



# AgVetLink

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**Insert** Approvals and ACVM Group contacts

## From the Director

*The last two months have been exceptionally busy ones for the Group. Several articles in this issue relate to the new role we have undertaken – managing Approvals for NZFA. (There will be more about this in future issues of AgVetLink.)*

*Since the last issue, substantial progress has also been made in furthering working relationships with national and international organisations, and Group members have attended many international fora (pages 7-11).*

*The Antibiotic Resistance Expert Panel has completed its report, which was publicly released on 11 October. A brief summary appears on page 2, and the entire report is available on the ACVM website.*

*Preliminary results from this year's Food Residue Surveillance Programme are provided on page 3.*



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

### Antibiotic resistance review

The report of the Antibiotic Resistance Expert Panel was publicly released at the New Zealand Food Safety Authority's annual conference (11-12 October). The full report can be found on the ACVM website along with two peer reviews of the report and the recommendations of the Antibiotic Resistance Steering Group.

#### Expert Panel conclusions

The Expert Panel concluded that, while it is generally acknowledged that antibiotic resistance in humans is the result of the use and misuse of antibiotics in human medicine, the transfer of resistant organisms from animal and environmental bacteria to humans has also been identified as a potential pathway.

The Panel noted that the "development of resistance in bacteria is a natural response to exposure to antimicrobials and the prevalence of resistance is directly related to the degree of exposure" but they added that conclusions cannot be drawn on the specific relationship between the levels of resistance in animals and the levels of resistance in humans because available information is fragmented.

While research shows that some levels of resistance may be rising in New Zealand, in comparison with Australian, American and European data our rates are relatively low and the Panel considered the preservation of this favourable status should be a priority for NZFSA and industry.

The Panel suggests that resistance levels could be reduced by:

- administering antibiotics only when they are proven to be beneficial
- adopting vaccination and infection control systems (wherever possible) that do not utilise antibiotics
- controlling the pathways by which resistant bacteria can be transmitted to other bacteria (e.g. in food handling situations).

#### Key recommendations

The Panel made a number of recommendations. Key ones included:

#### *Development of a surveillance and monitoring programme to monitor levels of resistance in animals and provide a clear picture of the New Zealand situation*

The Panel found that, although some testing is done by industry, there is no wide-ranging surveillance and monitoring system that would provide information on the prevalence, patterns and trends of resistance levels in animals. The instigation of this programme was also a recommendation of the 1999 report but was not implemented due to the lack of international standards and conflicting priorities. The Panel reiterated that the implementation of this programme is of importance.

#### *The development of 'best practice' guidelines for veterinarians in the prudent use of antibiotics*

The Panel found that few resources are available to veterinarians to provide guidance in treatment options. Such resources are available in human

medicine and provide a 'hierarchy of drug choice' and best practice treatment options. The Panel considered that with this information available to them veterinarians would be in a position to make the best choices for treatment and 'prudent use' would, in itself, preserve the efficacy of antibiotic products and reduce the need for regulatory intervention.

#### *An ongoing advisory body*

The Panel recommended that a group be appointed to provide ongoing advice on antibiotic use in animals and plants, antibiotic resistance and the design and implementation of the surveillance programme.

Recommendations were also made on individual antibiotics but no recommendations were made to ban or restrict use of them.

Recommendations were made to reconsider the registration of two antibiotic groups of high relevance to human medicine at the next review cycle.

#### Steering Group response

The Steering Group was generally in agreement with the recommendations of the report but felt that some required further clarification or comment. They recommended that parties considering the report should be encouraged to take into account all the information provided and that no part(s) should be considered in isolation. (The complete response of the Steering Group can be found on the website.)

#### Next steps

Now that the report has been made public, NZFSA will undertake a period of public consultation of approximately four months. Following receipt and analysis of submissions, NZFSA will provide their own response to the Expert Panel report and initiate appropriate action.

### OECD REMINDER

New Zealand will host meetings of two of the OECD pesticides groups (the Risk Reduction Steering Group and the Registration Steering Group) in November. See the June AgVetLink for details.

## GENERAL INTEREST

### Food Residue Surveillance Programme – preliminary results

Preliminary results from this year's Food Residue Surveillance Programme (FRSP) once again indicate a high level of compliance with regulatory standards. The 2004/2005 FRSP tested for a range of 217 agricultural compound residues in seven fruits and vegetables, and two imported animal products.

The plant products chosen were lettuce, pears, strawberries, potatoes, oranges, peanuts and taro; 48 samples of each were tested. This amounts to a large number of possible residue findings, although a realistic estimate of possible food/residue combinations would be lower because only certain agricultural compounds are routinely used on particular crops. In total, 191 residues were detected in the seven crops tested, and three of those residues were above the Maximum Residue Level (MRL).

#### MRLs

The MRL is a number, usually expressed as 'mg/kg' or 'parts per million', that should not normally be exceeded if accepted agricultural practices are followed. A breach of an MRL does not indicate that a food contains unsafe levels of an agricultural compound, but it may indicate that a grower has not followed Good Agricultural Practice (GAP), which is the generally accepted way of ensuring effective and safe use of agricultural compounds. Residues found to be above an MRL are investigated further to find out what went wrong in the production of that food, and appropriate action is taken if necessary.

In addition to the plant products, imported pork and prawns were tested for a range of antibiotic residues. No residues were detected in any of the 50 pork samples. Five of the 48 prawn samples were found to contain barely detectable levels of metabolites of the nitrofurans class of antibiotics. Because those metabolites can also arise from

natural sources, the results are only indicative of a possible use of nitrofurans. The findings were at levels too low to have any health significance. None breached MRLs.

#### Agricultural compounds

Food makes a significant contribution to the New Zealand economy because we export the majority of food that we produce. Depending on the food-producing crop or animal, and the prevalence of pests in the environment, it is often necessary to use agricultural compounds to produce food economically and of a suitable quality for retail sale and export.

Controls are set on the use of these compounds to ensure that exposures are many times lower than those which might cause harm. Examples of controls that can be applied include:

- requiring directions for use to be displayed on labels
- restricting access to trained users (e.g. veterinarians)
- specifying withholding periods between use and harvest.

#### Compliance programmes

NZFSA and other regulatory authorities have compliance programmes to ensure that agricultural compounds are being used appropriately. The FRSP is an ongoing programme to assess the effectiveness of current controls on the use of agricultural compounds in New Zealand produce, and residues on imported foods. It complements NZFSA's other monitoring programmes, such as the Animal Products Residue Monitoring Programme, the Dairy Residue Monitoring Programme and the Total Diet Survey.

NZFSA is encouraged by the results of last year's FRSP as they indicate a high level of compliance with regulations. However, because the FRSP is primarily a tool for gathering information and

finding out where there may be problems, NZFSA will now focus its attention on areas where less information is available.

The FRSP sets out to identify specific problems, so it is more likely to identify problems than a purely random survey would. It is therefore likely that future surveys will sometimes show more non-compliant residues than last year's. Such problems can be dealt with only when they are identified.

### COMPLIANCE UPDATE

The ACVM Group is pleased to report that non-compliance investigations are at an all-time low. Only seven products are being investigated – mainly for advertising of unapproved claims.

However, we must note that there is an increase in the number of unregistered veterinary medicines that importers are trying to get into New Zealand. The ACVM Group is working closely with MAF Quarantine Services to educate these importers on ACVM requirements.

We encourage you to advise us of any possible non-compliances. Information you provide helps us with effective investigation and quick resolution.

## GENERAL INTEREST

### New application type

Under the ACVM Act and Regulations only products that are registered or exempt from the requirement for registration may be imported for general sale and use. A registered trade name product (TNP) may be imported or sold only if its conditions of registration are met. One of those conditions is that it must be sold with the label text as included in the current approval.

It is recognised, however, that in certain situations (see 3 below) it will not be possible for a registered TNP to be sold in New Zealand with the approved label text. In consequence, it has been necessary to implement a system that will allow the importation and sale of incorrectly labelled product if certain specific criteria can be met. Approval will be issued via this mechanism only if the following criteria are fulfilled.

1. The registrant of the registered TNP must make the request and be in a position to maintain control of product from the time of importation until the time of sale to the prescribing veterinarian or end user (i.e. product must not be made available to third party wholesalers or intended for retail shelves).
2. Product requested for importation must be identical to a product currently registered in New Zealand in all respects other than the label.
3. One of the following two circumstances resulting in correctly labelled product being unavailable to the New Zealand market must apply. Either:
  - a. it is the result of unforeseen circumstances (e.g. demand outstripping ability to supply) and where there will be significant issues for animals or users if the product is not supplied; or
  - b. it is the result of limited product sales where it is not viable to maintain New Zealand labelled stock on-hand and where otherwise the registered TNP would be withdrawn from the market. This is considered to be predictable product unavailability.
4. Where 3b applies, approval will be granted only for supply to specified individuals where imminent need for product can be satisfactorily established.

Approvals that are issued under this system will be referred to as 'Temporary Approvals' and will be for a specified quantity of product and time period.

The conditions as specified in the product's current approval continue to apply to product imported under the temporary approval with the exception of the requirement that it must be labelled as per the label content specified in the current approval.

All temporary approvals will be subject to conditions that will vary according to the proposed risk management systems. A common condition will be that product imported under this system will not be able to be specifically offered for sale and can be supplied only upon request as a substitute.

The application form (which includes further information regarding the information that must be supplied) is located on the Import Approvals section of the website. A fee of \$123.75 per application applies.

### 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 15 December 2005, your name will be removed from the mailing list.**

## GENERAL INTEREST

### Staff update



**Ana Zdradkovich**  
Advisor (Animals)

“I was born and raised by the Danube in Eastern Serbia. I gained my veterinary degree from the University of Belgrade in 1986. My working life back home was in research (production animal nutrition) and large animal practice.

New Zealand has been my home for the last ten years. I lived with family in Palmerston North and Wellington before getting my veterinary registration in 2003. While preparing for registration I did social work, helping people with disabilities. I joined the ACVM Group in September, after working in small animal practice in Levin. A warm welcome and support from all team members made my start enjoyable. I look forward to the future as a part of the ACVM Group.”



**Alice Palmer**  
Advisor (ACVM and Non-Food Products)

“I grew up in Heriot, Waipukerau, Taumarunui and Te Awamutu (just like a Kiwiburger.) Then I headed to Otago University to study Physics, French and Socialising. I have just spent the last two years globe trotting, and my favourite places were Barcelona and Beijing. I also taught English in France and South Korea.

I moved back to New Zealand to be closer to my family. I love sports (especially basketball, skiing and touch) and am mad about cheese. I’m really looking forward to working with everyone in the ACVM Group and would like to thank them for their warm and jovial welcome.”



**Simon Ellery**  
Advisor (ACVM and Non-Food Products)

“Hi, my name is Simon Ellery. I am 27 years old and was born and raised in Ashburton. After leaving school I served an apprenticeship as a butcher. Once completed I worked as a lamb boner at various meat plants in New Zealand and Australia. Supervising at the Fairton freezing works was the next step. After three and a half years at Fairton, I headed south. Dunedin was home for two years while working in the PPCS head office as a production scheduler.

Throughout my ten years working in the meat industry, food safety and quality has always been paramount. From this background I look forward to a challenging and diverse career with NZFSA. I moved to Wellington in June of this year and am enjoying it greatly. When not working, I enjoy playing the guitar.”

### Approvals under ACVM Group

Under NZFSA’s restructure, all applications for approvals made under the Animal Products Act, the ACVM Act, and the Food Act were brought into one Group to ensure consistency and cost-effectiveness across the organisation.

As part of this new strategy, and in addition to her current role, **Maree Zinzley** is acting as Programme Manager, Food Service, Sale and Import until this role is filled. This particular area is responsible for the assessment and approval of Food Safety Plans (FSPs), Multiple Release Permits (MRPs), and Non-Food approvals, such as for rubber-wear and ceramics.

This work is all new for Maree and will take some time to digest before new streamlined systems and processes can be put into place. There is a lot of work to be developed in regards to criteria and standards in the food area and we are hopeful that some of the difficulties and processes may be ironed out as a result of the Imported Food Review (IFR).

The Food Service, Sale and Import area is not fully staffed at present but we are pleased to welcome **Natalie Watson**, who joined the Approvals Group on 10 October. Natalie has a background in Food Technology and will be a welcome resource to the Approvals Team.

## GENERAL INTEREST

### Chemical approvals

The ACVM Group has been assessing applications and issuing approvals for the use of chemicals in animal product production and processing. Approvals relate to the safety and suitability of chemicals that may directly or indirectly come into contact with the animal produce. (Although the ACVM Group issues the approvals, they are issued under the Animal Products Act 1991, not under the ACVM Act.)

The scope of these approvals is likely to be broader in the near future as the Domestic Food Review identifies the need to manage risks associated with the use of processing chemicals in the production, manufacture and processing of other kinds of foods, such as horticultural produce and wine, and in the preparation of food.

#### Policy change

The underlying policy for chemical approvals has been changed because of the potential hazard to NZFSA staff as a result of handling and testing samples. This will result in changes in the approval process itself. The new chemical approval process will be designed around the principles that:

- no samples will be required
- approvals and the application of codes will be issued on the basis of

declarations from the applicant regarding the formulation of the product and its intended uses. This aspect of the process will be strengthened, e.g. the nature of the declaration etc.

- one communication will be provided about information deficiencies with a specified time to provide the information; if the information is not provided in the time frame set, the approval will be refused
- approvals will be issued with a reference to the product formulation and intended use(s), and a warning that the approval is valid only if the product complies with the formulation as declared in the application and only if the product is used for the purposes appropriate for the code that has been approved.

#### No significant risk

NZFSA considers that issuing approvals without examining samples does not pose a significant risk if, along with the changes in the process, NZFSA makes it clear to all parties, including the food processing industry using the chemicals, exactly what the approvals are based on and how they can be nullified by not complying with the product specifications.

NZFSA will also initiate communications with users to educate them about the significance of the codes and to warn them that approvals are issued on the basis of the formulations provided. When an approved chemical is used in a process, users should be aware that it is possible the product may not comply.

An adverse event reporting system will be introduced to handle reports from users about products. Suspicions or allegations that products do not comply with their approvals will be investigated and approvals may be withdrawn if necessary. NZFSA is confident that such a process with appropriate ties to verification and compliance will provide at least as robust a regulatory environment as the present system.

At the moment, all chemical approvals are being revalidated using the existing process, including the testing of some samples. Approval holders have been advised that they have an obligation to provide the necessary information and take care if samples need to be submitted for testing. Once the present revalidation process is completed, the new process will come into effect and parties will be advised. An update will be published in *AgVetLink* as well.

### Review of regulatory control of fertilisers

In 2004 the ACVM Group initiated public discussion on a standard for the fertiliser group of products. (The fertiliser group includes fertilisers, fertiliser additives and soil conditioners such as compost and mulches, but it does not include soil components such as clay, sand, shingle etc.) Only a few submissions were received and the standard was adjusted where necessary. However, the standard was not issued after the consultation because the New Zealand Standards Group of NZFSA intends to carry out a more comprehensive 'back to basics' review and consultation to establish if there is any need to adjust expectations regarding the risks that fertilisers may pose and the level of regulatory control needed to manage those potential risks.

Because of more pressing priorities, the review will be delayed. Consequently, the ACVM Group has issued its standard to clarify the current regulatory expectations and show how they relate to the existing exemption for fertilisers and fertiliser additives in the ACVM Regulations 2001. The standard can be found on the ACVM website under publications.

## GENERAL INTEREST

### Notification of changes not yet on label

The majority of products licensed under the Animal Remedies and Pesticides Acts have now been updated to comply with the requirements of the ACVM Act. In some cases, the update review process has resulted in changes to important user information and conditions of registration such as applicable withholding periods, use patterns and prescription animal remedy (PAR) status.

The ACVM Group has endeavoured to be as flexible as possible during the transition phase with respect to the timing of label changes in order to accommodate large 'old' label reserves and the ERMA process, and many registrants have been granted grace

periods before the currently approved label needs to be used.

#### Users not informed

It has come to our attention, however, that in some cases where important changes have been made to the registration of products, registrants with old labels in the marketplace have not informed users of these changes. This leads to user confusion between what is currently approved by the ACVM Group and what is perceived to be approved as a result of label content. Even where current labels are being used, intelligence from the marketplace suggests that unless changes are specifically brought to the attention of the user there remains a reasonable risk

that the changes will remain unnoticed for some time. Although the ACVM register is updated at regular intervals, it is useful only where users actively seek the information.

In consequence, where changes have been made to the conditions of registration or label statements that impact on product users and where old labels will remain in the marketplace, registrants should notify all product purchasers or users of the relevant changes either via product representatives or at the point of sale. It would be advantageous to all parties involved if this activity were undertaken for all products where changes have occurred even if new labels are in use.

### Australia/New Zealand harmonisation of approvals

The ACVM Group recently met with the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority (APVMA) to discuss plans to harmonise their market approval processes for agrichemicals and veterinary medicines. Both parties agree that mutual recognition of market approvals is not a likely option at this time, but believe they can work together more closely in several areas to facilitate common approaches. This will eventually lead to acceptance of product evaluations between Australia and New Zealand.

The reasons why agrichemicals and veterinary medicines were permanent exemptions from the Trans Tasman Mutual Recognition Arrangement remain valid. Nevertheless, the countries have reached an agreement on mutual recognition of Good Manufacturing Practice (GMP) approvals and find that there is little material difference between their chemistry standards.

The agencies will meet again on 28 October to progress a five-year plan based on three stages. The first stage will be to become familiar with each other's marketing approval processes and to align chemistry, pesticide manufacturing, safety and efficacy standards as well as research/trial standards and good laboratory/clinical/field practice (GLP/GCP/GFP) requirements. The second stage will be to work toward acceptance of data assessment reports, develop information sharing processes and possibly acceptance of evaluation reports for products not used on food-producing animals, e.g. companion animal products. The third stage will be to work toward acceptance of a wider range of evaluation reports.

Alignment of standards, information requirements, data assessments and evaluation reports will provide pre-market approval processes and requirements quite similar in both markets, while still allowing each country to make final market approvals and impose conditions on those approvals that are most appropriate for each country.

#### Streamlining importation of fertilisers

As part of the ACVM Group's effort to facilitate importation of exempt groups of products, we have worked with MAF Quarantine Services to clarify the definitions of fertilisers and fertiliser additives as well as the kinds of claims that can be made about exempt products. Border officials will use these to determine whether the product meets exemption criteria and can be released or whether the ACVM Group should be contacted for further advice. Please note:

- it is still the importer's responsibility to meet the conditions for exemption
- Biosecurity and ERMA New Zealand may have additional requirements that must be met.

## GENERAL INTEREST

### 42<sup>nd</sup> Congress of European Societies of Toxicology

**John Reeve**, Principal Adviser (Toxicology), attended this conference that was held in Krakow, Poland. The Congress served to keep NZFSA toxicology up-to-date in its many rapidly developing fields. The Congress covered areas such as:

- developments in carcinogenicity research (including the extrapolation to low doses in carcinogenesis)
- the use of cell nuclear responses to predict the start of potential toxicity
- the effect of genetics in toxicity.

A course on immunology and immunotoxicology was also run.

Useful information was also gained from visiting the industry stands, particularly those of reference book publishing companies. Newly published information on acrylamide in foods, the establishment of thresholds of toxicological concern (similar to ADIs when the toxicology data package is not up to current requirements) and information on whether toxicological threshold levels can be determined for allergenic foods was also brought back for digestion.

### 12<sup>th</sup> Royal Australian Chemical Institute Convention

This convention in Sydney, which was attended by **Warren Tully**, Senior Advisor (Chemicals), occurs every five years. This year it had up to 12 seminars running simultaneously, so there was a smorgasbord of choice. The seminars most relevant to ACVM included:

#### Chemical challenges in developing pharmaceutical products for the 21<sup>st</sup> century

Recent recalls of pharmaceuticals have led to widespread debate in the media about the effectiveness of regulatory agencies in approving safe medicines to be marketed. The rapid advances in analytical technologies have led to characterisation and quantification of active ingredients, impurities and metabolites in minute amounts. This raises such questions as:

- Has this led to much safer and efficacious medicines?
- How important is it to get all the impurities measured and to minute quantities?
- What are the risks associated with allowing the release of a product that is 9.9 % below the active claim and not releasing one at 10.1% below the active claim?

Efficacy and safety problems often arise because the trials are not able to reflect all the different situations in which the products will be used, e.g. they cannot take into account all the medical, genetic or exposure histories of potential patients.

#### Regulation of agricultural and veterinary chemicals: current challenges and priorities

- Is compliance too much focused on low risk products? This may be important commercially but is not risk-based.
- Applicants, not regulators, must prove products are safe.
- The importance of interface with other national regulators to provide international consistency was stressed.

#### BP/EP/USP – What's the difference?

The *British Pharmacopoeia* (BP) used to be the official standard for Australia's Therapeutic Goods Administration (TGA). All therapeutic goods (ingredients and formulated products) must meet the pharmacopoeia requirements. Currently, exemptions from BP are by application to TGA.

What the official standard for medicines in New Zealand and Australia will be is under review. How will the TGA decide what to adopt?

Information of note:

1. By law, BP incorporates the *European Pharmacopoeia* (EP); therefore BP is EP + some extras.
2. The correct term for USP is '*USP-NF*' (*United States Pharmacopoeia – National Formulary*).
3. BP generally has tighter and more comprehensive specifications than USP-NF.
4. USP-NF has wider coverage.
5. USP-NF is not as active at updating older monographs.
6. USP-NF is more active at updating general methods.
7. BP monographs on dosage forms whereas EP is on ingredients.

Another seminar of note was *Chemical Regulation in Australia: An Historical Perspective*. Historical examples such as arsenic in beer via cheap methods of production make us lucky we now have a better regulatory system than days past.

## GENERAL INTEREST

### NZFSA Academy

From time to time, NZFSA needs the advice of experts in areas where it either has no staff expertise or confirmation of the advice of its expert staff would be valuable. Occasionally NZFSA also needs to establish expert groups or seek more specific assistance in relation to particular issues.

To this end, NZFSA has established a Science Academy, bringing together a group of New Zealand experts to cover topics as diverse as public health, food technology, human nutrition, microbiology, veterinary science, biotechnology, toxicology and epidemiology.

The role of the Academy is to:

- provide a means of identifying experts who might be needed in specific scientific and other areas in a timely and effective manner
- provide advice to NZFSA on issues that may be raised with Academy members
- alert NZFSA to emerging issues that may be of interest to NZFSA in their fields of expertise
- provide statements and complement NZFSA communications and positions as appropriate in specific scientific or other areas.

The contribution is not intended to replace work that would constitute a contractual arrangement in other circumstances.

## VETERINARY MEDICINES

### Codex Working Group on veterinary drugs without current ADIs and MRLs

The Working Group of the Codex Committee on Veterinary Drugs in Foods (CCRVDF) has been charged with coming up with recommendations on how to deal with veterinary compounds for which there is no current Acceptable Daily Intake (ADI) and hence no current Codex Maximum Residue Level (MRL). The issue that the Working Group is trying to resolve arises from the rules associated with international MRL setting. The Joint Expert Committee on Food Additives (JECFA) provides the CCRVDF with advice on the ADIs and MRLs that can be adopted, but is required to recommend ADIs only when the toxicology data package is up to current standard requirements.

Many veterinary drugs (particularly older drugs that no longer have data protection) do not have modern data

packages, and because they are essentially 'orphan' drugs, do not have any sponsor willing to update their packages. JECFA is thus obliged to withdraw the ADI for these drugs because the data package does not meet modern standards; this then requires the CCRVDF to withdraw the Codex MRLs. Thus, even though there are no concerns regarding the risk arising from residues of these drugs in foods, there are few Codex MRLs set for them and so no residue is acceptable in international trade and a non-tariff barrier is effectively set up.

The countries most affected by this scenario are the third world countries that cannot afford the newer chemistry that is available to developed countries and the barrier to their exports does not allow them to develop economically as they should. Countries such as New

Zealand are also affected because perfectly useful, cheaper veterinary drugs cannot be used for fear of causing disruptions in our produce trade.

New Zealand (amongst other countries) has been a strong advocate for JECFA to develop another parameter (to sit alongside ADIs) that establishes the dietary intake that does not represent a risk to consumers, and that enables Codex to recommend acceptable levels of residues in foods in international trade. **John Reeve**, Principal Advisor (Toxicology), therefore joined the Working Group that met on 15 September in Brussels to finalise a paper for the consideration of the 16<sup>th</sup> CCRVDF (that will meet in May 2006). The recommendations are expected to become available for consultation before the end of 2005.

### Standard for unregistered veterinary medicines requiring veterinary overview

The ACVM Group has prepared a draft *Standard for Unregistered Veterinary Medicines Requiring Veterinary Overview* for public consultation. The standard covers the use of human medicines, specially compounded preparations, and unregistered products being used as veterinary medicines in New Zealand.

When the ACVM Group issued a draft of the standard for consultation last year, comments received indicated that more development was needed in regard to specially compounded veterinary medicines. A working party made up of participants from the veterinary pharmaceutical industry, compounding pharmacists and veterinary practitioners has suggested the specifications that are included in the new draft.

The only other area of significant change in the draft is in regard to veterinary consultation and providing emergency or follow-up care. The new wording was developed in consultation with the Veterinary Council of New Zealand and ties expectations on veterinary consultation to those of the Council's *Code of Professional Conduct*.

Submissions on the draft standard, which is available on the ACVM website, should be sent by **30 November 2005** to:

Chris Boland  
Senior Programme Manager  
(Approvals and ACVM Standards)  
NZFSA  
PO Box 2835  
WELLINGTON

## Labelling Forum

**Warren Hughes** attended the Australian Pesticides and Veterinary Medicines Authority (APVMA) labelling forum in Canberra on 22 September 2005. The forum, which was attended by representatives from the agrochemical industry, user groups, states, and public interest groups, discussed:

- current labelling requirements and practices with regards to instructions and information (the what), and format and placement (the how and where)
- issues to consider in revising labelling requirements and practices in this regard
- the scope of APVMA label approval
- issues to consider in devising an efficient process and delivering outcomes.

The common issues raised at the forum were:

- consistency vs prescription (format and wording)
- mandatory vs advisory instructions
- quantity, utility, simplicity of information
- interpretation of label terminology
- role of industry standards/codes
- better understanding of enforcement requirements for stakeholders
- withdrawal of label approval for superseded label
- trans-Tasman harmonisation of labels.

The APVMA intends to set up a working group to discuss the issues in more detail. A number of them are relevant to the New Zealand situation.

## Registration Liaison Committee Meeting

The 29th Registration Liaison Committee (RLC) meeting was held in Canberra in September, and was attended by **Brian Pidford** and **Maree Zinzley**. Major items of interest from the Australian Pesticides and Veterinary Medicines Authority (APVMA) included notice of:

- the development of a discussion paper concerning the scope of regulation of agrochemicals in Australia for initial endorsement by the Product Safety and Integrity Committee (PSIC) within the Department of Agriculture, Fisheries and Forestry (DAFF)
- a proposed review to be undertaken of the existing *Guidelines for Determining Minor Uses* (of agrochemicals)
- the development of efficacy and crop safety guidelines for minor uses of agrochemicals in minor crops
- a paper on a proposed strategy to extend permitted minor uses of agrochemicals to the approved label.
- a paper outlining a new approach to labelling of medicated stockfeeds with respect to scheduling, first aid instructions and safety directions required on the label of final medicated stockfeeds
- proposals for the regulation of animal semen extender products.

## VETERINARY MEDICINES

### Good Manufacturing Practice update

#### Inspection programme

The programme of inspection for GMP compliance has been developed for 2005-2006, and the manufacturers involved have been notified. They will be contacted directly by an inspector to schedule the visit.

A workshop of GMP inspectors is being held on 18 October 2005 for training and collaboration. An invited representative from industry has kindly agreed to provide industry input to the proceedings.

#### TPMA, a new industry organisation

The New Zealand Therapeutic Products Manufacturers Association Inc (TPMA) is an association formed by manufacturers of nutritional and pharmaceutical products "to provide leadership to New Zealand's therapeutic product manufacturers, to influence the direction of related legislation and to promote education and training in relation to Good Manufacturing Practice".

Nine organisations came together in 2003 to address the need for training for technical operators and for GMP. The membership is now twenty-five organisations, and more than 60 people attended the Association's AGM in August 2005.

Two industry qualifications have been registered on the New Zealand Qualifications Authority framework:

- National Certificate in Pharmaceutical and Allied Products Manufacturing, Levels 1 and 2
- National Certificate in Engineering and Technology (Pharmaceuticals and Allied Products), Levels 1 and 2.

Level 3 courses are being developed.

The Association has an operational focus to develop technical training and

retention of trained employees, to improve communications and mutual support within the industries, and to develop GMP expertise and improved GMP compliance.

#### New European Manufacturers Database – EudraGMP

Of interest to manufacturers whose products enter the EC under the mutual recognition agreement (MRA) for GMP, the European Medicines Agency (EMA) is implementing a new Internet-based database for manufacturers of veterinary medicines, called EudraGMP. The main drivers for this development are to:

- comply with European Directives
- bring all the existing databases of the individual member states into a new centralised database
- facilitate the exchange of information between member states regarding manufacturing authorisations,

GMP certificates of sites within member states, GMP certificates of sites in third countries inspected by EC inspectors, negative GMP compliance reports, and GMP inspection schedules

- manage the large number of European manufacturers efficiently (currently the EMA database holds 800 manufacturers. The new European legislative requirements will increase this to around 20,000, not including manufacturers of active ingredients, in the 25 member states).

New Zealand, as a MRA partner with the EC, has been advised of the development and asked whether we would like to participate with access to the database either on a read only basis, or on a write access basis. As further information is provided, affected manufacturers will be consulted on the extent of participation and on the information that might be required to be made available to the database.

#### Memorandum of understanding between NZFSA and VCNZ

NZFSA and the Veterinary Council of New Zealand have signed a memorandum of understanding to formalise their policy and operational relationship. The primary objectives are to:

- enhance the way in which they work together
- clarify roles and responsibilities
- provide clear lines of communication
- avoid duplication of effort in areas where veterinarians take the crucial risk management role in the use of prescription animal remedy veterinary medicines or unregistered veterinary medicines requiring veterinary overview.

The MoU is based on a mutual acceptance of the differences in the responsibilities, and therefore the operating principles, of the two organisations. Even though there are differences in focus, the two agencies have a common interest in and would benefit from sustaining the effectiveness and credibility of veterinarians as risk managers. The MoU includes three specific operational agreements covering:

- development and implementation of operational policies, standards and guidelines of common interest
- investigation and enforcement
- monitoring.

## VETERINARY MEDICINES

### Status of product branding

Certain prescription animal remedy (PAR) veterinary medicines are registered with a PAR condition primarily because veterinary diagnosis and decision that the product is suitable for use is necessary or because unwarranted or uncontrolled use may lead to risks to international trade. In such circumstances, it is considered unnecessary and detrimental to the ability of the veterinarian to select the most appropriate treatment if such products are being advertised to end users. Therefore, these products (e.g. antibiotics, anabolic steroids) will be approved with a specific condition that prohibits advertising to end users.

The ACVM Group has been approached with the following questions regarding the scope of advertising for PAR products such as antibiotics:

1. Is it advertising to use product brand names and trade names on merchandise such as pens, jotter pads, calendars and whiteboards that will be provided to non-veterinarians?
2. Is it advertising to include trade names, Material Safety Data Sheets, graphics of the label and product pack shots on company websites that are accessible to the public?

Following internal discussions it was agreed that such activity is not considered to be advertising as per the definition included in the labelling guide for the following reasons:

1. The use of brand or trade names in isolation from any information regarding the product is not considered to be an attempt to promote the product, but rather induce product recognition in users should they encounter it later.
2. It has been previously accepted that approved traders may advise customers what products they stock, which in effect will result in lists of product trade names being publicly available.

3. The ACVM website already includes basic product information and complete approved label text.

An opportunity is being provided for industry to comment on this interpretation. All comments will be analysed and the final policy advised in the next *AgVetLink*. The advertising section of the labelling guide will then be updated accordingly.

Comments should be sent no later than **15 November 2005** to:  
Jennie Moran, Approvals and ACVM Group  
PO Box 2835, Wellington  
jennie.moran@nzfsa.govt.nz

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### Retail display of PAR products

**Registrants and veterinarians are reminded that section 3.11 (prescription animal remedies) of the *ACVM New Zealand Labelling and Advertising Guide for Veterinary Medicines Requiring Registration* states that PAR products must not be displayed in public view, prompting the interest of purchasers. This means that it is unacceptable for any PAR product to be displayed or 'stored' in the retail showroom space amongst goods that are offered for sale without restriction. Such products must be kept in areas that are not intended for members of the public.**

## VERTEBRATE TOXIC AGENTS

### Approval of VTA traders

The ACVM Group has started to implement the programme for approval of VTA traders. A package of information and application form has been sent to all known single site retailing outlets and corporate multi-branch retailers of the products. The ACVM Group proposes to inspect and approve all single site operated retail outlets individually. For large multi-branch organisations retailing nationally, it is proposed to inspect and approve the quality system of the organisation that manages the control of sale of VTAs through its branches as a single multi-branch approval.

All VTA retailers that respond by 1 November 2005 will be provided with conditional ACVM approval as a VTA trader. The conditional approval will then be converted into a full approval when the site or quality system, as appropriate, has been inspected for compliance with the *ACVM Standard for Vertebrate Toxic Agents*.