



SEPARATING OFF PORTIONS OF REGISTERED TRADE NAME PRODUCTS POLICY

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Approval

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ACVM GROUP OPERATIONAL POLICY SEPARATING OFF PORTIONS OF REGISTERED TRADE NAME PRODUCTS

1 INTRODUCTION

This policy provides a basis for separating off registered trade name product in portions less than that contained in the packaging approved for sale. It relates to the practice of opening the ACVM-approved container of a trade name product and removing only a portion of the content into a different container, possibly with different label information, for immediate use or to supply to another person.

2 PURPOSE OF POLICY

This policy provides guidance to the ACVM Group when:

- assessing products for registration that may be separated off and on-sold or supplied to other persons;
- giving advice to persons inquiring about their legal obligation in regard to separating off portions of products; or
- investigating suspicions or allegation of non-compliance to conditions of registration.

3 BACKGROUND

Two of the considerations in the assessment and registration of an agricultural compound or veterinary medicine trade name product are the container or packaging in which the product will be offered for sale and the labelling of the product. Breaching the original container/packaging and removing a portion of the product could result in significant changes in the product. It could also separate that portion from the information that must be provided with the product. Consequently, both the container/package and label are tools used to manage risks and are integral components of the ACVM approval for the product.

To avoid confusion about the possible terms such as decanting, separating, dispensing, etc. that could be used to describe the breaching of a container and removal of a portion, the ACVM Group will use the general term 'separating off' no matter what the physical state or formulation type is.

This policy relates to separating off product into volumes or quantities that are different from those specified in the ACVM approval for the product and for which the container or packaging approved for general sale is breached. It does not refer to breaking down shipments or palletes of products when the integrity of packages approved for general sale is not breached.

While there may be circumstances in which separating off portions of products may be appropriate, doing so may nullify the relevance of the registration approval.

The following are the rules of acceptable practice governing the separating off of portions of registered agricultural compound and veterinary medicine trade name products.

4 OPERATIONAL POLICY

4.1 General

It is a breach of the ACVM Act (section 8) to offer for sale any product that is not registered or exempt from registration. Separating off portions of proprietary products into different containers with different label information alters characteristics of a registered product and, consequently, may nullify the relevance of the registration. Therefore, sale of only a portion of a registered product may be a breach of the ACVM Act.

There are no limitations under the ACVM Act on the separating off of portions of products that are exempt from registration. This may not be the case in regard to the requirements for such products under relevant HSNO approvals.

4.2 Acceptable practices after purchase of registered products

4.2.1 After purchase by a person

Once the purchaser of a registered trade name product takes possession of the product the purchaser is responsible for the appropriate care and use of that product, including any subsequent separating off of portions of the product. Separating off portions of the product by the owner of the product in any manner is not an offence under the ACVM Act as long as the result is not offered for sale. However, it may be an offence under some other legislation such as the Hazardous Substances and New Organisms Act 1996.

4.2.2 After purchase by a group

If a product is purchased by a group of persons, each person in the group is considered by the ACVM Group to be an owner of the product and they can manage the care and use of that product as they see fit.

4.2.3 After purchase by a contractor or service provider

Agricultural contractors (including chemical application contractors or dipping/tailing/shearing contractors, farm management services, pest control contractors, etc) and service providers may separate off portions of registered trade name products in the course of providing their services. Contractors must not sell separated off portions of trade name products separately from their services (i.e. sell portions of the products they are using to any other person, including the person who contracted them). Selling leftover quantities (i.e. surplus to the actual contract service requirements) that are still in the original container with the original label information can be supplied. These rules apply as well in a contractor/subcontractor arrangement, as in the supply of pest control services.

Whether an individual person or a group or a contractor is involved in the management of the product, the management of the product should be consistent with Standards New Zealand Standard P8409 *Management of Agri-chemicals*.

4.3 Acceptable sales practices

Separating off portions of product into different containers with different labels for sale or supply could be selling or supplying an unregistered product and that would be a breach of the ACVM Act. Separated off portions are also still subject to the requirements of the relevant approvals under the HSNO Act and separating off portions may lead to breaches under that Act. There are only specific circumstances under which supply of separated off portions of products would still comply with regulatory requirements.

4.3.1 Provision for separating off portions as part of registration

Where separating of portions of a product and subsequent sale was anticipated and provided for in the registration of a product, then the practice is not a breach of the ACV Act, as long as it is carried out in accordance with the approved instructions for the product. The registration will specify what the minimum requirements (re containers, labels and management of the process) are for the product. Persons doing this must still comply with any HSNO approval requirements as well.

If separating off portions was not provided for in the registration, then it must not be carried out and the results offered for sale. Traders in registered products should stock products in appropriate container/packaging sizes to meet their customers' needs. Traders should recommend appropriate alternatives for over-the-counter products if certain products are not marketed in convenient sizes. Traders must not recommend alternatives for PAR veterinary medicines prescribed by a veterinarian.

4.3.2 Provision of separating off portions of veterinary medicines by a veterinarian or under the direction of a veterinarian

As a service provider, a veterinarian who determines that, for the health and welfare of the animals concerned, a specific quantity (less than the total quantity in an approved package size) of a registered veterinary medicine is required, that veterinarian may separate off a portion of any registered veterinary medicine trade name product and sell/supply the required amount. If this is done, the veterinarian must take full responsibility for the appropriate packaging and labelling of the product supplied to ensure that:

- the quality of the product is not jeopardised;
- the container packaging is safe and appropriate;
- sufficient information is provided to allow the product to be used according to the veterinarian's instructions and complies with both the ACVM Registration and HSNO approval requirements; and
- the veterinarian's and/or veterinary practice's name and contact information are included.

Veterinarians must not offer for general sale separated off portions of registered products. Those portions offered for sales are trade name products in their own right and require registration.

Traders in animal remedy veterinary medicines may (but are not obliged to) separate off a portion of a registered product under the instructions of a veterinarian. However, in doing so the trader must always follow exactly the instructions of the prescribing veterinarian, including instructions about appropriate packaging and labelling. If some aspect is uncertain or might require variation from those instructions, this must be discussed with and endorsed by the directing veterinarian.