



# AgVetLink

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The NZSFA conference will be held in Auckland, 25-26 March 2003. The theme is 'building and maintaining confidence in New Zealand food'.

## Recent events

- **Data Assessment Service workshops** were held in Auckland, Wellington and Christchurch (see page 4).
- **ARPPA AGM** – The ACVM Group was invited to give a presentation to the annual general meeting of the Animal Remedy and Plant Protection Association. ARPPA provided a series of questions to be covered (see page 7).
- **Agcarm subcommittee meetings** – ACVM Group staff members have attended a number of meetings of the Agcarm subcommittees. Chris Boland and Debbie Morris attended the first meeting of the Distributors group. It is likely that this group will become a critical control point for management of ACVM Act risks in the future, and the discussions were very useful. Warren Hughes and Debbie Morris attended the Agrichem subcommittee, and Chris Boland travelled to Auckland to talk to the Animal Health meeting.
- **AVMAC's** most recent meeting was held on 21 November 2002. Agenda items covered expiry dates and shelf life, policy development for prescription animal remedy controls, endorsement of VICH standards, a proposal for dual approval by the Ministry of Health and NZFSA of manufacturing GMP (see page 12), and ACVM Act compliance.
- **JMPR** – Dave Lunn has attended his first meeting after being appointed as one of the eight world experts on the Codex Joint Meeting on Pesticide Residues.
- **Anthrax simulation** – ACVM Group staff took part in the recent anthrax simulation that was run by MAF Biosecurity Authority. It provided some valuable lessons that will be followed up.

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- **NZVA Industry Liaison Group meeting** – Debbie Morris and Chris Boland attended the meeting in Auckland on 28 November 2002 to discuss the policy development of PAR controls.
- **New Zealand Research on Antibiotic Resistance** – The ACVM Group's technical staff was invited to hear researchers from Southern Community Laboratories and Otago University present their latest findings in this area in the Beehive Banquet Hall on 28 November 2002.

## Christmas Closedown

The ACVM Group office will close on Friday 20 December 2002 and reopen for business on Monday 6 January 2003. We'd like to take the opportunity to wish all of you a safe and happy Christmas and New Year.

**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.

## Updating registrations

The ACVM (Transition Provisions) Regulations 2002 came into force in July 2002. The Regulations deemed all applicable animal remedy licences and pesticide registrations to be ACVM registrations. The Regulations imposed a limited registration period with an expiry for all deemed registrations of 1 July 2004. This provided a period in which the products could continue to be marketed under their existing conditions and approved labels. Therefore, while the products are now registered under the ACVM Act, many of them still look like animal remedy or pesticide products.

To take advantage of the limited registration period provisions of the Regulations a registrant must not request any changes that would alter the identity of products or change how they are packaged or labelled. If such changes are requested, the ACVM Group considers that the products are no longer the products that were first deemed to have been registered under the ACVM Act, and new registrations will be issued.

All registrants must apply for new registrations before 1 July 2004 or the registrations of their products will lapse. In effect, the new registrations will be updates of the existing registrations, ensuring that the conditions on registration, product data sheets and label contents are made current and approved.

The ACVM Group has been processing a steady stream of applications where the applicants have either requested or been prepared to have new registrations issued. Applicants have provided the necessary updated information and the new registrations have been issued. However, some applicants have requested changes to existing registrations but have also requested deferral of the associated update at this time.

It is assumed that applicants have some commercial reason for wishing to maintain the existing conditions and labels, but the ACVM Group can see no benefit if the changes already prompt an immediate alteration in labels.

The ACVM Group has tried to be helpful in approving requests to change some aspects of the existing registrations while postponing the actual updates. However, the only changes that could be made are the ones that would not change the identity of products or the way they are packaged or labelled. Most registrants have been understanding of the situation and have restricted their requests to minor changes when they do not want to update their registrations yet. However, a few registrants have requested significant changes and have objected when the ACVM Group has required new registrations.

The purpose for the limited duration registration was to allow time so that registrants had to make changes only once to incorporate both new ACVM conditions and any controls imposed under the Hazardous Substances and New Organisms Act 1996. To make changes prior to this defeats that purpose of the ACVM (Transitional Provisions) Regulations 2002. To make significant changes in the existing registrations is also contrary to the other purpose of the Regulations which was to allow the product to be marketed as long as the product stays the same as it was approved at the time the Regulations came into force.

Therefore, in recognition of the fact that the time for applying for new registrations is getting shorter and to clear up any misunderstanding and further debate, the ACVM Group restates its updating policy as follows:

- If registrants wish to postpone the issuing of new registrations

temporarily they should not request any variations in the existing registration until they are ready to update the registrations.

- If registrants must make changes in the existing registrations they must be prepared to accept that new registrations will be required (updated product data sheets and label content) at the same time if the changes requested alter the product itself, the claims made or the appearance of the product, **i.e. any changes requiring changes in the label.**

The ACVM Group recognises that it had provided advice that some minor changes in labels could be made without updating the product files and that some registrants are acting on that advice. The ACVM Group wishes to make it clear that any advice on this matter is no longer relevant. The current advice is:

- **As of 1 February 2003 no changes to the label of any kind will be approved unless the new registration is issued at the same time.**
- **As of 1 September 2003 no changes of any kind will be approved unless the new registration is issued at the same time.**

All registrations must be reissued as new registrations before 1 July 2004. Initially the ACVM Group had suggested that registrants temporarily delay updating registrations to give ERMA NZ time to transfer substances and specify the new controls. This would have minimised the cost of compliance by facilitating only one label change. The ACVM Group now advises all registrants that, given that there are now less than two years before all registrations must be reissued, **registrants should apply for new registrations as soon as they are ready to update their registrations.**

## Milk withholding period statement wording

The wording of the milk withholding period (WHP) statement for veterinary medicines has been an issue of some confusion in the past. The meat withholding period statement is able to be expressed clearly – it is simply a statement of the period of time that must elapse before treated animals may be slaughtered to produce meat or offal for human consumption.

However, the milk statement is more complicated because it attempts to state not only the time in hours or days that must elapse before milk is presented for human consumption, but also the number of milkings that must elapse to ensure herd milk compliance with the relevant maximum residue limits. In relation to this, the ACVM Group would like comment on two points of concern.

### 1. The relationship between withholding period hours and milkings

The current statement reads:

“Milk intended for human consumption must be discarded during treatment and for ‘x’ hours (‘x’ milkings) following the last treatment”

which may be shortened to:

“Withholding period: Milk ‘x’ hrs or ‘x’ milkings”.

The assessed number of milkings and the assessment for a WHP assumes that a 12-hourly cycle is in place and the correct interpretation of the statement requires that the hours and number of milkings are congruent. In addition, the intent of the statement is to express the actual time that milk must not be sent for human consumption. The consequence is that if a product has a 36 hour milk withholding period (i.e. milk must be discarded for 36 hours) the correct number of milkings that should appear on the label is 2 (i.e. milk must be discarded for 2 milkings but may be

sent for human consumption on the third milking following treatment, provided 36 hours has elapsed).

The ACVM Group recognises that there has been some inconsistency in the use and label wording of the milk withholding period in the past. In an attempt to ensure that all labels give clear and unambiguous milk withholding period directions the following statement is proposed as the preferred method of expression (with numerical example):

“Milk intended for human consumption must be discarded during treatment and for 36 hours (equivalent to 2 milkings) following the last treatment. Milk may be taken for human consumption at 36 hours (3 milkings)”

which may be shortened to:

“Withholding period: Milk 36 hrs equivalent to 2 milkings”.

It is recognised that this statement is longer than that currently required and that it may present some logistical problems with respect to space on labels. In consequence we are seeking input from industry on this matter.

### 2. The contribution to milk residues of an individually treated animal

Some labels have a withholding period qualification on them referencing milk residues in individual animals. Milk withholding periods are not assessed on an individual animal basis and the withholding period for any individually treated animal is the same as that for the whole herd. The current label advice that appears on some products to test individual animal milk prior to returning the milk from that animal to the human food chain is deemed irrelevant and unnecessary. The ACVM Group proposes that such statements will no

longer be approved and will not be carried forward with ACVM Act transfers.

If you have any comments or concerns on these issues, please send them in writing by **15 January 2003** to:

Jennie Yee

Assessor (Technical Standards – Veterinary Medicines)

ACVM Group

New Zealand Food Safety Authority

Post Office Box 2835

WELLINGTON

Email: [jennie.yee@nzfsa.govt.nz](mailto:jennie.yee@nzfsa.govt.nz)

## Product ingredients (oral nutritional compounds) on public register

The ACVM Group wishes to advise that for products such as oral nutritional compounds, **unless otherwise requested by the registrant**, all active ingredients and their concentrations are placed on the public register (website).

The ACVM Group will, however, align the website details as closely as possible to what is required on the label, especially for products where the disclosure of information could result in a commercial disadvantage.

Requests should be made in writing to Maree Zinzley, Programme Manager (Operations)  
PO Box 2835, WELLINGTON  
Email: [maree.zinzley@nzfsa.govt.nz](mailto:maree.zinzley@nzfsa.govt.nz)

## Responding to email requests

The ACVM Group has found that the use of electronic means of communication by companies has increased two-fold. In the past we treated emails (as well as phone calls to some extent) as 'quick' queries – setting them a shorter response time than letters.

In fact, many of the queries we are getting, especially via the email system, are quite complex and take considerable time (and often technical input) to answer.

In light of this, we advise that if your query is specifically product related, requires some research, or is about registration of products etc., it will be treated as if it were hard copy, written communication. This means that it will be recorded as inward mail, date stamped, and will be placed in the relative recipient's queue.

If the queries relate to a specific application, or request advice from ACVM staff, there may be a charge associated for the time taken to respond. We will also be attempting to make sure that complex telephone enquiries are treated in the same manner.

We do not want to deter companies from communicating by email or by phone, but with the high workloads, and the need to work to regulated time-frames in the registration process we will be using a single response period for email and written queries.

## Data Assessment Service workshops

The ACVM Group ran a series of workshops in early November to facilitate the changes proposed in future data assessment. Workshops, which were held in Auckland, Christchurch and Wellington, were generally well attended with around 75 people in total.

These workshops were run in response to concerns that were expressed in the ACVM Amendment Act discussion document covering the time-frames for approvals under the ACVM Act. While the ACVM Act, like the HSNO Act, has regulated time-frames for the assessments of applications, there is no regulatory agency worldwide that can complete a full data assessment in the 40 to 75 days allowed in the Act. The ACVM Group had envisaged the use of accredited people in this role, but there is insufficient work at present to make this effective.

Now that the ACVM Group and registrants have been working with the standards and guidelines for some time, it was felt that there was the opportunity for companies to undertake their own assessments, or to contract individual assessors to do this. This is consistent with the method used by ERMA New Zealand for HSNO applications.

We intend to survey attendees to find out if the workshops provided the information they required and to seek

suggestions for future sessions. It was mentioned at the workshops, for example, that it could be useful to cover the area of residues in more detail.

A number of suggestions/questions from the workshops are being followed up. These include:

- Provide (on the website) a list of commonly used proprietary formulants that the ACVM Group has assessed.
- Supply sample copies of completed chemistry and manufacturing data assessment reports on the website.
- Check with the ACVM Group experts who are currently contracted to see if they agree to having their names published on the ACVM website for others to use.
- Check terminology in ACVM forms and documents – veterinary terminology appears in some plant compound forms.
- There may be duplication between the product data sheet and the data assessment reports – is this really needed?
- Is the data package review still needed?
- Can a list of ACVM-approved manufacturers be put on the website (along with the categories for which they are approved) or, alternatively, can we provide the criteria we use for the approval of overseas manufacturers?

### PREScription MEDICINES: UK COMPETITION COMMISSION REPORT

The United Kingdom's Competition Commission is investigating allegations that the supply of prescription only animal remedies in the UK may constitute a monopoly. The ACVM Group is studying the provisional conclusions of the investigation, especially in light of the comments from the equivalent body in New Zealand. The report and background information can be found at: <http://www.competition-commission.org.uk/inquiries/vetmed.htm>.

The report information covers a range of ideas that could be of interest in New Zealand. One of the recommendations of interest concerns the separation of dispensing and administration from consulting/prescribing. It appears that most of the recommendations in the report have been covered in previous proposals from the ACVM Group.

## Plants not to be included in oral and topical preparations

Oral and topical preparations for uses associated with animals are regulated by the ACVM Group. These products are exempt from registration when they are prepared from either any part of a plant or an unrefined extract from a plant, except where the plant is included in Schedule 6 of the ACVM Regulations 2001. The conditions of this exemption state that where these products are used as a veterinary medicine the product label must identify the compound as an herbal preparation. Additionally, the label must include a statement that if the preparation fails to alleviate the condition being treated the user should seek veterinary advice.

The ACVM Group recognises that in certain situations a plant, or plant extract, may have toxic properties. Schedule 6 of the ACVM Regulations

lists plants not to be included in oral and topical preparations if the preparation is to be exempt from registration. The list enables conditions to be placed on products containing plants that are known to be toxic, or produce a pharmacological effect, through the conditions of the product registration.

To have a plant included on this list an application expressing the general concern surrounding the safety of the plant must be made to the ACVM Group. (The consequence of including a plant in this schedule is that it may not be used in products without them first being registered.)

The Group will consider the application and prepare a public notice of intent, inviting public comment on the proposal (if it is agreed to continue to process

the application). A similar mechanism will be used to remove plants from the list – an application to have a plant removed must be accompanied by data supporting the fact that a plant has a history of safe use. The final decision to include or remove a plant from the list will be made by the ACVM Group.

To ensure that all relevant parties are informed of proposed modifications to the list and are invited to comment, the ACVM Group would like to create a network of relevant parties who will be sent public discussion documents. If you are interested, or know of any party who may be interested, please contact Nicola Reeves, Assessor

(Technical Standards – Toxicology)  
Phone: 04 463 2535 or  
Email: nicola.reeves@nzfsa.govt.nz

## Agents and consultants

The use of an ‘agent’ for products registered under the Pesticides Act or licensed under the Animal Remedies Act has a different meaning to the term ‘New Zealand Agent’ under the ACVM Act.

Under the ACVM Act anyone can register a product in New Zealand. Under s24 (b) they must also specify who their New Zealand Agent is. This means that if an overseas company is making an application, communication for the registration process is between the ACVM Group and that company.

The ACVM Group considers that the New Zealand Agent has some legal obligations. For instance, should any adverse event occur with the product in New Zealand, the New Zealand Agent is contacted and has responsibility for taking the appropriate actions. The New Zealand Agent is also entered on the public register (this detail is available on the website).

On the other hand, a ‘consultant’ is a person who assists the applicant in compiling and/or making the application. A consultant can act on behalf of the applicant throughout the process of registration. They are not necessarily the New Zealand agent and do not appear on the public register on the website unless they are the Agent as well.

We advise that:

- all applicants/registrants need to ensure that their New Zealand Agent for a product is clearly identified on the Registration and Product Data Sheet (PDS); and
- the New Zealand Agent details are listed on the public register.

### Annual fees

**Veterinary medicine annual fee invoices were sent out in September 2002. If payment of these fees is not received by 24 January 2003 registrants will be contacted and advised of the additional steps (likely to be suspension or revocation of existing registrations) that will be taken.**

**Plant compounds annual fee invoices have been delayed. These should be posted by the end of December 2002 and will be due for payment before March 2003. If you have any queries, please contact Sarah Smyth, Coordinator (Business Services)  
Phone: 04 463 2553 or  
Email: sarah.smyth@nzfsa.govt.nz**

## Codes of practice

A new code, *The Code of Practice for the Use of Veterinary and Human Medicines in Research, Testing, and Teaching Organisations*, sponsored by the Royal Society of New Zealand, has been approved under section 28 of the ACVM Act. This approval completes a number of years' work by senior scientists in universities, CRIs and private commercial organisations to provide a framework to manage the risks under the ACVM Act from the use of PARs and human medicines by non-veterinarian staff under indirect supervision. The code contains an appendix that provides guidelines for the preparation of operational instructions from the veterinarian to the non-veterinarian for the administration of the medicines.

Another code, *The Code of Practice for the Use of Prescription Animal Remedies by Grooms Travelling with Horses by Air or Sea*, has been developed by the Equine Branch of the New Zealand Veterinary Association. It is currently under assessment by the ACVM Group for approval by the Director General. This code is also the culmination of many years' development to manage risks in potentially high profile situations.

Eight codes (excluding the grooms code) have now been approved under the ACVM Act. Approved codes are the property of the owner or the sponsor, and anyone wishing to access or adopt an approved code should contact the owner. A register of approved codes containing the contact details of their owners may be found on the ACVM Group website at the following location:  
<http://www.nzfsa.govt.nz/acvm/registers-lists/cop.htm>

## Antibiotic review

The ACVM Group is updating information surrounding the control of veterinary medicine usage now that the majority of the changes proposed by the Expert Panel and Steering Group have been effected.

The breakdown of sales figures supplied by registrants, along with our interpretation of the results to date, has been checked with the main industry groups and with representatives of the key user groups. We expect to have this information available this month.

The feedback from this process suggests that change has not been as quick to occur as we had previously thought, at least with users and prescribing veterinarians, although we are advised that the required changes have been made from 1 July 2002.

Because there has been considerable change in the area over a relatively short period of time, the ACVM Group is working with the NZFSA Compliance and Investigation team on a 'reality check' audit that will be carried out in the near future. The audit is intended to highlight any areas where further work is needed to effect the required changes. It is likely to concentrate on:

- products that have changed from OTC to prescription status all through the supply chain from the registrant to the user;
- the intensive farming industries and the use of prescriptions for in-feed medications;
- PAR products where the use has been limited, either by removing the opportunity for 'off-label' use by veterinarians or where the veterinarian is required to confirm the appropriateness of the product prior to use.

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## Policy development: agricultural security thresholds

The ACVM Group is working with MAF Biosecurity Authority to revise the thresholds relating to agricultural security. This is likely to have an impact on the information requirements for products in this area in the short term.

To date the ACVM Group has indicated that for plant compound products, there is no requirement for efficacy information or for information on plant safety. Indications from MAF Biosecurity are that they will require this in the future. If a product is being used to eradicate a pest or disease in New Zealand, MAF Biosecurity needs to be assured that it works – hence the probable need for efficacy information. They will also need to have an understanding of the effects on the host plant and, in some instances, depending on the use pattern, on off target plants as well.

This is a likely change to the current thresholds found in the *Guidelines for risk assessment and hazard analysis under the ACVM Act 1997*. As soon as the proposals are finalised they will be circulated to interested and affected parties for comment and advised via the website. Comments on this issue in the ACVM Act Amendment discussion paper will also be taken into account.

## All manufacturing sites listed in the manufacturing specification

The ACVM Group reminds registrants and applicants that **all** manufacturing sites must be listed in the manufacturing specifications for a registered trade name product. Manufacture, in relation to any agricultural compound, means to make up, prepare, produce, or process the agricultural compound; and includes the packing (and labelling) of an agricultural compound in a container for the purposes of sale. Therefore any site that carries out any of these activities (or any subdivision of these activities such as quality testing) must be listed in the manufacturing specification.

Any changes in manufacturers or manufacturing sites must be notified to the ACVM Group so the approved manufacturing specification can be updated. If you are concerned that a manufacturing site may not have been included in the manufacturing specifications that were provided with the application to register a product you should notify the ACVM Group. Modifying the manufacturing specification on the product file presumes that:

- its absence from the manufacturing specifications was an historical oversight; and
- the site is actually an approved manufacturing site.

If the site is in fact a new site then a registrant must lodge an application to vary a registration to get the new site properly approved.

Failure to provide comprehensive manufacturing specifications may jeopardise the continued registration of a product.

### ARPPA AGM (see page 1)

A number of questions posed at the AGM were very easily answered because they related to issues that have already been addressed, e.g. the charging of actual time versus set fees for class determinations, and information on the data assessment process, which was covered in the recent workshops.

Other questions concerned ACVM Act implementation. There is general confusion on the rationale for the split of prescribing and dispensing. It appears that people think that the ACVM Group is advocating a change in this area, rather than simply clarifying the basis for setting conditions on sale and use of PAR products under the ACVM Act.

Another query in this area was mandatory wording on labels – it seems that this is another area for further clarification. This meeting provided a very useful opportunity to understand the issues facing a number of the registrant companies.

## Use period statements for multi-use vaccine vials

The article that appeared in the October issue of *AgVetLink* regarding the proposed default in-use stability period for multi-use vaccine vials prompted only one comment. The comment did not directly impact on the proposed statement so the ACVM Group has formally adopted the policy.

In consequence, the following statement will be a mandatory label statement for all multi-use vaccines where no in-use stability data is or has been provided (with the exception noted below):

“Unused vaccine must be discarded within 10 hours of opening”.

The statement will **not** be allowed where the vaccine will retain stability for periods shorter than 10 hours (e.g. reconstituted live vaccines). In this instance the standard will apply and supporting data must be provided.

Registrants of products that currently carry in-use statements not supported by data must ensure that the discard statement is modified to conform with the above policy when the product is updated to the ACVM Act or at the next label reprint, whichever comes first.

Note that the *ACVM Labelling Guide for Veterinary Medicines Requiring Registration* has recently been revised and this policy will not be included until the next revision.

## Compliance update

### Border activity

Maree Zinzley and Linley Thorburn have been working with the MAF Quarantine staff at the border and have been assisting in their training for the ACVM Act appointments. We expect several hundred MAF Border Services staff to be appointed under the ACVM Act prior to Christmas. Already this work has seen some positive results – an increased awareness has resulted in a higher than usual number of products being questioned at the border prior to release.

### ACVM Group appointments as inspectors

All of the ACVM Group advisors and technical assessors have now been appointed as ‘inspectors’ under the

ACVM Act, along with the Programme Manager (ACVM Verification) and the Programme Manager (ACVM Operations). This will assist in the role that is becoming increasingly important to the ACVM Group activity under the ACVM Act of ensuring compliance with the ACVM Act.

### NZFSA Compliance and Investigation Group

The NZFSA Compliance and Investigation Group (CIG), headed by Geoff Allen, has taken over some of the enforcement staff previously reporting to Jockey Jensen. CIG is now responsible for all enforcement activity for the NZFSA in addition to their previous responsibilities. The balance of CIG staff who will be working in the investigation area for the ACVM Act will be appointed as soon as possible. The ACVM Group will continue to have some contact with compliance activities in the biosecurity area because of the overlapping responsibilities for animal welfare and for agricultural security.

The ACVM Group is working with CIG to set the strategy for the coming year, and will also be revising the ACVM Compliance Policy in the near future.

### ACVM Act powers

The ACVM Act has a number of powers that are proving useful in ensuring compliance, without taking the time-consuming, costly step of prosecuting breaches.

Section 64 of the Act provides powers of entry for inspection for the purpose of determining whether or not any person is complying with the Act. It provides the opportunity to take samples and query records and, more importantly, to order the person in charge to identify and hold any agricultural compound for up to five working days. This power can be used with importers, manufacturers, distributors (including veterinarians) or users.

Section 65 provides that inspectors (or authorised persons) who have reasonable grounds to believe that anyone is manufacturing, selling or using any agricultural compound in contravention of the Act and Regulations, or the conditions of registration, can issue prohibition notices. These can cover manufacture, sale or use until the breach is rectified to the satisfaction of the inspector.

Both of these sections have the effect of stopping the potential breach of the Act at an early stage, and encourage any offender to comply as quickly as possible because of the financial considerations.

The CIG team has used the prohibition notice for ACVM Act breaches. In other situations, companies have come into compliance when advised of the process that is being initiated.

### Future appointments

In addition to the activity with CIG, it is also likely that both MAF Verification Agency (MAFVA) staff and AgriQuality staff will be appointed as ‘authorised persons’ under the ACVM Act. Section 61 allows for the appointment of people for certain functions. The MAFVA staff work with the Animal Products Act on farm and in processing facilities, and such appointments would be useful in their investigation of breaches in their areas of responsibility. Likewise, AgriQuality staff functions (when they are undertaking audits on behalf of the ACVM Group or other parts of NZFSA) would be enhanced with the ACVM Act ‘authorised person’ status.

### Compliance activity

Most compliance activity results from either adverse event reporting or complaints received by the ACVM Group. There is some activity that occurs as a result of the monitoring systems in place in either the Animal Products area, the Dairy and Plants area, or work done in response to animal welfare complaints. The NZFSA related

### Dairy Industry Act moving into the Animal Products Act

The NZFSA Policy and Dairy teams are working hard to progress the movement in this area. It is hoped that the legislation will have its first reading in the house in December this year. There are plans for an implementation date of June 2003 for the legislation with a period of three years for the changes to occur.

Anyone interested in the details of the changes should keep an eye on the Policy and Dairy parts of the NZFSA website. One of the first areas of consultation will be in the draft specifications with workshops being proposed on the topic in January 2003. Details are also available in the *Dairy Connection* newsletter on the website.

ones are usually about the residue monitoring programmes run for the various sectors.

Since the start of the ACVM Act there has been an increase in the numbers of complaints relating to unregistered products – some 21 in the five months since the implementation of the Act, compared with 40 in the whole of last year. Many of these complaints regard products that fit in one or other of the exempt categories. We expect that this will continue to be a confusing area as the class determinations for such products rely on a combination of the ingredients in the product and the claims made in relation to it.

### Adverse event activity

There have been 31 adverse reports notified and investigated for the period 1 August - 31 October 2002

Most of the adverse events have been answered to our satisfaction, although we will review the incidents longer term and will follow up in the next round of GMP inspections. One product is likely to be reviewed as a result of the adverse events received in this period. In the first instance the ACVM Group will be obtaining information from the registrants and industry groups concerned.

### Complaints

There have been 17 complaints received in the period from 1 August to 31 October 2002. While each individual complaint is followed through to our satisfaction, the information the ACVM Group holds showed that a number of them had a common source. This has resulted in ACVM Group staff visiting the company in question. A number of issues raised in the visit are being followed up. Several of the other complaints have been passed on to the CIG for further investigation.

Work in this area since the ACVM Act implementation has shown that enforcement is extremely complex. It is crucial to distinguish the role that a particular person or organisation is playing in the process. In one case relating to a horse trainer, it appeared that the trainer could have been acting as the distributor, manufacturer and user, or a varying combination of these roles depending on the form of the contract that he had with the feed supplier and each of the owners, and the activities that he undertook in relation to feeding each of the animals he was looking after. It is clear that when the ACVM Group places conditions on products, it must specify exactly which party is bound by those conditions.

## Food Residue Coordination Group

The Director of the ACVM Group has the NZFSA-wide responsibility for coordination of food residue activities for the organisation. The Food Residue Coordination Group (FRCG) has been operational for several years now and includes members from the Animal Products Group, Dairy and Plants, Imported Foods, Domestic Food, Policy, and Codex Coordination.

One current activity, under the leadership of MAF Policy, is the development of a discussion document on the Animal Products Act to replace the current Meat Residue Regulations. It is intended that the document will also be replicated in the MRL standard in the future and will update many of the current MRLs for compounds used on animals. A number of changes will be incorporated; for example, where an MRL is estimated but has not been shown in the past because it was at or below the default, it will be stated. The terminology is also being updated to make it as consistent as possible with Codex terminology. The paper will be available at <http://www.nzfsa.govt.nz/policy-law/consultation/index.htm> – if you are interested, you can register to receive email advice of updates to this section of the NZFSA website in addition to the ACVM section.

This is the first step in ‘house keeping’ the MRL standard. There is work being done on milk MRLs and we have a work programme to update the plant MRLs over the next one to two years.

## Staff changes

Maree Zinzley has recently appointed Rowena Lee to replace Deborah Alexander in the role of ACVM Group Coordinator (Operations). Rowena will take over from Deborah (who is now an Advisor with the ACVM Group) as the main contact point for queries from registrants and applicants.

### Rowena Lee

"My family and I moved to New Zealand when I was 13 years old. I grew up and studied in Taihape, where I learned to adapt to a whole new lifestyle on the farm and gained knowledge of the family beekeeping business. I have completed a Diploma in Business Services and Tourism (majoring in Japanese). I have also worked in Australia at the NSW City Registry Office. I enjoy travelling, arts/crafts, as well as outdoor activities such as skiing, tramping & native forest/bush walks. I have been in Wellington only for a short while, but feel I have settled in well and enjoy working as part of the ACVM Group."

## VICH update

### International conference and Steering Committee meetings

The second international conference for VICH was held in Tokyo from 9 to 11 October 2002. It was held in conjunction with a meeting of the Steering Committee and meetings of the active working groups. A total of 239 people registered for the conference; 110 of these were from Japan.

There was no significant presence outside of the Asian region apart from members of the Steering Committee, the working groups and speakers. Dr Bill Jolly, the New Zealand Veterinary Counsellor in Brussels, was one of the keynote speakers.

Debbie Morris, Director of the ACVM Group, took over as the Australia New Zealand regulatory representative on the steering group following the completion of the Steering Committee meeting. John Reeve is a member of the Safety working group which met on 7 and 8 October. Brian Pidford also attended the conference – Brian was a member of the working group on Good Clinical Practices which has completed its work but will review the standards at some

stage in the future. Also in attendance were Alison Turner of the NRA and Peter Holdsworth representing the ANZ Industry Groups. Jack Holland and Fred Bover (both working group members from Australia) were also at the conference.

A meeting of the regulators in advance of the Steering Committee was held on 7 October (and a similar one for the industry representatives). Canada was in attendance for the first time as an observer.

The Steering Group agreed the adoption of GL 31, 32, 33 and 28 at step 6 with 12 months to implement them. The Guidelines (both those that have been adopted and those for consultation) and details of the VICH process are available on the NZFSA website at <http://www.nzfsa.govt.nz/policy-law/vich/index.htm>.

A number of possible new topics were discussed:

- the revision of **GL10 and 11** could not be progressed as the United States is unable to allocate resources;

- a paper on **Biologicals quality stability testing** was tabled on the day and cannot be considered until the next meeting;
- the paper from the EU on **Metabolism and residue kinetics** will be discussed at the next Steering Committee meeting.

The next Steering Committee meeting is to be held (7 - 8 May 2003) in London followed by a meeting (7 - 8 October) in Washington. The VICH 3 conference will be in the USA (somewhere around the Washington region) in 2005.

### New Zealand endorsement of VICH guidelines

At the AVMAC meeting on 21 November 2002 the following VICH guidelines were endorsed:

- GL15 Anthelmintics - equine: Efficacy requirements for anthelmintics: specific recommendations for equines. (July 2002)
- GL16 Anthelmintics - swine: Efficacy requirements for anthelmintics: specific recommendations for swine. (July 2002)
- GL19 Anthelmintics - canine: Efficacy requirements for anthelmintics: specific recommendations for canine. (July 2002)
- GL20 Anthelmintics - feline: Efficacy requirements for anthelmintics: specific recommendations for feline. (July 2002)
- GL21 Anthelmintics - poultry: Efficacy requirements for anthelmintics: specific recommendations for poultry. (July 2002)
- GL22 Safety reproduction: Studies to evaluate the safety studies for veterinary drug residues in human food: reproduction testing studies. (August 2002)
- GL23 Safety genotoxicity - studies to evaluate the safety studies for veterinary residues in human food: genotoxicity testing studies (August 2002)

## MRL update

Discussion paper 05/02 *Proposed New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standard 2002* completed its consultation period on 29 October 2002.

The document proposed to establish a new maximum residue limit (MRL) for a specified agricultural compound (Spinosad) in stonefruit. It also covered some 'housekeeping' changes to the MRL standard to consolidate the seven amendments that have been made since 1999, in order to reflect recent changes in the legislative framework around food and agricultural compounds regulation, and to correct miscellaneous inconsistencies.

The NZFSA Policy team is working with MAF Legal to finalise the standard in the near future. The next MRL discussion document is expected in December. Because of the Christmas break, there will be a six-week consultation period rather than the usual three weeks.

GL25 Biologicals: Formaldehyde - testing of residual formaldehyde

(May 2003)

GL26 Biologicals: Moisture - testing of residual moisture

(May 2003).

AVMAC will be copied the final version of the following guidelines along with a proposal for New Zealand endorsement at the next meeting in 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)\*

In addition, the following guidelines are at Step 4 (for consultation):

GL24 Pharmacovigilance: Adverse experience reports.

GL27 Antibiotic resistance: Pre-approval information for registration of new veterinary medicinal products: controlled list of terms.

GL29 Pharmacovigilance: Management of periodic safety update reports.

GL30 Pharmacovigilance: Controlled list of terms.

GL34 Testing for detection of mycoplasma contamination.

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 in any related legislation. We will take into account any changes made through consultation in the final documents.

\* Hard copies of these guidelines will be circulated at the meeting.

## Website

### Updates

- ACVM Standard for Good Manufacturing Practice
- ACVM Guideline for Good Manufacturing Practice
- ACVM Standard for Distributors of Hormonal Growth Promotants
- ACVM Registration Standard and Guideline for Determination of a Residue Withholding Period for Veterinary Medicines
- Declaration for a product not intended for use as an agricultural compound
- Information requirements for classification of substances as GRAS
- New Zealand Labelling Guide for Veterinary Medicines Requiring Registration

### Discussion Papers

- ACVM Registration Information Requirements for Veterinary Medicines
- ACVM Registration Information Requirements for Provisional Registration
- ACVM Registration Information Requirements for Plant Compounds
- ACVM Information Requirements for Research Approval
- ACVM Registration Standard and Guideline for the Chemistry of Plant Compounds
- Proposal for new substances to be added to the GRAS list (by regulation)
- Discussion paper 5/02 to consolidate and update the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standard
- Draft paper: The role of veterinarians in the management of risks posed by the use of veterinary medicines.

### New

- ACVM Standard and Guideline for the Therapeutic Equivalence of Trade Name Products (which replaces the Bioequivalence Standard)
- Operational Policy on Product Advertising

You can receive email advice every time there is an update to the ACVM website by following this simple process. Go to the bottom left of the ACVM front page menu and click on 'Notification of updates to the site'. Enter your email address in the space provided, hit 'send' and you will get advice every time something is added or amended on the site. It is just as easy to cancel your notifications.

## Dual approval of manufacturing GMP

At its meeting on 21 November, AVMAC endorsed an ACVM Group proposal to accept inspections for good manufacturing practice (GMP) compliance carried out by Medsafe pharmaceutical inspectors for the purpose of issuing a NZFSA Certificate of GMP Compliance.

Inspections of manufacturers of registered veterinary medicines are carried out at regular intervals for the assessment of compliance with the ACVM standard and guidelines, where relevant, for GMP. We have learned from the routine inspections carried out that a small number of manufacturers are involved with the production of veterinary and human pharmaceutical products and are therefore inspected under both the ACVM and Medsafe inspection programmes.

We believe that these duplicate inspections comprise excessive regulatory control for a number of reasons:

- Veterinary and human pharmaceutical manufacturing activities associated with specific types of products are generally very similar.
- The scope, outcomes and procedures for both types of inspection are similar.
- Both inspection groups are applying the same standard for GMP to the assessment.
- Both inspection groups operate under the same mutual recognition agreement for GMP assessment with the European Community.
- Inspections of manufacturers of human and veterinary pharmaceuticals are often carried out by the same inspectors in other regulatory systems such as the EC.

- The ACVM Group has contracted to Medsafe for specific technical expertise for GMP inspection in the past and may wish to do so in the future.

The dual inspection process would work as follows. The inspection cycle time for a combined veterinary and human GMP inspection would remain the same, that is every two years. Prior to the Medsafe inspection all parties would agree that the particular inspection would be a dual one. The ACVM Group would advise Medsafe of any specific issues brought to notice since the last inspection that should be addressed.

The Medsafe inspection would include an additional time component when veterinary medicines, or a sample of them if a significant number are being manufactured, will form the focus of the inspection. The ACVM Group will then provide an ACVM GMP Certificate on receipt and review of the Medsafe inspection report. The cost of the additional time component payable to

Medsafe for the veterinary medicine component of the inspection will be recovered from the manufacturer.

We believe there are significant benefits for the manufacturers and for the regulators from this proposal. The total inspection cost to the manufacturer will reduce because only one slightly longer inspection instead of two separate inspections will be cost recovered.

The collaboration on inspections will strengthen the technical link between ACVM Group and Medsafe on standards and processes for inspections and will provide a link into the development of the trans-Tasman single pharmaceutical agency.

Finally, only a few people with the training and experience required to conduct pharmaceutical inspections are available. A formal collaboration will make best use of scarce resources and will make it easier to call on alternative technical expertise if required in the future.

### ACVM Group opportunity

The ACVM technical team is seeking a part-time veterinarian to assist with work in the veterinary medicines area. Hours are flexible: part-time 5 days a week through to 8 hours a day for up to three days a week. The person we are looking for must be Wellington-based to work closely with Neil Kennington and Jennie Yee. The work will involve undertaking class determinations and assisting in all parts of the regulatory assessment process. This would be a great opportunity for someone getting back into the workforce, especially if you are planning to set up a consultancy business in the future.

A job description is available from:

Gill Wilson

(email [gill.wilson@nzfsa.govt.nz](mailto:gill.wilson@nzfsa.govt.nz) or phone 04 463 2539) or

Jodie Trubshoe

(email [jodie.trubshoe@nzfsa.govt.nz](mailto:jodie.trubshoe@nzfsa.govt.nz) or phone 04 463 2540).