



# Guidance Document

## Labelling Agricultural Chemicals

10 September 2020

## Title

Guidance Document: Labelling Agricultural Chemicals

## About this document

This document explains the information that must 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	5.8, 5.9	Additional detail on legibility and permanence of information

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## 1 Purpose

- (1) This document explains the information that must 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. 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.

## 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

**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 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 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 must include:
- a) trade name\*
  - b) active ingredient(s) and quantities\*
  - c) use claims
  - d) directions for use
  - e) registration number and statement\*
  - f) withholding period statements, crop rotation statements and clean feed periods or slaughter intervals (if required)
  - g) registrant/New Zealand agent (if different from the registrant) and contact information (name, address [physical, postal, email or website] and New Zealand phone number)\*
  - h) batch number \*\*
  - i) date of manufacture\*\*
  - j) shelf life statement or expiry date (if applicable)
  - k) net contents\*
  - l) storage instructions (only necessary in relation to stability)
  - m) resistance management statement (if applicable)
  - n) 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) withholding period(s), if applicable
- 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, 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.

### 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 must be consistent with the international coding system for pesticide formulation types.
- (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 must have the same active ingredients (or combinations) and the same formulation type.

## 5.2 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, g/litre or g/kg).
- (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, 400g/litre phosphorous acid as the dipotassium salt in the form of a soluble concentrate).

- (4) For biological products, the relevant concentration must be included. If the weight/weight concentration is not directly relevant for use, then this is discretionary (for example, in the statement “contains 146g/kg dried *Bacillus subtilis* [QST 713 strain] and contains not less than  $7.3 \times 10^9$  cfu/g in the form of a wettable powder”), the “not less than  $7.3 \times 10^9$  cfu/g” is relevant, and the “146 g/kg” is discretionary).

### 5.3 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”). Should such it become present in New Zealand, the claim must be removed from the label or a variation application made to approve the pest/disease/parasite/weed.

### 5.4 Directions for use

- (1) Directions for use must be simple, clear and concise.
- (2) Directions for use must 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 must be expressed as a dilution rate per 100L water to the point of runoff.

#### 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 must 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.

- (5) Compatibility statements may be added if desired.
- (6) 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."

## 5.5 Registration number and statement

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

"Registered pursuant to the ACVM Act 1997, No. Pxxxx  
See [www.foodsafety.govt.nz](http://www.foodsafety.govt.nz) for registration conditions."
- (2) 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) 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 must appear on all labelling (primary, secondary and leaflet) if a withholding period has been set.
- (2) All withholding period statements must clearly stand out and be separate from the main body of the text.
- (3) The label must 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 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.
- (5) 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. See the Guidance Document: Residue Data for Agricultural Chemicals for commodities considered to be primary animal feed.
- (6) Specific withholding periods for export crops to meet export requirements must not be placed on the label in addition to WHPs to support New Zealand Good Agricultural Practice. Instead, a general statement regarding additional restrictions for export crops may be used.

#### **Additional 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."
- "Allow X days between last application and introduction of stock for grazing."
- "Silage/green feed: Allow X days between last application and cutting."
- "For export crops contact your exporter or industry crop advisor for any specific restrictions."

### 5.6.2 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”).

### 5.6.3 Clean Feed/Slaughter intervals

- (1) The clean feed period or slaughter interval is 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).
- (2) Clean feed periods or slaughter interval statements will be considered on a case by case/product by product basis. For more information on your particular product, contact us at [approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz).
- (3) A clean feed period or slaughter interval must be stated on the label for products used in vineyards after dormancy as the use of sheep for leaf-plucking is an established practice in New Zealand. For leaf-plucking in vineyards, a 6 month default slaughter interval is applied. If sufficient residue and animal metabolism data have been provided to ACVM, this default can be reduced to 2 months. Currently, for products requiring an MRL, only 2 and 6 month default periods 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 [residue guidelines](#) for further information on data required).

#### 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 months prior to slaughter or collection of milk for human consumption.”
- “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).”

## 5.7 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: address (physical, postal, email or website) and New Zealand phone number(s).
- (3) If a website is included, you must ensure that all information relating to the TNP is compatible with the approved label claims and registration conditions.

## 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 manufactured. 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, this should be a clearly noted step in the manufacturing specifications. The label should include the headings and direction to the location of the stamp, e.g. "See bottom of pack", if the location and/or purpose of the stamp is not obvious to an end user.
- (4) All ink must be indelible and any sticker specifying the batch number and date of manufacture must 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.

\*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 must 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 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. 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 must be indelible and any sticker specifying the expiry date must 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) must be stated in metric units, for example:  
g (gram)

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

- (2) This statement must 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

- (1) 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 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 strategies and MOA groups see the New Zealand Plant Protection Society (NZPPS) website (<http://resistance.nzpps.org/>).

**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.

## 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, contra-indication, and safety type statements (see Part 5.14).
- (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 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). For products with no WHP requirements, include the statement in bold immediately above or with the directions for use:

**“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.”**

### 5.13.2 Use on animals

- (1) If Condition 84 is applied, the following regulatory statement must 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 Alternative wording

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

### 5.13.4 Other regulatory statements

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

### 5.13.5 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 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.

## 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 must be consistent with those on the primary label.

#### 6.1.1 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.

#### 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 must 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 must be ACVM approved and must 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

- (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 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 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 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.

## 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 must be notified to ACVM.

### 7.1 Timeframes

- (1) Label changes which are required due to review of ACVM policy or guidance must be made at the next variation application unless otherwise directed.

### Additional guidance

- If label changes are required as a result of an approved variation application for a specific trade name product, it is generally accepted that these changes will be made 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.

### 7.2 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. 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.