



AgVetLink

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What's coming up

- During June the ERMA New Zealand roadshow workshops on the **1 July 2004 transfer of pesticides to the Hazardous Substances and New Organisms (HSNO) Act 1996** continue with ACVM Group representatives Maree Zinzley and Warren Hughes. Workshops in Gisborne (21 June) and Whangarei (23 June) have been added to the original list. Questions and answers from the workshops will be put on the ERMA website (www.ermanz.govt.nz/hs/transfer-pesticides.asp).
- There will be an ERMA New Zealand **Test Certifiers workshop** on 11 June.
- NZFSA will have a stand at the **Mystery Creek Fielddays** (16-19 June), and staff from the ACVM Group will be in attendance. We will visit as many as possible of the stall holders dealing in agricultural compounds and veterinary medicines to make sure that they are aware of their obligations under the ACVM Act.
- A report on the recent '**slice of life**' audits will be available on the website before the end of June.
- Some **changes to the NZFSA structure** will take place on 1 July. The Dairy and Plant Products directorship, which covers a huge range of products, will be split. Director Tim Knox will assume responsibility for standards under the Food Act and another Director will be appointed for dairy and plant products. Also on 1 July, the MAF Verification Agency will come under the NZFSA umbrella as NZFSA VA.

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- The ACVM Group has accepted an invitation to speak to the Board of the **Companion Animal Society (CAS)** of the New Zealand Veterinary Association on PAR standards, workshops, compounding and discretionary use issues. Information will also be provided for the CAS newsletter.
- There will be a **customer satisfaction survey** in the August issue of *Agvetlink*.
- An **imports workshop** at the NZFSA conference (29-30 September) in Wellington will include ACVM-related issues. See article page 5.

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.

Recent events

Vet workshops

The extensive series of workshops held to discuss PARs, residues, and other issues with veterinarians has finished. The ACVM Group feels the workshop effort was worthwhile and will continue efforts to improve communication e.g. *Agvetlinks* for veterinarians.

VTA workshop

Attendance at the recent workshop to explain new conditions of registration for vertebrate toxic agent (VTA) products was disappointing. Only three of 18 registrants attended. However, those who attended brought staff and some regional council representatives. Participants said they had a better understanding of why the conditions are needed by the end of the day. Registrants will now have the opportunity to give their assessment of appropriate conditions for their products from a list provided by the ACVM Group.

AVA conference

ACVM Group veterinarian Jennie Moran presented a well received paper ('The Importance of Animal Welfare in the Regulatory Process in New Zealand') to the animal welfare/ethics stream of the Australian Veterinary Association conference in Canberra in May. Also at the conference, a police profiler presented findings demonstrating the link between animal abuse and human abuse, and said that several high profile crimes in Australia could have been solved earlier if there had been records of the criminals' history of animal abuse.

Quadrilateral meeting

ACVM Group Director Debbie Morris attended the 13th Annual Food Safety Quadrilateral meeting held in Canada in May. Regulators from Canada, USA, Australia and New Zealand discussed areas of mutual interest and concern.

LEGISLATION

Proposals for Amendments to the ACVM Act

A discussion paper to present proposed amendments to deal with issues that have arisen since the ACVM Act was written, and to deal with operational issues identified during the administration of the ACVM Act was released 24 May 2004 for a six-week consultation period concluding on 2 July 2004.

The discussion paper, which is available on the NZFSA website, is divided into two parts:

- Part 1 relates to changes in, or clarification of, policy underlying the ACVM Act;
- Part 2 covers amendments of a more technical nature, such as the removal of redundant provisions and the updating of terminology.

Schedule 3 of the ACVM Regulations

It is proposed that products (such as topical veterinary medicine preparations and plant compound adjuvants) covered by Schedule 3 of the ACVM Regulations 2001 be moved to Schedule 2: exempt subject to conditions. Schedule 3 would then be eliminated because notification is costly; and the information, which is of limited value, is readily accessed from other sources. Systems are in place to deal with any possible concerns. Any comments on this proposal should be sent to Maree Zinzley (maree.zinzley@nzfsa.govt.nz).

New products under the ACVM Act

The definition of an agricultural compound under the ACVM Act includes groups of products that were not previously regulated under the Pesticides, Animal Remedies and Fertiliser Acts. Under the transitional provisions of the ACVM Act, such products had three years to be either registered or exempted from registration. The transitional provisions finish on 1 July 2004.

A small working group of ACVM and industry personnel was formed to discuss potential problems with bringing in products under the ACVM Act. A number of actions have resulted from the working group's discussions, including:

- looking at additional exemption regulations and additions to the GRAS lists via the ACVM Regulations;
- minimising registration requirements such as additions to annex II of the chemistry standard (which indicates no need to provide stability data for the compounds listed);
- model 'waiver' applications (with later changes to the standards); and
- short-term registrations.

At this time the most important thing is for potential registrants to get their applications into the ACVM Group prior to 1 July 2004.

INJECTION SITE REQUIREMENTS

As a result of operator safety concerns expressed by vet workshop participants, the ACVM Group has undertaken to look at injection site requirements under the Animal Products Act.

MANUFACTURING MATTERS

Points of interest to manufacturers of veterinary medicines

GMP Inspectors workshop

A GMP Inspectors workshop was held at the end of April in Auckland:

- to review the inspection programme for the year;
- to discuss any particular GMP issues that inspectors had encountered; and
- to consider the process for approval of traders of PAR veterinary medicines when that programme is introduced.

Inspectors noted that not all manufacturing sites visited had complete and current site master files even though this is a requirement under section 2.4.4 of the *ACVM Standard for Good Manufacturing Practice*. Guidelines for the preparation of a comprehensive site master file can be obtained from Brian Pidford (brian.pidford@nzfsa.govt.nz).

If you have a small manufacturing operation, it is appropriate that you keep the form 'Application for Authorisation to Manufacture Agricultural Compounds and Veterinary Medicines' up to date, and are able to provide it to the Inspector or the ACVM Group when requested **before** an inspection takes place. This form contains the basic minimum information that could be considered acceptable as a site master file for a small or uncomplicated manufacturing operation.

Packing and labelling, and the security of storage and reconciliation of these product specific printed items were also areas of mixed performance by manufacturers. Inspectors will continue to look carefully at these processes for deficiencies.

Inspectors were briefed on the importance of the biosecurity system in maintaining New Zealand's record as an ideal place for manufacture because of its freedom from critical pathogens. Manufacturers are reminded that a biosecurity clearance is mandatory for all materials of animal origin that have been imported for the manufacture of a veterinary medicine. Inspectors will be checking in future for the presence of materials of animal origin, especially those derived from ruminant animals, and the relevant biosecurity clearances.

APVMA

Australian Pesticides and Veterinary Medicines Authority

The APVMA has agreed to work with the ACVM Group on the mutual acceptance of regulatory assessments in the area of animal welfare for companion animal products. It is likely that this will be done as part of the Registration Management Committee work programme, post July 2004.

During a recent visit to Australia to attend the Registration Liaison Committee meeting (see page 5), ACVM Group staff took the opportunity to progress discussions on cooperation on investigations and compliance activity. There is no firm progress on the draft Memorandum of Understanding in this area yet.

The ACVM Group has collaborated for many years with the APVMA on informally recognising the competence of each other's manufacturers of veterinary medicines. This collaboration has included regular visits to maintain contact and to understand the Australian regulatory programmes. A Memorandum of Understanding is being developed with the APVMA to formalise the arrangements for accepting each other's manufacturing approvals.

APVMA visitor

Kathy Winterton, who administers the Manufacturers GMP Programme in Australia, visited New Zealand for two weeks in April to familiarise herself with the GMP approval process in New Zealand as part of the ongoing informal mutual recognition agreement between New Zealand and Australia. During her visit Kathy observed an ACVM Group GMP inspection and visited three other manufacturers who currently export to Australia. She also attended the GMP Inspectors workshop, and briefed the ACVM Group on the APVMA GMP Programme.

Transfer of substances under the HSNO Act

In transferring substances to the main framework of the Hazardous Substances and New Organisms (HSNO) Act 1996, there is a legal requirement to consult on the classification and controls that will apply following transfer. While proposed classifications will be checked, it is advised that registrants are aware of the controls being applied to their specific products and ensure that these are appropriate. The Hazardous Substances (Classification) Regulations 2001 assign a classification to substances with hazardous properties and can be used for reference.

REVIEWS

Long-acting dexamethasone esters

The long-acting dexamethasone esters have been reassessed under section 29 of the ACVM Act with specific emphasis on the following:

■ Residues

There is concern that the currently approved milk withholding period does not adequately manage the residue risk for some long-acting dexamethasone esters.

■ Target Animal Welfare

The risk to welfare of animals (determined by an assessment of whether the use of the compound could produce demonstrable evidence of unnecessary pain or distress) resulting from treatment has been considered. The welfare issues have been considered in three components:

1. the welfare of the calf resulting from the birth induced by long-acting corticosteroids;
2. acute anaphylactic reactions;
3. other associated negative consequences including acute

infections, retained foetal membranes, photosensitization, metabolic disease and immunosuppression.

As a result of this review the following actions were advised as being under consideration:

- a revised meat withholding period of 35 days and milk withholding of 12 days;
- removal of claims on labels relating to non-therapeutic or routine induction of calving in dairy cattle.

The proposal is to require the necessary label changes by February 2005.

Impact on animals

The impact of the use of these drugs on the cow and the resulting premature calf is considered to be unnecessary pain and distress. Where there is no resulting benefit to the welfare of treated animals, the likely negative impact on animal welfare is not considered warranted under the ACVM Act.

Some uses unaffected

The following existing therapeutic indications for induction of calving remain unaffected:

1. where dystocia is anticipated either in heifers too small to calve safely or cows with a known dystocia risk due to pelvic fractures or injuries;
2. induction in animals with 'dropsy' e.g. hydroallantois;
3. induction in 'downer cows' and

cows showing a degree of paralysis prior to calving.

Other potential uses of corticosteroids in other species as well as cattle will also be unaffected by this review. These include the following indications:

1. treatment of primary ketosis;
2. orthopaedic conditions including arthritis, tenosynovitis, bursitis;
3. shock, stress;
4. allergic conditions;
5. acute laminitis.

Alternative risk management

This review does not specifically prohibit the use of these drugs in routine inductions. As a result, even if the label claim is removed, there is still the ability for alternative forms of risk management other than that already provided for by PAR conditions and the label. The possibility remains for product registration conditions to allow for an ACVM-approved code of practice and standard operating procedures providing for more intensive management of the induction process. Such a proposal can still be considered not only for the management of animal welfare but also to allow for the degree of control required to reduce the milk withholding period.

Following concerns expressed as to the practicality of meeting the proposed deadlines, particularly for withholding periods, AVMAC has set up a subgroup (led by Fonterra) to resolve the issues.

AVMAC

Now that the ACVM Act has been operational for some time, a review of the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC) has been undertaken to examine this advisory body and see if it could be used more effectively. Questions being asked include:

- Is AVMAC the right body to take on some of the regulatory functions in the ACVM Act?
- Could it play a larger role in areas such as Technical Consultative Committees and the Antibiotic Steering Group?

Antibiotic Resistance Monitoring

The Antibiotic Resistance Advisory Group of the Ministry of Health is considering the requirements for monitoring of antibiotic resistance in food animals. The group concluded that monitoring is required to describe the current situation as well as to establish trends. There is a proposal to develop a preliminary study in a limited range of bacteria, which are considered to be a priority. The likelihood is that monitoring will initially focus on samples collected at slaughter rather than at the retail end of the supply chain.

REVIEWS

EU banned substances

An ACVM Group review of substances banned in the EU for food-producing animals is underway. (This group of products includes the nitrofurans, which have been the subject of recalls or advisory notices in Canada and in Australia recently.) The substances are not banned in New Zealand, but there is concern that their presence might endanger market access.

The recommendations for control of use conditions under the ACVM Act will be peer reviewed by a group of toxicologists from other regulatory bodies before formal consultation with affected registrants takes place. This process is likely to take about three months.

Animal feeds

NZFSA is looking at overlaps/gaps in the ACVM and Animal Products Acts in the area of animal feeds. Issues and options will be considered over the next few months. Australia is conducting a similar review.

Imports

The imports review team is close to finalising a document for public consultation. There will also be a workshop on imports at the NZFSA annual conference (29-30 September) in Wellington that will include ACVM-related issues. To accommodate participants, the workshop will be held on both days of the conference: 3.30 - 5.00 on the 29th, 10.45 - 12.30 on the 30th.

Registration Liaison Committee

The 26th Registration Liaison Committee (RLC) meeting was held in Canberra in March 2004. Brian Pidford and Maree Zinzley of the ACVM Group attended.

The agenda covered the following:

1. The representatives from the States and Territories seemed more prepared to require action by the APVMA on outstanding project commitments than has been noticed in the past. However, the States and the APVMA appear to be trapped by conflicting interpretations that constrain some of their activities and, on a number of occasions, APVMA stated that it was unable to move on an issue until further legal advice had been obtained. There were positive references by some States' representatives to the way New Zealand regulates in certain areas, in particular our:

- default withholding period;
- PAR classification system;
- registration system that does not rely on permits.

2. Long-term (three years) issues relating to Appendix J were discussed. The States have long wanted APVMA to declare dangerous chemicals as restricted products and establish policy on training requirements and competencies for their use so that States can play their part in control of use. APVMA claims not to have the legal ability to restrict products and therefore continually places them into Appendix J of their poisons schedule system. This in turn leaves each State (under its own legislation) to determine what controls and training for use are needed. APVMA states that a law change will be required to resolve this issue.

3. The APVMA is in the process of developing an 'account management system' for dealing with other agencies. No details or specified contacts were provided.

4. There was much discussion on permits. In particular States continue to have problems with the operational implementation of permits – they are being

provided too slowly and the process is inefficient. APVMA was questioned on the closure of the Permit Group, and the transfer of issuing of permits to the Registration Groups, with a consequent lack of consistency. States said the issuing of permits seems to be outstripping registrations.

5. The APVMA review of 1080, which had been stalled, is being reactivated under the leadership of Subbu Putcha. Some significant issues to be resolved are variability of use between States and variability of pests. States suggested that New Zealand experience with 1080 be accessed and the ACVM Group will provide appropriate contacts if requested.

6. The issue of the appropriate disposal of dips continues unresolved. The APVMA is now asking States for a priority list of dip chemicals for which controlled disposal methods are required. APVMA is considering recommencing work on its draft guideline. NSW provided the meeting with a desk top review of dip disposal advice taken from APVMA approved labels of ectoparasiticides and post harvest dipping products. The advice statements vary greatly for the same chemical. States recommended a focus on high risk products first rather than trying to implement a complete scheme to cover all chemical types.

7. Work on the new labelling guide has slipped by a year so far. APVMA is looking for more State support.

8. Another issue yet to be resolved concerns the development of policy on disposal of timber treated with copper-chrome-arsenate (CCA) preservative. CCA-treated timber may be employed in structures and then need to be disposed of many years after any actions on the regulation of the chemical occurs. APVMA has taken the first step by restricting the use of CCA treatment of timber used for decks and playground structures.

RESIDUES

Food Residues Surveillance Programme: Web consultation form

In the October 2003 *AgVetLink*, we introduced the Food Residue Surveillance Programme (FRSP). The FRSP will be a systematic programme of residue analysis designed to increase our knowledge of levels of agricultural chemical residues in various food commodities. The background to the FRSP project can be found on the NZFSA website, under 'Science & Technology/Research Projects'.

NZFSA invites your input into two key areas of the FRSP:

- the criteria for ranking which foods are to be prioritised for research, and
- the project's guiding principles.

Submissions can be made through a web form (available on the NZFSA website from 1 June). You can also request to be informed when the FRSP section of the site has been updated, and subscribe to NZFSA's free magazine *Food Focus*, which will have updates on the FRSP.

Chemical residues

A survey commissioned by NZFSA has revealed a fairly high degree of public concern about chemicals in food. In response to this, the NZFSA communications team is developing a chemical risk communication strategy, which will be based on communications principles such as always publishing material in context and in a way that is readily understood by non-scientific people. NZFSA will also prepare a collection of chemical residue-related resources e.g. the FAQ section on residues on the website.

The 26 April NZFSA press release of the results of chemical residue testing in a wide range of products showed little reason for concern. However, monitoring will be ongoing and any unexpected findings will be investigated.

Codex Committee on Pesticides Residues

Dave Lunn and Warren Hughes attended the Codex Committee on Pesticide Residues (CCPR) meeting held in New Delhi, India, 19 - 24 April 2004. Good progress was made with the routine work of setting Maximum Residue Limits (MRLs) – 310 MRLs were finalised and a further 150 were advanced in the Codex procedure.

Discussions about potential dietary intake risks from residues of some acutely toxic pesticides (mostly organophosphates) were ongoing. As progress in developing new risk assessment procedures (based on probabilistic modelling) is likely to be slow, these will be considered for deletion next year.

A meeting of the Friends of Joint Meeting on Pesticide Residues (JMPR) was held during the CCPR meeting. It discussed the financial difficulties faced by both the FAO and the WHO panels of this expert technical assessment group, noting that there was still some doubt as to whether the WHO toxicology panel would have the funds to meet in September. Although the pesticide industry (Crop-Life International) is prepared to contribute to a trust fund for JMPR, FAO and WHO are reluctant to accept this funding for public perception reasons. A letter outlining the financial difficulties and the associated implications to the work of Codex will be sent to Ministers and heads of the relevant Ministries in all Codex member countries.

MRL update

Approximately every three months NZFSA seeks the Minister's approval to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, which are issued under section 11C of the Food Act 1981. These regular updates reflect changing uses of agricultural compounds, and progress in NZFSA's review of existing uses of agricultural compounds.

Status of Maximum Residue Limits (MRLs):

- as indicated in the December 2003 *Agvetlink*, the fourth MRL round for 2003 introduced an MRL for doramectin in milk and an exemption of canola oil and 9,10-anthraquinone (when used as a bird repellent on grapes);
- on 5 April 2004 consultation finished on this year's first MRL round, proposing an exemption for thymol in honey, and an MRL for indoxcarb in lettuce;
- NZFSA is consulting on the second MRL round for 2004. This round proposes new MRLs for tolylfluanid in pomefruit, meloxicam in pig meat, kidney and liver, and further exemptions from MRLs.

**Last month
to update
your products**

VICH

Steering Committee meeting

The 14th Steering Committee (SC) meeting was held in Tokyo, Japan, in May. As has become normal practice, the SC meeting was preceded by a half day meeting of the regulatory parties and a meeting of the industry parties. The main result of the regulators' meeting was the initiative taken by Ian Alexander of the Veterinary Drugs Directorate in Canada to facilitate a meeting to attempt to resolve the issues around the pharmacovigilance guidelines (see page 8). For those interested in this issue, the VICH papers are on the website (<http://www.nzfsa.govt.nz/policy-law/vich/guidelines/index.htm>).

At the main meeting there was discussion about plans for the third VICH conference, which will be held in Washington 25 - 27 May 2005. A draft programme will be available soon.

There was also considerable discussion over the development of a strategy for the future of VICH. It has been agreed that the updating of guidelines is an important function now that there are over 30 guidelines implemented in the European Union, the United States, Japan, Canada, Australia and New Zealand. The SC is still looking at ways of linking effectively to ICH (the equivalent body for human drugs), and ensuring that there is no duplication of effort with other international standard setting bodies such as Codex.

One of the main points agreed is that the development of new guidelines remains a key function of VICH, but that much more effort must be put in at the early stages of development of the concept papers to do a realistic feasibility assessment. The industry groups have undertaken to do a 'gaps analysis' to show where efforts can best be directed in the future – no doubt Agcarm and ARPPA, as the New Zealand industry groups associated, will be looking at this as well.

The SC also reviewed a proposal for amending VICH GL 28 (*Studies to evaluate the safety of residues of veterinary drugs in human food: Carcinogenicity testing*) and agreed to release this revised Guideline for a shortened two month consultation period at step 4, limited to the additional new text to the Guideline. Another milestone was achieved by the sign-off of the last two Safety Guidelines at step 6: VICH Guideline 36 (*General approach to establish a microbiological ADI*), and VICH Guideline 37 (*Repeat-dose [chronic] toxicity*) for implementation by May 2005.

The Steering Committee congratulated the members and the chairman of the Expert Working Group (see article at right) for the successful drafting of 8 VICH Safety Guidelines and their commitment to this difficult task.

A meeting of the ANZ management group in late June will cover this and the other actions coming out of the last SC meeting and prepare for the next meeting in Berlin in October. In the interim there is a meeting of the strategy taskforce planned for mid July in Paris.

Expert Working Group

The Food Safety Expert Working Group was charged with agreeing on a harmonised toxicology data package that regulatory authorities would utilise for supporting applications for veterinary medicines used in food-producing animals. John Reeve, Programme Manager (Toxicology and Residues) of the ACVM Group, represented Australia and New Zealand.

The group met eleven times from April 1997 to completion of its mandate in March 2004. Full international harmonisation was achieved except for one aspect of the toxicology package – whether one or two long-term feeding studies should be required. Analysis of the reviews of all the substances that have been subject to regulatory scrutiny could not resolve this issue to the satisfaction of all countries represented, and the group was evenly split as to their requirements. New Zealand, USA and Europe accept one long-term study as part of the package (mainly on the grounds that very little extra information is obtained from a second study, and this group concluded that, because of animal welfare considerations, it was not a good use of animals to carry out a second study). Japan, Australia and Canada require two long-term studies unless a scientific argument can be provided to show only one is necessary (mainly on the grounds that extra information that could modify the conclusions from the studies could occasionally be obtained from a second study, even if only rarely).

The full members of the VICH (European Union, USA and Japan) will be required to adopt the harmonised package, and the observers (Australia, New Zealand and Canada) are also committed to its adoption. This will give certainty to proprietors wishing to register veterinary medicines for their major markets in terms of the production of the required toxicology dossier.

The group has achieved its success in a relatively short time and was able to resolve many issues because of the trust that built up amongst the delegates (both regulators and industry representatives). New Zealand, which was seen as politically neutral by the major participants (Japan, USA and Europe), was able to broker many solutions to impasses through its pragmatic, strictly scientific approach.

Compliance

Two major non compliance matters are with the NZFSA Compliance and Investigation Group (CIG) at present. One in the veterinary medicines area is going through to prosecution, and is likely to become public shortly.

Information for a plant compound investigation in regards to unregistered product being sprayed on produce is still being collected. However, we can confirm that there were no residue concerns.

On a day to day basis, we are still receiving advertising complaints in regards to competitive products. In

some cases a company is making reference to its competitor's products in a manner that claims one to be superior to the other. The ACVM Group has referred the complainants to the Commerce Commission.

There are companies in the equine industry who just don't seem to get the 'message' on arthritis and muscle products in regards to claims and registration. We have recently intercepted a muscle powder product that was advertised in a local newspaper as being manufactured ready for sale. We contacted the proprietor, and have been told that we

should be receiving an application in the very near future.

We have compiled an active compliance list of companies in regards to continual non compliance. These companies may be included in our ongoing audit programme.

The ACVM Group is expecting an increase in compliance activity as we implement the PAR trader process.

In addition, compliance activity may increase if companies have not updated their products to the ACVM Act by 1 July 2004.

Registrants:

If you do not get your products 'stamped received' into the system on or before 1 July 2004, your products will be illegal, and non compliance action will be taken. General applications received into the system take precedence over update applications, with requests for review and evaluation actioned first to ensure that the regulatory timeframes are met.

Class Determination Expiry Date

The ACVM Group has reviewed the current two year expiry on class determinations and has changed this date to three years to bring it into line with the three year expiry on registered trade name products.

We remind class determination requesters that it is your responsibility, **before** the expiry date on the outcome letter is due, to apply to have the determination reconsidered and rolled over for a further three years. When you apply for reconsideration the following must be supplied:

- letter declaring that the trade name product has not changed since the first determination was made;
- one copy of the label;
- full formulation information;
- fee of \$60.75.

VICH Pharmacovigilance

First steps in breaking the deadlock in achieving international agreement on the management of pharmacovigilance under VICH were taken at a special meeting of regulators held in Canada in March. Australia and New Zealand were represented by Dr Peter Dagg from the Australian Pesticides and Veterinary Medicines Authority (APVMA).

A number of proposals were developed and submitted to the VICH Steering Committee in May (see page 7) for wider discussion with regulatory and industry groups of the VICH participating members.

These related to:

- the formal international birth date of a product and the synchronising of adverse event (caused by the product) reporting;
- the reporting of adverse events to third countries and the timing of such reports;
- the standard terms to be used in adverse event reports and the format appropriate for electronic transfer of reports;
- a common dictionary; and
- information sharing between VICH regulatory authorities.

Standards

Standard for Fertiliser Group of Agricultural Compounds

The ACVM Group has developed a draft standard for the fertiliser group of agricultural compounds. This group includes:

- fertilisers and fertiliser additives derived from chemical, mineral, organic or biological sources; and
- soil conditioners derived from soil components or organic material.

The standard makes reference to products claimed to be fertilisers that are raw or composted organic wastes. Such products are considered to be wastes unless they have been processed to the point that they have a consistent formulation and potential contaminants are adequately controlled. While these waste products are exempt from registration under the ACVM Act, it is

expected that their use will continue to be regulated under the Resource Management Act 1991.

The standard includes definitions and descriptions of the kinds of products covered and specifications for their manufacture, importation, sale and use. The standard also recognises that, for this group of agricultural compounds, there is a significant cottage industry in fertiliser and soil conditioner products as well as an established commercial fertiliser industry.

The draft is identified as version 2. The first version was used in limited consultation with specific parties to reach a point of development that could be opened up to general public consultation. Therefore, this draft should be considered the first

opportunity for public comment. The ACVM Group intends to repeat the process for subsequent drafts until the standard is appropriate and practical.

Standard for Vertebrate Toxic Agents

Submissions on a previous draft of the above standard were presented in the April 2004 *Agvetlink*. This standard has now been revised.

Drafts of the two standards are available on the website (www.nzfsa.govt.nz/acvm). Comments should be sent by **16 July 2004** to:

Christopher Boland
Programme Manager (Technical Policy)
ACVM Group
PO Box 2835, WELLINGTON
Email:
christopher.boland@nzfsa.govt.nz

Generally Recognised as Safe (GRAS)

Procedure

Over the past year, the ACVM Group has re-vamped the GRAS procedure in order to make the process more efficient and more effective. The new procedure has halved the time it takes for an application 'put on our doorstep' to be considered GRAS (for approved substances).

In order to shorten the GRAS process further, all communication from this point, including the expert consultation and public consultation, will occur via electronic mail. The address for all correspondence will be: toxassessor@nzfsa.govt.nz. Further to this, a new cover sheet has been created to clarify exactly what is required for an application. The new cover sheet template for all GRAS applications can be found on our website (<http://www.nzfsa.govt.nz/acvm/subject/registration/gras.htm>).

Experts meeting

A face-to-face meeting of the GRAS experts to review the current system, discuss potential changes to the ACVM Act and see if there are ways to improve the process generally is being organised.

Possible changes to fees

MAF Quarantine Services (Border Control), who monitor compliance on behalf of the ACVM Group, have raised their fees (under the Biosecurity Act 1993) from \$57.38/hr to \$72.30/hr. The new fees are higher than allowed in the ACVM Fees Regulations, so it is likely that ACVM fees will be updated to reflect the changes in the near future.

Draft Standard for Use of Human Medicines, Compounded Products and Special Use Imported Products

There is a draft standard out for targeted consultation covering the use of human medicines, specially compounded medicines and 'special use' imported products by veterinarians (done under the 'discretionary use' exemption regulations under the ACVM Act). Aspects of the proposed standard were discussed with veterinarians in the recent workshops as a recent 'slice of life' audit has highlighted the need for greater clarity and for education in this area.

FEES

Annual fee invoices for the period 1 July 2004 - 30 June 2005 were sent out in the last week of May. **Please note that these invoices are due for payment by 1 July 2004.** In light of this, it is not appropriate that we extend credit terms (instalments) to certain registrants – to do so for some while we are penalising others is unfair.

Fee waivers of cancelled products

Once we have received notification from registrants that they no longer wish to register their product, and the applicable information has been supplied to enable us to cancel the product's registration, a fee waiver may be applicable. The waivers are as follows:

- 75% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 2 July to 30 September 2004;
- 50% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 October to 31 December 2004;
- 25% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 January to 31 March 2005;
- No waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 April to 30 June 2005.

Newly registered products

All registrants of veterinary medicine and plant compound products registered with the ACVM Group will be required to pay a percentage of the annual fee taken the date registered. The percentages are as follows:

- Full annual fee payable for all products registered with the period 2 July 2004 to 30 September 2004;
- 75% annual fee payable for all products registered with the period 1 October to 31 December 2004;
- 50% annual fee payable for all products registered with the period 1 January to 31 March 2005;
- 25% annual fee payable for all products registered with the period 1 April to 30 June 2005.

If you have not received your invoice or if you have queries in relation to the charges, contact:

Nathaniel Hinde
Acting Coordinator
(Business Services)
ACVM Group
PO Box 2835, WELLINGTON
Tel: 04 463 2553
Fax: 04 463 2566
Email:
nathaniel.hinde@nzfsa.govt.nz

Staff update



Rachel Green
Advisor
(Operations)

'After five years in Christchurch, where I completed a Bachelor of Arts in English, I decided to come back home to Wellington. Last year I completed my Honours degree at Victoria University and knew that I wanted to stay in Wellington to work. I was looking for a job where I could use my previous work experience as well as learning new skills, facing new challenges every day and, most importantly, working in a great team environment. I am extremely happy in my role with the ACVM Group because it continues to meet all my expectations. My transition in the Group has been made easily because of the friendly and supportive people, and I am excited about the future.'

BACKLOG

The backlog of data assessment reports, particularly in the plant compounds area where we are still training new staff, means that it may take 4-5 months for reports to get through the system. It is an option for applicants to withdraw applications and source their own data assessment. Refer to the ACVM website for up-to-date information on the DAS process.

OPERATIONS UPDATE

Of the 2870 products registered (includes both veterinary medicines and plant compounds), 1348 product Update C9 type applications have not been submitted to the ACVM Group.

The following report shows details and figures as at 13 May 2004.

ACVM Update Numbers

	Under Action	Approved	Completed	Total Registered	No TNPs	Outstanding
Veterinary Medicines	94	254	624	1,937		965
Plant Compounds	105	50	395	933		383
Totals	199	304	1,019	2,870		1,348