



# AgVetLink

ISSN 1174 - 3735 ISSUE NO 36 FEBRUARY 2003

## What's coming up

### ■ AVMAC meeting

The next meeting will be held in Wellington on Thursday, 27 February 2003.

### ■ Industry Liaison Group meeting

The ILG meetings are now held every six months and are lined up with the dates of the AVMAC meetings to make sure that travel is rationalised as much as possible. Attendees are the ACVM Group, Federated Farmers, the New Zealand Veterinary Association, Agcarm, ARPPA, VegFed / Fruit Fed, and the Poultry Industry Association. The next meeting will be held in Wellington on Thursday, 27 February. The meeting provides an opportunity for each of the industry groups to give an update on issues from their particular viewpoint and to discuss any operational matters.

### ■ GMO medicines

The ACVM Group is providing input (along with the Ministry of Health, MAF, and ERMA NZ) into a Ministry for the Environment Cabinet paper on GMO medicines. Some important policy issues, such as the interface of the various pieces of legislation and how to deal with an urgent requirement for a veterinary medicine from a biosecurity perspective, are being worked through. Details will be available on the Ministry for the Environment website (<http://www.mfe.govt.nz/>).

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## Recent events

### ■ Consultation on changes to Animal Products legislation

The NZFSA Policy team extended the consultation period for the document *Proposed Animal Products (Residue Specifications) Notice 2002 : Discussion paper 6/02* until 31 January 2003. This document provides a template for future changes to New Zealand MRLs.

**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.

## Antibiotic resistance management

In response to the direction of the Animal Remedies Board (December 1999), the ACVM Group has been refining its regulatory control on antibiotic products used as veterinary medicines. The changes have been made to minimise the likelihood that the use of antibiotics in animals may contribute to the development of antibiotic resistance in human pathogens (i.e. bacteria causing disease in humans).

### Progress on review of antibiotic product registrations

It was intended that the registrations for antibiotic products would be reissued with conditions designed to manage the antibiotic resistance problem before the commencement of the ACVM (Transitional Provisions) Regulations 2002. In almost all cases this was achieved. However, there were a few products for which the reissuing of registrations was delayed because of unrelated matters. When the registrations of these few products are updated, all antibiotics of significance to the antibiotic resistance problem will be prescription only medicines.

All antibiotic products will also have a stratified prescription animal remedy (PAR) I level based on the public health significance of the antibiotic. This will introduce additional obligations on the prescribing veterinarian to limit the use of significant antibiotics to cases in which alternative antibiotic are not likely to be effective. The effects of these

changes should begin to appear in the 2002 sales statistics.

### Sales of antibiotics

Pharmaceutical companies have voluntarily provided sales statistics for the last two years. The collective statistics (in kilograms of active ingredient grouped into antibiotic families) are shown in the table below.

The totals must be considered only indicative because of the variability in calculating and recording quantities by different companies. Therefore, little significance can be attributed to minor differences in totals from year to year.

In addition, actual use relative to kinds of animals treated may be different than reported by the companies because veterinarians may have prescribed antibiotics for a group of animals other than what a company had anticipated. Consequently, the 'unspecified animals' column is based on an undetermined ratio of non-food animals to food animals.

Given the statistical limitations, the table indicates an overall increase in the total sales of antibiotics. However, when the statistics were examined by species of animals treated in either feed or water, there was either no significant change or a decrease in sales of those antibiotics that are assessed as significant for use in humans (e.g. aminoglycosides and macrolides/lincosamides).

The statistics indicate an increase in the sales of antibiotics assessed as not relevant to the potential antibiotic resistance problem (i.e. ionophores, zinc bacitracin and avilamycin). Almost all of the increase in the 'other' antibiotics group relates to an increase in sales of in-feed zinc bacitracin, which the expert panel considered unlikely to contribute to the antibiotic resistance problem.

There were increases in sales of penicillins, cephalosporins and sulphonamides administered by injection. This administration route is considered unlikely to contribute to antibiotic resistance in human pathogens.

It must be noted that the collection of the survey information is still undergoing refinement. Recording and reporting the information is improving. This means that with only two years' data over a period of such marked regulatory and industry change, the variations in amounts must be taken as indicative at best. Analysis of the data is also hampered by variations in animal health challenges from one year to the next. It is expected to take a number of years before this compounding factor can be addressed in any meaningful analysis.

It must also be noted that sales during 2001 were based on the regulatory requirements at the time. The changes in the conditions of registrations that will give effect to:

Antibiotic group	Non-food animals (in kilograms)	Food animals	Total	Unspecified animals	Total 2001	Total 2000
penicillins	265	5161	5426	4997	13747	10423
cephalosporins	15	674	689	150	879	839
aminoglycosides	77	690	767	1355	1692	2122
macrolides/lincosamides	-	6358	6358	243	5293	6601
tetracyclines	42	2168	2210	957	2840	3167
sulphonamides	1380	731	2111	3460	5930	5571
ionophores	-	36215	36215	-	50169	36215
others	46	15176	15222	239	25013	15461
<b>Totals</b>	<b>1825</b>	<b>67173</b>	<b>68998</b>	<b>11401</b>	<b>105563</b>	<b>80399</b>

- the prohibition on using certain antibiotics of concern for growth promotion;
  - the introduction of the stratified prescription animal remedy classification for antibiotics; and
  - the mandatory requirements to provide calendarised annual sales of antibiotics
- have not yet influenced the pattern of sales.

While overall sales of antibiotics increased during 2001, there was a shift away from the use of antibiotics important in human medicines to ones that have been assessed as not relevant to the potential antibiotic resistance problem. There were no sales of antibiotics for growth promotion purposes during the year. Of equal significance, there was not a marked rise in the sale of the relevant antibiotics for prophylactic or therapeutic purposes that would indicate a superficial shift from growth promotion to prophylactic or therapeutic uses.

### Surveillance and monitoring

In 2000 the Animal Remedies Board recommended that there be a review of the surveillance programme for zoonotic animal pathogens and commensal bacteria that may contribute to the potential antibiotic resistance problem. Initial meetings were held between the Ministry of Health and the Ministry of Agriculture and Forestry to examine existing surveillance programmes and determine what specifications should be set for a programme that would provide useful information about the development of antibiotic resistance in animals. It was noted that little surveillance that would shed light on the role of animal to human transfer of resistance was being carried out. While there is extensive microbiological monitoring of specific pathogens in food-producing animals, the programmes are not designed to gather information specific to antibiotic resistance. At that stage there was

insufficient definition of the problem to create meaningful parameters for an appropriate surveillance programme. No changes in existing programmes were made at that time.

Recently the Ministry of Health, New Zealand Food Safety Authority and ESR have met to consider any new information that might help set appropriate surveillance parameters. The outcome of discussions will be reported in a future issue of *AgVetLink*.

### Non-regulatory initiatives to minimise antibiotic resistance

In addition to the revision of antibiotic registrations mentioned above, there have been other initiatives to minimise antibiotic resistance.

The ACVM Group is considering a code of practice lodged by the New Zealand Veterinary Association (NZVA) for approval under section 28 of the ACVM Act. This will give statutory recognition to standards for veterinary prescription

writing that are equivalent to those that must be met by medical practitioners when writing prescriptions. Although the proposed code of practice is not necessarily intended to reduce the use of veterinary antibiotics, it should ensure that they are prescribed in a professional and consistent manner. While the code of practice has not been approved yet, it has already been adopted by the NZVA and incorporated into their members' manual.

The NZVA, Veterinary Council of New Zealand and the veterinary pharmaceutical industry have endorsed a standard for the promotion of prescription products, including antibiotics. This standard discourages the promotion of products in a manner that puts pressure on veterinarians to prescribe antibiotics unnecessarily.

The regulatory changes have progressed as intended and the effects of the changes should begin to have an impact on use and sales in the near future.

## Codes of Practice Update

### Royal Society Code of Practice

The code of practice developed by the Royal Society covering the use of veterinary and human medicines by non-veterinarians in research, testing and teaching institutions has been approved under the ACVM Act.

### Grooms Code of Practice

The New Zealand Veterinary Association's code of practice covering the use of veterinary medicines by grooms travelling with horses has also been approved under the ACVM Act.

Details of where to obtain the codes of practice, along with details of other approved codes, can be found on the ACVM website (<http://www.nzfsa.govt.nz/acvm/registers-lists/cop.htm>).

## Post-harvest treatments

At present the ACVM Group's interpretation of the definition of an agricultural compound used post-harvest only includes compounds used for pest control and disinfestation on primary produce.

However, it has been argued to us that all post-harvest treatments should be agricultural compounds. This recognises that there may be risks under the ACVM Act posed by other post-harvest products, such as the potential for residues and unacceptability of unregistered products used in official spray programmes for export.

Initial public discussion on proposed amendments to the ACVM Act supported the inclusion of other post-harvest treatments as agricultural compounds, and policy development on the amendment has begun. Because it seems likely that all post-harvest treatments will become agricultural compounds, we would have no objection to companies making applications for registration of such products if they would otherwise be disadvantaged. If you have previously had a class determination for a product in this situation, indicating that it did not require registration under the ACVM Act and you now wish to revisit this class determination outcome, please contact us.

This decision will be reviewed soon after any amendment is made, or prior to 2 July 2004, to ensure that the amendment and recent registration decisions are consistent. Further comments on the inclusion of other post-harvest treatments as agricultural compounds may be submitted at any time. Please contact Sarah Lester ([sarah.lester@nzfsa.govt.nz](mailto:sarah.lester@nzfsa.govt.nz)) if you have any questions.

## Milk withholding period statement

There was a significant response to the article that appeared in the December 2002 issue of *AgVetLink* requesting comments on the proposal to alter the current milk withholding period (WHP) statement and to move away from the emphasis placed on individual animal testing currently featuring on some product labels.

The comments focused primarily on the complex relationship that exists between the number of milkings and hours that must elapse before milk from treated animals is eligible for sale for human consumption, particularly in relation to different milking regimes that may be placed at any particular time. The overwhelming consensus was that the proposed statement would not help to clarify this relationship and was more likely to lead to further confusion. There was a general consensus of the limited value of individual cow testing to determine the return of treated animals to the milking cohort.

In consequence, the ACVM Group has abandoned the proposed statement and is considering the development of administration route-specific WHP statements. It is known that the way in which residues are depleted in, and excreted from, the body is dependent on the active substance, excipients and route of administration. The importance of these differences and their relevance to the number of milkings and/or hours that must elapse before milk is eligible for human consumption is under investigation.

The ACVM Group is working with the NZFSA Dairy team to develop a discussion paper and is seeking expert opinion on its content. The outcome of these initial discussions and a request for public submissions will be made in a future issue of *AgVetLink*.

## Register of products on website

Although the ACVM Group does its best to ensure that information appearing on the public website is 'label' level information and not that which is considered confidential or commercially sensitive, there was an instance recently where some information was entered in error.

We are making plans to change ISAC (our support information system) to provide more checks and balances, but we would ask that registrants make a point of checking details of any registered products, especially those newly registered, and to let us know asap if there are any problems. Contact Maree Zinzley, Programme Manager (Operations) (phone 04 463 2564 or email [maree.zinzley@nzfsa.govt.nz](mailto:maree.zinzley@nzfsa.govt.nz)) with any queries or concerns.

Until all products are updated to ACVM registrations, we are working with a mix of old and new data requirements, which makes the current period especially difficult.

## Standard for 'operational procedures'

During the pre-consultation process for the prescription animal remedy (PAR) operational policy, it has been brought to our attention that a number of aspects of the risk management process rely on the use of 'operational procedures', and that it would be useful to have these given formal status.

The ACVM Group developed a *Model for Operational Procedures* for use in the code of practice covering the use of veterinary medicine and human medicine products in research, testing and teaching. This is effectively an ACVM standard.

The organisations involved in the development of the code of practice were the Ministry of Health, the New Zealand Veterinary Association, Massey University Veterinary School and the ACVM Group, so the model has already been extensively discussed by most of the relevant parties in this context.

While this standard was developed for a specific purpose, it contains the components that would need to be covered in other operational procedures – for instance where a veterinarian was delegating to personnel for a specific purpose, or where a vertebrate pest control operator had people performing functions under supervision. It may also

have some application under the Good Manufacturing Practice standard.

The ACVM Group has used the original model to develop a further model covering the general requirements for the use of veterinary and human medicines by non-veterinarians from the perspective of the ACVM Act. We expect that other standards will be developed as needed either by the ACVM Group or as part of a code of practice.

Both of these draft standards are on the website for consultation, and will be discussed by AVMAC at the next meeting on 27 February 2003.

## Standards update

The revised *ACVM Registration Standard and Guideline for Determination of a Residue Withholding Period for Veterinary Medicines* is now available on the website and through Manor House Press (see enclosed order form). The residue standard for plant compounds is nearing completion of the internal comment stage.

The public consultation period for *ACVM Registration Standard and Guideline for the Chemistry of Plant Compounds* has finished. Comments and suggestions are being considered and the final document should be available this month.

The public consultation period for the updated registration information packages and the *New Zealand Labelling Guide for Plant Compounds Requiring Registration* has also finished. These documents will be available soon.

Currently on the website for public discussion are:

- *ACVM Model for Operational Procedures: Model 1: The Use of Veterinary and Human Medicines by Non-veterinarians for Research, Testing and Teaching Purposes*
- *ACVM Model for Operational Procedures: Model 2: The Use of Veterinary and Human Medicines by Non-veterinarians Generally*

The following standards have been updated to include NZFSA details. No substantive changes have been made.

- *ACVM Registration Standard and Guideline for Efficacy of Antibloat Products*
- *ACVM Registration Standard and Guideline for Efficacy of Emetics*
- *ACVM Registration Standard and Guideline for Efficacy of Vertebrate Pesticides*

## Annual Fees

**Annual fees for plant compounds for 2002/2003 are due for payment by 28 February 2003. If payment of these fees is not received by this date, registrants will be contacted and advised of the additional steps (likely to be suspension or revocation of existing registrations) that will be taken.**

**If you have any queries, contact:  
Sarah Smyth  
phone 04 463 2553  
email  
sarah.smyth@nzfsa.govt.nz**

## Update: draft PAR operational policy

### Background

The ACVM Group received a number of submissions in the pre-consultation phase of the development of the prescription animal remedy (PAR) operational policy from the New Zealand Veterinary Association (NZVA), the Veterinary Council of New Zealand (VCNZ) and the National Animal Ethics Advisory Council (NAEAC).

The draft was circulated to NZFSA business groups, MAF Biosecurity business groups and the Ministry of Health as part of the internal process. In addition to this, ACVM Group and NZFSA staff attended several meetings where the issues were discussed, and we received written comments from a number of organisations.

Some of the comments provided have been used to make improvements to the original draft policy circulated at the last AVMAC meeting and are reflected in the version that has now gone out for public consultation (available at <http://www.nzfsa.govt.nz/acvm/publications/discussion/operational-policies/index.htm>). The other comments will be considered along with submissions from the public consultation process.

At present the ACVM Group is in discussion with the Commerce Commission regarding their concerns about the potential for restrictive trade practices, and these will be considered as part of the consultation process.

### Definitions

One of the most important changes in the current draft policy is to include working definitions for 'veterinary consultation' and 'immediate or direct care'. The ACVM Group has included the definitions that are used in the VCNZ *Code of Professional Conduct for Veterinarians*. Both the NZVA and the VCNZ have suggested that the definition of immediate or direct care should be tightened and have noted that

several overseas jurisdictions adopt the Royal College of Veterinary Surgeons definition for *direct care* which states that:

- (a) the veterinary surgeon must have been given responsibility for the health of the animal or herd in question by the owner or the owner's agent;
- (b) responsibility must be real and not nominal;
- (c) the animal or herd must have been seen immediately before prescription and supply; or
- (d) recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe;
- (e) the veterinary surgeon must maintain clinical records of that herd/flock/individual.

What amounts to 'recently enough' would be a matter for the professional judgement of the veterinary surgeon in the individual case.

The ACVM Group is aware that such a definition could cause changes in current practices in a few specialised areas. This is possibly at odds with our desire to, as far as possible, allow current practices to continue providing ACVM Act risks can be managed. We are discussing this with the Commerce Commission, and we are interested in comments from respondents on this point.

It has also been suggested that the risk management process would be made more robust if the definitions had some legal effect. In the short term it would appear that this could be done by way of approval of a code of practice. In the longer term it may be more effective to amend the ACVM Act (and/or the

Veterinarians Act) to provide additional regulation making powers. This has been advised to the NZFSA Policy Group for consideration.

### Operational procedures

NZVA has also suggested that risk management would be improved by a 'legal definition' of operational procedures. The ACVM Group agrees and has proposed a standard based on one already used (see page 5).

### Trade in veterinary medicines

A number of concerns in this area have been expressed although the ACVM Group has made efforts to stress that we are not **advocating** change but are allowing for legitimate practices. The ACVM Group, after hearing the initial concerns in this area, proposed the code of practice for trade in PARs to add some robustness and controls.

It has been suggested that there would continue to be risks posed by new entrants to the trade in PARs that do not exist at present even given the powers provided by the ACVM Act to register (and to de-register) traders. While we don't expect there to be many new entrants, there is a potential to handle this concern in the implementation process. For instance, existing traders could be included on the register at no cost on the basis that they are operating in business as usual mode. New entrants could be subject to a positive compliance programme of audits for a period of time in a 'confidence building' period. In this case there would be a cost for new entrants but no additional cost of compliance for anyone currently operating in the business.

We are interested in the views of *AgVetLink* readers to this proposal.

### Other concerns

While the ACVM Group is not advocating or forcing changes in the  
*concluded at right*

## Who's who in the NZFSA : Programme Development Group

The role of the Programme Development Group (Director **Steve Hathaway**) is to develop risk-based programmes for food safety in New Zealand. These must include generic implementation tools that deliver agreed levels of consumer protection, be harmonised with international approaches, and facilitate judgement of equivalence in trading situations. Strong representation of New Zealand food safety strategies and goals in international fora is an important activity. There is a close linkage between the ACVM Group and the Programme Development Group, and a working relationship with most of the experts in the group.

**Dr Roger Cook** is Programme Manager (Microbiology). Dr Cook is charged with the identification, design, coordination and reporting on research and development programmes related to food microbiology that ensure continued scientific validity, competitiveness, and cost-effectiveness. Dr Cook provides

extensive operational support to the NZFSA research and development programmes, with particular reference to microbiological surveys and the national microbiological database (NMD) meat industry process-control monitoring programme.

Dr Cook also provides consultation to the meat, seafood and game industries and associated organisations with regard to microbiological aspects of meat and food processing.

**Dr Judi Lee** is Assistant Director (Programme Development). Dr Lee is responsible for assisting in the development of HACCP-based food control strategies and the provision of technical expertise to stakeholders regarding design and application of HACCP-based programmes. Dr Lee also manages the Animal Products Group's development programme.

**Dr Bob Boyd** (a member of the Pesticides and Animal Remedies Boards

for many years) is now part of the New Zealand Food Safety Authority. Dr Boyd is a Principal Advisor (Public Health Medicine) in the Programme Development Group.

**Dr Stuart MacDiarmid** is the most recent addition to the small Programme Development Group. Stuart is the Principal Advisor (Zoonoses and Animal Health). Stuart is internationally recognised as an expert in animal health risk analysis and BSE, and he brings a wealth of scientific knowledge to NZFSA.

As an expert in zoonoses he will develop generic approaches to their prevention and control in food both imported and produced in New Zealand, and will work in assessing risks and providing input to food safety standards for specific pathogens. He will also continue to work with OIE, bringing a new food safety focus to elaboration of OIE standards for animals and animal products in international trade.

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### PAR operational policy, concluded

supply chain, there are concerns that there is a potential for change and the flow on effect that this will have on the economics of rural veterinary practices and the rural economy. Many of the concerns are not able to be directly linked to the agreed ACVM Act thresholds and criteria. The VCNZ has advised that it will be giving advice to the Minister on this issue as it is required to do under its legislation.

The ACVM Group has brought these concerns to the attention of the NZFSA Policy team for discussions with MAF, and will also discuss this in the meetings with the Commerce Commission.

### Consultation process

The revised draft policy was published on the ACVM website on 10 January 2003 with a close-off date for submissions of 28 February 2003. The ACVM Group expects that it will take about two weeks to finalise consideration of the submissions and revise the policy, but it could be longer depending on arguments presented and the outcome of discussions with the Commerce Commission.

A final version will be provided to AVMAC for endorsement and will be approved by the decision-making committee. It will be implemented by changing the wording of the conditions of registration and by advising via *AgVetLink*.

## Staff Update

In early March 2003, Jodie Trubshoe, Executive Manager (Business Services), will go on maternity leave for a period of 12 months for the birth of her first child. We wish Jodie and her husband all the best, and we are currently interviewing people to find a replacement for Jodie for this period.

In the interim, Sarah Smyth (phone 04 463 2553 or email [sarah.smyth@nzfsa.govt.nz](mailto:sarah.smyth@nzfsa.govt.nz)) is the contact for any finance-related queries.

## Conferences and meetings

### ANZCCART Conference 2002

The Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) annual conference was held in Brisbane in October. The conference theme was 'Animal Welfare and Animal Ethics Committees: Where Are the Goalposts Now?'. Not surprisingly, there was a focus on topical issues such as genetically modified organisms, speciesism and the daily difficulties faced by Animal Ethics Committees (AECs) when attempting to find the delicate balance between scientific progress and animal welfare.

New Zealand was well represented with excellent presentations from Kate Hellstrom (MAF Animal Welfare) and John Schofield (University of Otago). New Zealand delegates were active participants in the various workshops and displayed an admirable knowledge about, and willingness to protect, the welfare of animals used in research and teaching establishments. It was evident from discussions regarding the way in which Animal Ethics Committees are audited in New Zealand compared to New South Wales that New Zealand compares favourably to the Australian situation.

ANZCCART is to be congratulated on the organisation of such a varied and lively conference. Despite attendance from a large cross-section of the community including scientists, AEC members, government regulators and members of the public, the conference delivered something of interest to all participants.

### NZ Plant Protection Conference

Assessors Sarah Lester and Warren Tully attended the NZ Plant Protection Conference recently held in Rotorua. This annual conference brings together researchers, agrichemical company representatives, regulators and various industry sectors to hear and discuss papers presented on plant protection matters.

A symposium addressing the role of science in biosecurity was held on the first day, and animated discussion ensued. This theme continued throughout the conference. Other topics covered included:

- forestry
- grassland weeds
- horticultural entomology and pathology
- application technology
- entomology and pathology in vegetables
- arable and horticultural weeds
- arable entomology and pathology
- pasture entomology
- storage pests.

The conference had a large attendance and gave ACVM Group attendees the opportunity to talk with other delegates on a range of issues.

### Food and Dietary Risk Assessment Conference

Assessor Warren Hughes attended the 1<sup>st</sup> International Fresenius Conference on Food Safety and Dietary Risk Assessment held in Mainz, Germany, 5 - 6 December 2002. The conference provided an opportunity to learn how food safety, particularly pesticide residues, are handled in Europe and to learn more about the use of probabilistic modelling in dietary intake risk assessments.

In addition to attending this conference, Warren visited the Pesticide Safety Directorate in York, United Kingdom, and Bayer Cropscience in Monheim, Germany. The visit to the former provided the opportunity to meet key personnel and discuss in some detail the regulatory system in the United Kingdom, including the linkages to the EU system. The visit to Bayer Cropscience provided insight in operations of a major R&D agrochemical company and to advise on changes occurring in the New Zealand regulatory system.

### Agcarm Crop Protection Meeting

ACVM Group Director Debbie Morris attended the recent Agcarm Crop Protection meeting in Auckland to discuss ACVM Act related matters. Key topics of discussion were the revision of the Chemistry and Manufacturing standards (Agcarm members have provided some excellent material in their submissions) and the issue of requiring expiry dates on registered products. The ACVM Group is developing an operational policy in this area – watch *AgVetLink* for further details.