Advertising and own use guidance for compounds for management of disease in beehives

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Title

Guidance Document: Advertising and own use guidance for compounds for management of disease in beehives

About this document

This document is intended to provide some basic guidance for beekeepers on the topics of:

- (1) advertising requirements for compounds intended to treat diseases in beehives; and
- (2) the compounding of substances for their own use.

Related Requirements

ACVM Registration Information Requirements for Agricultural Chemicals in New Zealand

Document history

Version Date	Sections changed	Change(s) Description	
November 2019		New document	

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1 Purpose

- (1) This document is intended to provide some basic guidance for beekeepers on the topics of:
 - advertising requirements for compounds intended to treat diseases in beehives; and
 - b) the compounding of substances for their own use.

2 Background

- (1) The importation, manufacture, sale or use of agricultural compounds in New Zealand is governed by the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). The purpose of the ACVM Act is to prevent or manage risks associated with agricultural compound use. These risks are risks to:
 - a) public health;
 - b) trade in primary produce;
 - c) animal welfare; and
 - d) agricultural security.
- (2) The ACVM Act also ensures residues in food comply with domestic residue standards. The ACVM Act achieves this purpose by providing that no agricultural compound may be used in New Zealand unless authorised under the ACVM Act.
- (3) An agricultural compound covers any substance (chemical or biological) used to manage directly (or indirectly) plants and animals for a range of specified purposes. It does include post-harvest use. Examples include agricultural chemicals, veterinary medicines, fertilisers, and feed for animals. The term 'agricultural compound' has a specific definition detailed in the ACVM Act.
- (4) Whether a product fits within the scope of an agricultural compound is made on a case-by-case basis depending on the usage and/or purpose of the product. If it does fit, then it would be considered an agricultural compound and subject to the requirements of the ACVM Act.
- (5) A product that is intended to control any pathogen of honey bees fits the definition of agricultural compound and must be authorised under the ACVM Act. This includes common diseases and parasites such as: *Varroa destructor, Nosema* spp. as well as viral and bacterial infections. In the case of agricultural compounds intended for use to control pathogens of honey bees, authorisation for use is usually through:
 - a) registration of a product; or
 - b) the own use exemption under Schedule 2 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 (the ACVM (E&PS) Regulations).
- (6) A product that is exempt from registration is still subject to the ACVM Act and there are requirements under the ACVM (E&PS) Regulations that importers, manufacturers, retailers and end users must follow.
- (7) Products that are registered under the ACVM Act have been assessed to ensure they are manufactured reliably, are efficacious (including management of resistance) and safe. Further, registration means that agricultural chemical residues in honey, when used according to label instructions, will comply with legislated limits. This level of regulatory oversight is not present if a beekeeper chooses to use a compound for their own use. In that situation the beekeeper is responsible for managing the risks associated with compounds they have prepared. If beekeepers do not manage the risks, then they could be subject to compliance action under the ACVM Act and its related legislation.
- (8) This document is intended to provide some basic guidance for beekeepers on the topics of:

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- a) advertising requirements for compounds intended to treat diseases in beehives; and
- b) the compounding of substances for their own use.

The document has been written to address specific issues that commonly arise around these two topics, which should assist beekeepers in complying with the rules. It does not replace other ACVM-related legislation or information requirements. Beekeepers may have responsibilities under other legislation such as the Food Act 2014 or Hazardous Substances and New Organisms Act 1996.

3 Advertising of products

3.1 Claims

- (1) Advertising of product that makes a claim fitting the definition of an agricultural compound is only allowed if the product is either registered or complies with an exemption from registration category.
- (2) If the product is registered, it can be advertised. However, it cannot be advertised until it is registered.
- (3) Advertising must be limited to those claims on the approved label as part of the registration.
- (4) The above requirements also apply to advertising of a product that complies with an exemption from registration category. However, there is an important exception to this. Advertising of a product (or compound) that complies with the own use exemption is not permitted. This is because as soon as a person advertises this, the product (or compound) no longer complies with the own use exemption. For more details, see section 4 below on own use.

3.1.1 Examples of claims that are not permitted without registration

- (1) Claims made to control the following pathogens and parasites are not permitted unless the product is registered. This list is intended to provide examples only and is not exhaustive.
 - a) Varroa destructor: This pest is an ectoparasite of honey bees and is the key vector for transmitting Deformed wing virus. There are several products registered in New Zealand for the treatment of Varroa.
 - b) Nosema spp: These pests are microsporidian pathogens that affect honey bees. At the time of writing, two species of Nosema are confirmed to be present in New Zealand. There are no products currently registered for the treatment of Nosema in New Zealand.
 - c) **Viruses**: Many different viruses have been detected in honeybees. There are no products currently registered in New Zealand to treat viral infections of honey bees.
 - d) **Bacteria**: Many different bacteria are associated with honeybees. Some of these bacteria are pathogenic. There are no products currently registered in New Zealand to treat bacterial infections of honeybees.

3.1.2 Testimonials

- (1) Testimonials are a form of advertising. Therefore, use of testimonials for product that infer or make statements that the product manages a disease for bees is not acceptable unless the product is registered. For example, the following statements would be prohibited:
 - a) "The product controls Varroa."
 - b) "It's a great treatment for Nosema."
 - c) "There were no more deformed wings."
- (2) The ACVM team does not provide an advertising checking service. For further information on advertising, please see our advertising guidance document.

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4 Own use exemption

- (1) Schedule 2 of the ACVM (Exemptions and Prohibited Substances) Regulations 2011 provides for an exemption from registration under the ACVM Act referred to as the 'own use' exemption. The exemption applies to a substance or compound prepared by a person for use on animals or plants that they own, or on any land, place or water that they own or occupy.
- (2) In a beekeeping context, the 'own use' exemption is commonly used when a beekeeper prepares and applies preparations containing generic substances, such as oxalic acid or formic acid, to their own hives for control of *Varroa* mites.
- (3) For the purposes of this exemption, it is important to note that:
 - The substance or compound must not be sold. Sale under the ACVM Act includes gifting.
 - b) The product must still be fit for purpose under the ACVM (E&PS) Regulations. The term 'fit for purpose' has a specific meaning under the ACVM (E&PS) Regulations. The elements of the definition that are most relevant to beekeepers are that the product should not:
 - i) reduce the efficacy of medicines used on humans;
 - ii) 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;
 - iv) transmit disease, result in physical harm, or cause unnecessary pain and distress, to animals treated with or exposed to the compound;
 - v) 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; or
 - vi) otherwise create or be likely to create any of the risks specified in section 4(a) of the ACVM Act.
- (4) It is the responsibility of the person using the compound to ensure its use complies with the fit for purpose and any other requirement under the ACVM (E&PS) Regulations. Part of this responsibility is that users have a good understanding of the compound and measures in place to ensure it remains fit for purpose when used. If this responsibility cannot be complied with, then the compound should not be used.
- (5) Failure to comply with any requirement under these ACVM Act or its Regulations, could lead to an investigation and potentially compliance action.

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