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**ACVM
NEW ZEALAND
LABELLING AND
ADVERTISING GUIDE FOR
VERTEBRATE TOXIC AGENTS
REQUIRING REGISTRATION**

This document may be altered at any time. It was current as at the date in the footer of each page of the document. It is recommended that anyone intending to use this document should contact the ACVM Group of NZFSA or check its website (<http://www.nzfsa.govt.nz/acvm/>) to confirm that it is the current version.

Endorsement:

Date:

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MANDATORY LABEL INFORMATION FOR SPECIFIC CIRCUMSTANCES

Refer to the ACVM Group website for updates of this annex
(<http://www.nzfsa.govt.nz/acvm/>).

ACVM NEW ZEALAND LABELLING AND ADVERTISING GUIDE FOR VERTEBRATE TOXIC AGENTS REQUIRING REGISTRATION

1 INTRODUCTION

This document sets out the requirements for label content of vertebrate toxic agents in accordance with the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, and the ACVM Group's expectations regarding advertising and promoting products.

The ACVM Act emphasises a shift from compliance with the label to placing 'conditions' on registration. These conditions will direct a registrant as to the specific statements that must appear on the label. **(The word 'must' indicates a mandatory requirement. 'Should' is used where some flexibility is allowed.)**

The ACVM Group approves label content only as it relates to the ACVM Act to ensure compliance with these registration conditions. This approval does not include any specific requirements under other relevant legislation that may affect the label, e.g. Hazardous Substances and New Organisms (HSNO) Act 1996 and accompanying Regulations, but there has been an effort to ensure that requirements do not conflict. The ACVM Group will advise on label content to ensure that sufficient information is provided to allow the product to be used safely and effectively. However, it is the applicant's responsibility to comply with all other relevant legislation.

This document contains:

- a section covering the items that must appear on the label of all vertebrate toxic agents;
- a section containing additional items that must appear under certain circumstances;
- a section detailing the ACVM Group's policy on advertising and promotion under the ACVM Act.

Labels of agricultural compounds and veterinary medicines that are exempt from registration under the ACVM Act must be factual, scientific and must not mislead. All these labels must comply with the requirements as outlined in Regulation 6 of the ACVM Regulations 2001.

Where a mandatory requirement is stated, the labelling guide must be followed unless a waiver has been granted by the ACVM Group.

1.1 Scope

This document must be followed by all registrants of trade name products where a condition on the product registration states that compliance with the labelling guide is required.

This document covers specifications for:

- mandatory label information for all vertebrate toxic agents
- mandatory label information for specific circumstances
- advertising and promotion policy
- general labelling advice.

1.2 Definitions and abbreviations

Active ingredient

The substance in a product that is responsible for the effect being claimed for the product, and as distinct from other formulation components such as surfactants, carriers or diluents.

Advertisement

Any publication to the community or to any section of the community of any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device *used to promote the sale of any agricultural compound*; and 'to advertise' has a corresponding meaning (ref: section 2 ACVM Act). Advertising does not include general information transfer or disease state awareness.

FAO

Food and Agricultural Organisation of the United Nations

Label

Any written, pictorial or other descriptive material (including cartons, vials, leaflets), affixed to or contained in or on the packaging, which gives information about the vertebrate toxic agent that is to be marketed or sold.

Label content

The content of the label as required under the ACVM Act and Regulations.

Primary label

The label on the container that is in physical contact with the chemical product, e.g. bottle, bag etc.

Secondary label

The label on the packaging in which the primary container is enclosed for sale, e.g. the immediate packaging around the bottle, bag etc.

Vertebrate toxic agent

Any substance, mixture of substances or biological compound used, or intended for use, to kill or reduce the viability of vertebrate animals. It does not include attractant or repellent substances that are not toxic.

Water-soluble bags

Bags designed to preclude operator exposure by dissolving on contact with water in a spray tank.

1.3 References

- *ACVM Registration Information Requirements for Vertebrate Toxic Agents in New Zealand*

Booklets to be read in conjunction with this document:

- The Commerce Commission has drafted a guide for manufacturers and distributors on environmentally friendly claims and the Fair Trading Act.
- HSNO Labelling Guide (when completed)
- OSH: refer to the Dangerous Goods (Labelling) Regulations 1978
- FAO International Code of Conduct on the Distribution and Use of Pesticides

2 LABELLING GUIDE FOR VERTEBRATE TOXIC AGENTS REQUIRING REGISTRATION

2.1 Mandatory label information for all vertebrate toxic agents requiring registration

Labels must be factual, scientific and must not mislead. All vertebrate toxic agent labels must include the following information:

- Trade name
- Name(s) and proportion(s) of active ingredient(s)
- Claim(s)
- Directions for use
- Registration statement (including registration number)
- Registrant's name and New Zealand agent if the registrant resides overseas
- Batch number
- Expiry date statement
- Net contents
- Storage instructions
- Adverse effects/precautions.

The following sections set out requirements for each of these items.

2.1.1 Trade name

- The full chosen trade name, as specified on the application form, must appear clearly.
- The trade name must be consistent throughout the label.
- The trade name must not be identical to the active ingredient name, e.g. not Brodifacoum, but Brodifacoum 50EC..
- Wherever any trade name appears on the label, the full trade name should be used.
- The chosen trade name must be obvious especially when it occupies more than one line.
- Any product description must be distinctly separate from the trade name.

2.1.2 Active ingredient statement

The active ingredient statement on the label must appear in the following format:

- Concentration: must be metric units, wherever possible; use g/litre for liquids and g/kg for solids.
- Chemical name: use the common name accepted by the ACVM Group.
- Formulation type: the ACVM Group follows the FAO naming of formulations, for example:

“Contains 800 g/kg potassium cyanide in the form of a ready-to-use bait.”

Definitions of formulation types can be found as Attachment 4 of the ACVM document *ACVM Registration Information Requirements for Vertebrate Toxic Agents in New Zealand* available on the ACVM Group website (<http://www.nzfsa.govt.nz/acvm/publications/information-requirements/index.htm>).

NB: For the expression of biological active ingredients, you may wish to consult the ACVM Group.

2.1.3 Claim(s)

This section should include a brief description of the product claim, for example:

“For the control of possums.”

Labels must be factual, scientific and must not mislead. Advertising type words and superlatives should not be contained on labels.

Labels must refer to the use situation that occurs in New Zealand. For the purposes of harmonisation with Australia, vertebrate pests occurring in Australia may be included accompanied by a disclaimer, for example:

“This vertebrate pest does not occur in New Zealand.”

2.1.4 Directions for use

Directions for use must be simple, clear and concise. This section should state how, what, when, and where the product is used.

The use of subheadings or tables is preferred.

HOW: how to use the product, e.g. mixing instructions, rate of use, concentration of mixture, amount per bait stations.

WHAT: what is the desired effect.

WHEN: when to use the product (if applicable), e.g. time of year.

WHERE: where the product is to be used.

If settling is an issue, the product label should state appropriate measures to avoid problems with stability and settling-out, for example:

“Shake contents adequately before use.”

“Stir, do not shake.”

2.1.5 Registration statement (including registration number)

The registration statement (including the registration number) must appear on all labelling and is generally located near the bottom of the label. The standard statement is:

“Registered pursuant to the ACVM Act 1997, No. ...”

This standard statement may be shortened to “ACVM No. ...” on very small containers such as sachets.

Labels are required to include the statement:

“See www.nzfsa.govt.nz/acvm for registration conditions.”

2.1.6 Registrant/New Zealand agent

The registrant’s full name must appear on all labelling. Where the registrant is not a New Zealand company or individual, the New Zealand agent’s full name must also appear on all labelling.

Where another company name appears on the labelling, in addition to the registrant, (e.g. manufacturer, distributor etc.) the words “Registered to ...” must appear before the registrant’s name to identify the registrant.

2.1.7 Batch number

This label requirement is the number or letter (or combination) by which the manufacturer uniquely identifies each production batch and should be preceded by the words “Batch number (or No.)” or the symbol “B” or another appropriate indicator that can be understood.

2.1.8 Expiry date statement

All labels must show the expiry date that relates to the approved shelf life for the formulation. This is the date (month and year) after which the product should not be used. The shelf life will be stated as a condition on registration.

2.1.9 Net contents

The net contents must be stated on the front of the label. The word(s) “Net” or “Net Contents” must also be included.

- Use g or grams or kg for solids.
- Use mls or litres for liquids.

Where units of vertebrate toxic agents are individually packaged (e.g. baits in bags or cartons or pails) and then included in multiple numbers in containers, the actual number of individual units included per container does not need to be stated on the label approved by the ACVM Group provided the container in which the individual units are sold does not contribute to the stability profile of the product. In consequence, where changes are made to the number of individual units included per container no formal ACVM approval is required provided there are no changes to the individual unit or ACVM-relevant approved label text.

2.1.10 Storage instructions

These are instructions regarding storage that are necessary to ensure the stability of the product, for example:

- “Store below 30°C.”
- “Store in a dry place.”
- “Keep tin closed.”
- “Keep away from light.”

Any mandatory storage instructions will be stated as a condition on registration.

2.1.11 Adverse effects/precautions

Registrants must state possible adverse effects/precautions of significance on labels. Such adverse effects/precautions will be stated as registration conditions, for example:

- “Only apply in bait stations.”

It should be noted, however, that those adverse effects/precautions stated as registration conditions may not form an exhaustive list and the registrant may add others, for example:

- “Do not apply around the house.”

2.2 Mandatory label information for specific circumstances

Specific labelling requirements are mandatory in certain circumstances such as the following:

- Withholding periods
- Treatment of accidentally poisoned non-target animals
- Restricted Sale and Restricted Use Statements
- Regulatory statements
- HSNO requirements (the ID regulations – priority and secondary identifier information for hazardous substances).

For further information on these requirements see the Annex, which will be updated regularly as needed (<http://www.nzfsa.govt.nz/acvm/>).

Other product specific conditions may be placed on the registration.

2.3 Labelling of packaging

2.3.1 Primary and secondary container labelling

Where the product is packaged within secondary packaging, all labelling must comply with the minimum requirements of the relevant legislation.

2.3.2 Water-soluble bags

Certain information, shown below, must appear on all water-soluble bags or on the outer foil sachets for each bag. Extra statements may be added in addition to the following required wording:

Trade Name

Concentration, units and active ingredient
e.g. 0.05 g/kg brodifacoum

Statement referring user to outer label
for directions for use

Registered pursuant to the ACVM Act 1997, No...

Net contents statement

2.3.3 Fold out labels

The use of fold out labels containing label information is acceptable. The part of the label affixed to the actual container must contain the trade name.

2.3.4 Plastic sleeve labelling

The use of plastic sleeves containing label information is acceptable.

2.3.5 Outers

The following wording must be shown on outers:

- trade name
- New Zealand registrant
- registration statement and number
- net contents;
- active ingredient(s).

2.3.6 Labelling of combined product

It is acceptable for two registered products to be sold in ‘convenience packs’ where the registered products are sold bound together by outer packaging without specific ACVM approval. Both products must be sold in their registered packs with all approved label text and in full compliance with the conditions of registration. Any external packaging used must contain at minimum all relevant information that is required for outer packaging as per section 2.3.5. In addition, where the external packaging obscures the approved product packaging, including information necessary for the consumer to access when deciding upon an appropriate product selection, this information must be included on the external packaging.

3 ADVERTISING AND PROMOTION

3.1 Compliance with conditions

All product registrations (or as a condition on an exemption from registration) shall have a condition imposed to the effect that any advertisement, by any person, of the product must comply with the relevant ACVM labelling guide and, if a registered product, be consistent with any specific advertising conditions on the registration.

3.2 Websites

The only websites that may be referenced on the approved label content and in an advertisement for a registered product are those where the content of the website is under the complete control of the registrant. The registrant who uses a website to advertise a product will be responsible for ensuring that the advertisement is consistent with the registration or the conditions on the exemption from registration. Any third party who advertises a product via a website will be held responsible for the compliance of that advertisement.

3.3 Reference to registration

No advertisement for a trade name product may make reference to the registration of that product, except for the statement that it has been registered under the ACVM Act.

3.4 Restrictions on use

Where there are restrictions on the use of a trade name product, every advertisement of that trade name product shall contain a statement to that effect.

3.5 Products that may not be advertised

No advertisement may be made for a trade name product:

- that is not registered but is required to be; or
- that is subject to a provisional registration/research approval if the product is not a registered product; or
- that is subject to a provisional registration/research approval and is a registered product where the advertisement is inconsistent with what is already approved in the full registration; or
- where the advertising is inconsistent with the current registration; or
- where the advertising is inconsistent with the conditions imposed on an exemption from registration under the ACVM Regulations 2001.

3.6 Imminent registration

Where registration is imminent, i.e. only administrative approval remains to be undertaken, advertisement or promotion may be undertaken with the written permission of the appropriate ACVM Decision Maker, via the ACVM Group. This permission is likely to be given only under exceptional circumstances, e.g. for presentations to professional bodies, scientific forums etc.

3.7 Claims exceeding approval

Claims published in advertisements must not exceed those that have been approved during the registration of the trade name product or exceed the use(s) specified in the relevant exemption from registration.

3.8 Compliance

Where an advertisement contains any inaccurate or misleading statements or contravenes any conditions of registration or exemption from registration, the person advertising the product shall modify the advertisement in such a manner as to be in compliance. The ACVM Decision Maker may require that every subsequent advertisement to be published by the offender in relation to that trade name product be submitted to the ACVM Decision Maker for prior approval.

3.9 Vertebrate pests not present in New Zealand

Where any part of an advertisement includes reference to vertebrate pests that do not occur in New Zealand, a disclaimer for those vertebrate pests must be included in the advertisement.

3.10 Registration statement

Every advertisement for a registered trade name product must contain the registration phrase:

“Registered pursuant to the ACVM Act 1997 No....”
with the registration number to be included in the phrase.

3.11 Offences

Where it is brought to the attention of the ACVM Group that any party is advertising a product in a way that is inconsistent with the registration, or the conditions on exemption from registration, the ACVM Group shall advise that party of the inconsistencies in their advertisement with that product's registration, or ACVM Regulations 2001 and/or ACVM Act. They will be advised that they may be committing an offence under section 55 of the Act.

3.12 Assessment service

The ACVM Group will provide a service to assess advertisements and give advice to parties who are unsure if their advertisement conforms to the product's registration. Obtaining the ACVM Group's advice on advertisement is not compulsory. Where advice is requested, the requester will be charged on an hourly basis.

3.13 Other relevant legislation

Registrants will be referred to ERMA NZ (www.ermanz.govt.nz) for the advertising requirements imposed under the Hazardous Substances and New Organisms Act 1996. Both the ACVM Group and ERMA NZ requirements should be met. However, the ACVM Group will enforce only the requirements imposed under the ACVM Act.

Note: Under the ACVM Act there is no specific section regarding the advertising of trade name products. Section 23 Conditions on trade name products (1)(d) states that:

“The Director-General may register a trade name product in accordance with section 21, subject to all or any of the following conditions: ...
(d) A condition specifying the labelling, advertising, or other information requirements for the trade name product.”

4 GENERAL ADVICE FOR LABELLING VERTEBRATE TOXIC AGENTS

The registrant should ensure that the label complies with other relevant legislation, such as the Fair Trading Act and the HSNO Act, and that the product does not infringe on any proprietary rights, e.g. trade marks, patents.

4.1 Pictograms and graphics

In addition to written precautionary advice, pictograms (giving a pictorial representation of a subject) may be used on labels. If they are employed they should be added to the base of the label. Preferred pictograms to use are those developed by the FAO. Appropriate information on them may be obtained from the FAO website (<http://www.fao.org/ag/agp/agpp/pesticid/code/download/label.doc> - A pictogram is a symbol).

Graphics may be included on labels but the registrant should ensure that they do not interfere with the legibility of the text. Pictures or illustrations must not depict or imply usage contrary to the current approval.

4.2 Colouring

Colours are often used on labels and they can assist the readability of the text. However, some colour combinations are easier to read than others. An indication of good and bad colour combinations is given below:

Good colour combinations	Don't use these
Black on yellow (best)	Yellow on black
Green on white	White on red
Red on white	White on green
Blue on white	White on black
White on blue	Red on yellow
Black on white	Green on red
	Red on green (worst)

Generally, dark prints on a dark background and light prints on a light background should be avoided.

4.3 Reprinting

Before reprinting ensure that the label still complies with ACVM requirements by referring to the latest ACVM labelling guide.

ANNEX

MANDATORY LABEL INFORMATION FOR SPECIFIC CIRCUMSTANCES

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- 2 Treatment of accidentally poisoned non-target animals
- 3 Restricted Sale and Restricted Use Statements
- 4 Regulatory statements
- 5 HSNO requirements (the ID regulations – priority and secondary identifier information for hazardous substances)

1 Animal withholding statements

An animal withholding statement is required where there is a recommended minimum interval that should elapse between the last application of a vertebrate toxic agent and: re-introduction of stock or domestic animals into treated area. An example of an acceptable withholding period statement is:

“Keep livestock and domestic animals out of treated area until either post-application monitoring indicates baits have been washed out by rain, or baits removed, or turned in.”

Another type of animal withholding period statement is to ensure stock and domestic animals cannot gain access to baits. An example of this type of acceptable withholding period statement is:

“Ensure livestock and domestic animals can not access baits by placing them in areas inaccessible to them.”

2 Treatment of accidentally poisoned non-target animals

A treatment of accidentally poisoned non-target animals statement must appear on the label where there is a known antidote or as applicable, for example:

“Take poisoned animal to veterinarian as soon as practical.”

3 Restricted Sale and Restricted Use statements

The following statements need to be added based on the conditions of registration that may be assigned to the registered vertebrate toxic agent:

“The product must be sold only to or used by a person holding a controlled substances licence issued by a test certifier who has been approved.”

“Signs must be posted in public areas to notify members of the public that this product has been applied in the area.”

“This product must be used only in bait stations.”

4 Regulatory statements

To clarify the distinction between regulatory statements and statements made by the registrant, the ACVM Group has developed a set of labelling principles:

- The current registration approval must expressly state all the conditions that have been imposed.
- Any condition that has a regulatory impact on the users of products must be stated as a regulatory statement in the label content.
- Each regulatory statement must be recognisable for what it is by its wording at least.
- The ACVM Group will allow registrants to make statements on the label only if the statements do not jeopardise regulatory control.
- Regulatory statements must be made explicit by requiring any one of the following:
 1. it is a condition on the registration that...;
 2. it is an offence under the ACVM Act (or ACVM Regulations) to...;
 3. failure to... may be an offence under the ACVM Act (or ACVM Regulations);
 4. by law....

These qualifiers should be as required, in particular in relation to Restricted Sale and/or Use statements above.

5 HSNO requirements

The HSNO Act applies to vertebrate toxic agents that contain substances that meet the thresholds specified in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. Labelling information required under the HSNO Act will be the following:

- Priority identifiers
(Signal words, for example: Dangerous Poison, UN/EU pictograms)
- Secondary identifiers
(Substance name, New Zealand contact details, nature of all toxic and ecotoxic hazards-warning/precautionary statements [e.g. harmful if swallowed, avoid skin contact], identification and concentrations of toxic ingredients).

For precise labelling requirements under the HSNO Act, contact ERMA New Zealand (<http://www.ermanz.govt.nz>).