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ACVM STANDARD FOR VERTEBRATE TOXIC AGENTS

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Endorsement:
Date:

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ACVM STANDARD FOR
VERTEBRATE TOXIC AGENTS

1 INTRODUCTION

1.1 Scope

This standard covers the requirements for vertebrate toxic agents (VTAs). VTAs include a number of active ingredients, each in a range of trade name products. Some of the active ingredients can be purchased as generic chemicals as well. For the most part regulatory control is focused on trade name products containing these active ingredients.

This standard provides the requirements for import, manufacture, sale and use of VTAs under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. A more detailed explanation of VTA products is provided in section 1.3.

Vertebrate toxic agents are also regulated under the Hazardous Substances and New Organisms (HSNO) Act 1996. There may be controls imposed under that Act that are the same as the conditions imposed under the ACVM Act. While this may seem redundant, it is essential that ACVM requirements are specifically stated to ensure that regulatory action can be taken under the ACVM Act.

1.2 Definitions specific to this standard
(for general ACVM terms see the Glossary)

Approval
Means approval by the ACVM Group of the New Zealand Food Safety Authority.

Breaking down and repackaging
To adjust the size, volume, number or weight of an agricultural compound trade name product and to place into an alternative package or container (should also have an alternative label).

Product specific approval
That part of an ACVM registration of a vertebrate toxic agent trade name product that specifies the particular use requirements for that product, in regard to notification, posting signage, establishing control, controlling re-entry etc.

Vertebrate toxic agent
A toxic substance used to kill or reduce the viability of vertebrate animals. It does not include attractant or repellent substances that are not toxic.

1.3 Subgroups of vertebrate toxic agents

This standard relates to vertebrate toxic agents as generic active ingredients as well as to those that are registered trade name products. The products are used to kill or reduce the viability of vertebrate animals. Vertebrate toxic agents do not include:

- attractants or repellents that are not toxic;
- products such as insecticides that are intended to kill invertebrates.

Conditions of registration applied to VTA trade name products relate to the degree of regulatory control required to manage the risks associated with them. Factors that influence the conditions applied are the:

- inherent safety or danger of the formulation;
- safety of its packaging;
- simplicity or complexity of use instructions, or extenuating circumstances affecting safe use;
- opportunity and likelihood of diversion or use outside the approved label use(s);
- potential for inadvertent exposure with consequential violative residues or pain or distress in coincidentally exposed animals (i.e. off-target exposure);
- need for public knowledge of where and when the products are to be used; and
- need to be able to trace product from manufacture through to use.

In all cases VTA products are carefully assessed for their effectiveness in killing animals in as humane a manner as possible. It cannot be assumed that their effect on different species of animals will be the same. Therefore, all VTA products must be used only as approved.

Products can be loosely categorised into three groups:

- unrestricted sale and use products;
- restricted sale products; and
- restricted sale and use products.

1.3.1 Unrestricted sale and use VTA products

These VTA products (commonly called over-the-counter or OTC) are considered to be safe for use by any person as long as:

- they are manufactured in accordance with the *ACVM Registration Standard and Guideline for the Chemistry of Vertebrate Toxic Agents* and the *ACVM Standard for Good Manufacturing Practice;*
- they conform to manufacturing specifications, and
- their use is restricted to label instructions for domestic or non-commercial use.

This means that the products are packaged and provided with label information sufficient to ensure that they can be used safely and appropriately without any additional instruction or supervision.

Off-label use by any person on species, or in ways, other than the ones for which the

product was registered is prohibited. There would be no restriction on their sale and no expectation that they would have to be traced through the wholesale/retail trade. There would be no notification requirements before or during use or any requirement to place signage in areas where the products are used.

For the most part the group contains poisons used in small quantities for domestic, non-commercial pest control purposes. However, there may be a few commercial pest control products that are:

- sufficiently safe and simple to use;
- complete in their label information to allow them to be used correctly without any additional guidance at the time of purchase; and
- require no notification, traceback capability or use restrictions.

1.3.2 Restricted sale VTA products

These are products that, in addition to compliance with the ACVM standards for good manufacturing practice and conformance with the chemistry and manufacturing specifications, require:

- additional instruction or advice (over and above the label information) at the point of sale to ensure that they are used safely and appropriately; or
- additional distribution or sales recording and reporting.

Use by any person on species or in ways other than the ones for which the product was registered is prohibited.

This group includes some products that are used for commercial pest control purposes. Besides restricting sale to competent approved persons there may be reporting obligations on those persons. This would be imposed if it were considered necessary to have a traceback capability.

Generally speaking users would not have to be approved by the ACVM Group. There would be no notification requirements before use and no signage requirements during use.

1.3.3 Restricted sale and use VTA products:

These are products that will attract conditions on both the traders and the users of the products. They are not considered sufficiently safe to use unless:

- their manufacture is subject to ACVM good manufacturing (GMP) approval;
- persons trading in the products are registered with the ACVM Group; and
- users are approved by the ACVM Group.

There will be requirements to provide adequate guidance at the point of sale and make it an obligation to ensure the purchaser has the authority to hold and/or use the products. Records will have to be kept of stock on hand and sales.

Users will have to be approved and will have to use the product as specified in the

conditions of registration, which will detail notification, location specification, signage, application, monitoring, clean-up, re-entry requirements and any other requirements that must be complied with to use the product appropriately and safely, and to avoid violative residues and unnecessary pain or distress in both target and off-target species.

Off-label use by any person on species or in ways other than the ones for which the product was registered is prohibited.

1.3.4 Compliance with conditions and product specific approvals

Conditions will be applied on a product-by-product basis according to an assessment of the risks posed. While VTA products can be grouped generally based on the conditions that have been imposed, no assumptions should be made about the actual conditions of registration.

It is the responsibility of all parties to comply with the conditions of registration that relate to their area(s) of activity. All regulatory requirements will be specified on labels (labels include any other approved information provided with the product such as inserts or leaflets). Persons must comply with those requirements. Off-label use is prohibited. Conditions of registration on products can be viewed on the ACVM Group website.

1.4 References

Agricultural Compounds and Veterinary Medicines Act 1997
Agricultural Compounds and Veterinary Medicine Regulations 2001
ACVM Registration Standard and Guideline for the Chemistry of Vertebrate Toxic Agents
ACVM Standard for Good Manufacturing Practice

2 REQUIREMENTS FOR VTA TRADE NAME PRODUCTS

2.1 General requirements

All VTA trade name products must be registered. Unregistered generic active ingredients must not be used as vertebrate toxic agents.

2.2 Manufacturing requirements

2.2.1 Responsibility

Ultimately, registrants are responsible for ensuring that their products comply with the conditions of registration. In particular, the manufacturer is responsible for ensuring that the product conforms to the manufacturing specification approved as part of the current registration of the product.

Manufacturers of restricted sale and use VTA trade name products must be approved by the ACVM Group. Manufacturers of unrestricted sale and use and restricted sale trade name products must manufacture their products according to the principles of GMP and may have to be approved by the ACVM Group as manufacturers for particular products. The requirement to be an approved manufacturer will be specified in the conditions of registration for each product.

2.2.2 Labelling

The manufacturer must ensure that the product is adequately labelled when it is offered for sale. The label is all the information that is provided with the product at the point of sale and is not limited to the information on or attached to the package. The label content must comply with the current registration for the product.

Some VTA trade name products may be sold in bulk to mix into bait on site. The requirements for handling, mixing, labelling and distribution of a product will be specified in the conditions of registration. It may be acceptable for the information relating to the product to be provided in a detached document, but it must be provided with the consignment of the product. The information must be presented to the person with the overall responsibility for the management of the product, the bait and the application of the compounded bait. This may mean that, in a vertically integrated operation or in one with multiple pest control operations, the information can be provided to the pest control operations manager (or an equivalent position) who specifies the details of the operation to individual pest control operators if those operators are only following the operation manager's instructions. The approved person must maintain control at all times.

There must be adequate information to facilitate investigations of adverse events or non-compliance. The contact information provided with the product must reflect the arrangements in the pest control contract and identify the person(s) responsible for the product, the compounded bait and the application of the bait. The information must

include a batch number, delivery reference or both so that the actual product used can be related to the manufacturing process. What is appropriate may vary for different kinds of vertebrate toxic agents. What is provided should be what is commonly used in the manufacture, distribution and sale for that kind of product.

There must be adequate information to allow the product to be used safely and appropriately, consistent with any expiry date.

2.2.3 Production to specifications

The VTA trade name product when offered for sale must conform to the approved formulation and have been manufactured according to the approved manufacturing specifications.

The manufacturer must have checks in place to ensure that the raw materials used to manufacture the product were fit for purpose.

The manufacturer must document the production process, specifying actions taken during manufacture to ensure that the ingredients were fit-for-purpose and the product met specifications. Areas of responsibility must be specified and production systems and instructions kept current.

It is expected that the manufacturing process (from specification of formulation through packaging, labelling and dispatch) would be subject to a documented quality system, using controlled copies of the quality system or operational manual, if necessary.

There must also be contingency plans in the quality system of operational manuals to recall defective product or mitigate adverse effects.

2.3 Importation requirements

Any vertebrate toxic agent imported into New Zealand must be registered, unless the substance that is being imported is not intended to be sold or used as an agricultural compound or it is being imported as a raw material to be incorporated into a registered trade name product. If the latter is the case, the pathway from the border to site of manufacture must be stipulated if it is not already known to the inspectors at the border.

There are companies that deal in generic chemicals that are the active ingredients in VTA products. However, the chemicals can also be used for other purposes. The chemicals are imported for no particular purpose and are likely to be sold with no restrictions on their use as an agricultural compound. Such chemicals must not be used as vertebrate toxic agents.

2.4 Trading requirements

VTA trade name products must be registered before they may be promoted, advertised or sold. Persons trading in such products should not alter the products in any way and must ensure that the information provided by the manufacturer is passed on to the user.

If products are altered, repackaged or relabelled by the trader, then the products are no longer the ones provided by the manufacturer. The trader must take full responsibility for any non-compliance in regard to the altered products unless the trader can show that the alterations were not the cause of the non-compliance. They must not repackage or relabel products and represent them as the original product unless they do it according to the recommendations of the relevant manufacturer.

Because a number of VTA products are sold in bulk form to be incorporated into baits, the trader must ensure that relevant information accompanies any bulk supplies.

Unrestricted sale and use VTA trade name products may be promoted and advertised in a responsible way that ensures that potential users are properly informed about the products. Restricted sale and use VTA trade name products must not be promoted or advertised. Traders must not misrepresent products in any advertisement or promotion. They must not make additional claims or promote any off-label use. Restricted sale and use products must be sold only to persons who are currently approved by the ACVM Group or who have in their possession an authorisation to purchase on behalf of a person who is currently approved by the ACVM Group. When in doubt about the validity of an authorisation to purchase, the trader must confirm the validity with the authorising person.

Traders will be expected to have quality systems that maintain the identity and integrity of the products they sell. They will be expected to maintain adequate records to address any suspicions or allegations of non-compliance. They must keep adequate records of sales for five years. Traders must be approved by the ACVM Group to sell restricted sale products and comply with the requirements in the product specific approvals for all VTA products.

2.5 Use requirements

VTA trade name products must be used only as specified in the label information. Off-label use is prohibited. Users must take note of any additional information provided to them at the point of supply and endeavour to apply the information correctly.

Users of restricted sale and use VTA trade name products must be approved by the ACVM Group.

Agricultural Compounds and Veterinary Medicines

Glossary of common terms

Advertisement
Any publication to the community or to any section of the community of any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device, used to promote the sale of any agricultural compound. 'To advertise' has a corresponding meaning.

Agricultural compound
Any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of:

a) Managing or eradicating pests, including vertebrate pests; or
b) Maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
c) Fulfilling special nutritional requirements; or
d) The manipulation, capture, or immobilisation of animals; or
e) Diagnosing the condition of animals; or
f) Preventing or treating conditions of animals; or
g) Enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
h) Marking animals;

and includes any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfestation of raw primary produce, and any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purpose of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 by Order in Council.

Animal
Any living stage of any member of the animal kingdom except human beings. It also does not include invertebrates unless specified as in the case of honey bees.

Animal material
Any live or dead animal, or any tissue or other material taken or derived from an animal.

Approval
Means approval by the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the New Zealand Food Safety Authority.

Breaking down and repackaging
To adjust the size, volume, number or weight of an agricultural compound trade name product and to place into an alternative package or container (should also have an alternative label).

Code of practice
Any document developed to specify the means by which parties meet the requirements in a

standard. A code may be approved in accordance with section 28 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, but does not have to be approved unless specified in the conditions of product registration or any product specific approval.

Compounding order
An instruction from a veterinarian to a manufacturer or contracted compounding pharmacist, detailing the formulation of a specially compounded medicinal preparation and any additional details on the method of compounding, packaging and labelling.

Control
To maintain full responsibility for and direction of the actions of others, and relates to the control of specified persons by persons approved or licensed by the ACVM Group to manufacture, trade in or use agricultural compounds or veterinary medicines.

Controlled copy
An operational or quality control reference document for which:

- responsibility for maintenance, updates, and changes will be undertaken by a limited and defined group of people; and
- all changes and updates will be recorded in writing and maintained for audit.

Direct management
Direct management includes any treatment used on/in the animal or plant; or any treatment that will be in direct contact with the animal or plant; or any treatment where the animal remains in the water/on the land during the treatment period; or when the animals are reintroduced to the water or land and the agricultural compound is still present.

Dispensing
To supply agricultural compounds or veterinary medicines as per instructions specified in a purchase/supply order, compounding order, veterinary prescription or veterinary authorisation.

Label
Any written, pictorial, or other descriptive matter under which the trade name product is sold and which purports to give some information about the agricultural compound or veterinary medicine. Includes any information that must be provided with the product at the time it is supplied.

Label content
The intended written, pictorial, or other descriptive information that can be provided with a product because it is consistent with and not beyond or in excess of what is permissible under the current approval for that product. The label content must be approved by the ACVM Group.

Prescribing
The act of deciding and specifying the appropriate veterinary medicine and treatment regime.

Prescription
A documented instruction to an approved trader in veterinary medicines from a veterinarian

specifying:

- a particular veterinary medicine;
- an animal or group of animals to be treated;
- a dosage and frequency; and
- instructions to be provided to the named person responsible for the animal(s) regarding warnings and/or associated care.

A prescription is required for the purchase of a registered PAR product by a person who is not a veterinarian. Only veterinarians may issue a prescription for a registered PAR product. A prescription may be issued for but is not required for the purchase of a veterinary medicine that is not a PAR product.

Prescription animal remedy (PAR) veterinary medicine

A veterinary medicine registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 with a condition limiting sale to:

- an approved trader in prescription animal remedies;
- a veterinarian currently registered under the Veterinarians Act 1994; or
- a person in possession of a relevant, *bone fide* veterinary prescription or authorisation from a veterinarian currently registered under the Veterinarians Act 1994.

Product specific approval

That part of an ACVM registration of an agricultural compound or veterinary medicine trade name product that specifies the particular use requirements for that product in regard to manufacture, importation, sale, establishing control, identifying treated plants or animals, avoiding violative residues, notifying purchasers or processors, etc.

Promotion

To encourage the sale of an agricultural compound or veterinary medicine trade name product by any means, including advertising.

Proprietary trade name product

An agricultural compound or veterinary medicine marketed under and protected by a registered trade name.

Relabelling

To transfer the relevant label information (provided with the product before breaking down and repackaging) to the package or container in which the agricultural compound or veterinary medicine trade name product is supplied for use.

Sale

Includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes:

a) delivering or disposing of by way of gift, loan, or otherwise; and

b) giving or distributing, in the course of business, as a sample or otherwise, without charge.

'General sale' means to make available to the public at large.

Trade

Trade in agricultural compounds or veterinary medicine trade name products includes general

sale and sale to specified/approved persons (wholesale and retail sales transactions as well as distribution, transport and storage). It also includes gifting or offering as samples as stated in the definition of sale.

Trader
Any person/corporate body/company who sells agricultural compounds or veterinary medicines. Traders can include, importers, product registrants, manufacturers, distributors, wholesalers and retailers, veterinarians and agricultural consultants, if they carry out any of the activities listed in the definition of sale above.

Veterinarian
A person currently registered as a veterinary surgeon under the Veterinarians Act 1994.

Veterinary authorisation
A documented approval from a registered veterinarian to a person to purchase and hold particular PAR veterinary medicines in anticipation of:

- their incorporation into other products (e.g. animal feeds) to be used under prescription;

or

- their use under operating instructions issued by a registered veterinarian.

Veterinary consultation
In relation to the administration of or the prescribing of any PAR veterinary medicine by a veterinarian to, or in respect of, an animal means:

(i) an examination of that animal, which is an animal in the immediate care of that veterinarian; or

(ii) the obtaining by that veterinarian of sufficient information about that animal, which is an animal in the immediate care of that veterinarian, to enable that veterinarian to make an informed decision with respect to the administration or prescribing of a PAR veterinary medicine to, or in respect of, that animal.