



# AgVetLink

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## From the Director

*The New Zealand Total Diet Survey for 2009 is in the planning stages. It will assess exposure to chemical residues, contaminant elements and selected nutrients across the average diet of different New Zealand age/sex groups (see page 2).*

*We are reviewing terms of reference for the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC) and welcome your input (page 3).*

*Access to veterinary medicines is also being reviewed as we bring the classification system up to date. See page 6 for the background.*

*We are working on a new proposal in the alignment with Australia project – it should save time and money in the registration process, and help in trialling would be appreciated (page 7).*



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

### New Zealand Total Diet Survey

Planning for the 2009 New Zealand Total Diet Survey (NZTDS) has commenced and a media release announcing this was made on 6 March 2008.

#### Assesses exposure to residues, contaminants, selected nutrients

New Zealand undertakes a TDS approximately every 5-6 years. The primary focus is to assess exposure to chemical residues, contaminant elements and selected nutrients, from approximately 120 representative foods, across the average diet of different age-sex groups within the New Zealand population.

A distinguishing characteristic of TDSs, including the NZTDS, is that foods are analysed on an 'as consumed' basis (e.g. banana, peeled; meat, cooked). This provides an assessment of any potential risk to the consumer at the point of consumption of the food.

#### Key features from 2003/04 to be included

The last NZTDS was undertaken in 2003/04 (published December 2005) and the 2009 NZTDS is expected to include the same key features of the 2003/04 survey in respect of the foods sampled and the age-sex population groups for which dietary exposures will be estimated.

Each food will be sampled twice during the 2009 calendar year in four sampling rounds – two for 'national foods' (those that are the same everywhere in New Zealand and are purchased in one location) and two for 'regional foods' (those that are locally produced and are sampled from Auckland, Napier, Christchurch and Dunedin).

#### Specific TDS tests

The specific tests that form the core of the NZTDS are:

- gas chromatographic multi-residue agricultural compounds screen (over 200 agricultural compounds)
- dithiocarbamates (DTCs) – the most commonly used fungicides in New Zealand
- four contaminant elements – arsenic, lead, cadmium and mercury
- two nutrient elements – iodine and selenium, which are naturally low in New Zealand.

The 2009 NZTDS is expected to focus on these core tests with the likely addition of extra analysis related to iodine (given our very low intakes) and sodium (the vehicle for iodine fortification but also at a high intake level which leads to other health problems).

#### International contribution

The NZTDS contributes to international commitments and obligations, such as the World Health Organization Global Environmental Monitoring Systems Food programme (WHO GEMS/Food), Codex Alimentarius and the WHO/FAO Joint Expert Committee on Food Additives (JECFA), and WHO/FAO Joint Meeting on Pesticide Residues (JMPR).

The NZTDS also provides valuable information that can contribute to the review of Maximum Permissible Concentrations (MPCs) in food with Food Standards Australia New Zealand and the setting of maximum residue limits (MRLs) for agricultural compounds and veterinary medicines by NZFSA.

### ACVM Regulations

A draft discussion paper on ACVM Regulations is currently completing the Cabinet Committee process. At this point, we expect to release the discussion paper for public comment in early May.

### Website Changes

The ACVM website is being updated and expanded in an effort to make it more useful to you and easier for you to access information relevant to your interests quickly and simply. As the year progresses we plan to develop new sections (like VetQuickSearch) specifically for registrants, manufacturers and so on. Your comments and suggestions are welcome. Use the 'contact this person' option on our homepage to email us. If you have not already done so, sign up to be notified when there is an update to the website.

## GENERAL INTEREST

### AVMAC Terms of Reference

The ACVM team and current members of AVMAC are in the process of reviewing the terms of reference for the Agricultural Compounds and Veterinary Medicines Advisory Council, or AVMAC as it is better known. We are seeking broader input from all interested and affected parties.

AVMAC's main purpose is to provide advice to the Director of the ACVM Group and to NZFSA generally on issues relating to the implementation and administration of the ACVM Act. It is not expected that this purpose will change. In the past AVMAC members have provided valuable input on a range of issues and continue to do so.

Over the next few years, as we implement the changes that come about as a result of the recent update of the ACVM Act and the review of processes and procedures, we expect that AVMAC will have a busy work programme.

It is important to note that AVMAC is not a decision making body. While it forms a valuable consultation function, we will continue to consult as widely as possible with any interested and affected parties on the framework that supports the ACVM legislation. AVMAC's main role is to work with the ACVM Group to refine proposals that go out for broader discussion.

The current terms of reference, including the membership of the Council, can be found at <http://www.nzfsa.govt.nz/acvm/forums/avmac/index.htm>.

If you have any comments or issues for consideration in the review, including suggestions on additions to the membership, please email these to Emma Miles-Buckler ([emma.miles-buckler@nzfsa.govt.nz](mailto:emma.miles-buckler@nzfsa.govt.nz)) as soon as possible.

### Whose Job Is It?

A recent amendment to the Hazardous Substances and New Organisms (HSNO) Act 1996 has clarified government department roles and areas of responsibility for organisms that could be introduced inadvertently as contaminants in agricultural compounds.

It is now clear that MAF, via Import Health Standards under the Biosecurity Act 1993, is responsible for setting controls that would prevent the introduction of such organisms and take action if it were to happen.

ERMA is responsible under the HSNO Act for setting controls on the intentional introduction of new organisms.

The process of authorisation of agricultural compounds that might harbour such organisms is still the responsibility of NZFSA under the ACVM Act.

In this authorisation process, the ACVM Group will continue to look to MAF for guidance in regard to setting information requirements and imposing conditions of registration that minimise agricultural security risks associated with these organisms.

### Out and About

**During the past few years, visits to and from registrants have been shown to be a good way to improve communication and understanding between the ACVM Group and our clients. With a number of new staff in the Group, visits can greatly improve their general understanding of the industry.**

**We would like to continue this practice, so if you are interested in having some of the ACVM team come to visit or to provide a presentation on ACVM-related issues to your organisation, or in coming to see us, contact Maree Zinzley ([maree.zinzley@nzfsa.govt.nz](mailto:maree.zinzley@nzfsa.govt.nz)).**

## GENERAL INTEREST

### Staff Update



**Beth Dye  
Advisor (Chemicals)**

*My qualifications are in chemistry from the University of Auckland. I have previously worked in research laboratories in DSIR, and in the ultratrace environmental organic analysis laboratory at ESR. Prior to coming to the ACVM Group, I worked for six years as an Advisor and then*

*as Applications Manager in the Hazardous Substances Group of ERMA New Zealand.*

*Outside work, I enjoy reading and embroidery, as well as developing our lifestyle property in the Wairarapa.*



**Daile Holz  
Advisor (Animals)**

*I originally come from sunny Nelson and have degrees in mathematics and veterinary science. After graduating from Massey, I spent three years in small animal practice in Palmerston North and Wellington. After clinical practice I moved on to*

*positions with Statistics New Zealand and then the Sustainable Farming Fund of the Ministry of Agriculture and Forestry.*

*I'm best known for my mad love of cats, coffee and a fair amount of shopping, but I also enjoy walking, a good book and time with friends.*



**Nasser Ahmed  
Advisor (ACVM  
Standards – Animals)**

*I am a veterinarian from India where I was a faculty member for 13 years in the College of Veterinary Science, Assam Agricultural University. Besides BVSc and AH (Animal Husbandry) degrees, I did my MVSc*

*and PhD in Animal Husbandry Extension.*

*One of my ACVM roles is to assess the technical dossiers submitted with the applications for veterinary medicine registration. Prior to the ACVM position, I was an Advisor in the Animal Response Team of MAF Biosecurity New Zealand.*

*I moved to New Zealand with my wife and son (who recently turned 14) in 2004. Cooking has become my favourite pastime now – I discovered the joys of cooking only after moving to this country.*



**Vivienne Turner  
Coordinator  
(Operations)**

*I joined the ACVM Group as a Coordinator in October 2007, and now work as a Coordinator between the Approvals and ACVM teams. Previously I was a Garment Technician for a clothing manufacturer based in Petone, and a*

*Production Planner for a small company that produced ceramics and jewellery.*

*My main interests include live music, dining out, sewing, reading and pretty much anything social (but not sport!). I am also currently studying some business accounting so that I can run my partner's business as well as his life!*

**Please be patient if there are some delays  
while our new staff members get up to speed.**

## GENERAL INTEREST

### Staff Update



**Kate Hartley  
Coordinator  
(Operations)**

*I arrived in New Zealand from the UK last November on a 12 month working-holiday visa. Since my arrival I have undertaken several temporary contracts to help fund my trip and allow me to visit as*

*many places as possible while I'm here. I'm really enjoying the whole experience of living and working in New Zealand and will definitely be sorry to leave.*

*Back in the UK I was a manager at a telecommunications company. I also have a degree in psychology, and I am keen to return to further study in this area when I return to the UK. In my spare time I like to keep fit – I enjoy swimming and aerobics. I also like reading and socialising with friends; however, I also love to travel as I enjoy visiting new places and getting the chance to meet different people.*



**Angela Waddell  
Advisor (Operations)**

*I recently completed a PGdip in psychology at Otago University. I did a brief stint at Teachers College before deciding that was not the path for me. I then moved to our esteemed capital in search of exciting times. I temped at early childcare centres (fun but I did not enjoy the daily snotty snail trails left on my pants) and a few offices.*

*I have been with the ACVM Group since November.*

*Some of my interests are playing hockey, reading, sewing, travel and cooking.*

#### Cost Recovery

**The paper on Cost Recovery went to Cabinet on 16 April. Their decision is expected by the end of April.**

## AGRI-CHEMICALS

### Codex Committee on Pesticide Residues

As this issue is being prepared, a New Zealand delegation made up of NZFSA and industry representatives is attending the 40<sup>th</sup> meeting of the Codex Committee on Pesticide Residues (CCPR). Representatives from NZFSA are:

- Debbie Morris (head of delegation)
- Dave Lunn (a member of the Joint Meeting on Pesticide Residues [JMPPR] and also appointed a rapporteur for the meeting)
- Warren Hughes.

Industry representatives are:

- Nikki Johnston (Market Access SolutionNZ Ltd)
- Bob Martin (Zespri International Ltd).

As well as coming to agreements on the maximum residue limits (MRLs) proposed by JMPPR, the meeting is considering a number of issues important to New Zealand.

The European Union provided a lunchtime update on harmonisation of MRLs in the EU, which has a large impact on exporters, and there are a number of discussions on minor use issues following the recent meeting on the topic in Rome.

Check the website for the full report which should be available shortly.

### Review of Veterinary Medicine Classification/Access

The ACVM Group has been working with an AVMAC subcommittee working party to review the operational policy on access to veterinary medicines.

#### Current classification

Currently, veterinary medicines are classified as either over-the-counter (OTC) or prescription animal remedies (PAR).

OTC veterinary medicines can be promoted and sold by any person to any person. They can be used by any person as long as those uses are consistent with the conditions of registration for those products. This does mean that they must be promoted and sold only for the intended purpose.

The promotion and sale of PAR veterinary medicines are restricted. The trader in PARs must be approved by the ACVM Group and the sale is subject to veterinary authorisation. PAR products have been subclassified (Classes I, II, III) according to the level of veterinary supervision required.

The PAR classification is not sustainable into the future in its

present form. Firstly, the term PAR is no longer appropriate. Not all veterinary authorisations are 'prescriptions' so the term misrepresents the actual situation. The term 'animal remedies' is no longer relevant. It was appropriate when the products were controlled under the Animal Remedies Act, but the current term recognised under the ACVM Act is 'veterinary medicine'.

#### 'Restricted' classification

Therefore, it is proposed to classify veterinary medicines with limitations on who can sell, authorise the sale of, and use them as 'restricted (R) veterinary medicines'. The term 'PAR' will be discontinued.

While the name change aligns the classification with the ACVM Act terminology, that is not the primary reason for the review. The main reason for change is that the subclassification of products (Class I, II and III) based on the level of veterinary oversight is not flexible enough to allow for essential or desirable alternative controls.

#### 'Unrestricted' classification

It is proposed to maintain the current

policy that access to veterinary medicines should not be restricted for ACVM Act reasons unless there is a risk management necessity. The working group has noted that in some cases products that are not restricted from an ACVM Act point of view may still not be sold OTC for marketing or product stewardship reasons. As at present, this is not a concern under the ACVM Act as risks remain adequately covered.

#### Issues for working party

At this stage there is general agreement on the intent of regulatory control, but parties are working through the issues to ensure that the new system is:

- practical as well as adequately flexible to allow alternative forms of oversight
- likely to provide the public with the necessary oversight to ensure risks relevant to the ACVM Act are avoided and products can be used safely and appropriately
- adequate to maintain appropriate product stewardship
- consistent with the Code of Professional Conduct of the Veterinary Council of New Zealand where veterinarians are expected to play a role
- implemented in a reasonable manner to avoid unnecessary disruption and costs, especially in relation to label changes.

As is usually the case, change is uncomfortable and new terminology can cause confusion. The working party is in the process of clarifying the proposals to make them easy to understand. When this is done the operational policy will be put out for wider discussion before finalising.

#### adverse event reporting is important

This information provides the critical feedback for all veterinary medicines, not only registered products. Reports may be just as critical for exempt products such as those containing oral selenium. Adverse events can take the form of unexpected side effects, residues and inefficacy as well as side effects and contraindications that are already included on the label. It is of value to report known issues when they occur at an unusual frequency or are of a serious nature. The ACVM Group encourages vets, registrants and others to provide adverse event reports (see the website at [http://www.nzfsa.govt.nz/acvm/publications/forms/aer\\_form.htm](http://www.nzfsa.govt.nz/acvm/publications/forms/aer_form.htm)).

## VETERINARY MEDICINES

### APVMA Visit – Alignment Update

The Director of the ACVM Group met recently with the newly appointed Chief Executive of the Australian Pesticides and Veterinary Medicines Authority (APVMA), Ms Eva Bennet-Jenkins.

The APVMA has confirmed the priority of the work on the ‘alignment project’ underway with NZFSA and ERMA NZ. This project is intended to align processes and systems to the maximum extent possible while recognising that agricultural compounds and veterinary medicines have a permanent exemption under the TTMRA (Trans Tasman Mutual Recognition Arrangement).

#### Proposal to reduce time/cost

New Zealand is progressing a proposal that is intended to reduce the time and cost to market for companion animal products that are registered in Australia. NZFSA (with the permission of the

Australian registrant company) will use the APVMA assessment of data as the basis for the New Zealand decision. As the cost of registration in New Zealand is based on the time taken and this should effectively reduce the time significantly, we are expecting that this will reduce the cost of registration. Over time, it will also increase the number of companion animal products available on the New Zealand market.

At this stage and degree of alignment, this option could apply only to:

- products specifically for use on aviary birds and pigeons
- products specifically for use on aquaria fish.

After trialling the option on these kinds of products, if it is decided that it is practical and meets risk management objectives in New Zealand, NZFSA will consider the

practicality of applying it to other kinds of products, such as those for dogs and cats. At present NZFSA does not consider that the option could be applied to any product likely to be used on food-producing animals, including horses.

**NZFSA would be happy to hear from any registrant companies who would be interested in taking part in a trial of this proposal.**

#### June visit planned

The APVMA will visit New Zealand in June and will cover the progress on this and other aspects of the alignment project. The agenda will also cover a review of the APVMA/NZFSA Memorandum of Understanding, a meeting of the ANZ VICH Management Group (see the website at <http://www.nzfsa.govt.nz/policy-law/vich/index.htm>) and a discussion on other opportunities to work together cooperatively.

### Antibiotic Sales Data

A data base has been developed to enable easy manipulation and retrieval of data as antibiotic sales information from more years becomes available. As we move toward a less ‘hands on’ assessment of data it becomes increasingly important that data is submitted to us in an accurate manner with easily understood units. Simple errors such as reporting the number of tablets or tubes sold in a column headed ‘kilograms’ can result in some interesting antibiotic sales figures!

The reporting forms will be changed in an attempt to prompt the right information. However, it is important that registrants take responsibility for clearly and accurately reporting volumes. As a default we prefer sales to be reported in kilograms or litres of total product where it is practical or by units such as numbers of tablets. Whatever the unit used, it helps us if it is clearly identified and consistent from year to year. We make the conversion to the quantity of active based on the normal label concentration ignoring overages and salts, which are not relevant to the activity.

## MANUFACTURING

### Qs and As: Contract Laboratories

#### *Who is responsible for compliance?*

The responsibility for compliance of the contract laboratory rests with you, the manufacturer. When using a contract laboratory, you need to be confident that the results being supplied are valid, are being performed as registered etc. The lab is, in fact, an extension of your manufacturing operations.

#### *Does IANZ accreditation meet GMP requirements?*

International Accreditation New Zealand (IANZ) accreditation is not equivalent to the requirements of good manufacturing practice (GMP) although it does provide some level of assurance regarding quality. IANZ accreditation also can be limited in its scope.

#### *Does IANZ accreditation reduce the need for auditing?*

As a manufacturer you may decide to reduce the level of auditing if a lab has IANZ accreditation, but this is a business decision. It is dependent on the tests the lab performs for you and the confidence you have in a particular lab and its understanding of your requirements regarding the testing they are performing under contract.

#### Manufacturer: Change to Applications

Applications for registration (or variations to registration) will soon define 'manufacturer' in a slightly different way. Instead of 'primary' manufacturer, applications will ask you to provide the 'responsible' manufacturer, i.e. the entity who ensures the product is in compliance with its NZFSA authorisation and releases it for sale.

'Other' manufacturer will replace 'secondary' manufacturer, and you will be asked to specify the function performed by this other manufacturer, e.g. filling.

## VERTEBRATE TOXIC AGENTS

### 1080 Review

Late last year NZFSA reviewed:

- the documentation available in regards to 1080 use for control and eradication of pest species
- the outcomes of the reassessment of 1080 under the HSNO Act.

The final outcome of this review is that there are currently insufficient grounds to consider 1080 products for reassessment under the ACVM Act. The information considered by ERMA NZ and their reassessment does not materially affect the current ACVM controls and risk management.

The ACVM Group will consider label directions and educational resources that may aid in reducing the impact to domestic animals resulting from accidental poisoning as part of the normal process when an application is received or registrations are renewed.

### VTA 'Slice of Life'

The 'slice of life' review of VTA manufacturing has been completed. Although the report has not been finalised by the Compliance and Investigation Group (CIG), the review found some important compliance issues:

- the requirement for everyone in the supply chain to have a controlled substances licence was not being met
- record keeping, which is a condition of registration, was not 'up to scratch'.

When the report is completed, the ACVM Group will work with ERMA NZ to advise manufacturers about their obligations under the Agricultural Compounds and Veterinary Medicines (ACVM) Act and the Hazardous Substances and New Organisms (HSNO) Act.