New Zealand Food Safety
Haumaru Kai Aotearoa

Proposal to Modify the Regulatory Controls Covering the Manufacture, Sale, Storage and Use of Brodifacoum Based Vertebrate Toxic Agent (VTA) Products

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This publication is also available on the Ministry for Primary Industries website at http://www.mpi.govt.nz/news-and-resources/publications/

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1 Request for submissions

New Zealand Food Safety invites public comment on this discussion document, which outlines the proposals to modify the regulatory controls covering the manufacture, sale, storage, and use of brodifacoum based Vertebrate Toxic Agents (VTAs).

For **each control** you are commenting on, please clearly indicate whether:

You agree or disagree with the proposed control?

Please feel free to include with your answer, any supporting discussion, data or examples that you feel are relevant.

Submissions close at 5pm on 11 December 2023. Your comments should be sent to:

Brodifacoum Consultation
New Zealand Food Safety
Ministry for Primary Industries
PO Box 2526
Wellington 6140

Email: ACVM.Consultation@mpi.govt.nz.

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read, as a number of copies of your submission may be made.

The Official Information Act

The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. The Ministry for Primary Industries will take such indications into account when determining whether to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2 Introduction

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 regulates agricultural compounds, which include veterinary medicines, agricultural chemicals and vertebrate toxic agents (e.g. rodenticides) along with a range of other compounds. The ACVM Act manages the risks to trade in primary produce, agricultural security, animal welfare and public health. It also ensures domestic residue standards are complied with.

New Zealand Food Safety (NZFS) has proposed to reassess all registered vertebrate toxic agent (VTA) products containing the active ingredient brodifacoum under section 29 of the ACVM Act. The purpose of the reassessment is to re-evaluate the approved label information, use patterns, and regulatory controls for all registered trade name products containing brodifacoum. The intended outcome is to ensure that the access to, and use of these products is consistent with the principles of prudent use of VTAs and minimises the risk of inadvertent consumption by non-target and food production animals.

The grounds for considering reassessment are as follows:

1. MPI has concerns regarding the efficacy of the controls to minimize exposure of food producing animals to VTAs. A VTA detection made in a New Zealand exported primary produce by one of our trading partners would likely have a negative impact on the trade of all produce to that country and worldwide.

2. As a result of the audits undertaken by MPI as well as information received from both users and registrants, it is apparent that, in terms of their use and minimising the risks associated with unintentional exposure, the VTA registration conditions and label requirements could be strengthened. This is driven in part by the fact that the existing conditions which were originally set in 2005, were based mainly on the controls from the previous regulatory regime. Since that time, new information indicates that the extent to which these products would be used in areas that may be accessed by food producing animals has changed over time and the current registration conditions and label requirements do not adequately manage the risks associated with the use of VTA's as specified by the ACVM Act.

3. One source of this new information is the National Chemical Residue Programme (NCRP) which monitors chemical residues in non-dairy animal products. Results of findings obtained in the period, 2014 to 2019, showed that there have been five reported detections of anticoagulant VTAs in food producing animals, three of which have involved brodifacoum. It is important to note that the levels found were not a food safety risk, however there is a legal obligation on food sellers under the Food Act to ensure that MRLs are complied with.

Brodifacoum is the first VTA NZFS is proposing to reassess. It is anticipated that NZFS will then propose to reassess all other VTA products, applying the same, or similar conditions to these VTA products.

2.1 Summary of Proposed Amendments

The proposed reassessment will cover all the areas of concern required under the ACVM Act. Controls may be applied to manage the risks to:

a) public health (only in relation to ACVM risk areas),
b) animal welfare,
c) trade in primary produce & agricultural security, and
d) ensure the use of agricultural compounds does not result in breaches to domestic food standards and ensure the provision of appropriate consumer information.

The proposed changes cover:

a. Recognition of persons
b. Controls around sale
c. Record keeping
d. Manufacturing controls

e. Controls on use
f. Requirement for Adverse Event reporting
g. Notifications, Signage & Boundaries
h. Minimising exposure to Non-Target Animals
i. Persons responsible for use

2.1.1 Recognition of Persons

The most significant change proposed is for individuals or organisations to be accredited as Recognised Persons (s) by the Ministry for Primary Industries.

Section 44E of the ACVM Act allows the Director General (or their delegate) to recognise persons to carry out specified functions and activities. This would require any person wanting to purchase, store, use, or supervise volunteers using quantities of brodifacoum containing VTA products greater than 300g to apply to the Ministry for Primary Industries for accreditation before carrying out these activities.

This requirement would be expressed as a condition under section 23(1)(ja) of the Act requiring users and sellers of larger quantities of brodifacoum to do so under the authority of, and in compliance with the requirements of a recognised agency or recognised person. This is specified in the following condition:

> "Users, other than those authorised by MPI, may not purchase, or have in their possession or store on their property any quantity greater than 300 g of any brodifacoum containing VTA."

There are two pathways to gain recognition:

i. Pathway 1: Individuals

1. The process of becoming a Recognised Person will require application to the Ministry for Primary Industries with proof of, or permission to, obtain documents outlining the competency, specified convictions, character and reputation of the applicant. The Recognised Person status will be valid for 5 years.

2. This will require completion or provision of all of the following documents:
   a. A Police Vetting Form application, or equivalent *e.g.* current and valid Firearms licence;
   b. The supply of two referees who will support the application.
   c. Proof that the applicant has undergone a suitable educational programme pertaining to the administration and use of brodifacoum containing VTA products.

3. The costs arising from this process are listed below.
   a. MPI administration fee $155.25 (inc. GST) – as specified in the current regulations Schedule 1 section 16 (Recognition of a person under section 44F of the Act)
   b. An Education Programme completion certificate would be estimated at $250.00-$500.00 (inc. GST) – based on similar programmes.
   c. The total approximate cost for a five-year approval is estimated to be $405.25-$655.25. A reduced charge may be applied for renewals if the applicant can show that they remain to be a competent and fit and proper person. This will require a signed declaration.

ii. Pathway 2: Organisations, Associations, or Institutions

1. Where an organisation, association, or institution have an in-house training programme for the use of brodifacoum containing VTA and have a process to ascertain that its members / employees are fit and proper persons, then the organisation can be recognised as having "Ministry for Primary Industries Recognised Person(s) status" upon submission of an Operating Plan. The cost for this is $155.25 (GST inc.) plus an hourly fee and it is valid for five years.

2. Operating plan guidance and template will be made available prior to the new conditions taking effect.

2.1.2 Controls Around Sale

A number of controls and restrictions are proposed with respect to the sale of brodifacoum containing VTAs to ensure appropriate access and prudent use. The following proposed controls are modifications to the existing Control 55 and Control 56 (refer to 2.2 Summary Table) and are focused on reducing the maximum pack sizes from 3kg to 300g.

The new conditions place restrictions on sellers of pack sizes greater than 300g or multiple packs totalling a weight greater than 300g to a single individual or an organisation. These being:

I. "The trade name product can only be sold by persons who are currently approved by the ACVM Group by being either:

   1. the registrant of the product, or

   2. a seller identified in and acting in accordance with the approved operating plan for that product, approved under section 28."

II. "For sales of quantities greater than 300 g: a seller must:

   1. Only sell to persons who are currently approved by the Ministry for Primary Industries and verified on presentation of photo identification.

   2. Not resell or re-distribute outside of the distribution channel documented in the approved operating plan without the approval of the Ministry for Primary Industries.

   3. Keep a register of sales, recording the trade name of the product sold, who the product was sold to, the quantity sold, their contact details and the Ministry for Primary Industries issued user authority number.

   4. Keep all records on the sale of the product for a minimum of five years and make available to the Ministry for Primary Industries upon request."

These requirements will be managed by a Condition of Registration on the brodifacoum containing product. Operating plan guidance and templates will be made available prior to the new conditions taking effect.

2.1.3 Record Keeping

The requirement for manufacturers and retailers to keep a register of sales greater than 300g? for a minimum of 3 years, recording who the product was sold to and the quantity sold has already been included as part of the existing Condition 56. It is proposed that this be modified to extend the period from 3 years to 5 years, and to explicitly state that these records are to be available to Ministry for Primary Industries upon request.

In addition, as part of the new proposed conditions for 'Use' that, under sections 23(1)(e) and (k) of the ACVM Act 'Recognised Users' must ensure records pertaining to the use of quantities of brodifacoum greater than 300 g must be kept for 5 years and made available to MPI on request.

2.1.4 Controls on Use

A number of new controls and restrictions are proposed with respect to the 'Use' of brodifacoum VTAs, both for quantities of 300g or less by domestic, non-commercial and commercial users, as well as for quantities greater than 300g.

The following are the proposed conditions of registration that control use of brodifacoum based VTAs:

a. "For each application of quantities of 300 g or less by domestic, non-commercial and commercial users,
    i. Bait must only be used in a bait station.
    ii. Bait stations must be monitored weekly to ensure a continuous supply of bait.
    iii. All uneaten baits must be collected and removed from the area when baiting has ceased."

b. "For each application of quantities greater than 300 g,
    i. Bait must only be used in bait stations unless otherwise specified in a Ministry for Primary Industries approved operating plan for that product.
    ii. Bait stations must be monitored regularly during the baiting programme, with records kept for each station detailing:
        1. the amount of bait added or removed;
        2. the method of disposal of surplus bait.
    iii. All uneaten baits must be collected and removed from the area when baiting has ceased."

c. All records on the use of the product must be kept for a minimum of five years and made available to Ministry for Primary Industries upon request.

2.1.5 Adverse Event Reporting

In addition to the existing Condition 64 detailing the responsibility of the registrant to report Adverse Events *i.e.*

> *"The registrant must investigate the significance of every adverse event associated with the use of the product; and report to Ministry for Primary Industries within 20 working days the outcome of this investigation.*

An additional condition is being proposed that will require Users to report adverse events to the registrant, irrespective of the quantity used; that being:

> "A user must notify the registrant of the Trade Name Product immediately upon becoming aware of an adverse event that seems to have seriously jeopardised the health and welfare of non-target animals, pets, livestock or food producing animal(s) through exposure to the trade name product."

2.1.6 Notifications, Signage & Boundaries

A number of controls and restrictions are proposed with respect to Notifications, Signage and Boundaries.

There are existing signage requirements which are enforced by applying Condition 57 in the conditions of registration and these currently relate to situations where brodifacoum containing baits are used in situations where the public have unrestricted access. The current Condition 57 wo0uld remain unchanged for the application of quantities less than 300g. It is proposed that the Condition 57 wording be modified for the application of quantities greater than 300g to the following:

> "For the application of quantities greater than 300 g, if the public has unrestricted access to the treatment area, then:
> a. Signs must be posted at every point or entry to the place where the trade name product is to be applied, and/or
> b. Each bait station shall display signage equivalent to that required for (1) above, or where this not practicable due the size of the bait station, each bait station shall display as a minimum, the name of the substance and that it is "toxic to humans and animals" with additional required information to be supplied by electronic media such as a QR code or similar, and
> c. Signage must remain legible for the length of time they are displayed."

The following requirements, which are in addition to the requirements detailed in other Legislation, remain applicable and are proposed to be supplemented with the following;

> "Signs must adhere to the following when applicable.
> a. State that it is an offence for any person other than the user to remove the signage;
> b. State that it is an offence for any person other than the user to remove the trade name product from the area;
> c. Warn of potential harm to pets, livestock and food producing animals, and
> d. Warn that feral animals may contain residues of the toxin and should not be taken for food"

In addition, new conditions are proposed to be included with regards to both ensure the notification to landowner or business owner for each application of quantities greater than 300g. These being:

> "For each application of quantities greater than 300 g:
> a. To use the product a person approved by the ACVM team must ensure that the landowner or business owner has sighted and signed a copy of the ACVM approved label for the Trade Name Product prior to its application.
> b. A copy of the consent must be kept for a minimum of five years and made available to the Ministry for Primary Industries upon request."

And to further strengthen the controls on the use of quantities greater than 300g where with the potential for exposure to the public or non-target animals, a new condition with respect to boundaries is proposed. That being:

> "For each application of quantities greater than 300 g, all operational boundaries, access points, bait stations and signage must be mapped (preferably by GPS). This information shall be recorded by the user. These records must be kept for a minimum of five years after the baiting programme has ceased."

2.1.7 Minimising Exposure to Non-Target Animals

The following requirements (or wording to their effect) are already stated on many product labels, however, for consistency, it is proposed that the following requirements are included in the conditions of registration to ensure this becomes standard practice.

The following are the new proposed Conditions of registration to be applied to ensure exposure to non-target animals is minimised:

I. Exposure of non-target animals: "The user must take all practicable measures to minimise access to baits by pets, livestock, and food producing animals."

II. Carcasses: "Access to the Trade Name Product by pets, livestock and food producing animals must be prevented. Poisoned carcasses must be collected and buried or burned (where practical or necessary) to prevent access by pets, livestock and food producing animals."

2.1.8 Persons Responsible for Use

It has been identified that the responsibility for the use of the trade name product has been typically considered to be implicit in the use of the product. However, to ensure that this is explicit and to ensure prudent use of these products, a new condition is proposed to detail who is responsible for the bait during its life cycle. This is detailed as follows,

> "The user / bait layer is responsible for the trade name product from the time of receipt until the time that the bait laid is assessed as being non-toxic or has been removed from the baited area."

2.1.9 Manufacturing Controls

There is already a Condition of registration to control manufacturing practice, which states that *"The product must be manufactured in accordance with the Ministry for Primary Industries Standard for Good Manufacturing Practice and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration;"* being Condition 2.

It is proposed that Condition 2 be modified to state that:

I. "A manufacturer of a trade name product must adhere to the principles of GMP. A manufacturer of a trade name product must be approved by the Ministry for Primary Industries' ACVM team as a Manufacturer.
II. All records on the manufacture of a trade name product must be kept for a minimum of five years and be made available to the Ministry for Primary Industries upon request."

2.2 Summary Table of all Proposed Conditions of Registrations

Condition #	Description	Existing Condition Text	Proposed Condition Text
New	**Recognition**		Users, other than those authorised by MPI, must not purchase, or have in their possession or store on their property any quantity greater than 300 g of any brodifacoum containing VTA.
55 revised	**Control of sale**	For pack sizes greater than 3kg, the product must be sold only by a person who has been approved by the Ministry for Primary Industries.	**For sales of quantities greater than 300 g: the** trade name product can only be sold by persons who are currently approved by the ACVM Group as either: (a) the registrant of the product, or (b) a seller identified in and acting in accordance with the approved operating plan for that product, approved under section 28.
56 revised	**Control of sale**	For pack sizes greater than 3kg, a register of sales must be kept (minimum of 3 years), recording who the product was sold to and the quantity sold.	**For sales of quantities greater than 300 g:** a seller must: • Only sell to persons who are currently approved by the Ministry for Primary Industries and verified on presentation of photo identification. • Not resell or re-distribute outside of the distribution channel documented in the approved operating plan without the approval of the Ministry for Primary Industries. • Keep a register of sales, recording the trade name of the product sold, who the product was sold to, the quantity sold, their contact details, and the Ministry for Primary Industries issued user authority number. • Keep all records on the sale of the product for a minimum of five years and make available to the Ministry for Primary Industries upon request.

Condition #	Description	Existing Condition Text	Proposed Condition Text
New	**Adverse Event reporting**	This is additional to Condition 64 *i.e.* The registrant must investigate the significance of every adverse event associated with the use of the product; and report to Ministry for Primary Industries within 20 working days the outcome of this investigation.	The user must notify the registrant immediately upon becoming aware of an adverse event that seems to have seriously jeopardised the health and welfare of non-target pets, livestock or food producing animals through exposure to the trade name product
New	**Use**		**For each application of quantities of 300 g or less by domestic, non-commercial and commercial users,** • Bait must only be used in a bait station. • Bait stations must be monitored weekly to ensure a continuous supply of bait. • All uneaten baits must be collected and removed from the area when baiting operation has ceased.
New	**Use**		**For each application of quantities greater than 300 g,** • Bait must only be used in bait stations unless otherwise specified in a Ministry for Primary Industries approved operating plan for that product. • Bait stations must be monitored regularly during the baiting programme, with records kept for each station detailing: ▪ the amount of bait added or removed; ▪ the method of disposal of surplus bait. ▪ All uneaten baits must be collected and removed from the area when the baiting programme has ceased. ▪ All records on the use of the product must be kept for a minimum of five years and made available to Ministry for Primary Industries upon request.
New	**Notifications**		**For each application of quantities greater than 300 g** ▪ To use the product, a person approved by the Ministry for Primary Industries must ensure that the landowner or business owner has sighted and signed a copy of the approved label for the Trade Name Product prior to its application. ▪ A copy of the consent must be kept for a minimum of five years and made available to the Ministry for Primary Industries upon request.
57 revised	**Signage**	If the product is applied where public may have access to the treatment area, signs must be posted in prominent places around the perimeter of the treated area. The signs must	For the application of quantities greater than 300 g, if the public has unrestricted access to the treatment area, then 1. Signs must be posted at every point of entry to the place

Condition #	Description	Existing Condition Text	Proposed Condition Text
		remain in place until monitoring confirms that the product is no longer present. Signs must state: a) that it is an offence for any person to remove the sign(s) prior to clearance of the area; b) that it is an offence for any person (other than the applicator) to remove/move baits from the area; c) a warning of potential harm to dogs d) a warning that feral animals may contain residues of the toxin and should not be taken for food.	where the trade name product is to be applied, and / or 2. Each bait station shall display signage equivalent to that required for (1) above, and 3. Signage must remain legible for the length of time that the sign is displayed. In addition to the requirements detailed in other legislation, signs must state the following, when applicable, 1. That it is an offence for any person other than the user to remove signage. 2. That it is an offence for any person other than the user to remove the trade name product from the area, 3. A warning of potential harm pets, livestock and food producing animals, and A warning of potential harm that feral animals may contain residues of the toxin and should not be taken for food.
New	**Boundaries**		**For each application of quantities greater than 300 g,** All operational boundaries, access points, bait stations and signage must be mapped (preferably by GPS). This information shall be recorded by the user. These records must be kept for a minimum of five years after the baiting programme has ceased.
New	**Carcasses**		**Carcasses:** Access to the Trade Name Product by pets, livestock and food producing animals must be prevented. Poisoned carcasses must be collected and buried or burned (where practical or necessary) to prevent access by pets, livestock and food producing animals.
New	**Non-Target Animals**		**Exposure of non-target animals:** The user must take all practicable measures to minimise access to baits by pets, livestock, and food producing animals.
New	**Responsibility**		The security, identity and application of the product must be under the control of the user. The user will be responsible for the trade name product from the time of receipt until the time that the product is assessed as being non-toxic or has been removed from the baited area.
2 revised	**Manufacturing control**	The product must be manufactured in accordance with the Ministry for Primary Industries Standard for Good Manufacturing Practice and to the chemistry and manufacturing specifications provided by the	A manufacturer of a trade name product must adhere to the principles of GMP. A manufacturer of a trade name product must be approved by Ministry for Primary Industries' ACVM team as a Manufacturer.

Condition #	Description	Existing Condition Text	Proposed Condition Text
		registrant and approved as part of the registration.	All records on the manufacture of a trade name product must be kept for a minimum of five years and be made available to the Ministry for Primary Industries upon request.