Ministry for Primary Industries
Manatū Ahu Matua

ACVM Requirement

Labelling Agricultural Chemicals

ACVM Labelling Requirements for Agricultural Chemicals Requiring Registration

6 May 2014

Issued under the Agricultural Compounds and Veterinary Medicines Act 1997

New Zealand Government

TITLE

ACVM Requirement: Labelling Agricultural Chemicals

COMMENCEMENT

This ACVM Requirement comes into force on 1 June 2014.

ISSUING AUTHORITY

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

Dated at Wellington this 6th day of May 2014.

Debbie Morris
Director, Systems, Support and 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 agricultural chemicals 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 agricultural chemicals) 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 agricultural chemicals 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 agricultural chemicals 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.

Who should read this ACVM Requirement?

(1) This requirement applies to …

a) all persons registering agricultural chemicals in New Zealand
b) all persons acting as consultants for registering agricultural chemicals in New Zealand.

Why is this important?

(1) If you fail to comply with this requirement, your application for product registration will be declined.

Contacts

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

Other information

(1) This document does not include any specific conditions or controls imposed under other relevant legislation that may affect the label (for example, the Hazardous Substances and New Organisms [HSNO] Act 1996, and accompanying Regulations, or the Fair Trading Act 1986).

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

(3) To meet all the statutory labelling requirements, read this document in conjunction with HSNO labelling guides such as the one produced by Agcarm. This guide includes information that must appear on the label of ACVM products: *Product labelling and documentation guide for agricultural chemicals and veterinary medicines* (http://agcarm.co.nz/?page_id=162)

Part 1: Mandatory label information

(1) All labels must include:

a) trade name*
b) active ingredient(s) and quantities*
c) use claims
d) directions for use
e) registration number*
f) withholding period statements, crop rotation statements and slaughter intervals (if required)
g) registrant/New Zealand agent (if different from the registrant) and contact information (name, address/phone number)*
h) batch number *
i) shelf life statement/expiry date
j) net contents*
k) storage instructions (only necessary in relation to stability)
l) resistance statement
m) regulatory statements and adverse effects, cautions and contraindications.

* 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 Glyphosate
  - Glyphosate 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. 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.

(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.

1.2 Active ingredient(s)

(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) If the active is present as a salt, the label description and concentration should be for the active molecule on which efficacy calculations are made (for example, 460g/L glyphosphate as the isopropylamine salt in the form of a soluble concentrate).

(4) For biological products if the concentration is not directly relevant for use, including concentrations is discretionary (for example, contains 146g/kg dried bacillus subtillis [QST 713 strain] and contains not less than 7.3 x 10^9 cfu/g in the form of a wettable powder).

1.3 Use claim(s)

(1) All labels must have accurate and objective claim(s). The claim(s) should, if practical, specify all the crops or situations for which the product is specifically approved. The primary label claim should appear near the 'Trade Name' and 'Active Ingredient(s)' as an immediate description of the product's intended use.

(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 only to pests/diseases/parasites/weeds that occur in New Zealand. For the purposes of harmonisation with Australia, pests/diseases/parasites/weeds occurring in Australia may be included accompanied by a disclaimer (for example, "This pest/disease/parasite/weed 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 hectare and frequency of application).
- **What** is the desired effect?
- **When** to use the product if applicable (for example, stage of growth, time of year).
- **Where** the product is to be used.

(3) Label rates for all fruit crops and vegetable crops grown under glass must be expressed on a dilution basis, together with a dilute spray per hectare. A product rate per hectare must also appear on the label. For other crops, a dilute spray per hectare is acceptable.

(4) Compatibility statements may be added if desired.

(5) 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:

a) "Shake contents adequately before use."
b) "Stir, do not shake."

1.5 Registration number

(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) ACVM Registration No ….
c) ACVM No. ….. (on small containers).

(2) All labels, including very small containers such as sachets or 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 Use statements

1.6.1 Withholding period statements

(1) Withholding periods are guidance to avoid non-compliant residues when the product is used for an approved claim.

(2) Consideration should also be given to feeding treated plant material to animals and using products (for example, herbicides) on/around orchards etc. and the obligation to avoid non-compliant residues in animal products.

(3) Withholding periods must appear on all labelling (primary, secondary and leaflet) if a withholding period has been set.

(4) All withholding period statements must clearly stand out and be separate from the main body of the text.

(5) In the case of some agricultural chemicals, the withholding period is implied in the directions for use because the products can be used only at certain stages of the crop lifecycle. In these cases, it is preferable to reinforce these implied withholding periods in the withholding period statement section.

(6) The label must include clear instructions for approved uses and the withholding periods necessary to ensure that any maximum residue limits (MRLs) set in New Zealand food standards are not exceeded.

Guidance

Examples of acceptable withholding period statements include:

- "Do not apply later than ... days before harvest."
- "Do not apply later than (growth stage)."
- "Use only in the (growth stage) period."
- "Keep livestock out of (crop) for ... days after treatment."

1.6.2 Crop rotation statements

(1) A crop rotation statement must appear on the label if there is potential for carry over residues into subsequent crops (for example, "Do not plant subsequent crops within 3 months of harvest").

(2) If there is a restriction on crops that can be planted in rotation, this must be noted (for example, "Only x crops may be planted on sites where {*the TNP*} has been used and grown in rotation").

1.6.3 Slaughter intervals

(1) Slaughter interval (SI) is the time that should elapse between exposure of an agricultural chemical to animals and their slaughter for export or the time between animals consuming plants or plant parts that are treated with an agricultural chemical and slaughter.

(2) Slaughter interval statements will be considered on a case by case/product by product basis. For more information on your particular product, contact us (mailto:approvals@pmi.govt.nz).

1.7 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 or 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).

1.8 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, this should be a clearly noted step in the manufacturing specifications.

1.9 Shelf life statement/expiry date

1.9.1 Shelf life of 24 months or longer

(1) For products with a shelf life of at least 24 months, which have condition 108* as part of their registration, you have 2 options:

a) Provide a shelf life statement on the label, such as:
"When stored appropriately, this product should show no significant degradation for {*shelf life*} years from the date of manufacture. When using this product beyond this shelf life, contact the registrant for further information." A 'date of manufacture' must also appear on the label.
OR

b) You can remove or amend the shelf life statement on the label if you manage the shelf-life requirements of registration condition 108 through other means.

(2) Products that do not have condition 108 as part of their registration must have a shelf life statement or expiry date on the label.

*Condition 108:

The registrant must provide sufficient consumer advice about the ongoing stability of the product for use if requested by any purchaser of the product.
The registrant must withdraw the product from the marketplace where evidence shows it is no longer capable of meeting its expiry specifications prior to its use, when stored in line with the manufacturer's recommendations.

1.9.2 Shelf life of less than 24 months

(1) If you cannot show 24 months stability, an "expiry date" must be used in lieu of the shelf life 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.

1.10 Net contents

(1) Net contents of the product(s) must be stated in metric units, for example:
g (gram)
kg (kilogram)
mL (millilitre)
L (litre)
biologicals-- cfu, pfu or 1 x 10^9 nematodes

(2) This statement must be clear and readable.

Guidance
- If individually packaged products (for example, bottles, bags, sachets of product) 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.

1.11 Storage instructions

(1) These are 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."

1.12 Resistance statement

(1) Labels must contain the mode of action group (MOA) and resistance management statements (if applicable) to manage the development of insect, pathogen and weed resistance. For details on the appropriate resistance management statements and MOA group see the New Zealand Plant Protection Society (NZPPS) website (http://resistance.nzpps.org/).

Guidance
- If the NZPPS website does not contain a resistance management strategy covering the group to which your product belongs, please contact the New Zealand Committee on Pesticide Resistance (NZCPR) for guidance on the development of a suitable strategy. In the interim the MOA group and general advice on managing resistance should be placed on the label.

1.13 Regulatory statements

(1) Labels must have regulatory statements if compliance by the user is a statutory obligation imposed by the conditions of registration. These are distinct from label statements that have no statutory obligations for user compliance. Examples of these generally fall into the adverse event, contra-indication, safety type statements (see Part 1.13).

(2) Regulatory statements must be in the most appropriate place on the label near use instructions and in bold. If appropriate the regulatory statements can be placed together.

(3) Most agricultural chemicals will have two conditions of registration requiring regulatory statements about management of residues and use on animals. (A small number of agricultural chemicals may have more conditions.)

1.13.1 Management of residues

(1) The following regulatory statement, which must be printed in bold near any withholding period statement, is to make users aware of their obligations regarding residues:
"It is an offence for the users of this product to cause residues exceeding the relevant MRL in the NZ (Maximum Residues of Agricultural Compounds) Food Standard."

1.13.2 Use on animals

(1) The following regulatory statement must be printed in bold near the use instruction (but not necessarily on the primary label):
"It is an offence to use this product on animals."

(2) If an agricultural chemical trade name product could not possibly be used on animals and the registrant has a plausible argument as to why the above statement would be undesirable, we will consider the omission of this statement on a case by case basis.

(3) If off-label use of the trade name product is allowed, then the above regulatory statement must be included in bold immediately above, or with, the directions for use on all agricultural chemical trade name products. This includes those intended for use in food/feed-producing crops that may have a nil withholding period.

1.13.3 Alternative wording

(1) You may request use of alternative wording for the above two regulatory statements provided the intent is the same. MPI will consider this on a case by case basis.

1.13.4 Other regulatory statements

(1) If other regulatory statements, such as not allowing off-label use, are required we will provide guidance on wording.

1.14 Adverse effects, cautions and contraindications

(1) Registrants must state possible adverse effects, cautions and any contraindications of significance on labels (for example, "Apply only at the 5 leaf stage of the crop"). The need for label warnings should take account of the frequency of adverse effects as well as the impact on efficacy, animal welfare, trade or residues. Label statements should be factual and not mislead.

(2) Label warnings required for regulatory purposes that have statutory obligations for the user should be made clear by way of the regulatory statements mentioned above.

(3) Label warnings that are discretionary (that is, placed on the label by the registrant) should not be misrepresented as regulatory statements in any way.

(4) Registrants may put other statements on the label, but we will decide if these statements misrepresent the scope of the product approval.

Part 2: Additional information on other types of packaging

2.1 Primary and secondary container labelling

(1) If the product is packaged inside secondary packaging, all label directions (for example, on sachets, leaflets, inserts and fold out labels) must comply with those on the primary label. One exception to this is if small pack sizes are accompanied by an outer primary label such as a brochure/pamphlet.

2.1.1 Fold out labels in pouches/plastic sleeves

(1) A portion of this must be fixed directly to the packaging to ensure that the label cannot be separated from the container. If the portion of the label affixed does not have crucial information, such as the trade name, active ingredient, registration number or registrant contact details, and the label gets removed from the container, there is a high risk that the end user will not know what is in the container. Misuse could result.

2.1.2 Leaflets and booklets

(1) If the size or shape of a container cannot accommodate all the required label information, or the use directions are too lengthy to be listed clearly, some information can be printed in a leaflet or booklet that is supplied with each container. In this case, the leaflet or booklet is part of the label.

2.2 Other types of packaging (if packaging is not considered primary or secondary)

(1) The information listed below must appear on all water-soluble bags or on the outer foil sachets of each bag. Extra statements may be added in addition to the following required wording:

a) trade name
b) concentration, units and active ingredient (for example, 500 g/kg diazinon)
c) statement referring user to outer label for use directions
d) registration number (may be shortened to “ACVM No…..”)
e) net contents.

(2) In addition to the above, outers of other types of packaging must show the New Zealand registrant/agent and sufficient contact information to allow easy contact (for example, telephone number). Physical address is not necessary.

2.3 Small trial/ sample pack sizes

(1) If you wish to give away free sample packs or small trial packs for user acceptance in one-off situations, these packs, which must be ACVM approved, must show the following information:

a) trade name
b) registration number (may be shortened to “ACVM No…..”)
c) net contents
d) restriction status, if applicable (not common for agricultural chemicals)
e) batch number
f) expiry date (if applicable)
g) concentration, units and active ingredient (for example, 500 g/kg diazinon)
h) statement referring user to the primary packaging label for use directions.

(2) If the size of the packaging limits label space, alternatives may be acceptable on a case by case basis provided the product is not marketed as a separate single unit.

2.4 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 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. External packaging must contain, at minimum, all relevant information that is required for other types of packaging (see Part 2.2).

(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.

(3) If products are sold together as an active and diluent, both items of packaging must have the appropriate information relating to the registration.

Part 3: General advice

(1) Ensure that the label complies with other relevant legislation, such as the Fair Trading Act 1986 and the Hazardous Substances and New Organisms Act 1996.

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

3.1 Graphics

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

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

3.2 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, avoid dark prints on a dark background and light prints on a light background.

3.3 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.

Agricultural chemical
means a subset of agricultural compound that is any substance, mixture of substances or biological compounds that are applied to plants or to land, places or water in which plants or animals are managed for the purpose of managing the animals or plants or to indirectly manage an animal.

Broad spectrum
means controls or is toxic to a wide range of pests or pathogenic organisms when applied correctly.

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 agricultural chemical that is to be marketed or sold. (If the label is read, understood and its directions followed, the likelihood of agricultural chemicals causing an adverse effect is remote.)

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. You must ensure that the primary label is affixed so it cannot become separated from the container.

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 container that is in physical contact with the agricultural chemical (for example, jerry container/can, bag, sachet).

Secondary label
means the label on the packaging in which the primary container is enclosed for sale (for example, the immediate packaging around the bag, sachet).

Water-soluble bag
means bags designed to dissolve on contact with water in the spray tank (for example, bags designed to preclude operator exposure or to ensure the correct quantity is measured).

Withholding period (WHP)
means the minimum period that should elapse between the last application and harvest of a treated commodity before human or animal consumption. This period covers the situations of:

- harvest of the treated crop for human or animal consumption
- grazing of the treated crop or crop residue/stubble

- release of the treated commodity for human or animal consumption
- grazing of surrounding pasture following treatment such as in an orchard.

(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.