



AgVetLink

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What's coming up

■ Australian Registration Liaison Committee

The next meeting, which will be held in Canberra on 7-8 May, will be attended by Brian Pidford (ACVM Group Programme Manager, Verification) and Maree Zinzley (ACVM Group Programme Manager, Operations). The meeting covers a range of registration and compliance issues and is attended by people from the Commonwealth as well as by representatives from the states and territories. Maree and Brian will take the opportunity to touch base with their counterparts in Australia. There will also be an opportunity to discuss parallel interests regarding international GMP and QA/QC assessment and adverse event reporting programmes for veterinary medicines and for agrichemicals.

■ VICH Safety Working Group

John Reeve will attend the meeting in Brussels in late April. This meeting is to progress the chronic toxicity and microbial safety guidelines.

■ VICH Steering Group

The 12th Steering Group meeting is to be held in London in early May. Debbie Morris will attend as the Australia/New Zealand representative.

■ The Australian Product Safety and Integrity Committee

(formally known as AVCPC – Ag and Vet Chemicals Policy Coordination Group) is meeting in Canberra in late April. Debbie Morris attends the meetings as an observer.

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■ The NZVA Society of Sheep and Beef Cattle Veterinarians seminar

is to be held in Christchurch, 21-23 May. Debbie Morris will speak to the group on the regulatory viewpoint covering PAR products.

■ AVMAC meeting

The next meeting will be held in Wellington on 22 May.

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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Recent events

- The Australian NRA (National Registration Authority) has changed its name and is now the Australian Pesticide and Veterinary Medicines Authority (APVMA). The website address is <http://www.apvma.gov.au/>
- The last AVMAC meeting was held in Wellington on 27 February. See page 8 for an overview of what was discussed.
- An Industry Liaison Group meeting was held on 27 February.
- The 12th Food Safety Quadrilateral meeting was held in Queenstown from 17-21 March and was attended by Debbie Morris from the ACVM Group. See page 6 for details.
- The NZFSA conference 'Building and Maintaining Confidence in New Zealand Food' was held in Auckland on 25 and 26 March and was attended by 250 delegates from a wide range of food and food related industries. See article at right.
- Chris Boland and Sarah Lester attended a Growsafe Trainers Course in Rotorua on 2 April.
- The ACVM Group's new **discretionary data assessment service** commenced on 1 April. The data assessment is now separate from regulatory review and evaluation. This means that assessment reports are returned to the applicant at the end of the data assessment. Alternatively, the assessment of any, or all, of the data may be carried out by an independent third party using the data assessment templates and standards available on the website. For more information, see the ACVM Group's website under 'Data Assessment Service'.

New Zealand Food Safety Authority conference – 'Building and Maintaining Confidence in New Zealand Food'

The NZFSA conference was held at the Stanford Plaza Hotel in Auckland and was opened by the Minister for Food Safety, Hon Annette King. The programme offered a range of national and international speakers. Well-known New Zealand names included Dick Hubbard, CEO of Hubbards Foods, and Tom Lambie, National President of Federated Farmers.

Some interesting perspectives were covered by the international speakers – Debbie Peters from Food Operations Australia and Sue Dibb from the United Kingdom National Consumers Council were both very well received. Louis Carson from the United States Food and Drug Administration provided a detailed presentation on the new requirements that are coming into place in the USA in response to bioterrorism. These will impact on almost all New Zealand exporters to the area in the short to medium term.

The ACVM Group hosted one of the workshop sessions and, while there were a few well-known faces, we also had the opportunity to talk with a number of people we don't normally see. Because the workshop was small, we were able to concentrate on dealing with issues and questions that were raised from the floor, such as the linkage with ERMA NZ and the HSNO Act, adding minor uses to labels, changes to PAR controls, and how exemptions and the GRAS lists operate.

The workshop of interest on the second day covered the terms of reference for the proposed strategic review of imported food and food related products (see page 9). While the process is being led by Tim Knox in his capacity as Acting Director of the Retail and Imported Foods area, this is also of interest to the ACVM Group because many of the risks posed by imported foods are also posed by the importation of animal feeds and feed ingredients – both of which are managed under the ACVM Act (in conjunction with the Biosecurity Act 1993).

ANNUAL FEES 1 July 2003 - 30 June 2004

All registrants will receive a letter in May outlining this year's annual fees for all registered plant compounds and veterinary medicines. Included in this mail out will be your product list. Any changes, updates or cancellations will need to be submitted to the ACVM Group by Friday, 13 June 2003.

If you have any queries, please contact:
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Draft policy on PAR products

The 49 submissions received on the draft operational policy on PAR products covered a broad range of views. A high number of the submissions were from veterinarians or organisations representing veterinarians; there were also submissions from user significant groups (such as Federated Farmers, Fonterra, and a combined submission from the Feed Manufacturers Association and the Poultry Industry Association) and from registrant companies. A summary of the submissions is available on the website.

There have been suggestions made that some of the assumptions used by the ACVM Group in developing the draft policy are incorrect. The NZFSA Compliance and Investigation Group is in the process right now of undertaking 'slice of life' audits covering a number of issues related to PAR products. We will take the opportunity to follow up on these suggestions to make sure that any assumptions used are supported in practice.

It appears that there are a number of areas of confusion where more communication is required. This confusion covers such points as:

- Why a PAR policy needs to be developed at all – unlike the Animal Remedies Act, the ACVM Act does not have any provision for assigning PAR status to products or providing for veterinary discretionary use. This is done by putting conditions of registration on products or via the use of codes of practice.
- The proposed code of practice for traders – there was a high level of concern over users being able to set up as traders, the lack of training, the controls, and how the system might work. These comments are all being considered carefully.
- How the 'cascading' system might work in relation to veterinary discretionary use of products – there were suggestions that this might force veterinarians to use inappropriate treatments just because they are registered. This is not the intended outcome so clarification will be provided.

There were also significant concerns expressed over how the proposal could damage animal welfare and biosecurity over time. Other submitters expressed concerns over the trade impacts of the implementation of the proposed policy. The ACVM Group and the NZFSA Policy team are working on how to address concerns and will contact a range of the stakeholders to work through adjustments to the policy.

Ongoing obligations of registrants

A new registration condition has been implemented to give effect to the ongoing obligations of the registrant of a trade name product. Registrants must advise the ACVM Group of any new studies on their product and of any data that contradict previous information supplied to the ACVM Group or that indicate unintended harmful effects from using their product (adverse events).

A summary of adverse events for the past year should be provided at the same time the annual fees are paid. Adverse events or any additional studies or data that have serious implications for the continued use of the product must be notified immediately. These obligations are described in more detail in the *ACVM Registration Information Requirements for Plant Compounds* and *ACVM Registration Information Requirements for Veterinary Medicines*.

Withdrawal of the low risk registration option

The low risk registration standard was introduced under the Animal Remedies and Pesticides Acts to provide a simple registration process for products where it was recognised that limited information was required. It primarily provided for products that were being considered for exemption from registration under the ACVM Act.

Since the implementation of the ACVM Act, the low risk registrations have consisted mainly of oral nutritional compounds that have not met the requirements for exemption because of the inclusion of feed additives not listed in the GRAS list in the regulations.

The ACVM Group plans to remove the option of low risk registration and replace it with guidelines for registration of product types where limited data is required. This is intended to provide an easy to follow process for putting together an application while preserving the advantages of the low risk system.

Until guidelines are available for the types of products currently being submitted as low risk, the registration requirements will remain on the website for guidance in submitting applications.

In the interim, the disclaimer that was previously required on labels is no longer being applied.

Changes in product advertising policy

The ACVM Group's policy on advertising (ref: Product Advertising Policy, 164 ACVM 10/02) states that the prescription only status on the product must be included in any advertisement. All other limitations on advertising in the policy are generic and refer to all agricultural compounds.

Several parties have advised the ACVM Group that this is inadequate guidance for a number of reasons. Some types of PAR products should not be advertised to the public at all. For those that may be advertised, the advertisement should always be consistent with the registrations.

Acting on this advice, the ACVM Group has amended the advertising policy. The New Zealand Veterinary Association code of practice *Promotion of Prescription Animal Remedies by Veterinarians and Industry* was taken into consideration when developing the following amendments.

Classes II and III PAR products must not be advertised in any way to the general public.

It is acceptable for registrants or third parties to advertise (either directly or via trade-specific publications such as special branch newsletters, the *New Zealand Veterinary Journal* or *Vetscript*) classes II and/or III PAR products to veterinarians who have the right to prescribe them. It is not acceptable to advertise such products to the general public or even to particular user groups.

Class I PAR products may be advertised under certain circumstances.

The advertisements must be technically correct and factual. Any product claims must be able to be substantiated (and consistent with the claims approved as part of the product's registration). There

must be no distortion through exaggeration, misleading statements or untrue emphasis. There must be no reference to websites that are not under the control of the registrant and that may present the product in a manner or make claims that are inconsistent with its registration.

Registrants may draw attention (including in television advertisements) to their products in a factual and technically correct manner. However, there must not be any inducement offered or any presentation of the product to the end user in a manner that causes undue influence on the prescribing veterinarian.

Prescription animal remedy (PAR classes I, II or III) products must not be displayed for general sale.

The revised product advertising policy can be viewed on the ACVM Group website.

Codes of practice becoming ACVM standards

Some parties have expressed confusion in regard to the nature and content of codes of practice approved under section 28 of the ACVM Act. Other parties have suggested that some of the codes of practice that have been developed by the ACVM Group and approved under section 28 do not have the commonly accepted characteristics of codes of practice.

For example, the *Code of Practice for Own Use of Compounds* is a statement of the regulatory expectations in regard to such use, but it does not provide any operational detail that would guide practice. This code is better described as a standard similar in content to schedule 4 of the ACVM Regulations that specifies the requirements for oral nutritional compounds. The New

Zealand Feed Manufacturers Association was able to use schedule 4 to develop a more traditional type code of practice that provides practical guidance to meet the requirements specifications in the schedule.

It is highly unlikely that the ACVM Group would have a need or be in a position to develop a true code of practice specifying operational requirements in any detail. The ACVM Group sees the soundness of the distinction between standards and codes of practice. Consequently, the Group will develop ACVM standards to state explicitly the regulatory expectations in regard to particular activities. The standards will be used when reviewing codes of practice submitted for approval under section 28 of the ACVM Act.

Standards will be put forward for public consultation as they are developed. There will be standards for other activities developed, but the following will be priority topics:

- use of prescription animal remedies by non-veterinarians;
- trading in prescription animal remedies; and
- distribution, sale and use of vertebrate toxic agents.

For the time being the *Code of Practice for Own Use of Compounds* will remain an approved code of practice to provide a basis for the first exemption in schedule 1 of the ACVM Regulations. However, it will be duplicated as an ACVM standard to be used to review any relevant code of practice proposed by third parties.

Identification of specific regulatory statements on labels

The ACVM Group has had discussions with a number of parties about identifying regulatory statements on labels. Under the Animal Remedies and Pesticides Acts the ACVM Group approved final labels and did not explicitly provide for off-label use. However, under the ACVM Act, only the label content relevant to the ACVM Act is approved rather than the whole final label. In addition, there is now a specific condition that allows for off-label use, if such use is acceptable.

There will be occasions when a registrant may want to make statements on a label that have nothing to do with the conditions of registration of the product. If the ACVM Group considers that inclusion of such statements on the label does not jeopardise regulatory control, then it will allow the statements.

To a user of products, such statements on labels may look like regulatory statements imposed under the ACVM Act. Concern has been expressed to the ACVM Group that allowing registrants to make use statements in addition to those approved makes it difficult for a user to distinguish between a direction from a registrant, an ACVM-approved statement and a regulatory statement.

To clarify the distinction between regulatory statements and statements made by the registrant, the ACVM Group has developed a set of labelling principles:

- The current registration approval must expressly state all the conditions that have been imposed.
- Any condition that has a regulatory impact on the users of products must be stated as a regulatory statement in the label content.
- Each regulatory statement must be recognisable for what it is by its wording at least.
- The ACVM Group will allow registrants to make statements on the label only if the statements do not jeopardise regulatory control.

■ Regulatory statements must be made explicit by requiring any one of the following:

1. it is a condition on the registration that...;
2. it is an offence under the ACVM Act (or ACVM Regulations) to...;
3. failure to... may be an offence under the ACVM Act (or ACVM Regulations);
4. by law....

These are only examples. There may be other phrases acceptable to the ACVM Group that make the regulatory statements equally explicit.

From now on the ACVM Group will be specific about the regulatory statements that must be included on the labels of products. For new registrations the

Group will discuss with registrants the statements that must be included on the labels. For existing registrations the label changes will be discussed as part of the registration updating process. For products that have already been updated the changes will be introduced in a timeframe agreed to with the affected registrants.

The inclusion of all the regulatory statements into a 'regulatory box' was suggested as a possible option to identify such statements clearly. It appears that, over time, a regulatory box may become the preferred way for registrants to meet the ACVM labelling requirements. However, initially at least, the position and form of the statements will not be prescriptive but the specific wording will be part of the label content approval.

Label content on website

In February 2003 the ACVM Group commenced publishing the label content of products on the public register.

It should be noted that label content is published only for products that have been registered under the ACVM Act or have had new (updated) registrations issued under that Act. Not all products have label content available as yet.

To view the label content of a product, go to the ACVM website and click on the 'Registers and Lists' link. Search for and select the required product, then click on the 'Label Content' link. There could be more than one link available depending on the related components.

There may be only one pack size for a product label appearing on the register; however, other sizes may have also been approved for that product.

If you have any comments or concerns with this new facility, please contact an Advisor (Operations).

Workshops on standards

The ACVM Group held workshops on 24 March 2003 in Auckland to explain finalised and proposed changes to some of the ACVM standards and guidelines. The workshops discussed the revision of three standards:

- chemistry (plant compounds)
- residues (veterinary medicines) and
- residues (plant compounds).

In the morning, plant compound participants were guided through the changes made in the *ACVM Registration Standard and Guideline for the Chemistry of Plant Compounds*, which is now in effect. The finalised standard and a summary of the submissions received is on the website (<http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/index.htm>).

In a concurrent session, veterinary medicine participants were given a rundown on changes to the *ACVM Registration Standard and Guideline for Determination of a Residue Withholding Period for Veterinary Medicines*. The finalised version of this standard is available at the website address above.

The equivalent residue session was held for plant compound participants in the afternoon. The submission period for the plant compound standard is still open. Any comments on the draft *ACVM Data Requirements for a Food or Feed Use Clearance: Plant Compounds* should be received by **26 April 2003**. The draft

document can be found on the website (<http://www.nzfsa.govt.nz/acvm/publications/discussion/standards-guidelines/index.htm>).

While there was limited participation from interested parties, those who attended the workshop found it informative.

NOTE: Users of the veterinary medicine residue standard should note that some changes have been made to the version originally posted on the website. Please ensure that the standard used to prepare an application for a veterinary medicine withholding period is the version **39 ACVM 03/03**.

Quadrilateral meetings

The 12th Food Safety Quadrilateral meeting (between New Zealand, Australia, Canada and the United States) was held alongside the Animal Health meeting in Queenstown from 17-20 March 2003. The Food Safety meeting was chaired by NZFSA Executive Director Dr Andrew McKenzie as head of the host country delegation, and New Zealand again took the opportunity to bring the two meetings together for one of the days to discuss common issues. A number of ACVM related issues were covered in the joint meeting including emergency response and animal feeds.

In the Food Safety meeting, topics of interest included antimicrobial resistance, bioterrorism, imported food and feed programmes, BSE/TSE, Codex issues, and contaminants. The meetings provide a great opportunity to meet with regulators from the Quad countries and to share a range of information and experiences. The next meeting will be held in Canada in 2004.

Product specific approvals on registrations

The ACVM Group has identified a limitation in the way registrations are documented. Currently, there is no obvious place in the registration certificate that states the statutory obligations on parties other than the registrant, manufacturer or user.

Under the ACVM Act the importation, manufacture, sale and use of agricultural compounds can be regulated. Where necessary, the ACVM Group imposes conditions on the registration of trade name products to control any of these activities that pose significant risks. For example, manufacturing is a common point of control and all registered products have a manufacturing condition explicitly stated on the registration certificate that must be met by the registrant and manufacturer. For prescription animal remedies access is restricted and sale is limited to persons holding a *bone fide* veterinary prescription. Therefore, users of such products will find their regulatory obligation explicitly stated on the product label.

The present registration certificate does not explicitly state the statutory obligations of other parties. Consequently, from now on the documentation of a current registration will include a part called the 'product specific approval'. This part will state the statutory obligations and the kinds of persons (importer, distributor, veterinarian, etc.) who must comply with the obligations regarding importation, distribution, promotion, product security, record keeping, reporting or any other activity that poses relevant risks. There will be a general condition applied to the registration certificate stating that every person must comply with the requirements specified in the product specific approval part of the current registration. The product specific approval will be on the public register so that all parties can readily see their statutory obligations.

Collaboration with UK Veterinary Medicines Directorate

Dr Jason Todd, Manager Immunological Inspections, Veterinary Medicines Directorate (VMD), UK, visited New Zealand to conduct regular quality assurance/quality control (QA/QC) inspections at four manufacturing sites in Upper Hutt, Palmerston North, Dunedin and Auckland between 3 March and 13 March 2003. These inspections were carried out jointly with Trish Whitaker, a GMP Inspector with AgriQuality Ltd, under contract to the ACVM Group.

QA/QC inspections are regular reviews of the quality systems of manufacturers of veterinary vaccines that are sold on the UK market. (The inspections are programmed to be carried out annually but slippage can occur when overseas manufacturers are involved.) QA/QC inspections comprise the programme that has been introduced by the UK to enable the release of each batch of veterinary vaccine onto the market by the regulatory authority. Other European regulatory authorities enable batch release of veterinary vaccines through sampling and testing provisions in the European Directives.

This process for the release of each batch of veterinary vaccine onto the market by a regulatory authority is called 'official batch release'. Official batch release is not covered under the Mutual Recognition Agreement (MRA) made with the European Community for conformity assessment of GMP. Therefore, while the visits of GMP inspectors from Europe to approve New Zealand sites for supply to Europe under the MRA have now stopped, inspectors from the VMD would still need to visit annually to enable batch release of vaccines to the UK market.

Prior to the visit, the ACVM Group and the VMD had reached agreement in principle that it would be possible for New Zealand GMP inspectors to perform QA/QC inspections of veterinary vaccine manufacturers'

quality systems on behalf of the VMD after an appropriate transitional period for mutual confidence of both regulators. It was agreed that the 2003 cycle of inspections would be carried out jointly and collaboratively by both regulatory authorities; single inspection reports combining the comments of both inspectors would be provided after the inspections.

It was also agreed that the next cycle of inspections due in March 2004 would be carried out by the New Zealand inspector and observed by the VMD inspector. Successful completion of this programme would form the basis of a technical agreement between the VMD and the ACVM Group for the conduct of future QA/QC inspections by the ACVM Group on behalf of the VMD.

The visit therefore had two main purposes:

- to enable the VMD to conduct its routine QA/QC inspections for batch release, and
- to enable the development of a harmonised approach to QA/QC inspections by both regulatory authorities for the development of the technical agreement.

The opportunity was also taken to keep up to date with European trends in GMP.

A good working relationship developed between the UK and New Zealand inspectors, with both playing full and equal parts in the inspections carried out. The UK inspector was pleased with the process and was satisfied that we are on track to complete the transition.

Trial location condition for Provisional Registrations and Research Approvals

The current condition that is imposed on substances subject to a Provisional Registration or Research Approval where the trial site is undecided at the time of application is: "The location of any trial sites not identified in the site and systems in the application must be notified to the ACVM Group as soon as they are known and before the expiry date shown on the certificate".

A review of this wording has revealed a potential problem with regard to tracking and tracing of any incidents relating to such a trial. Knowledge of trial location forms part of the 'track and trace' system to ensure that the whereabouts of animals and plants treated with the test substance is known from the time of treatment until the period of regulatory interest has elapsed. To require this information only prior to the expiry of the certificate, which could conceivably be several months following treatment or application of the substance, is not sound risk management and does not fulfil the intended purpose.

To rectify this, the condition has been changed to read: "*The location of any trial sites not identified in the site and systems in the application must be notified to the ACVM Group as soon as they are known*".

Applicants should be aware that where this condition applies to a Provisional Registration or Research Approval issued to them by the ACVM Group, it is their responsibility to fulfil this obligation. Failure to comply is likely to result in future applications involving undecided trial locations being declined until they are known.

Communicating with registrants and consultants on applications

It is common practice for applicants to engage the services of a regulatory consultant to prepare applications and to act as the primary point of contact with the ACVM Group during this time.

It is ACVM Group policy that where the nature of any correspondence is such that the Group deems it necessary for the registrant to be informed directly, such as where an application is deficient and is likely to be declined, it will be addressed to the registrant in addition to the consultant.

This is to ensure that communication is timely and to avoid any opportunity for misinterpretation.

Applicants should ensure that the ACVM Group is informed if a consultant is to be the primary point of contact for any particular application.

Where there is any uncertainty, the ACVM Group will communicate directly with the registrant.

AVMAC meeting - 27 February 2003

This was the 21st meeting of AVMAC and, as usual, the agenda was a full one.

- Chris Boland presented an update on the management of antibiotic resistance project. This is now posted on the ACVM Group website (<http://www.nzfsa.govt.nz/acvm/subject/antibiotic-resistance/index.htm>).
- The meeting was advised of two new codes of practice approved under the ACVM Act – one covering the writing of prescriptions for PAR products (New Zealand Veterinary Association and the Veterinary Council of New Zealand) and the other covering the use of PAR products by grooms travelling with horses. A full list of the ACVM Act approved codes of practice can be viewed on the website (<http://www.nzfsa.govt.nz/acvm/registers-lists/cop.htm>).
- Meriel Watts, consumer representative on the group, was invited to present a paper for discussion. This proved to be a useful addition to the meeting.
- There was considerable discussion on submissions to date on the proposed operational policy for the control of PAR products and the related issue of the development of a standard covering 'operating instructions'.
- Bruce Burdon provided an update on the likely timing of the ACVM Act Amendment Bill and changes to the exemptions/GRAS regulations.

Review of AVMAC membership

The meeting was asked to consider the membership of AVMAC given that the ACVM Act is now in force and that the group has been operating for a number of years. We want to know if there are organisations or individuals who consider that they should be represented on AVMAC either in addition to the current membership or as a replacement. If you have any suggestions or comments please forward them to Gill Wilson (email: gill.wilson@nzfsa.govt.nz).

Adoption of VICH guidelines

The following are final guidelines that were endorsed by AVMAC members at the meeting on 27 February 2003.

- GL28 Safety studies for veterinary drug residues in human food: Carcinogenicity studies. (October 2003)*
- GL 31 Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat dose (90 days). (October 2003)*
- GL32 Studies to evaluate the safety of residues of veterinary drugs in human food: Developmental toxicity testing. (October 2003)*
- GL33 Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to testing. (October 2003)*

The NZFSA proposes to apply these Step 4 guidelines (as appropriate) in its standards and guidelines for the registration of veterinary medicines under the ACVM Act and Regulations, and in any related legislation. Details of the VICH process and the finalised guidelines can be found on the website (<http://www.nzfsa.govt.nz/policy-law/vich/guidelines>).

Codex Committee on Residues of Veterinary Drugs in Foods

Bill Jolly (Veterinary Counsellor, Brussels) and John Reeve (Programme Manager, Toxicology and Residues, ACVM Group) were the New Zealand delegates at the 14th meeting of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDVDF), held in Washington DC from 3-7 March 2003.

Residues monitoring

At the 13th CCRVDVDF meeting, New Zealand had been accepted as the lead country in the development of a revised Codex guideline covering residue monitoring and control. The paper, developed with valuable contributions from other assisting countries, was presented at the 14th meeting, and was accepted as the basis for proceeding with the development of the revised guideline.

The paper contains new paradigms for the Codex system, and seeks to introduce the concept of proper risk management rather than the currently accepted practice of taking precipitate action on any shipment that contains residues above the Codex limits. This is particularly important for substances for which no Codex MRL has been set, where the current situation assumes that any detectable residue is unacceptable whether there is any risk to human health or not.

The acceptance of the paper by the 14th Committee means that any opposition can change the guideline only if scientific evidence supports such a move. There is a good chance that New Zealand will be able to bring about an appropriate change in the way international trade is controlled.

This acceptance also meant that a US paper seeking to control residues in milk and milk products (which gave us concerns) will now not go ahead. Instead, it will adopt the new paradigms and be assimilated into the 'New Zealand' guideline as an appendix.

Antimicrobial resistance

There was plenty of discussion on the draft code of practice to minimise and contain antimicrobial resistance that was presented to the Committee by the US. Many of the disagreements in the positions of the delegations arose because of the lack of a glossary, and the different perspectives of the delegations as to exactly what was being referred to when the term 'antimicrobial' was used. Most of the time the delegates were commenting only on antibiotics, and not anticoccidia and antifungal treatments, for example. It was clear that a glossary had to be developed before useful comment could be made, and so the paper is to be recirculated as currently drafted, with a comment deadline of 30 June 2003. The drafting

group will then prepare a revised version of the proposed draft code by the end of 2003 for circulation to all Codex countries, so that it and the subsequent comments can be considered at the 15th session of the Committee (tentatively scheduled for September 2004).

Substances advanced

Substances with residue limits advanced to step 8 Codex MRLs were clenbuterol (when used for approved therapeutic purposes only) and deltamethrin. (Ivermectin in milk was also recommended for adoption as a full Codex MRL.) A limit for dihydrostreptomycin and streptomycin in sheep milk was advanced to step 5/8, and a limit for cefuroxime in cattle milk was advanced to step 5.

Strategic review of imported food and food related products

This year the New Zealand Food Safety Authority is proposing to commission an independent strategic review of arrangements controlling imports of food and food related products into New Zealand.

The aim of the review is:

"To identify stakeholder needs and expectations in relation to imports, identify major food safety and security threats associated with importing food and food related products, and make recommendations on cost effective ways in which the existing imported controls could be improved to meet stakeholders needs and expectations and the likely demands of the future trading environment".

The independent reviewer/s will undertake extensive stakeholder consultation during the year, including surveys. It is important to note that the review will also cover food related products such as animal feeds and feed ingredients because these pose many of the same risks as food for humans. The Agricultural Compounds and Veterinary Medicines (ACVM) Act manages risks to trade in primary produce, agricultural security, animal welfare and domestic food residues. For this reason stakeholders are encouraged to review the terms of reference, which are available on the ACVM website under the 'discussion documents' area.

Although consultation on the terms of reference is closed, the opportunity to indicate interest is open as is involvement in the later part of the process. We look forward to hearing your views. Please forward any written comments to: Hazel Dobbie, NZFSA, PO Box 2835, Wellington
Email: hazel.dobbie@nzfsa.govt.nz; phone: 04 463 2661

Staff update

Rebecca Shakespeare Advisor (Business Services)



Rebecca Shakespeare joined the joint support team in March as the Financial Advisor, to assist the ACVM Group/Dairy and Plant Products in financial matters.

She completed the National Certificate in Business Studies and then commenced working for Massey University in their Finance Section.

From there she worked for a property company as an Accounts Administrator.

Itchy feet took over after five years and she went to the UK for 'the big OE' where she continued working in the property area with the focus on credit control. Over the last two years Rebecca has completed some studies in IT, and has worked for an IT company in their customer service area.

Rebecca's interests include health and fitness, sport, movies and socialising with friends.

Melanie Pero Co-ordinator (Operations)



Melanie was born and raised in Christchurch. She has enjoyed living in Wellington for the last nine years where she definitely supports the Hurricanes.

"I love rugby, indoor and outdoor netball, touch rugby, shopping, music and socialising. I completed my final year at college at

Wellington Girls in 2000, where I also was one of 12 student councillors who partake in running the college in designated areas, mine being cultural. I am of Cook Island and European descent. Throughout my years at college I danced the 'hula' in the Cook Island group, and in my last year danced and led the group. I was also a peer support leader, netball coach, touch coach and first aider. I am currently studying towards a diploma in psychology, health and human behaviour, and next year I am taking up criminal law and women's studies. I feel privileged to be a part of the ACVM Group, and I am enjoying working here."

Andrea Mackenzie Acting Executive Manager (Business Services)



Andrea has joined the ACVM Group/Dairy and Plant Products joint support team on a fixed term contract to cover Jodie Trubshoe's absence on maternity leave. Andrea was previously the Office Manager for Fish and Game New Zealand's Wellington regional office and was based in Palmerston North for the

past eight years. In 1993 she completed her National Certificate in Business Studies and is now studying towards a Bachelor of Accountancy degree through Massey University.

Andrea's interests include aerobics, cooking, horse riding, netball, swimming, tennis and socialising.

Operational update

Over the past few months, the ACVM Group has received a large number of applications. However, most are variations or 'C' type applications for ACVM updates. These applications have kept us busy in the administrative area and, in some cases, additional applications have arisen from these because of minor variations to these products.

The ACVM Group has not received many type 'A' (new innovative ingredient and new target species never assessed before) applications. During the October-December 2002 quarter, six type 'A' applications were received. From January to the end of March 2003, two were received. This is likely due to the applicant having to make an additional application for approval to ERMA New Zealand.

A steady number of veterinary medicine research approval applications have been received.

The generic approval from ERMA NZ for Thiomersal used in vaccines has opened the door for an influx of applications under the ACVM Act.

January through March is historically slow for plant compounds, but we have received more applications than we envisaged because some of the interpretations from ERMA NZ have been defined more clearly.