



AgVetLink

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What's coming up

- The next **AVMAC meeting** will be held in Wellington on 19 August 2004.
- An **Industry Liaison Group meeting** will also be held in Wellington on 19 August. This is an opportunity for industry groups to raise any issues or concerns with the ACVM team. We are in the planning stages for the next ACVM workshops and welcome suggestions on what the various groups would find most useful.
- A further meeting of the **Antibiotic Resistance Steering Group** is planned for 24 August in Wellington (see page 8).
- **NZFSA Conference** will be in Wellington this year (29-30 September). The imports workshop will cover ACVM-related issues. Current details are available on the website (<http://www.nzfsa.govt.nz/events/nzfsa-conference/index.htm>).

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Please take time to complete and return (stamped envelope enclosed) the ACVM Group customer survey. We have arranged for the surveys to be sent to an independent person for analysis in case you wish to remain anonymous. This is your opportunity to let us know the good, the bad and ideas for improvement!

AgVetLink is produced at least six times annually by the New Zealand Food Safety Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of agricultural compounds and veterinary medicines. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

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Disclaimer: This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.

Recent events

- The last **AVMAC** meeting was held in Wellington on 20 May 2004. Items discussed included proposed changes to the ACVM Act and Regulations, publication of the public release summaries for the 'slice of life' audits (see box at right), the reassessment of products under the ACVM Act, the AVMAC review and the latest VICH documents for consultation.
- The first meeting of the new **Antibiotic Resistance Steering Group** was held in Wellington on 8 July. See article on page 8 for details.
- Debbie Morris was one of the **VICH task force** members (representing the observer countries of Australia, New Zealand and Canada) at a recent meeting in Paris to discuss the revision of the VICH strategy and charter.
- Maree Zinzley and Warren Hughes gave a presentation covering ACVM Act operational issues and the plans for further exemption Regulations to the recent **Agcarm AGM** held in Wellington.
- Chris Boland gave a presentation on behalf of the ACVM Group at the **Feed Manufacturers AGM** in Wellington on 21 July.
- Debbie Morris attended a meeting of the **ARPPA Executive** in Auckland on 28 July.
- NZFSA has published a number of **fact sheets on chemical residues** in food. These are all available free of charge on the website (<http://www.nzfsa.govt.nz/consumers/food-safety-topics/chemicals-in-food/index.htm>).
- A list of **products not updated** to the ACVM Act is available on the website (<http://www.nzfsa.govt.nz/acvm/registers-lists/cancelled.htm>). These products are no longer registered agricultural compounds or veterinary medicines (but some may be covered by the exemption Regulations).

Overdue annual fees

Invoices for 10% penalty interest for any unpaid annual fees will be posted in the first week in August.

Fee waivers of cancelled products

Even at this late stage some companies are advising that they wish to cancel products, so we are reminding registrants of the business rules concerning refund of annual charges. Once we have received notification from registrants that they no longer wish to register their product, and the applicable information has been supplied to enable us to cancel the product's registration, a fee waiver may be applicable. The waivers are as follows:

- 75% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 2 July to 30 September 2004;
- 50% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 October to 31 December 2004;
- 25% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 January to 31 March 2005;
- No waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 April to 30 June 2005.

The ACVM Act section 82 prohibition on importation and manufacture for any unpaid annual fees is **automatic** – sale of any affected products is likely to be in breach of the Act. On confirmation of the receipt of the full outstanding amount, including penalty fees, the ACVM Group will waive the prohibition.

If you have any queries in relation to what you have been charged, contact:
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'Slice of life' audits

At the request of ACVM Group Director Debbie Morris, several 'slice of life' audits were conducted by the NZFSA Compliance and Investigation Group during the past year. The auditors reported on particular areas of ACVM-related activity and provided recommendations to the ACVM Group.

Public release summaries of the following audit reports are available on the website (<http://www.nzfsa.govt.nz/acvm/subject/compliance/index.htm>):

- **Discretionary Use of Veterinary Medicines, Products Compounded by or for the Prescribing Veterinarian, and Pharmacy-only or Restricted Human Medicines**
- **Oral Nutritional Compounds**
- **MAF Quarantine Service Clearance of ACVM Products**
- **Use of Specified Antibiotics Within the Pork and Poultry Industries**

LEGISLATION

Amendment to the ACVM Regulations 2001

The ACVM Group is proposing an amendment to the ACVM Regulations 2001. Because of the technical nature of these Regulations, amendments are needed regularly to:

- add or delete (amend the definition or conditions of) groups of agricultural compound products that are exempt from registration;
- add or delete items from the list of plants prohibited from use in exempted herbal veterinary medicines;
- add or delete substances prohibited from use as agricultural compounds; or
- add or delete items from the lists of generally recognised as safe (GRAS) substances.

Proposed changes

Highlights of the proposed changes in the Regulations are:

Removal of the obligation to notify trade name products in Schedule 3 of the Regulations

It is proposed to remove the obligation in Regulation 7 to notify and provide annual reports for products that fit the definition of agricultural compounds listed in Schedule 3. A new obligation will be imposed to provide information about particular products before they are first offered for sale in New Zealand. At

this stage, the new obligation will apply only to three entries in Schedule 3:

- topical skin preparations;
- anti-diarrhoea preparations; and
- respiratory tract modifiers.

Imposition of an obligation to avoid violative residues

It is intended to place an obligation on the proprietor of agricultural compound products used to manage plants that are exempt from registration to formulate, manufacture and label the products in a way that avoids any residues in violation of applicable food residue standards. This is consistent with conditions imposed in other parts of the Regulations and is more practical than requiring all the ingredients to be listed as generally regarded as safe (GRAS).

Removal of exemption for fertilisers and fertiliser additives that are raw or composted biological wastes

The ACVM Group considers wastes products that are not subject to adequate processing to manage the risks are still just wastes, no matter what claims are made about them. The Group considers that the application of wastes to land should be regulated under the Resource Management Act 1991 and should not be given the status of agricultural compound.

Removal of the unqualified exemption from registration for plant material

The removal of the exemption from registration for plant material will have two consequences. Firstly, herbal preparations containing naturally occurring active ingredients (pyrethrums, azidirectin etc.) will have to be registered. Secondly, feed commodities (hay, silage, grain etc. sold as animal feeds) will be subject to Regulation 8, exempting them from registration but obliging them to comply with the minimum standards in Schedule 4.

New exemptions

Exemptions are being proposed for:

- homeopathic preparations for the management of plants;
- plant tissue culture products;
- plant graft protection products; and
- animal semen extenders and ova media.

Discussion of proposals

The NZFSA Policy section is preparing a discussion document on the proposed amendments. It is expected that the document will be available (and posted on the ACVM Group website) during August. Readers who may be interested in the amendments and in making submissions on the proposal should check the website.

Amendment to ACVM Act

Seventeen submissions on the proposed amendment to the ACVM Act were received during the public consultation phase. Several submissions expressed concern about the public health/HSNO interface; comments were generally useful and constructive.

Analysis of the submissions has now been completed and will soon be published on the website. Issues raised will be worked through before the next step in the process, which is presenting the proposal to Cabinet for Select Committee consideration.

PDS not a 'pick + mix'

We wish to advise applicants that ALL sections of the Product Data Sheet (PDS) form the 'registration' of the product once it is approved. It is not an option to complete some parts and remove others. The PDS should not be tampered with in any way.

Advertising PARs

The *ACVM Standard for Prescription Animal Remedy Veterinary Medicines* states that:

A trader may advertise as an approved trader in PAR products and may indicate the types of PAR products stocked.

A trader must not display PAR products in public view.

As a basic principle, a trader should focus any advertising or promotion of PAR products to registered veterinarians who can legitimately prescribe the products. They should provide accurate and technically supportable information about their products that allows prescribing veterinarians to make informed judgements in regard to their use.

It is quite appropriate for traders to provide technical information on products and to foster awareness and understanding of disease conditions or health and production management options. In doing this it is reasonable for them to identify themselves or their company with the information and mention that they market a product or products that could be used to treat a particular disease condition or contribute to the management of health or production.

However, they must not promote the products as the preferred choice and must emphasise that end users should discuss treatment options with their veterinarian. They must not offer any purchasing incentives to end users or carry out any advertising campaigns targeting end users or face-to-face contacts with end users to promote particular PAR products.

These requirements relate only to advertising or promoting PAR products directly to the end user.

Conflicting opinions

Some members of the veterinary profession and other animal health care specialists have argued that the advertising practices of some parties have resulted in serious conflicts between them and their clients who, as a result of the advertising or promotion, demand products that the veterinarians do not consider appropriate under the particular circumstances. This same concern (and for the same reason) has been raised in regard to direct to consumer advertising of human medicines.

On the other hand, some veterinarians, end users, registrants of products, wholesalers and retailers have argued that the ACVM Group's requirements are unnecessarily restrictive. They consider that the prohibition on advertising may deny end users access to products because their veterinarians may be unaware of the products or, for some non-technical reason, would not prescribe some acceptable alternative.

The ACVM Group accepts that both arguments are reasonable and likely to be correct at times.

Standards

If all parties acted in a responsible manner there would be little need for the ACVM Group to set requirements in regard to advertising. However, experience has shown that such reasonable behaviour does not always prevail.

The ACVM Group's preference is that all parties set standards for responsible behaviour when it comes to advertising PAR products. Some industry associations and the New Zealand Veterinary Association have attempted to establish such a standard, but self-

regulation has not always been effective across the wider industry.

The ACVM Group's *Standard for Prescription Animal Remedy Veterinary Medicines* states the expectation that persons authorised to sell PAR products will exercise care not to jeopardise the ability of a veterinarian to prescribe the product considered most appropriate under the circumstances.

However, it recognises that there is often important information that the end user should have access to that could be supplied at the point of sale. The ACVM Group does not consider such information to be advertising.

The ACVM Group reserves the term 'advertising' for promoting a particular product in preference to other comparable products in order to increase the sales of that product. The Group recognises that traders are in business to sell the products they stock. Its restrictions on advertising focus on practices that encourage the end user to demand particular PAR products when the prescribing veterinarian may consider the use of some other PAR product (or not treating an animal at all) is the more appropriate course of action.

The ACVM Group intends to maintain the expectations as stated in the standard. The Group will actively participate in discussions with interested and affected parties to develop any refinements that make information on products readily available to all parties while protecting veterinary prescription as a mechanism to ensure the most appropriate products are used effectively and safely. However, the Group considers these expectations as guidance only. Compliance will not be mandatory unless there is a specific product condition prohibiting advertising to end users.

MRL update

The public consultation for the second round of amendments to the maximum residue limit (MRL) standards for this year has finished and will shortly be submitted to the Minister for her approval. The second amendment contains the following:

To exempt from the MRL Food Standards 2004

- Copper and its salt
- Sulphur in all foods from plant species
- Chitosan in all foods from plant species
- Pentosan polysulphate in all foods from animal species
- Cloprostenol and R-Cloprostenol in all foods from animal species
- Bismuth and its salts in all foods from animal species
- Buserelin in all foods from animal species
- Hydrocortisone in all foods from animal species
- Thymol

To provide an MRL for

- Tolyfluanid in pome fruit
- Meloxicam in pigs.

Third round

The public consultation phase of the third round of amendments should be starting soon. This round will propose:

To exempt from the MRL Food Standards 2004

- Thiopental sodium in all foods from animal species
- Iodine in all foods from animal species
- Ixosuprine in all foods from animal species
- Medroxyprogesterone acetate in all foods from animal species
- Oestradiol-17 beta and its esters or conjugates in all foods from animal species
- Etamiphyline cansylate in all foods from animal species
- Fatty acids containing 8 or more carbons, and their salts in all foods from plant species

To provide an MRL for

- Cyprodinil in grapes, stone fruit and pome fruit
- Xylazine in deer velvet
- Lignocaine in deer velvet
- Permethrin in kumara.

Total Diet Survey

The third quarter results of the New Zealand Total Diet Survey have been released by NZFSA and again show that the average New Zealand diet presents no chemical residue concerns.

The third quarter was the second analysis of a wide range of regional foods, i.e. those generally produced and sold locally such as fresh fruit/vegetables and takeaway foods. The analysis looked for environmental elements such as lead and cadmium, nutrients such as iodine, sodium and iron, and residues of agricultural compounds.

“There were no health concerns from any of the more than 45,000 analyses, and only three minor issues where results were slightly above the default New Zealand MRLs. In each case, there was no health or safety concern at all,” said Total Diet Survey project manager Cherie Flynn.

The three results that exceeded the New Zealand default MRL were for the fungicide Ethoxyquin found in chicken nuggets, and pesticides Pirimiphos-methyl found in celery and Procymidone found in capsicum. The use of the compounds was off-label. Therefore, there is no specific MRL for that compound/crop use and any residue must be lower than the New Zealand default.

To view the complete report, visit the website (<http://www.nzfsa.govt.nz/science-technology/research-projects/total-diet-survey/reports/quarter-3/index.htm>).

Pesticides under the HSNO Act

In June ERMA New Zealand ran workshops around the country on ‘Managing of Pesticides under the HSNO Act’. The ACVM Group was invited to present our perspective on ‘minimising the need for dual regimes’. Warren Hughes presented in the South Island and Maree Zinzley in the North Island.

The workshops, which were attended primarily by produce growers in the main growing regions, covered such topics as controls on hazardous substances. However, the Approved Handler and Test Certifier processes were the hot topics on the agenda and many questions were asked of ERMA New Zealand in regard to changes.

Timelines

Claud Warren (Technical Standards-Plant Compounds) will be leaving the ACVM Group at the end of July. Changing staff added to exceptionally heavy workloads may mean delays in meeting timelines. Please be patient.

COMPLIANCE

Transition to ACVM registrations

The ACVM (Transitional Provisions) Regulations 2002 provided that all products covered by the registration provision of the ACVM Act needed to be updated by 1 July 2004. On this date, the ACVM Group still had not received applications to update products for 70 registrants (92 veterinary medicines and 49 plant compounds). These registrants were sent a letter on 19 July advising them that their product registrations were cancelled. Their products are now illegal and prohibited from further import or manufacture. Product already in the distribution chain could be depleted, but no further product could leave storage or warehouse premises under the registrant's control.

A list of unregistered products and their registrants has been given to MAF Quarantine Services for detainment at the border. The list has also been placed on the ACVM website.

Exempt products/GRAS applications

However, some of these products may be exempt from registration under the ACVM Regulations. A Class Determination is needed to confirm exemption status, and registrants were told in the letter that they had seven working days to request a Class Determination for their product(s). An official Class Determination would be required for any imported product to facilitate border clearance.

If a registrant has had a product cancelled (through non-update) but it is likely to be exempt once an application for inclusion on the GRAS list is approved, the ACVM Group is unlikely to take compliance action *provided the application for GRAS inclusion has been made*.

New application

To reinstate cancelled products, an application for registration that includes relevant data packages must be made. If necessary, a HSNO approval may be required. It is possible to cross reference information held on file for recently cancelled products.

Vet Quick Search Area on ACVM website

In response to feedback received during the recent ACVM workshops for veterinarians, a new section specific to veterinarians has been added to the ACVM website homepage. The new section gathers together all documents likely to be of interest to veterinarians, including residue and withholding period information, presentations, publications, and current issues.

The ACVM Group also intends to include information pertaining to changes in registered product current approvals (e.g. new claims, altered WHPs) and new products in this section. The format is yet to be decided.

Fieldays

ACVM Group staff members attended the Hamilton Fieldays in June and visited many exhibitors to:

- assess the marketplace in veterinary medicines and plant compounds;
- confirm compliance of approved products with the conditions of their approval;
- provide education to people marketing agricultural compounds who were unfamiliar with their obligations under the Agricultural Compounds and Veterinary Medicines Act 1997.

As in previous years, some non-compliant products were identified at the Fieldays and the Group will take action as needed to rectify the situation.

Update

Compliance activity during the past few weeks has involved relatively minor issues split evenly between veterinary medicines and plant compounds. Most of the dozen or so concerns involve label claims.

At present, the ACVM Group is planning compliance programmes for the upcoming year. The Group anticipates a large commitment to compliance activity will be required when the new PAR trader system is operational.

Decisions are also being made on the 'slice of life' programme for the next 12 months.

STANDARDS

Development of regulatory control for vertebrate toxic agent products

The ACVM Group received seven submissions on version 4 of the *ACVM Standard for Vertebrate Toxic Agents*. In general the submissions reflected a level of concern that regulatory control in this area where two agencies have overlapping responsibilities may be redundant and possibly conflicting.

Respondents expressed concern over the consultation process, commenting that they have not been informed in an adequate and timely manner to allow them to make useful submissions.

The issues raised and the ACVM Group's responses can be found in the summary of submissions on the Group's website. However, to answer the concerns about the consultation process, the ACVM Group is still in the midst of consultation. It prepared a first draft of the standard to prompt discussion. It considered the submissions and modified the standard in light of the comments made. While it set a timeframe for submissions on version 4 of the standard to ensure the development process progressed, it has assured inquirers that any submissions received at any time in the process will be included in development of the standard.

The Group has adjusted the standard to make it clear that the conditions will be product specific. It has discussed the likely conditions with the product registrants. The proposed conditions are now in a form that the ACVM Group considers is specific enough to be used in the next and much wider round of consultation. The regulatory expectations and requirements for approved traders are also being prepared for consultation.

Regulatory expectations for approved users (comparable to the present

vertebrate pest control licences) are being discussed with ERMA New Zealand. Until vertebrate toxic agents are transferred into the main framework of the HSNO Act (see box below), the ACVM Group will administer user approvals via the VPC licensing for itself and for ERMA New Zealand. After transfer, the ACVM Group will maintain its own approval and will integrate with the ERMA New Zealand approved handler system as soon as it is operational.

It is intended to have another full round of public consultation on the management of vertebrate toxic agents. The consultation will cover:

- version 4 of the *Standard for Vertebrate Toxic Agents* (which is already available);
- conditions on vertebrate toxic agent trade name products;
- approval of traders in specific vertebrate toxic agents; and
- regulatory expectations for approval of users of specific vertebrate toxic agents.

This package of documents will be sent directly to product registrants as well as to local and central government agencies for comment. It will also be made available for wider public participation.

In the meantime all registrations for vertebrate toxic agent products have to be reissued as part of the ACVM registration updating process. Registrants will receive limited-life registrations for their products and will be advised that as soon as the product conditions are finalised their registrations will be changed to incorporate any new conditions.

Unregistered veterinary medicines

Three submissions were received on the *ACVM Draft Standard for the Management of Unregistered Veterinary Medicines Requiring Veterinary Overview*.

Many issues concerning compounding were raised by submitters and other parties and agencies (both in New Zealand and abroad) consulted by the ACVM Group during the consultation period.

There were also questions about:

- controls on the use of human medicines;
- classification of horses as food-producing animals;
- the scope of the standard;
- the ACVM Group's authority to set standards in this area;
- default withholding periods;
- establishment of the veterinarian/client relationship;
- importing veterinary medicines; and
- the decision rationale for preferentially choosing registered veterinary medicines over human medicines over specially compounded veterinary medicines.

The summary of submissions, which includes the ACVM Group's responses to concerns expressed and suggestions made, will soon be available on the website.

VTA transfer

ERMA New Zealand has advised that vertebrate toxic agent products will be transferred to the HSNO Act on 1 November 2004.

Antibiotic Resistance Steering Group

The first meeting of the new Antibiotic Resistance Steering Group was held in Wellington on 8 July to discuss terms of reference and composition of the expert panel for a further review of the New Zealand situation. The Steering Group consists of a representative of each of the organisations below, plus an additional consumer representative and a human health practitioner:

- NZFSA – ACVM Group (Convenor)
- NZFSA – Animal Products Group
- New Zealand Veterinary Association
- Ministry of Health
- Ministry of Research, Science and Technology
- Consumers Institute
- Poultry Industry Association
- New Zealand Pork Industry Board
- Federated Farmers
- AGCARM (Agricultural Chemical and Animal Remedy Manufacturers Association)
- Animal Remedies and Plant Protectants Association (ARPPA)
- PipFruit New Zealand Incorporated
- Dairy Insight

DAS reminder

When lodging an application, please remember to indicate in your covering letter if you wish the ACVM Group to undertake the data assessment or if you wish the application to go directly into review and evaluation.

LABELLING

Harmonisation of veterinary medicine labels with Australia

Changes in the Australian Agricultural and Veterinary Chemical Code Act (Agvet Code), which was introduced last October, have resulted in the need for the APVMA to approve final marketed product labels (or printers' proofs) rather than label content presented in text format as was the situation previously. The administrative flow-on effect has led to classifying minor label changes as Category 39 (fee attracting) whereas previously they were often classified as Category 38 (non-fee attracting).

APVMA approval may be required for harmonised labels that are being updated to comply with requirements of the ACVM Act in New Zealand. However, the APVMA has specified certain label changes that can be made to labels used in Australia without approval, subject to conformance with the stated conditions. These changes are contained in Permit 6868, which is issued under section 114 of the Agvet Code, and may be viewed on the APVMA website (<http://permits.apvma.gov.au/PER6868.PDF>). Part 3 of section A of Permit 6868 covers 'Addition and/or deletion of clearly identified New Zealand classification or approval details and relevant New Zealand contact details'.

Advice received from APVMA is that, to comply with the intent of the words 'clearly identified' in this section, changes to the New Zealand required statements should be prefixed by or contain words such as 'In New Zealand'. Alternatively, the use of a statement box identified as

'New Zealand relevant information' would ensure compliance.

The APVMA considers that the following changes are covered under Permit 6868:

- New Zealand registration statements, e.g. "Registered in New Zealand pursuant to the ACVM Act 1997, No. Axxxx" "See www.nzfsa.govt.nz/acvm for registration conditions";
- New Zealand PAR statement, e.g. "Prescription Animal Remedy P.A.R. Class 1 For use only under the authority or prescription of a veterinarian";
- New Zealand registrant/distributor contact details, e.g. name, street address, website, phone;
- New Zealand poisons information contact details, e.g. "New Zealand 0800 764 766 (0800 POISON)".

The APVMA has advised that Australia does not regard the horse as a food animal. For horse products that contain New Zealand restricted (EU or FDA banned) substances, harmonised labels are possible only if the New Zealand restraint statement is included in a text box identified as being relevant to New Zealand only. The inclusion of the statement in this manner would comply with the intent of Permit 6868.

The APVMA would need to examine situations that involve claims, instructions, recommendations, warnings or other statements that are different to those in Australia. Registrants are encouraged to contact the APVMA and the ACVM Group to seek further advice.

The ACVM labelling guides for plant compounds and veterinary medicines have been updated to reflect a change in policy – the physical address of the registrant is no longer required on the label.

Cat and dog internal parasites

The cat and dog parasites listed in the box will be considered for inclusion on the labels of veterinary medicines registered in New Zealand. There is insufficient data to suggest that any other parasites not included on the list and known to infect cats and dogs overseas are present in New Zealand to the extent that products will be required to treat them.

A treatment or prevention claim will not be approved for any new or existing product for such parasites (except for Australia-New Zealand harmonised labels which come under separate ACVM policy). Products updated with claims for unlisted parasite species are expected to remove the claims at the next reprint.

<p>Dogs</p> <p>Roundworms <i>Toxocara canis</i> <i>Toxascaris leonina</i></p> <p>Hookworms <i>Uncinaria stenocephala</i> <i>Ancylostoma caninum</i></p> <p>Whipworm <i>Trichuris vulpis</i></p> <p>Tapeworms <i>Echinococcus granulosus</i> (hydatid tapeworm) <i>Taenia ovis</i> (sheep measles) <i>Dipylidium caninum</i> (common flea tapeworm) <i>Taenia hydatigena</i> <i>Taenia pisiformis</i></p>	<p>Cats</p> <p>Roundworms <i>Toxocara cati</i> <i>Toxascaris leonina</i></p> <p>Hookworms <i>Uncinaria stenocephala</i>* *This parasite is not considered to be of clinical significance in the New Zealand cat population. It is a theoretical risk given the parasite is known to be present in New Zealand.</p> <p>Tapeworms <i>Dipylidium caninum</i> (common flea tapeworm) <i>Taenia taeniaeformis</i></p>
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Efficacy data

Applications for approval of cat and dog roundworm, hookworm and dog whipworm treatment and control claims must be supported by efficacy data. The applicable standards are the VICH documents *Efficacy of Anthelmintics: Specific Recommendations for Canines* and *Efficacy of Anthelmintics: Specific Recommendations for Felines* (see <http://vich.eudra.org/hm/guidelines.htm#t2>).

Efficacy data are not required to support a tapeworm treatment or prevention claim. The negative animal welfare that results from tapeworm infection in cats and dogs does

not breach the relevant ACVM threshold (at least moderate pain and distress). Furthermore, tapeworms are not currently subject to any Biosecurity Pest Management Strategies.

Veterinary medicine withholding periods

Registrants are reminded that it is a requirement for all veterinary medicines with claims for use in food-producing animals to state a withholding period (WHP) for all edible produce of the claimed species where one can be established.

Four different types of withholding periods may be approved:

Assessed WHP

The WHP determined by the ACVM Group after assessment of the trial data according to the rules and guidelines specified within the *ACVM Residue Standard* and evaluation of the various residue risks identified.

Allocated WHP

The WHP determined by the ACVM

Group to be appropriate to a reduced or non-existent data set but also takes into account other evidence supplied as part of a waiver.

Default WHP

The set of predetermined WHPs that will be applied in the absence of any residue data (and a supportable residues information waiver).

Standardised WHP

A WHP assigned to a group of formulations with at least one active ingredient in common and with the same method(s) of administration. The standardised WHP will correspond to certain specifications. Future registrations of products within these specifications need supply no residue data if the registrant elects to take the

standardised WHP. Standardised WHPs are included as an annex to the *ACVM Registration Standard and Guideline for Determination of a Residue Withholding Period for Veterinary Medicines*.

Any products that have previously been approved with a now superseded default, a 'do not use' statement in lieu of a WHP, or no WHP where one is applicable will be updated with the currently applicable default WHPs (see www.nzfsa.govt.nz/acvm/subject/vet/withholding.htm).

Applicants are reminded that an application may be made to have a WHP other than the default approved (this may include retention of a superseded default).

ACVM legislation, NZFSA, the ACVM Group, ERMA New Zealand and other government agencies

Discussions with the public on proposed changes to ACVM legislation have shown that the legislation and the roles of the New Zealand Food Safety Authority (NZFSA) and the Agricultural Compounds and Veterinary Medicines (ACVM) Group are not well understood. This article gives an overview.

Background

When the ACVM Act was passed in November 1997, the regulatory environment for agricultural compounds was very different than it is today. Up to that time, regulatory control had been mostly prescriptive. The agricultural legislation reform during that decade, which included the Hazardous Substances and New Organisms (HSNO) Act 1996, changed the process from prescriptive, blanket control to management of stated risks.

In the case of the ACVM Act, its purpose is to:

- a. prevent or manage specific risks associated with the use of agricultural compounds –
 - risks to trade in primary produce
 - risks to animal welfare
 - risks to agricultural security;
- b. ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards;
- c. ensure the provision of sufficient consumer information about agricultural compounds.

Two regimes

The ACVM Act was designed to manage risks to agriculture and, ultimately, to food. However, in 1997 two separate government ministries were responsible for these areas – the Ministry of Agriculture and Forestry (MAF) was responsible for the regulatory control of primary produce,

and the the Ministry of Health (MoH) was responsible for food safety.

As a result of these two different regimes, producers, processors and consumers faced issues such as:

- inconsistencies and a lack of co-ordination in the way domestic/export food safety was managed;
- increasing consumer concerns about food safety issues; and
- the potential for inconsistencies to develop in New Zealand's approach to imports and exports.

Creation of NZFSA

Government made the decision that a single agency would reduce duplication and allow the management of food-related risks from 'farmgate to the consumer's plate'. It would also strengthen the ability to determine an 'appropriate level of protection' for New Zealand consumers. A consistent approach to regulation of all food production, whether for export or for sale on the domestic market, could be achieved. Therefore, the two regimes were brought together in 2002 as the New Zealand Food Safety Authority.

NZFSA is part of the Ministry of Agriculture and Forestry for administrative purposes, but the Authority reports directly to the Minister for Food Safety.

NZFSA's job is to:

- regulate the safety of the domestic food supply;
- regulate the safety and certification of export primary produce and food;
- establish acceptable levels of food safety, carrying out food safety risk analyses and developing food safety standards.

Legislative base

NZFSA's statutory mandate is based on provisions and Regulations of the:

- Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997
- Animal Products Act 1999
- Dairy Industry Act 1952
- Food Act 1981
- Wine Act 2003.

NZFSA has several 'Groups' within its structure, each responsible for certain aspects of food safety in New Zealand. For example, the Animal Products Group is charged with setting and ensuring compliance with standards for the primary processing and export of meat, game, seafood, honey and other animal products while the Dairy and Plant Products Group provides assurance to consumers of New Zealand's dairy and plant food products that those foods are safe and true to label.

ACVM Group

The ACVM Group, which administers the ACVM Act, is responsible for the regulatory control of agricultural compounds (plant compounds, veterinary medicines, and vertebrate toxic agents) that are intended for use in agriculture, horticulture, pest control, and animal care and production.

In addition to food safety, the ACVM Group is concerned with:

- the welfare of animals treated with or exposed to agricultural compounds;
- possible residues in non-food primary produce; and
- the impact of agricultural compounds on the eradication, prevention and control of pests and unwanted organisms.

The approach used by NZFSA is one of integrated risk management. The Groups of NZFSA do not work in isolation.

Because ACVM ‘risks’ affect aspects of all areas of NZFSA responsibility, the ACVM Group provides input for the Animal Products Group, Dairy and Plant Products Group etc.

Amendment needed

The ACVM Act was designed specifically to manage products by placing controls on import, manufacture, sale and/or use. The ACVM Group assesses and regulates agricultural compounds under this Act. However, because the ACVM Act was written to ‘cover’ outcomes for primary produce under MAF and the requirements have expanded greatly since the NZFSA was created, the ACVM Act has to be amended to provide for the additional areas of responsibility.

ACVM Group and ERMA New Zealand

Recent submissions on proposed amendments to the ACVM legislation have asked why the ACVM Group and ERMA New Zealand are ‘doing the same job’ in public health. To understand the function of the two organisations, it is important to look at the purpose of the legislation they administer – the ACVM Act and the HSNO Act.

When looking at the list of risks covered by the ACVM Act, risks to human health and the environment are not there. These are covered by the HSNO Act. The purpose of the HSNO Act is to protect the environment and the health and safety of people by preventing or managing the non-food adverse effects of hazardous substances and new organisms.

This ‘non-food’ qualifier in the HSNO Act explains why the ACVM Act and the ACVM Group must be involved. The two organisations are not doing the same job in public health – they deal with

different aspects. The ACVM Group is concerned with the food aspects and ERMA New Zealand is concerned with non-food aspects.

Overlaps

Inevitably, though, there are overlaps. In such a case, the HSNO Act controls are preconditions to the ACVM Act controls. In other words, if an agricultural compound is also a hazardous substance, it must be approved by ERMA New Zealand before it can be registered by the ACVM Group. The ACVM Act process is additive to the HSNO Act process.

The two organisations need a close working relationship to avoid unnecessary duplication of requirements, extra compliance costs etc. They work together whenever possible.

Other agencies

Many other government agencies, such as the Ministry of Health and Ministry for the Environment, also have responsibilities in the public health area. Risks managed by the ACVM Act affect some of these aspects of public health as well, e.g. prescription medicines used as veterinary medicines require the prior approval of the Ministry of Health for public health reasons.

The ACVM Group ‘sits in the middle’, ensuring its work is consistent with outcomes required of NZFSA while at the same time not conflicting with outcomes required of these other government agencies. The Group has to ensure that ACVM risk areas are managed in all the relevant areas so that the outcomes and standards set under the entire NZFSA legislative regime or by international agreements are not compromised.

Liaison with veterinarians

ACVM Group veterinarian Jennie Moran has represented the Group at recent national and international meetings to liaise with veterinarians.

- In May she gave a presentation on ‘Animal Welfare and Its Relevance to the ACVM Regulatory Process’ at the Australian Veterinary Association Conference Ethics Stream, Brisbane.
- Also in May Jennie was invited to the Companion Animal Society of the New Zealand Veterinary Association Board Meeting, Wellington, to discuss companion animal veterinarian obligations. This discussion was to clarify and expand on some of the topics discussed at the ACVM workshops for veterinarians.
- In June she attended the combined NAEAC/NAWAC meeting, Christchurch, to give a presentation regarding the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines*. The ACVM Group was invited to make the presentation as a follow-up to a presentation made at an earlier meeting by NZVA CEO Murray Gibb on the same issue.

FAQ – Data Assessment Service (DAS)

Queries about the Data Assessment Service come into the ACVM Group regularly. Here are some of the most frequently asked questions and answers.

Q Can registrants do their own DAS report?

A Yes, they can. However, the person undertaking the report should not be the same person who compiles the data sets.

Q Does the ACVM Group still do DAS reports?

A Yes, the ACVM Group still does DAS reports on behalf of registrants.

Q Can registrants have both the ACVM Group and others undertake DAS reports for an application?

A Yes, this is acceptable. For example, an application requires DAS reports in the chemistry and residues areas. The registrant can request the ACVM Group does the residue DAS report, while they or another can undertake the chemistry DAS report.

Q Does the ACVM Group have a list of persons who can undertake DAS reports?

A No, not at present. While there is a list of consultants on the website (<http://www.nzfsa.govt.nz/acvm/registers-lists/consultants.htm>), these persons have requested their names be on this list (including their areas of expertise) in order to assist registrants prepare their data packages. This is a consultancy role, not a DAS assessment role.

Q Does this mean I cannot use anyone on this consultant list to prepare a DAS report?

A No, you can contact anyone on the list and ask whether they are prepared to undertake a DAS report. However, it is the responsibility of the registrant to ensure the person is competent to do the data assessment.

Q What should I consider as ‘competent’ when considering any person to undertake the DAS report?

A The person must have a good understanding of:

- the ACVM Act and the risks managed under it;
- the ACVM Group’s standards and guidelines; and
- the area of the DAS assessment (i.e. appropriate expertise and experience).

Q How can I determine whether people are ‘competent’?

A This is for you to ascertain. However, as a guide, you should consider reviewing their CVs to determine whether this relates to the DAS assessment you wish them to undertake. In addition, you could consider whether they have had previous experience in preparing DAS reports, and whether the ACVM Group had any issues or not with their reports. Bear in mind, lack of experience in preparing a DAS report does not mean they are incompetent.

For specialised areas such as efficacy DAS reports, their expertise and recent experience must be in the relevant areas. You should not assume that a person competent on herbicides is likely to be competent on insecticides. In addition, it should also not be assumed that a person who is competent on vegetables is likely to be competent on crops other than vegetables.

Q Who should I use – the ACVM Group or another?

A This is a commercial decision for you to make. However, the ACVM Group has stated that regulatory work takes priority over DAS assessments because the latter is a discretionary service. Consequently, the ACVM Group may take longer than someone else to complete a DAS assessment.

Q What if I have more questions?

A Please feel free to ring or email the ACVM Group. The February 2004 *AgVetLink*, which is available on the website, also contained an article on DAS business rules that should be read in conjunction with these FAQs.

AgVetLink for PAR traders

It has become apparent from applications coming into the ACVM Group from people/organisations wishing to register as PAR traders that the concept of trading in PARs is not clear. For this reason a special edition of *AgVetLink* has been published to answer frequently asked questions and to help people understand the new system. The trader *AgVetLink* covers:

- trading in PARs
- who must apply to become a trader
- what must be included in an application
- how veterinarians are affected
- how feed manufacturers are affected
- advertising
- ACVM and HSNO terminology.

This special issue will be sent to registrants of PAR products, organisations/individuals identified as traders, and will also be available on the website.