Ministry for Primary Industries
Manatū Ahu Matua

ACVM Requirement

Labelling Vertebrate Toxic Agents

ACVM Labelling Requirements for VTAs Requiring Registration

24 June 2014

Issued under the Agricultural Compounds and Veterinary Medicines Act 1997

New Zealand Government

TITLE

ACVM Requirement: Labelling Vertebrate Toxic Agents

COMMENCEMENT

This ACVM Requirement comes into force on 1 July 2014.

ISSUING AUTHORITY

This ACVM Requirement is issued under section 10 of the Agricultural Compounds and Veterinary Medicines Act 1997.

Dated at Wellington this 24th day of June 2014.

Warren Hughes
Principal Adviser ACVM
Ministry for Primary Industries
(acting under delegated authority of the Director General)
A copy of the instrument of delegation may be inspected at the Director General's office.

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Introduction

This introduction is not part of the ACVM Requirement, but is intended to indicate its general effect.

Purpose

(1) This document specifies the ACVM requirements for label content of vertebrate toxic agents that must be registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Background

(1) Before being imported, manufactured, sold or used in New Zealand, agricultural compounds (including vertebrate toxic agents) must be authorised under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. Authorisation is required:

a) to manage risks to trade in primary produce, public health, animal welfare, and agricultural security
b) to make sure that the use of agricultural compounds does not result in breaches of domestic food residue standards, and
c) to ensure the provision of sufficient consumer information.

(2) Authorisation of vertebrate toxic agents usually takes the form of a product registration, and approval of label content related to the ACVM Act risk areas is part of that registration. MPI approves label content only as it relates to the ACVM Act to ensure compliance with the relevant registration condition (that is, "The product must be labelled in accordance with the product and manufacturing specifications approved as part of this registration").

(3) This document sets out the generic and some specific requirements for label content of vertebrate toxic agents requiring registration under the ACVM Act. The word 'must' indicates a mandatory requirement if flexibility will not normally be allowed unless MPI grants a deviation. 'Should' is used if you are allowed some flexibility in the wording or to improve readability in a particular circumstance.

(4) This document includes guidelines intended to provide examples and more detailed information. The guidelines reflect the principles accepted as appropriate to achieve compliance. MPI does, however, recognise that alternative methods are capable of achieving the desired outcome. Guidelines are within the Guidance boxes and do not form part of the requirements.

(5) If you have any questions, contact us (approvals@mpi.govt.nz).

Who should read this ACVM Requirement?

(1) This requirement applies to:

a) all persons registering vertebrate toxic agents in New Zealand
b) all persons acting as consultants for registering vertebrate toxic agents in New Zealand .

Why is this important?

(1) If you do not comply with these requirements, your application for product registration will be declined.

Other information

(1) This document does not include any specific conditions or controls imposed under other relevant legislation, such as the Hazardous Substances and New Organisms (HSNO) Act and accompanying Regulations or the Fair Trading Act, which may affect the label.

(2) For labelling requirements under the HSNO Act, contact the Environmental Protection Authority (EPA) (http://www.epa.govt.nz/)

(3) For information on 'environmentally friendly' claims and the Fair Trading Act, check the Commerce Commission website (http://www.comcom.govt.nz).

(4) OSH: refer to the Dangerous Goods (Labelling) Regulations.

(5) FAO: *International Code of Conduct on the Distribution and Use of Pesticides*.

(6) For information on advertising and promotion, refer to *Advertising Guidelines for Products Registered under the ACVM Act,* which is available on our website.

Part 1: Mandatory label information

(1) All labels must include

a) trade name*
b) name(s) and proportion(s) of active ingredient(s)*
c) claim(s)
d) directions for use
e) registration statement*
f) registrant/New Zealand agent and contact information (name, address, phone number)
g) batch number*
h) expiry date statement*
i) net contents
j) storage instructions
k) adverse effects/precautions.

* Required to be on your primary label

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

1.1 Trade name

(1) The full trade name, as specified on the registration application form, must appear clearly in a prominent place, and must be consistent throughout the label.

a) The trade name must be distinctive and not misleading. It is your responsibility to ensure that the trade name is unique so as to not cause confusion in the marketplace.
b) Words, numbers or phrases included in company logos or trademarks, which are also positioned near the trade name, will not be considered part of the trade name.
c) If the trade name is not distinctive, such as a generic active ingredient, then the trade name should be preceded by another word to make it distinctive.

Guidance

- The company name could, for example, be incorporated into the trade name to distinguish it from other products having similar trade names.
- Examples of acceptable trade names:
  Company X Brodifacoum
  Brodifacoum Company X

d) If numbers are used as part of the trade name, they should relate to the level or concentration of active ingredient in the product.
e) Letters (that do not form a word) may be used only when they are formulation type codes and must be consistent with the international coding system for pesticide formulation types.
f) Any product description must be distinctly separate from the trade name.

(2) Ensure the trade name complies with trademarks and is not too similar to existing trade names. MPI does not routinely check these other than to ensure the trade name is not misleading (for example, if the trade name suggests the product controls a pest when in fact the label does not mention control of that pest).

(3) If you wish to adopt a previously used trade name for a new product, both products must have the same active ingredients (or combinations) and the same formulation type.

(4) The trade name must not be identical to the active ingredient name, for example not Brodifacoum, but Brodifacoum 50EC.

1.2 Active ingredient statement

(1) The names of all active ingredients must appear on the label along with their concentrations and units. The names must be described as either:

a) the International Standards Organisation (ISO) common name/International Non proprietary Name (INN) or
b) the full chemical name if a common name has not yet been approved or recognised.

(2) Units of concentration must be appropriate to the formulation type. (For example, grams/litre or grams/kilogram.)

(3) Use the FAO naming of formulations as in the table below, for example:
"Contains 800 g/kg potassium cyanide in the form of a ready-to-use bait."

Definitions of Formulation Types	
Aerosol	A container-held formulation that is dispersed generally as a propellant as fine droplets/particles upon the actuation of a valve.
Bait concentrate	A solid or liquid intended for dilution before use as a bait.
Bait (ready to use)	A formulation designed to attract and be eaten by the target pest (includes grain baits).
Dustable powder	A free flowing powder, suitable for dusting.
Emulsifiable concentrate	Liquid homogeneous formulation with emulsifiers in an organic solvent that forms a dispersion when added to water as a diluent.
Emulsifiable suspension	A stable emulsion for application to the seed either directly or after dilution.
Gas	A gas packed in a pressure bottle or pressure tank
Gas generating product	A product that generates gas by chemical reaction.
Gel	A homogeneous, gelatinous formulation to be applied as an emulsion after dilution in water.
Granule	Solid formulation comprising particles of defined size (>80µm diameter) for application without further dilution, usually to soil.
Grease	Very viscous formulation based on oil, solvent or fat.
Liquids (ready to use)	Self-defining
Paste	Water-based, film forming composition.
Soluble concentrate	A liquid, homogeneous formulation to be applied as a true solution of the active ingredient after dilution in water.
Suspension concentrate	A stable suspension of active ingredient(s) in a fluid, which may contain other dissolved active ingredient(s), intended for dilution with water before use.
Tablet	Solid formulation in the form of small, flat plates for dissolution in water.
Technical concentrate	A technical material either in solution or diluted with solid adjuvants for use only in the preparation of formulations.
Technical material	A material resulting from a manufacturing process comprising the active ingredient together with associated impurities. This may contain small amounts of necessary additives.
Vapour releasing product	A formulated product containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable formulations and/or dispensers.
Wettable powder	A powder formulation to be applied as a suspension after dispersion in water.

(4) For the expression of biological active ingredients, consult the ACVM Group.

1.3 Use claim(s)

(1) This section should include a brief description of the product claim(s), for example
"For the control of possums."

(2) Claims on the label must be consistent with the claims approved as part of the registration application. They must not overstate or misrepresent approved claims.

(3) 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."

1.4 Directions for use

(1) These must be simple, clear and concise.

(2) Directions for use must state how, what, when, and where the product is used.

Guidance
The use of subheadings or tables is preferred.
- **How** to use the product (for example, mixing instructions, rate of use, concentration of mixture, amount per bait station).
- **What** is the desired effect?
- **When** to use the product if applicable (for example, time of year).
- **Where** the product is to be used.

(3) If settling is an issue, the product label should state appropriate measures to avoid problems with stability (if maintaining stability is a requirement) and settling-out, for example:
"Massage tube before use."

1.5 Registration statement

(1) The registration number must appear on all labelling and is generally located near the bottom of the label. You may include this in one of the following ways:

a) Registered pursuant to the ACVM Act 1997, No …..
b) or ACVM Registration No ….
c) or ACVM No. ….. (on small containers).

(2) All labels, including very small containers such as sachets outer packs, must have the registration number on them.

(3) Labels must also include the statement: "See www.foodsafety.govt.nz for registration conditions."

1.6 Registrant/New Zealand agent

(1) The registrant's full name must appear on all labelling. If the New Zealand agent differs from the registrant, the agent must also appear on all labelling.

(2) If another company name appears on the labelling in addition to the registrant (for example, manufacturer, distributor) the words "Registered to ..." must appear before the registrant's name to identify the registrant along with contact information such as address/phone number(s).

1.7 Batch number

(1) This label requirement is the number or letter (or combination) by which the manufacturer uniquely identifies each production batch. It should be preceded by the words "Batch number (or No.)" or the symbol "B" or another appropriate indicator that can be easily understood by the end user.

(2) If the batch number (and date of manufacture) is stamped onto the container, clearly note this step in the manufacturing specifications.

1.8 Expiry date statement

(1) 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.

1.9 Net contents

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

a) Use g or grams or kg for solids.
b) Use mls or litres for liquids.

(2) This statement must be clear and readable.

Guidance

- If individually packaged products (for example, baits in bags or cartons or pails) are packed together in multiple numbers, the actual number of individual units included per pack does not need to be stated in the label content approved by MPI provided the container in which the individual units are sold does not contribute to the stability profile of the product.
- In consequence, if changes are made to the number of individual units included per container formal MPI approval is not required unless there are changes to the individual unit or relevant MPI-approved label text.

1.10 Storage instructions

(1) Provide any instructions regarding storage that are necessary to ensure the stability of the product, for example:
"Store below 30ºC."
"Store in a dry place."
"Keep container closed."
"Keep away from light."

(2) Any mandatory storage instructions will be stated as a registration condition.

1.11 Adverse effects/precautions

(1) 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."

(2) These registration conditions may not form an exhaustive list and you may add others, for example:
"Do not apply around the house."

Part 2: Mandatory label information for specific circumstances

(1) Specific labelling requirements, such as the following, are mandatory in certain circumstances:

a) animal withholding statements
b) treatment of accidentally poisoned non-target animals
c) Restricted Sale and Restricted Use statements
d) regulatory statements
e) HSNO requirements (the ID regulations – priority and secondary identifier information for hazardous substances).

2.1 Animal withholding statements

(1) An animal withholding statement is required if 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."

(2) Another type of animal withholding period statement is to ensure stock and domestic animals cannot gain access to bait. An example of this type of acceptable withholding period statement is:
"Ensure livestock and domestic animals cannot access baits by placing them in areas inaccessible to them."

2.2 Treatment of accidentally poisoned non-target animals

(1) 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."

2.3 Restricted Sale and Restricted Use statements

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

a) "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."
b) "Signs must be posted in public areas to notify members of the public that this product has been applied in the area."
c) "This product must be used only in bait stations."

2.4 Regulatory statements

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

a) The current registration approval must expressly state all the conditions that have been imposed.
b) Any condition that has a regulatory impact on the users of products must be stated as a regulatory statement in the label content.
c) Each regulatory statement must be recognisable for what it is by its wording at least.

d) The ACVM Group will allow registrants to make statements on the label only if the statements do not jeopardise regulatory control.
e) 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….

(2) The above qualifiers should be used as required, in particular in relation to Restricted Sale and/or Use statements.

2.5 HSNO requirements

(1) The Hazardous Substances and New Organisms (HSNO) Act 1996 applies to vertebrate toxic agents that contain substances that meet the thresholds specified in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. The following labelling information is required under the HSNO Act:

a) priority identifiers (signal words, for example: Dangerous Poison, UN/EU pictograms)
b) secondary identifiers (substance name, New Zealand contact details, nature of all toxic and ecotoxic hazards-warning/precautionary statements [such as harmful if swallowed, avoid skin contact], identification and concentrations of toxic ingredients.

For precise labelling requirements under the HSNO Act, contact EPA New Zealand (http://www.epa.govt.nz).

Part 3: Additional information on other types of packaging

3.1 Primary and secondary container labelling

(1) If the product is packaged within secondary packaging, all labelling must comply with the minimum requirements of the relevant legislation.

3.1.1 Fold out labels

(1) Fold out labels containing label information are acceptable. The part of the label affixed to the actual container must contain the trade name.

3.1.2 Plastic sleeve labelling

(1) Plastic sleeves containing label information are acceptable.

3.1.3 Outers

(1) The following wording must be shown on outers:

c) trade name
d) New Zealand registrant
e) registration statement and number
f) net contents.

3.2 Labelling of combined product

(1) Two registered products may be sold in 'convenience packs' if the registered products are sold bound together by outer packaging without specific MPI 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 must contain, at minimum, all relevant information that is required for other types of packaging (see section 3.1).

(2) If the external packaging obscures the approved product packaging, including information the consumer needs to see when choosing an appropriate product, this information must be included on the external packaging.

Part 4: General advice

(1) Ensure that the label complies with other relevant legislation, such as the Fair Trading Act and the HSNO Act.

(2) Ensure that the product does not infringe on any proprietary rights (for example, trademarks or patents).

4.1 Pictograms and graphics

(1) 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)

(2) Graphics may be included on labels but should not interfere with the legibility of the text.

(3) Pictures or illustrations must not depict or imply usage contrary to the current approval.

4.2 Colouring

(1) Colours are often used on labels and they can assist the readability of the text, but some colour combinations are easier to read than others. Generally, dark prints on a dark background and light prints on a light background should be avoided.

4.3 Reprinting

(1) Before reprinting, ensure that your label still complies with MPI requirements by referring to the latest labelling information requirements on our website.

Schedule 1 – Definitions

(1) In this document, unless the context otherwise requires:

Active ingredient
means the chemical(s) (or biological component) in a formulated product that is/are principally responsible for the effect being claimed and is/are distinct from other formulation components such as surfactants, carriers or diluents.

Bait bag
means a flexible, enclosed container which breaks down over time and is intended for a single use only; designed or adapted for the purpose of holding baits whereby the pest is required to open the bag to gain access to the baits.

Bait station
means a rigid, reusable device or container designed or adapted to physically contain baits in such a way as to allow unrestricted access by target pests while preventing or minimising spillage of bait and access of off-target species. Also used to protect baits from the elements and extend their usable life.

Label
means 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
means the information that is intended to be included with the product when it is offered for sale. It is supplied as part of the application for registration and must be complied with when generating the actual label, packaging and information sheets.

Non-degradable bait bag
means a flexible, enclosed container which does not break down over time and is intended for a single use only; designed or adapted for the purpose of holding baits whereby the pest is required to open the bag to gain access to the baits.

Outers
means the outer containers used for shipment of products from one destination to another.

Package leaflet
means a pull-out label inserted into the primary pack of the product that contains the mandatory label information for the user regarding the trade name product.

Primary label
means the label on the primary container that is in physical contact with the vertebrate toxic agent (for example, bottle, bag). This must contain the mandatory information, which is listed in section 1.

Secondary label
means the label on the packaging in which the primary container is enclosed for sale. In other words, it is the immediate packaging around the primary container (for example, carton, leaflets/inserts).

Vertebrate toxic agent
means 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.

(2) Any words or expressions used but not defined in this document that are defined in the ACVM Act have the meaning given to them in the Act.