



# AgVetLink

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## From the Director

*This issue of AgVetLink marks a milestone for the Group – we are in the final stage of transferring registrations to the ACVM Act (page 2).*

*It also marks a milestone for Brian Pidford, who is retiring in January after many years with us. We profile his career and introduce our new Assistant Director, John Bongiovanni, on page 4.*

*An overview of how our role has changed as a result of NZFSA restructuring to rationalise and harmonise functions is provided on page 3. We hope this helps to clarify the new system for you.*

*The recent OECD pesticides programmes workshops in Wellington were a great success, attracting record numbers of participants (page 6).*

*We wish you all a safe and happy holiday season-- details of the 'Christmas closedown' are on page 8.*

Debbie Morris  
Director  
Approvals and  
ACVM Group



**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.

## GENERAL INTEREST

### Final Stage of Transfer to ACVM Act

The ACVM Group has almost finished the update of product registrations. Most products are now under new registrations, complete with new certificates that include the revised conditions of registration and compulsory registration expiry date.

#### Registration expiry date needed

The registration expiry date of three years has been imposed on all products to enable confirmation that the product information held by the ACVM Group has not changed. This is needed because, even though it has been a legal requirement in the past for registrants to advise changes to products, the ACVM Group has found significant numbers of products were not kept 'up to date'. If products have not changed over the three years, then the information required is likely to be minimal for a renewal of registration. The ACVM Group is working with industry to set the information requirements and develop the process for the renewal of registrations.

#### Inconsistent registrations

The time lag between the date when the ACVM Act came into force and the

introduction of a registration expiry date requirement has meant that about 260 products have registrations that are not consistent with the current requirements. It was considered at the time that there was no need to ask each of the registrants of these products to provide another application so soon after the products were registered.

Consequently, the ACVM Group advised those registrants not to take any action in regard to the updating of their products at that time. Now, however, the only task left to do in the updating process is to issue the final registration certificates for the above-mentioned products with the same wording of conditions and registration expiry date.

#### No change, no charge

To simplify this task the ACVM Group will send each affected registrant a form to be signed and returned to initiate the process of issuing the new certificate of registration. The form will request confirmation that the product has not changed and the information held by the ACVM Group is still valid. This will allow the issuing of the certificate without an application and with no

charge. If the product has changed, then the registrant should contact the ACVM Group and discuss the matter.

#### Change from 'low risk' to 'specified requirements'

The ACVM Group is aware that the basis for registration (low risk to specified requirements standards) of about 20 products has changed significantly in the same time. The registrants of the affected products will be contacted individually to discuss the significance of the changes, which include revised conditions on registration and required label content. Notification of the information that would need to be supplied to enable the changes to be made will be advised in the letter to affected registrants. It should be noted that it is not a statutory requirement to request reassessment of the registration and all current registration certificates will remain valid although inappropriate for the type of registration. If reassessment is not requested, the product will automatically be put on a list of products to be audited within three years to ensure that the products are compliant with the legislation.

### MRL Update

Since the last update in August's issue of *AgVetLink*, several changes have been made to the maximum residue limit (MRL) standard, including the mid-year consolidation of the standard in order to address the formatting changes made in amendment 2 of 2005. The NZFSA has also gazetted its first amendment to the new consolidated MRL standard – the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005 (No 2). This is the third amendment of the year, and comes into force on 22 December 2005. It contains:

- 5 new MRLs
- 1 exemption, and
- 30 reassessments.

The fourth amendment of the year, which is currently in the consultation phase (closing 25 January 2006), contains four new MRLs. In addition, the first amendment to the 2006 standard is likely to contain a number of new MRLs, a number of exemptions, and the continuation of the reassessment project, which has already removed a number of existing MRLs from the default limit of 0.1 mg/kg to more appropriate levels that are consistent with the supported Good Agricultural Practice for that compound.

#### Agricultural Compounds and Veterinary Medicines Amendment Bill

An introductory copy of the Bill has been drafted by Parliamentary Counsel, and it has been circulated to government departments for comment. It should be ready for introduction early in the new year, subject to Government legislative priorities.

## GENERAL INTEREST

### Changes within the Approvals and ACVM Group

Over the years, the ACVM Group's primary focus has been on registration of veterinary medicines (previously animal remedies) and plant compounds (previously pesticides). Other activities involved the setting of standards and policies under the ACVM Act. However, since the recent restructure of NZFSA to rationalise and harmonise approaches for the business groups, the scope and functions of the Approvals and ACVM Group have changed.

#### Significant change

One of the most significant changes has brought together those elements of the various Acts that NZFSA administers (covering both the domestic and export industries) that are associated with approvals and standards setting into one functional grouping. The work of the Approvals and ACVM Group now covers setting standards and policy under the ACVM Act and a wide range of approvals, including registration of agricultural compounds and veterinary medicines, approvals of risk management programmes (RMPs), dairy product safety plans (PSPs), multiple release permits for imported foods, and chemical approvals.

The team is composed of staff from the existing ACVM Group, staff from the Animal Products Group, a staff member from the Imported Foods area and a new employee in the Food, Sale and Service area.

#### Key accountabilities and functions – Standards Setting Team

- Setting standards for ACVMs and MRLs
- Setting technical standards for regulatory and non-regulatory programmes and approval processes
- Developing monitoring and surveillance programmes
- Monitoring the international environment
- Providing input into science and risk assessment priorities
- Liaising with other standard setters, e.g. ERMA, Biosecurity NZ
- Providing technical input into approvals process
- Providing input to policy, science, international standards, and New Zealand standards
- Furthering alignment with Australia
- Contributing to consultation and communication

- Adjudicating, interpreting, clarifying standards
- Developing operational policy, e.g. antibiotic resistance
- Rationalising standards and systems.

#### Key accountabilities and functions – Approvals Team

- Providing technical assessment for approvals process
- Developing systems for approvals
- Developing decision making process for approvals under the ACVM, Animal Products, Wine and Food Acts
- Measuring performance of approvals process
- Acting as contact point for Compliance and Investigation Group
- Liaising with other regulatory approval groups, e.g. ERMA, Ministry of Health, public health units and local authorities
- Maintaining associated registers and lists
- Rationalising approval processes
- Providing technical input into standard setting and systems audit
- Removing approvals.

## FINAL NOTICE! (DID THAT GET YOUR ATTENTION?)

### DO YOU WANT TO RECEIVE AGVETLINK?

**We are updating our mailing list. If you want to keep receiving *AgVetLink*, we need you to email (or fax) your correct contact details to Mary Alexander**

**Email: [mary.alexander@nzfsa.govt.nz](mailto:mary.alexander@nzfsa.govt.nz)**

**Fax: 04 463 2566**

**If we don't hear from you by 23 December 2005, your name will be removed from the mailing list.**

## GENERAL INTEREST

### Reminder!!!

Is your registration due to expire? We remind you that it is your responsibility as a registrant to ensure that your product is compliant and has a valid three-year registration. The ACVM Group will endeavour to remind you via a letter one month before registration(s) expire; however, there may be times when glitches in the system miss the odd product.

#### WHAT IS REQUIRED TO RENEW?

If nothing has changed to your registration over the three-year period, then all that is required is a letter to the ACVM Group confirming this. We will, in turn, process a new registration certificate for the product(s) at no charge.

If there has been a 'drift' or a change in the registration, such as formulation, manufacturer etc., then you are required to supply the appropriate application type (i.e. supply a completed product data sheet, labels and relevant data if necessary). This will be processed and charged accordingly.

### CHECK YOUR REGISTRATION NOW!!!

### Staff Update



**Brian Pidford**  
Programme Manager – ACVM Programmes

In January, we will farewell Brian Pidford who is retiring after a long and varied career in the pharmaceutical industry. Brian's work in England before immigrating to New Zealand in 1977 included time in the R&D section of Evan Biologicals (Liverpool), working on rabies vaccine. He also worked for Pfizer (Sandwich, Kent) in the production and quality control of oral polio vaccine, primarily for the North American and European markets.

When Brian and his family came to New Zealand, he joined ICI Tasman's R&D division in Upper Hutt. As ICI Tasman went through a number of mergers and name changes (Coopers, Pitman Moore, Mallinkrodt), so too did Brian's role. He moved from R&D to virus production to becoming Operations Manager for all manufacturing and engineering on site and was Quality Manager when he left to join the MAF Agricultural Compounds Unit at Wallaceville in 1990.

Brian has been a key part of the ACVM Group's development of compliance programmes in the manufacture, import, sale and use of veterinary medicines and agricultural compounds. We will miss him and wish him all the best in his new ventures.



**John Bongiovanni**  
Assistant Director – Approvals

"Hi there. I took up this position in the Approvals and ACVM Group at the beginning of November. It was a new role created under NZFSA's restructure to bring together all approvals functions under the legislation administered by NZFSA. Beginning work in NZFSA felt very comfortable because there were so many familiar faces of people I'd worked with or known before. I spent the last eight years in New Zealand Post working in both the

Risk Review and Human Resources teams. But before that, I had spent twenty-three and a half years in MAF. Most of that time was in the MAF Quarantine Service, then five years in the Director General's Audit team and five years as National Advisor (Border Inspection) in MAF's Regulatory Authority.

Before MAF I obtained a horticultural degree from Massey. My wife Chris and I have recently moved to a large garden property in Waikanae on the Kapiti Coast where we can indulge in our mutual passion for gardening. It is here that we have established headquarters for, and maintain the network of, six children, their spouses/partners and seven grandchildren."

**Jennie Moran**, Senior Advisor (ACVM Standards – Animals), will be taking on a totally new role early in 2006. Jennie and Jeff's first child is due in March, and Jennie will begin a 12-month period of parental leave on 3 February 2006.

## GENERAL INTEREST

### Meetings Update

#### ARPPA AGM

Debbie Morris, the Director of the ACVM Group, was invited to the ARPPA AGM held in Auckland in November. Debbie's presentation covered the organisational structure, role and responsibility of the Approvals and ACVM Group that she now heads under the NZFSA restructure. The ARPPA agenda also included presentations from Chris Kelly, CEO of Landcorp (effectively New Zealand's biggest farmer), and Rob Forlong, CEO of ERMA New Zealand.

#### AVMAC meeting

AVMAC met for the 31<sup>st</sup> time in Wellington on 17 November. The main discussion at the meeting was a review of the management of agricultural compounds and veterinary medicines by AVMAC members. Generally feedback was positive and included some useful suggestions for improvement.

The agenda also covered:

- an update on the proposed ACVM Act changes from Bruce Burdon of NZFSA Policy Group,
- discussions on requirements for Good Laboratory Practice, Good Clinical Practice and Good Field Practice to support registration,
- an information paper on the fertiliser standard review,
- a discussion paper on the advertising of brands, and
- the Approvals and ACVM Group restructure.

AVMAC meeting dates for next year will be 28 February, 23 May, 22 August and 23 November.

#### Harmonisation with Australia

The ACVM Group met with APVMA officials in Canberra on October 28 to discuss a workplan to harmonise the marketing approval for agricultural compounds and veterinary medicines.

#### Australian workshops

The Group held registrant workshops in Sydney and Melbourne in October. They covered:

- changes to the ACVM Act and Regulations,
- alignment with APVMA,
- the registration process with emphasis on data assessment, review and evaluation,
- MRL setting, and
- compliance.

#### ERMA liaison meetings

ACVM staff attended the monthly meeting with staff from the Operations Group of ERMA on 2 December 2005. Warren Hughes gave a presentation on Confidential Supporting Information (CSI) – data protection. We will also attend a presentation from ERMA on 14 December on Group Standards.

#### Hazardous Substance Industry Consultative Group

This meeting was attended by Maree Zinzley on 24 November 2005 on behalf of the Approvals and ACVM Group.

### The 2005/06 Food Residues Surveillance Programme

NZFSA is preparing to start the 2005/06 Food Residues Surveillance Programme (FRSP).

As in previous years, a range of food/chemical combinations have been rated against criteria of toxicity of the chemicals, expected residues in food, food consumption, what NZFSA knows about 'real-life' residue findings (both domestically and overseas), known data gaps, stakeholder interest, availability of cost-effective analyses, and integrity in the food supply chain. Previous years' results can be found on the NZFSA website, under Science > Research projects and reports.

Over time, NZFSA plans to re-visit food/chemical combinations of interest (to cover seasonal variations and changing practices etc.) but in these early days, NZFSA is still trying to get the maximum coverage possible. Consequently, this year the focus will be on 'new' foods, using multi-residue screens.

Two types of multi-residue analyses will be used this year:

- the gas chromatographic multi-residue (GCMR) screen used in previous years, and
- a screen for dithiocarbamate fungicides (DTCs).

The DTC screen is limited in that it cannot distinguish between the different DTCs but, because MRLs are set on carbon disulfide (a breakdown product of all DTCs), this limitation was considered less important.

The foods and analyses that NZFSA is considering for this year are raspberries (GCMR, DTCs), apricots and plums (GCMR, DTCs), cucumbers (GCMR), wheat (GCMR), carrots (GCMR), and onions (GCMR, DTCs).

## PLANT COMPOUNDS

### OECD Pesticides Programme Meetings in Wellington

During the week of 28 November - 2 December, NZFSA and ERMA New Zealand jointly hosted a series of meetings and events on behalf of the OECD's Working Group on Pesticides Registration Steering Group and their Risk Reduction Steering Group. The meetings attracted record numbers of delegates from around the OECD member countries and New Zealand regulators.

#### Application technology

On the Monday, a field trip to the Wairarapa was held to show the delegates actual spraying equipment in action. Aerial and boom spraying were seen in the pastoral setting, air blast spraying in an apple orchard and over-row spraying in a vineyard. The demonstrations and subsequent discussions with the owners of the properties ably assisted the delegates in their seminar discussions on the use of application technology in pesticide risk reduction that took place on the Wednesday. This seminar allowed widespread discussion of this very relevant issue, and will as-

sisst the OECD in developing appropriate recommendations to assist all countries utilising pesticides in food production.

#### Steering Group meetings

The Risk Reduction Steering Group met on the Tuesday, and the Registration Steering Group on Thursday and Friday. These meetings further progressed OECD work in promoting reduced risk pesticide use and the harmonisation of data packages and work sharing amongst OECD countries that should lead to large savings in time and resources involved in the registration processes that are in place.

A further topic that was broached for the first time was that of re-examination of the current toxicology testing paradigm by the USA. They are looking at the value of the individual tests that are currently required – for example, does a two-year feeding study in a rat give any more or different data than is obtained from a one-year or even a 90-day study? The likely outcome could

well see some current tests no longer required with large reductions in the numbers of animals used in testing, as well as savings in resources as tests may no longer be required.

#### Media event

At the Thursday evening media event, the Minister of Food Safety (Hon Annette King) stated New Zealand's commitment to the OECD vision statement that seeks to have work sharing, and fully harmonised data requirements in all OECD countries within ten years. This event was attended by several ambassadors from the Asia/Pacific region, and so helped promote this message to non-OECD countries as well.

The delegates were very impressed with the venue of the meetings (Te Papa), the weather (Wellington was amazingly benign for that week), and the countryside. Many expressed their commitment to arranging holidays in New Zealand to further explore what this country has to offer.

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### The ERMA Integrating Initiatives for Pesticide Risk Reduction Workshop

The ERMA workshop was opened by the new Minister for the Environment, Hon David Benson-Pope, who set the scene for the day's discussions of integrated pest management, the Foundation for Research, Science and Technology (FRST) funding strategy, and trends in pesticide use.

#### Pipfruit sector achievements

Mike Butcher of Pipfruit NZ presented the impressive achievements of the pipfruit sector in integrated pipfruit production, based on bringing together better understanding of the relationships between pests, their hosts and parasites, and the climate. Growers have access

to daily updates of online information, allowing them to predict and respond to pests before they become a problem. Dr Butcher explained how integrated fruit production (IFP) has not, and is unlikely to, eliminate the need for use of traditional chemical interventions or the need for newer, more sophisticated chemistry. However, it allows for a more subtle response to pest problems with targeted chemical and biological interventions.

#### Integrated pest management

Philippa Stevens from HortResearch spoke about how integrated pest management (IPM) has been around

since the early 1970s but is by no means 'old hat'. It is a system that constantly evolves to meet new and emerging challenges, and requires input from a wide range of technical expertise.

Participants were asked to suggest what opportunities had become apparent during the course of the workshop. It was suggested that there could be more emphasis on integrated weed control. However, it was also apparent that most of the FRST-funded IPM work was focused on the larger sectors, and there would seem to be an opportunity for growers of minor crops.

## VETERINARY MEDICINES

### Animal Feeds – Fit for Purpose

The ACVM Group reminds feed manufacturers, including pet food manufacturers, that they have a statutory obligation to take due care in ensuring that their products are fit for purpose. The criteria for 'fit for purpose' are specified in Schedule 4 of the Agricultural Compounds and Veterinary Medicines Regulations 2001.

If the manufacturing of the products include the primary processing of animal products or the feeds (containing animal products) are to be exported and require official certification, then the manufacturer must operate under an approved risk management programme under the Animal Products Act 1999. It is anticipated that compliance to an approved risk management programme will be sufficient to meet the ACVM requirements as well.

However, even if manufacturers are not obliged to operate under an approved risk management programme under the Animal Products Act (because the products do not contain animal products or are not intended for export, requiring official certification), it is expected that every manufacturer will operate a programme that manages the manufacture of their products and ensures the products do comply with the criteria in Schedule 4 of the ACVM Regulations 2001.

During 2006 the ACVM Group will review the level of compliance of the feed manufacturing industry to the statutory requirements. This information, which will help us to become familiar with what the industry considers good manufacturing practices, will be used to inform the Group's compliance programme and any amendment to the Agricultural Compounds and Veterinary Medicines Regulations. Independent of the review, the ACVM Group will investigate any suspicions or allegations of non-compliance to the ACVM Regulations.

### Standards Update

#### **Standard for Unregistered Veterinary Medicines Requiring Veterinary Overview**

The consultation period on the draft *Standard for Unregistered Veterinary Medicines Requiring Veterinary Overview* has closed.

The ACVM Group received two formal submissions and had informal discussions with other parties. Most of the draft standard had gone through a previous consultation, but the section on compounding products was significantly different from the earlier draft.

One of the submissions received questioned the need for the standard, and the other submission raised several specific issues relating to areas such as alignment with VCNZ requirements, determination of 'suitably qualified to compound' veterinarians, and the mechanism for approving the sale of human medicines as specified in the Medicines Act.

These issues have been considered, and the standard will be issued as soon as a few areas have been resolved. The complete ACVM Group response to the submissions is available on the website.

## **VERTEBRATE TOXIC AGENTS**

### **Workshops for Test Certifiers of Approved Handlers for Vertebrate Toxic Agents**

Two workshops were arranged by ERMA New Zealand in Rotorua and Christchurch for test certifiers of approved handlers for vertebrate toxic agents (VTAs), to update them on the ERMA requirements, processes and systems and to discuss questions and problems. About forty people attended.

The ACVM Group was invited to participate and Brian Pidford provided a presentation reviewing the regulatory requirements for VTAs under the ACVM Act, the ACVM standard for VTAs, conditions of registration of VTAs and the expectations of test certifiers acting under the ACVM Act. The practical focus of the presentation demonstrated external access to the various parts of the ACVM website for the retrieval of relevant information that will assist test certifiers in their roles with clients.

# BEST WISHES FOR THE HOLIDAY SEASON...

*The Approvals and ACVM Group wishes you all  
a happy and safe holiday season.*

*Don't forget the New Zealand Foodsafe  
Partnership message of the four 'cs' –*

**clean** hands and food preparation surfaces  
**cook** food thoroughly  
**cover** food until ready to eat, and  
**chill** food correctly and quickly.



## Christmas/New Year Holidays

The Approvals and ACVM Group will close for Christmas  
on Friday, 23 December 2005.

The office will reopen on 9 January 2006, but there will be  
minimal staff in the office over the January period.