

What's coming up

- The next meeting of the **VICH Steering Committee** is being held in Washington, 6-8 October. In addition to hearing progress reports from each of the active working groups, the Steering Committee will review the future strategy of VICH and the proposed workplan. The agenda also includes review concept papers on new topics including a revision of guidelines 10 and 11. See the website (<http://www.nzfsa.govt.nz/policy-law/vich/index.htm>) for details of all the VICH guidelines, metabolism and residue kinetics, and stability in veterinary vaccines.
- The draft revision of the **ACVM Group Operational Policy on Compliance** has been put on the website; consultation is open until 15 October 2003. This draft was presented to AVMAC at the 22 May meeting along with a background explanatory paper (both available at <http://www.nzfsa.govt.nz/acvm/publications/discussion/operational-policies/index.htm>) for initial consultation and discussion.
- John Reeve, NZFSA Programme Manager (Toxicology and Residues), is to present a poster on the ACVM Group's 'Third Party' registration scheme that has been designed to deal with 'off-label' uses of registered pesticides on minor crops in a robust and transparent manner. The poster has been accepted for presentation to an international conference being organised by the **International Union of Pure and Applied Chemistry and the Korean Society of Pesticide Science**. The conference will be held in Seoul, 13-16 October 2003. The poster will also form

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the basis of the New Zealand presentation to the **OECD Pesticide Risk Reduction Workshop** to be held in Canberra on 4 November 2003.

- The next **AVMAC meeting** is planned to be held on 20 November 2003 in Wellington.

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 ACVM Group has given a series of presentations to the **MAF Verification Agency** staff on the proposals concerning prescription animal remedy (PAR) products, on ACVM Act issues that affect them, and on the interface with the Animal Products Act generally.
- **ACVM workshops**, which were an updated version of the November 2002 workshops run in New Zealand, were held in Sydney and Melbourne. They were well attended by Avcare and VMDA (Veterinary Medicines Distributors Association) members and had good feedback. Thanks to Avcare and the VMDA for their organisation of the venues and logistics.
- A **summary of submissions** received on the draft standards for prescribing PAR products and for trading PAR products is now available on the website (<http://www.nzfsa.govt.nz/acvm/archive/draft/standards-guidelines/index.htm>). The ACVM Group's response to the submissions is being considered at the moment and will be published as soon as it is available (see article at right).
- A new **fact sheet outlining the process for setting MRLs** has been posted on the website (<http://www.nzfsa.govt.nz/acvm/publications/information-papers/mrls0903.pdf>). Other fact sheets available on the website are *Veterinary Medicines and the ACVM Act*, *Plant Compounds and the ACVM Act* and *NZFSA's ACVM Group*. All are short (two page) information sheets available under the 'publications/information papers' section.
- The ACVM Group's **Compliance operating principles** have been updated on the website (<http://www.nzfsa.govt.nz/acvm/publications/information-papers/compl-op-principles.pdf>). This two page document explains how the ACVM Group will deal with any complaints and/or allegations received.
- The consultation period for the **Draft Standard for Oral Nutritional Compounds** closed on 15 September. Submissions were considered and a revised draft has been placed on the website for consultation (see article on page 5).
- Members of the ACVM Group Operations team have attended a training session of **MAF Quarantine Services** (MQS) staff in Tauranga. We now have approximately 300 MQS staff trained and approved as ACVM Act inspectors at the Border.
- The **Industry Liaison Group** met in Wellington on 21 August 2003.

Consultation on the draft standards for prescribing and dispensing prescription animal remedies

The ACVM Group has placed the summary of submissions on its draft standards for prescribing and dispensing prescription animal remedy veterinary medicines on its website. Thirty submissions were received, predominantly from either veterinary practices or veterinarians. A number of these were copied submissions bringing the total of unique submissions down to approximately 15.

The general concerns expressed by veterinarians in regard to the original draft policy were the same in regard to the draft standards. The veterinary respondents, pharmaceutical companies and product manufacturers' associations still considered that applying the standard would:

- increase the risks to trade in primary produce, animal welfare and agricultural security;
- jeopardise the viability of veterinary practices;
- encourage misuse and over use of PAR products;
- put veterinarians under pressure to prescribe PAR products unnecessarily;
- allow unscrupulous farmers and trading organisations to have access to PAR products.

They were also concerned that the ACVM Group would be unable to ensure compliance. These were all issues addressed in the ACVM Group's response to the summary of submissions on the draft policy.

Federated Farmers of New Zealand were still in favour of the standards and considered that the draft standards improved the regulatory control proposed in the draft policy. New Zealand Feed Manufacturers Association, Poultry Industry Association and practitioners involved in vertically integrated intensive livestock production were also supportive of the standards.

There were additional new comments in regard to how the standards could be improved. These are being considered as part of a revision process. The ACVM Group is also drafting a response to the summary of submissions on the draft standards, which will be placed on the website as soon as it is completed.

The ACVM Group considers it has sufficient information to finalise the standards. It is intended that the prescribing and dispensing standards will be combined into a single standard for prescription animal remedy veterinary medicines. This will also include existing requirements for importation, manufacture and use as well as the requirements for prescribing and dispensing such products. The endorsement of the standard will be announced in a later issue of *AgVetLink*.

AVMAC meeting (21 August 2003)

A number of issues were discussed at the recent AVMAC meeting in Wellington.

Legislation

The NZFSA Policy Group advised that work had recommenced on the **ACVM Act Amendment Bill**. The intention is to take the previous submissions and to prepare a further discussion document. It is likely that there will be some relatively significant changes because the ACVM Act policy was developed prior to MAF taking on responsibility for Forestry and NZFSA being formed with responsibilities covering the additional areas of the Food Act and the Wine Makers Act. It was noted that changes arising out of the Biosecurity Strategy are also likely to impact on the ACVM Act in the future. The **ACVM Regulations** covering additions to the GRAS lists are also progressing through the parliamentary process with an expectation of being finalised within the next 4-6 weeks.

PAR products

The ACVM Group's response to the submissions received on the draft operational policy for **PAR products** was discussed as were the draft standard for prescribing PAR products and the draft standard for trading PAR products. The ARPPA representative expressed the concern of members over the potential threat to traditional veterinary practices. Several of the council members expressed strong support for the work of the ACVM Group in this area.

Compliance and Standards

The revised **Compliance Policy** was a key discussion point. The background paper presented to AVMAC is available on the ACVM website (<http://www.nzfsa.govt.nz/acvm/publications/discussion/operational-policies/index.htm>) along with the revised draft of the policy for comment. Submissions close on 15 October 2003. AVMAC was also advised of the progress and plans for **ACVM standards development**.

Staff update

Meg Davies (Assessor Technical Standards Veterinary Medicines)

'I grew up in rural Otago before venturing north to complete a vet degree at Massey. After graduating with distinction in 1992 I spent 5 fulfilled years in mixed animal practice in South Otago. Then I flitted off overseas on my OE, working in small animal hospitals in the UK to fund my travels. When I returned to New Zealand I went back into practice in Canterbury, married a vet, moved to Wellington, worked part-time for Schering Plough Animal Health and had two children. Much as I love my children, I missed interaction with adults and was concerned about post natal cerebral drift so applied for a part-time position with the AVCM Group. I am excited to be here and look forward to meeting everyone over the next few months. I am an ardent sports fan, and am anticipating a lot of time on the couch watching the Rugby World Cup. The rest of my passions – tramping, travelling and lots of socialising – have been superseded by our two great kids (in the mean time anyway!)



Residues survey

A pilot residues surveillance programme is being undertaken in this (2003/04) financial year. In future years the NZFSA will rank and prioritise the programme of residue/commodity combinations to be investigated.

We expect that the principles and prioritisation criteria of the programme will be subject to stakeholder consultation in accordance with standard NZFSA procedures. Details of the work to be undertaken will be advised on the NZFSA website.

The two components planned for 2003/04 are an investigation of glyphosate residues in potatoes and a multi-residue screen of wine and certain fruits and vegetables.

The current proposals have the following goals:

- To provide information about the level of residues in primary plant products in New Zealand. This will help the NZFSA to ascertain whether agricultural compounds are being used in a manner consistent with their conditions of registration.
- Where residues are detected, their frequency and concentration will assist the review of regulatory measures, including amendment of MRLs, amendment of WHPs or label claims, or introduction of compliance monitoring.
- To contribute to the development and implementation of the broader ongoing Residues and Contaminants Surveillance Programme.

Because of a high level of interest in glyphosate expressed at the last NZFSA Consumers' Forum, the NZFSA has undertaken to conduct additional work this financial year to investigate glyphosate residues in cereals. The details of this survey have yet to be developed.

Transfer of hazardous substances into the main framework of the HSNO Act

The ACVM Group has been advised by ERMA NZ of the latest intentions to transfer hazardous substances that are agricultural compounds into the main framework of the HSNO Act. This is important from an ACVM perspective because it will have an impact on the updating of veterinary medicine and plant compound registrations due in July 2004.

When the ACVM (Transitional Provisions) Regulations 2002 came into force there was an expectation that updating registrations could be done with HSNO controls in mind. Registrants have to apply for updated ACVM registration before 1 July 2004, but they still do not know for certain what labelling requirements will be imposed as a result of substances being transferred into the main framework of the HSNO Act.

Pesticides

ERMA NZ has advised that they expect to have the technical work on the transfer of pesticides under the HSNO Act completed by 1 January 2004. This

will allow the Authority to issue transfer reports specifying the controls that will be placed on those substances. ERMA NZ has also advised that they will be providing sufficient guidance to allow parties to know how to comply with the controls, particularly in regard to labelling.

While the substances will actually be transferred on about 1 July 2004, registrants will be able to determine the HSNO labelling requirements and submit their new label content to the ACVM Group early in the new year. This will allow them not only to meet their obligations under the ACVM (Transitional Provisions) Regulations 2002 but also to incorporate the labelling requirements under the HSNO Act.

Veterinary medicines

The situation is not as fortunate for veterinary medicines. ERMA NZ has advised that the transfer reports for hazardous substances that are veterinary medicines are not likely to be available until mid-2004 at the earliest. The classification of substances and,

consequently, the controls that will be applied to them may not be known before registrants have to apply to update their ACVM registrations. Nevertheless, they must lodge their applications with the ACVM Group for new ACVM registrations early in 2004, given that it must be done before 1 July 2004 in order to comply with the ACVM (Transitional Provisions) Regulations.

Advice

The advice that the ACVM Group offers to registrants is to either:

- apply for the updating of the ACVM registrations without consideration of the future HSNO controls and make the necessary changes in labelling whenever the relevant substances are transferred; or
- anticipate the likely HSNO labelling requirement for their products and lodge the appropriate label content for ACVM registration updates.

Workshops

The ACVM Group recommends that registrants discuss the issues with ERMA NZ to help them anticipate appropriate label changes. We understand that this is likely to impact significantly on the compliance costs for registrants who need to update their products to the ACVM Act prior to the HSNO transition date.

For this reason we have undertaken to organise workshops with industry representatives and ERMA NZ to see what can be done to minimise unnecessary costs for veterinary medicines.

A similar workshop will also be run for products covered by the Pesticides Act, but it is likely that all of these products will be transitioned prior to 1 July 2004. The main topic for discussion is how the issue of product in the market with outdated labels will be managed.

MRL update

In May the NZFSA consulted on a new MRL for pymetrozine in lettuce and an exemption from an MRL for 9,10-anthraquinone when used as bird repellent on grapes. The MRL for pymetrozine was gazetted on 17 July 2003. The NZFSA is currently refining its policy on MRL exemptions, so the proposed exemption for 9,10-anthraquinone is being held back until the policy is finalised.

The third round of public consultation for MRLs is underway (the final date for submissions is 6 October 2003), and proposes new MRLs for lasalocid sodium in poultry and doramectin in pigs. Refer to the NZFSA website (<http://www.nzfsa.govt.nz/policy-law/consultation/mrl-2003-09/index.htm>) for details.

Redraft of the standard for oral nutritional compounds

The period for comment on the *Draft Standard for Oral Nutritional Compounds* has closed. Three submissions were received. While they were in support of the need for the standard, there were aspects that needed further consideration.

The main issue was in regard to the level of regulatory control needed for oral nutritional compounds with added therapeutic or pharmacological substances. These were called 'medicated oral nutritional compounds' in the first draft, but this term was not considered helpful so it has been removed.

The revised draft has subdivided oral nutritional compounds into groups depending on whether or not the product:

- contains only generally regarded as safe (GRAS) feed additives;
- is offered for general sale; and
- has only registered therapeutic or pharmacological products added.

Some concern was expressed that feed manufacturers and transport companies would not be able to comply with the standard in regard to labelling bulk product and ensuring the appropriate feed went to the specified animals. These concerns are being investigated by the ACVM Group to see if they are valid. However, this is not likely to alter the standard materially because the ACVM Group considers it essential that feed (including bulk feed) be labelled correctly and supplied to the specified animal(s) in a reliable manner.

The ACVM Group has revised its draft standard for oral nutritional compounds. It can be found on the ACVM Group website and people are invited to comment on this revised version. Comments should be sent to Chris Boland, Programme Manager (Technical Policy), by 1 November 2003.

Registration and Product Datasheets

When submitting applications under the ACVM Act for either plant compounds or veterinary medicines, applicants have been requested to forward an electronic copy of the Registration and Product Datasheet to datasheet@nzfsa.govt.nz. This request was made with a view to supplying a copy to ERMA New Zealand, should the need arise.

Applicants should note that **this is no longer necessary** and the direction at the top of the Product Datasheet to forward an electronic copy will be removed at the next review of the document.

In addition, some applicants are forwarding an electronic copy of the 'draft' label content at the time of submitting their application. This is not a requirement. We remind applicants that the only electronic copy of the label content required is the 'final' version requested by us once the application has been approved.

Low Risk Registration Replacement

In the April 2003 edition of *AgVetLink* it was signalled that the *Registration Information Requirements for Low Risk Products* was to be replaced.

Work on the replacement is now in the advanced stages. It will take the format of individualised standard and guideline documents, which will act as stand alone registration information requirements. Each document will detail exactly what information and documentation must be supplied to the ACVM Group to achieve product registration. Products registered via this option will be collectively known as 'Specified Requirements Products'. An abbreviated Product Data Sheet has been developed and should be used when registering a Specified Requirements Product.

The first standard and guideline that is being developed is specific to oral nutritional compounds with non-GRAS ingredients. It is expected that the final version will be available on the ACVM website by late October.

The ACVM Group will continue to identify groups of products that are suitable to be registered via this option.

Draft standard for vertebrate toxic agents

The ACVM Group has drafted a standard for vertebrate toxic agents (VTA). This standard reforms the control on vertebrate pest control products and other vertebrate poisons that were never incorporated into the Pesticides (Vertebrate Pest Control) Regulations 1983.

The standard proposes a new classification system based on an increasing need to bring all vertebrate poisons under a consistent regulatory programme. The programme will impose a range of controls on VTA products that vary from over-the-counter sale of registered products as the simplest conditions through to registration of traders and licensing of users.

The ACVM Group is aware that these kinds of products are likely to attract controls under the HSNO Act as well. However, because different risks are managed under the two pieces of legislation, the ACVM regulatory programme will still be needed even after ERMA NZ has applied the HSNO controls.

The ACVM Group is working closely with ERMA NZ to ensure that the two programmes are complementary and compatible with no duplication of effort. This intent is reflected in the draft standard, but the ACVM Group is interested in the comments from interested and affected parties. We are also working closely with the Animal Products Group of NZFSA who are addressing the concerns around the potential for VTA residues in feral game – the main impact is on hunters, processing plants and landowners.

Following internal consultation, the draft standard will be available on the ACVM website. (Make sure you register for email advice when the site is updated if you haven't already done this.) The Animal Products Group considerations are also available on their part of the website.

ACVM DOCUMENTS

For the past few years, it has been possible to download ACVM documents from the website or purchase them from Manor House Press. (Our thanks to Manor House for providing this 'hard copy' service.)

Now that nearly everyone who is using ACVM documents is downloading them, the electronic version will be the only one available as of 1 October 2003.

If you are unable to download documents, contact:
Melanie Pero (Coordinator Operations)
Ph: 04 463 2550 or
Email: melanie.pero@nzfsa.govt.nz

Overdue Annual Fees

Invoices for 10% penalty interest for any unpaid annual fees have been posted.

Even at this late stage, following a series of reminders, some companies are advising that they wish to cancel products.

We would remind registrants of the business rules around the refund of annual charges.

If a registrant advises of a cancellation (having met the ACVM Group requirements to take all reasonable actions to ensure that the product is no longer on the market), then the following refunds will be applied:

- Advice July to September
refund of 75% annual charges
- Advice October to December
refund of 50% annual charges
- Advice January to March
refund of 25% annual charges
- Advice April to June
no refund of annual charges

The relevant portion of any penalty interest will be charged as will any administrative costs for making the adjustments.

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.

The ACVM Group will waive the prohibition on confirmation of the receipt of the full outstanding amount, including the penalty interest component.

ACVM Group compliance activities

In recent months a number of complaints have been investigated in relation to non-compliant products or activities.

FIELDAYS

The ACVM Group's attendance at the Hamilton Fieldays in June 2003, with representatives from the Compliance and Investigation Group (CIG) of NZFSA, was a success from a compliance and education of exhibitors perspective.

This year the ACVM Group took a different approach in that we visited organisations with stands rather than spending the majority of the time on the NZFSA stand. Actions taken by the ACVM Group were placed into four categories:

- compliance issues – educational
- compliance issues – repeat offenders
- miscellaneous incidents – non-compliance
- prohibition notices served.

Educational

In this category, some of the companies were unknown to the ACVM Group, and were generally spoken to in regards to therapeutic claims made on their veterinary medicine products. Product types consisted of either oral nutritional or oral herbal compounds.

Non-compliant information on products was either noted on labels or in leaflets provided on their exhibition stands. Companies were advised of their responsibilities under the ACVM Act.

Repeat offenders

Three companies were approached in regard to continuing to advertise and sell products that the ACVM Group had informed them already were non-compliant.

Each of the companies was making claims on products that categorised them as veterinary medicines requiring registration. As a result of these activities a prohibition notice was served on one of the companies.

Miscellaneous incidents/non-compliance (vendors not spoken to at the time)

Over the four day period of the Fieldays, the ACVM Group picked up various product pamphlets that were then reviewed and classified by way of a class determination once we had returned to the office.

Most of the non-compliances in this area were for non-approved claims, not on the labels as such but in pamphlets and / or advertising material. Companies have been contacted regarding their responsibilities under the ACVM Act.

Prohibition notices

Three further companies were issued prohibition notices with a requirement for product to be removed from the shelves at the Fieldays. This action was taken only where there had been a prior dialogue with the ACVM Group and the company concerned.

As a result of collecting a pamphlet obtained at the Fieldays, and a follow up investigation, a further prohibition notice was placed on one company for advertising a product where claims were not approved.

These prohibition notices prohibit the manufacturing, selling, or using any agricultural compound in contravention

of any provision of the ACVM Act and Regulations.

'SLICE OF LIFE' AUDITS

As per our August *AgVetLink* article, the ACVM Group has agreed a programme outline with the CIG for the current year for 'slice of life' audits. These audits are additional to any investigative work carried out by CIG.

In mid-June the first part of an audit of Border activities was carried out at MAF Quarantine Service in Auckland, covering Air Cargo, the International Mail Centre and the Airport Terminal. It covered the importation of both veterinary medicines and plant compound products. In mid-July the audit covered the airport in Christchurch. ACVM staff were present at both Borders and have given technical advice where needed on clearance of ACVM products. We are currently waiting for a legal opinion on Biosecurity/ACVM Act interface issues before recommendations are finalised and the report is drafted. In the interim, we can advise that the outcomes of both visits were, in general, favourable.

A further 'slice of life' audit will commence soon in regards to the use of human medicines by veterinarians. The terms of reference have been drafted and agreed for this review.

Harmonisation with Australia

During a recent visit to Australia the ACVM Group again raised the issue of the opportunity to harmonise with Australia on assessments of products for companion animals (cats, dogs, aviary birds, aquaria fish, reptiles, etc. but excluding horses) and possibly even to harmonise labels. One of the key industry associations in Australia is very interested and will progress matters with the Australian APVMA. New Zealand organisations that we have spoken to so far are also supportive of the initiative. This activity fits within the mandate of the ANZ registration liaison committee that is already in place to facilitate harmonisation initiatives.

ACVM Group move to limited registration periods

Section 21(2) of the ACVM Act provides for registrations to be given a date of expiry. In the past the ACVM Group has not had expiry periods for the majority of full registrations but there was a requirement under the old legislation that certain information must be kept up to date.

Changes required

The ACVM Group has been dealing with a number of updates of products as we near the end of the transitional period, and we have noted that a high number are not 'simple' updates and actually require changes to be made. This means that the requirements of the previous legislation were not being met.

We also expect that, because of the complex nature of the interfaces that the ACVM Act has with other legislation, future changes in the ACVM Act and in related legislation will mean that ACVM risk management must be

updated via changes in conditions on products. Changes to labels are likely to occur as a result.

Limited period

The ACVM Group is therefore proposing to introduce limited period registrations. For most products the period is likely to be three years, although where there are known changes likely to occur or other reasons prevailing it could be a shorter period. Wherever products are changed within the expiry period (as part of an application for such change), the expiry period would be for (up to) three years from the date of the approval of the change.

We are working to ensure that compliance costs will be minimised. The following are proposed as operational 'rules':

- Prior to the expiry date of the product, registrants will be reminded

of the need to confirm product details.

- Registrants will be required to provide the Product Data Sheet (PDS) and to declare that there have been no changes to the registered product.
- Where there has been no change there will be no charge for the new registration certificate.
- Where there are label changes required the ACVM Group will work with the registrant to agree a reasonable timeframe for implementation but this will be within a defined period.
- Where there are changes to the register required or where the change requires an application, normal charges will apply.

PAR Class II label wording

In the August 2003 issue of *AgVetLink* comments were requested on the proposal to change the mandatory label wording for veterinary medicines registered with a PAR Class II condition from:

“For use only in the presence of a veterinarian”

to:

“For use only by, in the presence of, or under the direct control of a veterinarian”.

No comments were received on this proposal and the proposed statement.

Further review

However, the ACVM Group has further reviewed the wording requirements for

products to line them up with the management of PAR products. The label wording for PAR Class II products will be:

“For use only by, in the presence of, or under the control of a veterinarian”

Conditions on registration

The conditions on registration will also be altered and will be:

1. For Sale:

“This product must not be sold by any person except an approved trader and to any person other than an approved trader, or under a veterinary prescription or authorisation.”

2. For Use:

“This product must be used only by, in the presence of, or under the control of a registered veterinarian.”

Discretionary use

In addition there is a proposed change to the wording of the 'discretionary use' registration condition on PAR Class II products (and other registered veterinary medicines) to:

“The product may be used at the discretion of a registered veterinarian, only when acting in accordance with the applicable ACVM standards unless that use is not permitted in the current registration.”