

## Obligations under the ACVM Regulations

**Statutory obligations for agricultural compounds exempt from registration under the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011**

ACVM guideline (July 2020)

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### 1. Introduction

Even if your agricultural compound is exempt from registration under the ACVM Regulations, you must comply with statutory obligations when you import, manufacture, sell or use the product in New Zealand. Each of these activities has specific obligations (see below), but your basic responsibility is to be sure that your product:

- is fit for its intended purpose
- conforms to its specifications, and
- is represented truthfully and accurately.

You have a legal obligation to know your product and to be open and truthful about potential harm your product could cause.

[Agricultural Compounds and Veterinary Medicines \(Exemptions and Prohibited Substances\) Regulations 2011](#)

### 2. 'Fit for intended purpose'

'Fit for intended purpose' means that your product, when used as intended, will not:

- spread organisms to a level or in a manner that could be harmful to humans
- reduce the efficacy of medicines used on humans

- result in residues in primary produce that exceed the limits prescribed in applicable food residue standards set in or under any enactment
- be toxic to animals treated with or exposed to the compound to an extent that causes unnecessary or unreasonable pain or distress
- fail to reduce or eliminate pain or distress to animals treated with the compound where the elimination of pain or distress is a stated purpose of the product
- transmit disease, result in physical harm, or cause unnecessary pain and distress, to animals treated with or exposed to the compound
- transmit pests or unwanted organisms as defined in the Biosecurity Act 1993 or specified in any national or regional pest management plan made under that Act
- otherwise create or be likely to create any of the risks specified in section 4(a) of the Act (risks to public health, trade in primary produce, animal welfare and agricultural security).

(ref: ACVM [Exemptions and Prohibited Substances] Regulations 2011, Regulation 7)

## **Know your product**

You must know your product well enough to be confident (and have supporting evidence) that your product will not cause any of the harms listed above<sup>1</sup>. You must know what is in your product, how it is made and how you intend it to be used. You must make sure that it always is what you think it is (that is, it conforms to its specifications and is free from harmful contamination).

The obligation to know your product and assess its risk is yours. You cannot argue that you did not know what was in the product or that it was not manufactured properly or that it would cause one of the harms listed.

If something goes wrong, your compliance with the Regulations will be measured by your evidence of the care you took to know your product and analyse the potential risks as well as by the magnitude and predictability of the harm caused.

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<sup>1</sup> Note that the harm occurs when your product is used but your risk analysis has to look at where and when the hazard that could cause that harm was introduced (such as present in the product when imported or introduced during manufacturing).

### 3. Importing

#### Importing an agricultural compound as a finished product

The following requirements are relevant if you have purchased the product overseas or contracted someone overseas to manufacture the product for you. The imported product must be in its final form and packaging and have the label that will be used in New Zealand. If this is not the case, and you intend to modify the product in any way (formulation, packaging or labelling), you will be manufacturing and you should refer to the manufacturing section below.

#### Fit for intended purpose

For a finished product, you must ensure that the product is fit for its intended purpose (ref: Regulation 7). You must know enough about the product to be able to assess the relevant risks. If you do not know what is in the product or how it was manufactured, you may not be able to meet your statutory obligations. If you do not have first-hand knowledge of these matters, you may be able to rely on (and have evidence of) the regulatory status of the product in its country of origin. However, be warned that if the regulatory requirements in the country of origin are not equivalent to those in New Zealand, the regulatory status may not be acceptable proof that you have taken due care.

#### Record keeping

You must keep the following records in relation to the product you import:

- the name and contact details of the overseas manufacturer of the product
- the batch numbers for the imported consignment
- the name or description under which the product will be sold in New Zealand.

(ref: Regulation 15)

#### Labelling

The label of the product must include the following information:

- a description of the product or preparation sufficient to enable the user to determine the nature and purpose of it
- the name and contact details of the manufacturer or importer
- the active ingredients
- directions for use
- use-by date or expiry date, if applicable
- details of precautions (if any) to be taken to prevent or manage the relevant ACVM risks when using the product or preparation

- in the case of an exempt compound product only, the batch number or other information sufficient to allow the date and place of manufacture or preparation to be ascertained
- any other information specified in Schedule 2 in relation to your particular product type.

(ref: Regulation 12)

## **Importing unfinished agricultural compounds**

If you are importing an agricultural compound that is not a finished product (such as components or ingredients whether or not they are finished products in their own right or products that require further processing or repackaging/relabelling), refer to the section on manufacturing below.

If you have to modify the label to meet the requirements in Regulation 12, you will be manufacturing. Refer to the next section.

## **4. Manufacturing**

The following requirements are relevant if you are manufacturing the product in New Zealand or if you are modifying a product you have imported. (Manufacturing includes all the steps from setting the specifications for a product through its preparation, packaging and labelling.)

### **Fit for purpose**

When setting the specifications for your product, you must ensure that the product you are manufacturing is fit for its intended purpose (ref: Regulation 7). You must consider the formulation and manufacturing process from a risk analysis perspective and ensure that your product is not likely to cause any of the harms listed in Regulation 7. Then you must ensure that your product always conforms to the final product specifications and the way you manufacture it complies with the final manufacturing specifications.

For agricultural compounds that are exempt from registration, New Zealand Food Safety (NZFS) does not approve or even examine your product and manufacturing specifications. It is your responsibility to set specifications conscientiously and comply with them so that your product is fit for its intended purpose.

### **Documented system**

You must have evidence that you are taking due care to meet your product and manufacturing specifications. Regulation 9 requires your product to be manufactured in accordance with a documented system. The documented system must contain the following:

- the specifications for the product, specific processes to be followed, and requirements to be met that are sufficient to ensure that the product, when used as recommended, complies with the conditions of exemption applicable to the product

- the formulation or recipe of the product
- a description of the manufacturing process
- the name or description under which the product will be sold in New Zealand
- a description or illustration of any packaging and labelling specifications for the product
- a nominated person or persons to monitor compliance with the requirements of the documented system
- any other matter relevant to the manufacture of the product that is specified by the Director-General (of MPI).

### **Record keeping**

The documented system and the records you keep while monitoring the manufacturing process is your evidence of taking due care when manufacturing your product. Therefore, Regulation 14 requires that the documented system be recorded or otherwise maintained so that its content is readily accessible and retrievable at any time.

Your documented system will not be approved or even reviewed by NZFS unless there are suspicions or allegations that you are not complying with the Regulations.

With regard to the product and manufacturing specifications for your product, you must keep records of how the specific processes are applied and how required steps are taken.

If you must modify an imported product to comply with the Regulations, that modification is considered manufacturing and you must have a documented system that covers the modifications. You must also carry out the work in accordance with that documented system. The documented system must contain the same information as above to cover any modifications you are making that affect the fitness of the product. The documented system does not have to detail the manufacturing steps that were carried out by the overseas manufacturer.

### **Label**

The label on your product must include:

- the name (if any) under which it is sold or supplied
- a description of the product or preparation sufficient to enable the user to determine the nature and purpose of it
- the name and contact details of the manufacturer or importer
- the active ingredients
- directions for use

- use-by date or expiry date, if applicable
- details of precautions (if any) to be taken to prevent or manage the risks of harms as listed in Regulation 7 when using the product or preparation
- the batch number or other information sufficient to allow the date and place of manufacture or preparation to be ascertained
- any other information specified in Schedule 2 in relation to your kind of product.

(ref: Regulation 12)

## Compounded veterinary preparations

A veterinarian preparing one-off medications<sup>2</sup> to treat animals under his or her care is a special case and is governed by its own exemption from registration (ref: entry 10 in Schedule 2 of the Regulations<sup>3</sup>).

If you are a veterinarian compounding your own preparation for use on animals, or directing a third party to manufacture the preparation according to your instructions, you must ensure that it is fit for its intended purpose and it must be made in accordance with a documented system covering that activity. You are responsible for the documented system. It will not be approved or even reviewed by NZFS unless there are suspicions or allegations that you are not complying with the Regulations. The basic obligations are the same as above, but the documentation will focus exclusively on the preparation process rather than on a more extensive manufacturing process for a commercial over-the-counter veterinary medicine. For example, your labelling specification might be quite different because you will be dispensing the preparation only after personally discussing the use of the product with your client.

Nevertheless, the documented system must contain at least:

- a statement of the purpose of the preparation
- a description of the preparation that is supplied to users
- the formulation or recipe of the preparation
- a description of the compounding process that is sufficient to ensure that the preparation, when used as recommended:

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<sup>2</sup> This special case does not allow veterinarians to prepare medications to be sold as unrestricted veterinary medicines over-the-counter without a veterinary consultation.

<sup>3</sup> The condition is quite specific to you as a veterinarian and prevents you from using this exemption to produce a commercial over-the-counter veterinary medicine.

- (i) complies with the conditions of exemption applicable to the preparation under these Regulations, and
  - (ii) is fit for its stated purpose
- a description or illustration of packaging and labelling requirements (if any<sup>4</sup>) for the preparation
  - a nominated person or persons to monitor compliance with the requirements of the documented system (which must be, or include, you as the compounding veterinarian)
  - any other matter relevant to the manufacture of the product that is specified by the Director-General (of MPI).

You must keep records of:

- the application of the specific processes, and taking of required steps, identified in your documented system
- the date and place the preparation was prepared.

(ref: Regulation 14)

## 5. Selling

If you are not involved in importation or manufacture of a product but are a wholesaler/retailer or provider of other services that may include the sale of the product, you still must be confident that the product is fit for purpose (ref: Regulation 7). Unless you have reasons to suspect otherwise (or that the product seems to have deteriorated or been altered), it is reasonable for you to assume that other parties have complied with their statutory obligations before they sold the product to you.

However, if you offer the product for sale for any purpose outside the scope of the exemption under which it was imported or manufactured, you may invalidate the exemption. No advertisement or label may include any comment, reference, or explanation in relation to the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, proportion, ingredients, or components of the product or preparation, or its effectiveness for any particular purpose, that is inconsistent with the conditions to which that product or preparation is subject under the Regulations (ref: Regulation 13). This means that you must not say anything that is inconsistent with the scope of the exemption under which the product was imported or manufactured.

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<sup>4</sup> You are required to label the product only if you are sending the preparation with your client expecting them to administer it some time when you are not present. It is essential that the critical information stays with the product (such as a stick-on label) so that the actions of your client do not undermine your risk management.

## 6. Using

If you are not involved in importing, manufacturing, or selling a product, the only obligations you have relate to how you use it (ref: Regulation 8).

You must be sure that you use it as it was intended and be confident that it is still fit for purpose (ref: Regulation 7). Unless you have reasons to suspect otherwise (or that the product seems to have deteriorated or been altered), it is reasonable for you to assume that other parties have complied with their statutory obligations before they sold the product to you.

If you use it for any purpose outside the scope of the exemption under which it was imported or manufactured or sold to you, you may invalidate the exemption.

For more information, contact us ([approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz)).