

What's coming up

■ Fieldays, Mystery Creek, 10 - 15 June 2003

NZFSA will have a stand at Fieldays, and staff from the ACVM Group will also 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. See the website (<http://www.fieldays.co.nz/>).

■ Pan Commonwealth Veterinary Conference (PCVC)

The third PCVC will be held in Wellington, 27 - 29 June 2003, in conjunction with the New Zealand Veterinary Association conference. The major focus of the conference will be on animal welfare. NZFSA Executive Director Andrew McKenzie will present a paper. Contact Virginia Williams (vwilliams@xtra.co.nz) for more information.

■ Agcarm AGM

Agriculture House, Wellington, 22 - 23 July 2003.

■ Produce Plus

Auckland, 28 - 31 July 2003.

■ ANZCART Conference 2003

The Australian and New Zealand Council for the Care of Animals in Research and Teaching conference will be held in Christchurch, 18 - 19 August 2003. The theme is 'Lifting the veil: finding common ground'. Details can be found on their website (<http://www.adelaide.edu.au/ANZCCART/>).

■ AVMAC meetings

Meetings are planned for 21 August and 20 November 2003.

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■ 19th Conference of Residue Chemists

This conference will be held in Brisbane, 16 - 18 September 2003. It will be attended by Warren Hughes and Jennie Yee from the ACVM Group. See page 10 for details.

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.

General enquiries: Gill Wilson

ACVM Group, New Zealand Food Safety Authority, PO Box 2835, Wellington, New Zealand

Phone: 04 463 2539, fax: 04 463 2566, email: gill.wilson@nzfsa.govt.nz, website: www.nzfsa.govt.nz/acvm

Disclaimer: This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.

Recent events

- The final report from the United Kingdom Competition Commission on Veterinary Medicines was released on 11 April 2003. The full report and the summary are available on their website (<http://www.competition-commission.org.uk/inquiries/archive.htm>).
- The draft review report from the Australian Pesticide and Veterinary Medicines Authority (APVMA) on Virginiamycin was released in March 2003. See their website (<http://www.apvma.gov.au/>) for details.
- A full summary of submissions received during consultation on the draft Policy for the Regulatory Control of Prescription Animal Remedies is available on the ACVM website (<http://www.nzfsa.govt.nz/acvm/archive/draft/policies/index.htm>).

Fibrosarcomas at injection sites of cats

The European Medicines Evaluation Agency (EMA) Committee for Veterinary Medicinal Products has issued an advisory notice on the development of fibrosarcomas in cats following subcutaneous injection.

This states it is not possible to make firm conclusions on the risk associated with any product or type of product that causes inflammation after subcutaneous injection in cats. However, it advises that there may be an increased risk of fibrosarcoma at that site and that, if more specific information becomes available, this has the potential to impact on regulatory information requirements and risk assessments.

A copy of this report may be viewed on the EMA website (www.emea.eu.int/pdfs/vet/press/pos/020503en.pdf).

Attention all PAR product registrants!

During the investigation of a possible residue violation, the ACVM Group has found that the *IVS*, published by Havas MediMedia (NZ) Ltd, is not providing the most up to date information regarding the use conditions for a product. This means that registrants may be 'advertising' incorrect information to prescribing veterinarians in possible breach of the ACVM Act. This is of particular concern because prescribing veterinarians need to be aware of many recent changes to registration conditions, especially of antibiotic products.

We ask that all registrants immediately check the information published in *IVS* in relation to their products, and correct any errors both with *IVS* and with prescribing veterinarians. If similar information is provided by registrants to other publications or if the information is shown on websites, then information should be checked and updated as needed.

The ACVM Group reminds all registrants and prescribing veterinarians that under the ACVM Act **a product may be used only according to the conditions of registration.** There is no provision for a veterinarian or anyone else to prescribe or use a product other than in the manner approved.

In many instances there is still an allowance for products to be used on species other than those shown on the label. In this case there will be a registration condition to the effect that the product may be used on other species for other conditions providing the ACVM Act concerns over residues and animal welfare are managed. For PAR products, the prescribing veterinarian is responsible for these risks and for advice to the owner of the animals concerned.

Where there is a registration condition restricting the use of a product to specific species (for example, a number of antibiotic products are limited to use in pigs and poultry), or there is a statement such as 'not for use in food animals', it is a breach of the ACVM Act for a veterinarian to prescribe products in conflict with their conditions. It is also a breach of appendix 1 of the *Code of Professional Conduct*, which is approved under section 28 of the ACVM Act.

Who is responsible for the ACVM Act?

The ACVM Act and all other NZFSA administered legislation, including the Food Act, the Meat Act, the Animal Products Act, the Dairy Industry Act and the Winemakers Act, are now the responsibility of the Minister for Food Safety, Hon Annette King.

In some parts of the ACVM Act, such as section 21 (Decision on Application) and section 28 (Codes of Practice), there is reference to the powers of the Director-General (of MAF) to make decisions or approve. In each of these instances the powers and functions of the Director-General have been delegated to the ACVM Group Director and, in some cases, to members of the ACVM Group.

What is the role of AVMAC?

The Agricultural Compounds and Veterinary Medicines Advisory Council was set up to give balanced and comprehensive advice to the Director of the ACVM Group. It is **not** a decision-making body but it does form a very important part of the consultation process, given the range of organisations that are represented and the perspectives that they bring to the table.

AVMAC meetings are held every quarter. (The most recent meeting was 22 May 2003, and meetings are to be held 21 August 2003 and 20 November 2003.) ACVM standards, guidelines and operational policies (including changes) are all endorsed at AVMAC meetings as part of the development process. ACVM Group staff are not members of AVMAC but they often attend meetings in order to hear the full discussion by AVMAC of relevant papers and issues because this assists in refining operational policies prior to fuller consultation where this is taking place.

Initially the ACVM Group concentrated on aligning AVMAC membership to the primary purposes of the ACVM Act, namely managing risks to trade in primary produce, animal welfare, and agricultural security. More recently we have added a representative of a consumer organisation to bring a new perspective to the discussions at AVMAC meetings.

The current membership of AVMAC is:

Meriel Watts	Consumer Representative
Tony Ivicevich	Vegetable and Potato Growers
Michael Brooks	Poultry Industry Association
Lindsay Burton	Dairy Insight
John Millar	Meat Industry Association
Donald Hannah	ERMA New Zealand
Richard Kempthorne	Fruitgrowers Federation
Randy Muderwich	Federated Farmers
Murray Gibb	New Zealand Veterinary Association
Jack Richardson	Agcarm Inc
Gabrielle Deuss	Animal Remedies and Plant Protection Association
David Bayvel	National Animal Welfare Advisory Council
Caryll Shailer	MAF Biosecurity Authority
Carole Inkster	NZFSA Policy

We remain aware that there will be further changes in focus over time. For this reason we have built in a review of the AVMAC purpose, functions and membership to ensure that it continues to be as effective as possible. The ACVM Group is in the process of conducting this review now that the ACVM Act is almost fully operational. Any comments or suggestions are welcome and should be forwarded to Gill Wilson (gill.wilson@nzfsa.govt.nz).

Have your say on proposed HSNO and ACVM Act changes

In February 2003 the Government announced proposals to amend the HSNO Act and related Acts – this includes the ACVM Act. The New Organisms and Other Matters Bill was introduced into Parliament on 29 April 2003 to amend laws governing new organisms, particularly organisms arising from the use of genetic modification. Parliament referred the Bill to a Select Committee for in-depth consideration before it reports back to Parliament on 5 September 2003.

The Education and Science Committee has called for submissions on the New Organisms and Other Matters Bill. **The closing date for submissions is Friday, 13 June 2003.**

The Office of the Clerk of the House of Representatives has prepared information on making a submission to a Select Committee. To help you prepare your submission, the Ministry for the Environment has drawn up a *Guide to the New Organisms and Other Matters Bill*, which outlines the issues and the relevant clauses in the Bill.

For further information about the Bill and how it was developed, visit the Ministry for the Environment's website (www.mfe.govt.nz).

IMPORTANT INFORMATION ON FEES – SEE PAGE 6.

Compliance under the ACVM Act

This article is intended to be a brief review of our current compliance programmes and notice of developments as the programmes evolve. In all cases the programmes will continue to be developed around the risks to be managed and tailored to the complexity of the operations being performed.

Inspections or verification activities are carried out to provide assurance that participants, processes and facilities are complying with standards that have been set or legislative requirements that have been implemented to manage certain risks.

The frequency of visits varies and is related to the level of risk to be managed. For example, continuous checking of passengers and their luggage by questionnaires and electronic screening is in place at the borders. This

is to manage risks from importation of unregistered agricultural compounds and veterinary medicines, and risks to the country's biosecurity.

On the other hand, manufacturers of veterinary medicines undergo regular inspections of their sites and operations every two years.

Manufacturers of registered veterinary medicines

Inspections of manufacturers of registered veterinary medicines are carried out to confirm that the registered veterinary medicines are being manufactured in accordance with the information and processes that were notified at the time of registration and in appropriate facilities. The basis of the inspection is the assessment of a manufacturer's level of compliance with the *ACVM Standard for Good Manufacturing Practice* and, where

appropriate, the *ACVM Guideline for Good Manufacturing Practice* for manufacture of specific categories of products.

Products under this category vary in complexity from high risk veterinary pharmaceuticals to low risk dietary products. The scope and intensity of the inspections are matched to the risk levels of the products being manufactured. These inspections are carried out by trained inspectors in a third party agency, AgriQuality New Zealand, under contract to the ACVM Group. The costs of the inspection are recovered from the manufacturers by the ACVM Group.

Manufacturers of other products

Vertebrate pest control products were controlled under the Pesticides Act, and manufacturers were not subject to inspection for Good Manufacturing Practice (GMP) compliance. These products have now been brought under the ACVM and HSNO Acts. Because the products are used for the management of animals, the manufacturers have been included in the regular GMP inspection programme for manufacturers of veterinary medicines.

Manufacturers of veterinary medicines exempt from registration

Agricultural compounds and veterinary medicines that are exempt from registration with conditions are set out in Regulations dated 28 May 2001, under the ACVM Act 1997. Manufacturers of products that are exempt from registration with conditions are expected to comply with the *ACVM Standard for Good Manufacturing Practice*, but they are not subject to regular inspection.

However, all aspects of the ACVM Act are covered by responsive compliance. This means that any allegation or suspicion of non-compliance with the conditions of exemption from registration will be investigated and may

Prohibition notices

The ACVM Group advises that we have recently issued prohibition notices in regards to the suspected illegal importation of product.

Under section 65 of the ACVM Act 1997, inspectors or authorised persons may give written prohibition notices for non-compliance with the requirements of the Act and Regulations. These notices advise the recipient of the actions required to rectify concerns to the satisfaction of the inspector or authorised person. Such notices may include a requirement for the recipient to recall all product from the market, and to cease all manufacturing and sale. The powers granted to inspectors under the Act include being able to obtain information about who distributors are, who sales have been made to, the batch numbers of products etc.

Prohibition notices are usually served by NZFSA Compliance and Investigation Group staff, but ACVM Group staff are also warranted to exercise the powers set out in sections 64 to 67 of the ACVM Act 1997. As previously advised in *AgVetLink*, ACVM technical assessors and advisors have been appointed as inspectors under the ACVM Act.

result in implementation of regular inspection of the manufacturer.

It should be noted that the ACVM Group considers that there may be risks associated with the manufacture of animal feeds that contain dietary supplements or antibiotics. Consideration is being given to whether additional regulatory controls need to be applied to this category of manufacturer and, if so, at what frequency.

Traders of veterinary medicines

Proposed changes to the conditions of registration of prescription animal remedies (PARs) will require increased controls on the distribution chain for these products. Traders of PARs will be required to be registered and to operate in compliance with a standard for traders of PARs. Existing veterinary wholesalers and veterinary practices of registered veterinarians will be placed on the register automatically, and new traders of PARs will be inspected for compliance with the standard before being registered. The programme will be reviewed during the next 2 to 3 years to determine whether regular cost recovered compliance inspections need to be implemented to secure the distribution and sale of PARs.

Manufacturers of plant compound products

The ACVM Group has not implemented regular inspection of manufacturers of plant compound products to date. All of the complex chemical actives are manufactured overseas and the specifications of the actives used in products formulated in New Zealand are assessed during the registration process for purity and freedom from residues.

The animal welfare risk area in the Act does not usually apply to these products and, over many years, any adverse events recorded have related to misuse rather than inappropriate manufacture. Therefore, the imposition of regular

inspections as an overarching requirement is not considered to be justifiable at this time.

A general condition of registration is placed on the registration of all plant compound products. The product must be manufactured in accordance with the *ACVM Standard for Good Manufacturing Practice*. Some manufacturers of plant compound products have requested to be inspected and approved as manufacturers, and this activity has been provided as a discretionary service.

Manufacturers of biological products could be considered to be in a separate

category from manufacturers that only formulate, fill and pack. Consideration is being given to whether regular monitoring should be implemented in the future for manufacturers of those biological plant compound products. It is likely that the decision on this will be subject to the outcome of future 'slice of life' audits in this area.

Traders of plant compound products

As for the manufacturers of plant compound products, it does not appear to be appropriate to introduce registration of traders of plant compound products as a general requirement at this time.

Suspected illegal importation

The ACVM Group, in conjunction with the NZFSA Compliance and Investigation Group, is investigating the suspected illegal importation into New Zealand of unregistered veterinary medicines. Information was received in the form of a complaint to the ACVM Group.

If the investigation shows illegal importation has occurred, this is a serious breach of the ACVM Act and it could also result in breaches under other legislation. The importation of unapproved veterinary medicines products has the ability to undermine the ACVM risk management process.

Where the ACVM Group has reasonable grounds to believe that any person manufacturing, selling, or using any agricultural compound is acting in contravention of any provision of the Act, or conditions on the registration of a trade name product, the Group will use the powers of the ACVM Act to issue a prohibition notice (see box at left) in the first instance. Subsequent investigation will provide the evidence to make the decision on progressing to a prosecution under the ACVM Act or any related legislation. A prohibition notice requires the recipient to cease all manufacturing, sale, or use of that product or the agricultural compound until such time as the contravention of the Act is rectified.

Offences under the ACVM Act can attract penalties of up to \$30,000 for a person or \$150,000 for a corporation.

Non-payment of annual fees

The ACVM Group reminds registrants that if annual fees are not paid by the due date, under section 18 of the Ministry of Agriculture and Fisheries (Restructuring) Act 1995, a 10% penalty interest will be charged. If payment is still ignored, further processes will occur:

1. the recovery of the debt will be placed in the hands of Bay Corp debt collectors, and
2. under the ACVM Act, section 82 Prohibition of importation or manufacture by registrant for non-payment of fees - (1) Where the registrant of a trade name product is liable, in accordance with regulations made under section 81, to pay any fee or charge in respect of that trade name product and that fee or charge remains unpaid after the expiration of time provided by section 18 of the Ministry of Agriculture and Fisheries (Restructuring) Act 1995, the registrant is, in addition to any other penalty payment imposed by this or any other Act, prohibited from importing or manufacturing the trade name product while the debt and any penalty payment remains unpaid.
3. A further 10% is added for every subsequent 6 month period that the debt remains unpaid.

We can advise that the ACVM Group has exercised the serving of prohibition notices on two registrants for non-payment of fees for last year and has placed 'Red Alert' notification at the border through MAF Quarantine for any future imports of their registered products.

ANNUAL FEES REMINDER

The ACVM Group sent out letters to all registrants on 5 May 2003. The letter included a list of registered products specific to each registrant for confirmation of correctness. If you have not received your letter, please advise us immediately.

We wish to remind you that any changes or cancellations must be requested to the ACVM Group by **Friday, 13 June 2003**. Supporting information in the form of last batch number(s) and amount of stock in trade will be required to support cancellation and to deal with product(s) that could remain in the market.

Invoices will be sent out in early July, and payment for all annual fees will be required by no later than **20 July 2003**. Unpaid annual fee invoices will attract a penalty interest of 10% if not paid by the due date. Products affected will not be able to be imported or manufactured (see box at left).

For enquiries on ACVM annual fees, please contact:
Sarah Smyth, Coordinator Business Services
Phone: 04 463 2553 or email: sarah.smyth@nzfsa.govt.nz

Revised fees associated with the Data Assessment Service and regulatory process

With the recent separation of the Data Assessment Service (DAS) from the regulatory process, the ACVM Group has established new fees associated with the regulatory process.

The DAS involves the assessment of data to support an application for registration. The fees associated with this service are based on an estimate of time (\$108.00 + GST per hour) that is likely to be taken to complete the assessment. A screening fee of \$243.00 must accompany the request to assess the data, unless the applicant is an approved creditor. The ACVM Group will then inform the applicant of the estimated number of hours, costs and likely time to complete the DAS.

The regulatory process consists of reviewing data assessment reports and evaluating the risks that must be managed under the ACVM Act 1997. It is estimated that this part of the process will be quicker, and therefore attract a lower fee. Fees associated with this process are also based on an estimate of time to review the data assessment reports (\$108.00 + GST per hour), plus operational charges and any disbursements associated with the application.

For further information on fees associated with the Data Assessment Service and regulatory process, refer to the website (<http://www.nzfsa.govt.nz/acvm/publications/fees/index.htm>).

Proposed Food Residues Surveillance Programme

The NZFSA proposes to develop and implement an ongoing Food Residues Surveillance Programme (FRSP) as part of the science strategy. The purpose of the FRSP is to investigate compounds and commodities not covered in existing residues monitoring programmes and to assess effectiveness of controls placed on residues in those commodities covered by the programme. The work will cover both imported and domestically-produced commodities, and will be undertaken by the Institute of Environmental and Science Research (ESR).

Contribution to regulatory outputs

Unlike the Total Diet Survey, which takes a 'snapshot' of the public's exposure to a range of residues and elements, the FRSP will contribute directly to regulatory outputs. Those regulatory outputs could be:

- increased monitoring
- new or amended controls on foods or agricultural compounds, or
- consumer information.

If the programme highlights any problems, they will be investigated to clarify the issues and determine the most appropriate action for the NZFSA to take. For example, if residues in a particular commodity are found to exceed the maximum residue limit (MRL), investigation may illustrate that the MRL or the associated withholding period is inappropriate and needs to be amended. This may occur where agricultural practices have changed without being reflected on the label.

Action taken may involve a re-evaluation of the available residue data based on current Good Agricultural Practice, or additional residue data may be required.

Alternatively, the MRL may be appropriate but the trade name product containing the compound is being

misused because of inadequate label information or carelessness. In this case, the appropriate action may range from altering user information or education to formal compliance activity.

Pilot programme

It is expected that a pilot programme will be undertaken in the 2003/04 financial year. In following years a NZFSA project team will rank and prioritise the programme of residue/commodity combinations to be investigated using risk-based criteria.

Consultation and scope

The principles and prioritisation criteria of the programme will be subject to

stakeholder consultation in accordance with standard NZFSA procedures. Details of the work to be undertaken will be advised in future editions of *AgVetLink*.

Obviously, the programme cannot cover all residue/commodity combinations in one year. Its scope may vary from year to year according to dietary significance of the food, use of the agricultural compound and findings from previous years.

It is expected that results of the survey will be published by NZFSA on an annual basis for the life of the programme.

Operational agreements with ERMA NZ

The ACVM Group has recently signed two Memoranda of Understanding (MoUs) with ERMA NZ. They are:

1. Operational Agreement for Administering the Transitional Provisions of the Hazardous Substances and New Organisms Act 1996, and
2. Operational Agreement for Administering the Transitional Provisions of the Hazardous Substances and New Organisms Act 1996, Vertebrate Pest Controls.

The first agreement's objective is to facilitate the efficient and effective administration of transitional provisions pending the transfer of pesticides under the new legislation.

The purpose of the second agreement is to facilitate the efficient and effective administration of transitional provisions relating to vertebrate pest controls (VPCs), pending the transfer of pesticides under the HSNO Act.

Until such time as pesticides are transferred, ERMA NZ has delegated its functions, powers and duties, including decision making powers, to personnel in the ACVM Group.

Generally Regarded as Safe (GRAS) registers

Why do we have GRAS registers?

The ACVM Group uses GRAS registers to prevent unnecessary reassessment of substances that are considered to be of low or no regulatory interest under the ACVM Act and Regulations when they are included in a trade name product used to manage plants or animals. This means that the focus of the ACVM Group regulatory assessments can be on substances where there is insufficient knowledge and experience for them to be considered safe or where known risks occur.

Further, trade name products whose formulations consist solely of GRAS substances are usually exempted from the requirement to be registered under the ACVM Act (refer schedule 1 [10] of the ACVM Regulations 2001).

The Operational Policy explaining the GRAS process was developed in March 2003 and is available on the website (<http://www.nzfsa.govt.nz/acvm/publications/policies-procedures/gras-policy.pdf>). The policy covers a number of the issues debated and agreed at that time such as the fact that GRAS listings will not be initiated by the ACVM Group unless there is a compelling public good reason.

Applying to have a substance GRAS registered

A GRAS application consists of a completed application form and **nine** copies of the supporting rationale. The rationale must consist of a case supporting the fact that the proposed GRAS substance is well known, is in common use and has a history of safety in the context of its use.

This can be done by reference to the GRAS register of another appropriate regulatory authority such as the US Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), or the European authorities. In this case, nine copies of the referenced entry should be submitted.

No charge is made for the GRAS application process; therefore only complete applications not requiring any significant resource input from the ACVM Group should be submitted.

Processing of applications depends upon the workloads of the staff involved and, as a result, it is not possible to give a definite timeframe for the application process. However, all applications are dealt with as quickly as possible. Applications are considered by a group of (industry) technical experts and are advised for public comment.

GRAS registers and ACVM Regulations

Currently there are three GRAS registers maintained by the ACVM Group. The GRAS Substances for Oral Nutritional Compounds and the GRAS Substances for Plant Compounds registers are found in Schedule 7 of the Agricultural Compounds and Veterinary Medicines Regulations 2001. The Veterinary Medicines Other than Oral Nutritional Compounds GRAS register is not included in the Regulations – these substances are dealt with administratively by the ACVM Group.

The purpose of these registers is to confirm to both regulators and applicants that a substance can be included in a particular trade name product and does not require repeated, in-depth assessment.

The process of modifying the GRAS registers, either adding/deleting a substance or modifying an existing entry, requires consultation with experts and the public. Those lists currently found in Regulations can be formally altered only by amendments. This process can be interrupted by other Government priorities.

Therefore, once a decision has been made to approve a substance for inclusion in Schedule 7 of the Regulations, the ACVM Group has

decided to treat this substance as GRAS even though it may be some time before the Regulations are updated to include the substance.

For this reason the ACVM Group has created administrative versions of each GRAS register. These versions include all substances that are currently in Schedule 7 of the Regulations and substances that will be added to the Regulations when they are next updated. The lists are available on the website (www.nzfsa.govt.nz/acvm/register-lists/gras/), and all substances listed here may be used as GRAS substances in the formulation of products.

Limitations applied to GRAS substances

Substances included in the registers must be used in accordance with any stated limitation and the conditions applicable to GRAS substances. Where a product contains only GRAS substances it may still require assessment depending on the characteristics of the product.

A substance declared as GRAS by the ACVM Group is **considered GRAS only for the purposes of the risks stated in section 4 of the ACVM Act 1997**. These substances still may pose risks that are managed under other New Zealand legislation.

Public consultation

There is currently a 'Proposed Changes to GRAS Registers' discussion document on the ACVM website (<http://www.nzfsa.govt.nz/acvm/publications/discussion/gras-register/gras.pdf>). You are invited to take this opportunity to comment on the appropriateness of the proposed substances. All comments should be submitted to the ACVM Group by **23 June 2003**.

For further information on GRAS registers, please see the ACVM website or contact the Assessor (Technical Standards – Toxicology).

Applications made by a third party for additional uses on registered products

Under the ACVM Act, applications for additional claims on registered trade name products are not restricted to the registrant. Applications can be made by third parties where they are supported by sufficient data.

Minor uses

It is likely that this will be most useful for minor uses of plant compounds, where grower groups may have access to residue and Good Agricultural Practice information and where there is an interest in having a registered product to deal with known pests and diseases.

In many of these instances the potential market value to the registrant is not high. This makes the costs of additional claims unattractive to the initial registrant, but

provides the opportunity for interested third parties to make an application.

There are similar possibilities in the veterinary medicines area for the addition of claims relating to minor species such as goats and ratites.

Approved uses

Uses that are approved through this route may subsequently be added to relevant product labels (by the registrant and only with their approval) or an information sheet can be produced (supported by a regulatory approval) by the user group concerned.

Trial applications

The ACVM Group has worked through some trial applications with a user group

to test the process. It is our preference that the registrant company is involved in the application.

Where they are not, the registrant will be advised of the application and the ACVM Group will make a request for the supply of any relevant information held by the registrant company. The information, either in support or against the addition of the claim, will be part of the consideration of the application by the ACVM Group.

The ACVM Group is in the process of developing an application form and further information on 'Third Party Applications' will be available on the website shortly.

Product Data Sheets – Why do we need them for old compounds?

There have been some recent enquiries as to why the ACVM Group requests companies to complete product data sheets for products that are already registered and will be transferred without changes to the HSNO Act. The reasons are as follows.

When many of these old compounds were registered, the information required was minimal – a one page application form was all that was required. Since the implementation of the ACVM Act 1997, criteria set in the legislation requires more information, such as additional details for inclusion in the public register. There are also different risks being managed. In addition, ERMA NZ has started work on the transition of products to the HSNO legislation and further details on trade name products are required in relation to the hazardous substance assessment.

Therefore, to prevent an applicant filling out two different forms – one for ERMA NZ and one for the ACVM Group – a single form was developed to capture both sets of information requirements. During the updating of products to the ACVM Act, using the current Product Data Sheets, ERMA NZ is able to review product files to seek the updated information, or alternatively request the Product Data Sheet for their reference.

We believe this is an effective and efficient time saving process to deal with the wide range of criteria required under the ACVM and HSNO Acts.

Conference of Residue Chemists

The 19th Conference of Residue Chemists (19CRC) is to be held at the Novotel Hotel, Brisbane, from 16 - 18 September 2003.

The conference is designed to provide both a formal transfer of knowledge and an opportunity to meet and socialise with other residue chemists, researchers and government regulators from throughout Australia and New Zealand. It is expected to attract approximately 140 delegates from Australia, New Zealand and the Asia-Pacific Region.

Dr Bob Epstein, Deputy Administrator of the USDA's Agricultural Marketing Services (AMS) Science and Technology programmes, has been invited as guest speaker. The conference has no specific theme but will cover a wide range of topics including:

- reports on environmental investigations, monitoring and research
- residues in foods from use of pesticides and other chemicals
- laboratory accreditation, quality control and quality assurance
- developments in methodology and techniques
- recent advances in instrumentation and equipment
- regulatory issues: national and international perspective.

For more information contact:
The Secretariat
Phone: +61 7-33682644
Fax: +61 7-33693731
Email: jon@ccm.com.au

Good Manufacturing Practice seminar

The ACVM Group has been advised that a GMP seminar is being organised by the International Society of Pharmaceutical Engineers (ISPE) on 26 or 27 June. The seminar will be presented by Joe Phillips*, a former director of the Food and Drug Administration (FDA).

The proposed agenda for the seminar (about four hours) is:

- FDA's new risk-based GMP
- FDA quality systems audit approach
- Trends in inspectional observations
- Questions and answers.

The cost is expected to be relatively modest; the venue and final date are to be confirmed. We believe this will be a single rare opportunity to workshop GMP topics with an acknowledged expert. If you wish to receive the seminar details and a registration brochure, please contact Maurice Parlane (email: info@newwayz.co.nz or phone: 09 419 8029).

* Joseph X Phillips, a Bachelor of Science graduate of St Joseph's University, is Vice President for Pharmaceutical Services at Quintiles Consulting, Rockville, Maryland. Before joining the private sector, he spent 44 years with the FDA. He served as Deputy Regional Director for the Central Region for the last ten years. He has been a frequent lecturer, both domestically and internationally, at ISPE events. He was one of the FDA's principal negotiators for the development of the Mutual Recognition Agreement (MRA) with the European Union and was the FDA's Lead to the International Cooperation on Harmonisation (ICH) Expert Working Group (Q7A) in developing the API GMP Guidance. While at the FDA he was instrumental in forming the partnership between ISPE and FDA for the development of the Baseline® Pharmaceutical Engineering Guide series and the scale-up and post-approval changes (SUPAC) 'Similar Equipment' Addendum. He serves on the ISPE Technical Documents Steering Committee, the Training Committee, and others. He has received ISPE's Richard B Purdy Distinguished Achievement Award, and three Vice President Al Gore's Hammer Awards for reinventing government.

Lime sulfur products

There has been some confusion over the expression of the active ingredient and its concentration for lime-sulfur based agricultural compounds. The registrants of such products were asked for their views on the matter, and the general consensus was that the following statement should be used:

X g/litre sulfur as calcium polysulfide in the form of a soluble concentrate.

Where X is the amount of sulfur in calcium polysulfide. For example, if the formulation contained approximately 295g/litre calcium polysulfide, this would generally equate to 190 g/litre sulfur content. This amendment can be made when registrants next reprint affected labels.

VICH Food Safety Expert Working Group

At a meeting in Brussels on 28 - 30 April 2003, this working group finalised the last two draft guidelines to complete the mandate to produce the guidelines necessary for the provision of harmonised toxicology data packages supporting the registration of veterinary medicines used in food-producing animals. These were the chronic toxicity guideline, and one for the establishment of a microbiological Acceptable Daily Intake. The guidelines will be put out for comment prior to their formal adoption after any modifications that may be necessary following the comment period (which is to end in November 2003).

Microbiological ADI guideline

The 'Microbiological ADI' guideline is completely new, incorporating new concepts relating to microbial resistance and drug effects on the gut microflora. It was drafted after a thorough review of the current scientific literature.

Chronic toxicity guideline

The 'chronic toxicity' guideline does not

represent a fully harmonised approach by the regulatory authorities. The current state of toxicological knowledge does not allow a differentiation between the potential need for chronic studies generated in two species as opposed to only one species required for proper assurance of the long-term safety of the consumption of veterinary drug residues in foods. Generally, the data (comparing the information obtained from the many assessments of chronic toxicity data carried out by international bodies) showed that one species gave all information that was used in the estimation of an ADI.

However, assessment of data on one or two substances did provide extra data that would not have been found except for the second test. The different ADI estimated was not greatly less than that obtained in the least sensitive animal in these cases, and the decision as to whether to require data from only one species, or whether data from two species was required came down to the choice between conservatism and the

need to limit the use of animals in toxicity testing.

The six countries/regions represented at the working group were split evenly with Japan, Canada and Australia opting for the need for two species to be tested, and USA, Europe and New Zealand opting for only one species.

Action to be taken

The working group will:

- finalise these two guidelines when the comment period is over
- ensure all the toxicity guidelines are fully compatible, and
- make a single coherent package for proprietors and regulators to use.

Copies of the draft guidelines are available on the NZFSA website (<http://www.nzfsa.govt.nz/policy-law/vich/index.htm>).

The Australia/New Zealand representative on the working group is John Reeve who can be contacted at john.reeve@nzfsa.govt.nz.

Data requirements for veterinary medicine exotic disease claims

The ACVM Group currently applies the following rule in relation to allowing claims for diseases and parasites that do not occur in New Zealand to appear on veterinary medicine product labels:

Labels must refer only to diseases/parasites that occur in New Zealand. For the purposes of harmonisation with Australia, diseases/parasites occurring in Australia may be included accompanied by a disclaimer, for example, 'This disease/parasite does not occur in New Zealand'.

In the event of such an exotic disease/parasite becoming established in New Zealand, it would be difficult and costly to both industry and regulatory groups to undertake a post registration review to ascertain whether such claims are supportable. In addition, although some of these diseases are not endemic to New Zealand, situations arise where prophylactic treatment of animals for export or post importation is required.

Registrants should note that exotic disease/parasite claims are subject to the normal ACVM registration procedure that requires assessment of efficacy, safety and/or residue data where necessary to support the proposed claim. This requirement is not specifically stated in any of the current ACVM standards and guidelines. However, it will be added to the Registration Information Requirements at the next update.

What's new on the ACVM Group website

The website remains one of the key communication mechanisms for the ACVM Group. *AgVetLink* readers are reminded that they can be emailed automatically with advice of any updates by going to the bottom of the ACVM homepage and following the instructions after clicking on the 'Notifications of updates to the site' heading.

Please visit the 'Recent Updates' page on the ACVM website to find the latest version of *AgVetLink*, as well as back issues. The address for recent updates is <http://www.nzfsa.govt.nz/acvm/whatsnew/index.htm>

The ACVM part of the website is updated regularly. Since February 2003 the following new and updated items have been added:

Discussion documents/Draft policies

- *Summary of Submissions – Regulatory Control of PAR Products*
- *Strategic Review of Arrangements for Controlling the Importation of Food and Food Related Products*
- *ACVM Registration Standard and Guideline for Chemistry (Veterinary Medicines)*
- *ACVM Data Requirements for a Food or Feed Use Clearance for Plant Compounds*

Updated documents

- *Proposed Changes to GRAS Lists*
- *Fees for Applications – Veterinary Medicines*
- *Fees for Applications – Plant Compounds*
- *Register of Codes of Practice Approved under ACVM Act*
- *Research Approval Forms for Plant Compounds and Veterinary Medicines*
- *Provisional Approval Forms for Plant Compounds and Veterinary Medicines*
- *Information Requirements for Provisional Registration*
- *Information Requirements for Research Approval*
- *Fees for Discretionary Services under the ACVM Act*

New items

- *Data Assessment Service*
- *Regulatory Control of Antibiotics to Manage Antibiotic Resistance: Progress Report January 2003*
- *ACVM Standard and Guideline for Therapeutic Equivalence of Trade Name Products*
- *Operational Policy on Product Advertising*
- *Data Assessment Report for WHP Recommendation – Veterinary Medicines*

NZFSA website

The wider NZFSA website has a range of other information that is likely to be of interest to some readers of *AgVetLink*.

The May 2003 edition of the *Animal Products Bulletin* can be found at <http://www.nzfsa.govt.nz/animalproducts/bulletins>. It has a number of items of interest such as the development of a national livestock and animal tracing information system by Terry Ryan.

The Policy and Law area has a copy of the discussion paper on voluntary GM Free labelling at <http://www.nzfsa.govt.nz/policy-law/consultation/index.htm>. Comments close on 30 May 2003.

There is also the latest information on the recall of products from Pan Pharmaceuticals in Australia.