



# AgVetLink

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## From the Director

*This issue of AgVetLink provides updates in many areas – from antibiotic management to a code of practice for colostrum to changes in the way agricultural compound imports for private use will be handled at the border.*

*New Zealand will host OECD pesticides meetings in November; the planned field trip and seminar are outlined on page 5.*

*The University of Otago's system for PAR management is featured in this issue – the ideas presented may be useful to those of you who are developing similar initiatives. See page 8.*

*ERMA has announced its intention to transfer 1080 products into HSNO now because of the delay in the 1080 reassessment. If you are a 1080 product registrant, see page 10 for more information.*



Debbie Morris  
Director  
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

### Update of Own Use Standard

The ACVM Group has updated the *ACVM Standard for Own Use of Agricultural Compounds* (59 ACVM 06/04) to include the changes in Schedule 1 of the Agricultural Compounds and Veterinary Medicines (ACVM) Regulations 2001.

#### Code of practice required

The exemption for own use of agricultural compounds in Schedule 1 of those Regulations has been amended to include a restriction on the use of certain compounds unless there is a specific code of practice approved under section 28 of the ACVM Act. These compounds are:

1. active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981)
2. antibiotic active ingredients
3. hormones
4. substances that are prohibited by

countries importing New Zealand primary produce\*

5. vertebrate toxic agents.

\* Substances prohibited by countries importing New Zealand primary produce change from time to time. A definitive list is available on the ACVM Group website.

For most compounds there is no need to have a specific code of practice approved and the *ACVM Standard for Own Use* is the minimum requirement. However, for the compounds listed above, a specific code of practice must be approved before they may be used under the own use exemption from registration in Schedule 1. The code of practice must include more operational detail that specifically relates to the compound to be used and addresses matters such as:

- how use will be restricted to use only on their animals or plants while on

their own land or body of water on their own property;

- how the compound is to be stored, prepared, administered or applied, and disposed of in a manner that does not expose themselves or other persons, stock or crops, or the environment in general to unnecessary hazards;
- what steps are to be taken to protect the welfare of any animals that may come into contact with the compound and mitigate any pain or distress caused by the exposure;
- if relevant, how third parties likely to be affected by any hazards to themselves or their property are to be advised of intended use;
- where necessary, how officials are to be advised of the use, and the time and place of administration or application;
- what records are to be kept to show that due consideration was made of the matters above, and due care was taken to comply with them; and
- how subordinate persons or employees are to be trained and provided with whatever is needed to carry out the instructions safely.

### ANNUAL FEE REMINDER

You should have received your invoice for the ACVM annual fees by now as they were posted out in the middle of May.

Please remember that all invoices are due for payment **before 1 July 2005**. If payment is not received before this date, the following action will be taken:

- You will receive a 10% penalty invoice under section 18 of the Ministry of Agriculture and Fisheries (Restructuring) Act 1995.
- Your product(s) will be prohibited from importation and/or manufacture under section 82 of the ACVM Act.
- Removal of the prohibition notice will occur only after payment on all outstanding debts and any penalty fees has been received.

If you have an issue with your invoice contact:

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#### Standard for Codes of Practice

The ACVM Group has published a *Standard for Codes of Practice* that can be used as guidance in preparing a code of practice for approval under section 28. The application to get approval does not have to take any particular form. It can be a simple covering letter to the ACVM Group.

To save time it is suggested that anyone contemplating lodging a code of practice for approval contact the ACVM Group for advice to make sure the code is no more complex or onerous than is necessary. For information on codes of practice contact:

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## GENERAL INTEREST

### MRL Update

The annual MRL process as of 2 June has gazetted its first amendment of the year. This round contained five MRLs to be set and three MRL exemptions. These MRLs and MRL exemptions will come into legal effect on 30 June 2005.

We are currently consulting on a second amendment to the NZ (MRL) Food Standards. This amendment, as mentioned in the April *AgVetLink*, is considerably larger than any put forward before and contains several changes to the standard including:

- a reformatting of the MRL table, including adding a CAS number and residue definition column, and altering terms to be consistent;
- a proposal to include limit of quantification MRLs for 40 plant compound active ingredients; and
- removal of three obsolete plant compounds and their MRLs from the standard.

As well as the above changes, this amendment proposes to set three MRLs and one MRL exemption. Because this is such a large amendment to the NZ (MRL) Food Standards we actively invite anyone to view this consultation and return comments or queries on it to NZFSA. The consultation document can be viewed at the following link: <http://www.nzfsa.govt.nz/policy-law/consultation/consultation-web.htm>

Upon the gazettal of this amendment round (expected July-August) we will consolidate the entire standard to bring it up to date with the changes made in the amendment.

We are planning a third amendment to the NZ (MRL) Food Standards which again seeks to remove several obsolete MRLs, set Limit of Quantification MRLs or other below the default MRLs for approximately 30 more reassessed plant compounds, and set several MRL exemptions. The content for this round is not as yet confirmed, however, so further changes may occur. We intend to begin public consultation for this amendment when consultation on amendment 2 is completed.

### Private Consignment Importation Exemption

The ACVM Group, in conjunction with MAF Quarantine Services, is working through procedures for allowing clearance of exempt (by Regulation) ACVM goods that are not accompanied by an ACVM class determination to a private importer, providing the importer complies with certain conditions, e.g. limited quantities, goods for own use on own animals or land etc.

**THIS EXEMPTION WILL NOT APPLY TO COMMERCIAL IMPORTATIONS.**

These changes will line-up with current New Zealand Biosecurity operations for private consignment clearances. We are working towards putting this private consignment exemption in place by the end of June 2005.

### NOTICE TO ALL REGISTRANTS

**The labelling and advertising guides for plant compounds, veterinary medicines and vertebrate toxic agents provide information on advertising. You are required to abide by these restrictions.**

## GENERAL INTEREST

### Amendment to the ACVM Act

The ACVM Group and NZFSA Policy have sent all of the policy papers on the amendment to the ACVM Act to Cabinet for consideration. There were no new matters included that were not part of the public consultation carried out last year.

Cabinet approved the policies and directed MAF/NZFSA to prepare the drafting instructions for the Parliamentary Counsel Office.

We have been advised that a first draft of the Bill will be available before the end of June. This would allow the ACVM Group to test the wording of the draft to ensure it would support the intention of the amendments and still have the Bill ready for introduction in the third quarter of this year.

The amendment is needed to align the ACVM Act with the broader food safety responsibilities adopted with the establishment of NZFSA. It will also provide some refinements to existing provisions to facilitate achieving the purpose of the Act.

### Staff Update



#### Chris Scott Advisor Operations

“I have spent the last 23 years of my life trying to grow up in the beautiful city of Wellington. For those of you who don’t know, I am actually rather ancient in the ACVM Group. I started employment here in 2001 when I worked during the University holidays as a part-time assistant/gopher/filer/recall liaison officer/manager of covert operations.

In between working here at ‘The Group’, I studied in the southern town of Timaru where I began a degree in

Outdoor Recreation majoring in white-water kayaking, rock-climbing, mountaineering and relaxing. Two years after starting this course I thought better and decided that I wanted to be rich, so I returned to Wellington where I began a Bachelor of Commerce in Marketing and Management at Victoria University. I am currently finishing this degree and hope to graduate in December.

Recently I was appointed an Advisor in the Operations team where I am responsible for managing all ACVM approval processes and supporting other key ACVM outputs and activities. I also provide professional and quality advice to all internal and external stakeholders. I am an approachable fellow and I thoroughly look forward to working with everyone at the ACVM Group.”

### Colostrum Code of Practice Update

The Dairy & Plants Group of NZFSA is in the final stages of approving the Fonterra Code of Practice for the Supply of Colostrum as an alternative to applying the milk (and therefore colostrum) withholding times specified for colostrum in NZFSA Standards D105:Milking Animal Health and D115:Raw Milk Acceptance under the Dairy Industry Act, which became the Animal Products (Dairy Processing) Specification on 1 June 2005.

Conditions that are intended to ensure not only that all product produced in accordance with the Code will meet applicable residue thresholds but also to enable ongoing validation of the risk management steps incorporated in the Code will be placed on the approval. NZFSA has reserved its right to withdraw approval of the Code at any time should it become evident that the Code is unable to deliver the level of risk management required.

There has been some concern expressed during the development of the Code that any reliance upon the extension of a product approved pre-natal treatment interval (PNTI) as a residue risk management strategy is inappropriate. In recognition of these concerns, the following condition of approval will be enforced:

“The PSP/RMP Operator(s) must provide to NZFSA, in an electronic form acceptable to NZFSA, results from all Inhibitory Substance and residue testing associated with the collection and processing of colostrum. This is to include results for all individual raw colostrum consignments, in-process tests and final product tests. This data will be used to establish whether extending the PNTI by 20 days will deliver the stated outcome of colostrums that conforms to residue requirements’.

## PLANT COMPOUNDS

### OECD Meetings Planned for November 2005

New Zealand will host meetings of two of the OECD pesticides groups (the Risk Reduction Steering Group and the Registration Steering Group) in November 2005.

#### International representation

The OECD has asked that a media event be arranged to coincide with these meetings to promote the future direction of the pesticides group to governments in the Asia-Pacific region, and it is hoped that Ministers or senior government officials will agree to be associated with this event. The meetings will have international representation and the Japanese have already signaled that they will consider having a 'high level official' at the event.

#### Field trip

As part of the Risk Reduction Steering Group activities, a field trip and seminar are being arranged to illustrate the use of application technology in pesticide risk reduction. The field trip is designed to show the international regulators

pesticide application in the pastoral, orchard and vineyard sectors in the Wairarapa.

#### Seminar

The seminar, which will be open to limited numbers of non-government people, is designed to:

- identify key issues (e.g. spray drifts) related to pesticide risk reduction through better application technologies;
- review technical requirements for application technologies, focusing on the minimum requirements for performance, maintenance and control of application technologies;
- review regulatory (e.g. equipment inspections) and voluntary (e.g. spray drift management guidelines) mechanisms that exist to address these issues;
- consider how countries could stimulate the development and use of pesticide application technologies that reduce risks (to humans and the environment), including the

economics and practicability of such technologies; and

- identify options available to OECD countries and key stakeholders in OECD and non-OECD countries regarding steps that can be taken to address these issues.

In order to facilitate lively discussions, the number of participants will be kept to no more than 50 including:

- members of the OECD Working Group on Pesticides, including members of the Pesticide Risk Reduction Steering Group and Registration Steering Group;
- invited experts from key stakeholder groups such as contract sprayers and equipment manufacturers; and
- practitioners from government, industry, farmers/growers and other stakeholder groups and non-OECD countries.

(The actual meetings of the Risk Reduction Steering Group and Registration Steering Group are not open to non-members.)

### Codex Committee on Pesticides Residues – April 2005

**Dave Lunn** and **Warren Hughes** attended the Codex Committee on Pesticide Residues (CCPR) held in The Hague, The Netherlands, 18-23 April 2005.

Just under 390 MRLs were recommended for adoption as Codex MRLs or advanced a step (for a last round of country comments). There were ongoing discussions on potential dietary intake risks from residues of some acutely toxic pesticides (mostly organophosphates) and probabilistic modelling.

The Committee has agreed to fast track MRLs recommended by JMPR, possibly by setting temporary CXLs. This is in response to ongoing concerns expressed by some countries and industry sectors over the slow progression of MRLs through the Codex system.

WHO advised the Committee of serious funding issues regarding the ability to host the 2005 toxicological panel for JMPR. If funding is not found and it continues to be an issue, this could have major impact on the ability of the committee to progress MRLs through Codex in the upcoming years.

**The Chemistry and Manufacturing Standard – Plant Compounds has been updated and placed on the website. Thank you to all who provided submissions and comments.**

## VETERINARY MEDICINES

### Antibiotic Management Update

The ACVM Group has published its annual report on the management of antibiotics to manage antibiotic resistance (see the ACVM Group website for *Regulatory Control of Antibiotics to Manage Antibiotic Resistance Annual Report 2004*).

#### New registration conditions

The report notes that all antibiotic product registrations have been updated with new conditions that:

- remove growth promotion as an approved use, unless the active ingredient is not used in human medicine and is not implicated in the development of cross-resistance;
- establish a stratification of limited use and veterinary involvement based on the level of concern about resistance developing for particular active ingredients; and
- impose reporting obligations for active ingredients of concern.

#### Sales statistics

Total sales of antibiotics have increased but the increase appears to coincide with, and can be explained by, the marked increases in livestock numbers. The 2003 sales statistics and the review of antimicrobial use in the intensive livestock sectors indicate that there is a

high level of commitment to the principle of prudent use of antibiotics.

#### Methodology

A revised methodology for collecting and analysing sales statistics was applied to the 2003 data in an attempt to reduce variations in interpretation and the subjectivity of some of the estimates. The new methodology was applied in retrospect to the 2002 data as well. While some of the statistics differed as a result of this re-examination, the revised totals were not materially different from those reported.

From now on reports will be prepared using this year's methodology, and reports should begin to show reliable trends as the same collection and analysis protocols are applied to subsequent survey data.

#### Antibiotic Resistance Expert Panel report

The Antibiotic Resistance Expert Panel has produced a first draft of its report, which was presented to the Steering Group on 3 June 2005. Panel Chair, Dr Peter O'Hara, gave a presentation on the report and answered questions from Steering Group members.

The report noted that New Zealand regulatory control was consistent with international standards and expectations

except in regard to monitoring and surveillance. There were specific monitoring and surveillance recommendations focusing on modifications to existing microbiological surveillance programmes for a start.

The Panel reviewed common antimicrobial use in the pork and poultry industries and found practices to be consistent with international and domestic expectations of prudent use of such products.

There were also preliminary recommendations in regard to the role of an ongoing technical resource to address issues as they arise and provide advice to human and veterinary medicine regulators (i.e. ACVM Group and MedSafe).

It was suggested that the specific technical issues identified in the technical brief to the Expert Panel would be better addressed by that technical resource than by the present Expert Panel, which focused on more general issues.

#### Final report

Dr O'Hara has asked Steering Group members to take time to consider the report fully and provide comments by 24 June. The final report will be presented to the Steering Group in July and then sent out for peer review.

### PAR Trader Approvals

The ACVM Group has completed the implementation process of approvals for traders of PAR veterinary medicines. Certificates were sent during the last week of May to all the principal practices listed on the Schedule of Approved Traders of PAR Veterinary Medicines. The Schedule can be found on the website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)). Any changes or errors to the approval should be notified to Mary Alexander ([Mary.Alexander@nzfsa.govt.nz](mailto:Mary.Alexander@nzfsa.govt.nz) or phone 04 463 2550).

The next stage in the PAR Trader Programme will be monitoring the quality systems. This will be based on random sampling of organisations across the country to assess compliance with the ACVM Standard. The monitoring programme will be used to determine if there is any need for regular monitoring (and the frequency of any such programme) or, alternatively, if random monitoring is sufficient.

### Combining Two Products Under One Registration

Under the Animal Remedies Act some companies had elected to take two separately licensed products and combine them under a new single licence, complete with a different trade name and number. This most commonly occurred in the case of animal vaccines where one product could be used as the diluent for another, or where the two products could be used concurrently in the vaccination programme.

#### Past ARB procedure

In the past, the Animal Remedies Board (ARB) approved the licences even though the relevant licensing information (trade name and number) that appeared on the individual product vial labels was that relevant to the individual product's licence, and not that of the combined licence. An example

would be taking Trade Name X ARB No. A01 and Trade Name Y ARB No. A02 and selling the individual vials (with that licensing information) in packaging with the registration information Trade Name XY ARB No A03.

This is no longer considered acceptable. It is common practice in New Zealand veterinary clinics for product vials to be removed from the outer packaging for variable periods up to the time of use. Following that removal, the only identifying information would be that included on the vial label, which must be relevant to the registration under which it is sold.

#### New requirement

In consequence, all products identified as being affected have been required to

comply with one of the following actions:

1. modify all vial labelling to include the relevant registration information; or
2. cancel the registration.

In the opinion of the ACVM Group, it is acceptable for two registered products to be sold in 'convenience packs' where the registered products are sold bound together. The expectation is that both products will be sold in their registered packs with all approved label text and in full compliance with the conditions of registration. Any external packaging used must also contain all relevant information that is required for outer packaging as per the relevant ACVM Labelling Guide (including, but not limited to, the registration statement and full approved trade names).

### VICH 3 Conference in Washington DC

More than 170 delegates from around the world attended the third VICH conference in May in Washington DC. (VICH is an international cooperation programme set up between Japan, EU and the USA to develop international guidelines for the registration of veterinary medicinal products.) There were three New Zealand attendees from the ACVM Group. **Debbie Morris** is a member of the VICH Steering Committee and gave a presentation to the Conference on the benefits of VICH from the regulator's viewpoint.

Keynote speaker Mr Pedro Lichtinger, President of Pfizer Animal Health and President-elect of IFAH, the International Federation of Animal Health, highlighted the utmost importance of international harmonisation through VICH for the research based Animal Health Industry developing new products in a sustainable global market. "VICH has been for this Industry a key strategic initiative since its creation nine years ago... We need a regulatory environment that encourages innovative Research and Development and our Industry therefore supports the process, the philosophy and the transparency of VICH."

The conference marked the conclusion of the first phase of the VICH programme and all regions confirmed their commitment as the pivotal key element for continued success of VICH. The VICH3 conference sessions provided an opportunity for participants to obtain detailed information on the processes and scientific rationale for achieving the harmonised VICH Guidelines in the fields of Quality, Safety, Ecotoxicity, Biologicals Quality Monitoring, Pharmacovigilance, Target Animal Safety and Antimicrobial Resistance, and to discuss them with the experts.

The 17<sup>th</sup> meeting of the Steering Committee is scheduled for 1-2 November 2005, in Kyoto, Japan.

### Antibiotic Annual Sales Returns

Reminder to all  
registrants of  
antibiotic  
products

Your annual sales  
returns should have  
been compiled and  
submitted to the  
ACVM Group by 1  
June. If you have  
not returned your  
statistics, please do  
so as soon as  
possible.

## VETERINARY MEDICINES

### SPECIAL FEATURE: PAR Management at the University of Otago

When asked to picture the use of veterinary medicines (VM) in the mind's eye, visions of cows, sheep, cats and dogs are most likely brought to mind. An image not often conjured is the use of prescription animal remedies (PARs) and human medicines within the numerous research, testing and teaching organisations throughout New Zealand.

Historically, these substances have been in common use on animals within these organisations by non-veterinarians, without appreciable veterinarian supervision. It is now expected, and legally required, that within institutional settings all PAR and human medicine use on animals will be under the supervision of a registered veterinarian. The introduction of the ACVM Act has enabled effective risk management tools such as codes of practice to be developed to ensure the continued and controlled access to medicines within institutional settings where veterinarian presence may be limited.

#### Frontrunner

The University of Otago has been one of the frontrunners in this area and since the approval of the *Code of Practice for the Use of Veterinary and Human Medicines in Research, Testing and Teaching Organisations* (sponsored by The Royal Society of New Zealand) it has developed a comprehensive system of VM management based on the requirements of the Code.

John Schofield, the Director of Animal Welfare and the sole registered veterinarian on campus, has been the driving force behind the project. He detailed the critical elements of the PAR system as the following.

“To ensure a reasonable level of security and control, orders for PARs and human medicines are processed centrally through the Animal Welfare Office (AWO). All orders must be linked to a study protocol that has Animal Ethics Committee approval. Researchers will soon be able to request veterinary and human medicines on-line. For each approved AEC protocol an Institutional Drug Administration Order, or IDAO, is prepared by the AWO. This document is a comprehensive summary that includes the drugs, dose rates, animals, location of storage and use, and the training and experience of the personnel who will administer these medicines. In effect, the document is ‘the mother of all prescriptions’ by virtue of its complexity. This prescription is signed by the veterinarian, confirming the use of specified medicines for a particular research study. A mechanism has been developed to deal with any changes to the script that may be required from time to time.

Because the University of Otago operates three research animal facilities, it has appointed a Drug Control Officer (DCO) at each facility to assist with the management of veterinary and human medicines. Each DCO is the local agent for the veterinarian and, working together, they provide ongoing support and guidance for researchers who have to come to terms with the legislative changes now in force. We worked closely with our local Ministry of Health MedSafe officials in the development of this programme, and their input has simplified auditing procedures.



John Schofield

A customised logbook, the controlled drugs register (CDR), has been printed and issued to research laboratories. Drug safes have been provided where necessary. These measures, along with visits by the DCO, have promoted compliance with the legislative requirements and helped users cope with a new level of bureaucracy. The goal is to have a uniform and standard system of drug control throughout the institution.”

#### Progressive implementation

The new system has been progressively implemented over the last 15 months following a development period of three years. PAR Roadshows were held to advise and consult with the research community prior to implementation of the Code. Effective communication with researchers has been established through the ‘in-person’ visits by the DCO. This has assisted a reasonably smooth transition to the new system. In addition, the control measures put in place have been so effective that University staff members attempting to circumvent the system and purchase drugs themselves have been unable to do so.

“The drug wholesaler involved was commended for prompt action and willingness to assist the university establish this drug control programme.”

#### Benefits

As well as significantly improving the control of medicines used in the management of experimental animals, there have been some additional benefits.

“The legislation clearly places the responsibility for the assessment of appropriate medicine use with the registered veterinarian, rather than with the AEC or the researcher. This is a significant change and provides the opportunity, almost on a daily basis, for

## VETERINARY MEDICINES

the veterinarian to suggest best practice techniques and new drug regimes to researchers who might otherwise resort to less satisfactory historical methods.”

“Many researchers have enthusiastically embraced the new drug control programme as it has exposed them to new anaesthetic options that have facilitated research manipulations and improved animal welfare.”

### Support

The implementation of this programme has been possible only with the full support of the University and the dedicated team working with John.

“The University of Otago identified the management of veterinary and human medicines as a potential risk that required appropriate funding and resources to ensure compliance with the ACVM Act while at the same time ensuring that scientists were not disadvantaged by bureaucracy and could continue with their research.”

Now that the system has been in operation for some time, John notes that “once researchers understood that the AWO had no intention of limiting their access to drugs, but rather intended to supply, according to the script, reasonable quantities, the scientists’ concerns have diminished.”

### Continuing development

John and his team are continuing to develop resources to facilitate an increased knowledge of VM use in laboratory animals amongst University staff and students. The AWO was awarded a grant to develop an on-line training programme using Blackboard™, which is a course management software programme that also integrates online communication software.

“The use of Macromedia Flash™, allows for highly interactive and engaging content on what may be regarded as a dull and difficult subject. A series of case studies focuses on practical applications of anaesthetics,

analgesics and antibiotics. In addition to best practice recommendations, these case studies also explore the misuse of these agents as observed during site visits in the past.”

### ACVM Group comment

ACVM Group staff members were given the opportunity to view the system on a recent visit to Dunedin. The opinion of those present was that the system in place not only achieves, but exceeds the minimal requirements for adequate VM

management as specified in the ACVM-approved Code of Practice.

The ACVM Group intends to include an assessment of New Zealand research, testing and teaching organisational systems as one of the 2005-2006 ‘slice of life’ reviews. If all organisations are found to have systems as comprehensive as that established for the University of Otago, the review is likely to conclude that any immediate ACVM Group intervention is unnecessary.

## Veterinary Biologics Training Programme

The Institute for International Cooperation in Animal Biologics (IICAB) provides a course annually in May in conjunction with Iowa State University, the USDA Center for Veterinary Biologics and the USDA National Veterinary Laboratories. The programme is run over 12 days in three blocks dealing with:

- basic immunology
- an overview of the US licensing system, regulations, product testing and inspection of manufacturers
- an introduction to the main test methods employed.

The course this year was well attended by both company and government representatives (including the ACVM Group’s **Neil Kennington**) from a wide range of countries with strong participation from Africa, Russia and Kazakhstan.

The structure and content is designed to provide value to participants from a wide range of backgrounds, particularly those dealing with regulatory affairs without expertise in the biologics industry. It provides a good understanding of the regulatory aspects for technical staff and gives a different perspective for many foreign participants who are involved in manufacturing and developing vaccines for government disease control programmes.

Iowa State University now has a large concentration of microbiologists and veterinarians involved in regulation, diagnosis and disease management, and emergency response. The US government is investing in new facilities intended to house most of the biologics-based laboratories at Iowa State other than those still based at Plumb Island (New York).

As a footnote, it seems that vaccines produced in plant cell cultures are now imminent. One advantage these vaccines offer is the elimination of risks associated with adventitious agents. The stability of antigens produced in plants is likely to be a major boost for vaccines used in tropical climates, particularly in developing regions.

## VETERINARY MEDICINES

### Meeting with Canadian Regulators on GMP

**Brian Pidford's** attendance at the 3<sup>rd</sup> VICH Conference on Harmonisation of Requirements for the Registration of Veterinary Medicines at Washington DC (see page 7) provided an opportunity to call on Canadian regulators in Ottawa to discuss matters of mutual interest relating to good manufacturing practice (GMP) of veterinary medicines.

The points of mutual interest for discussion, which were agreed before the meeting, fell into two categories – domestic programmes and international agreements. The domestic programme issues concerned:

- GMP standards
- training of GMP inspectors
- integration of product registration data with the GMP process
- equilibration of inspections carried out by different inspectors who are geographically separated
- application of GMP standards to manufacturers of varying size with operations of varying complexity.

The international agreements issues included:

- mutual recognition agreements (MRAs) with the EC
- the situation regarding the new EC member states
- MRA with the USA
- local implementation of amendments to EC Directives
  - a) continuous particle counting in Class A clean zones
  - b) GMP for manufacturers of active pharmaceutical ingredients
- possibility for closer technical collaboration between New Zealand and Canada on GMP.

Staff at Health Canada who regulate pharmaceutical products and at the Canadian Food Inspection Authority who regulate veterinary biologicals were very helpful and informative on their control programmes and their international partnership activities. They expressed an interest in considering the development of closer technical contacts on GMP for veterinary medicines with NZFSA.

#### GMP Agreement Signed with Australia

**A Memorandum of Understanding has been signed between the NZFSA's ACVM Group and the Australian Pesticides and Veterinary Medicines Authority (APVMA) for the acceptance of each party's good manufacturing practice assessments and certification of manufacturers of veterinary medicines. The signing formalises a process that has been proceeding through strong technical contacts between the ACVM Group and the APVMA for a number of years.**

## VERTEBRATE TOXIC AGENTS

### Transfer of 1080 into HSNO

When ERMA transferred vertebrate toxic agents into the Hazardous Substances and New Organisms (HSNO) Act 1996 on 1 November 2004, 1080 products were not included. ERMA had decided that transferring 1080 products at that time could cause confusion with the reassessment of 1080, which was expected to occur late 2004 or early 2005.

ERMA has announced it will now transfer 1080 products into HSNO because of the delay in the 1080 reassessment. This means relevant industry sectors will need to implement their changes sooner than they expected for 1080 products.

The impact of this change on the ACVM Group should be minimal because it has already advised registrants of requirements for 1080 products. However, the change may mean some adjustments to the ACVM Group implementation timeframe to allow registrants to align their labels with HSNO requirements.