



# AgVetLink

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insert: Approvals and ACVM Group contacts

## From the Director

*The Memorandum of Understanding with Australia, which was introduced in the last issue of AgVetLink, has been signed and development of the three-year workplan is underway (page 2).*

*A public discussion document on proposed amendments to the ACVM Regulations 2001 has been released and we invite your comments on any aspect of the proposals (page 2). To help you with the process, we have included an article about points to consider when making submissions (page 5).*

*Queries about information waivers have been frequent this month. See page 3 for an overview.*

*While we applaud waste management schemes in principle, plans to reuse plastic containers for ACVM products present significant risks and could result in unregistered products. The article on page 3 explains the situation.*



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

### Closer Alignment Between New Zealand and Australia

NZFSA has signed a memorandum of understanding (MoU) with the Australian Pesticides and Veterinary Medicines Authority (APVMA). The MoU establishes the operational relationship between the ACVM Group and the APVMA in regard to co-operation and regulatory control of veterinary medicines and agricultural compounds (known in Australia as agricultural chemicals).

The primary purpose of the MoU is to work towards aligned standards and requirements for the approval of agricultural and veterinary chemical products to the extent that is appropriate. The MoU will also enhance the way in which the APVMA and ACVM Group work together in achieving a common approach to the regulatory control of ACVM products.

The objectives of the MoU are to:

- work towards appropriate aligned

regulatory standards and requirements relevant to the risks posed;

- share (with a medium-term view to accepting) product assessment reports where they are relevant to approval decisions in each country;
- in the longer term, move towards determining whether it is possible to recommend to Government that the ACVM Group and APVMA should accept registration decisions for specified products or kinds of products;
- establish effective lines of communication to allow sharing of information on approvals, compliance, surveillance and adverse experience reporting/pharmacovigilance; and
- develop a joint work programme with a set of defined milestones over a three-year period to establish common approaches to risk assessment methods and processes.

#### Workplan

The three-year workplan will initially focus on developing a sound understanding of each other's registration processes. The agencies have started a side-by-side comparison of five veterinary products that have been registered in both countries in the last three years.

This comparison should highlight commonalities and differences that will help align registration requirements or standards. This is likely to be followed by a similar exercise for plant compound/agricultural chemical products.

Both agencies are confident that progress through the workplan will lead to a better understanding of the registration processes in both countries and is likely, over time, to facilitate the movement of products between the two countries.

### Amendment to the ACVM Regulations 2001: Public Consultation

NZFSA seeks submissions from all interested parties on any aspect of the proposals to amend the ACVM Regulations 2001. These Regulations are technical in nature and contain lists of types of products that are exempt from the requirement to be registered if certain conditions are met. The Regulations include minimum standards for products such as oral nutritional compounds (animal feeds and nutritional supplements), fertilisers and fertiliser additives. The Regulations also include a list of feed additives that are generally recognised as safe (GRAS).

The proposal for amendment includes some types of products that NZFSA considers could be managed without registration. It also includes additional substances that are being considered for listing as GRAS.

The discussion document has already been posted on the NZFSA website. This notice is to draw attention to the document and advise you that submissions close at **5.00pm, 10 July 2006**. Submit your response to:

Chad Tustin, Policy Group  
New Zealand Food Safety Authority  
PO Box 2835, WELLINGTON

Alternatively, fax responses to (04) 463 2583 or email to [chad.tustin@nzfsa.govt.nz](mailto:chad.tustin@nzfsa.govt.nz)

## GENERAL INTEREST

### To Fill Or Not To Fill... (reusing plastic containers)

The ACVM Group is aware of an initiative to manage wastes from used plastic containers by:

- recycling agricultural compound product containers (i.e. using the plastic in old containers to manufacture new plastic products); or
- reusing the containers (refilling old containers with the same or a different product).

The ACVM Group supports the intention to manage wastes. However, we wish to point out that there are significant risks associated with refilling used containers because the assessments of the product and the risk management conditions are no longer valid when a product is refilled into old or different containers.

A few registrants have developed reliable systems to minimise the risks associated with refilling. Those systems have been assessed and approved during their product registration. The ACVM Group accepts that refilling can be done safely, but only if significant planning and administration of distribution systems are used. Any party considering refilling as a means of managing wastes from old plastic containers should contact the ACVM Group early on in their planning.

In fact, unless there have been specific arrangements that will allow refilling old containers under controlled conditions approved as part of the registration process, refilling into the same container or a different container results in unregistered products. Sale or use of unregistered products is an offence under the ACVM Act and a person may be liable to a fine of up to \$30,000 (or \$150,000 for a corporation).

### Compliance Update Fieldays 2006

A number of staff attended the annual Fieldays from 14 - 16 June 2006. We always use this time to talk with exhibitors and to provide information about their obligations under the ACVM legislation.

#### Non-compliance

If we come across non-compliant advertising or product displayed, and the exhibitor has not been on our radar screen before, we use our visit as an education exercise. It is pleasing to advise that this year we only had a couple of non-compliant exhibitors and they appeared to be unaware of the legislative requirements. In general, the non-compliances that we notice at the Fieldays involve smaller equine companies that purchase products and sell on behalf of unapproved GMP manufacturers. These matters are investigated and progressed.

#### Old registration statement

We did notice a number of registered veterinary medicine products still displaying the old registration statement, 'Pursuant to the Animal Remedies Act'. We will discuss this in-house and our policy on this will likely be published in the next issue of *AgVetLink*, taking into consideration ERMA's timeframe for updating labels with HSNO requirements for veterinary medicine products.

#### Overall

It was pleasing to see that exhibitors of ACVM products are in the main compliant. The feedback from a number of exhibitors was that our presence at the Fieldays and our efforts to educate on compliance are welcome.

### Information Waivers

The ACVM Group has been receiving queries from applicants on when an information waiver is required, and whether it needs to be submitted with the review and evaluation (R&E) application or separately.

The guidance document can be found on our website (<http://www.nzfsa.govt.nz/acvm/subject/registration/information-waivers.htm>). This document outlines the types of situations where an information waiver application is required. In general terms, the more complicated the information waiver request the more likely the ACVM Group will require its submission prior to submitting the R&E application. As R&E applications are subject to regulatory timeframes, it is difficult to complete them within this timeframe while a complicated information waiver request is being processed concurrently. If you are unsure whether an information waiver is required, or whether it should be submitted prior to or with the R&E application, please contact the ACVM Group for advice.

## GENERAL INTEREST

### All about the packaging...

*We have had several queries about packaging requirements recently. Here is a reminder of some basic parts of our packaging policy.*

#### Pack sizes

Provided the appropriate data and information are supplied, the ACVM Group will approve a range of pack sizes at initial registration. From that point, all pack sizes with a risk profile that falls within the assessed range (such as the same packaging material) are considered approved.

For existing products applications can be made to approve a range of pack sizes as a normal C3, with referencing to data already on file, or via the provision of additional information. In either case, the ACVM Group requires notification of the actual pack sizes being marketed in the form of a formal letter, which must be provided each time a new pack in the approved range is introduced to the market. In addition, any subsequent applications requiring a product data sheet to be submitted must state the marketed pack sizes as well as the approved range. Labels for additional packs do not require approval provided the content does not differ from that already approved.

For new packs falling outside of the approved risk profile, new data and a C3 application (and fee) are required.

#### Multiple packs

It is common practice for veterinary medicine products to be packaged in foils, blisters, pouches and vials and sold as multiple lots in containers. Although it is less common for vertebrate toxic agent and plant compound products, smaller individually packaged bottles of product may be sold in bulk lots in a similar fashion.

Where units are individually packaged (e.g. tablets in foils or blisters, vaccine vials, bottles of product) and then included in multiple numbers in containers, the actual number of individual units included per container does not need to be stated on the label approved by the ACVM Group provided the container does not contribute to the stability profile of the product.

In consequence, where changes are made to the number of individual units included per container, no formal ACVM Group approval is required provided there are no changes to the individual unit or ACVM-relevant approved label text.

Where the container contributes to the stability profile of the product the usual policy regarding approved pack sizes (which must be identified on approved label text and for which C3 applications are required prior to changes being made) is likely to apply.

### Staff Update



*"Hi, my name is **Jane Chuang**. I joined NZFSA in the Approvals and ACVM Group in May, working with Hine Van Leeuwen as Co-ordinator (Business Services). I worked at Inland Revenue in Palmerston North before my shift to Wellington. It's been a great move to the capital – even greater to work with a bunch of good people!!"*

#### Toxicology Assessor

Our Toxicology Assessor **Nikki Gibbins** has left us to return to the University of Surrey to complete her final year studies. She will be replaced by **Andrew Pearson**, who was our Surrey student two years ago. Andy is taking up the position as a permanent employee at the end of June.

### Registration Renewals

This is a reminder of the requirements for renewing registrations.

**If there has been no change to your product**, send in the following documentation:

- a Registration and Product Data Sheet (PDS)
- a copy of the current marketed label
- a covering letter indicating that nothing has changed.

There is no fee for this renewal.

**If your product has changed in any way**, e.g. formulation, it is no longer a simple renewal. You will be advised to submit the appropriate application and relevant fee.

## GENERAL INTEREST

### Making Submissions on Discussion Documents

#### Who can make submissions?

In general documents issued by NZFSA are open to comment from anyone. Submissions are sought from all interested parties on any aspect of the proposals presented in its documents.

NZFSA values the time parties take to consider and comment, and it considers that its regulatory control is improved as a result of the input from interested and affected parties.

#### How should submissions be written?

Clear, concise comments will help to ensure that the significance of your comments is understood. The following points may be of assistance in preparing comments.

- Wherever possible, comments should be specific to a particular

section of the document.

- Comments on other matters should be clearly stated and indicated.
- Comments should be to the point and, where possible, accompanied by supporting reasons and data.
- The use of examples to illustrate particular points is encouraged.
- A number of copies may be made of your comments, so please use good quality type, or make sure that your comments are clearly handwritten in black or blue ink.

#### Will information in my submission be made public?

Submissions may be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available unless there are

grounds for withholding it (such grounds are set out in the OIA).

Submitters may wish to indicate grounds for withholding specific information contained in their submission, e.g. that the information is commercially sensitive or personal (such as name and contact details). Any decision to withhold information requested under the OIA is reviewable by the Ombudsman.

#### What happens to submissions?

Submissions received are all analysed and changes made to proposals as appropriate. The amended proposals form the basis of regulatory control and may be incorporated into Cabinet papers that would lead to amendments in standards, guidelines or even Acts and Regulations.

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## MRL Update

A number of technical and typographical errors have been found in Schedule One of the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005 (No.2) and Amendment No.1 to those Standards.

Schedule One is the main table of the Standards, containing the maximum residue limits (MRLs). Schedules Two and Three of the Standards cover MRL exemptions for plant compounds and veterinary medicines, respectively. The errors and corrections relate only to Schedule One.

The purpose of this notification is to bring the corrections to your attention, and to provide you with the opportunity to comment.

The issues have arisen through technical drafting errors, and largely relate to

inconsistencies between the wording of what was already in the Standards, and the wording in Amendment No.1 to the Standards. Additionally, some of these corrections affect the proposals contained in the discussion document currently out for consultation (due to close on 21 June 2006).

The errors and corrections do not materially affect the MRLs themselves (except in the case of toltrazuril), but generally relate to other issues, such as residue definitions and chemical abstract service (CAS) numbers.

There are two documents relating to these errors and corrections. One is a document outlining the errors and proposed corrections, the other is a draft re-issue of the Schedule, with the corrections colour coded. These documents can be accessed on the

website (<http://www.nzfsa.govt.nz/policy-law/consultation/mrl-2006/nz-mrl-fs-2005-2-schedule-1re-issue.htm>). Please direct queries and requests for hard copies to:

MRL Food Standards  
New Zealand Food Safety Authority  
PO Box 2835, WELLINGTON  
Email: [policy@nzfsa.govt.nz](mailto:policy@nzfsa.govt.nz)  
Fax: 04 463 2583  
Phone: 04 463 2535

Once the re-issued Schedule is finalised, it will form part of the regular consolidation of the Standards that happens once a year, forming new Standards — the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006. This is due to occur early-mid August. The new consolidated Standards will then be posted on the NZFSA website.

## GENERAL INTEREST

### Approved Creditor Status

If your organisation would like to become an ACVM Group 'approved creditor', visit our website and fill out the Approved Creditor Request Form (<http://www.nzfsa.govt.nz/acvm/publications/policies-procedures/approved-creditor-ins.htm>).

Please ensure that you read through the following sections at this link to become familiar with our procedures:

1. Application form
2. ACVM checks
3. Acceptance as an approved creditor
4. Terms and Conditions

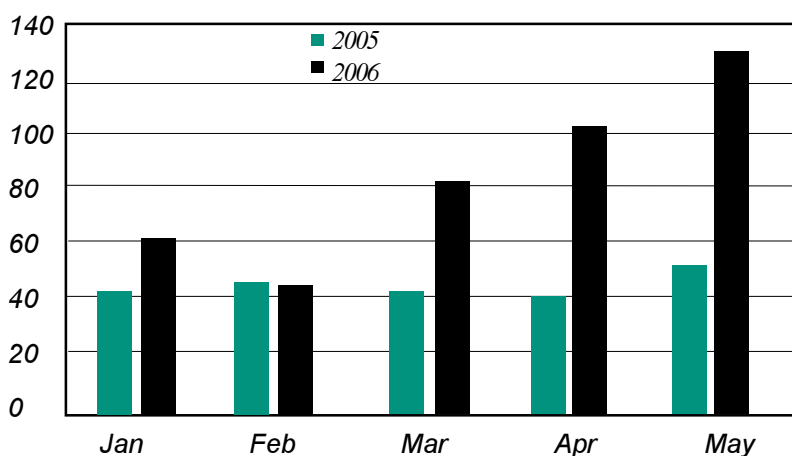
If you have any queries contact:

Jane Chuang  
Co-ordinator (Business Services)  
Approvals and ACVM Group  
PO Box 2835  
Wellington  
Tel: 04 463 2563  
Fax: 04 463 2566  
Email:  
[jane.chuang@nzfsa.govt.nz](mailto:jane.chuang@nzfsa.govt.nz)

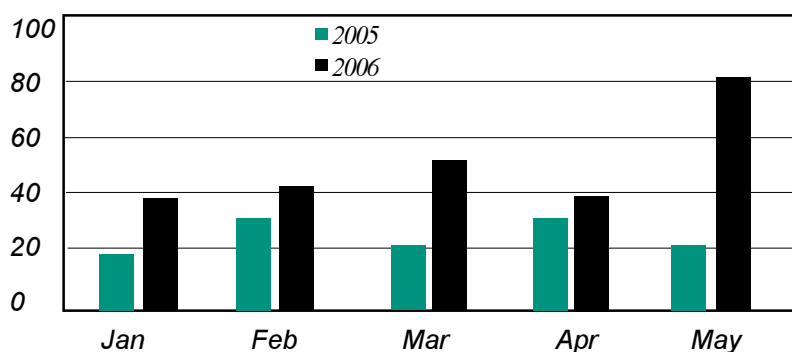
### Applications Update

The ACVM Group continues to receive a significant number of review and evaluation (R&E) applications, in addition to label updates for HSNO requirements. This is placing considerable strain on resources within the Group. While the ACVM Group is making every effort to ensure regulatory timeframes are met, there may be delays in some instances. Your understanding at this time would be appreciated. The graphs below compare the first five months of this year with last year.

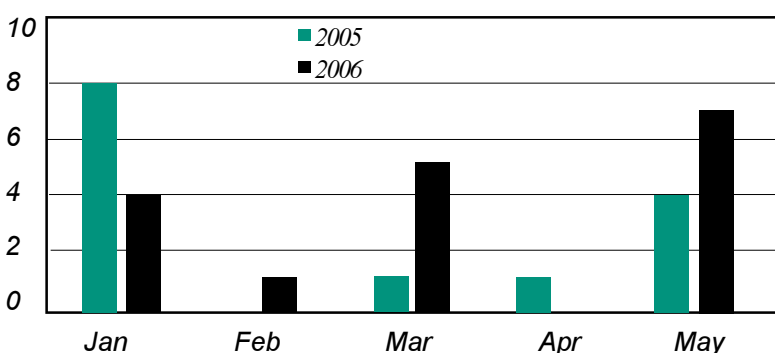
#### R&E applications received: veterinary medicines



#### R&E applications received: plant compounds



#### R&E applications received: vertebrate toxic agents



## GENERAL INTEREST

### Codex Update

#### Task Force on Antimicrobial Resistance

The Codex Alimentarius Commission has agreed in principle to establish an ad hoc task force to consider antimicrobial resistance with a focus on human health. A draft terms of reference has been circulated with the final version to be agreed at the next meeting in early July.

The general focus of this work is to produce science-based guidance on managing potential antimicrobial resistance in humans arising from food. The scope is likely to cover antimicrobials used in agriculture, including those used on plants as well as those used on animals (including aquaculture).

The task force is expected to operate over a defined period, probably in the range of four to five years. Given the size of the job, the work will have to be prioritised after identifying the antibiotics most critical to humans. The task force will have to agree on a policy for risk assessment and it has the ability to seek independent scientific advice including risk assessments. The resulting guidance provided will be in the form of specific risk management advice, which has to take into account the agricultural need for antimicrobials.

This work has the potential to establish some internationally agreed principles for managing antimicrobial resistance against specific drugs and to provide valuable information needed for individual countries to make risk management decisions. There will be opportunities for New Zealand-based organisations to have input via our representation in Codex.

#### 16th Codex Committee on Veterinary Drug Residues in Foods

The 16th Codex Committee on Veterinary Drug Residues in Foods was held in Cancun, Mexico, from 8 to 12 May 2006, and was attended by Dr Neil Kennington and Dr Bill Jolly from NZFSA.

The following veterinary drug maximum residue limits (MRLs) were progressed further in the Codex system.

##### To step 8:

- Trichlorofon - Cattle milk
- Pirlimycin - Cattle tissues and milk
- Cypermethrin and alpha-cypermethrin - Cattle and sheep tissues
- Doramectin - Cattle milk

##### To step 5:

- Colistin - Cattle, sheep, goat, pig, chicken, turkey and rabbits
- Ractopamine - Cattle and pig tissues

**Not progressed and retained at the current step** in the process were:

- Flumequine - Shrimp
- Erythromycin - Chicken and turkey
- Melengesterol acetate - Cattle tissues
- Triclabendazole - Cattle, sheep and goat tissues

New Zealand leads a working group that has proposed *The Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals*. This guideline updates the current guideline dealing with residue programmes and responses not only at the national level but at borders. The revision, which focuses on the use of a risk-based approach, was progressed to the next step in the process.

There is ongoing work on prioritising veterinary drugs for assessment of MRLs. A number of compounds causing trade issues have been proposed. The major barrier remains the availability of information meeting current standards required to set a formal Codex MRL. No significant progress was made on alternative ways to set internationally agreed residue levels for those drugs where acceptable daily intakes (ADIs) and MRLs cannot be set. The issue affects a large number of older drugs that have a history of safe use and, as a result, the working group on veterinary drugs without an ADI/MRL has been re-established.

#### OECD meeting, 30 May - 1 June, Dublin

Principal Adviser (Toxicology) John Reeve has recently returned from an OECD Pesticides Programme's Registration Steering Group meeting in Dublin. Progress was made on the project to review the paradigm that is currently used in toxicology data requirements and assessment to ensure that unnecessary testing and assessment is not being done. This project has already identified some data that can be deleted from requirements because the toxicity information is available from other core data. The first global work sharing arrangement for the assessment of a new Du Pont pesticide was also finalised. The ground breaking work will start early next year, with New Zealand involved in the assessment of residue data.

## VETERINARY MEDICINES

### VICH Update

The 18th VICH Steering Committee (SC) meeting was held from 31 May 2006 to 1 June 2006. Items of interest from the meeting included the following:

- The EU is developing a 'Monitoring and Maintenance' guideline for updating existing VICH guidelines.
- The Metabolism and Residue Kinetics working group has agreed priorities and topics. The group is to develop guidelines over 27 months with two face-to-face meetings and electronic meetings as needed. Acute reference dose calculations for injection site residues are not to be part of their remit in the first phase.
- The Quality working group was given approval for one more face-to-face meeting, subject to further clarification of reasons for the meeting and identification of issues to be finalised.
- The Pharmacovigilance working group (Guideline [GL] 35 list of terms) was authorised to hold one more face-to-face meeting to finalise 'list of terms'. This meeting is to take place prior to the next VICH SC meeting.
- Standard Language (GL 29) was signed off at Step 6.
- Electronic Standards for Transfer of Data (GL 35) was deferred to wait the outcome of the ICH meeting on the same issue.
- The Biologicals Quality Monitoring working group was directed to put activities on hold until the working group has had the opportunity to revisit guideline content in relation to the newly available mycoplasma reference strains. This issue will be on the next SC meeting's agenda. (The possibility of Australia/New Zealand laboratories taking reference strains is being discussed.)
- Pharmacovigilance Control list of terms (GL30) progressed to Step 4 for public comment.
- Target Animal Safety for Pharmaceuticals (GL43) is to be released at Step 4 for public comment.
- Pharmacovigilance on Management of Periodic Summary Updates (PSUs) (GL 29) was adopted at Step 7 for regional update by regulators.



*Several ACVM Group staff members were part of the NZFSA team that recently won the Wellington Indoor Sports Social Corporate Lunchtime Soccer Competition. It was a well fought final that went right down to the wire with a penalty shoot out!*