

# Labelling Agricultural Chemicals

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## Title

Guidance Document: Labelling Agricultural Chemicals

### About this document

This document explains the information that should be on the label of an agricultural chemical registered in New Zealand under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

### **Related Requirements**

Registration Information Requirements for Agricultural Chemicals

### **Document history**

Version Date	Section Changed	Change(s) Description	
April 2017			
May 2020	All	Change from Requirements to Guidance document Correction of residue statement Addition of 'date of manufacture' requirement Clarification of slaughter interval statement Clarification of application rate presentation for horticultural crops	
September 2020	hber 2020 5.8, 5.9 Additional detail on legibility and permanence of information		
March 2023	All 5.1 5.2 5.2 5.3 5.6.1 5.6.3 5.6.4 5.6.5 5.6.6 5.6.7 5.8.2 5.13.3 (previous) 5.13.3 7(2) 7.1 (2) 7.5	'Must' changed to 'should' throughout Clarification on trade name Additional detail on active ingredient Addition of general label claim Clarification of the general label claim content Additional information on withholding period statements Clarification of clean feed/slaughter interval statements Clean feed/slaughter interval statement for leaf plucking Labelling requirements for crops that are not primary animal feeds Addition of animal feed statement for industrial hemp Impractical WHP or clean feed statements Clarification of date of manufacture Removal of alternative wording section Example provided for other regulatory statements Additional advice on non-ACVM label content Additional advice for changes made as a result of other legislation Reference to websites or social media, including QR codes	

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# 1 Purpose

(1) This document explains the information that should be on the label of an agricultural chemical registered in New Zealand under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

# 2 Background

- (1) Before being imported, manufactured, sold or used in New Zealand, agricultural compounds (including agricultural chemicals) must be authorised under the ACVM Act. 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.

# 3 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 an agricultural compound other than one used or intended to be used in the direct management of animals, and does not include a vertebrate toxic agent

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

**clean feed/slaughter interval** means the time that should elapse between animals consuming plants or plant parts that are treated with an agricultural chemical, and slaughter or collection of animal products (e.g. milk) The animals are to be fed "clean" feed, or feed that has not been treated with or exposed to agricultural chemicals, during the slaughter interval.

**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

**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

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, grazing, or feeding of a treated commodity. 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 and its Regulations have the meaning given to them in the Act and its Regulations.

### 4 Information needed

- (1) The minimum information MPI considers necessary is numbered in each section. Extra guidance is given (without numbers) in boxes as 'Additional guidance'.
- (2) Guidelines reflect principles commonly recognised by the scientific community as appropriate and necessary for collecting scientific data. MPI recognises that there are acceptable methods, other than those described in this guideline, that are capable of achieving the principles of this document.
- (3) Applicants are responsible for providing all information required by MPI to make a decision on the application. Applications that do not contain the required information will not be assessed. If further advice is required, you are advised to contract the services of an appropriate consultant prior to submitting your application.

# 5 Mandatory label information

- (1) All labels should include:
  - a) trade name\*
  - b) active ingredient(s) and quantities\*
  - c) general label claim (see 5.3 (5))\*
  - d) registration number and statement\*
  - e) use claims
  - f) directions for use
  - g) withholding period statements, crop rotation statements and clean feed periods or slaughter intervals (if required)\*
  - h) registrant/New Zealand agent (if different from the registrant) and contact information (name, address [physical, postal, email or website] and New Zealand phone number)\*
  - i) batch number \*\*
  - j) date of manufacture\*\*
  - k) shelf life statement or expiry date (if applicable)
  - I) net contents\*
  - m) storage instructions (only necessary in relation to stability)
  - n) resistance management statement (if applicable)
  - o) regulatory statements and adverse effects, cautions and contraindications.
  - \* Required to be on your primary label

\*\* May be stamped or stencilled onto primary container rather than printed onto the primary label (see 5.8(3))

- (2) For labels of restricted size the following minimum information would be acceptable provided the complete information is conveyed on secondary labels and/or the package leaflet, and the product is not marketed as a separate unit:
  - a) trade name
  - b) active ingredient(s) and quantities
  - c) registration number
  - d) net contents
  - e) general label claim (see 5.3 (5))
  - f) batch number
  - g) expiry date (if applicable) or date of manufacture
  - h) restriction status, if applicable (not common for agricultural chemicals)
  - i) statement referring user to the leaflet, booklet or box for use directions.

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

### 5.1 Trade name

- (1) The full trade name, as specified on the registration application form, should appear clearly in a prominent place, and should be consistent throughout the label.
  - a) The trade name should 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 may be preceded by another word to make it distinctive.

#### Additional 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 Sodium Chloride
  - Sodium Chloride 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 should be consistent with the international coding system for pesticide formulation types.
- e) The use of terms such as 'plus', 'extra', 'extra strength' in the trade name should be justified.
- (2) Ensure the trade name does not impinge on an existing trademark. This may include ensuring that it is not too similar to existing trade names. It is not the responsibility of MPI to check these. MPI will only check the trade name to ensure it is not misleading (see (1)(a) above).
- (3) If you wish to adopt a previously used trade name for a new product, both products should have the same active ingredients (or combinations) and the same formulation type.

### 5.2 Active ingredient(s)

- (1) The names of all active ingredients should appear on the label along with their concentrations and units. The names should 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) Proprietary names for the active ingredient should not be used in place of the ISO or full chemical name in the active ingredient statement or the resistance management statement.
- (3) If a proprietary active ingredient name is used elsewhere on the label, then it should be clearly stated in at least one place on the label that the name refers to the ISO or full chemical name of the active ingredient.
- (4) Units of concentration should be appropriate to the formulation type (for example, g/litre or g/kg).
- (5) When the active ingredient consists of a specific isomeric ratio, this should be included with the active ingredient statement in situations where this is essential information for the user.
- (6) If the active ingredient is present in another form (e.g. as a salt or ester), the label description and concentration should be for the active molecule on which efficacy calculations are made (for example, 400 g/litre phosphorous acid present as the dipotassium salt in the form of a soluble concentrate).
- (7) For biological products, the relevant concentration should be included. If the weight/weight concentration is not directly relevant for use, then this is discretionary (for example, in the statement "contains 146 g/kg dried *Bacillus subtilis* [QST 713 strain] and contains not less than 7.3 x 10<sup>9</sup> cfu/g in the form of a wettable powder"), the "not less than 7.3 x 10<sup>9</sup> cfu/g" is relevant, and the "146 g/kg" is discretionary).
- (8) If a synergist or safener is present in the formulation, the name and concentration of the ingredient should be stated on the label. If included, it should be clearly identified as a synergist or safener and placed after the active ingredient in the active ingredient statement.

### 5.3 Use claim(s)

- (1) All labels should 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.
- (2) Claims on the label should be consistent with the claims approved as part of the registration application. They should not overstate or misrepresent approved claims.
- (3) Labels should 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"). Should it become present in New Zealand, the claim should be removed from the label or a variation application made to approve the pest/disease/parasite/weed.
- (4) Names of pests/diseases/parasites/weeds listed on the label should be those most commonly used in New Zealand. This may the common name or the full scientific (Latin binomial) name, or both, as applicable.
- (5) The general label claim should appear near the 'Trade Name' and 'Active Ingredient(s)' on the front panel of the label as an immediate and concise description of the product's intended use. This should include an indication of the product type, use situation and claims.

#### Additional guidance

Examples of general label claims are:

- "Pre-emergent herbicide for control of some broadleaf weeds in wheat and barley"
- "Fungicide for the control of various diseases in apples, beans, citrus, grapes, kiwifruit, onions, pears and stone fruit"
- "Insecticide for the control of diamondback moth in vegetable brassica, Kelly's citrus thrip in citrus and thrips in onions"
- (6) Use claims should be described in detail in the Directions for Use (see 5.4)

### 5.4 Directions for use

- (1) Directions for use should be simple, clear and concise.
- (2) Directions for use should state how, what, when, and where the product is used.

#### Additional 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) Rates on crops where the volume of water required to obtain good coverage is unlikely to change significantly over the growing season should be presented as the product rate per hectare.
- (4) When applied as a foliar spray on horticultural crops, where the volume of water required to obtain good coverage is likely to change significantly over the growing season, the application rate should be expressed as a dilution rate per 100L water applied to achieve complete coverage to the point of runoff. A minimum or maximum product rate per hectare should not be included in the Directions for Use in these situations.

#### Additional guidance

- Additional guidance can be provided in brief, for example:
  - For concentrate spraying, adjust rate accordingly to achieve the same rate of active ingredient per hectare as the dilute spray.
  - Refer to XXX industry guidance for application rate calculations.
- Any information provided outside the label by the registrant should be consistent with the label in all respects, including the approved dilution rate/100L water.
- Typical water rate ranges can be stated on the label.
- Where a maximum product rate per hectare has been imposed due to other legislation, this may be stated elsewhere on the label.
- (5) Compatibility statements may be added if required.
- (6) If physical stability, such as settling, is an issue, the product label should state appropriate measures to avoid problems with stability (if maintaining stability is a requirement), for example:
  - a) "Shake contents adequately before use."
  - b) "Stir, do not shake."

### 5.5 Registration number and statement

(1) The registration statement, registration number and website address in its entirety should appear on at least **one** component of the labelling:

"Registered pursuant to the ACVM Act 1997, No. Pxxxx See <u>www.foodsafety.govt.nz</u> for registration conditions."

- (2) The registration number should 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) ACVM Registration No. P....
  - b) ACVM No. Pxxxx.....
  - c) ACVM # Pxxxx (on very small containers).

### 5.6 Use statements

### 5.6.1 Withholding period statements

- (1) Withholding periods should appear on the label if a withholding period has been set.
- (2) All withholding period statements should clearly stand out and be separate from the main body of the text.
- (3) The label should include clear instructions for approved uses and the withholding periods necessary to ensure that any maximum residue levels (MRLs) set in New Zealand food standards are not exceeded.
- (4) In the case of products where no MRL applies to the active ingredient (i.e. the active ingredient is exempt from the requirement for an MRL in the NZ food standards), a withholding period is required to reinforce good agricultural practice (GAP).
- (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.

#### Additional guidance

Examples of acceptable withholding period statements are:

- "Do not apply later than (growth stage)."
- "Use only in the (growth stage) period."
- "Not required when used as directed"
- (6) All WHPs should reflect GAP. 'Nil' WHPs should not be used unless it can be justified as GAP.

#### Additional guidance

- By July 2022, all existing products with a nil WHP should have been changed to either 1 day (with no supporting information required), or to an appropriate WHP if this can be justified as Good Agricultural Practice.
- See the NZFS Position Statement '<u>Agricultural Chemicals: 1-day withholding period</u>' for more information
- (7) For a primary animal feed, a WHP specific to animal consumption should be stated on the label. In some situations, a clean feed/slaughter interval may be substituted (see 5.6.2). The <u>Guidance</u> <u>Document: Residue Data for Agricultural Chemicals</u> lists the commodities considered to be primary animal feed.

#### Additional guidance

Examples of acceptable withholding period statements include:

- "Keep livestock away from (crop) for ... days after treatment."
- "Allow X days between last application and introduction of stock for grazing."
- "Silage/green feed: Allow X days between last application and cutting."
- (8) Specific withholding periods for export crops to meet export requirements should not be placed on the label. Instead, a general statement regarding additional restrictions for export crops may be used.

#### Additional guidance

An example of an acceptable statement is:

• "For export crops contact your exporter or industry crop advisor for any specific restrictions."

### 5.6.2 Crop rotation statements

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

#### 5.6.3 Clean Feed/Slaughter intervals

- (1) Clean feed/slaughter interval statements should be positioned together with any Withholding Periods on the label.
- (2) The term 'Withholding Period' should not be used to refer to the slaughter interval or clean feed period. Refer to Section 3 for definitions of these terms.
- (3) Any clean feed or slaughter interval proposed should be consistent with GAP, in terms of timing of applications, harvest, introduction and exit of animals into/out of the treated crop, and common length of time until slaughter.

### Additional guidance

Examples of acceptable clean feed period or slaughter interval statements include:

- "Livestock that have been grazing or fed treated crops should be placed on clean feed for X days prior to slaughter or collection of milk for human consumption."
- "Postharvest vineyard/orchard grazing: Sheep that have grazed in treated orchards should be placed on clean feed for X days prior to slaughter or collection of milk for human consumption."

### 5.6.4 Clean Feed/Slaughter intervals for Leaf Plucking in Vineyards

- (1) The use of sheep for leaf-plucking in vineyards is considered to be a special case. The use of sheep for leaf-plucking occurs while the grapevines are actively growing, and sheep may be present at the time of, or soon after, agricultural chemical application.
- (2) A clean feed period or slaughter interval should be stated on the label for products used in vineyards as the use of sheep for leaf-plucking is an established practice in New Zealand. This statement should be a separate statement to any postharvest grazing slaughter interval/clean feed statement, and positioned together with any other any Withholding Periods and Clean feed/Slaughter intervals on the label.
- (3) For leaf-plucking in vineyards, a 6 month default slaughter interval is applied from the time sheep are removed from the treated area. If sufficient residue and animal metabolism data have been provided to ACVM, this default can be reduced to 2 months. This timing is considered to align with GAP and applies to MRL exempt active ingredients for this reason. Currently only 2 and 6 month slaughter intervals will be accepted. Where there is information to suggest that there is a potential concern even with a 6 month default slaughter interval, grazing may be prohibited. (See the <u>residue guidelines</u> for further information on data required).

#### Additional guidance

An example of an acceptable clean feed period or slaughter interval statement for sheep leaf plucking is:

• "Leaf plucking in vineyards: Sheep must not be sent for slaughter or milked for X months after being removed from the vineyard (and placed on clean feed)."

#### 5.6.5 Labelling requirements for crops that are not primary animal feeds

(4) For crops or plants where treated plant material is not routinely fed to animals; or for products (for example, herbicides) which have approved uses on or around orchards where animals may graze, a

WHP, clean feed/slaughter interval or other label advice may be considered in order for the user to have access to sufficient information to avoid non-compliant residues in animal products.

#### Additional guidance

Inclusion of a postharvest orchard/vineyard grazing WHP is not mandatory. However, if animal consumption on or around treated plants or plant parts occurs at a particular crop timing, such as postharvest grazing in orchards or vineyards, this timing should be clearly specified on the label.

An example of an acceptable withholding period statement for postharvest grazing in vineyards or orchards is:

• "Postharvest vineyard/orchard grazing: Do not graze livestock in the vineyard/orchard for X months after the last application".

#### 5.6.6 Industrial hemp - animal feed restriction

(1) Where a label claim for industrial hemp is approved on a label, a label statement should be added excluding the crop and its products from use as an animal feed. (See <u>ACVM Alert Notification 22-001</u> Industrial Hemp as Agricultural Compounds).

#### 5.6.7 Impractical WHP or clean feed statements

(1) Indefinite WHPs may not be used if the statement is impractical. For example, prevention of animal grazing on treated permanent crop areas, such as orchards or vineyards, is impractical unless a time length or mitigating circumstance is proposed.

#### Additional guidance

For products containing chlorothalonil, which historically had an open-ended 'Do not graze' statement which included orchards and vineyard situations, a reassessment occurred in 2021. Chlorothalonil products can no longer be used on grapes, and the following label statement should now be used:

By law, the following restrictions must be complied with:

As <trade name> contains minute quantities of HCB, a compound that can be taken up by grazing stock to give unacceptable residues in meat and milk, the following restrictions on the use of the product must be observed:

DO NOT graze treated crops; and

DO NOT feed any part of a treated crop to stock.

These two restrictions do not apply if either of the following is undertaken:

CULTIVATE treated areas thoroughly (i.e. do not use direct drilling or other minimum tillage techniques) before sowing pasture or any animal feed crop, or

SOIL TESTING in compliance with the protocol 'Guideline for Management of Sheep Grazing in Vineyards or Orchards Contaminated with Hexachlorobenzene' of the vineyard/orchard area indicates HCB residues are less than 0.001 mg/kg in the soil.

### 5.7 Registrant / New Zealand agent

- (1) The registrant's full name should appear on at least one component of labelling. If the New Zealand agent differs from the registrant, the agent should 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 ..." should appear before the registrant's name to identify the registrant along with contact information: address (physical, postal, email or website) and New Zealand phone number(s).

### 5.8 Batch number / Date of Manufacture

- (1) The batch number 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) The date of manufacture is the date that the formulated product was originally manufactured (not repacked). This should be preceded by "DOM" or other appropriate identification, and should be in a format that can be easily understood by the end user.
- (3) If the batch number and date of manufacture are stamped onto the container, the location and purpose of the stamp should be clear to the end user.
- (4) All ink should be indelible and any sticker specifying the batch number and date of manufacture should be appropriately affixed to the primary label or primary container, so that the information remains in place and is legible throughout the products' shelf-life in the conditions that they are used.
- (5) If the product label is required to state an expiry date, the date of manufacture is not required.

#### Additional guidance

The intent of the batch number requirement is to allow for the traceability of non-conforming batches and/or products back to the place of manufacture, and identification of other units manufactured as part of the same batch.

### 5.9 Shelf life statement/expiry date

#### 5.9.1 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) You can 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."

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, such as ongoing stability testing of retained samples or processes to manage availability of product in the marketplace.

\*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.

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

### 5.9.2 Shelf life of less than 24 months

- (1) If you cannot show 24 months stability, an expiry date should be used in lieu of the shelf life statement. All labels should 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 date, which should be in a format that can be easily understood by the end user, should be preceded by the words "Expiry Date", "Expiry" or the abbreviation "Exp."
- (2) All ink used should be indelible and any sticker specifying the expiry date should be appropriately affixed to the primary label or primary container, so that the information remains in place and is legible throughout the products' shelf-life in the conditions that they are used.

### 5.10 Net contents

(1) Net contents of the product(s) should be stated in metric units, for example:

g (gram) kg (kilogram) mL (millilitre) L (litre) biologicals-- cfu, pfu

(2) This statement should be clear and readable.

#### Additional 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.

### 5.11 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 container closed." "Keep away from light."

### 5.12 Resistance statement

(1) Labels should 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 strategies and MOA groups see the New Zealand Plant Protection Society (NZPPS) website (<u>http://resistance.nzpps.org/</u>). For insecticide resistance, the Insecticide Resistance Action Committee (IRAC) may also be referred to (https://irac-online.org/mode-of-action/classification-online/)

#### Additional 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, or advice which aligns with the International Resistance Action Groups, should be placed on the label.

• For herbicides, in May 2021 the NZPPS decided to move to a new code system that has recently been adopted not only by HRAC but all other countries in the world. All NZ labels should be updated to the new coding system.

### 5.13 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, contraindication, and safety type statements (see Part 5.14).
- (2) Regulatory statements should 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 prevention of off-label use on animals. (A small number of agricultural chemicals may have more conditions.)

#### 5.13.1 Management of residues

(1) For products registered with Condition 83 that have WHP recommendations, place the following statement in bold above the recommended withholding period(s) (Refer to 5.6.1):

"It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds."

#### 5.13.2Use on animals

(1) If Condition 84 is applied, the following regulatory statement should be included in bold immediately above, or with, the directions for use (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 (and the associated condition) on a case by case basis.

#### 5.13.3 Other regulatory statements

 If other regulatory statements, such as not allowing off-label use, are required we will provide guidance on wording. For example, the chlorothalonil label statement referred to in 5.6.6 is required by Condition 6.

#### 5.13.4 Regulatory statements required under other legislation

- (1) Regulatory statements required under other legislation (e.g. HSNO Act) should be presented in line with the recommendations from the relevant authority (e.g. EPA).
- (2) Care should be taken with placement of such statements to ensure that ACVM label content is not impacted.

### 5.14 Adverse effects, cautions and contraindications

(1) Registrants should 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.

# 6 Additional information on other types of packaging

### 6.1 Primary and secondary container labelling

(1) If the product is packaged inside secondary packaging, all label directions should be consistent with those on the primary label.

### 6.1.1 Fold out labels in pouches/plastic sleeves

(1) A portion of this should be fixed directly to the packaging to ensure that the label cannot be separated from the container.

### 6.1.2 Leaflets, booklets and boxes

(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, or directly onto the box that contains the primary packaging. In this case, the leaflet, booklet or box is part of the label.

### 6.2 Water soluble bags or foil sachets

- (1) The information listed below should appear on all water-soluble bags or on the outer foil sachets of each bag:
  - 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 as per advice under 5.5.2)
  - e) net contents.
- (2) Extra statements may be added if desired.

### 6.3 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 should be ACVM approved and should show the following information:
  - a) trade name
  - b) registration number (may be shortened as per advice under 5.5.2)
  - c) net contents
  - d) restriction status, if applicable (not common for agricultural chemicals)
  - e) batch number
  - f) expiry date (if applicable) or date of manufacture

- 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.

### 6.4 Labelling of combined product 'convenience packs'

- (1) Two registered products may be sold in 'convenience packs' without specific ACVM approval if the registered products are sold bound together by outer packaging. Both products should be sold in their registered packs with all approved label text and in full compliance with the conditions of registration. External packaging should contain, at minimum, all relevant information that is required for other types of packaging (see Part 6.2).
- (2) If the external packaging obscures the approved product packaging, including information the consumer needs to see when choosing an appropriate product, this information should be included on the external packaging. The minimum additional information required is a general label claim (see 5.3(5)), batch number and date of manufacture/expiry date, and restriction status, if applicable.
- (3) The external packaging should contain the relevant information for each product packed inside the convenience pack.
- (4) If products are sold together as an active and diluent, both items of packaging should have the appropriate information relating to the registration.

# 7 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 or patents).

#### Additional guidance

- ACVM will not review non-ACVM legislative requirements. It is the responsibility of the registrant to ensure the label complies with other legislation such as the HSNO Act. However, if changes are made as a result of other legislation, these should be notified to ACVM (see 7.1(3) for timeframe and additional guidance).
- Descriptions or statements for marketing purposes, such as "natural" or "organic", should be truthful under consumer protection legislation. Legitimacy will not be checked by ACVM. However, you are likely to be required to justify statements which may impact on ACVM risk areas, for example purity of active ingredient or where it may impact prudent use of the product.

### 7.1 Timeframes

- (1) If label changes are required as a result of an approved variation application for a specific trade name product, it is expected that these changes will be made to the marketed label at the next label reprint or within the next 12 months, whichever comes first, unless advice has been provided to the contrary by ACVM. Alternative timeframes will be considered on a case-by-case basis.
- (2) Label changes which are required due to review of ACVM policy or guidance, which are not the result of an approved variation application for a specific trade name product, should be made at the next variation/registration renewal application unless otherwise directed.

(3) If changes are made to non-ACVM label content (for example as a result of other legislation or for marketing or commercial purposes) these can be updated on the marketed label. These self-assessed changes can be notified to ACVM immediately and the amended label uploaded to the website, or included in the next variation/registration renewal.

### Additional guidance

- To notify self-assessed non-ACVM label content changes to ACVM, provide the following:
  - Amended copy of the label with changes highlighted;
  - Clean copy of the amended label (to be uploaded to the ACVM web register); and
  - Confirmation that you have assessed that the changes do not impact or contradict ACVM label content.
- Note that the registration expiry date will remain unchanged as a result of a notification.
- Time for administration of this will be charged.
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### 7.2 Graphics

- (1) Graphics may be included on labels but should not interfere with the legibility of the text.
- (2) Pictures or illustrations should not depict or imply usage contrary to the current approval. For instance, you may not include pictures of grapes if the product is only approved for onions.

# 7.3 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.

# 7.4 Reprinting

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

### 7.5 Reference to Websites or Social Media, including QR codes

- (1) For products where the label references any other publications e.g. websites and social media (including Facebook and other web-related media), the content should be consistent with the approved label claims and registration conditions. For further guidance, please consult the <u>"Advertising</u> guidelines for products authorised under the ACVM Act" May 2021.
- (2) QR codes and similar technologies
  - a) Registrants can add QR Codes or similar technologies to labels at their own discretion.
  - b) The information provided in the link should be useful for the end user.
  - c) The inclusion of a QR code or similar type technologies should not obscure or affect the legibility of the existing information approved for the packaging.
  - d) Information which is required to be on the label (as per this labelling guidance) cannot be replaced by use of a QR code or similar type technologies.
- (3) It is the responsibility of the registrant to ensure the information being linked to complies with 7.5 (1) and (2) above. There will be no verification by ACVM.