits, nor a skin sensitiser in guinea pigs.

The APVMA holds acute toxicity data on a 0.75% coumatetralyl product. The product has low acute oral toxicity in mice and rats (LD_{50} >10000 mg/kg in mice and 1500 mg/kg in rats) and low acute dermal toxicity in rats (LD_{50} >5000 mg/kg). In an inhalation study in rats, no deaths occurred at 80 mg/m³. The product is not a skin or eye irritant in rabbits. Skin sensitisation was not assessed.

The existing APVMA repeat dose toxicological database consisted of studies conducted with a 0.75% (w/w) coumatetralyl powder product. This includes a 16-week dietary study in rats, in which the no observed adverse effect level (NOAEL) was 0.0068 mg a.c./kg bw/day in male rats and 0.0083 mg/kg bw/day in female rats based on increase in blood clotting time at the next higher dose. In developmental studies in rats and rabbits, there were no treatment-related reproduction and foetal findings, with NOAELs of 0.035 mg a.c./kg bw/day and 0.0125 mg a.c./kg bw/day for maternal effects in rats and rabbits, respectively. Coumatetralyl causes depletion of vitamin K dependent coagulation factors, resulting in haemorrhaging that leads to death. The toxicological findings reported in the sub-chronic and developmental studies were reflective of this mechanism.

New studies submitted to the APVMA as part of the current review included acute toxicity studies conducted on products containing no more than 0.75% coumatetralyl. The study outcomes reiterated coumatetralyl containing products have low acute oral, dermal and inhalation toxicity and are not skin or eye irritants, or skin sensitisers. A further submitted genotoxicity study supported previous findings that coumatetralyl as not being genotoxic. The APVMA also received pilot sub-acute dose-range finding studies that did not impact existing conclusions on coumatetralyl.

4.2.2 Diphacinone

Diphacinone has high acute oral toxicity in rats (LD₅₀ 2.1-8 mg/kg bw) and moderate acute oral toxicity in mice (LD₅₀ 133-147 mg/kg bw). The acute dermal toxicity in rabbits is high (LD₅₀ 3.6 mg/kg bw). The inhalation toxicity in rats LC₅₀ is <2000 mg/m³. Diphacinone is not a skin irritant but is a slight eye irritant in rabbits. It is not a skin sensitiser in guinea pigs.

The APVMA holds acute toxicity data on two 0.05% diphacinone products. They have low acute oral toxicity in rats (LD₅₀>5000 mg/kg) and low acute dermal toxicity in rabbits (LD₅₀>2000 mg/kg). The products are no more than slight skin or eye irritant in rabbits. A Buehler study determined one of the products is not a skin sensitiser.

No new toxicity studies were submitted to the APVMA as part of the current review. The existing APVMA repeat dose toxicological database consists of studies conducted technical grade diphacinone. In a 14-day oral toxicity study in rats, the NOAEL was 0.04 mg/kg bw/d based on increased coagulation parameters at 0.085 mg/kg bw/d. In a 21-day dermal study in rabbits, the NOAEL was 0.1 mg/kg bw/d, based on mortality, clinical signs, and gross pathological abnormalities seen at necropsy of animals at and above 1.0 mg/kg bw/d. A four-week inhalation study has been conducted in rats, however, because of methodological flaws a NOAEC could not be established. In a developmental study in rats, maternal toxicity in rats was observed at 0.075 mg/kg bw/d as characterised by clinical signs and mortality, accompanied by increased early resorptions. The NOAEL for maternal toxicity was 0.025 mg/kg bw/d. There was no evidence of teratogenic effects. Diphacinone was not genotoxic in *in vitro* and *in vivo* studies.

APVMA also holds clinical studies that have been conducted in dogs and humans. The amount and duration of Vitamin K1 therapy appeared to be the most important aspects of treatment for diphacinone intoxicated dogs. In the human clinical evaluation of diphacinone as a potential new anticoagulant therapy, diphacinone given at and above 1.0 mg caused a dose-related depression in prothrombin levels in human subjects. Vitamin K given intravenously at 100 mg/individual re-established the normal plasma prothrombin levels in 24-48 h.

4.2.3 Warfarin

No new studies have been provided to the APVMA for the review of warfarin or products containing warfarin as the active constituent.

The sodium salt of warfarin has been used extensively as an anticoagulant therapeutic drug. Currently there are several registered warfarin medicines for human use in Australia with label doses ranging from 1 to 10 mg daily for the prevention and treatment of venous thrombosis and its extension and pulmonary embolism. A therapeutic dose range from 1 to 10 mg daily equates to approximately to a dose of 0.0125 to 0.125 mg/kg bw/d, and a theoretical NOAEL for warfarin may be predicted at a dose ten-fold lower than the lowest therapeutically active dose (i.e., a theoretical NOAEL of 0.00125 mg/kg bw/d).

Warfarin is indicated for the prophylaxis and/or treatment of the thromboembolic complications associated with atrial fibrillation, and it is also indicated for use as an adjunct in the treatment of coronary occlusion (Therapeutic Goods Administration (TGA) 2024). The critical factor in warfarin dosing is the international normalised ratio (INR). Given that exposure of users to rodenticides containing warfarin as the active constituent is several orders of magnitude lower than the doses that are administered to patients receiving anticoagulant therapy, quantitative risk

assessment was not conducted for warfarin in this review. Of note, in 2015 the TGA reviewed warfarin product information to ensure its continued safe use (TGA, 2015).

4.2.4 Brodifacoum

Brodifacoum has high acute oral toxicity (LD₅₀ 0.3-0.8 mg/kg bw (rat)), high acute dermal toxicity (LD₅₀ 10-50 mg/kg bw (rat) and LD₅₀ 0.25-0.62 mg/kg bw (rabbit)) and high acute inhalational toxicity (LC₅₀ 0.5-5 mg/m³ (rat)). Rats administered (gavage) a single dose of 0.02, 0.15 or 0.35 mg/kg bw, exhibited significantly increased prothrombin clotting time (PT) at the highest dose, with a NOAEL established at 0.15 mg/kg bw. Brodifacoum is a slight skin and eye irritant but is not considered a skin sensitiser. The outcomes of acute toxicity studies (including other animal species) submitted to the APVMA as part of the current review confirmed these findings with only small variations.

The APVMA holds acute toxicity data on several products containing up to 0.25% (w/w) brodifacoum. They have low acute oral, dermal and inhalational toxicity in rats. The products are no more than slight skin or eye irritants in rabbits. None are skin sensitisers. Product toxicity studies submitted to the APVMA as part of the current review indicated the same findings.

The existing APVMA repeat dose toxicological database consists of studies conducted with technical grade brodifacoum. No studies are held on repeat dose dermal or inhalation toxicity. Repeated oral exposure results clinical signs and toxicity consistent with the known mode of action of the rodenticide and its anti-coagulant properties. No new pivotal studies were submitted to the APVMA as part of the current review.

Oral administration of 0.046 to 0.1 mg/kg bw/d brodifacoum to rats for 5 days resulted in mortality in approx. 50% animals. All deaths were associated with massive peritoneal haemorrhages.

In a 90-day rat feeding study at 0.02 ppm and 0.08 ppm brodifacoum (equivalent to 0.001 and 0.004 mg/kg/bw/d), the NOAEL was 0.02 ppm, equivalent to 0.001 mg/kg bw/d, based on statistically significant increases in both kaolin-cephalin time (KCT) and prothrombin time (PT) at 0.004 mg/kg bw/day at the end of the study. No treatment related effects on haematological parameters were evidenced at any dose at 45 days. In dogs given oral brodifacoum (0.0001- 0.01 mg/kg bw/d), for 42 days, the NOAEL for haematological effects was 0.003 mg/kg bw/d (LOAEL 0.01 mg/kg bw/d).

Brodifacoum did not induce developmental or reproductive effects in studies in rats and rabbits. In rats dosed 0.001, 0.01 or 0.02 mg/kg bw/d, maternal haemorrhages were observed at dose levels at and above 0.01 mg/kg bw/d (NOAEL 0.001 mg/kg bw/d), whereas no effects were seen in foetuses at any dose level. In rabbits, gavage dosed at 0.001, 0.002 or 0.005 mg/kg bw/d, the highest dose of 0.005 mg/kg bw/d was associated with a high incidence of maternal deaths, together with a high incidence of abortions. In a two-generation study in rats, findings confirmed those of developmental toxicity studies, both qualitatively (parental toxicity with haemorrhages, no reproductive effects in the absence of maternal toxicity) and quantitatively (NOAEL 0.001 mg/kg bw/d).

Brodifacoum was not genotoxic in *in vitro* and *in vivo* studies, which was confirmed with data submitted in this review. The lack of evidence of genotoxicity in *in vivo* and *in vitro* studies, even with a lack of chronic or carcinogenicity studies on brodifacoum, indicates a low hazard for neoplastic effects.

4.2.5 Bromadiolone

Based on APVMA data holdings and new studies submitted under this review, bromadiolone has high acute oral toxicity (LD₅₀ 0.56-0.84 mg/kg bw (rat) and 10.7 mg/kg bw (dog)), high acute dermal toxicity (LD₅₀ 1.3-2.38 mg/kg bw (rabbit)) and high acute inhalational toxicity (LC₅₀ 0.43 mg/m³ (rat)). Bromadiolone is not a skin irritant nor is it considered a skin sensitiser, but it is a slight eye irritant.

APVMA data holdings and new studies in rats submitted under this review indicate products containing up to 0.005% (w/w) bromadiolone have low acute oral (>2000 mg/kg bw), dermal (>2000 mg/kg bw) and inhalational (>2000 mg/m³) toxicity in rats. The products are no more than slight skin or eye irritant in rabbits. None are skin sensitisers.

The existing APVMA repeat dose toxicological database consists of studies conducted with technical grade bromadiolone. In a subchronic toxicity study in dogs, adverse effects were all associated with the mechanism of action with haemorrhages and haematomas at multiple sites and absolute heart weight increased at the mid dose. The NOAEL was 0.008 mg/kg bw/day. Developmental studies were conducted in rats and rabbits. In rats, increased mortality was observed in high dose dams, with bleeding disorder observed prior to death. The NOAEL for maternal toxicity and fetotoxicity was 0.035 mg/kg bw/day. In rabbits, two high dose females died following abortion; uterine bleeding was noted in many others in the same group. Increased resorptions and decreased foetal and litter weights were also noted in the high dose group. The NOAEL for maternal and fetotoxicity was 0.004 mg/kg bw/day. Bromadiolone was not genotoxic in any of the existing or newly submitted studies.

Many new studies were submitted for the review of bromadiolone. Most of the studies confirmed the known properties of bromadiolone and would not affect the point of departure for risk assessment, however notable exceptions include a developmental toxicity study in rabbits, which did not establish a NOAEL (LOAEL for maternal toxicity = 0.002 mg/kg bw/day) and a 90-day oral toxicity study in rabbits, which had a NOAEL of 0.0005 mg/kg bw/day based on increased prothrombin time at 0.001 mg/kg bw/day. Both studies were evaluated by the EU (2011) and the maternal LOAEL of 0.002 mg/kg bw/day from the rabbit developmental toxicity study was used as the basis for the EU's acceptable exposure level for single use (AEL_{acute}). A two-generation rat reproductive toxicity study was also submitted and was assessed by the EU; the NOAEL from that study was 0.005 mg/kg bw/day for parental and offspring toxicity with no adverse effects reported at the highest dose tested. Based on the lack of effects at any dose tested, the EU concluded that the study was not acceptable for risk assessment but could be used as complementary information.

4.2.6 Difenacoum

Difenacoum is highly acutely toxic via the oral, dermal and inhalation routes of exposure (acute oral LD₅₀ 1.8-2.6 mg/kg bw, acute dermal LD₅₀ 17.2-63 mg/kg bw, acute inhalation LC₅₀ 3.6-5.8 mg/m³ in rats). The technical grade active constituent was non-irritating to rabbit skin and eyes nor was it a dermal sensitiser in guinea pigs.

APVMA data holdings indicate products containing up to 0.005% (w/w) difenacoum have low acute oral (>28000 mg/kg bw) and dermal (>2000 mg/kg bw) toxicity in rats. No acute inhalation data is available for the products; however, it is expected to be low based on the very low vapour pressure of the active constituent. Available irritation data are variable depending on the formulation type; blocks were slightly irritating to the eye and moderately irritating to the skin. Pelleted formulations were non-irritating to skin but slightly irritating to the eyes.

Gel and paste formulations were estimated non-irritant to skin, with the paste estimated to be non-irritant to the eye and the gel slightly irritating to the eye. None of the formulated products are considered skin sensitisers.

In a short-term dermal toxicity study in rats, prothrombin time was increased at doses of 20 mg/kg bw and above. No effects were reported at 10 mg/kg bw. Dogs received difenacoum in gelatine capsules for 6 weeks. All dogs except the lowest dose group (0.01 mg/kg bw/day) were killed prematurely for humane reasons. There was no NOAEL in the study as the low dose animals had prolonged prothrombin time and kaolin-cephalin time. In a subchronic toxicity study in rats, a NOAEL was established at 0.01 mg/kg bw/day, with effects at higher doses including prolong prothrombin and kaolin-cephalin times and haemorrhage in multiple tissues/organs.

Difenacoum did not induce mutations at the thymidine kinase locus or in *S. typhimurium*, nor did it induce micronuclei in the bone marrow of mice. It was positive for chromosomal aberrations in human lymphocytes but was negative for unscheduled DNA synthesis both *in vitro* and *in vivo*. It was concluded that difenacoum was unlikely to be genotoxic *in vivo*.

Additional studies submitted for the review confirmed the information in the existing database for difenacoum, however additional data was provided to fill the lack of reproductive and developmental toxicity data. The rat reproductive toxicity study had NOAELs in the same range as the previously evaluated subchronic toxicity data and showed no adverse effects on reproductive performance or developmental toxicity. The teratology study in rabbits did not establish a NOAEL; there were effects on dams at the lowest dose tested, 0.001 mg/kg bw/day. The LOAEL for the study was based on evidence of haemorrhage in multiple tissues in all treatment groups.

4.2.7 Difethialone

Difethialone is highly acutely toxic via the oral, dermal and inhalation routes of exposure (acute oral LD₅₀ 0.57 mg/kg bw, acute dermal LD₅₀ 5.3 mg/kg bw and inhalation LC₅₀ 5 mg/m³ in rats). The technical grade active constituent was slightly irritating to the eyes and skin of rabbits but was not a sensitiser in guinea pigs.

Available product toxicity data indicate that formulated products that contain difethialone are of low toxicity via the oral and dermal routes of exposure. Depending on the formulation, products may be slightly to moderately irritating to the eyes and slightly irritating to the skin. Products containing difethialone are not expected to be skin sensitisers. The eye irritation study that showed moderate irritation was not of acceptable regulatory quality and was not able to be relied upon. A liquid concentrate was tested in an ocular irritation and reversibility study in rabbits. The preparation contained approximately 50 times the concentration of difethialone compared to the pelleted formulation, and it was classified as a slight eye irritant. The same liquid concentrate was tested in a Guinea Pig Maximisation Test and although the study was confounded by multiple deaths, the test item was determined to be non-sensitising to guinea pig skin.

The existing APVMA repeat dose toxicological database consists of studies conducted with technical grade difethialone. No studies are held on repeat dose dermal or inhalation toxicity. The toxicity database includes a short-term study in pigs, subchronic oral toxicity studies in rats and dogs, developmental toxicity studies in rats and rabbits and a battery of genotoxicity studies. In addition, an antidote study was performed in dogs, that demonstrated effective treatment of difethialone poisoning with vitamin K1. Repeat dose toxicity studies revealed haemorrhagic findings in rats and dogs at doses as low as 0.004 mg/kg bw/day in rats and 0.02 mg/kg bw/day in dogs. The lowest NOAEL from repeat dose studies was established at 0.00125 mg/kg bw/day in the rabbit

developmental toxicity study. Available genotoxicity studies showed no potential for genotoxicity either *in vitro* or *in vivo*. No new toxicity studies were submitted to the APVMA as part of the current review.

4.2.8 Flocoumafen

Flocoumafen is highly toxic via the oral and dermal routes of exposure (oral LD₅₀ approximately 0.25 mg/kg bw in rats; dermal LD₅₀ 0.54 mg/kg bw in rats). There is no acute inhalation toxicity data available for flocoumafen. It is neither irritating nor sensitising to the skin and is not an eye irritant.

Available product toxicity data and previous evaluations of flocoumafen products indicate that the formulated products are of low acute oral and dermal toxicity, slightly irritating to the skin and eye and are not skin sensitisers.

The existing APVMA repeat dose toxicological database consists of studies conducted with technical grade flocoumafen. No studies are held on repeat dose dermal or inhalation toxicity. The toxicity database includes short-term and subchronic oral toxicity studies in rats, developmental toxicity studies in rats and rabbits and a battery of genotoxicity studies. The prominent toxic effects of repeated oral dosing of flocoumafen were associated with its anticoagulant properties. The lowest NOAEL from repeat dose studies was established at 0.0014 mg/kg bw/day. Available genotoxicity studies showed no potential for genotoxicity either *in vitro* or *in vivo*. No new toxicity studies were submitted to the APVMA as part of the current review.

4.2.9 Toxicokinetics

In general, these substances are rapidly and reasonably efficiently absorbed following oral administration. They have a high affinity for liver and may take a considerable amount of time to be eliminated from the body, with half-lives extending up to several months. Based on this, the statement “repeated minor exposure may have a cumulative poisoning effect” is recommended to be included in the safety directions of all product labels. In addition, in establishing tolerable daily intake values, an additional uncertainty factor of 10 has been applied to address the lack of chronic toxicity studies for any of the active constituents.

4.3 Human adverse events involving anticoagulant rodenticide exposure in Australia

Data from the NSW Poisons Information Centre (NSW PIC) which handles approximately 200,000 calls, or 50% of all poisoning related calls in Australia, show that anticoagulant rodenticides were the 78th most frequent substance that PIC received calls on in 2013. Over the 12-year period between 2004 to 2015, NSW PIC received 9,829 calls relating to rodenticides with approximately 70% of these involving children aged between 1 and 4 (NSW Government, 2017).

For the two-year period from July 2014 to June 2016, there were 537 brodifacoum poisoning incidents. 486 were accidental and most involved a very small quantity. Over 75% of these callers reported that the child's exposure fell somewhere between the tasting or chewing of a partial pellet, to the consumption of ½ to 2 pellets. Over 85% of cases were classified as “stay at home” cases and did not require medical intervention (NSW Government, 2017).

Only a fraction of poisoning incidents have been reported directly to the APVMA. Nineteen incidents involving humans with first- and second-generation anticoagulant rodenticides were reported to the adverse experience reporting program (AERP) at the APVMA in the period from 1995 to September 2024.

These data collectively demonstrate that the current anticoagulant rodenticide risk mitigation measures are not effectively preventing accidental ingestion of baits by children.

The addition of a bittering agent to all product formulations to reduce the likelihood of ingestion by a child is recommended. The addition of a marker dye to provide a visual reference to indicate that a child may have ingested some of the product is also recommended.

4.4 Use Patterns of Registered Products

Products containing first- and second-generation anticoagulant rodenticides are registered with instructions for use for the control of rats and mice in and around domestic homes, industrial and commercial buildings, animal houses, farms, wharves, public service buildings, food factories, hospitals, inside transport vehicles (including ships) and around grain terminals feature. These products are formulated in a variety of ways such as solid bait (blocks, pastes, pellets, treated grain, and dry bait prepared from powder and a cereal or fruit bait matrix), contact formulations (powder) and liquid formulations.

4.5 Exposure and Risk Assessment

The human health exposure and risk characterisations associated with the professional and domestic use of first- and second-generation anticoagulant rodenticides have been reevaluated. This includes exposure assessments and risk characterisation for professional and non-professional users applying first- and second-generation anticoagulant rodenticides and associated rehandling activities such as the removal and disposal of carcasses, and bait cleanup.

The quantity of anticoagulant rodenticide handled by a typical user varies widely depending on the use pattern. In risk characterisations, the maximum application rates for each active constituent were used.

4.5.1 Selection of points of departure for risk assessment

For repeat-exposure risk assessment, the NOAEL from an appropriate study is used as a comparator with the estimated exposure to determine the margin of exposure (MOE). Ideally, the study selected should be a dermal or inhalation study to reflect the expected route of occupational exposure. The requirement for the study selected is that the NOAEL is protective of the effects seen in all repeat-dose studies in the database and that the endpoint is relevant to potential effects in humans.

Based on the likely exposure route and product use pattern for rodenticides the most appropriate NOAEL for risk assessment for applying the product would be from a short-term dermal toxicity study. However, the toxicity databases for the FGAR and SGAR are limited and do not include short-term dermal studies. In lieu of the preferred study type for each active constituent, the most appropriate available NOAEL for use in each of the respective risk assessments of professional and non-professional users is presented below.

4.5.2 First-generation anticoagulant rodenticides

Coumatetralyl

The most appropriate NOAEL from data in the APVMA's holdings for use in a risk assessment of coumatetralyl for professional and non-professional users is 0.0068 mg/kg bw/day from a 16-week dietary toxicity study in rats, based on prolonged blood clotting (prothrombin) time at the next higher dose (Andrews, P., Romeike, A., 1997). This NOAEL was relied upon by the APVMA to establish the tolerable daily intake (TDI) for coumatetralyl.

Diphacinone

The most appropriate NOAEL from data in the APVMA's holdings for use in a risk assessment of diphacinone for professional and non-professional users is 0.025 mg/kg bw/day from an oral developmental toxicity study in rats, based on maternal and embryo toxicity based on increased incidence of early resorptions and post implantation loss at the next higher dose (Daniel E M., 1993). This NOAEL was relied on by the APVMA to establish the TDI for diphacinone.

4.5.3 Second generation anticoagulant rodenticides

Brodifacoum

The most appropriate NOAEL from data in the APVMA's holdings for use in a risk assessment of brodifacoum for professional and non-professional users is 0.001 mg/kg bw/day from a 13-week dietary toxicity study in rats, based on prolonged blood clotting (prothrombin) time at the next higher dose (Batten P, *et al.*, 1984). This NOAEL was relied on by the APVMA to establish the TDI for brodifacoum.

Bromadiolone

The most appropriate NOAEL from data in the APVMA's holdings for use in a risk assessment of bromadiolone for professional users is 0.0005 mg/kg bw/day from an oral subchronic toxicity study in rabbits, based on increased prothrombin time at the next higher dose (Béres E, 2006). This NOAEL was relied on by the APVMA to establish the TDI for bromadiolone.

For non-professional users, exposure will be much less frequent, therefore the most appropriate point of departure is the LOAEL of 0.002 mg/kg bw/day from a rabbit developmental toxicity study (Druga A, 2004a)

Difenacoum

The most appropriate NOAEL from data in the APVMA's holdings for use in a risk assessment of difenacoum for professional and non-professional users is a LOAEL of 0.001 mg/kg bw/day from a developmental toxicity study in rabbits, based on haemorrhage in multiple tissues/organs at the lowest dose tested (Druga A, 2004b). This LOAEL was relied upon by the APVMA to establish the TDI for difenacoum.

Difethialone

The most appropriate NOAEL for use in a risk assessment of professional and non-professional users is 0.00125 mg/kg bw/day from an oral developmental toxicity study in rabbits, based on depressed weight gain in dams,

elevated incidence of incompletely ossified 5th sternebra at the next highest dose of 0.0025 mg/kg bw/day (Briffaux J.P., 1986). This NOAEL was relied on to establish the TDI for difethialone.

Flocoumafen

The most appropriate NOAEL from data in the APVMA's holdings for use in a risk assessment of flocoumafen professional and non-professional users is 0.0014 mg/kg bw/day (0.02 ppm) from a 90-day dietary toxicity study in rats, based on increased levels of serum cholesterol at the next highest dose of 0.0036 mg/kg bw/day (0.05 ppm) (Clark, D.G., Esdaile, D.J., 1989). This NOAEL was relied on by the APVMA to establish the acceptable daily intake (ADI) for flocoumafen.

4.6 Selection of dermal and inhalation absorption factors

Default values for dermal and inhalational absorption were used across FGAR and SGAR active constituents, with a dermal absorption value of 10% and inhalation absorption value of 100% applied during exposure and risk characterisations.

4.7 Basic parameters used in the exposure assessments and risk characterisations

4.7.1 Occupational & non-professional health risk assessment

Principal exposure to anticoagulant rodenticides will occur via the skin, or dermal route during bait placement, loading, refilling, rehandling including removal of carcasses, cleanup and removal of used bait stations.

Minor accidental oral exposure may also occur considering the potential inhalation of dust generated during transport, within the packaging of loose, pelleted baits. Inhalation exposure from other formulations of bait (e.g., wax blocks, sachets) is expected to be minimal.

No user exposure studies were submitted for assessment for any rodenticide products. The US EPA Occupational Pesticide Handler Exposure Calculator (OPHEC) (US EPA 2021) and US EPA Standard Operating Procedures (SOP) for Residential Pesticide Exposure Assessment (US EPA 2012) were used to estimate professional and non-professional user exposure during product use.

The parameters and assumptions used to determine exposure estimates during the use of products containing each of the various active constituents are listed in Table 60, below.

Table 60: Parameters, assumptions and models used in risk assessment for rodenticide users

Active constituent	Point of Departure for risk assessment (mg/kg bw/day)	Model(s)
Coumatetralyl	0.0068	Occupational users: <i>US EPA Occupational Pesticide Handler Exposure Calculator (OPHEC)</i>
Diphacinone	0.025	
Warfarin	Not applicable	Non-professional e.g., residential users and Residential/domestic use: <i>US EPA Standard Operating Procedures (SOP) for Residential Pesticide Exposure Assessment</i>
Brodifacoum	0.001	
Bromadiolone	0.0005 – occupational	
	0.002 – non-professional	
Difenacoum	0.001	
Difethialone	0.00125	
Flocoumafen	0.0014	

Parameter	Value(s)
Acceptable margin of exposure (MOE) - occupational	1000*
Acceptable margin of exposure (MOE) - non-professional	300*
Body weight (adult)	80 kg
Dermal absorption factor	10% (fraction 0.1)
Inhalation absorption factor	100% (fraction 1)
Number of bait stations for rats/mice loaded per day	3 (non-professional); 30 (professional)
Area treated (professional users - loose bait)	930 m ² (default value of US OPHEC)
Area treated (non-professional users - pellets)	100 m ²

* The acceptable MOE for occupational users is based on a 10-fold uncertainty factor (UF) for inter-species extrapolation, and a 10-fold UF for intra-species differences in susceptibility to effects. An additional uncertainty factor of 10 is applied to account for the lack of chronic toxicity studies in any of the toxicology databases for FGAR and SGAR. For non-professional users, the additional uncertainty factor of 3 is applied as the frequency of use is much more sporadic than occupational users of these products.

4.8 Risks associated with using anticoagulant rodenticide baits

4.8.1 Professional users

The principal exposure routes for professional users of anticoagulant rodenticides will occur via the dermal route during bait placement, loading, refilling, rehandling, including during removal of carcasses, and cleanup and removal of used bait stations. Minor or accidental oral or inhalation exposure may also occur.

The US EPA Occupational Pesticide Handler Exposure Calculator (OPHEC) was used to estimate worker exposure during FGAR and SGAR product application modelling loose baits or refill of traps/bait stations. Due to the wide range of product application rates, exposure modelling used high application rates for each active constituent under review.

Table 61: Exposures for professional uses of FGARs using broadcast loose bait products

Active constituent	Application rate (g a.c./ha)	MOE Hand dispersal	MOE Using cup	Level of PPE
Coumatetralyl	1.14	310	170 000	SL/G
Diphacinone	0.68	520	280 000	SL/G

Table 62: Exposures for professional users of FGARs using loose bait products in refillable bait stations

Active constituent	Application rate mg a.c./bait station	MOE Refilling by hand	MOE Using cup	Level of PPE
Coumatetralyl	38.1	29	16 000	SL/G
Diphacinone	22.5	180	100 000	SL/G

SL = single layer of clothing, equivalent to a long-sleeve shirt, long pants, shoes and socks; G = gloves

Table 63: Exposures for professional uses of SGARs using broadcast loose bait products

Active constituent	Application rate (g a.c./ha)	MOE Hand dispersal	MOE Using cup	Level of PPE
Brodifacoum	0.3	170	92 000	SL/G
Bromadiolone	0.68	39	21 000	SL/G
Difenacoum	0.3	170	92 000	SL/G
Difethialone	0.12	150	82 000	SL/G
Flocoumafen	4	170	91 000	SL/G

Table 64: Exposures for professional users of SGARs using loose bait products in refillable bait stations

Active constituent	Application rate mg a.c./station	MOE Hand dispersal	MOE Using cup	Level of PPE
Brodifacoum	10	16	8 900	SL/G
Bromadiolone	22.5	3.6	1 900	SL/G
Difenacoum	10	16	8 900	SL/G
Difethialone	4	50	28 000	SL/G
Flocoumafen	4	57	31 000	SL/G

SL = single layer of clothing, equivalent to a long-sleeve shirt, long pants, shoes and socks; G = gloves.

MOE values below 1000 in Table 64 indicate an activity that cannot be supported, such as Professional users laying loose bait or refilling bait stations by hand. Using a cup, scoop, or measure to conduct these activities results in MOEs that are acceptable for occupational handlers of anticoagulant rodenticides.

4.8.2 Non-professional users

Exposure estimates for FGARs and SGARs in domestic situations was undertaken using US EPA's Standard Operating Procedures for Residential Pesticide Exposure Assessment- Residential Handler SOP Calculator. Findings are presented below.

Table 65: Exposures for non-professional users of FGAR loose bait products.

Active constituent	mg a.c./station	MOE
Coumatetralyl	22.9	1 300
Diphacinone	22.5	2 200

Table 66: Exposures for non-professional users of SGAR loose bait products.

Active constituent	mg a.c./station	MOE
Brodifacoum	10	740
Bromadiolone	22.5	660
Difenacoum	10	740
Difethialone	4	2 300
Flocoumafen	4	2 600

Non-professional use and exposure to FGARs and SGARs is expected to be intermittent, and individuals handling these products have not been assumed to be wearing specialised PPE. MOE values below 300 in Table 66 cannot be supported. Based on the exposure and risk estimates, FGAR and SGAR products can continue to be used domestically when used according to the directions on the label.

4.8.3 Bystander exposure

Bystanders may be exposed to baits laid in both indoor and outdoor environments. Inadvertent exposure can be mitigated by placing baits in areas inaccessible to children, and/or tamper-proof bait stations. If the contents of a bait station can be accessed by moving or shaking the bait station, the bait station must be secured in place to prevent this.

As noted in section 4.3 **Human adverse events involving anticoagulant rodenticide exposure in Australia**, it is also recommended that all product formulations contain a bittering agent and dye. The bittering agent is intended to reduce the likelihood of accidental ingestion of bait by a child, and a marker dye provides a visual reference to indicate that a child may have ingested some bait.

4.8.4 Risk associated with re-handling and clean-up activities

Workers performing post-application activities including clean-up and disposal operations of baits and bait stations and handling rodent carcasses may be exposed to residues from dermal contact. For products formulated as blocks, pellets or paste (in a caulking gun), it is expected that exposure to FGAR and SGAR residues from rehandling activities will be lower or similar than the exposure that was estimated for occupational and residential users of anticoagulant rodenticide products. For re-handling of sachet baits, exposure may also occur if the packaging is broken and bait exposed and it is expected that exposure to FGAR and SGAR residues from these re-handling activities will be lower or similar than the exposure that was estimated for occupational and residential users of anticoagulant rodenticide block, pellet and paste products. Due to the inherent properties of anticoagulant rodenticides, and to promote good occupational hygiene, APVMA recommends the use of a single layer of clothing and gloves during bait station servicing and clean-up activities. Remaining baits and carcasses should be disposed of in accordance with local, state or territory government regulations.

4.9 Risk Management Recommendations

4.9.1 First Aid Instructions

The following first aid instructions are required for all anticoagulant rodenticide products in all formulations and pack sizes

First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

Vitamin K1 (Phytomenadione) is antidotal.

Warning statements

Nil

4.9.2 Safety Directions

Products in sachets or single use bait boxes/place packs

Brodifacoum, bromadiolone, flocoumafen or coumatetralyl in sachets or single use bait boxes/place packs

The following safety directions are required for brodifacoum, bromadiolone, flocoumafen and coumatetralyl products in sachets or place packs with the concentrations listed in Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

When using the product wear disposable gloves.

During cleanup, disposal operations of bait and bait stations and when handling rodent carcasses wear single layer clothing and disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

After each day's use wash contaminated clothing.

Table 67.

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

When using the product wear disposable gloves.

During cleanup, disposal operations of bait and bait stations and when handling rodent carcasses wear single layer clothing and disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

After each day's use wash contaminated clothing.

Table 67: Active constituent concentration of brodifacoum, bromadiolone, flocoumafen and coumatetralyl products in sachets or place packs

Substance	Formulation	Statement Codes
Brodifacoum	RB 0.05 g/kg or less in sachet or place pack	190 279 283 290 292b
Bromadiolone	RB 0.05 g/kg or less in sachet or place pack	321 during cleanup, disposal operations and when handling rodent carcasses
Coumatetralyl	RB 0.4 g/kg or less in sachet or place pack	252 360 366
Flocoumafen	RB 0.05 g/kg or less in sachet or place pack	

Difenacoum products in sachets or single use bait boxes/place packs

The following safety directions are required for difenacoum products in sachets or place packs with the concentrations listed in **Safety Directions**

Repeated minor exposure may have a cumulative poisoning effect.

When using the product wear disposable gloves.

During cleanup, disposal operations of bait and bait stations and when handling rodent carcasses wear single layer clothing and disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

After each day's use wash contaminated clothing.

Table 67.

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

Will irritate the skin. May irritate eyes. Avoid contact with eyes and skin.

When using the product wear disposable gloves.

During cleanup, disposal operations of bait and bait stations and when handling rodent carcasses wear single layer clothing and disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

After each day's use wash contaminated clothing.

Table 68: Active constituent concentration of difenacoum products in sachets or place packs

Substance	Formulation	Statement Codes
Difenacoum	RB 0.05 g/kg or less in sachet or place pack	190 161 164 160 162 210 211 279 283 290 321 290 292b 321 during cleanup, disposal operations and when handling rodent carcasses 252 360 366

Difethialone products in sachets or single use bait boxes/place packs

The following safety directions are required for difethialone products in sachets or place packs with the concentrations listed in **Safety Directions**

Repeated minor exposure may have a cumulative poisoning effect.

When using the product wear disposable gloves.

During cleanup, disposal operations of bait and bait stations and when handling rodent carcasses wear single layer clothing and disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

After each day's use wash contaminated clothing.

Table 67.

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

May irritate eyes. Avoid contact with eyes.

When using the product wear disposable gloves.

During cleanup, disposal operations of bait and bait stations and when handling rodent carcasses wear single layer clothing and disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

After each day's use wash contaminated clothing.

Table 69: Active constituent concentration of products in sachets or place packs

Substance	Formulation	Statement Codes
Difethialone	RB 0.025 g/kg or less in sachet or place pack	190 160 162 210 162 279 283 290 231 290 292b

321 during cleanup,
disposal operations and
when handling rodent
carcasses 252 360 366

Products in block formulation

Brodifacoum, bromadiolone, coumatetralyl, diphacinone and flocoumafen products in block formulation

The following safety directions are required for products formulated as blocks with the concentrations listed in Table 70.

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

DO NOT touch bait, use scoop or measure.

When using the product wear disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

Table 70: Active constituent concentration of products in block formulation

Substance	Formulation	Statement Codes
Brodifacoum	RB 0.05 g/kg or less in block formulation	190 250 251 279 283 290 321 252
Bromadiolone	RB 0.05 g/kg or less in block formulation	
Coumatetralyl	RB 0.4 g/kg or less in block formulation	
Diphacinone	RB 0.05 g/kg or less in block formulation	
Flocoumafen	RB 0.05 g/kg or less in block formulation	

Difethialone products in block formulation

The following safety directions are required for products containing up to 0.025 g/kg difethialone and formulated as blocks (RB 0.025 g/kg or less in block formulation).

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect. May irritate eyes.

Avoid contact with eyes.

DO NOT touch bait, use scoop or measure. When using the product wear disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

Difenacoum products in block formulation

The following safety directions are required for products containing up to 0.05 g/kg difenacoum and formulated as blocks (RB 0.05 g/kg or less in block formulation).

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

*Will irritate the skin. May irritate eyes. Avoid contact with eyes and skin.
DO NOT touch bait, use scoop or measure. When using the product wear disposable gloves.
If on skin and after each baiting, wash thoroughly with soap and water.*

Products in loose pellet/grain bait formulation

Brodifacoum, bromadiolone, coumatetralyl and diphacinone products in loose pellet/grain bait formation

The following safety directions are required for products formulated as loose pellets or grain baits with the concentrations of brodifacoum, bromadiolone, coumatetralyl and diphacinone listed in Table 71.

Safety Directions

*Repeated minor exposure may have a cumulative poisoning effect.
Avoid contact with eyes and skin. DO NOT inhale dust.
DO NOT touch bait, use scoop or measure. When using the product wear disposable gloves.
If on skin and after each baiting, wash thoroughly with soap and water.*

Table 71: Active constituent concentration of brodifacoum, bromadiolone, coumatetralyl and diphacinone products in loose pellets/grain formulations

Substance	Formulation	Statement Codes
Brodifacoum	RB 0.05 g/kg or less in pellet formulation	190 210 211 220 221 250 251 279 283 290 321 252
Bromadiolone	RB 0.05 g/kg or less in pellet formulation	
Coumatetralyl	RB 0.4 g/kg or less in pellet formulation	
Diphacinone	RB 0.05 g/kg or less in pellet formulation	

Difethialone and difenacoum products in loose pellet/grain bait formation

The following safety directions are required for products formulated as loose pellets or grain baits with the concentrations of difenacoum and difethialone listed in Table 72.

Safety Directions

*Repeated minor exposure may have a cumulative poisoning effect.
May irritate eyes. Avoid contact with eyes and skin. DO NOT inhale dust.
DO NOT touch bait, use scoop or measure. When using the product wear disposable gloves.
If on skin and after each baiting, wash thoroughly with soap and water.*

Table 72: Active constituent concentration of difenacoum and difethialone products in loose pellets/grain formulations

Substance	Formulation	Statement Codes
Difenacoum	RB 0.05 g/kg or less in pellet formulation	190 160 162 210 211 220 221 250 251 279 283 290
Difethialone	RB 0.025 g/kg or less in pellet formulation	321 252

Products for use in a caulking gun (paste)

The following safety directions are required for products formulated as paste for use in a caulking gun with the concentrations listed in.

Safety Directions

Repeated minor exposure may have a cumulative poisoning effect.

Do not touch bait. When using the product wear disposable gloves.

If on skin and after each baiting, wash thoroughly with soap and water.

Table 73: Active constituent concentration of products as a paste formulation for use in a caulking gun

Substance	Formulation	Statement Codes
Bromadiolone	BA 0.1 g/kg or less as a paste in caulking gun	190 250 279 283 290 321 252
Brodifacoum	BA 0.05 g/kg or less as a paste in caulking gun	

Products powder or liquid bait formulations

Products formulated as powder or liquid are recommended to be cancelled and accordingly no safety directions have been recommended

4.9.3 Additional Labelling Recommendations

The following statements are intended to supplement any restraints that may appear on existing product labels and are not meant to replace current label restraints.

Restraints

DO NOT place bait in areas that are accessible to children. In child-accessible areas baits must be placed in tamper-proof bait stations¹⁴. If bait can be dislodged from bait station, bait station must be secured¹⁵ in place.

Re-handling Statements

During cleanup and disposal operations of bait and bait stations, wear a single layer of clothing and disposable gloves.

¹⁴ Tamper-resistant bait station means a bait station that: (a) is capable of displaying precautionary statements in a prominent location; (b) can contain bait with minimal spillage or tracking; (c) prevents the displacement of bait out of the bait station in the event the station is moved or shaken; (d) if the bait station is refillable, children should not be able to gain access via the refilling openings or procedures; (e) does not have openings larger than 65 mm in diameter so as to prevent access by children under six years of age; (f) prohibits opening, entry, disassembly, or destruction by children under six years of age (with access to common objects).

¹⁵ Securable bait station means a bait station that: (a) meets all the criteria of a tamper-resistant bait station; and (b) is capable of being anchored securely so as to resist efforts to move the station; and (c) includes a mechanism to secure the bait within the bait compartment.

Wear disposable gloves when handling rodent carcasses.

Wash clothes after performing re-handling activities.

4.9.4 Formulation Recommendations

The addition of a bittering agent and a marker dye to product formulations is recommended for all products to assist with mitigation of the risk of poisoning incidents in children.

4.10 Poison Standard

The Poison Standard consists of decisions regarding the classification of medicines and poisons into Schedules to promote uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia.

Most of the active constituents considered in this review are included in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with cut-off concentrations to Schedule 6, meaning these active constituents found below the cut-off concentration are scheduled differently. Coumatetralyl has an additional cut-off concentration to Schedule 5.

Diphacinone is included in Schedule 6 with no exceptions or cut-offs. Warfarin is included in Schedule 4 for human therapeutic use, Schedule 5 when in rodent baits containing 0.1% or less warfarin, and otherwise included in Schedule 6.

Diphacinone and warfarin both meet the Scheduling Policy Framework criteria for inclusion into Schedule 7, considering acute hazard. A proposal to amend these entries will be prepared separately.

Based on the concentration of active constituents in currently registered anticoagulant rodenticide products, all products include the appropriate signal words on their product labels.

4.11 Health Based Guidance Values

Traditional health-based guidance values such as acceptable daily intake (ADI) or acute reference dose (ARfD) are not appropriate when products are not applied to foods, and their residues not expected to enter the food chain, as is the case with anticoagulant rodenticides. Evidence of secondary poisoning, and residues detected in commodities including pork and components of traditional indigenous diets (e.g., snake, goanna) suggest potential for exposure through the diet. Therefore, health-based guidance values for chemical contaminants have been considered, such as the tolerable daily intake (TDI) and the acute tolerable intake.

4.11.1 Tolerable daily intake – TDI

The tolerable daily intake (TDI) is a measure of a chemical contaminant that can be taken daily over a lifetime without appreciable health risk. TDI values are proposed for each active constituent reviewed here (Table 74). The only exception is warfarin, as the value derived from a standard risk assessment methodology would be significantly smaller than a therapeutic dose.

An uncertainty factor of 1000 has been used in each calculation, which incorporates the traditional uncertainty factor of 100 to account for inter-species extrapolation (10x) and intra-species variability in response (10x), with an additional uncertainty factor of 10 to account for a relative paucity of chronic data available for each active constituent combined with evidence that repeat exposure to these active constituents may produce a cumulative effect.

While the point of departure for difenacoum is based on a LOAEL (rather than a NOAEL), the additional uncertainty factor of 10 is considered adequate as the endpoint of concern is the same (i.e., haemorrhage in multiple tissues).

4.11.2 Acute tolerable intake (acute reference dose – ARfD)

The acute tolerable intake represents the maximum, single day oral exposure of a chemical contaminant which is anticipated to be without appreciable risk for the general population. Acute tolerable intake (ARfD) values are proposed for each second-generation active constituent reviewed here (Table 74).

A standard uncertainty factor of 100 has been used in each calculation (except where the critical point of departure is based on a LOAEL, in which case an additional factor of 3 is applied to determine the acute tolerable intake). The additional 10-fold uncertainty applied in the establishment of TDIs is not relevant to acute exposure.

Table 74: Health-based guidance values recommended for publication on the APVMA website

Active Constituent	Measure		Based upon
Brodifacoum	TDI	0.000001 mg/kg bw/day	NOAEL of 0.001 mg/kg bw/day for prolonged prothrombin time in a 90-day dietary toxicity study in rats.
	ARfD	0.00001 mg/kg bw	NOAEL of 0.001 mg/kg bw/day from both the rat and rabbit developmental toxicity studies.
Bromadiolone	TDI	0.0000005 mg/kg bw/day	NOAEL of 0.0005 mg/kg bw/day for increased prothrombin time in a subchronic toxicity study in rabbits
	ARfD	0.0000007 mg/kg bw	LOAEL of 0.002 mg/kg bw/day for maternal toxicity in a developmental toxicity study in rabbits.
Coumatetralyl	TDI	0.0000068 mg/kg bw/day	NOAEL of 0.0068 mg/kg bw/day for significantly increased blood clotting time and haemorrhage from a 16-week dietary toxicity study in rats.
Difenacoum	TDI	0.000001 mg/kg bw/day	LOAEL of 0.001 mg/kg bw/day for haemorrhage in multiple tissues/organs in a developmental toxicity study in rabbits.
	ARfD	0.00003 mg/kg bw	LOAEL of 0.001 mg/kg bw in a developmental toxicity study in rabbits.
Difethialone	TDI	0.0000013 mg/kg bw/day	NOAEL of 0.00125 mg/kg bw/day for incidence of incompletely ossified sternebrae from a developmental toxicity study in rabbits.

	ARfD	0.000013 mg/kg bw/day	NOAEL of 0.00125 mg/kg bw/day from a developmental toxicity study in rabbits.
Diphacinone	TDI	of 0.000025 mg/kg bw/day	NOAEL of 0.025 mg/kg bw/day for increased incidence of maternal toxicity in a rat developmental toxicity study.
Flocoumafen	TDI	0.0000014 mg/kg bw/day	NOAEL of 0.0014 mg/kg bw/day for incidence of increased levels of serum cholesterol from a subchronic dietary toxicity study in rats.
	ARfD	0.00002 mg/kg bw/day	NOAEL of 0.002 from a developmental toxicity study in rabbits.
Warfarin	TDI	Not established by the APVMA	
	ARfD	Not established by the APVMA	

5 Residues and trade

Anticoagulant rodenticides are not registered for use on crops intended for human consumption, nor for application to food-producing livestock or poultry. Therefore, any plant or animal exposures to these chemicals would be the result of off-label use or incidental contamination by the pests which the products are registered to control (e.g., animal droppings, movement of baits, consumption of the treated pest by livestock or other non-target animals used for human consumption). This residues and trade risk assessment considered whether anticoagulant rodenticide product labels contain adequate instructions and warning statements to prevent residues in foods as well as consumer safety and trade.

Analytical methods for detection of residues of the anticoagulant rodenticides are available in various commodities. However, these are not relied on in this assessment because there are no registered uses in food crops or animals.

5.1 Potential for contamination in food producing situations

5.1.1 Field crops

There are no registered uses of first- or second-generation anticoagulant rodenticides for direct application to food crops. Use patterns/labels indicate bait must be placed in a bait station in such a way to ensure the bait will not come into direct contact with the ground or a crop.

Four coumatetralyl-containing products are currently registered for use in agricultural cropping situations (sugarcane, macadamias and pineapples) where they may be used as component of a comprehensive rodent control program, as specified on the label. In these situations, baits (blocks or prepared loose grain/fruit) are contained in bait stations located around the perimeter of crops. Baits are not in direct contact with the ground and not accessible to birds or other wildlife.

The labels of the aforementioned product's describe the construction of a bait station. Commercially available bait stations limit the quantity of bait material an applicator could apply. It is recommended that baiting in field crops be restricted to using commercially available, tamper-proof and weather-resistant bait stations to reduce the quantity of bait that can be applied in a single use.

Table 75 shows the restraints and critical comments are currently associated with field crop uses for the control of rats from APVMA product numbers 52098, 52182, 82217 and 86417:

Table 75: Restraints and critical comments associated with specific products field crop uses (52098 52182, 82217, 86417).

Situation	Critical comments
Field crops as below:	<p>For block products: Follow the Baiting Strategies for in crop situations detailed below. Bait must be placed in bait stations as described in Preparation of Bait Stations below.</p> <p>For powder/concentrate products: As a dry bait: Mix one part by weight of the concentrate with 20 parts of suitable bait material such as cereals or fruit. Choose bait which offers the rodents an alternative to the type of foodstuffs usually available.</p> <p>For both formulations: Baiting must be used as part of a comprehensive rodent control program. Clear gullies, weeds and scrub. Keep headlands well slashed or bare to discourage rats and to expose them to predators</p>
Sugar cane	Practise in-crop grass and weed control. Obtain rat population monitoring data from district organisations and bait according to local recommendations. Strategic baiting is best carried out in December and January.
Macadamias	If not possible to clear orchard boundaries, rehabilitate to rain forest. Monitor rodent damage levels prior to baiting. Concentrate baiting in the outer 3 rows of crop closest to scrubby habitats and when nuts are available.
Pineapples	Place bait stations at 9-metre intervals, 1 metre inside the block on all sides where rats are entering the block. Bait should be added to bait stations when fruit begins to form and bait replenished until after harvest.

Rate: 2 blocks (22.2 mg a.c./station) / 60-100 g prepared bait at 1:20 dilution (22.5-40 mg a.c./station) - no longer supported

The restraint statements in Table 76 are recommended to be applied to all products registered for in-field use to reduce the risk of livestock and horticultural commodities exposure.

Table 76: Restraint statements for in-field anticoagulant rodenticide use

Active	Restraint Statements
Coumatetralyl	<p>DO NOT place bait in food crop situations unless in tamper-proof and weather-resistant bait stations.</p> <p>DO NOT graze or feed livestock near treated areas whilst bait is present.</p>

The critical comment statements in Table 77 are recommended to be applied to all products for commercial use containing the listed active to reduce the risk of exposure to livestock and horticultural commodities when used for in-field applications. This includes amendments to the critical comments for use in macadamia crops, noting that the critical comments in Table 75 conflict with the product instructions for macadamia, which allow the placement of bait stations within the crop. From a residues and trade perspective, this placement is of bait stations within the crop acceptable, but the bait must not come into direct contact with the food commodity (i.e., macadamia nut), the crop (i.e., parts of the tree), or the soil in which the crops are grown.

Table 77: Critical comment statements for in-field anticoagulant rodenticide use

Active	Critical Comments
Coumatetralyl	<p>Use in tamper-proof and weather-resistant bait stations only. Bait stations must be fixed to the ground or other structures so as to prevent mobility.</p> <p>The bait material must be placed in a bait station. Bait must not come into direct contact with crops, food products or soil in which crops are grown.</p> <p>Locate bait stations around crop perimeters or in the outer 3 rows for macadamia cropping (particularly between the crop and grassy or bush habitats), near obvious rat runs, and/or close to known rat hiding spots such as stumps, rocks, logs or burrows.</p>

5.1.2 In and around buildings

Livestock and poultry housing, food and feed preparation areas

All anticoagulant rodenticides are registered for use in and around buildings. The use of rodenticides in and around agricultural buildings is the use scenario that poses the greatest risk of entering the human food chain. This includes use in and around animal husbandry facilities such as stables, milking parlours, cow sheds, poultry sheds, pig arks, and any building concerned in the storage, preparation, distribution, sale or consumption of food.

The potential for contamination in these situations has been historically evident, as the APVMA was notified that low levels of warfarin and coumatetralyl had been detected in pig livers in 2015. In response, the APVMA in coordination with Food Standard Australian New Zealand (FSANZ) and the Department of Agriculture established temporary MRLs for both actives (Gazette No. 8, 21 April 2015, Amendment instrument 2015 (No.3)¹⁶. A working group was set up and an industry best-practice standard developed¹⁷. State and Territory governments introduced PigPass, a mandatory reporting program designed to ensure the transport of pigs meets agreed industry and government standards relating to food safety, welfare standards, and animal disease control. The APVMA is not aware of further detections or incidents related to warfarin or coumatetralyl in pigs.

The following restraint statements are recommended be applied to all products containing the listed actives. When the restraints and critical comments proposed are followed, and industry best practices applied, residues of first- and second-generation rodenticides should not occur in livestock or poultry feeds, or animal commodities including meat, offal, milk, and eggs.

¹⁶ Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2015 (No. 3) – [Link](#)

¹⁷ Australian Pork Ltd – Industry Rodenticide Stewardship Plan – July 2021 – [Link](#)

Table 78: Restraint statements for anticoagulant rodenticide use in and around buildings

Active	Restraint Statements
Coumatetralyl	DO NOT place bait in areas where there is a possibility of contaminating food, livestock feed or surfaces that come in direct contact with food or livestock feed.
Diphacinone	DO NOT place baits in locations that are accessible to domestic animals, livestock, non-target native animals or birds.
Warfarin	DO NOT place in animal or livestock housing unless used in tamper proof and weather resistant bait stations fixed to the ground or other structures.
Brodifacoum	DO NOT place bait or bait stations above areas which would allow them to contaminate pig and poultry food or drinking water.
Bromadiolone	
Difenacoum	
Difethialone	
Flocoumafen	

The following critical comment statements are recommended to be applied to all products containing the listed actives for commercial use.

Table 79: Critical comments for anticoagulant rodenticides use in and around commercial buildings

Active	Critical Comments
Coumatetralyl	Careful consideration is necessary when placing bait stations in food producing animal housing situations to prevent contamination of water, feed, or livestock with rodenticide.
Diphacinone	
Warfarin	
Brodifacoum	
Bromadiolone	
Difenacoum	
Difethialone	
Flocoumafen	

The environment risk assessment also recommended that all first- and second-generation rodenticides products with instructions for use in commercial situations should be declared Restricted Chemical Products to be supplied and used by only authorised persons. This recommendation is supported in this residues risk assessment, as authorised individuals would be expected to have specific training or qualifications in the safe handling and use of these products and industry best practices, greatly reducing the risk of unintentional or incidental exposure involving commodities for human consumption.

In and around buildings – Non-agricultural uses

All first- and second-generation rodenticides are registered for use in and around domestic and industrial buildings which may or may not be associated with the storage, preparation, distribution, sale or consumption of food. Restraints and critical comments associated with uses in and around buildings having to do with livestock and poultry housing, and food and feed preparation areas are considered sufficient to address the risks associated with non-agricultural uses.

Transport vehicles

Bromadiolone, brodifacoum, coumatetralyl, flocoumafen and warfarin are registered for use inside transport vehicles. This includes ships (and their wharfs) which may transport edible commodities, or commercial livestock. Restraints and critical comments associated with uses in and around buildings having to do with livestock and poultry housing, and food and feed preparation areas are considered sufficient to address the risks associated with non-agricultural uses.

5.1.3 Bait formulation

Ready-to-use coumatetralyl wax blocks and coumatetralyl powder concentrates for dry-bait preparation (1:20 product to cereal or fruit bait matrix) are currently registered for use in crops. Solid bait formulations (blocks, pastes, pellets, treated grain, and consumer prepared dry-bait), contact formulations (powder), and liquid formulations of anticoagulant rodenticides are registered for use in and around buildings.

The use of anticoagulant rodenticide tracking powders, drinks, and non-ready-to-use products are not supported by the environment risk assessment recommendations (see section 3.4.1 above). These types of products present increased risks of unintentional exposure and misuse due to a high concentration of active constituent applied in a particular area or single baiting location. These safety concerns are also applicable to the potential contamination of food or feed or exposure of non-target livestock or other animals when these products are used in food producing situations, and therefore are also not supported in this residues risk assessment.

Further, the use of loose pellets or grains is also not supported in livestock and poultry housing, food and feed preparation areas, as these formulation types also present a greater chance of being removed from a bait station by an animal, or a spill occurring during routine checking or refilling (compared to solid block formulations).

5.1.4 Edible wildlife (non-target) exposure

The monitoring data available on anticoagulant rodenticide residues found in fish, terrestrial invertebrates, native rodents, and rodent-eating species in Australia (snakes, lizards, quolls and raptors) are limited, but have shown evidence that secondary exposure to anticoagulant rodenticides is occurring in urban and agricultural areas (see section 3.3.2 Risks to terrestrial vertebrates above). Some of these species that eat rodents may be components of the traditional diets of Australia's indigenous peoples. This suggests the possibility of secondary poisoning of species that may be consumed by humans.

Goannas (*Varanus* spp.) are considered a culturally and economically important constituent of a traditional diet for some indigenous peoples. The target tissue of anticoagulant rodenticides, the liver, is consumed preferentially to other parts of the goanna, along with its fatty tissues (Lohr & Davis 2018). No data is available describing the

quantity of goanna consumed, and data on the consumption of other wildlife, culturally significant and important to traditional diets of peoples from around Australia, is also insufficient.

Monitoring data on the concentrations of first- and second-generation anticoagulant rodenticide residues found in *Varanus* spp. has not been provided to this review. Data that has been provided describing FGAR and SGAR residues in reptiles is summarized in Table 80, however this is not sufficient to complete a meaningful dietary-exposure risk assessment.

Mitigation measures to prevent either primary or secondary exposure of non-target animals, as recommended in section 3.4 above, will make it unlikely that people will be unintentionally exposed to residues of anticoagulant rodenticides through their diet.

Table 80: Summary of Monitoring Data in Australian reptiles. APVMA Environment Report - Anticoagulant rodenticides - Fate and behaviour in the environment

Active	Rodenticide data	Reference
Coumatetralyl	--	--
Diphacinone	--	--
Warfarin	Max liver residues 11 µg/kg in 4/11 dugites from 2014-18, not detected in 10 bobtails or 11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
Brodifacoum	Max liver residues 330 µg/kg in 7/11 dugites, 109 µg/kg in 6/10 bobtails from 2014-18, and 14 µg/kg in 5/11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
Bromadiolone	Max liver residues 700 µg/kg in 5/11 dugites, 73 µg/kg in 4/10 bobtails from 2014-18, and not detected in 11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
Difenacoum	Max liver residues 53 µg/kg in 4/11 dugites, 2 µg/kg in 1/10 bobtails in 2014-18, and not detected in 11 tiger snakes in 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
Difethialone	--	--
Flocoumafen	Max liver residues 4 µg/kg in 1/10 bobtails from 2014-18, not detected in 11 dugites (2014-18) or 11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020

Note: Dugites (n=11) and bobtails (n=10) were collected opportunistically as roadkill or non-rotten carcasses donated by wildlife care centres between 2014 and 2018, and tiger snakes (n = 11) were wild caught and euthanised between 2018 and 2019.

The following restraint and critical comments are also recommended to be applied to all products containing the listed actives, in addition to those recommended by the environment risk assessment, to further reduce the risk of rodenticide exposure to edible wildlife or game, present in the surrounding areas:

Active	Restraints / Critical Comment Statements
Coumatetralyl	DO NOT bait in areas where wildlife may be collected for human consumption.
Diphacinone	Caution should be used when baiting near areas where hunting of wildlife may occur.
Warfarin	Careful consideration of bait placement is necessary to avoid secondary exposure from contaminated wildlife that may be consumed.
Brodifacoum	
Bromadiolone	
Difenacoum	
Difethialone	
Flocoumafen	

5.1.5 Carcass management

The environmental risk assessment recommendations include instructions to reduce the risk of exposure to wildlife which may be present near the treatment area (see **3.4.2 Supported products and uses** above). It is noted the omnivorous nature of swine and poultry, as well as predatory behaviours of goanna, snakes and wild boars, does not preclude them from consuming dead or moribund rodents or invertebrates having ingested rodenticidal baits. Therefore, it is recommended that the following amended instructions be included on all available products, to incorporate the risks also posed to livestock and poultry:

Hazardous to livestock, poultry and wildlife. Search for and dispose of dead rodents and slugs/snails in the infested area at each visit to prevent secondary poisoning. In case slugs/snails are present, move bait station to another location within the rodent infested site, away from slugs/snails. Dispose of slugs/snails in a way non-target animals are not exposed. Dispose of dead rodents and uneaten bait in compliance with local, state or territory government regulations.

The following restraint statements are also recommended to be applied to all products.

5.2 Dietary risk assessment

First and second-generation anticoagulant rodenticides are non-food-use pesticides. Product contact with crops, commercially raised livestock, food products, or the soil in which crops are grown should not occur. It is unlikely dietary exposure could occur via consumption of livestock, their commodities, crops, or from residues in ground or surface waters.

5.3 Residue-related aspects of trade

Anticoagulant rodenticides are not registered for use on food producing crops or for treatment of food producing animals. Significant residues are not expected in livestock feeds. For completeness, a comparison of Australian MRLs with Codex and overseas MRLs is presented in Table 81 below.

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides, which are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Rodenticides have not been considered by Codex.

Table 81: Comparison between Australian and Codex MRLs: anticoagulant rodenticides.

Commodity	Overseas MRLs/tolerances (mg/kg)						
	Australia ^{18,A}	Codex ¹⁹	EU ²⁰	Japan ²¹	Korea ²²	Taiwan ²³	USA ²⁴
Coumatetralyl							
Pig fat	T*0.001	--	--	--	--	--	
Pig meat	T*0.001	--	--	--	--	--	
Pig, edible offal of {except Liver}	T0.003	--	--	--	--	--	Registered HG & CO
Pig, liver	T0.004	--	--	--	--	--	
Animal commodities	--	--	--	--	--	--	
Plant commodities	--	--	--	--	--	--	
Diphacinone							
N/A	--	--	--	--	--	--	Registered HG & CO
Warfarin							
Pig fat	T0.007	--	*0.01	*0.001	--	--	
Pig meat	T0.007	--	*0.01	*0.001	--	--	
Pig, edible offal of {except Liver}	T0.007	--	*0.01	*0.001	--	--	Registered HG & CO
Pig, liver	T0.04	--	*0.01	*0.001	--	--	

¹⁸ A full listing of MRLs current at the time of evaluation can be found in the *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023* – [Link](#).

¹⁹ CODEX Alimentarius – MRLs for Residues of Pesticides in Food – [Link](#)

²⁰ European Commission – EU Pesticides database – [Link](#)

²¹ The Japan Food Chemical Research Foundation – [Link](#)

²² Korean Residue material information (Pesticides and Veterinary Drugs Information) – [Link](#)

²³ Taiwan Food and Drug Administration – Standards for Pesticide Residue Limits in Foods – [Link](#)

²⁴ USFDA CFR Title 40 – §180.1223 – Imazamox; exemption from the requirement of a tolerance – [Link](#)

Commodity	Overseas MRLs/tolerances (mg/kg)						
	Australia ^{18,A}	Codex ¹⁹	EU ²⁰	Japan ²¹	Korea ²²	Taiwan ²³	USA ²⁴
Animal commodities	--	--	*0.01	*0.001	--	--	
Plant commodities	--	--	*0.01	*0.001	--	--	
Brodifacoum							
N/A	--	--	--	--	--	--	Registered CO
Bromadiolone							
Mammalian fat	--	--	*0.01	--	--	--	
Mammalian kidney	--	--	*0.01	--	--	--	
Mammalian liver	--	--	*0.01	--	--	--	Registered CO
Mammalian muscle	--	--	*0.01	--	--	--	
Plants	--	--	*0.01	--	--	--	
Difenacoum							
Animal commodities	--	--	*0.01	--	--	--	Registered CO
Plant commodities	--	--	*0.01	--	--	--	
Difethialone							
N/A	--	--	--	--	--	--	Registered CO
Flocoumafen							
N/A	--	--	--	--	--	--	Registered CO

Note: The United States does not have MRLs for individual rodenticides but limits the availability of SGARs to commercial operators (CO) and allows FGAR use in home and garden (HG) settings by the general public.

^A Australian TMRLs are expected to be removed following this review

5.4 Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

5.4.1 Residue definitions

Residues definitions for brodifacoum, coumatetralyl and warfarin are defined in Table 3 of the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 (MRL Standard) as parent for each active. The residues definition for brodifacoum was established by the Pesticides and Agricultural Chemicals Standing Committee (PACSC) in August 1992 as an MRL for GS 0659 Sugarcane was established at

*0.0005 mg/kg. Residue definitions for coumatetralyl and warfarin were established when temporary MRLs were established for pig meat, fat and edible offal.

Table 5 of the MRL Standard lists uses of substances where MRLs are not necessary. MRLs are not considered necessary in situations where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or otherwise are of no toxicological significance. Entries for difethialone, diphacinone and flocoumafen are found in Table 5 of the MRL Standard but the residue definitions are not listed in Table 3.

Noting that all anticoagulant rodenticides fit the category of a Table 5 entry, as their use patterns constitute situations where residues should not occur in foods or animal feeds, associated residue definitions will be recommended for deletion from Table 3 of the MRL Standard.

5.4.2 Anticoagulant rodenticide entries in the MRL Standard

As residues of any anticoagulant rodenticide are not expected in livestock or animal feeds, it is recommended that the temporary MRLs listed in Table 82 be deleted from the MRL Standard for both warfarin and coumatetralyl.

Table 82: Table 1 entries in the APVMA MRL Standard relevant to the current reconsideration

Compound	Food	MRL (mg/kg)
Coumatetralyl		
MF 0818	Pig fat	T*0.001
MM 0818	Pig meat	T*0.001
MO 0818	Pig, edible offal of {except Liver}	T0.003
MO 1285	Pig, liver	T0.004
Warfarin		
MO 0818	Pig, edible offal of {except Liver}	T0.007
MF 0818	Pig fat	T0.007
MO 1285	Pig, liver	T0.04
MM 0818	Pig meat	T0.007

The *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023*, Table 5 lists uses of substances in situations where MRLs are not necessary. Active constituents that do not have uses in food crops or species usually do not require an MRL, and if not, they are listed in Table 5.

All first- and second-generation rodenticides are registered for use in, and around livestock or poultry housing, and food and feed preparation areas. When industry best-practices and label statements are followed, residues of anticoagulant rodenticides should not occur in foods or feeds. Therefore, the following Table 5 entry is recommended: *“For use in baits as a rodenticide, in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas.”*

Only products containing the anticoagulant rodenticide active constituent *coumatetralyl* are currently approved for use in situations involving food production such as agricultural cropping situations. The Table 5 entry for *coumatetralyl* should be amended from “*in baits as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur*” to “*in bait stations as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur*”.

Table 5 contains entries for *difethialone*, *diphacinone*, *flocoumafen* and *warfarin* “*in baits as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur*”. These instructions no longer apply to any products containing the listed active constituents, and therefore the entries should be removed from Table 5.

5.4.3 Summary of recommended amendments to the MRL Standard

Noting that the use of the anticoagulant rodenticides, according to the recommended instructions and restraints discussed above, is not expected to result in residues of anticoagulant rodenticides in livestock or animal feed, it is recommended that the current MRLs and residues definitions for warfarin and coumatetralyl be deleted from Table 1 and Table 3 of the MRL Standard. MRL amendments recommended for Tables 1 and 3 below will be considered for inclusion in Schedule 20 of the Australia New Zealand Food Standards Code.

The recommended amendments to be made to the MRL Standard are summarised below.

Table 1, Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

COMPOUND	FOOD	MRL (mg/kg)
Coumatetralyl		
DELETE:		
MF 0818	Pig fat	T*0.001
MM 0818	Pig meat	T*0.001
MO 0818	Pig, edible offal of {except Liver}	T0.003
MO 1285	Pig, liver	T0.004
Warfarin		
DELETE:		
MO 0818	Pig, edible offal of {except Liver}	T0.007
MF 0818	Pig fat	T0.007
MO 1285	Pig, liver	T0.04
MM 0818	Pig meat	T0.007

Table 3, Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

COMPOUND	Residue
DELETE:	
Brodifacoum	Brodifacoum
Coumatetralyl	Coumatetralyl
Warfarin	Warfarin

Table 5, Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

SUBSTANCE	USE
DELETE:	
Coumatetralyl	<ul style="list-style-type: none"> In baits as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur
Difethialone	<ul style="list-style-type: none"> In baits as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur
Diphacinone	<ul style="list-style-type: none"> In baits as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur
Flocoumafen	<ul style="list-style-type: none"> In baits as a rodenticide in situations where contact with crops, food products, or soil in which crops are grown will not occur
Warfarin	<ul style="list-style-type: none"> In baits as a rodenticide in situations where contact with crops, food products, or soil in which crops are grown will not occur
ADD:	
Coumatetralyl	<ul style="list-style-type: none"> In bait stations as a rodenticide in situations where contact with crops, food products or soil in which crops are grown will not occur In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas
Brodifacoum	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas
Bromadiolone	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas
Difenacoum	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas
Difethialone	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas
Diphacinone	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas

SUBSTANCE	USE
Flocoumafen	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas
Warfarin	<ul style="list-style-type: none"> In baits as a rodenticide in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas

5.5 Recommendations

5.5.1 Labelling requirements

Anticoagulant rodenticides are not registered for use on food producing crops or for treatment of food producing animals. Noting that the recommendations of the environment risk assessment are intended to mitigate the potential risks of unintentional primary and secondary exposure of non-target animals, it is recommended that the additional restraints and critical comments compiled in Table 83 and Table 84 are required to mitigate the potential risks associated with anticoagulant rodenticide contamination in food producing situations.

The following restraints and critical comments are recommended to be applied to all products containing the coumatetralyl for commercial use in field cropping situations:

Table 83: Restraints and critical comments required for supported uses in cropping situations

Active	Restraint Statements
Coumatetralyl	<p>DO NOT place bait in food crop situations unless in tamper-proof and weather-resistant bait stations.</p> <p>DO NOT graze or feed livestock near treated areas whilst bait is present.</p>
Active	Critical Comments
Coumatetralyl	<p>Use in tamper-proof and weather-resistant bait stations only. Bait stations must be fixed to the ground or other structures to prevent mobility.</p> <p>The bait material must be placed in a bait station. Bait must not come into direct contact with crops, food products or soil in which crops are grown.</p> <p>Locate bait stations around crop perimeters or in the outer 3 rows for macadamia cropping (particularly between the crop and grassy or bush habitats), near obvious rat runs, and/or close to known rat hiding spots such as stumps, rocks, logs or burrows.</p>

The following restraints and/or critical comments are recommended to be applied to all products containing the following actives for use in and around buildings.

Table 84: Restraints and critical comments required for supported uses in and around buildings

Active	Restraint Statements
Coumatetralyl	DO NOT place bait in areas where there is a possibility of contaminating food, livestock feed or surfaces that come in direct contact with food or livestock feed.
Diphacinone	

Warfarin	DO NOT place baits in locations that are accessible to domestic animals, livestock, non-target native animals or birds.
Brodifacoum	DO NOT place in animal or livestock housing unless used in tamper proof and weather resistant bait stations fixed to the ground or other structures.
Bromadiolone	DO NOT place bait or bait stations above areas which would allow them to contaminate pig and poultry food or drinking water.
Difenacoum	DO NOT allow livestock or poultry to consume dead or moribund mice and rats. All dead or moribund animals and rodent faeces from baited rodents MUST be removed from areas accessible to livestock or poultry.
Difethialone	
Flocoumafen	

Active	Critical Comments
Coumatetralyl	When used in food producing animal housing situations careful consideration is necessary regarding the placement of bait stations to ensure any rodenticide contamination of water, feed or livestock is prevented.
Diphacinone	
Warfarin	Hazardous to livestock, poultry and wildlife. Search for and dispose of dead rodents and slugs/snails in the infested area at each visit to prevent secondary poisoning. In case slugs/snails are present, move bait station to another location within the rodent infested site, away from slugs/snails. Dispose of slugs/snails in a way non-target animals are not exposed. Dispose of dead rodents and uneaten bait in compliance with local, state or territory government regulations.
Brodifacoum	
Bromadiolone	
Difenacoum	
Difethialone	
Flocoumafen	

5.5.2 Uses not supported by this assessment

All products formulated as powder, loose grain, loose pellets, or liquid are not supported for use in any food producing situations considered in this assessment. Specifically, use of these formulations in field crops (sugar cane, macadamia, pineapples) and use in and around animal, livestock and poultry houses, associated equipment, and food and feed processing areas is not supported.

5.5.3 Assessment against the Trade Criteria

There are no anticoagulant rodenticide products registered with instructions for use in food producing crops or animals. Use according to the recommended instructions outlined above is not expected to result in residues in trade commodities.

Appendix A – Listing of environmental endpoints

Coumatetralyl

Fate and behaviour in the environment

Table 85: Coumatetralyl – Physical and chemical properties

Study	Result	Reference
Vapour pressure	$<1.0 \times 10^{-3}$ Pa at 20°C	Olf 2000
Henry's law constant	$<6.6 \times 10^{-2}$ Pa m ³ mol ⁻¹	Stöcker 2004
Solubility in water	pH 5, 20°C: 4.8 mg/L pH 7, 20°C: 460 mg/L pH 9, 20°C: 4650 mg/L	Erstling & Jungheim 2002a
Partition coefficient	pH 5: log P _{OW} 3.4 pH 7: log P _{OW} 1.5 pH 9: log P _{OW} -0.1	Erstling & Jungheim 2002b
Dissociation constant	pKa 3.9	Wiche & Ziemer 2014
UV-VIS absorption (max)	λ_{\max} ϵ (L mol ⁻¹ cm ⁻¹) 271 nm 11769 282 nm 12059 308 nm 10623	Kaussmann 2000

Table 86: Coumatetralyl – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Aerobic soil metabolism	Sandy loam: DT ₅₀ 8.7 d	Kreschnak 2014, Scholz 1987a
		Sandy loam: DT ₅₀ 8.2 d	Kreschnak 2014, Scholz 1987b
		Silt loam: DT ₅₀ 5.9 d	
		Geomean DT ₅₀ 7.5 d	

Compartment	Study	Result	Reference
		44-51% mineralisation after 81-90d 34-38% bound residues after 81-90d No major metabolites	
	Anaerobic soil metabolism	Sandy loam: stable <1% mineralisation after 60d 5% bound residues after 60d No major metabolites	Scholz 1987a
	Adsorption/desorption	Soil pH %OC Kd Koc	
		clay 5.6 3.3 15 468	Goller 2014
		loam 5.7 3.0 9.0 299	
		sandy loam 6.6 1.2 5.0 283	
		silt loam 6.8 1.3 0.41 31	
		silt loam 7.1 3.7 2.1 57	
		sandy loam 4.3 1.1 8.1 735	Slangen 2002
		clay 5.7 2.3 2.7 115	
		sand 6.0 0.56 2.3 403	
		silt loam 6.5 3.0 2.1 71	
		clay loam 7.4 1.7 3.1 185	
		pH <6.5: mean Kd 7.4 mL/g, Koc 404 mL/g pH ≥6.5: mean Kd 2.5 mL/g, Koc 125 mL/g	
Water and sediment	Hydrolysis	pH 4, 50°C: stable pH 7, 50°C: stable pH 9, 50°C: stable	Lange 2014
	Aqueous photolysis	DT ₅₀ 0.82 d in summer at 40°N DT ₅₀ 3.6 d in winter at 40°N	Lange 2015
	Readily biodegradable	No	Desmares-Koopmans & van de Waart 2001a
	Inherently biodegradable	No	Desmares-Koopmans & van de Waart 2001b

Compartment	Study	Result	Reference
Air	Tropospheric degradation	DT ₅₀ 2.4 h (OH radical reaction) DT ₅₀ 2.0 h (ozone reaction)	Hellpointner 2004
Biota	Rat	75-86% oral absorption 42-49% elimination after 7d Liver DT ₅₀ 55 d	Anderson 1999b Parmar <i>et al.</i> 1987
	Mouse	Liver DT ₅₀ 16 d	Vandenbroucke <i>et al.</i> 2008
	Red deer	Liver DT ₅₀ 19 d	Crowell <i>et al.</i> 2013
	Fish	BCF 11, CT ₅₀ ~15 h	Grau 1992c

Table 87: Coumatetralyl – Residues monitoring data

Compartment	Location	Result	Reference
Water	Europe	<LOQ (0.2 µg/kg) in suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019
Target rodents	Australia	Max liver residues 25000 µg/kg in canefield rat and 560 µg/kg in climbing rat following 375 mg/kg paste treatment at two sites in North Qld sugarcane	Brodie & Dyer 2002a
		Max liver residues 17000 µg/kg in canefield rat and 1000 µg/kg in climbing rat following 375 mg/kg wax block treatment at two sites in North Qld sugarcane	Brodie & Dyer 2002b
Non-target mammals	Australia	Max liver residues 290 µg/kg in northern brown bandicoot following 375 mg/kg paste treatment at two sites in North Qld sugarcane	Brodie & Dyer 2002a
		Max liver residues 220 µg/kg in northern brown bandicoot following 375 mg/kg wax block treatment at two sites in North Qld sugarcane	Brodie & Dyer 2002b
		Not detected in brushtail possum in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Not detected in 53 brushtail possums, 82 ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024
	UK	Max liver residues 9.7 µg/kg in 6/45 stoat, 60 µg/kg in 3/10 weasel following open area baiting in English estates between 1996-97	McDonald <i>et al.</i> 1998

Compartment	Location	Result	Reference
		Not detected in liver of polecat that made heavy use of agricultural premises using anticoagulant rodenticides in UK between 1993-95	Birks 1998
	Europe	Not detected in liver or muscle of 51 wild boars in urban area, 20 wild boars in suburban area, or 13 wild boars in rural area of Spain	Alabau <i>et al.</i> 2020
		Not detected in 29 herbivores, 3 insectivores, 96 carnivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Birds	Australia	Max liver residues 1.6 µg/kg in barn owls; not detected in little ravens, Australian kestrels, whistling kites, barking owls, southern boobooks, powerful owls, tawny frogmouths in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 161 µg/kg in 5/38 powerful owls in Sydney basin urban areas between 2015 and 2021	Birdlife Australia 2022
		Not detected in 5 eastern barn owls, 12 southern boobooks, 19 tawny frogmouths, 24 powerful owls in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Not detected in 5 Carnaby's cockatoos from Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
		Not detected in 73 southern boobooks in urban & peri-urban areas of WA	Lohr 2018
		Max liver residues 14 µg/kg in 1/50 (2%) wedge-tailed eagles across Tasmania between 1996 and 2018	Pay <i>et al.</i> 2021
	Tawain	Geomean liver residues 6 µg/kg in 1/1 common buzzard; not detected in 74 black-winged kite, 46 crested goshawk, 42 collared scops-owl, 12 crested serpent-eagle, 8 black kite, 6 oriental honey-buzzard, 6 short-eared owl, 3 eastern grass-owl, 3 eurasian kestrel or 11 other raptor species, in Taiwan between 2010 and 2018	Hong <i>et al.</i> 2019
		Not detected in 112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022
	North America	Not detected in 50 Cooper's hawk, 78 red-tailed hawk, 22 screech owls, 53 great horned owl in New York between 1998 and 2001	Stone <i>et al.</i> 2003
	Europe	Max liver residues 9.1 µg/kg in 8/48 northern goshawk; not detected in 41 red kite, 60 white-tailed eagle, 23 Eurasian sparrowhawk, or 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021

Compartment	Location	Result	Reference
		Max liver residues 18 µg/kg in 10/80 barn owls, 435 µg/kg in 13/141 buzzards, 64 µg/kg in 9/66 kestrels, 29 µg/kg in 3/38 long-eared owls, 3 µg/kg in 2/31 rough-legged buzzards, 39 µg/kg in 9/44 tawny owls from intensively managed landscapes in Denmark	Christensen <i>et al.</i> 2012
		Not detected in 142 granivorous birds, 129 predatory birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Reptiles	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Fish	Europe	<LOQ (0.2 µg/kg) in bream of two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 1.6 µg/kg in 13/32 fish in bioaccumulation ponds and 0.02 µg/kg in 1/12 fish in receiving streams of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019
		Max liver residues 0.06 µg/kg in 27/46 fish in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 88: Coumatetralyl – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ²⁵	Reference
Mammals	Acute	<i>Rattus norvegicus</i>	LD ₅₀ 15 mg/kg bw	Bowmann 1992
	Dietary	<i>Meriones hurrianae</i>	LDD ₅₀ 0.53 mg/kg bw/d	Mathur & Prakash 1983
		<i>Tatera indica</i>	LDD ₅₀ 0.60 mg/kg bw/d	
	Palatability & avoidance	<i>Felis catus</i>	0.37 g/kg paste: AV 1.0	Hopkins & Kerwick 2001
Birds	Acute	<i>Columbia livia</i>	LD ₅₀ >37 mg/kg bw	Bhide & Naik 1989a
		<i>Gallus domesticus</i>	LD ₅₀ >37 mg/kg bw	Bhide & Naik 1989b
		<i>Coturnix japonica</i>	LD ₅₀ >2000 mg/kg bw	Grau 1992a

²⁵ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Group	Exposure	Species	Toxicity value ²⁵	Reference
	Dietary	Coturnix japonica	LC ₅₀ 1733 mg/kg food	Grau 1992b
		Passer melanurus	LDD ₅₀ 38 mg/kg bw/d	Heyl 1986
	Reproduction	Coturnix japonica	NOEC 20 mg/kg food	Barfknecht 2004
	Palatability & avoidance	Gallus domesticus	0.0375 g/kg paste: PD 0	Barfknecht 2005a
			0.0375 g/kg paste: AV 0.60	Barfknecht 2005b
Reptiles	Acute	Sceloporus occidentalis	LD ₅₀ >1750 mg/kg bw	Weir <i>et al.</i> 2016

AV: avoidance factor (1.0 =no avoidance, 0= 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0= no food consumed)

Table 89: Coumatetralyl – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Mammals	Rattus norvegicus	211 mg/kg sparrow for 8-9 days	2/2 died after consuming 9.5% of body mass daily	Heyl 1986
	Felis catus	211 mg/kg sparrow for 14 days	1/1 died after consuming 3.1% of body mass daily	Heyl 1986
	Mustela furo	5.0 mg/kg rat for 3 days	2/9 died after consuming higher proportion of their body weights (average 83% of body mass for all 9)	O'Connor & Eason 1999a, O'Connor <i>et al.</i> 2003
Birds	Buteo vulpinus	211 mg/kg sparrow for 18 days	1/1 survived after consuming 13% of body mass daily	Heyl 1986
	Bubo africanus	211 mg/kg sparrow for 18 days	1/1 survived after consuming 9.8% of body mass daily	Heyl 1986
	Tyto alba	3.9 mg/kg rat for 6 days	4/4 survived after consuming 22-25% of body mass daily	Fisher <i>et al.</i> 2003

Group	Species	Poisoned food	Study details & result	Reference
	Gallirallus australis	5.0 mg/kg rat for 3 days	10/10 survived after consuming 25% of body mass daily	O'Connor & Eason 1999b, O'Connor <i>et al.</i> 2003

Table 90: Coumatetralyl – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
Qld sugarcane	375 mg a.c./kg bait 28.1 mg a.c./location	Mortality of northern brown bandicoot attributed to wax block treatment but not paste	Brodie & Dyer 2002a, 2002b
Grampian UK	Approved tracking powder use in piggery	2 fox poisonings adjacent to treated farm	Fletcher <i>et al.</i> 2000
Various counties across UK	Unspecified	1 fox poisoning in 1998	Fletcher <i>et al.</i> 1999
		3 fox poisonings in 1999	Fletcher <i>et al.</i> 2000
Various counties across UK	Unspecified	1 fox poisoning in 2000	Barnett <i>et al.</i> 2002a
		1 fox poisoning, in very thin condition and signs of bacterial septicaemia in 2003	Barnett <i>et al.</i> 2004
		1 fox found ill in garden and died in 2005	Barnett <i>et al.</i> 2006
		No wildlife incidents that involved approved uses or unspecified exposure in 2001, 2002, 2004, and 2006	Barnett <i>et al.</i> 2002b, 2003, 2005, 2007
New York, USA & adjoining states	Unspecified	1 white-tailed deer poisoning in 1971-1997	Stone <i>et al.</i> 1999
		No wildlife incidents that involved approved uses or unspecified exposure in 1999-2001, 2003, 2005-2006	Barnett <i>et al.</i> 2002a, 2002b, 2004, 2006, 2007, Fletcher <i>et al.</i> 2000
		4 crows poisoned (accessed protected bait points) in 2004	Barnett <i>et al.</i> 2005

Table 91: Coumatetralyl – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 53 mg/L	Sewell & McKenzie 2003
	Chronic	Oncorhynchus mykiss	NOEC 0.0050 mg/L	Grau 1992d
Invertebrates	Acute	Daphnia magna	EC ₅₀ >14 mg/L	Heimbach 1991a
		0.75 g/kg powder: EC ₅₀ >10 mg/L		Heimbach 1991b
	Chronic	Daphnia magna	NOEC 0.10 mg/L	Heimbach 1992
Algae	Chronic	Scenedesmus subspicatus	E _r C ₅₀ >18 mg/L	Heimbach 1991c

Table 92: Coumatetralyl – Effects on bees

Species	Life stage	Exposure	Toxicity value	Reference
Apis mellifera	adult	Contact	LD ₅₀ 0.63 µg/bee	Bhide & Naik 1989c

Table 93: Coumatetralyl – Effects on soil organisms

Group	Exposure	Species/process	Toxicity value	Reference
Macro-organisms	Acute	Eisenia fetida	LC ₅₀ 225 mg/kg dry soil	van Erp 2001

Table 94: Coumatetralyl – Effects on biological methods of sewage treatment

Test	Endpoint	Reference
Activated sludge	EC ₅₀ 4210 mg/L	Müller & Hartmann 1991

Diphacinone

Fate and behaviour in the environment

Table 95: Diphacinone – Physical and chemical properties

Study	Result	Reference
Vapour pressure	1.5×10^{-5} Pa at 25°C	Flack 1999

Study	Result	Reference																					
Henry's law constant	$2.6 \times 10^{-9} \text{ Pa m}^3 \text{ mol}^{-1}$	Flack 1999																					
Solubility in water	9.7 mg/L at 20°C	Flack 1999																					
Partition coefficient	pH 4: log P _{OW} 3.6 pH 7: log P _{OW} 1.4 pH 10: log P _{OW} 1.3	Flack 1999																					
Dissociation constant	pKa 2.7	Flack 1999																					
UV-VIS absorption (max)	<table border="1"> <thead> <tr> <th>solution</th> <th>λ_{max}</th> <th>ϵ (L mol⁻¹ cm⁻¹)</th> </tr> </thead> <tbody> <tr> <td>acidic</td> <td>238 nm</td> <td>27500</td> </tr> <tr> <td>acidic</td> <td>286 nm</td> <td>30900</td> </tr> <tr> <td>neutral</td> <td>202 nm</td> <td>38400</td> </tr> <tr> <td>neutral</td> <td>284 nm</td> <td>35100</td> </tr> <tr> <td>basic</td> <td>220 nm</td> <td>36700</td> </tr> <tr> <td>basic</td> <td>283 nm</td> <td>37300</td> </tr> </tbody> </table>	solution	λ_{max}	ϵ (L mol ⁻¹ cm ⁻¹)	acidic	238 nm	27500	acidic	286 nm	30900	neutral	202 nm	38400	neutral	284 nm	35100	basic	220 nm	36700	basic	283 nm	37300	Flack 1999
solution	λ_{max}	ϵ (L mol ⁻¹ cm ⁻¹)																					
acidic	238 nm	27500																					
acidic	286 nm	30900																					
neutral	202 nm	38400																					
neutral	284 nm	35100																					
basic	220 nm	36700																					
basic	283 nm	37300																					

Table 96: Diphacinone – Fate and behaviour in environmental media

Compartment	Study	Result	Reference																														
Soil	Aerobic soil metabolism	Sandy loam: DT ₅₀ 30 d 34-40% mineralisation after 90d 18-33% bound residues after 90d	Yan & Heim 1996																														
	Adsorption/desorption	<table border="1"> <thead> <tr> <th>Soil</th> <th>pH</th> <th>%OC</th> <th>K_f</th> <th>K_{oc}</th> </tr> </thead> <tbody> <tr> <td>Honouluili</td> <td>6.9</td> <td>1.2</td> <td>26</td> <td>2135</td> </tr> <tr> <td>Molokai</td> <td>7.0</td> <td>1.8</td> <td>17</td> <td>945</td> </tr> <tr> <td>Kapaa</td> <td>6.1</td> <td>3.4</td> <td>160</td> <td>4692</td> </tr> <tr> <td>Hilo</td> <td>5.7</td> <td>5.5</td> <td>176</td> <td>3201</td> </tr> <tr> <td>Kukaiau</td> <td>5.5</td> <td>5.6</td> <td>214</td> <td>3800</td> </tr> </tbody> </table> Mean K _f 119 mL/g, K _{oc} 2955 mL/g	Soil	pH	%OC	K _f	K _{oc}	Honouluili	6.9	1.2	26	2135	Molokai	7.0	1.8	17	945	Kapaa	6.1	3.4	160	4692	Hilo	5.7	5.5	176	3201	Kukaiau	5.5	5.6	214	3800	Nomura 1978
	Soil	pH	%OC	K _f	K _{oc}																												
Honouluili	6.9	1.2	26	2135																													
Molokai	7.0	1.8	17	945																													
Kapaa	6.1	3.4	160	4692																													
Hilo	5.7	5.5	176	3201																													
Kukaiau	5.5	5.6	214	3800																													
Column leaching		38100 mm elution over 30d, sand soil: >98% in top 5 cm 0.12% in leachate	Weber 1978																														

Compartment	Study	Result	Reference
		500 mm elution, four soils aged 30d: 76-117% in top 6 cm Not detected in leachate	Riekema 1995a
Water	Hydrolysis	pH 5, 24°C: DT ₅₀ 44 d pH 7, 24°C: stable pH 9, 24°C: stable	Riekema 1995b
Biota	Rat	15% oral absorption 47-77% elimination after 8d Liver DT ₅₀ 3.0 d	Yu & Atallah 1980 Fisher <i>et al.</i> 2003
	Mouse	15% oral absorption 73-80% elimination after 4d	Yu & Atallah 1980
	Cattle	Liver DT ₅₀ >90 d	Bullard <i>et al.</i> 1976
	Pig	Liver DT ₅₀ 12 d	Crowell <i>et al.</i> 2013
	Red deer	Liver DT ₅₀ 6.0 d	Crowell <i>et al.</i> 2013
	American kestrel	Liver DT ₅₀ 2.5 d	Rattner <i>et al.</i> 2011
	Eastern screech owl	Liver DT ₅₀ 29 d	Rattner <i>et al.</i> 2014
	Fish	BCF 10 (muscle), 80 (viscera) 70% (muscle), 80% (viscera) eliminated after 14 d depuration	Ells 1976

Table 97: Diphacinone – Residues monitoring data

Compartment	Location	Result	Reference
Terrestrial invertebrates	North America	390 µg/kg in carrion beetles; not detected in carabid beetles, wasps, snails, slugs, worms, or maggots in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014

Compartment	Location	Result	Reference
Target rodents	North America	Liver residue 640 µg/kg in 1/2 rats in two farms in area of intensive poultry farming; not detected in 5 rats in bromadiolone baited farm in Canada	Elliott <i>et al.</i> 2014
Non-target mammals	North America	Not detected in 23 voles, 6 shrews, 3 deer mice in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
	Europe	Not detected in 29 herbivores, 3 insectivores, 96 carnivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
	South Africa	Detected but not quantifiable in 8/24 caracals in Greater Cape Town, South Africa between 2014 and 2017	Serieys <i>et al.</i> 2019
Birds	Tawain	Geomean liver residues 15 µg/kg in 7/46 crested goshawk, 10 µg/kg in 3/42 collared scops-owl, 9 µg/kg in 1/6 oriental honey-buzzard; not detected in 74 black-winged kite, 12 crested serpent-eagle, 8 black kite, 6 short-eared owl, 3 eastern grass-owl, 3 eurasian kestrel, 1 common buzzard or 11 other raptor species in Taiwan between 2010 and 2018	Hong <i>et al.</i> 2019
		Detected in 2/112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022
	North America	Detected in 2/20 in 2013, and 3/77 in 2015 red-tailed hawk blood samples from Marin Headland, California	Abernathy <i>et al.</i> 2018
		Not detected in 1 sparrow, 7 starlings in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
		Max liver residues 12 µg/kg in 4/61 great horned owls, 12 µg/kg in 1/25 barred owls, 20 µg/kg in 3/78 barn owls in BC & Yukon Territory of Canada between 1988 and 2003	Albert <i>et al.</i> 2010
		Not detected in 37 red-tailed hawks, 24 barred owls, 17 great horned owls, 16 eastern screech-owls in Massachusetts between 2012 and 2016	Murray 2017
		Liver residues 100 µg/kg in 1/50 Cooper's hawk, 340 µg/kg in 1/78 red-tailed hawk; not detected in 22 screech owls, 53 great horned owl in New York between 1998 and 2001	Stone <i>et al.</i> 2003
		<LOQ (50 µg/kg) in 1/43 red-tailed hawks in Massachusetts between 2017 and 2019	Murray 2020
	Europe	Not detected in 142 granivorous birds, 129 predatory birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012

Compartment	Location	Result	Reference
Reptiles	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012

Effects on non-target species

Table 98: Diphacinone – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ²⁶	Reference
Mammals	Acute	<i>Rattus norvegicus</i>	LD ₅₀ 1.9 mg/kg bw	Gaines 1960
		<i>Mustela furo</i>	0.06 g/kg gel: LD ₅₀ 11 mg/kg bw	Ross & Henderson 2003
Birds	Acute	<i>Colinus virginianus</i>	LD ₅₀ >400 mg/kg bw	Campbell <i>et al.</i> 2001
		<i>Anas platyrhynchos</i>	LD ₅₀ 3158 mg/kg bw	Fink 1976a
	Dietary	<i>Colinus virginianus</i>	LC ₅₀ >5000 mg/kg food	Long <i>et al.</i> 1992a
			LC ₅₀ 4485 mg/kg food	Fink 1976b
			0.05 g/kg pellet: LC ₅₀ >10000 mg/kg food	Fink 1975a
		<i>Anas platyrhynchos</i>	LC ₅₀ 905 mg/kg food	Long <i>et al.</i> 1992b
			LC ₅₀ >10000 mg/kg food	Fink 1976c
		0.05 g/kg pellet: LC ₅₀ >10000 mg/kg food	Fink 1975b	
Reptiles	Acute	<i>Boiga irregularis</i>	LLD 10 mg/kg bw	Brooks <i>et al.</i> 1998
		<i>Ameiva ameiva</i>	LD ₅₀ >2.5 mg/kg bw	Mauldin <i>et al.</i> 2020
		<i>Boa constrictor</i>	LD ₅₀ >1.2 mg/kg bw	
		<i>Rhinoclemmys pulcherrima</i>	LD ₅₀ >1.8 mg/kg bw	
		<i>Iguana iguana</i>	LD ₅₀ >4.0 mg/kg bw	
		<i>Sceloporus occidentalis</i>	LD ₅₀ ~1750 mg/kg bw	Weir <i>et al.</i> 2016

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

²⁶ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Table 99: Diphacinone – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Birds	Tyto alba	13 mg/kg rats for 10 days	No mortality or signs of toxicity in any treatment group after 20d (1.3-1.7 mg/kg/d)	Mendenhall & Pank 1980

Table 100: Diphacinone – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
New York, USA & adjoining states	Unspecified	2 white-tailed deer, 1 gray squirrel, 1 snowy owl poisoning in 1971-1997	Stone <i>et al.</i> 1999

Table 101: Diphacinone – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Ictalurus punctatus	LC ₅₀ 2.1 mg/L	Bentley 1975
		Oncorhynchus mykiss	LC ₅₀ 2.6 mg/L	Machado <i>et al.</i> 1994a
			LC ₅₀ 2.8 mg/L	Bentley 1975
		Lepomis macrochirus	LC ₅₀ 7.5 mg/L	Machado <i>et al.</i> 1994b
			LC ₅₀ 7.6 mg/L	Bentley 1975

Warfarin

Fate and behaviour in the environment

Table 102: Warfarin – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Aerobic soil metabolism	Turfgrass: DT ₅₀ 5.5 d Groundcover: DT ₅₀ 4.3 d Geomean DT ₅₀ 4.9 d	Lao & Gan 2012

Compartment	Study	Result	Reference
Water and sediment	Readily biodegradable	No	Brorson <i>et al.</i> 1994
		Reduced by <i>Nocardia</i> and <i>Arthrobacter</i> spp. to the alcohol	Davis & Rizzo 1982
Biota	Rat	Liver DT ₅₀ 26 d	Fisher <i>et al.</i> 2003
	Mouse	Liver DT ₅₀ 67 d	Vandenbroucke <i>et al.</i> 2008

Table 103: Warfarin – Residues monitoring data

Compartment	Location	Value	Reference
Water	North America	Not detected in groundwater samples from 1231 sites in California collected 2004-2010 representing a range of hydrogeologic conditions and land use patterns	Fram & Belitz 2011
		Not detected in 84 stream samples (from 1999-2000) representing a wide range of residential, industrial, and agricultural areas across the USA	Kolpin <i>et al.</i> 2002
	Europe	<LOQ (0.2 µg/kg) in suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019
Terrestrial invertebrates	North America	Not detected in carrion beetles, carabid beetles, wasps, snails, slugs, worms, or maggots in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
Target rodents	North America	Not detected 7 rats in bromadiolone baited farm or two farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
	Europe	Max liver residues 6 µg/kg in 1/12 house mice from farms in Northern Ireland within 30m from buildings (no warfarin usage)	Tosh <i>et al.</i> 2012
Non-target mammals	Australia	Mean liver residues 5 µg/kg in 1/9 western quolls and 41 µg/kg in 1/20 Tasmanian devils in Tasmania and Western Australia	Lohr 2022
		Not detected in brushtail possum in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 57 µg/kg in 3/53 (6%) brushtail possums; not detected in 82 ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024

Compartment	Location	Value	Reference
	North America	Not detected in 23 voles, 6 shrews, 3 deer mice in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
	Europe	Not detected in liver or muscle of 51 wild boars in urban area, 20 wild boars in suburban area, or 13 wild boars in rural area of Spain	Alabau <i>et al.</i> 2020
		Liver residue 612 µg/kg in 1/106 Algerian hedgehogs; not detected in 48 European hedgehogs in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Not detected in 29 herbivores, 3 insectivores, 96 carnivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Max liver residues 9 µg/kg in 2/55 wood mice from farms in Northern Ireland more than 30m from buildings (no warfarin usage)	Tosh <i>et al.</i> 2012
Birds	Australia	Not detected in little ravens, Australian kestrels, whistling kites, barking owls, southern boobooks, powerful owls, tawny frogmouths, and barn owls in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 5 µg/kg in 2/38 powerful owls in Sydney basin urban areas between 2015 and 2021	Birdlife Australia 2022
		Not detected in 5 eastern barn owls, 12 southern boobooks, 19 tawny frogmouths, 24 powerful owls in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Not detected in 5 Carnaby's cockatoos from Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
	Australia	Max liver residues 2 µg/kg in 2/73 southern boobooks (2.7%) in urban & peri-urban areas of WA	Lohr 2018
		Max liver residues 2 µg/kg in 2/50 (4%) wedge-tailed eagles across Tasmania between 1996 and 2018	Pay <i>et al.</i> 2021
	North America	Not detected in 1 sparrow, 7 starlings in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
		Max liver residues 720 µg/kg in 3/61 great horned owls, 5 µg/kg in 1/25 barred owls, 8 µg/kg in 1/78 barn owls in BC & Yukon Territory of Canada between 1988 and 2003	Albert <i>et al.</i> 2010

Compartment	Location	Value	Reference
		Not detected in 37 red-tailed hawks, 24 barred owls, 17 great horned owls, 16 eastern screech-owls in Massachusetts between 2012 and 2016	Murray 2017
		No detected in 43 red-tailed hawks in Massachusetts between 2017 and 2019	Murray 2020
		Liver residues 100 µg/kg in 1/50 Cooper's hawk, 730 µg/kg in 1/53 great horned owl; not detected in 78 red-tailed hawk, 22 screech owls in New York between 1998 and 2001	Stone <i>et al.</i> 2003
	Tawain	Not detected in 112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022
	Europe	Not detected in liver of 48 northern goshawk, 41 red kite, 60 white-tailed eagle, 23 Eurasian sparrowhawk or 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021
		Not detected in 33 scops owls, 41 barn owls, 27 tawny owls, 14 eagle owls, 12 long-eared owls, 7 little owls, 56 common buzzards in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Not detected in 142 granivorous birds, 129 predatory birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Reptiles	Australia	Max liver residues 11 µg/kg in 4/11 dugites from 2014-18, not detected in 10 bobtails or 11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Fish	Europe	<LOQ (0.2 µg/kg) in bream of two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 0.05 µg/kg in 3/32 fish in bioaccumulation ponds; not detected in 12 fish in receiving streams of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019
		Detected in 12/46 fish but <LOQ (0.02 µg/kg) in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 104: Warfarin – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ²⁷	Reference
Mammals	Acute	Rattus norvegicus	LD ₅₀ 3.0 mg/kg bw	Gaines 1960
			LD ₅₀ 58 mg/kg bw	Hagan & Radomski 1953
		Cavia porcellus	LD ₅₀ 182 mg/kg bw	Hagan & Radomski 1953
		Canis familiaris	LD ₅₀ 200 mg/kg bw	
		Mus musculus	LD ₅₀ 374 mg/kg bw	
		Oryctolagus cuniculus	LD ₅₀ ~800 mg/kg bw	
		Mustela vison	LC ₅₀ 12 mg/kg food	Aulerich <i>et al.</i> 1987
Birds	Acute	Gallus domesticus	LD ₅₀ >1000 mg/kg bw	Hagan & Radomski 1953
Reptiles	Acute	Boiga irregularis	LLD 40 mg/kg bw	Brooks <i>et al.</i> 1998

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

Table 105: Warfarin – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Mammals	Mustela vison	23 mg/kg rabbit	10/10 survived after consuming 12-13% of body mass daily	Aulerich <i>et al.</i> 1987
		for 28 days		
	Mustela vinalis	0.42 mg/kg mice	2/2 survived after consuming 22% of body mass daily	Townsend <i>et al.</i> 1984
		for 90 days		
		1.6 mg/kg mice	1/2 died and 1/2 survived after consuming 22% of body mass daily	Townsend <i>et al.</i> 1984
		for 90 days		
		2.9 mg/kg mice	2/2 died after consuming 22% of body mass daily	Townsend <i>et al.</i> 1984
		for 12-57 days		

²⁷ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Group	Species	Poisoned food	Study details & result	Reference
Birds	Strix aluco	1.6 mg/kg mice for 90 days	4/4 survived after consuming 11% of body mass daily	Townsend <i>et al.</i> 1981

Table 106: Warfarin – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
Humberside UK	Approved grain baiting in haulage yard	1 sparrow poisoning, likely accessed bait box	Fletcher <i>et al.</i> 2000
Various counties across UK	Unspecified	No wildlife incidents that involved approved uses or unspecified exposure in 1998, 2000-2006	Barnett <i>et al.</i> 2002a, 2002b, 2003, 2004, 2005, 2006, 2007, Fletcher 1999
New York, USA & adjoining states	Unspecified	2 gray squirrel, 1 peregrine falcon, 1 bald eagle poisonings in 1971-1997	Stone <i>et al.</i> 1999

Brodifacoum

Fate and behaviour in the environment

Table 107: Brodifacoum – Physical and chemical properties

Study	Result	Reference
Vapour pressure	2.6 × 10 ⁻²² Pa at 20°C 1.9 × 10 ⁻²¹ Pa at 25°C	White & Mullee 2006
Henry's law constant	2.4 × 10 ⁻¹⁸ Pa m ³ mol ⁻¹	White & Mullee 2006
Solubility in water	pH 5, 20°C: ≤3.2 × 10 ⁻⁶ mg/L pH 7, 20°C: 5.8 × 10 ⁻⁵ mg/L pH 9, 20°C: 1.9 × 10 ⁻³ mg/L	White & Mullee 2006
Partition coefficient	pH 5: log P _{OW} 6.1 pH 7: log P _{OW} 4.9 pH 9: log P _{OW} 4.8	White & Mullee 2006

Study	Result	Reference
UV-VIS absorption (max)	solution λ_{max} ϵ (L mol ⁻¹ cm ⁻¹)	Garofani 2001a
	acidic 266 nm 40191	
	acidic 308 nm 15629	
	neutral 266 nm 37759	
	neutral 308 nm 14089	
	basic 263 nm 33601	
basic 312 nm 16677		

Table 108: Brodifacoum – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Aerobic soil metabolism	Sandy clay loam: DT ₅₀ 157 d	Hall & Priestley 1992
		Sandy loam: DT ₅₀ ~56 d	Arnold <i>et al.</i> 1978
		Clay loam: DT ₅₀ ~84 d	
		Sand: DT ₅₀ >84 d	
		Geomean DT ₅₀ 95 d	
	Adsorption/ desorption	Soil pH %OC Ka	Newby & White 1979
		Coarse sand 7.6 1.2 358	
		Sandy clay loam 7.1 6.3 1265	
		Sandy loam 7.6 11 1126	
		Koc 525 mL/g	Drake 2005b
Column leaching	510 mm elution, four soils aged 30d: 81-87% in top 6 cm Not detected in leachate	Jackson & Hall 1992	
Water and sediment	Hydrolysis	pH 4, 50°C: stable	Fabbrini 1997c
		pH 7, 50°C: stable	
		pH 9, 50°C: stable	
	Aqueous photolysis	DT ₅₀ <1 d	Drake 2004a
	Readily biodegradable	No	Drake 2003a, Kelly & Clayton 2003a

Compartment	Study	Result	Reference
	Inherently biodegradable	No	Drake 2005d
	Anaerobic biodegradable	No	Drake 2005e
Air	Tropospheric degradation	DT ₅₀ 2.2 h (OH radical reaction) DT ₅₀ 2.0 h (ozone reaction)	Worthington 2007
Biota	Rat	Liver DT ₅₀ 130 d	Parmar <i>et al.</i> 1987
		Liver DT ₅₀ 114 d	Fisher <i>et al.</i> 2003
		Liver DT ₅₀ 282 d	Hawkins <i>et al.</i> 1991
	Mouse	Liver DT ₅₀ 307 d	Vandenbroucke <i>et al.</i> 2008
	Brush-tail possum	Liver DT ₅₀ >252 d	Eason <i>et al.</i> 1996
	Sheep	Liver DT ₅₀ >250 d	Laas <i>et al.</i> 1985
	American kestrel	Liver DT ₅₀ >50 d	Rattner <i>et al.</i> 2020
	Garden slug	Elimination DT ₅₀ 2.5 d	Alomar <i>et al.</i> 2018

Table 109: Brodifacoum – Residues monitoring data

Compartment	Location	Result	Reference
Water	Europe	<LOQ (2.0 µg/kg) in suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019
Terrestrial invertebrates	New Zealand	Mean residues 760 µg/kg in cockroaches, 860 µg/kg in weta, 210 µg/kg in beetles, 260 µg/kg in all others captured up to 10m from bait stations containing 20 mg/kg brodifacoum in three forest sites in New Zealand; residues eliminated to background levels within 5 weeks	Craddock 2003
	North America	70 µg/kg in slugs; not detected in carrion beetles, carabid beetles, wasps, snails, worms, or maggots in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
Target rodents	North America	Max liver residues 150 µg/kg in 2/5 rats in bromadiolone baited farm, 410 µg/kg in 1/2 rats in two farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014

Compartment	Location	Result	Reference
	Europe	Max liver residues 22 µg/kg in 1/12 house mice from farms in Northern Ireland within 30m from buildings (no brodifacoum usage)	Tosh <i>et al.</i> 2012
Non-target mammals	Australia	Mean liver residues 655 µg/kg in 3/9 western quolls, 16 µg/kg in 1/3 northern quolls, 137 µg/kg in 2/5 tiger quolls, 520 µg/kg in 8/15 eastern quolls, and 162 µg/kg in 7/20 Tasmanian devils in Tasmania, Western Australia, NSW, and ACT	Lohr 2022
		Max liver residues 770 µg/kg brushtail possum in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 1708 µg/kg in 47/53 (89%) brushtail possums, 45 µg/kg in 29/82 (35%) ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024
	North America	Liver residue 18600 µg/kg in 1/23 voles; not detected in 6 shrews, 3 deer mice in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
	Europe	Max liver residues 120 µg/kg in 1/45 stoat and not detected in 10 weasel following open area baiting in English estates between 1996-97	McDonald <i>et al.</i> 1998
		Mean liver residues 110 µg/kg in 24/51 wild boars in urban area, 20 µg/kg in 7/20 wild boars in suburban area, and 8.7 µg/kg in 1/13 wild boars in rural area of Spain; mean muscle residue 12 µg/kg in 4 wild boars in urban area; not detected in muscle of wild boars in suburban or rural areas	Alabau <i>et al.</i> 2020
		Max liver residues 1533 µg/kg in 18/106 Algerian hedgehogs, 1390 µg/kg in 24/48 European hedgehogs in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Max liver residues 270 µg/kg in 2/29 herbivores, 92 µg/kg in 1/3 insectivores, 4500 µg/kg in 15/96 carnivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Detected in 3 foxes in Hertfordshire, UK in 2002 (unspecified source)	Barnett <i>et al.</i> 2003
		Not detected in liver of polecat that made heavy use of agricultural premises using anticoagulant rodenticides in UK between 1993-95	Birks 1998
	Liver residues 8 µg/kg in 1/29 polecats from west Midlands of England between 1992 and 1994	Shore <i>et al.</i> 1996	
	Max liver residues 70 µg/kg in 2/50 polecats from recolonised areas in central and eastern Britain between 1993 and 1999	Shore <i>et al.</i> 2003	

Compartment	Location	Result	Reference
		Max liver residues 640 µg/kg in 4/55 wood mice from farms in Northern Ireland more than 30m from buildings (no brodifacoum usage)	Tosh <i>et al.</i> 2012
	South Africa	Mean liver residues 250 µg/kg in 22/24 caracals in Greater Cape Town, South Africa between 2014 and 2017	Seriesys <i>et al.</i> 2019
Birds	Australia	Max liver residues 240 µg/kg little ravens, 310 µg/kg Torresian crows, ~100 µg/kg Australian magpies, 84 µg/kg Australian kestrels, 38 µg/kg barking owls, 552 µg/kg southern boobooks, 600 µg/kg powerful owls, 120 µg/kg tawny frogmouths, 2950 µg/kg barn owls in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 448 µg/kg in 34/38 powerful owls in Sydney basin urban areas between 2015 and 2021	Birdlife Australia 2022
		Max liver residues 55 µg/kg in 5/5 eastern barn owls, 1034 µg/kg in 11/12 southern boobooks, 1014 µg/kg in 18/19 tawny frogmouths, 600 µg/kg in 21/24 powerful owls in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Liver residues 439 µg/kg in 1/5 Carnaby's cockatoos in Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
		Max liver residues 4002 µg/kg in 53/73 southern boobooks (73%) in urban & peri-urban areas of WA	Lohr 2018
		Max liver residues 635 µg/kg in 28/50 (56%) wedge-tailed eagles across Tasmania between 1996 and 2018	Pay <i>et al.</i> 2021
	New Zealand	Max liver residues 4000 µg/kg in 1 paradise duck, 1500 µg/kg in 2 seagulls, 340 µg/kg in 2 hawks, 480 µg/kg in 1 magpie, 8100 µg/kg in 1 passerine bird following open area baiting at 1245-3320 kg bait/ha (50 mg a.c./kg bait) in Canterbury & Browns Island, NZ	Rammell <i>et al.</i> 1984
		Max liver residues 1230 µg/kg in 7 ducks, 660 µg/kg in Australasian harrier, 1350 µg/kg in 9 pukeko, 580 µg/kg in 1 gull, 780 µg/kg in 2 blackbirds, 2310 µg/kg in 3 chaffinch, 1270 in 3 myna, 990 µg/kg in 2 magpies following two aerial broadcasts at 8 + 3.5 kg bait/ha in Motuihe Island, NZ	Dowding <i>et al.</i> 1999
		Max liver residues 770 µg/kg in dotterels (>50% mortality) feeding on sandhoppers, 920 µg/kg in pied stilt following two aerial broadcasts at 8 + 7 bait/ha (20 mg a.c./kg bait) in Tawharanui Regional Part, NZ	Dowding <i>et al.</i> 2006

Compartment	Location	Result	Reference
	Tawain	Geomean liver residues 73 µg/kg in 61/74 black-winged kite, 28 µg/kg in 18/46 crested goshawk, 34 µg/kg in 17/42 collared scops-owl, 18 µg/kg in 4/12 crested serpent-eagle, 43 µg/kg in 6/8 black kite, 10 µg/kg in 1/6 short-eared owl, 111 µg/kg in 2/3 eastern grass-owl, 483 µg/kg in 1/3 eurasian kestrel; not detected in 6 oriental honey-buzzard or 1 common buzzard or 11 other raptor species in Taiwan between 2010 and 2018	Hong <i>et al.</i> 2019
		Max liver residues 590 µg/kg in 90/112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022
	North America	Liver residue 73 µg/kg in 1 sparrow; not detected in 7 starlings in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming; not detected in pellets of 9 rat-eating barn owls from agricultural barn sites in Canada	Elliott <i>et al.</i> 2014
		Mean liver residues before & after implementation of risk mitigation measures in Canada (barred owl, barn owl, great-horned owl): 1988-2013: 100, 30, 90 µg/kg 2014-2018: 40, 50, 100 µg/kg	Elliott <i>et al.</i> 2022
		50 µg/kg residue in 1 barn owl, not detected in 33 barn owls in following 50 mg/kg bait (in & around buildings) in NJ, USA farms and other areas	Hegdal & Blaskiewski 1981, Morris & Kakeinen 1980
		Detected in 0/20 in 2013 and 1/77 in 2015 red-tailed hawk blood samples from Marin Headland, California	Abernathy <i>et al.</i> 2018
		Max liver residues 220 µg/kg in 12/50 Cooper's hawk, 1280 µg/kg in 42/78 red-tailed hawk, 470 µg/kg in 8/22 screech owls, 970 µg/kg in 42/53 great horned owl in New York between 1998 and 2001	Stone <i>et al.</i> 2003
		Max liver residues 609 µg/kg in 28/61 great horned owls, 927 µg/kg in 17/25 barred owls, 470 µg/kg in 35/78 barn owls in BC & Yukon Territory of Canada between 1988 and 2003	Albert <i>et al.</i> 2010
		Detected in 36/37 red-tailed hawks, 21/24 barred owls, 16/17 great horned owls, 16/16 eastern screech-owls in Massachusetts between 2012 and 2016	Murray 2017
		Max liver residues 930 µg/kg in 43/43 red-tailed hawks in Massachusetts between 2017 and 2019	Murray 2020
	Europe	Max liver residues 107 µg/kg in 29/48 northern goshawk, 72 µg/kg in 19/41 red kite, 15 µg/kg in 11/60 white-tailed eagle; not detected in 23 Eurasian sparrowhawk or 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021

Compartment	Location	Result	Reference
		Max liver residues 957 µg/kg in 50/80 barn owls, 613 µg/kg in 78/141 buzzards, 298 µg/kg in 32/66 kestrels, 40 µg/kg in 20/38 long-eared owls, 34 µg/kg in 19/31 rough-legged buzzards, 220 µg/kg in 24/44 tawny owls from intensively managed landscapes in Denmark	Christensen <i>et al.</i> 2012
		Max liver residues 110 µg/kg in 7/16 golden eagles, 158 µg/kg in 4/8 eagle owls; not detected in 3 osprey, 2 peregrine falcon, 1 gryfalcon across Norway between 2009 and 2011	Langford <i>et al.</i> 2013
		Max liver residues 158 µg/kg in 9/33 scops owls, 839 µg/kg in 22/41 barn owls, 1582 µg/kg in 17/27 tawny owls, 2008 µg/kg in 13/14 eagle owls, 42 µg/kg in 4/12 long-eared owls, 574 µg/kg in 5/7 little owls, 1356 µg/kg in 26/56 common buzzards in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Max liver residues 830 µg/kg in 9/129 predatory birds; not detected in 142 granivorous birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Detectable residues in 8/172 tawny owls, 9/431 barn owls, 8/73 kestrels across Britain between 1990-93 or 2003-05	Walker <i>et al.</i> 2008
		Not detected in >97% of 89 barn owl pellets collected winter of 1988-1989 over five counties in southern Eire, UK	Eadsforth <i>et al.</i> 1996
		Detected in 17/449 barn owls in Britain between 1988 and 1994	Newton <i>et al.</i> 1997
		Mean liver residues 116-155 µg/kg in 41/241 common kestrels in UK between 1997 and 2011	Roos <i>et al.</i> 2021
Reptiles	Australia	Max liver residues 330 µg/kg in 7/11 dugites, 109 µg/kg in 6/10 bobtails from 2014-18, and 14 µg/kg in 5/11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Amphibians	Australia	Max 1000 µg/kg in 13/77 frogs (1/3 eastern banjo frog, striped marsh frog, 10/55 green tree frog, 1/9 Person's tree frog, 1/4 cane toad) across eastern NSW between 2021 and 2022	Rowley <i>et al.</i> 2024
Fish	Europe	Max liver residues 13 µg/kg in bream from two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 1.9 µg/kg in 11/32 fish in bioaccumulation ponds and 6.4 µg/kg in 8/12 fish in receiving streams of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019

Compartment	Location	Result	Reference
		Max liver residues 30 µg/kg in 46/46 fish in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 110: Brodifacoum – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ²⁸	Reference
Mammals	Acute	Oryctolagus cuniculus	LD ₅₀ 0.20 mg/kg bw	Godfrey <i>et al.</i> 1981
		Rattus norvegicus	LD ₅₀ 0.27 mg/kg bw	Hadler 1974
		0.05 g/kg paste: LD ₅₀ >10 mg/kg bw		Vaze 2011
		Sus scrofa	LD ₅₀ >0.50 mg/kg bw	Ross & Roberts 1976
		Canis familiaris	LD ₅₀ 1.1 mg/kg bw	Godfrey <i>et al.</i> 1981
		Macropus rufogriseus	LD ₅₀ 1.3 mg/kg bw	Godfrey 1984
		Ovis aries	LD ₅₀ 11 mg/kg bw	Godfrey <i>et al.</i> 1985
		Felis catus	LD ₅₀ 25 mg/kg bw	Parkinson 1979
Birds	Acute	Porphyris melanotus	LD ₅₀ 0.95 mg/kg bw	Godfrey 1985
		Prunella occidentalis	LD ₅₀ >3.0 mg/kg bw	
		Turdus merula	LD ₅₀ >3.0 mg/kg bw	
		Lophortyx californicus	LD ₅₀ 3.3 mg/kg bw	
		Passer domesticus	LD ₅₀ >6.0 mg/kg bw	
		Zosterops lateralis	LD ₅₀ >6.0 mg/kg bw	
		Circus approximans	LD ₅₀ 10 mg/kg bw	
		Phasianus colchicus	LD ₅₀ 10 mg/kg bw	
		Tadorna variegata	LD ₅₀ >20 mg/kg bw	
		Anas platyrhynchos	LD ₅₀ 0.31 mg/kg bw	Ross <i>et al.</i> 1980
	LD ₅₀ 4.6 mg/kg bw	Godfrey 1985		

²⁸ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Group	Exposure	Species	Toxicity value ²⁸	Reference
		<i>Gallus domesticus</i>	LD ₅₀ 4.5 mg/kg bw	Ross <i>et al.</i> 1977a
		<i>Coturnix japonica</i>	LD ₅₀ 12 mg/kg bw	Ross <i>et al.</i> 1977b
			LD ₅₀ 19 mg/kg bw	Gáty 2005a
	Dietary	<i>Larus atricilla</i>	LC ₅₀ 1.6 mg/kg food	Grimes & Fink 1979
		<i>Colinus virginianus</i>	LC ₅₀ 201 mg/kg food	Fink 1976d
		<i>Anas platyrhynchos</i>	LC ₅₀ 2.7 mg/kg food	Beavers & Fink 1978
			LC ₅₀ 778 mg/kg food	Fink 1976e
Reptiles	Acute	<i>Ameiva ameiva</i> <i>Boa constrictor</i> <i>Rhinoclemmys pulcherrima</i> <i>Iguana iguana</i> <i>Sceloporus occidentalis</i>	LD ₅₀ >1.3 mg/kg bw LD ₅₀ >0.62 mg/kg bw LD ₅₀ >0.89 mg/kg bw LD ₅₀ >2.3 mg/kg bw LD ₅₀ >1750 mg/kg bw	Mauldin <i>et al.</i> 2020 Weir <i>et al.</i> 2016

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

Table 111: Brodifacoum – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Birds	<i>Tyto alba</i>	6.9 mg/kg rats for 1, 3, 6 or 10d	No mortality or haemorrhage in 1d exposure group after 20d (1.4 mg/kg/d). All owls haemorrhaged and died in remaining exposure groups after 8-11d (0.33-1.4 mg/kg/d)	Mendenhall & Pank 1980
		0.53 mg/kg mice for 1, 3 or 6d	4/6 owls died in 1d group (0.14 mg/kg/d), 2/2 owls survived in each of 3d and 6d groups (0.10 mg/kg/d). Haemorrhaging observed in all exposure groups. Increased blood coagulation time in survivors, returning to normal within 78d	Newton <i>et al.</i> 1990, Wyllie 1995
		2.2-4.4 mg/kg mice for 15d	1/4 owls died after 15d (0.39 mg/kg/d), 3/4 owls survived to 30d (0.13-0.39 mg/kg/d), minor haemorrhaging in all surviving owls	Gray & Dutton 1992; Gray <i>et al.</i> 1994a, 1994b

Table 112: Brodifacoum – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
NJ farms and other areas	50 mg a.c./kg bait (in & around buildings)	No barn owl deaths attributed to brodifacoum	Hegdal & Blaskiewski 1981, 1984, Morris & Kakeinen 1980
Various counties across UK	Unspecified	2 red kite and 3 grey squirrel poisoning in 1998	Fletcher <i>et al.</i> 1999
		1 buzzard and 2 red kite poisonings in 1999	Fletcher <i>et al.</i> 2000
		No wildlife incidents that involved approved uses or unspecified exposure in 2000 or 2003	Barnett <i>et al.</i> 2002a, 2004
		1 red kite and 1 buzzard poisoning in 2001	Barnett <i>et al.</i> 2002b
		3 fox poisonings; 1 tawny owl was possible road traffic accident victim, but also exposed to brodifacoum in 2002	Barnett <i>et al.</i> 2003
		1 fox, 2 buzzards, 2 tawny owls, 4 crows (accessed protected bait points), and 2 red kite poisonings in 2004	Barnett <i>et al.</i> 2005
		1 barn owl and 1 buzzard poisoning in 2005	Barnett <i>et al.</i> 2006
		3 fox and 1 barn owl poisoning in 2006	Barnett <i>et al.</i> 2007
United Kingdom	Approved use	1 fox poisoning in 1990-1994	de Snoo <i>et al.</i> 1999
New York, USA & adjoining states	Unspecified	5 gray squirrel, 1 chipmunk, 6 raccoons, 2 red fox, 1 opossum, 5 white-tailed deer, 1 raven, 1 crow, 1 golden eagle, 2 screech owl, 13 great horned owl, 7 red-tailed hawk poisonings in 1971-1997	Stone <i>et al.</i> 1999
		No wildlife incidents that involved approved uses or unspecified exposure in 1999-2001, 2003, 2005-2006	Barnett <i>et al.</i> 2002a, 2002b, 2004, 2006, 2007, Fletcher <i>et al.</i> 2000
		4 crows poisoned (accessed protected bait points) in 2004	Barnett <i>et al.</i> 2005

Table 113: Brodifacoum – Field studies and adverse incidents involving terrestrial vertebrates from rodent eradication and ecological restoration programmes

Use area	Exposure	Effect	Reference
Lord Howe Island, NSW	20 mg a.c./kg bait (two aerial broadcasts at 12 + 8 kg/ha; 19,000 bait stations)	58 bird deaths (49 buff-banded rails, 4 currawong, 2 silvereye, 2 purple swamphen, 1 golden whistler); post-eradication populations increased for all species except purple swamphen (recorded individuals reduced from 50 to 43)	O'Dwyer <i>et al.</i> 2024
Adele Island, WA	20 mg a.c./kg bait (two aerial broadcasts at 37 + 7.2 kg bait/ha)	40 bird deaths (5 buff-banded rails, 7 silver gulls, 28 ruddy turnstones) attributed to brodifacoum poisoning, no impact on populations	Palmer 2014
Cabbage Tree Island, NSW	20 mg a.c./kg bait (one aerial broadcast at 11.5 kg bait/ha)	3 bird deaths (2 buff-banded rails, 1 pied currawong) potentially attributed to brodifacoum poisoning	Priddel <i>et al.</i> 2000
Macquarie Island, Tasmania	20 mg a.c./kg bait (aerial broadcast at 24 kg bait/ha per year)	1 st year (1000 ha): 960 bird deaths (385 kelp gulls, 323 giant petrels, 230 skua, 22 ducks) attributed to brodifacoum poisoning 2 nd year (12875 ha): 1464 bird deaths (603 kelp gulls, 439 giant petrels, 282 skua, 135 ducks, 5 unknown)	PWS 2014
Penguin Island, WA	50 mg a.c./kg bait (350 bait stations)	8 King's skink deaths attributed to brodifacoum poisoning	Bettink 2015
Norfolk Island, ACT	50 mg a.c./kg bait (5 months)	Chick(s) of one pair of hybrid boobooks found feeding their young on rats died in 2011	Debus 2012
Montebello Islands, WA	50 mg a.c./kg bait (11,000 bait stations)	White-bellied sea-eagles observed eating flesh only of dying rats; evidence of secondary exposure of bungarras (<i>Varanus gouldii</i>); however, no non-target or secondary poisoning was noted in first year. Bar-shouldered doves, brown quail and various raptors as common or more following year.	Burbridge 2004
Mokoia Island, NZ	20 mg a.c./kg bait (one aerial broadcast at 10 kg bait/ha)	3/14 radio-tagged moreporks died, 7/14 other monitored moreporks disappeared	Stephenson <i>et al.</i> 1999

Use area	Exposure	Effect	Reference
Ulva Island, NZ	20 mg a.c./kg bait (two aerial broadcasts at 11.5 kg bait/ha)	12/13 robin nestling deaths attributed to brodifacoum poisoning	Masuda <i>et al.</i> 2014
Coastal grassland in Otango Peninsula, NZ	20 mg a.c./kg bait (7 kg bait/ha hand-applied in transects)	Secondary poisoning of stoats, feral ferrets and feral cats observed; probable poisoning of possums, hedgehogs and chaffinches	Alterio 1996
Kapiti Island, NZ	20 mg a.c./kg bait (two aerial broadcasts at 9.0 + 5.1 kg bait/ha)	'Catastrophic' impact on weka population requiring risk mitigation; other bird species and reef fish populations relatively unaffected	Empson & Miskelly 1999
Frégate Island, Seychelles	50 mg a.c./kg in bait stations + 20 mg a.c./kg bait at 1.3 kg/ha	Several critically endangered Seychelles magpie-robins died	Thorsen <i>et al.</i> 2000
Pinzon Island, Galápagos, Ecuador	25 mg a.c./kg bait (one aerial broadcast)	22/32 captive-held Galapagos hawks died between 12 and 170 days after release 12-14 days after baiting ceased; one short-eared owl death attributed to brodifacoum 773 days post-baiting	Rueda <i>et al.</i> 2016
Seymour Norte, Galápagos, Ecuador	50 mg a.c./kg bait (25m intervals along lines 25m apart at 1.4 + 3.0 kg bait/ha)	~4.5% overall mortality of land iguana population estimated	Harper <i>et al.</i> 2011
Desecheo Island, Puerto Rico	25 mg a.c./kg bait (two aerial broadcasts at 17 + 9.1 kg bait/ha)	No population-level impacts on two species of lizard (ameivas, anoles)	Herrera-Giraldo <i>et al.</i> 2019
Farallón de San Ignacio island, Mexico	25 mg a.c./kg bait (one aerial broadcast at 24.4 kg bait/ha)	8 house sparrows, 2 ground doves, 1 house finch deaths likely due to brodifacoum; no population-level impacts	Samaniego-Herra <i>et al.</i> 2009
San Pedro Mártir island, Mexico	25 mg a.c./kg bait (two aerial broadcasts at 17.6 kg bait/ha)	1 raven death, 6 yellow-footed gull deaths likely due to brodifacoum; no population level impacts	Samaniego-Herra <i>et al.</i> 2009

Use area	Exposure	Effect	Reference
Rat Island, Alaska	25 mg a.c./kg bait (two aerial broadcasts at 8.0-33 kg bait/ha cumulative)	Majority of 420 bird deaths (mostly gulls & eagles) attributed to AR poisoning. Max liver residues 2600 µg/kg eagles, 2400 µg/kg gulls, 27 µg/kg emperor goose, 1200 µg/kg peregrine falcon, 44 µg/kg sandpipers, 1200 µg/kg finch, 44 µg/kg cormorant, 57 µg/kg northern fulmar	Ebbert & Burek-Huntington 2010

Table 114: Brodifacoum – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 0.040 mg/L	Hill <i>et al.</i> 1976a
			LC ₅₀ 0.042 mg/L	Craig 2003a
			LC ₅₀ 0.053 mg/L	Hill 1978a
		0.25% concentrate: LC ₅₀ 0.026 mg/L	Hill 1978b	
		Lepomis macrochirus	LC ₅₀ 0.16 mg/L	Hill <i>et al.</i> 1976b
Invertebrates	Acute	Daphnia magna	EC ₅₀ 0.25 mg/L	Craig 2003b
			EC ₅₀ 0.98 mg/L	Getty & Wilkinson 1978
Algae	Chronic	Raphidocelis subcapitata	E _r C ₅₀ 0.040 mg/L	Craig 2003c

Table 115: Brodifacoum – Effects on soil organisms

Group	Exposure	Species/process	Toxicity value	Reference
Macro-organisms	Acute	Eisenia fetida	LC _{50corr} >497 mg/kg dry soil	Staniland 2005a

Table 116: Brodifacoum – Effects on biological methods of sewage treatment

Test	Endpoint	Reference
Activated sludge	EC ₅₀ >0.058 mg/L	Desmares-Koopmans 2001, Staniland 2004

Bromadiolone

Fate and behaviour in the environment

Table 117: Bromadiolone – Physical and chemical properties

Study	Result	Reference
Vapour pressure	<0.05 × 10 ⁻³ Pa at 45°C	Fabbrini 1997a
	2.1 × 10 ⁻⁸ Pa at 25°C	Pesselman 1991a
Henry's law constant	9.0 × 10 ⁻⁷ Pa m ³ mol ⁻¹	Curl 2003
Solubility in water	pH 7, 25°C: 1.2 mg/L	Anderson 1999a
	pH 5, 20°C: 0.11 mg/L	Mullee & O'Connor 2006a
	pH 7, 20°C: 2.5 mg/L	
	pH 9, 20°C: 180 mg/L	
	pH 4, 20°C: 0.099 mg/L	Hahn 2002a
	pH 7, 20°C: 18 mg/L	
	pH 10, 20°C: 1230 mg/L	
Partition coefficient	12 mg/L at 25°C (distilled water)	Pesselman 1992
	pH 5: log P _{OW} >5.0	Mullee & O'Connor 2006b
	pH 7: log P _{OW} 3.8	
	pH 9: log P _{OW} 2.5	
	pH 4: log P _{OW} >5.7	Sarff 2002
	pH 7: log P _{OW} 4.1	
	pH 10: log P _{OW} 3.2	
	pH 6: log P _{OW} 3.9	Ricau 2008
	log P _{OW} 7.0 (distilled water)	Anderson 1999a
	log P _{OW} 4.3 (distilled water)	Pesselman 1991b
Dissociation constant	pKa 3.6, 3.8, 4.0, 5.4, 6.3, 6.8	Hahn 2002b
UV-VIS absorption (max)	solution λ _{max} ε (L mol ⁻¹ cm ⁻¹)	

Study	Result	Reference
CH ₂ Cl ₂ 310 nm	10900	Guiotto & Nicolini 1996
CH ₂ Cl ₂ 283 nm	24300	
CH ₂ Cl ₂ 265 nm	34700	
EtOH 311 nm	12500	
EtOH 263 nm	31500	
acidic 265 nm	36850	Anderson 1999a
acidic 311 nm	13100	
neutral263 nm	36400	
neutral310 nm	13700	
basic 260 nm	33000	
basic 312 nm	15450	
CH ₃ OH 263 nm	32325	Drake 2005a
CH ₃ OH 310 nm	11095	

Table 118: Bromadiolone – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Aerobic soil metabolism	Sandy loam: DT ₅₀ 269 d	Misra 1995
		Loamy sand: DT ₅₀ 12 d Silt loam: DT ₅₀ 7.4 d Sand: DT ₅₀ 9.0 d Loam: DT ₅₀ 2.8 d Geomean DT ₅₀ 14 d 1.7-23% mineralisation after 90-98d 8.8-21% bound residues after 90-98d Max 40% ketone, DT ₅₀ 209 d Max 25% M9 (increasing) Max 19% unk 1, DT ₅₀ 175 d Max 16% M4 Max 14% M5 Max 11% M3	Völkl & Galicia 1992
	Adsorption/	Soil pH %OC Kd/Kf Koc 1/n	

Compartment	Study	Result	Reference
	desorption	soil 2 7.5 1.9 71 3750 soil 3 6.4 3.2 113 3530 soil 4 4.5 3.0 1250 41600 soil 5 6.4 1.5 153 10200 soil 7 4.2 11 >1190 >10400 Loamy sand 7.3 0.61 10 1709 0.89 Silt loam 7.7 0.34 5.3 1563 0.65 Geomean Kd 397 mL/g, Koc 14770 mL/g	O'Connor & Woolley 2007
	Column leaching	508 mm elution over 1d, four soils: 80-105% in top 5 cm 0.1-0.3% in leachate 560 mm elution, loamy sand aged 30d: 99% in top 5 cm 0.1% in leachate	Spare 1993 Spare 1981b
Water and sediment	Hydrolysis	pH 7, 50°C: stable pH 9, 50°C: stable pH 5, 25°C: stable pH 7, 25°C: stable pH 9, 25°C: stable	Laky 2002 Spare 1992b
	Aqueous photolysis	DT ₅₀ 1.2 h in summer at 52°N DT ₅₀ 13 h in winter at 52°N at quantum yield of 0.01 DT ₅₀ 0.60 h in summer at 50°N in natural water	Drake 2005a Phaff 2004
	Readily biodegradable	No	Clarke 2003, Gáty 2002a
	Inherently biodegradable	No	Drake 2005f
	Anaerobic biodegradable	No	Drake 2005g

Compartment	Study	Result	Reference
Air	Tropospheric degradation	DT ₅₀ 2.1 h (OH radical reaction) DT ₅₀ 2.0 h (ozone reaction)	Curl 2004a
Biota	Rat	>70% oral absorption 52-69% elimination after 7d Liver DT ₅₀ 170 d Liver DT ₅₀ 318 d	Punlar 2008 Parmar <i>et al.</i> 1987 Hawkins <i>et al.</i> 1991
	Mouse	Liver DT ₅₀ 28 d	Vandenbroucke <i>et al.</i> 2008
	Sheep	Liver DT ₅₀ 256 d	Nelson & Hickling 1994
	Garden slug	Elimination DT ₅₀ 1.9 d	Alomar <i>et al.</i> 2018

Table 119: Bromadiolone – Residues monitoring data

Compartment	Location	Value	Reference
Water	Europe	<LOQ-7.6 µg/kg suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019
Terrestrial invertebrates	North America	Not detected in carrion beetles, carabid beetles, wasps, snails, slugs, worms, or maggots in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
Target rodents	Europe	Max liver residues 16.6 mg/kg in water vole trapped 135 days after burrow baiting at 20 kg/ha (50 mg a.c./kg bait) in France Mean liver residues 6.0 mg/kg in water vole following burrow baiting (50 mg a.c./kg bait) in France Mean whole body residue 0.13 mg/kg house mice trapped within 20m of 50 mg a.c./kg bait boxes in Denmark Max liver residues 6 µg/kg in 1/12 house mice from farms in Northern Ireland within 30m from buildings (with bromadiolone usage)	Sage <i>et al.</i> 2008 Giraudoux <i>et al.</i> 2006 Elmeros <i>et al.</i> 2019 Tosh <i>et al.</i> 2012
	North America	Mean whole body residue 1.9 mg/kg rats, 1.2 mg/kg mice, and 0.49 mg/kg ground squirrels following typical 50 mg a.c./kg baiting in California	Poché 1988

Compartment	Location	Value	Reference
		Max liver residues 4260 µg/kg in 3/5 rats in bromadiolone baited farm; not detected in 2 rats in farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
Non-target mammals	Australia	Mean liver residues 41 µg/kg in 3/9 western quolls, 3 µg/kg in 1/5 tiger quolls, 7 µg/kg in 2/15 eastern quolls, and 34 µg/kg in 4/20 Tasmanian devils in Tasmania, Western Australia, NSW and ACT	Lohr 2022
		Not detected in brushtail possums in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 9610 µg/kg in 9/53 (17%) brushtail possums, 186038 µg/kg in 5/82 (6%) ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024
	North America	10 µg/kg in 1/23 voles; not detected in 6 shrews, 3 deer mice in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming; not detected in pellets of 9 rat-eating barn owls from agricultural barn sites in Canada	Elliott <i>et al.</i> 2014
	Europe	Mean liver residues 1.6 mg/kg roe deer, 1.4 mg/kg rabbits & hares, 0.6 mg/kg wild boar, 1.5 mg/kg red fox, 0.8 mg/kg stone-marten, 1.3 mg/kg lynx, 1.9 mg/kg badger attributed to vole baiting (100 mg a.c./kg bait) in France 1991-1994	Berny <i>et al.</i> 1997
		Mean whole body residue 0.045 mg/kg harvest mouse, 0.22 mg/kg yellow-necked mouse, 0.004 mg/kg common shrew, 0.010 mg/kg bank vole, and 0.009 mg/kg field vole trapped within 20m of 50 mg a.c./kg bait boxes in Denmark	Elmeros <i>et al.</i> 2019
		Mean liver residues 48 µg/kg in 13/51 wild boars in urban area, 62 µg/kg in 4/20 wild boars in suburban area, not detected in liver of 13 wild boars in rural area of Spain; not detected in muscle	Alabau <i>et al.</i> 2020
		Max liver residues 2548 µg/kg in 35/106 Algerian hedgehogs, 1110 µg/kg in 13/48 European hedgehogs in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Max liver residues 49 µg/kg in 2/3 insectivores, 17900 µg/kg in 22/96 carnivores; not detected in 29 herbivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Max liver residues 4200 µg/kg in 4/78 mink, 9000 µg/kg in 5/33 polecats, and 7100 µg/kg in 2/11 otters in southwestern France between 1990 and 2002	Fournier-Chambrillon <i>et al.</i> 2004
	UK	Max liver residues 380 µg/kg in 3/45 stoat and 250 µg/kg in 1/10 weasel following open area baiting in English estates	McDonald <i>et al.</i> 1998

Compartment	Location	Value	Reference
		Detected in 3 foxes in Hertfordshire, UK in 2002 (unspecified source)	Barnett <i>et al.</i> 2003
		Not detected in liver of polecat that made heavy use of agricultural premises using anticoagulant rodenticides in UK between 1993-95	Birks 1998
		Max liver residues 217 µg/kg in 3/29 polecats from west Midlands of England between 1992 and 1994	Shore <i>et al.</i> 1996
		Max liver residues 186 µg/kg in 5/50 polecats from recolonised areas in central and eastern Britain between 1993 and 1999	Shore <i>et al.</i> 2003
		Max liver residues 41 µg/kg in 2/55 wood mice from farms in Northern Ireland more than 30m from buildings (without bromadiolone usage)	Tosh <i>et al.</i> 2012
	South Africa	Mean liver residues 80 µg/kg in 19/24 caracals in Greater Cape Town, South Africa between 2014 and 2017	Serieys <i>et al.</i> 2019
Birds	Australia	Max liver residues 14 µg/kg Australian kestrels, 69 µg/kg southern boobooks, 45 µg/kg whistling kites, 43 µg/kg powerful owls, 4740 µg/kg barn owls; not detected in little ravens, barking owls, tawny frogmouths in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 4335 µg/kg in 22/38 powerful owls in Sydney basin urban areas between 2015 and 2021	Birdlife Australia 2022
		Max liver residues 5414 µg/kg in 4/5 eastern barn owls, 15092 µg/kg in 2/12 southern boobooks, 8114 µg/kg in 6/19 tawny frogmouths, 654 µg/kg in 5/24 powerful owls in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Not detected in 5 Carnaby's cockatoos from Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
		Max liver residues 214 µg/kg in 23/73 southern boobooks (32%) in urban & peri-urban areas of WA	Lohr 2018
		Max liver residues 241 µg/kg in 11/50 (22%) wedge-tailed eagles across Tasmania between 1996 and 2018	Pay <i>et al.</i> 2021
	Tawain	Geomean liver residues 50 µg/kg in 25/74 black-winged kite, 16 µg/kg in 9/46 crested goshawk, 9 µg/kg in 5/42 collared scops-owl, 9 µg/kg in 4/8 black kite, 54 µg/kg in 1/6 short-eared owl, 20 µg/kg in 2/3 eastern grass-owl, 14 µg/kg in 1/1 common buzzard; not detected in 12 crested serpent-eagle, 6 oriental honey-buzzard, 3 eurasian kestrel or 11 other raptor species in Taiwan between 2010 and 2018	Hong <i>et al.</i> 2019

Compartment	Location	Value	Reference
North America		Not detected in 1 sparrow, 7 starlings in bromadiolone or brodifacoum baited farms or farms in area of intensive poultry farming in Canada	Elliott <i>et al.</i> 2014
		Mean liver residues before & after implementation of risk mitigation measures in Canada (barred owl, barn owl, great-horned owl): 1988-2013: 130, 30, 70 µg/kg 2014-2018: 180, 50, 230 µg/kg	Elliott <i>et al.</i> 2022
		Detected in 0/20 in 2013 and 1/77 in 2015 red-tailed hawk blood samples from Marin Headland, California	Abernathy <i>et al.</i> 2018
		Max liver residues 571 µg/kg in 34/61 great horned owls, 1012 µg/kg in 19/25 barred owls, 720 µg/kg in 31/78 barn owls in BC & Yukon Territory of Canada between 1988 and 2003	Albert <i>et al.</i> 2010
		Detected in 19/37 red-tailed hawks, 8/24 barred owls, 13/17 great horned owls, 2/16 eastern screech-owls in Massachusetts between 2012 and 2016	Murray 2017
		Max liver residues 600 µg/kg in 5/50 Cooper's hawk, 500 µg/kg in 6/78 red-tailed hawk, 500 µg/kg in 3/22 screech owls, 1080 µg/kg in 10/53 great horned owl in New York between 1998 and 2001	Stone <i>et al.</i> 2003
Europe		Max liver residues 480 µg/kg in 27/43 red-tailed hawks in Massachusetts between 2017 and 2019	Murray 2020
		Max liver residues 37 µg/kg in 18/48 northern goshawk, 56 µg/kg in 12/41 red kite, 9.7 µg/kg in 3/60 white-tailed eagle, 41 µg/kg in 3/23 Eurasian sparrowhawk; not detected in 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021
		Max liver residues 252 µg/kg in 43/80 barn owls, 282 µg/kg in 33/141 buzzards, 679 µg/kg in 24/66 kestrels, 33 µg/kg in 13/38 long-eared owls, 130 µg/kg in 10/31 rough-legged buzzards, 496 µg/kg in 33/44 tawny owls from intensively managed landscapes in Denmark	Christensen <i>et al.</i> 2012
		Mean liver residues 2.5 mg/kg swan, 2.3 mg/kg mallard, 0.4 mg/kg buzzards & kites, 6.1 mg/kg harrier, 0.2 mg/kg heron attributed to vole baiting (100 mg a.c./kg bait) in France 1991-1994	Berny <i>et al.</i> 1997
		Max liver residues 127 µg/kg in 2/142 granivorous birds, 490 µg/kg in 18/129 predatory birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
	Max liver residues 154 µg/kg in 7/16 golden eagles; not detected in 8 eagle owls, 3 osprey, 2 peregrine falcon, 1 gryfalcon across Norway between 2009 and 2011	Langford <i>et al.</i> 2013	

Compartment	Location	Value	Reference
		Max liver residues 44 µg/kg in 5/33 scops owls, 180 µg/kg in 19/41 barn owls, 77 µg/kg in 10/27 tawny owls, 208 µg/kg in 12/14 eagle owls, 12 µg/kg in 2/12 long-eared owls, 80 µg/kg in 1/7 little owls, 586 µg/kg in 22/56 common buzzards in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Detectable residues in 20/172 tawny owls, 53/431 barn owls, 22/73 kestrels across Britain between 1990-93 or 2003-05	Walker <i>et al.</i> 2008
		Detected in 48/449 barn owls in Britain between 1988 and 1994	Newton <i>et al.</i> 1997
		Mean liver residues 177-236 µg/kg in 116/241 kestrels in UK between 1997 and 2011	Roos <i>et al.</i> 2021
	Tawain	Detected in 33/112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022
Reptiles	Australia	Max liver residues 700 µg/kg in 5/11 dugites, 73 µg/kg in 4/10 bobtails from 2014-18, and not detected in 11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Fish	Europe	Max liver residues 7.1 µg/kg in bream from two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 2.0 µg/kg in 12/32 fish in bioaccumulation ponds and 2.0 µg/kg in 5/12 fish in receiving streams of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019
		Max liver residues 7.5 µg/kg in 19/46 fish in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 120: Bromadiolone – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ²⁹	Reference
Mammals	Acute	<i>Rattus norvegicus</i>	LD ₅₀ >0.56 mg/kg bw	Mally & Porret-Blanc 1987

²⁹ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Group	Exposure	Species	Toxicity value ²⁹	Reference
			LD ₅₀ 1.3 mg/kg bw	Sebestyén 1996
		Canis familiaris	LD ₅₀ 8.1 mg/kg bw	Reagan 1987
			LD ₅₀ ~10 mg/kg bw	Poché 1988
	Dietary	Putorius furo	LC ₅₀ 9.8 mg/kg food	Poché 1988
	Chronic	Oryctolagus cuniculus	LOAEL 0.002 mg/kg bw/d	Druga 2004
			NOAEL 0.004 mg/kg bw/d	Virat 1981
Birds	Acute	Coturnix japonica	LD ₅₀ 134 mg/kg bw	Gáty 2005b
		Colinus virginianus	LD ₅₀ 138 mg/kg bw	Shapiro 1985a
		Anas platyrhynchos	LD ₅₀ 1293 mg/kg bw	Rodgers 2000
	Dietary	Colinus virginianus	LDD ₅₀ 8.3 mg/kg bw/d	Shapiro 1985b
	Reproduction	Coturnix japonica	NOEC 0.26 mg/L	Gáty 2005c

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

Table 121: Bromadiolone – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Birds	Tyto alba	17 mg/kg rats for 1, 3, 6 or 10d	No mortality in 1, 3 or 5d exposure groups after 20d (1.8-3.8 mg/kg/d). In 10d exposure group, 1 owl died (0.99 mg/kg/d), one survived (1.4 mg/kg/d) No haemorrhage in survivors.	Mendenhall & Pank 1980
		5.4 mg/kg rats on day 1, 3, 5, 7	1/4 birds showed signs of haemorrhaging on days 6/7; 4/4 showed reduced weight at 7d; all birds recovered by 30d	Salim <i>et al.</i> 2014
		0.10 mg/kg mice for 1, 3 or 6d	No mortality or haemorrhage in 1d group (0.035 mg/kg/d), 3d exposure group (0.013 mg/kg/d), or 6d exposure group (0.012 mg/kg/d). Increased blood coagulation time, returning to normal within 7d.	Wyllie 1995

Group	Species	Poisoned food	Study details & result	Reference
	Bubo virginianus		Rats fed 6 ppm bait for 3d followed by 1d untreated feed. 1 poisoned rat fed daily to each owl for 7d. All owls died within 37 days except 1 that avoided eating livers and intestines. Surviving owl showed evidence of earlier internal haemorrhaging. Estimated lethal dose 0.056 mg/kg/d.	Fletcher 1987
			Ground squirrels fed 25 or 50 ppm bait for 3 or 4d. 1 poisoned squirrel fed daily to owls for 3 or 4d. No treatment related mortality after 31d. Estimated non-lethal dose 0.96-4.2 mg/kg.	Poché 1988
	Buteo jamaicensis		Ground squirrels fed 25 or 50 ppm bait for 3 or 4d. 1 poisoned squirrel fed daily to owls for 3 or 4d. No treatment related mortality after 31d. Estimated non-lethal dose 4.1-5.2 mg/kg.	Poché 1988
Reptiles	Crotalus viridis		Mice fed 50 ppm bait until moribund. 1 poisoned mouse fed weekly to snakes for 3 weeks. No snakes died after 30d Estimated non-lethal dose 7.7-32 mg/kg bw	Poché 1988

Table 122: Bromadiolone – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
Large residential garden in Victoria	Unspecified	5 bird deaths (1 peacock, 1 little raven, 1 purple swamphen) attributed to bromadiolone poisoning a few days after baits set out	Reece <i>et al.</i> 1985
Poultry shed in Victoria	Unspecified	57 hen deaths and significant reduction in egg production attributed to bromadiolone poisoning in back-to-back sheds	Reece <i>et al.</i> 1985
Irrigated sunflower in NSW	50 mg a.c./kg bait (one aerial broadcast at 5 kg bait/ha)	1 straw-necked ibis death attributed to AR poisoning	Saunders 1983

Use area	Exposure	Effect	Reference
Central & Highland counties UK	Approved rodent control measures	One adult female red kite at its nest site died from internal haemorrhaging (0.24 mg/kg liver residue); one red kite road traffic casualty had significant residue (0.13 mg/kg liver residue) thought to increase susceptibility; one red kite chick death (0.35 mg/kg liver residue)	Barnett <i>et al.</i> 2002a
Tayside UK	Wheat-based bait in tunnel boxes	~150 ducks were able to access bait from tunnels of insufficient length despite baffles being present to limit movement from hopper	Barnett <i>et al.</i> 2002b
Norfolk UK	Wholewheat bait in bait boxes to control rodents	1 dead weasel near a cottage neighbouring a treated property. Liver was within the lethal range, although no haemorrhage was found	Barnett <i>et al.</i> 2006
Strathclyde UK	Rat bait in garden area by local district council	1 dead grey squirrel with liver residue in lethal range and pale blue/green material in stomach/intestines	Barnett <i>et al.</i> 2006
Border county UK	Rodent control on farm by local authority	1 fox poisoning, some dead rats recovered between bales in an open barn	Barnett <i>et al.</i> 2007
Suffolk UK	Approved use of baiting points	1 fox poisoning, found in farm outbuilding, may have eaten poisoned rats	Fletcher <i>et al.</i> 2000
Dorset UK	Approved use of baiting boxes	3 grey squirrel poisonings, chewed corner of a bait box allowed access	Fletcher <i>et al.</i> 2000
Highland UK	Bait laid along walls in pipes/under boards	3 juvenile red kite poisonings, few rat bodies found after baiting	Fletcher <i>et al.</i> 2000
Grampian UK	Approved bait use in piggery	2 fox poisonings adjacent to treated farm	Fletcher <i>et al.</i> 2000
Various counties across UK	Unspecified	1 fox and 6 red kite fledglings in 1998	Fletcher <i>et al.</i> 1999
		1 red kite, 1 buzzard and 5 fox poisonings	Fletcher <i>et al.</i> 2000
		2 badgers, 2 foxes, 1 pheasant, and 3 red kite poisonings in 2000	Barnett <i>et al.</i> 2002a
		1 fox, 1 barn owl, 1 tawny owl, 1 red kite, and 2 buzzard poisonings in 2001	Barnett <i>et al.</i> 2002b

Use area	Exposure	Effect	Reference
		6 fox, 2 dog and 1 red kite poisonings; 1 badger death from trauma but bromadiolone may have contributed.	Barnett <i>et al.</i> 2003
		4 red kites (one in rural area with sheep farming) and 22 feral pigeon poisonings	Barnett <i>et al.</i> 2004
		5 fox, 1 sparrowhawk, 1 tawny owl, 1 barn owl, 4 crows (accessed protected bait points), and 4 buzzard poisonings in 2004	Barnett <i>et al.</i> 2005
		1 otter, 4 fox, 1 barn owl, and 1 red kite poisoning in 2005	Barnett <i>et al.</i> 2006
		1 grey squirrel, 6 fox, 1 barn owl, 1 red kite, and 1 buzzard poisoning in 2006	Barnett <i>et al.</i> 2007
France, UK, Netherlands	Approved use	7 roedeer, boar, 4 rabbit, dunnoek, fox poisonings in 1990-1994, 1 wild duck in 1994-1995	de Snoo <i>et al.</i> 1999
New York, USA & adjoining states	Unspecified	3 skunk, 1 opossum, 1 great-horned owl poisonings in 1971-1997	Stone <i>et al.</i> 1999

Table 123: Bromadiolone – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 2.9 mg/L	Scheerbaum 2007a, 2007b
			LC ₅₀ >8.0 mg/L	Wetton & McKenzi 2003
Invertebrates	Acute	Daphnia magna	EC ₅₀ 2.0 mg/L	Boeri & Ward 1991
			EC ₅₀ 5.8 mg/L	Noack 2007
Algae	Chronic	Scenedesmus subspicatus	E _b C ₅₀ 0.17 mg/L	Müllerschön 1990
			E _r C ₅₀ 1.1 mg/L	Scheerbaum 2007c
			E _r C ₅₀ >3.4 mg/L	Ward & Boeri 2002

Table 124: Bromadiolone – Effects on soil organisms

Group	Exposure	Species/process	Toxicity value	Reference
Macro-organisms	Acute	Eisenia fetida	LC _{50corr} >665 mg/kg dry soil	Staniland 2005b
			LC _{50corr} >4.7 mg/kg dry soil	Odin-Feurtet 1999

Table 125: Bromadiolone – Effects on biological methods of sewage treatment

Test	Endpoint	Reference
Pseudomonas putida	EC ₅₀ >0.058 mg/L	Mather & Tapp 1988
Activated sludge	EC ₅₀ 133 mg/L	Gáty 2002
	EC ₅₀ 32 mg/L	Kelly & Clayton 2002

Difenacoum

Fate and behaviour in the environment

Table 126: Difenacoum – Physical and chemical properties of difenacoum

Study	Result	Reference
Vapour pressure	<0.05 × 10 ⁻³ Pa at 45°C	Fabbrini 1997b
	1.9 × 10 ⁻³ Pa at 25°C (estimate)	Russell 1996
Henry's law constant	<0.046 Pa m ³ mol ⁻¹	Worthington 2006a
Solubility in water	pH 5, 20°C: 0.048 mg/L pH 7, 20°C: 0.48 mg/L pH 9, 20°C: 3.7 mg/L	Woolley & Mullee 2005
	pH 4, 20°C: <0.05 mg/L pH 7, 20°C: 1.7 mg/L pH 9, 20°C: 61 mg/L	Russell 1996
Partition coefficient	log P _{OW} 7.6 (estimate)	Worthington 2006b, Russell 1996
Dissociation constant	pKa 4.5	Anon 2004a

Study	Result	Reference
UV-VIS absorption (max)	solution λ_{max} ϵ (L mol ⁻¹ cm ⁻¹)	
	acidic 259 nm 29085	Garofani 2001b
	acidic 308 nm 13279	
	neutral 259 nm 28515	
	neutral 308 nm 12926	
	basic 252 nm 28004	
	basic 312 nm 14901	
	acidic 262 nm 36600	Garofani 2001c
	acidic 310 nm 13290	
	neutral 262 nm 34800	
	neutral 310 nm 15470	
	basic 262 nm 30170	
	basic 310 nm 14630	
	CH ₂ Cl ₂ 259 nm 46600	Russell 1996
	CH ₂ Cl ₂ 311 nm 17100	

Table 127: Difenacoum – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Adsorption/ desorption	Koc 67 mL/g	Drake 2005c
		pH 2.5: log Koc >5.63	Hogg 2003
		pH 3.6: log Koc >5.63 pH 7.0: log Koc <1.25	
	Column leaching	200 mm elution over 2d, three soils: Difenacoum not detected in leachate	Stevens & Arnold 1982
Water and sediment	Hydrolysis	pH 4, 50°C: stable	Fabbrini 1997d, Russell 1996
		pH 7, 50°C: stable	
		pH 9, 50°C: stable	
		pH 5, 25°C: stable	Lewis 1992
		pH 7, 25°C: DT ₅₀ 1000 d	
		pH 9, 25°C: DT ₅₀ 80 d	

Compartment	Study	Result	Reference
	Aqueous photolysis	DT ₅₀ 0.053 d in summer at 52°N DT ₅₀ 0.32 d in winter at 52°N	Drake 2004b, 2005h, Gomez 2005
		Summer sunlight in Scotland: pH 5: DT ₅₀ 0.14 d pH 7: DT ₅₀ 0.34 d pH 9: DT ₅₀ 0.30 d	Hall <i>et al.</i> 1992
	Readily biodegradable	No	Drake 2003b, Kelly & Clayton 2003b
	Inherently biodegradable	No	Drake 2005i
	Anaerobic biodegradable	No	Drake 2005j
Air	Tropospheric degradation	DT ₅₀ 2.1 h (OH radical reaction) DT ₅₀ 2.0 h (ozone reaction)	Anon 2004b
Biota	Rat	67-68% oral absorption 41-71% elimination after 7d Elimination DT ₅₀ 1.3-2.3 d	Swan 2006
		74-82% oral absorption 40-60% elimination after 7d	Phillips 1996
		Liver DT ₅₀ 120 d	Parmar <i>et al.</i> 1987
	Mouse	Liver DT ₅₀ 62 d	Vandenbroucke <i>et al.</i> 2008
	Fish	BCF 1100, CT ₅₀ 5 d	Sacker 2004

Table 128: Difenacoum – Residues monitoring data

Compartment	Location	Value	Reference
Water	Europe	<LOQ (1.0 µg/kg) in suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019
Target rodents	UK	Max liver residues 27 µg/kg in 2/12 house mice from farms in Northern Ireland within 30m from buildings (no difenacoum usage at sites with detections)	Tosh <i>et al.</i> 2012

Compartment	Location	Value	Reference
Non-target mammals	Australia	Mean liver residues 96 µg/kg in 1/9 western quolls, 7 µg/kg in 3/15 eastern quolls, and 3 µg/kg in 1/20 Tasmanian devils in Tasmania, Western Australia, NSW	Lohr 2022
		Not detected in brushtail possums in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 7 µg/kg in 2/53 brushtail possums, 3 µg/kg in 4/82 ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024
	Europe	Mean liver residues 54 µg/kg in 5/51 wild boars in urban area (mean muscle residues 2.8 µg/kg in 2); not detected in liver or muscle of 20 wild boars in suburban area or 13 wild boars in rural area of Spain	Alabau <i>et al.</i> 2020
		Max liver residues 659 µg/kg in 29/106 Algerian hedgehogs, 672 µg/kg in 12/48 European hedgehogs in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Max liver residues 15 µg/kg in 1/29 herbivores, 520 µg/kg in 7/96 carnivores; not detected in 3 insectivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Liver residues 300-1400 µg/kg in 2/2 polecats that made heavy use of agricultural premises using anticoagulant rodenticides in UK between 1993-95	Birks 1998
		Max liver residues 321 µg/kg in 7/29 polecats from west Midlands of England between 1992 and 1994	Shore <i>et al.</i> 1996
		Max liver residues 917 µg/kg in 14/50 polecats from recolonised areas in central and eastern Britain between 1993 and 1999	Shore <i>et al.</i> 2003
		Max liver residues 14µg/kg in 1/55 wood mice from farms in Northern Ireland more than 30m from buildings (no difenacoum usage at sites with detections)	Tosh <i>et al.</i> 2012
South Africa	Detected but not quantifiable in 8/24 caracals in Greater Cape Town, South Africa between 2014 and 2017	Serieys <i>et al.</i> 2019	
Birds	Australia	Max liver residues 29 µg/kg barn owls, 4 µg/kg southern boobook; not detected in little ravens, Australian kestrels, whistling kites, barking owls, powerful owls, tawny frogmouths in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 1226 µg/kg in 12/38 powerful owls in Sydney basin urban areas between 2015 and 2021	Birdlife Australia 2022

Compartment	Location	Value	Reference
		Max liver residues 12 µg/kg in 2/5 eastern barn owls, 9 µg/kg in 2/19 tawny frogmouths, 25 µg/kg in 3/24 powerful owls; not detected in 12 southern boobooks in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Liver residues 33 µg/kg in 1/5 Carnaby's cockatoos in Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
		Max liver residues 97 µg/kg in 11/73 southern boobooks (15%) in urban & peri-urban areas of WA	Lohr 2018
		Not detected in 50 wedge-tailed eagles across Tasmania between 1996 and 2018	Pay <i>et al.</i> 2021
Tawain		Geomean liver residues 21 µg/kg in 8/74 black-winged kite, 9 µg/kg in 3/46 crested goshawk, 6 µg/kg in 2/42 collared scops-owl, 4 µg/kg in 1/12 crested serpent-eagle; not detected in 8 black kite, 6 oriental honey-buzzard, 6 short-eared owl, 3 eastern grass-owl, 3 eurasian kestrel, 1 common buzzard or 11 other raptor species in Taiwan between 2010 and 2018	Hong <i>et al.</i> 2019
		Detected in 9/112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022
North America		Not detected in 50 Cooper's hawk, 78 red-tailed hawk, 22 screech owls, 53 great horned owl in New York between 1998 and 2001	Stone <i>et al.</i> 2003
		Detected in 3/37 red-tailed hawks, 1/24 barred owls, 1/17 great horned owls, 2/16 eastern screech-owls in Massachusetts between 2012 and 2016	Murray 2017
		<LOQ (50 µg/kg) in 8/43 red-tailed hawks in Massachusetts between 2017 and 2019	Murray 2020
Europe		Max liver residues 83 µg/kg in 32/48 northern goshawk, 57 µg/kg in 19/41 red kite, 28 µg/kg in 13/60 white-tailed eagle; not detected in 23 Eurasian sparrowhawk or 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021
		Max liver residues 223 µg/kg in 12/80 barn owls, 170 µg/kg in 17/141 buzzards, 450 µg/kg in 12/66 kestrels, 52 µg/kg in 8/38 long-eared owls, 0.11 µg/kg in 7/31 rough-legged buzzards, 90 µg/kg in 10/44 tawny owls from intensively managed landscapes in Denmark	Christensen <i>et al.</i> 2012
		Detectable residues in 10/172 tawny owls, 72/431 barn owls, and 37/73 kestrels across Britain between 1990-93 or 2003-05	Walker <i>et al.</i> 2008
		Max liver residues 181 µg/kg in 2/8 eagle owls; not detected in 16 golden eagles, 3 osprey, 2 peregrine falcon, 1 gray falcon across Norway between 2009 and 2011	Langford <i>et al.</i> 2013

Compartment	Location	Value	Reference
		Max liver residues 10 µg/kg in 8/33 scops owls, 198 µg/kg in 10/41 barn owls, 84 µg/kg in 6/27 tawny owls, 281 µg/kg in 9/14 eagle owls, 53 µg/kg in 3/12 long-eared owls, 2 µg/kg in 1/7 little owls, 1921 µg/kg in 12/56 common buzzards in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Max liver residues 56 µg/kg in 3/129 predatory birds; not detected in 142 granivorous birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Not detected in >97% of 89 barn owl pellets collected winter of 1988-1989 over five counties in southern Eire, UK	Eadsforth <i>et al.</i> 1996
		Detected in 76/449 barn owls in Britain between 1988 and 1994	Newton <i>et al.</i> 1997
		Mean liver residues 61-118 µg/kg in 120/241 kestrels in UK between 1997 and 2011	Roos <i>et al.</i> 2021
Reptiles	Australia	Max liver residues 53 µg/kg in 4/11 dugites, 2 µg/kg in 1/10 bobtails in 2014-18, and not detected in 11 tiger snakes in 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020
	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Fish	Europe	Max liver residues 0.7 µg/kg in bream from two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 1.8 µg/kg in 9/32 fish in bioaccumulation ponds and 1.8 µg/kg in 3/12 fish in receiving streams of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019
		Max liver residues 16 µg/kg in 33/46 fish in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 129: Difenacoum – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ³⁰	Reference
Mammals	Acute	Rattus argentiventer	LD ₅₀ 0.7 mg/kg bw	Bull 1976
		Mus musculus	LD ₅₀ 0.8 mg/kg bw	
		Canis familiaris	LD ₅₀ 50 mg/kg bw	
		Cavia porcellus	LD ₅₀ 50 mg/kg bw	
		Sus scrofa	LD ₅₀ 80 mg/kg bw	
		Felis catus	LD ₅₀ 100 mg/kg bw	
	Rattus norvegicus	LD ₅₀ 1.8 mg/kg bw	Gardner 1995a	
			LD ₅₀ 2.6 mg/kg bw	Gardner 1995b
			LD ₅₀ >5 mg/kg bw	Szakonyi 2004a
			0.05 g/kg pellet: LD ₅₀ 1.3 mg/kg bw	Redpath 1997
	Chronic	Rattus norvegicus	LOAEL 0.010 mg/kg bw/d	Szakonyi 2004b
Birds	Acute	Gallus domesticus	LD ₅₀ 50 mg/kg bw	Bull 1976
		Coturnix japonica	LD ₅₀ 133 mg/kg bw	Gáty 2005d
		Anas platyrhynchos	LD ₅₀ >2000 mg/kg bw	Nolan-Smith 1997
	Dietary	Coturnix japonica	LC ₅₀ 1.4 mg/kg food	Stafford 2006
		Phasianus colchicus	LDD ₅₀ 2.9 mg/kg bw/d	Nolan-Smith 2000a
		Anas platyrhynchos	LDD ₅₀ >17 mg/kg bw/d	Nolan-Smith 2000b
		Colinus virginianus	LDD ₅₀ 82 mg/kg bw/d	Nolan-Smith 1998
	Reproduction	Coturnix japonica	NOEL 0.011 mg/kg bw/d	Linder 2006
NOEC 0.31 mg/L			Gáty 2005e	

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

³⁰ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Table 130: Difenacoum – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Birds	Tyto alba	18 mg/kg rats for 1, 3, 6 or 10d	No mortality or haemorrhage in 1 or 3d exposure groups after 20d (2.1-4.0 mg/kg/d). In 6 and 10d exposure groups, all owls survived but haemorrhaged (0.98-1.2 mg/kg/d).	Mendenhall & Pank 1980
		0.35 mg/kg mice for 1, 3 or 6d	6/6 owls survived to 36d in each of 1d group (0.093 mg/kg/d), 3d group (0.062 mg/kg/d), and 6d group (0.026-0.052 mg/kg/d). No haemorrhage. Increased blood coagulation time, returning to normal within 9d.	Newton <i>et al.</i> 1990, Wyllie 1995
		1.1-5.2 mg/kg mice for 15d	1/4 owls died after 14d (0.28 mg/kg/d) 3/4 owls survived to 30d (0.11-0.37 mg/kg/d), minor haemorrhaging in 2 surviving owls	Gray & Dutton 1992, Gray <i>et al.</i> 1994a, 1994b

Table 131: Difenacoum – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
Highland & Tayside counties UK	Approved rat control measures (potato store, agricultural buildings, distillery)	3 buzzard (0.03-0.18 mg/kg liver residue), 2 red kite chicks (0.36-0.38 mg/kg liver residue); possible multi-point exposure	Barnett <i>et al.</i> 2002a
Strathclyde UK	Rat bait in garden area by local district council	1 dead grey squirrel with liver residue in lethal range and pale blue/green material in stomach/intestines	Barnett <i>et al.</i> 2006
Humberside UK	Approved grain baiting in haulage yard	1 sparrow poisoning, likely accessed bait box	Fletcher <i>et al.</i> 2000
United Kingdom	Approved use	2 barn owl, polecat poisonings in 1990-1994	de Snoo <i>et al.</i> 1999
Rat infested farms in England	50 mg a.c./kg bait (150g bait per tray replenished for 9-21d)	No impact on frequency of observations of birds during treatment (11-13 species)	Bates 1997a, 1997b
Mouse infested commercial & domestic sites in England	50 mg a.c./kg bait (30g bait per tray replenished for 9-15d)	No impact on frequency of observations of birds during treatment (3-5 species)	Bates 1997c, 1997d
Various counties across UK	Unspecified	1 buzzard poisoning in 1998	Fletcher <i>et al.</i> 1999

Use area	Exposure	Effect	Reference
		1 red kite, 2 tawny owl, and 3 buzzard poisonings	Fletcher <i>et al.</i> 2000
		1 fox, 2 badger, and 1 red kite poisoning in 2000	Barnett <i>et al.</i> 2002a
		1 badger, 2 red kite, and 2 buzzard poisonings in 2001	Barnett <i>et al.</i> 2002b
		5 red kites, 1 cat (recovered), 1 dog and 3 fox poisonings; 3 red kites, 5 buzzards with sublethal residue; 2 dog poisonings in shut stable in 2002	Barnett <i>et al.</i> 2003
		1 red kite and 22 feral pigeon poisonings; 1 rabbit and 2 crow poisonings in seabird recovery project rat control programme where great care had been taken to protect non-target species in 2003	Barnett <i>et al.</i> 2004
		2 badgers, 3 fox, 4 crows (accessed protected bait points), 1 sparrowhawk, 1 red kite, and 6 buzzard poisonings in 2004	Barnett <i>et al.</i> 2005
		1 badger, 2 red kites, and 3 buzzard poisonings in 2005	Barnett <i>et al.</i> 2006
		1 fox, 2 barn owls, 3 red kites, 3 peacocks, and 2 buzzard poisonings in 2006	Barnett <i>et al.</i> 2007

Table 132: Difenacoum – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 0.064 mg/L	Wyness 1995a
			LC ₅₀ 0.33 mg/L	Craig 2003d
		Lepomis macrochirus	LC ₅₀ 0.26 mg/L	Wyness 1995b
Invertebrates	Acute	Daphnia magna	EC ₅₀ 0.52 mg/L	Kent <i>et al.</i> 1991
			EC ₅₀ 0.61 mg/L	Wyness 1995c
			EC ₅₀ 0.91 mg/L	Craig 2003e
Algae	Chronic	Raphidocelis subcapitata	E _r C ₅₀ 0.51 mg/L	Craig 2003f

Group	Exposure	Species	Toxicity value	Reference
			E _r C ₅₀ 0.80 mg/L	Wyness 1995d
			E _r C ₅₀ >2.5 mg/L	Smyth <i>et al.</i> 1991

Table 133: Difenacoum – Effects on soil organisms

Group	Exposure	Species/process	Toxicity value	Reference
Macro-organisms	Acute	Eisenia fetida	LC _{50corr} >497 mg/kg dry soil	Staniland 2005c

Table 134: Difenacoum – Effects on biological methods of sewage treatment

Test	Endpoint	Reference
Pseudomonas putida	EC ₅₀ >2.3 mg/L	Mather & Tapp 1989
Activated sludge	EC ₅₀ >999 mg/L	Staniland 2005d

Difethialone

Fate and behaviour in the environment

Table 135: Difethialone – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Aerobic soil metabolism	loamy sand: DT ₅₀ 524 d	Völkl & Galicia 1993
		sand: DT ₅₀ 224 d	
		Sandy loam: DT ₅₀ 204 d	Spare 1987a
		Geomean DT ₅₀ 317 d	

Compartment	Study	Result	Reference
	Adsorption/ desorption	Soil pH %OC Kf Koc 1/n clay 5.7 1.40 8.8×10 ⁶ 6.2×10 ⁸ 0.38 sand 5.9 0.23 8.8×10 ⁵ 1.0×10 ⁸ 0.50 sandy clay loam 7.1 0.45 8.8×10 ⁷ 5.3×10 ⁹ 0.32 sandy loam 6.1 0.26 8.8×10 ⁵ 2.7×10 ⁸ 0.42 mean Koc 1.6×10 ⁹	Spare 1992a
Water and sediment	Hydrolysis	pH 5, 25°C: stable pH 7, 25°C: DT ₅₀ 175 d pH 9, 25°C: DT ₅₀ 155 d	Spare 1986
	Aqueous photolysis	pH 5, 28-35°C: DT ₅₀ 60 min pH 7, 28-35°C: DT ₅₀ 62 min pH 9, 28-350°C: DT ₅₀ 55 min with natural sunlight pH 7, 20°C: DT ₅₀ 23 min with artificial sunlight	Spare 1987b Lynn <i>et al.</i> 2003
	Readily biodegradable	No	Daniel & Swarbrick 2003a
	Anaerobic biodegradable	No	Daniel & Swarbrick 2003b
Air	Tropospheric degradation	DT ₅₀ 2.2 h (OH radical reaction) DT ₅₀ 2.0 h (ozone reaction)	Curl 2004b
Biota	Mouse	Liver DT ₅₀ 29 d	Vandenbroucke <i>et al.</i> 2008

Table 136: Difethialone – Residues monitoring data

Compartment	Location	Value	Reference
Water	Europe	<LOQ (1.4 µg/kg) in suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019

Compartment	Location	Value	Reference
Target rodents	-	Max whole body residues 2.8 mg/kg after 3d consumption and 3.1 mg/kg after continuous consumption until death (4-7d) of 25 mg a.c./kg bait	Savarie 2005
		Mean whole body residues 2.0 mg/kg after 3d consumption or continuous consumption until death of 25 mg a.c./kg bait	Goldade <i>et al.</i> 2001
Non-target mammals	Australia	Not detected in brushtail possums in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 10 µg/kg in 3/53 brushtail possums, 66 µg/kg in 1/82 ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024
	Europe	Liver residues 5.9 µg/kg in 1/51 wild boars in urban area (not detected in muscle); not detected in liver or muscle of 20 wild boars in suburban area or 13 in rural area of Spain	Alabau <i>et al.</i> 2020
		Max liver residues 256 µg/kg in 4/106 Algerian hedgehogs, 142 µg/kg in 2/48 European hedgehogs in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
	South Africa	Max liver residues 926 µg/kg in 1/96 carnivores; not detected in 29 herbivores, 3 insectivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Mean liver residues 50 µg/kg in 22/24 caracals in Greater Cape Town, South Africa between 2014 and 2017		Serieys <i>et al.</i> 2019	
Birds	Australia	Max liver residues 690 µg/kg Australian kestrels, 190 µg/kg barn owls; not detected in little ravens, whistling kites, barking owls, southern boobooks, powerful owls, tawny frogmouths in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 6 µg/kg in 3/19 tawny frogmouths, 8 µg/kg in 2/24 powerful owls; not detected in 5 eastern barn owls, 12 southern boobooks in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Not detected in 5 Carnaby's cockatoos from Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
		Max liver residues 775 µg/kg in 6/73 southern boobooks (8.2%) in urban & peri-urban areas of WA	Lohr 2018
		Not detected in 50 wedge-tailed eagles across Tasmania between 1996 and 2018	Pay <i>et al.</i> 2021
North America	Max 310 µg/kg in pellets of 8/9 rat-eating barn owls from agricultural barn sites in Canada	Elliott <i>et al.</i> 2014	

Compartment	Location	Value	Reference
		Mean liver residues before & after implementation of risk mitigation measures in Canada (barred owl, barn owl, great-horned owl): 1988-2013: 20, 20, 10 µg/kg 2014-2018: 30, 40, 20 µg/kg	Elliott <i>et al.</i> 2022
		Max liver residues 30 µg/kg in 3/61 great horned owls, 17 µg/kg in 1/25 barred owls, 720 µg/kg in 10/78 barn owls in BC & Yukon Territory of Canada between 1988 and 2003	Albert <i>et al.</i> 2010
		Detected in 23/37 red-tailed hawks, 5/24 barred owls, 6/17 great horned owls, 8/16 eastern screech-owls in Massachusetts between 2012 and 2016	Murray 2017
		Max liver residues 610 µg/kg in 17/43 red-tailed hawks in Massachusetts between 2017 and 2019	Murray 2020
		Not detected in 50 Cooper's hawk, 78 red-tailed hawk, 22 screech owls, 53 great horned owl in New York between 1998 and 2001	Stone <i>et al.</i> 2003
	Europe	Max liver residues 119 µg/kg in 8/48 northern goshawk, 37 µg/kg in 8/41 red kite, 8.5 µg/kg in 2/60 white-tailed eagle; not detected in 23 Eurasian sparrowhawk or 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021
		Not detected in 16 golden eagles, 8 eagle owls, 3 osprey, 2 peregrine falcon, 1 gryfalcon across Norway between 2009 and 2011	Langford <i>et al.</i> 2013
		Not detected in 142 granivorous birds, 129 predatory birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Reptiles	Europe	Not detected in 2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
Fish	Europe	Max liver residues 6.3 µg/kg in bream from two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 0.8 µg/kg in 1/32 fish in bioaccumulation ponds and 5.2 µg/kg in 3/12 fish in receiving streams of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019
		Max liver residues 4.0 µg/kg in 16/46 fish in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 137: Difethialone – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ³¹	Reference
Mammals	Acute	Rattus norvegicus	0.025 g/kg paste: LD ₅₀ >0.050 mg/kg bw	Andrews 2001
			0.025 g/kg block: LD ₅₀ >0.13 mg/kg bw	Glaza 1987
			0.025 g/kg pellet: LD ₅₀ >0.13 mg/kg bw	Rutkowski 1987
	Dietary	Mustela furo	LDD ₅₀ 760 mg/kg bw/d	Goldade <i>et al.</i> 2001, Savarie 2005
Birds	Acute	Colinus virginianus	LD ₅₀ 0.26 mg/kg bw	Fletcher 1988a
		Coturnix japonica	LC ₅₀ 23 mg/kg bw	Lorgue 1987
	Dietary	Colinus virginianus	LC ₅₀ 0.56 mg/kg food	Fletcher 1988b
Birds	Dietary	Anas platyrhynchos	LC ₅₀ 1.9 mg/kg food	Fletcher 1986
		Pica pica	LDD ₅₀ 7.4 mg/kg bw/d	Goldade <i>et al.</i> 2001, Savarie 2005

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

Table 138: Difethialone – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Birds	Tyto alba	0.30-0.45 mg/kg rats for 1, 3 or 6d	LD ₁₀₀ 0.27-0.39 mg/kg bw. Ingested difethialone readily available; excretion/ metabolism low during 56d period	Saravanan & Kanakasabai 2004

Table 139: Difethialone – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 0.051 mg/L	Nicholson 1986a
		Lepomis macrochirus	LC ₅₀ 0.075 mg/L	Nicholson 1986b

³¹ All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Group	Exposure	Species	Toxicity value	Reference
Invertebrates	Acute	Daphnia magna	EC ₅₀ 0.0044 mg/L	Nicholson 1986c
Algae	Chronic	Raphidocelis subcapitata	E _r C ₅₀ >0.18 mg/L	Swarbrick 2003

Table 140: Difethialone – Effects on soil organisms

Group	Exposure	Species/process	Toxicity value	Reference
Macro-organisms	Acute	Eisenia fetida	LC _{50corr} >500 mg/kg dry soil	Hughes & Paterson 2003

Table 141: Difethialone – Effects on biological methods of sewage treatment

Test	Endpoint	Reference
Activated sludge	EC ₅₀ >100 mg/L	Swarbrich 2002

Flocoumafen

Fate and behaviour in the environment

Table 142: Flocoumafen – Physical and chemical properties

Study	Result	Reference	
Vapour pressure	<2.7 × 10 ⁻⁷ Pa at 55-77°C	Camilleri & Weaver 1985	
	<1.0 × 10 ⁻³ Pa at 20, 25 and 50°C	Franke 2001	
Solubility in water	1.0 mg/L	Camilleri & Weaver 1985	
Partition coefficient	log P _{ow} 4.7	Camilleri & Weaver 1985	
	pH 7: log P _{ow} 6.1	Daum 2002a	
	pH 9: log P _{ow} 5.1	Daum 2002a	
Dissociation constant	pKa 4.5	Daum 2002b, Martin 2001	
UV-VIS absorption (max)	solution	λ _{max} ε (L mol ⁻¹ cm ⁻¹)	
	CH ₃ CN	308 nm 131000	Camilleri & Weaver 1985
	CH ₃ CN	282 nm 158000	Camilleri & Weaver 1985

Study	Result	Reference
	CH ₃ CN 271 nm 155000	
	CH ₃ OH 308 nm 135400	
	CH ₃ OH 283 nm 82900	
	CH ₃ OH 274 nm 66400	
	pH 0.7 315 nm 20291	Daum 2003
	pH 5.0 309 nm 13173	
	pH 6.8 311 nm 14162	
	pH 13 309 nm 14326	

Table 143: Flocoumafen – Fate and behaviour in environmental media

Compartment	Study	Result	Reference
Soil	Aerobic soil metabolism	loamy sand: DT ₅₀ 296 d	Derz 2006
		silt loam: DT ₅₀ 223 d	
		silty clay loam: DT ₅₀ 73 d	
		loamy sand: DT ₅₀ 432 d	
		Geomean DT ₅₀ 256 d	
	Adsorption/desorption	Koc 101684 mL/g	Weissenfeld 2002
	Column leaching	200 mm elution over 2d, four soils: 0.09-0.18% in leachate	Wallace & Eadsforth 1984
Water and sediment	Hydrolysis	pH 5, 50°C: DT ₅₀ 30 d	Camilleri & Weaver 1985
		pH 7, 50°C: DT ₅₀ 447 d	
		pH 9, 50°C: DT ₅₀ 445 d	
			pH 5, 50°C: stable
		pH 7, 50°C: stable	
		pH 9, 50°C: stable	
	Aqueous photolysis	DT ₅₀ 1.7 d in April, central Europe	Hennecke 2006
	Readily biodegradable	No	Dengler 2004

Compartment	Study	Result	Reference
	Anaerobic biodegradable	No	Schwarz 2004
Air	Tropospheric degradation	DT ₅₀ 1.5 h (OH radical reaction) DT ₅₀ 2.0 h (ozone reaction)	Martin 2002
Biota	Rat	28-42% elimination after 7d 23-26% elimination after 7d Liver DT ₅₀ 220 d Liver DT ₅₀ 159 d	Huckle & Warburton 1986 Warburton & Hutson 1985a, 1985b, Huckle <i>et al.</i> 1989a Hawkins <i>et al.</i> 1991
	Mouse	Liver DT ₅₀ 94 d	Vandenbroucke <i>et al.</i> 2008
	Sheep	Liver DT ₅₀ >256 d	Nelson & Hickling 1994
	Dog	Liver DT ₅₀ >300 d	Veenstra <i>et al.</i> 1991
	Chicken	68% elimination after 1d	Eadsforth <i>et al.</i> 1993, Huckle 1988
	Japanese quail	76% elimination after 7d Liver DT ₅₀ >100 d	Huckle & Warburton 1985 Huckle <i>et al.</i> 1989b
	Fish	BCF 24300, CT ₅₀ 38 d	Wenzel 2011

Table 144: Flocoumafen – Residues monitoring data

Compartment	Location	Value	Reference
Water	Europe	<LOQ (1.0 µg/kg) in suspended particulate matter at 16 sampling locations in German rivers in 2015	Kotthoff <i>et al.</i> 2019
Target rodents	UK	Max liver residues 8 µg/kg in 1/12 house mice from farms in Northern Ireland within 30m from buildings (flocoumafen use)	Tosh <i>et al.</i> 2012
Non-target mammals	Australia	Not detected in brushtail possums in rural & urban areas across Australia between 2006 and 2021	WHA 2022

Compartment	Location	Value	Reference
		Max liver residues 1400 µg/kg in 2/53 (4%) brushtail possums, 1497 µg/kg in 5/82 (6%) ringtail possums in Victoria in 2022	Scammell <i>et al.</i> 2024
Europe		Mean liver residues 7.0 µg/kg in 2/51 wild boars in urban area (not detected in muscle); not detected in liver or muscle of 20 wild boars in suburban area or 13 in rural area of Spain	Alabau <i>et al.</i> 2020
		Max liver residues 29 µg/kg in 6/48 European hedgehogs; not detected in 106 Algerian hedgehogs in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
		Max liver residues 353 µg/kg in 8/96 carnivores; not detected in 29 herbivores, 3 insectivores in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Not detected in liver of polecat that made heavy use of agricultural premises using anticoagulant rodenticides in UK between 1993-95	Birks 1998
		Not detected in 29 polecats from west Midlands of England between 1992 and 1994	Shore <i>et al.</i> 1996
		Not detected in 50 polecats from recolonised areas in central and eastern Britain between 1993 and 1999	Shore <i>et al.</i> 2003
		Max liver residues 615 µg/kg in 2/55 wood mice from farms in Northern Ireland more than 30m from buildings (flocoumafen use)	Tosh <i>et al.</i> 2012
Birds	Australia	Not detected in little ravens, Australian kestrels, whistling kites, barking owls, southern boobooks, powerful owls, tawny frogmouths, barn owls in rural & urban areas across Australia between 2006 and 2021	WHA 2022
		Max liver residues 88 µg/kg in 4/38 powerful owls in Sydney basin urban areas between 2015 and 2021	Birdlife Australia 2022
		Max liver residues 5 µg/kg in 2/5 eastern barn owls; 1 µg/kg in 1/19 tawny frogmouths; not detected in 12 southern boobooks or 24 powerful owls in urban, forest, & agricultural areas of Vic, SA & NSW between 2003 and 2022	Cooke <i>et al.</i> 2023
		Not detected in 5 Carnaby's cockatoos from Kalamunda WA in 2024	Le Souëf <i>et al.</i> 2024
		Max liver residues 818 µg/kg in 2/73 southern boobooks (2.7%) in urban & peri-urban areas of WA	Lohr 2018
		Max liver residues 348 µg/kg in 20/50 (40%) wedge-tailed eagles across Tasmania between 1996 and 2018 (40%)	Pay <i>et al.</i> 2021

Compartment	Location	Value	Reference	
Tawain		Geomean liver residues 22 µg/kg in 40/74 black-winged kite, 12 µg/kg in 13/46 crested goshawk, 9 µg/kg in 11/42 collared scops-owl, 26 µg/kg in 5/12 crested serpent-eagle, 95 µg/kg in 1/8 black kite, 2 µg/kg in 1/6 oriental honey-buzzard, 15 µg/kg in 1/3 eastern grass-owl; not detected in 6 short-eared owl, 3 eurasian kestrel, 1 common buzzard or 11 other raptor species in Taiwan between 2010 and 2018	Hong <i>et al.</i> 2019	
		Detected in 54/112 black-winged kites from Taiwan airports between 2013 and 2016	Lin <i>et al.</i> 2022	
	Europe		Max liver residues 14 µg/kg in 2/48 northern goshawk, 88 µg/kg in 12/41 red kite, not detected in 60 white-tailed eagle, 23 Eurasian sparrowhawk or 13 osprey in Germany between 1996 and 2018	Badry <i>et al.</i> 2021
			Max liver residues 34 µg/kg in 14/80 barn owls, 115 µg/kg in 16/141 buzzards, 20 µg/kg in 18/66 kestrels, 2 µg/kg in 6/38 long-eared owls, 42 µg/kg in 8/44 tawny owls; not detected in 31 rough-legged buzzards from intensively managed landscapes in Denmark	Christensen <i>et al.</i> 2012
			Max liver residues 117 µg/kg in 2/16 golden eagles, 13 µg/kg in 1/8 eagle owls; not detected in 3 osprey, 2 peregrine falcon, 1 gryfalcon across Norway between 2009 and 2011	Langford <i>et al.</i> 2013
			Max liver residues 10 µg/kg in 2/33 scops owls, 299 µg/kg in 3/41 barn owls, 118 µg/kg in 7/27 tawny owls, 90 µg/kg in 4/14 eagle owls, 33 µg/kg in 1/7 little owls, 175 µg/kg in 7/56 common buzzards; not detected in 12 long-eared owls in Mediterranean region of Spain between 2011 and 2013	López-Perea <i>et al.</i> 2015
			Max liver residues 143 µg/kg in 1/142 granivorous birds, 400 µg/kg in 8/129 predatory birds in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012
		Detectable residues in 0/172 tawny owls, 5/431 barn owls, 0/73 kestrels across Britain between 1990-93 or 2003-05	Walker <i>et al.</i> 2008	
	Not detected in >97% of 89 barn owl pellets collected winter of 1988-1989 over five counties in southern Eire, UK	Eadsforth <i>et al.</i> 1996		
	Detected in 6/449 barn owls in Britain between 1988 and 1994	Newton <i>et al.</i> 1997		
Reptiles	Australia	Max liver residues 4 µg/kg in 1/10 bobtails from 2014-18, not detected in 11 dugites (2014-18) or 11 tiger snakes from 2018-19 in Greater Perth, WA	Lettoof <i>et al.</i> 2020	
	Europe	Liver residues 540 µg/kg in 1/2 reptile species in Spain between 2005 and 2010	Sánchez-Barbudo <i>et al.</i> 2012	

Compartment	Location	Value	Reference
Fish	Europe	Max liver residues 0.3 µg/kg in bream from two German rivers between 1992 and 2015	Kotthoff <i>et al.</i> 2019
		Max liver residues 1.0 µg/kg in 3/12 fish in receiving streams; not detected in 32 fish in bioaccumulation ponds of municipal wastewater treatment plants in Germany between 2013 and 2016	Regnery <i>et al.</i> 2019
		Max liver residues 1.7 µg/kg in 17/46 fish in receiving streams of municipal wastewater treatment plants in Germany in 2019	Regnery <i>et al.</i> 2020

Effects on non-target species

Table 145: Flocoumafen – Primary poisoning studies on terrestrial vertebrates

Group	Exposure	Species	Toxicity value ³²	Reference
Mammals	Acute	<i>Rattus norvegicus</i>	LD ₅₀ 0.13 mg/kg bw	Price 1984
Birds	Acute	<i>Anas platyrhynchos</i>	LD ₅₀ 24 mg/kg bw	Roberts 1985a, 1985b
	Dietary	<i>Anas platyrhynchos</i>	LDD ₅₀ 5.6 mg/kg bw/d	Gallagher <i>et al.</i> 2002a
			LDD ₅₀ 2.7 mg/kg bw/d	Roberts <i>et al.</i> 1985c, 1985d
		<i>Colinus virginianus</i>	LDD ₅₀ 14 mg/kg bw/d	Gallagher <i>et al.</i> 2002b
		<i>Coturnix japonica</i>	LDD ₅₀ 14 mg/kg bw/d	Roberts <i>et al.</i> 1985e, 1985f
		<i>Gallus domesticus</i>	LC ₅₀ 16 mg/kg food	Eadsforth <i>et al.</i> 1993

AV: avoidance factor (1.0 = no avoidance, 0 = 100% avoidance); PD: proportion of diet (1.0 = 100% food consumed, 0 = no food consumed)

Table 146: Flocoumafen – Secondary poisoning studies on terrestrial vertebrates

Group	Species	Poisoned food	Study details & result	Reference
Birds	<i>Tyto alba</i>	1.0-4.3 mg/kg mice for 15d	2/4 owls died after 16d (0.15-0.19 mg/kg/d), 2/4 owls survived to 30d (0.12-0.13 mg/kg/d), minor haemorrhaging in 1 surviving owl	Gray & Dutton 1992, Gray <i>et al.</i> 1994, 1994b
		0.58 mg/kg mice for 1, 3 or 6d	Mortality was 0/5 in 1d group (0.15 mg/kg/d), 0/5 in 3d group (0.11 mg/kg/d), and 1/5 in 6d (0.15 mg/kg/d).	Wyllie 1995

³² All substances were tested as the technical active constituent unless otherwise indicated; all toxicity values are expressed in terms of the specified active constituent

Group	Species	Poisoned food	Study details & result	Reference
			Haemorrhaging observed in 6d exposure group only. Increased blood coagulation time in survivors, returning to normal within 16d.	
		6.3-7.9 mg/kg mice for 1d	4/4 owls survived to 8d (0.11-0.23 mg/kg bw)	Dutton & Eadsforth 1990, Eadsforth <i>et al.</i> 1991
		0.65 mg/kg mice for 1, 3 and 6d	4/5 owls survived all treatments (0.13-0.21 mg/kg/d); 1 moulting owl died from haemorrhaging at 4d post-dosing after 6d treatment (0.16 mg/kg/d)	Gray 1991, Newton <i>et al.</i> 1994

Table 147: Flocoumafen – Field studies and adverse incidents involving terrestrial vertebrates from approved or unspecified use

Use area	Exposure	Effect	Reference
Various counties across UK	Unspecified	1 tawny owl poisoning in 1998	Fletcher <i>et al.</i> 1999
		No wildlife incidents that involved approved uses or unspecified exposure in 1999-2001, 2003, 2005-2006	Barnett <i>et al.</i> 2002a, 2002b, 2004, 2006, 2007, Fletcher <i>et al.</i> 2000
		4 crows poisoned (accessed protected bait points) in 2004	Barnett <i>et al.</i> 2005

Table 148: Flocoumafen – Effects on aquatic species

Group	Exposure	Species	Toxicity value	Reference
Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 0.070 mg/L	Zok 2002a
		Lepomis macrochirus	LC ₅₀ 0.11 mg/L	Zok 2002b
Invertebrates	Acute	Daphnia magna	EC ₅₀ 0.18 mg/L	Jatzek 2002a
Algae	Chronic	Raphidocelis subcapitata	E _r C ₅₀ >18 mg/L	Jatzek 2002b

Table 149: Flocoumafen – Effects on soil organisms

Group	Exposure	Species/process	Toxicity value	Reference
Macro-organisms	Chronic	Eisenia fetida	EC _{10corr} 2.8 mg/kg dry soil	Simon 2011

Table 150: Flocoumafen – Effects on biological methods of sewage treatment

Test	Endpoint	Reference
Activated sludge	EC ₅₀ >4.0 mg/L	Hick & Canez 2002

Appendix B – Listing of toxicological endpoints

Coumatetralyl

Table 151: Toxicological endpoints for coumatetralyl active constituent and formulated products

Study type	Endpoint	Reference
Acute oral studies (Active)	The acute oral LD50 for coumatetralyl is 30 mg/kg bw in male and is approximately 15 mg/kg bw in female rats.	Bomann, W., 1992
Sub-chronic studies (Product)	NOEL 0.0068 mg/kg bw/day of coumatetralyl in males and 0.0083 mg/kg bw/day of coumatetralyl in female rats.	Andrews, P.; Romeike, A., 1997
Acute oral studies, Active	The acute oral LD50 for coumatetralyl is >500 mg/kg bw in males and >750 mg/kg bw in female rabbits.	Bomann, W., 1992
Genotoxicity (Mutagenicity) studies	Not mutagenic	Herbold, B., 1986a
Acute dermal studies (Active)	The acute dermal LD50 for coumatetralyl is between 100 and 500 mg/kg bw in male and is 258 mg/kg bw in female rats.	Bomann, W., 1992
Acute inhalation studies (Active)	LC50 in rats is 39 mg/m ³ (0.039 mg/L) in rats	Pauluhn, J., 1982
Genotoxicity (Mutagenicity) studies (Active)	Not mutagenic	Herbold, B., 1986b
Genotoxicity (Mutagenicity) studies (Active)	Not mutagenic	Herbold, B., 1987
Development (Teratology) Studies (Active)	NOEL was 0.0125 mg/kg bw/day for maternal effects and 0.05 mg/kg bw/day for developmental effects.	Becker, H.; Biedermann, K., 1996
Development (Teratology) Studies (Active)	NOEL was 0.035 mg/kg bw/day for maternal effects and 0.14 mg/kg bw/day for developmental effects.	Becker, H.; Biedermann, K., 1996
Acute skin irritation studies, (Active)	Not a skin irritant in rabbits.	Bhide, M. B., 1984

Study type	Endpoint	Reference
Acute eye irritation studies, (Active)	Not an eye irritant	Bhide, M. B., 1984
Acute oral toxicity, (Product)	Oral LD50 cut-off of Coumatetralyl 0.0375% paste bait is 1000 mg/kg body weight	Schuengel, M., 2003
Acute dermal toxicity (Product)	Dermal LD50, rat male/female : > 4000 mg/kg body weight	Schuengel, M., 2003
Acute skin irritation studies, (Active)	Not irritating to the skin (exposure period: 4 hours, observation period: 72 hours).	Renhof, M., 2003
Other information	Waiver for neurotoxicity - Data available for anticoagulant rodenticides shows that no neurotoxicity has been evidenced for this class of compounds.	Lautraite, S., 2004
Acute skin sensitisation studies (Active)	Non-sensitiser	Lautraite, S., 2004
Genotoxicity (Mutagenicity) studies	Non mutagenic	Herbold, B., 2004
Acute skin sensitisation studies (Product)	Non-sensitiser	Repetto-Larsay, M., 2006
Acute Skin Irritation Studies (Product)	Non-irritant	Bhide, M. B.; Naik, P. Y., 1989
Acute Eye Irritation Studies (Product)	Non-irritant	Bhide, M. B.; Naik, P. Y., 1989
Acute Inhalation Studies (Active)	LC50 in rats is 80 mg/m ³ (0.080 mg/L) in rats	Bhide, M. B., 1989
Acute oral studies (Product)	The median lethal oral dose (LD ₅₀) for rats was considered bigger than 5000 mg/kg bw	Aparecido de Souza, R., 2016

Study type	Endpoint	Reference
Genotoxicity (Mutagenicity) studies	Non mutagenic	Chang, S., 2021
Acute oral studies (Product)	The median lethal oral dose (LD50) for rats was considered higher than 2000 mg/kg bw.	de Souza, R. A., 2021
Acute dermal studies (Product)	The dermal median lethal dose (LD50) of Racumin Polvo (Coumatetralyl 0.75 CP) was found to be greater than 2000 mg/kg bw in rats	de Souza, R. A., 2021
Acute inhalation studies (Product)	The median lethal concentration (LC50) of the test item after 4 hours of inhalation exposure was estimated to be greater than 1.115 mg/L.	de Souza, R. A., 2021
Acute skin sensitisation studies (Product)	Non- sensitizer.	Castro, L. M., 2021
Acute skin irritation studies (Product)	Non-irritant	Rocha, A. C. R., 2021
Acute eye irritation studies (Product)	Non-irritant	Rocha, A. C. R., 2021

Diphacinone

Table 152: Toxicological endpoints for diphacinone active constituent and formulated products

Study type	Endpoint	Reference
Acute Toxicity Studies	Oral LD50 6.8 mg/kg bw (M) 8.0 mg/kg bw (F)	Shapiro, R., 1990a
Acute Toxicity Studies	Oral LD50 (mg/kg bw) (mice) 147 mg/kg bw (M) 133 mg/kg bw (F)	Wazeter FX& Goldenthal El., 1975a
Acute Toxicity Studies	Oral LD50 (mg/kg bw) (Rats and Rabbits) 2.5 mg/kg bw (M) 2.1 mg/kg bw (F)	Wazeter FX& Goldenthal El., 1975b
Acute Toxicity Studies	Dermal LD50 (mg/kg bw) 3.6 (M)	FitzGerald G B., 1992

Acute Toxicity Studies	Diphacinone was classified as a slight eye irritant	Shapiro R., 1990b
Acute Toxicity Studies	Classified as a slight skin irritant.	Shapiro R., 1990c
Acute Toxicity Studies	Data showed it was not a sensitizer post-topical application in guinea pigs	Bier C B & Oliveira P H., 1979
Studies on End-use product	Oral LD50 (mg/kg bw) >5126.0 (M/F)	Dean, W P & Jessup, C., 1976
Studies on End-use product	Oral LD50 (mg/kg bw) >17678 (M/F)	Wazeter FX & Goldenthal EI., 1974
Studies on End-use product	Dermal LD50 (mg/kg bw) >20000 (M/F)	Dean, W P & Jessup, C., 1978
Short-term Repeat dose studies	NOEL after repeat dosing for 14 days was 0.04 mg/kg bw/d based on increased PT and APTT at 0.085 mg/kg bw/d	Rogers A J., 1994
Short-term Repeat dose studies	The NOEL in this study was 0.1 mg/kg bw/d. based on mortality, clinical signs, and gross pathological abnormalities seen at necropsy of animals at and above 1.0 mg/kg bw/d	Laveglia J., 1981
Developmental Studies	NOEL for maternal developmental toxicity was 0.025 mg/kg bw/d	Daniel E M., 1993
Genotoxicity studies	Not mutagenic	Stankowski L F., 1992a
Genotoxicity studies	Not mutagenic	Jagannath D R & Brusick D J., 1978
Genotoxicity studies	Not mutagenic	Stankowski L F., 1992b
Genotoxicity studies	Not mutagenic	SanSebastian J R., 1992
Studies on End-use product	Oral LD50 (mg/kg bw) >5000 (M/F)	Merriman, TN., 1994a
Studies on End-use product	Dermal LD50 (mg/kg bw) >2000 (M/F)	Merriman, TN., 1994b
Studies on End-use product	The product was classified as a slight eye irritant.	Merriman, TN., 1994c
Studies on End-use product	The product was classified as a slight skin irritant.	Merriman, TN., 1994d
Studies on End-use product	Based on the findings test substance was not a skin sensitiser in guinea pigs.	Merriman, TN., 1994e

Brodifacoum

Table 153: Toxicological endpoints for brodifacoum active constituent and formulated products

Study type	Endpoint	Reference
Acute Dermal	Dermal LD50 >2000 mg/kg bw (rat)	Simone N. Jeans, -
Acute Dermal	Dermal LD50 >2000 mg/kg bw. (rat)	Simone N. Jeans, -
Acute oral	Oral LD50 is >5000 mg/kg (rat)	Simone N. Jeans, -
acute oral	Oral LD50 is >5000 mg/kg. (rat)	Simone N. Jeans, -
dermal sensitisation	Brodifacoum block 0.005% is not considered to be a contact sensitiser. (guinea pig)	Jennifer Durando, -
dermal irritation	Non-irritant. (rabbit)	Simone N. Jeans, -
dermal irritation	Non-irritant.(rabbit)	Simone N. Jeans, -
eye irritation	Not an irritant.(rabbit)	Simone N. Jeans, -
eye irritation	Not an irritant. (rabbit)	Simone N. Jeans, -
Acute oral	Oral LD50 of PP581 to the broiler chicken was 4.5 mg/kg.	Ross D, Roberts N, Cameron D, 1977
acute oral	Oral LD50 of PP581 to the broiler chicken was 4.5 mg/kg.	Ross D, Roberts N, Cameron D, 1977
acute oral	LD50 can not be determined (chicken)	Hadler M, 1975
Acute oral	The LD50 was calculated to be 2.78 mg brodifacoum/kg (95% limits 1.25 – 6.19 mg brodifacoum/kg). (guinea pig)	Hadler M, 1975
sub-acute oral	Sub-acute oral LD50 by Horn method: 0.464 mg/kg X 5 (guinea pig)	Hadler M, 1975
eye irritation	Slight irritant. (rabbit)	Lees D, 1996
eye irritation	Not an irritant. (rabbit)	Hadler M, 1975
acute oral	LD 50 : 0.287 mg/kg and its similar to male Wistar rats	Hadler M, 1975
eye irritation	Slight irritant. (rabbit)	Parkinson G, 1978
eye irritation	Slight irritant. (rabbit)	Parkinson G, 1978
eye irritation	Slight irritant. (rabbit)	Lees D, 1996

Study type	Endpoint	Reference
acute dermal	Dermal LD50 for GFU084 was >2000 mg/kg. (rabbit)	Parkinson G, 1981
Acute oral	Oral LD50 calculated using the method of Litchfield and Wilcoxon was 0.31 mg/kg (male and female duck)	Ross D, Roberts N, Fairley C, 1980
Acute oral	The LD50 value was 2.0 mg/kg 95% CI : 0.8-4.8 mg/kg. (duck)	Ross D, Roberts N, Cameron D, 1978
Acute oral	The LD50 value for male and female was 0.545 mg/kg 95% CI :none. (ring-necked pheasant)	Roberts N, Fairley C, 1986
acute oral	The LD50 value of PP581 in Japanese quail was 11.6 mg/kg 95% CI :none.	Ross D, Roberts N, Cameron D, 1977
acute oral	The acute oral LD50 in the beagle dogs was found to be 0.25 – 1 mg/kg. Oral LD50 value in cat was estimated to be 25 mg/kg.	Parkinson G, 1976
acute oral	The acute oral LD50 in the beagle dogs was found to be 0.25 – 1 mg/kg. Oral LD50 value in cat was estimated to be 25 mg/kg.	Parkinson G, 1979
acute oral	The acute oral LD50 in male rats was 0.418 mg/kg (95% CI – 0.350 – 0.500) and 0.561 mg/kg in females (95% CI – 0.472 – 0.667).	Duerden L, 1993
Acute Dermal	The acute dermal LD50 in male rats was 5.21 mg/kg (95% CI – 1.95 – 13.8) and 3.16 mg/kg in females (95% CI – 1.0– 10.0).	McCall J, Leah A, 1993
Inhalation	The 4 hour LC 50 for brodifacoum was 4.86 µg/L for male and 3.05 µg/L for female.	R Parr-Dobrzanski, 1993
acute oral and dermal	The formulations tested are nontoxic by inhalation at the concentration tested.	Vernall A, Culleton C, 1976
genotoxicity	Non mutagenic	Callander R, 1983
acute oral	The acute oral LD50 in male rats was 0.418 mg/kg (95% CI – 0.350 – 0.500) and 0.561 mg/kg in females (95% CI – 0.472 – 0.667).	Duerden L, 1993
acute oral	The acute oral LD50 in male rats was 0.418 mg/kg (95% CI – 0.350 –	Duerden L, 1993

Study type	Endpoint	Reference
	0.500) and 0.561 mg/kg in females (95% CI – 0.472 – 0.667).	
acute oral	The LD50 was > 5000 mg/kg for the 3-(4'-bromobiphenyl 4-yl)-1-Tetralol. (rats and mice)	Hadler M, 1978
sub-acute oral	The LD50 was > 5 X 1000 mg/kg in rats and 5 X 2000 mg/kg in mice for the 3-(4'-bromobiphenyl 4-yl)-1-Tetralol.	Hadler M, 1978
acute oral	Acute oral LD50 by best line of fit was 0.27 mg/kg (rat)	Hadler M, 1974
sub-acute oral	Female rats are more resistant and sub-acute oral LD50 for WBA 8119 is 5 X 0.06 mg/kg in males.	Hadler M, 1974
sub-acute oral	Sub-acute oral LD50 homozygous resistant male rat : 0.05 mg/kg/day X5 (rat)	Hadler M, 1975
acute oral	The acute oral median LD50 brodifacoum 0.05 g/kg RB formulation > 5000 mg/kg. (rat)	Johnson I, 1999
acute oral	Acute oral LD50 by best line of fit was 0.4 mg/kg in male mice	Hadler M, 1974
acute oral	Oral LD50 for brodifacoum Block (A12720G) is > 5000 mg/kg. (rat)	Furlan M, 2012
acute oral	The acute oral LD50 in male rats was 0.418 mg/kg (95% CI – 0.350 – 0.500) and 0.561 mg/kg in females (95% CI – 0.472 – 0.667). (rat)	Duerden L, 1993
acute oral	Acute oral LD50 brodifacoum formulation (0.259% w/w) was estimated to be 163 mg/kg (95% CI 97 to 275) male rats and 152 mg/kg (95% CI 132 to 175).	Lees D, Leah A, 1996
sub-acute oral	Sub-acute oral LD50 for WBA 8119 is 5 X 0.06 mg/kg in males. (rat)	Hadler M, 1974
sub-acute oral	Estimated LD50 by best line of fit by eye on log paper was 0.06 mg/kg X 5. The LAC for male rats was 0.35 mg/kg X 5.	Hadler M, 1976
sub-acute oral	LD50 by best line of fit on the log for male LAC mice – 0.035 mg/kg X 5.	Hadler M, 1975

Study type	Endpoint	Reference
acute dermal	The acute dermal median LD50 Brodifacoum formulation concentrate (0.25% w/w) > 2000 mg/kg. (rat)	Lees D, Leah A, 1996
Acute Dermal	The acute dermal LD50 in male rats was 5.21 mg/kg (95% CI – 1.95 – 13.8) and 3.16 mg/kg in females (95% CI – 1.0– 10.0).	McCall J, Leah A, 1991
Acute Dermal	Acute dermal LD50 for 3-(4'-Bromobiphenyl 4-yl)-1-tetralol is >1000 mg/kg. (rat)	Hadler M, 1978
Acute Dermal	WBA 8119 has demonstrated a high acute dermal toxicity. (rat)	Hadler M, 1976
Inhalation	The 4 hour LC 50 for brodifacoum was 4.86 µg/L (mg/m3) for male and 3.05 µg/L (mg/m3) for female. (rat)	R Parr-Dobrzanski, 1993
Inhalation	LC50 for delayed death lies between 0.62 to 4.5 mg/m3. (rat)	Buch S, 1979
Inhalation	The formulations tested are nontoxic by inhalation at the concentration tested. (rat)	Vernall A, Culleton C, 1978
acute oral	LD 50 from the trial 2 was 3.56 mg/kg (95% CI 2.13 to 6.03 mg/kg) and for trial 1 LD 50 was 1.09 mg/kg (95% CI 0.49 – 2.24 mg/kg). (dog)	Godfrey M, Reid T, McAllum, 1981
n/a	Not relevant to human health assessment as related to mode of action. (dog)	Chart I, 1986
acute oral	LD 50 - 11.6 mg/kg based on dosing at 1.56 - 12.5 mg/kg (sheep)	Godfrey M, Laas F, Rammell C, 1985
acute oral	LD50 > 25 mg/kg (sheep)	Parkinson G, 1976
acute oral	The LD50 was not possible as the cohort of animals was too small therefore LD50 of WBA8119 in pigs was in the range of 0.5 to 2.0 mg/kg. (pig)	Ross D, Roberts N, 1976
sub-acute oral	Total 2.63 mg of WBA8119 was consumed by male rats.	Hadler M, 1976
90-day feeding	NOEL is 0.02 ppm and LOEL is 0.08 ppm brodifacoum. Corresponding to 1 and 4 microgram/kg bw/day (rat)	Batten P, <i>et al.</i> , 1984

Study type	Endpoint	Reference
Mutagenicity	Non toxic and Non Mutagenic (cultured human lymphocytes)	Mellano D, Berruto G, 1984
Mutagenicity	Not to be clastogenic to human lymphocytes <i>in vitro</i>	Mackay J, 1990
Mutagenicity	Negative and non-mutagenic. (salmonella)	Callander R, 1983
Teratogenicity	LOEL: 0.02 mg/kg/day (rat)	Hodge M, Banham P, Richards D, Weight T, Wilson J, 1980
acute oral	the LD50 for Brodifacoum 0.25% in female rat was between 100 to 150 mg/kg and male rats 150 to 225 mg/kg.	anon, 1996a
acute dermal	not irritant for the skin (rabbits)	anon, 1996c
acute eye irritation	Not a irritant. (rabbits)	anon, 1996d
skin sensitisation	Brodifacoum 0.25% is not considered to be a contact sensitiser. (guinea pigs)	anon, 1996e
90-day feeding	The no-observable effect level for brodifacoum is 0.04 mg/kg/day for male rats (cumulative dose over 90-days is 3.6 mg/kg) and 0.08 mg/kg/day for female rats (cumulative dose over 90-days is 7.2 mg/kg).	anon, 1995a
developmental toxicity	the no-observed effect level (NOEL) for maternal toxicity in this study was 0.04 mg brodifacoum/kg/day and the NOEL for developmental toxicity was also 0.04 mg brodifacoum/kg/day.(rat)	anon, 1995b
developmental toxicity	The no-observed effect level (NOEL) for maternal toxicity in the current study was 0.004 mg brodifacoum/kg/day at the NOEL for developmental toxicity was 0.004 mg brodifacoum/kg/day. (rabbit)	anon, 1995c
skin sensitisation	Not a skin sensitizer (mouse)	anon, 2006
acute skin irritation	Not a irritant (rabbit)	anon, 2004a
acute oral	LD50< 5 mg/kg bw (female) rat	anon, 2004b
acute dermal	Dermal LD 50 7.48 mg/kg bw female rat	anon, 2004c

Study type	Endpoint	Reference
reproduction toxicity	NOAEL for males: 3 µg/kg/day NOAEL for females: 1 µg/kg/day NOAEL for reproductive performance of the males: 3 µg/kg/day NOAEL for reproductive performance of the females: 3 µg/kg/day NOAEL for developmental toxicity: 3 µg/kg/day (rat)	anon, 2004d
Mutagenicity	Non toxic and Non Mutagenic (salmonella typhimurium)	Thompson PW, 2002
Mutagenicity	Non toxic and Non Mutagenic (cultured human lymphocytes)	Wright NP, 2003
acute dermal	>2000 mg/kg (rats (0.25% concentrate))	anon, 1996b
acute eye irritation	Not an irritant (rabbits)	anon, 2004a
		anon

Bromadiolone

Table 154: Toxicological endpoints for bromadiolone active constituent and formulated products

Study type	Endpoint	Reference
Acute dermal, product	LD50 >2,000 mg/kg product	Rogers A.J., 1992
Acute dermal, product	LD50 >5,000 mg/kg product	Lindgren B.V., 1992
Acute dermal, product	LD50 >5,000 mg/kg product	Pitterle, P, -
Acute dermal, product	LD50 >5,000 mg/kg product	Rogers A.J., -
Skin sensitisation, product	Not a sensitiser	C. Noc, -
Skin sensitisation, product	Not an irritant	Pitterle, P, -
Eye irritation, product	Not an irritant	Rogers A.J., -

Eye irritation, product	It is a slight eye irritant.	Rogers A.J., -
Eye irritation, product	It is a slight eye irritant.	Rogers A.J., -
Skin sensitisation, product	not a sensitiser	Noc <i>et al.</i> , -
acute oral, product	The LD 50 is between 0.56 and 0.84 mg/kg for male and female.	Mally, C. and Porret-Blanc, G., 1987
Acute oral studies, active	Acute oral LD50 in male Beagle dogs, 10.7 mg/kg body weight Acute oral LD50 in females 6.3 mg/kg body weight	Reagan, E.L., 1987
acute dermal, active	Acute percutaneous LD50 of Bromadiolone in male rabbits, 1.3 mg/kg bodyweight. The LD50 in females 2.38 mg/kg bodyweight	Myers, R.C. and Christopher, S.M., 1993
acute inhalation	The acute inhalation LC50 of Bromadiolone in male rats, 0.46 microgram/L. The LC50 in females was calculated to be >0.33 & < 0.46 microgram/L.	Holbert, M.S., 1991
Skin sensitisation, active	Non-irritant	Shapiro, R., 1977
Skin sensitisation, active	The material is slight irritant.	Shapiro, R., 1977
Skin sensitisation, active	0.1% of bromadiolone was considered non sensitising.	Kuklinski, M., 1990
90-day oral	NOEL : 8 ug/kg day	Lorgue, G., 1981
Mutagenicity	Negative non-mutagenic	Lawlor, T.E., 1992
Mutagenicity	Negative non-mutagenic	Murli, H., 1993
Mutagenicity	Negative non-mutagenic	Cifone, M.A., 1993
Mutagenicity	Negative non-mutagenic	Murli, H., 1993
teratology	NOEL for materno and foeto toxicity was 35 microgram/kg/day	Monnot, G., Fave, A., Illat, T. and Briet, Ph., 1990
teratology	NOEL was 4 ug/kg/day, based on maternotoxicity	Virat, M., 1981
acute oral, product	LD50 for Maki Paraffin Block with Bitrex was >5000 mg/kg bw.	Glaza, S.M., 1993

acute oral, product	The peroral LD50 for Maki mini blocks was >5000 mg/kg bw.	Myers, R.C. and Christopher, S.M., 1993
Acute dermal, product	The dermal LD50 is > 2000 mg/kg bw.	Glaza, S.M., 1993
Acute dermal, product	Dermal LD 50 of 2000 mg/kg bw.	Parker, R.M., 1992
Skin sensitisation, product	Non-irritant.	Glaza, S.M., 1993a
Skin sensitisation, product	Non-irritant.	Glaza, S.M., 1993b
Eye irritation, product	Slight irritant.	Glaza, S.M., 1993c
Eye irritation, product	Slight irritant.	Shapiro, R., 1977
Skin sensitisation, product	Not a sensitiser in guinea pigs.	Glaza, S.M., 1993
Skin sensitisation, product	Not a sensitiser in guinea pigs.	Glaza, S.M., 1994
Acute oral studies, active	LD50 for male and female was calculated to be 1.3 mg/kg bw	Sebestyen I, 1996
Acute dermal studies, active	Dermal LD50 for male: 20.16 mg/kg bw, for females: 32.08 mg/kg bw and combined male and female: 23.31 mg/kg bw.	Sebestyen I, 1996
Acute dermal studies, active	Non-irritant.	Kuhn JO, 1999
Acute skin sensitisation studies, active	No sensitisation reaction was reported.	Stahl, Janos, 2004
Short-term studies	NOEL was 0.0025 mg/kg bw/day for male and female rats	Szakonyi IP, 2002
Genotoxicity (mutagenicity) studies	Negative non-mutagenic	Hernadi D, 2001
Genotoxicity (mutagenicity) studies	Negative non-mutagenic	Béres E, 2002

Genotoxicity (mutagenicity) studies	Negative non-mutagenic	Béres E, 2002
Sub-chronic studies	Active NOAEL: 0.0005 mg/kg bw/d	Béres E, 2006
Developmental studies	LO(A)EL maternal toxic effects: 2 µg/kg/day of bromadiolone. NO(A)EL maternal toxic effects: less than 2 µg/kg/day of bromadiolone. LO(A)EL embryotoxic/teratogenic toxic effects: malformations seen in two animals at 4 µg/kg/day of bromadiolone and in one animal at 8 µg/kg/day of bromadiolone. NO(A)EL embryotoxic/teratogenic toxic effects: 8 µg/kg/day of bromadiolone.	Druga A, 2004a
Developmental studies	NOAEL for males, female, reproductive performance of the males, for reproductive performance of the females , developmental toxicity: 5 µg/kg/day	Szakonyi IP, 2004

Difenacoum

Table 155: Toxicological endpoints for difenacoum active constituents and formulated products

Study Type	Endpoint	Reference
Acute oral	Oral LD 50 for difenacoum was 25.0 mg/kg bw	Szakonyi IP, 2004
Acute dermal	Dermal LD 50 for difenacoum was 51.54 mg/kg bw.	Szakonyi IP, 2004
acute inhalation	Difenacoum 4 hour median lethal concentration in the rat was 20.74 µg/L (M) and 16.27 µg/L (F).	Morris K, 1995
acute skin irritation	Difenacoum classified as non-irritant to skin.	Stahl J, 2004
acute eye irritation	Classified as non-irritant.	Stahl J, 2004
90 day feeding	NOEL: 0.03 mg/kg bw/day (M) and 0.06 mg/kg bw/day (F)	Morris K, 1995
mutagenesis	Non mutagenic	Thompson PW, 2002
mutagenesis	Weak mutagen	Durward R, 2004
mutagenesis	Non mutagenic	Morris K, 1995
mutagenesis	Non mutagenic	Morris K, 1995
developmental	NOEL for maternal toxicity was 0.03 mg/kg bw/day difenacoum and NOEL for development toxicity was 0.09 mg/kg bw/day	Morris K, 1995
developmental	Teratogenic dose not found. Dose toxic for does: 1 µg/kg bw/day (0.001 mg/kg bw/day) and dose causing intrauterine mortality not found.	Druga A, 2004b
Reproduction	NOAEL for males and females: 10 µg/kg bw/day NOAEL for reproductive performance of the males: 20 µg/kg bw/day NOAEL for reproductive performance of the females: 20 µg/kg	Szakonyi IP, 2004

Study Type	Endpoint	Reference
	bw/day NOAEL for developmental toxicity: 20 ug/kg bw/day	
acute oral, product	Oral LD50 for the formulation was calculated to be 74.2 mg/kg male (95% CI 57.9 and 95.1) and 65.7 mg/kg female (95% CI 51.2 84.2).	Morris K, 1995
acute oral, product	Dermal LD50 for the formulation was calculated to be 930.0 mg/kg male (95% CI 750, 1200) and 1285 mg/kg female (95% CI 900 1550)	Morris K, 1995
Eye irritation	Slight eye irritant	Morris K, 1995
Skin sensitisation	Non irritant	Morris K, 1995
Acute oral	Oral LD50 (mg/kg bw) >2.6 (F)	Gardner, JR, 1995
Acute oral	Oral LD50 (mg/kg bw) >1.8 (M)	Gardner, JR, 1995
Acute oral	Oral LD50 (mg/kg bw) >2.5 (M)	Gardner, JR, 1995
Acute dermal	Dermal LD50 (mg/kg bw) >27.4 (M) & 17.2 (F)	Brammer, A & Leah, AM, 1991
Acute dermal	Dermal LD50 (mg/kg bw) = 63.0 (F)	Gardner, JR, 1995
Inhalation	Inhalation LC50 = 3.6 and 5.8 mg/m ³ 0.0038 - 0.0058 mg/L (M & F)	Shepherd, NM, 1996
Dermal irritation	Substance was not irritating to the rabbit skins.	Gardner, JR, 1995
Acute oral	LD50 of Neosorex Pellet bait is 38 and 39 g/kg bw in males and females respectively	Redpath, CS, 1997
Acute dermal	LD50 of Neosorex Pellets in rats is estimated to be >2000 mg/kg bw.	Donald, E, 1998
Acute oral	LD50 of Neosorex Pellet bait is 27.6 and 28 g/kg bw in males and females.	Redpath, CS, 1992
Acute dermal	Dermal LD50 of Neosorex Pellet bait is >2000 mg/kg bw in males and females.	Edgar, F & Donald, E, 1998
Subchronic	NOEL - 0.01 mg/kg bw (M) over 78 days and 0.03 mg/kg bw (F) over 93 days	Horner, JM, 1991
Genotoxicity	Not a mutagen.	Callander, RD, 1986
Genotoxicity	Not a mutagen.	Kennelly, JC, 1990
Genotoxicity	Not a mutagen.	Clements, J, 1995

Study Type	Endpoint	Reference
Genotoxicity	Not a mutagen.	Ballymore, M, 1995
Genotoxicity	Not a mutagen.	Ridley, S, 1995
Genotoxicity	Not a mutagen.	Ridley, S, 1996
Genotoxicity	Not a mutagen.	Clare, C, 1996

Difethialone

Table 156: Toxicological endpoints for difethialone active constituents and formulated products

Study Type	Endpoint	Reference
acute oral	Oral LD50 (mg/kg bw) >5000 (M/F)	Glaza, S M, 1993
Acute Dermal Studies, Product	Dermal LD50 (mg/kg bw) >2000 (M/F)	Glaza, S M, 1993
eye irritation	Classified as a slight eye irritant.	Glaza, S M, 1993
skin irritation	Was not a skin irritant in rabbits	Glaza, S M, 1993
skin irritation	Based on the findings test substance was not a skin sensitiser in guinea pigs when treated by the closed patch technique.	Glaza, S M, 1993
acute oral, product	Oral LD50 (mg/kg bw) >5000 (M/F) & Dermal LD50 (mg/kg bw) >2000 (M/F)	Rutkowski, J V. , 1987
Acute Dermal Studies, Product	LD50 was >2000 mg/kg	Glaza, S M, 1997
Acute Eye Irritation Studies, Product	Slight eye irritant	Myers, R C & Christopher, S M, 1992
skin irritation	Slight skin irritant	Glaza, S M, 1997
oral developmental toxicity	NOEL 0.00125 mg/kg bw/day	Briffaux JP, 1986

Flocoumafen

Table 157: Toxicological endpoints for flocoumafen active constituents and formulated products

Study type	Endpoint	Reference
Animal Commodity Residue Direct Application	Not applicable	Huckle, K.R. , 1988
Animal Commodity Residue Direct Application	Not applicable	Eadsforth CV, Gray A, Huckle KR, Inglesfield C , 1993
Sub-chronic Studies	A NOEL was established at 0.02 ppm (0.0014 mg/kg bw/day).	Clark, D.G., Esdaile, D.J. , 1989
Developmental (Teratology) Studies	Maternal NOEL was 0.002 mg/kg bw/day in rabbits	James P., Jones K., Masters R.E. , 1989
Acute Oral Studies, Active	The NEL was 0.1 ppm (0.0025 mg/kg/day).	Price, J.B. , 1984
Worker Exposure	Not applicable	Chambers, J.G., Snowdon, P.J. , 2004

Acronyms and Abbreviations

Shortened term	Full term
ac	active constituent
AF	assessment factor
APVMA	Australian Pesticide and Veterinary Medicines Authority
BCF	bioconcentration factor
bw	body weight
cm	centimetre(s)
d	day(s)
DMSO	dimethyl sulphoxide
ds	dry soil or sediment
DT ₅₀	period required for 50% dissipation
ECHA	European Chemicals Agency
EC _x	concentration causing X% effect (E _r C _x is used for growth rate; E _b C _x is used for biomass; E _y C ₅₀ is used for yield)
EFSA	European Food Safety Authority
ER _x	rate causing X% effect
g	gram(s)
GLP	good laboratory practice
h	hour(s)
ha	hectare(s)
HPLC	high performance liquid chromatography
K _d or K _f	(Freundlich) adsorption constant
kg	kilogram(s)
K _{oc} or K _{foc}	(Freundlich) organic carbon partition coefficient
L	litre(s)
LC _x	lethal concentration to X% of the tested population
LD _x	lethal dose to X% of the tested population

Shortened term	Full term
LDDx	lethal daily dose to X% of the tested population
LSC	liquid scintillation counting
m	metre(s)
max	maximum
mg	milligram(s)
mL	millilitres(s)
mm	millimetre(s)
mPa	millipascal(s)
MWHC	maximum water holding capacity
n/a	not applicable
nm	nanometre(s)
NOAEL	No observable adverse effect level
NOEC	no observed effect concentration
NOEC	no observable effect concentration
NOEL	no observable effect level
OC	organic carbon
OECD	Organisation for Economic Co-operation and Development
Pa	pascals
PBT	persistent – bioaccumulative – toxic
PEC	predicted environmental concentration
POP	persistent organic pollutant
Pow	octanol-water partition coefficient
QSAR	quantitative structure–activity relationship
RAL	regulatory acceptable level
RQ	risk quotient
SFO	single first order
SL	soluble concentrate

Shortened term	Full term
TLC	thin layer chromatography
unk	unknown
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VIS	visible
w/w	weight per weight
w/w	weight per weight
µg	micrograms

Glossary

Term	Description
active constituent	The substance that is primarily responsible for the effect produced by a chemical product
acute exposure	Contact between a pesticide and a target occurring over a short time (e.g., less than a day)
acute tolerable intake	For humans: the amount of a chemical contaminant in food or drinking-water, (expressed as mg/kg of body weight), that can be ingested or absorbed over 24 hours or less, without appreciable health risk.
acute toxicity	Adverse effects of finite duration occurring within a short time (up to 14 d) after administration of a single dose (or exposure to a given concentration) of a test substance or after multiple doses (exposures), usually within 24 h of a starting point (which may be exposure to the toxicant, or loss of reserve capacity, or developmental change, etc.)
adsorption constant	A measure of the tendency of a chemical to bind to soils
adverse effect	Change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or subpopulation that results in impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences
aged residue	Residues of a pesticide or its degradates in soil that have diffused into intra-particulate regions following application and have become less accessible to mass transfer and bioabsorption processes, although still amenable to solvent extraction
agricultural crop	Any terrestrial plant species grown commercially for food, fibre, foliage, fuel or medicinal production, with the exception of plants that are not part of a crop under management at the time of pesticide application (eg blackberries or volunteer grain plants that have escaped from a cropped area and become weeds in another area)
aquatic	Relating to water or sediment, as distinct from land or air
assessment factor	Reductive factor by which an observed or estimated endpoint of a pesticide is divided to arrive at a regulatory acceptable level
bioaccumulation	Progressive increase in the amount of a substance in an organism or part of an organism that occurs because the rate of intake exceeds the organism's ability to remove the substance from the body
bioconcentration	Uptake of a pesticide residue from an environmental matrix, usually through partitioning across body surfaces to a concentration in the organism that is usually higher than in the environmental matrix
bioconcentration factor	Ratio between the concentration of pesticide in an organism or tissue and the concentration in the environmental matrix (usually water) at apparent equilibrium during the uptake phase
bound residue	Residue associated with one or more classes of endogenous macromolecules that cannot be disassociated by extraction or digestion without alteration
cation	Monatomic or polyatomic species having one or more elementary charges of the proton
chronic exposure	Continued or intermittent long-term contact between an agent and a target

Term	Description
chronic toxicity	Adverse effects following chronic exposure
concentration	Amount of a material, agent (e.g., pesticide) dissolved or contained in unit quantity in a given medium or system
degradate	Chemical that is formed when a substance breaks down
dissipation	Loss of pesticide residues from an environmental compartment due to degradation and transfer to another environmental compartment
dissociation constant	The ratio of concentration of dissociated ions to the concentration of original acid
dose	Total amount of a pesticide or agent administered to, taken up or absorbed by an organism, system, or (sub-) population
dry weight basis	Pesticide residue concentration reported as if the residue were wholly contained in the dry matter of the sample
effect assessment	Combination of analysis and inference of possible consequences of the exposure to a pesticide based on knowledge of the dose–effect relationship associated with that agent in a specific target organism, system, or (sub-) population
endpoint	Measurable ecological or toxicological characteristic or parameter of the test system (usually an organism) that is chosen as the most relevant assessment criterion (e.g., death in an acute test or tumor incidence in a chronic study)
endpoint	Measurable ecological or toxicological characteristic or parameter of the test system that is chosen as the most relevant assessment criterion
environmental fate	Destiny of a pesticide or chemical after release to the environment involving considerations such as transport through air, soil, or water, bioconcentration, degradation, etc.
environmental risk	Probability that an adverse effect on humans an environmental system/receptor will be observed for a given exposure to a pesticide based on the probability of that exposure and the sensitivity of the system/receptor
exposure	Concentration or amount of a particular substance that is taken in by an individual, population or ecosystem in a specific frequency over a certain amount of time
exposure assessment	Evaluation of the exposure of an organism, system, or (sub-) population to a pesticide or agent (and its derivatives)
formulation	A combination of both active and inactive constituents to form the end use product
Freundlich isotherm	Empirical relationship describing the adsorption of a solute from a liquid or gaseous phase to a solid in which the quantity of material adsorbed per unit mass of adsorbent is expressed as a function of the equilibrium concentration of the sorbate
good laboratory practice	The formalized process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported, and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data
half-life	The time taken for the reactant concentration to fall to one-half its initial value

Term	Description
hazard	Inherent property of a pesticide having the potential to cause adverse effects when an organism, system, or (sub-) population is exposed to that agent or situation
Henry's law constant	A gas law that states the amount of gas absorbed by a given volume of liquid at a given temperature is directly proportional to the partial pressure of that gas in equilibrium with that liquid. As such it provides an indication of the preference of a chemical for air relative to water i.e., its volatility
herbicide	Pesticide used for the control of unwanted plants or weeds
hydrolysis	Chemical decomposition induced by water
immobilisation	Process leading to restricted mobility of a pesticide in a plant or soil due to strong binding
indicator species	Species whose presence shows the occurrence of defined environmental conditions
intake	Process by which a pesticide or agent crosses an outer exposure surface of a target without passing an absorption barrier, i.e., through ingestion or inhalation
larva	Recently hatched insect, fish, or other organism that has different physical characteristics than those seen in the adult, requiring metamorphosis to reach the adult body structure
median effective concentration	Statistically derived concentration of a pesticide in an environmental medium expected to produce a certain effect in 50 % of the test organisms in a given population under defined conditions
median lethal concentration	Statistically derived concentration of a substance in an environmental medium expected to kill 50 % of test organisms in a given population under defined conditions
median lethal dose	Statistically derived dose of a chemical or physical agent (radiation) expected to kill 50 % of test organisms in a given population under a defined set of conditions
metabolite	Any intermediate or product resulting from metabolism in an organism
microcosm	Man-made study system containing associated organism and abiotic components that is large enough to be representative of a natural ecosystem, yet small enough to be experimentally manipulated
mineralisation	Conversion of an element from an organic form to an inorganic form. Mineralisation of pesticides most commonly refers to the microbial degradation to carbon dioxide as a terminal metabolite
mode of action	Biochemical effect that occurs at the lowest dose or concentration or is the earliest among a number of biochemical effects that could, understandably, lead to the death of the pest
necrosis	Sum of morphological changes resulting from cell death by lysis and/or enzymatic degradation, usually affecting groups of cells in a tissue
no observed effect level	Greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the target organism under defined conditions of exposure

Term	Description
non-target species	Organism affected by a pesticide or exposed to a pesticide although not an intended object of its use
partition coefficient	log Pow is the logarithm (base-10) of the partition coefficient between n-octanol and water
persistence	Residence time of a chemical species (pesticide and/or metabolites) subjected to degradation or physical removal in a soil, crop, animal, or other defined environmental compartment
photolysis	Chemical decomposition induced by light or other radiant energy
regulatory acceptable level	Criterion or standard that is considered safe or without appreciable risk
soil incorporation	Application of a pesticide to soil by mixing or injection into the soil body
solubility in water	The mass of a given substance (the solute) that can dissolve in a given volume of water
soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active constituent after dilution with water
terrestrial	Relating to land, as distinct from water or air
tolerable daily intake (TDI)	For humans: a level of intake of a chemical contaminant (expressed mg/kg bw/day; milligrams per kilogram of body weight per day) that can be ingested daily over an entire lifetime without any appreciable risk to health,
translocation	Movement of a substance within the test system or organism
vapour pressure	The pressure at which a liquid is in equilibrium with its vapour at a given temperature. It is a measure of the tendency of a material to vaporise. The higher the vapour pressure the greater the potential
volatile	Any substance which evaporates quickly
watercourse	<p>A river, creek or other natural watercourse (whether modified or not) in which water is contained or flows (whether permanently or from time to time); and includes:</p> <ul style="list-style-type: none"> • a dam or reservoir that collects water flowing in a watercourse • a lake or 'wetland' through which water flows • a channel into which the water of a watercourse has been diverted • part of a watercourse <p>an estuary through which water flows.</p>
wetland	<p>An area of land where water covers the soil—all year or just at certain times of the year. They include:</p> <ul style="list-style-type: none"> • swamps, marshes • billabongs, lakes, lagoons • saltmarshes, mudflats

Term	Description
	<ul style="list-style-type: none">• mangroves, coral reefs• bogs, fens, and peatlands. <p>A 'wetland' may be natural or artificial and its water may be static or flowing, fresh, brackish or saline.</p>
xylem	Part of the plant's vascular system adapted to the transport of water and solutes from the roots to aerial parts

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