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### Recent events

- **AVMAC and Industry Liaison Group meetings**  
These meetings were held on 23 May in Wellington.  
Check the ACVM website for the papers that were discussed.

### What's coming up

- **ACVM Fees Regulations**  
The new fees regulations are due to come into effect on **1 July 2002**.  
A copy will be made available on the website.
- **ACVM Transitional Provision Regulations**  
These regulations are also due to come into effect on **1 July 2002**. They will transfer all current licensed and registered products that are agricultural compounds to the ACVM Act. Subscribe to the ACVM website to be advised by email of when details are posted.
- **'Third party' applications**  
The ACVM Group has been working with VegFed and a proprietor to develop the information requirements for third parties wishing to have minor crop/species claims added to a registration. Watch this space!
- **Technical Consultative Committee Review**  
The ACVM Group is reviewing the TCC process. This will cover the make up of the committee and the terms of reference.
- **ERMA New Zealand conference**  
'Regulation and Beyond: Innovative Strategies'  
Wednesday 26 and Thursday 27 June at the Waipuna Conference Centre, Auckland

*AgVetLink* is produced at least six times annually by the MAF Food Assurance Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of animal remedies and pesticides. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

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## Clarifying MRL responsibilities under the Food/ACVM Acts

### Issue

The ACVM Group forms part of the New Zealand Food Safety Authority (NZFSA) that is expected to start on 1 July 2002. The responsibility for setting maximum residue limits (MRLs) under the New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999 will transfer to the ACVM Group at that date. This paper is to clarify the expected changes in operational procedures resulting from the transfer of responsibilities.

### Background

*The New Zealand Domestic MRL setting process – May 2002* outlines the current\* process. In effect the ACVM Group has undertaken the technical work needed in support of an MRL (or a change to an existing MRL) as part of the Animal Remedies and Pesticides Acts approval process, and cost recovered under this legislation.

The Ministry of Health (MoH) functions under the Food Act that will transfer to the ACVM Group are:

- peer review of any proposals for MRLs,
- public consultation, and
- promulgation.

No MoH staff have permanent responsibility for this activity and it tends to be carried out infrequently, which has resulted in high levels of frustration for industry in the recent past.

### Proposed operational process

#### 1. Technical evaluation

In the main this function will continue to be done as part of the ACVM Act approval process or on request from an applicant. It will be undertaken in relation to an application for a new registration or as part of a request for a variation to a currently registered product, and will be cost recovered as part of the ACVM Act processes. No

### changes to this activity are proposed.

There is a need for updating the Food Standard to rationalise the definitions and terminology used because this has not been consistent over the period that the legislation has been in place. This work is the responsibility of the MAF Food Residue Coordination Group\*\* at the moment but it is low priority – there is limited funding from any of the business groups (or staff resource) to devote to the activity under MAF Food administered legislation.

There may also be a need for MRLs to change as a result of the transfer of substances under the HSNO Act. It is expected that this work will form part of the programme to update the Food Standard and will not require separate funding. **The ACVM Group plans to devote some of the funding from the proposed business case for the NZFSA to this activity, providing the business case is approved.**

#### 2. Ministry of Health functions

##### General

The MoH functions are not cost recovered under the Food Act. It is expected that this will be the subject of future policy development for the NZFSA but that it will be done in conjunction with a general review of cost recovery across the various pieces of legislation.

##### Peer review

There is a continued need for peer review to ensure a robust process. The ACVM Group is investigating options for provision of this in a cost effective manner.

##### Public consultation

It appears that the public consultation process may be able to be streamlined. At present, several hundred copies of a very comprehensive document are distributed each time with limited (usually under 20 submissions)

response. There remains a need for advice to the public on what active ingredients are being considered for a domestic MRL.

Our objective is to develop a communications plan for the MRL setting process that would include some easily understandable information available on the NZFSA website or in hard copy if required. This would mean that the public advice could be reduced to information on what actives are being considered, where to find the process used, and the specific background for interested parties. The specific background material would also be available on the website or in hard copy if required.

### Promulgation

No changes to the current process are proposed.

### Other

- At the present time there is no regular **timetable** for the setting of MRLs. The ACVM Group proposes that we set a 'rolling' timetable so that there are two to three sets of MRLs promulgated per year.
- There is no **comprehensive listing** of New Zealand MRLs (the updates to the Food Standards appear as standalone documents). The ACVM Group proposes to provide a complete list of MRLs on the NZFSA website. It would be updated each time new MRLs are promulgated.

\* The ACVM Group and ERMA New Zealand are working through operational processes that take into account activities under the HSNO Act.

\*\* This group is made up of representatives from the Animal Products Group, the Dairy and Plants Group, the ACVM Group, MAF Food Policy Coordination, and the MAF Policy Codex representatives. It has responsibility across MAF Food for higher level operational policy concerning residues.

## Operational agreement with Medsafe

Under section 13 of the ACVM Act 1997 the ACVM Group must notify government departments that have expressed an interest in applications to register agricultural compound trade name products. Section 14 provides circumstances under which notification does not have to occur. In effect and for the purpose of the operational agreement, all applications that involve issues that the Ministry of Health (MoH) has not had a previous opportunity to comment on will be notified to them.

In addition, subsection 21(4) of the ACVM Act 1997 states that: *The Director-General must not register a trade name product under this section without the consent of the Director-General of Health if that product is a prescription medicine within the meaning of section 3 of the Medicines Act 1981.*

The ACVM Group considers that the Director-General of Health would also be interested in substances that are restricted medicines and any Class A, B, or C drugs as scheduled in the Misuse of Drugs Act 1975. Therefore, the ACVM Group will consider that the obligation in subsection 21(4) extends to the issuing of registrations

for any of these groups of medicines and drugs to be used as agricultural compounds.

Section 16 of the ACVM Act places a time limitation on the processing of applications for registration. Since, in most cases, the decision must be made within 40 days, it will be important that a response from MoH can be processed in time for the ACVM Group to meet its statutory deadlines.

When the ACVM Group receives an application for registration of an agricultural compound trade name product, it will screen the formulations to identify any ingredient that is a:

- Prescription medicine
- Restricted medicine
- Class A drug
- Class B drug or
- Class C drug,

and will advise MoH accordingly.

The ACVM Group is currently in discussions with MoH and we expect the agreement to be signed off in the very near future. In the meantime, MoH is testing the operational agreement by processing those applications in the system that fall within the above categories.

### Prescription Medicines

**As mentioned above, section 21(4) of the ACVM Act states: *The Director-General must not register a trade name product under this section without the consent of the Director-General of Health if that product is a prescription medicine within the meaning of section 3 of the Medicines Act 1981.***

**The ACVM Group advises that this has the potential to delay the approval of your products. However, we are meeting with the Ministry of Health to work through the regulatory obligations that we have in meeting deadlines.**

## Mutual Recognition Agreement for GMP

The EC has agreed to implement the Mutual Recognition Agreement on Good Manufacturing Practice with New Zealand from 1 June 2002.

This is the result of work over the last five years that included a number of meetings in Europe and New Zealand, and a three-year transition period during which the exchange and analysis of relevant legislation, standards and procedures took place. Technical reviews of the conduct of inspections and of the management of the inspection process were also carried out.

The effect of this agreement is that the inspections by ACVM inspectors, of manufacturers who are supplying veterinary medicines to the European market, will be accepted by the EC. There will no longer be a requirement for European inspectors to visit New Zealand to conduct GMP inspections of manufacturers exporting to the EC.

As part of the agreement, there will be a programme to maintain contact with the Europeans on any changes to standards, structures or procedures that take place in either territory, and for the emergency recall of deficient products.

The ACVM Group will continue to work with service providers to improve the systems and provide added value from the inspection process.

## New application process for A1 (new active) applications

Since the commencement of the ACVM Act and the HSNO Act on 2 July 2001 it has become apparent that there are some operational obstacles for those applicants wishing to register a trade name product with a new active ingredient for use in New Zealand.

A significant hurdle for applicants is the time it now takes to pass through the combined regulatory systems of the ACVM Group and ERMA New Zealand to register a new active. The reasons for this are as follows:

- When an application is submitted to the ACVM Group, under the current operational system it must undergo prescreen and data assessment prior to formal acceptance. The ACVM Group must do this to comply with the legislative timeframes laid out in the ACVM Act.
- Under the HSNO Act, agricultural compounds only receive data protection by reference to section 73 of the ACVM Act. ERMA New Zealand does not have a formal acceptance process and if an application is sent to ERMA New Zealand **prior** to formal acceptance by the ACVM Group, data protection cannot apply. In essence, this means that applicants who wish to obtain data protection

for their products can submit an application to ERMA New Zealand only after the ACVM Group has formally accepted their application.

The result is that applications for new actives requiring data protection must go through the ACVM registration process and the HSNO process **sequentially** rather than going through both systems in **parallel**.

### New administrative process for A1 applications

In order to allow a parallel application process through both agencies it is proposed that:

- The ACVM Group will formally accept A1 applications after the prescreen process **on the request of the applicant**. This will be carried out on the understanding that:
  1. The applicant agrees to the ACVM Group 'stopping the clock' (i.e. the ACVM Group will not carry out any work on the consideration of the application for a regulatory decision) until the data assessment has been completed and the data assessment report (DAR) has been produced.
  2. The applicant provides all the data required to complete the data assessment.
- On formal acceptance of an A1 application the ACVM Group will notify other government departments of formal receipt of the application and initiate public notification through the *New Zealand Gazette* as long as there is sufficient information to undertake the public consultation process effectively.\*
- A letter confirming the successful passage through prescreen and the formal acceptance of the application by the ACVM Group will be sent to the applicant.
- On receipt of this letter, the applicant should be able to make a parallel application to ERMA New Zealand and receive the data protection provided under the ACVM Act.
- Following public notification, the ACVM Group ceases all work on processing the application (although work will continue on the data assessment) for the period of time required for submissions to be received (i.e. 30 days).
- Thirty days after notification, the ACVM Group will officially stop the clock on the consideration of the application (although work will continue on the data assessment) with the consent of the applicant.
- Consideration of the application will commence **once the data assessment has been completed and the DAR has been submitted for review and evaluation**. When this occurs, the ACVM Group will be obliged to make a decision to approve or decline the application within 40 days.
- Following a regulatory decision of the ACVM Group's Decision Making Committee (DMC) to register the product, the product will be registered if an approval has been provided by ERMA New Zealand or if the product is non-hazardous.
- The new administrative approach will be carried out on a case by case basis.

\* Where there is insufficient information (due to the lack of a data assessment report), the clock will be stopped prior to public notification. Public notification will then be undertaken as soon as the information is provided by the applicant or when the data assessment is completed.

### Website update

Recent updates to the website are:

- Revised Report form for (Schedule 3) Exempt Agricultural Compounds
- Revised Annual Report form for (Schedule 3) Exempt Agricultural Compounds
- Minor revision to the Guiding Principles for Class Determinations

## Explanatory notes for insert: Request or enquiry regarding research/trials

### Type of product?

The first deciding factor is if the product is a plant compound or a veterinary medicine.

Applications that come in where the product is **already a licensed animal remedy (AR) or a registered pesticide (PX)** will be processed within the areas of the chart noted:

- plant compound/PX or
- veterinary medicine/AR.

### OUTCOMES

#### No requirement

Product applications fall into the 'no requirement' category if:

- Product is **exempt** from the requirement to be registered.
- Product **does not require a food/feed approval** and proposed use **does not breach the conditions** of the registered pesticide/licensed animal remedy.

- Product is **not an end use formulation** and there is **no food/feed approval required**.

### Research approval

Product applications fall into the 'research approval required' category if:

- Product is **not exempt** from the requirement to be registered and is **not an end use formulation but a food/feed approval is required**.
- Product is a **registered pesticide/licensed animal remedy** but there is either a **food/feed approval required or a breach in conditions**.

For example, a food/feed approval is required or there is a breach in conditions if the approved label states that the product is not for use in grapes, but you want to trial for further development of product for

this use. In this situation a research approval would be required.

Please note that a research approval is **not** a statutory requirement. However, obtaining a research approval helps clients meet their obligations under other legislation.

### Provisional registration

Product applications fall into the 'provisional registration required' category if:

- Product is **not exempt** from the requirement to be registered and there is **an end use formulation**.

Applicants should note that ERMA NZ will be notified of all provisional registrations and that without an ERMA NZ statement of non-concern the provisional registration cannot be issued.

## Policy on publishing label content

The ACVM Group has drafted the following policy on the publishing of label content under the ACVM Act 1997.

Details of registered trade name products are published on the ACVM Group's website ([www.maf.govt.nz/acvm/registers-lists/index.htm](http://www.maf.govt.nz/acvm/registers-lists/index.htm)) as is required by section 24 of the ACVM Act.

Under section 24(k), the product's label content is also to be published at the point of registration, unless the registrant can give good reason to delay publishing, e.g. for marketing purposes.

The ACVM Group will publish either the entire label or the label

content as it relates to the areas of risk managed under the ACVM Act.

Where a registrant indicates on the Registration and Product Datasheet that they wish the publishing of the label content to be deferred until such time as they are ready to advertise or market, the ACVM Group will do so if the delay period is within reason.

The ACVM Group will retain a list of those products for which the publishing of label content is being held and, if within six months of registration the registrant has not provided notification of intent, the label content will be published.

Once label content has been published, the registrant may request that the

label details be updated by the ACVM Group, and no fee will be charged for doing so (provided the update is minor and able to be actioned in under ten minutes). In these instances, the previous version of the label content will remain on the website as an 'archived' document for a period of 12 months.

If you have any comments or concerns on this policy, send them in writing by **30 June 2002** to:

Catherine Alsford  
Customer Services Officer  
ACVM Group, MAF  
PO Box 2526  
WELLINGTON  
Email: [alsfordc@maf.govt.nz](mailto:alsfordc@maf.govt.nz)

## Notification of manufacturers

There has been some confusion concerning *manufacturers\** who are required to be advised to the ACVM Group. The following explains what information is legally required to be provided after products have been transferred under the Agricultural Compounds and Veterinary Medicines (ACVM) Act.

### Legislation

The Animal Remedies (AR) Act 1967 specifies that all manufacturing sites must be included on the (product) licence and on the Register of Licensed Products. The ACVM Act specifies that the registrant must be on the (product) registration certificate, but all manufacturing sites must be on the Register of Registered Products.

### Requirements under the Animal Remedies Act 1967 (and the Transitional Period)

Two types of 'licences' are provided to stakeholders. One is a licence to manufacture or import an animal remedy under the Animal Remedies Act section 19. This has generally become known as the 'product licence'. The second is certification that a manufacturer is in compliance with Good Manufacturing Practice (GMP) requirements.

Under the AR Act section 19 (2)(b) all the details relating to the preparation of the licensed product are required to be supplied to the ACVM Group, including all subcontracting manufacturers. Section 21 (7)(d) of the AR Act is explicit in requiring: *The address of every place where the animal remedy is being or is to be manufactured.*

The AR Act section 31 requires the Registrar to keep a register of (product) licences, and to include under section 31 (2)(b): *The name and principal business address of the licensee and the address of every*

*place where the manufacture or, as the case may be, importation of the remedy is carried on by the licensee.*

Therefore, since products are currently licensed as animal remedies, and since we are still operating within the transitional period, the ACVM Group is legally required to state the address of every place where the animal remedy is being manufactured on the (product) licence.

### Requirements under the ACVM Act

The position will be different under the ACVM Act. Animal remedies and pesticides will be transferred under the ACVM Act as agricultural compounds or veterinary medicines.

Under the ACVM Act section 24, the Director-General must keep a register of all trade name products (agricultural compounds) registered under section 21 or section 27. Under section 24 (2)(j), this register must specify: *The address of every place of business where the registered trade name product is being or is to be manufactured ...*

Under the ACVM Act section 25, the Director-General must issue a certificate of registration of an agricultural compound, which must specify:

- s. 24(a), one trade name
- s. 24(b), name and address of registrant
- s. 24(d), application number and date granted
- s.24(e), whether product is registered under s.21 or s.27
- s. 24(f), conditions on any registration
- s. 24(i), registration expiry date and, in addition under section

24(k), may specify such other matters as the Director-General thinks fit.

Therefore, after products are transferred under the ACVM Act there is no legal requirement for the ACVM Group to place names of manufacturers or subcontracting manufacturers on the registration certificate (unless a good regulatory or compliance reason for requiring the inclusion becomes apparent).

However, there is a legal requirement for MAF to include all manufacturing sites concerned with a product on the register, and the register is a public document in whatever form it appears.

Considering the above requirements, if there should be additional manufacturers involved with the manufacturing, packing or testing of products that a licensee or registrant has not notified to the ACVM Group, **please ensure that all manufacturers are included when you update your registrations (for the transfer process).**

\* A **manufacturer** is any person or organisation that manufactures\*\* an agricultural compound. Where the process of manufacturing an agricultural compound or veterinary medicine is carried out on different sites or by contractor manufacturers on behalf of the registrant, all such contributors shall be recorded as manufacturers of the product in the register.

\*\* **Manufacture**, in relation to an agricultural compound or a veterinary medicine, includes any of the following activities:

- Acquiring materials, making up, preparing, producing or processing and assessing the trade name product for release for sale, and
- Packing an agricultural compound in a container, or labelling or re-labelling for the purposes of sale.

## Pack size approval

The ACVM Group has introduced a policy to modify the method of pack size approval. The new methodology provides an adequate level of product quality assurance to the ACVM Group at a greatly reduced expense to registrants.

The current system requires that all new pack sizes be the subject of a formal application (C3), with variable data requirements and expense to the applicant. Under the new policy, provided the appropriate data and information are supplied, the ACVM Group will approve a range of pack sizes at initial registration. From that point, all pack sizes with a risk profile that fall within the assessed range (such as the same packaging material) will be considered approved.

For existing products applications can be made to approve a range of pack sizes as a normal C3, with referencing

to data already on file, or via the provision of additional information.

In either case, the ACVM Group will require notification of the actual pack sizes being marketed in the form of an official letter, which must be provided each time a new pack in the approved range is introduced to the market.

In addition, any subsequent applications requiring a product data sheet to be submitted must state the marketed pack sizes as well as the approved range. Labels for additional packs will not require approval provided the content does not differ from that approved. For new packs falling outside of the approved risk profiles, new data and a C3 application will still be required.

A fee of \$364.50 is applicable. This is in addition to the prescreen fee of \$364.50.

## Annual fees

**It is that time of the year again when information is collected for charging of fees for the 2002/2003 financial year. By now you should have received a letter and product list explaining what is required of each company this year.**

**If you have not received the letter and product list, or if you have any questions, please contact:**

**Sarah Smyth  
04 460 8753 or  
smyths@maf.govt.nz**

## RLC meeting

The ACVM Group was represented at the 22<sup>nd</sup> Registration Liaison Committee Meeting at the Australian National Registration Authority (NRA) by Brian Pidford and Maree Zinzley. Six-monthly updates of current issues and initiatives are provided by the NRA, the regulatory authorities in the States and Territories, and by MAF at the meeting. Key points noted included the following:

- There is a continuing difficulty of setting and implementing controls on the use of agricultural chemicals on a national basis in Australia because compliance is undertaken by States and Territories under their local legislation.
- The NRA proposes to reform the labelling requirements of agricultural chemical products so that all mandated information and voluntary information is provided in seven panels. Label information in this context includes user information leaflets. A discussion paper will be provided for comment.
- The NRA is submitting proposals to the EMEA in Europe for its own GMP approval process to be accepted as equivalent to the European process under their mutual recognition agreement. Australian manufacturers who export to the EC are currently approved by the TGA.
- Notice of the proposed NRA review of 1080 has drawn large public interest (250 submissions were made on the scope of the review). The review scope document and agricultural evaluation should be available in June. The NRA is not expecting 1080 will need to be withdrawn, but the review will be contentious.
- Concerns exist for an apparent lack of scrutiny in regard to the statistical validity of trials involving animals. There is no requirement by the NRA for biometric input into proposed trials to ensure consistency and validity. This might result in too many animals being used, or invalidate studies because of too few test subjects. Priority was assigned to dealing with this issue at the next meeting.

## Stock in trade (subject to cancellation or revocation)

We have put in place a policy for products that fall within the following areas:

1. Request by registrant to cancel product(s)
2. Product licences revoked by the ACVM Group
3. Products cancelled for non-payment of fees.

### Request by registrant

When a company advises the ACVM Group that they wish to cancel a registered product, and/or the ACVM Group advises that the licence is revoked, the following actions will be taken:

- Batch number and records of the last product distributed from the warehouse and/or other documentary evidence of cancellation will be requested.
- The company will be advised that, should any adverse events be reported, they will be charged the actual time taken (based on the current hourly rate) to conduct an

investigation.

- In all cases except revocation of a licence, the ACVM Group will advise the company that product released from the warehouse before the licence is cancelled may continue to be sold in the marketplace. Stock contained in the warehouse **MUST NOT** be released. Companies that release such stock will be in breach of the Act, and compliance action will be undertaken.

### Revocation of licence

The ACVM Group will advise that all stock must be immediately removed from the marketplace until completion of the investigation.

### Unpaid fees

When a company has not paid annual fees by the date specified, the following action will be taken:

- ACVM Group will initiate the standard debt management process, up to enforcing section 82 of the

ACVM Act, which suspends importation and manufacture of the product (this includes charging penalty interest).

- The company will be advised that section 82 has been enforced and they will be asked to provide batch number and records of last product distributed from their warehouse. Any additional stock contained in the warehouse **MUST NOT** be released. Companies that release such stock will be in breach of the Act, and compliance action will be undertaken.
- The company will be advised that payment of outstanding debt must be made within one month or section 83 of the ACVM Act, which allows the Crown to recover costs through the court system, will be enforced.
- If payment is not received, section 83 will be enforced with a recommendation made to the court to revoke the licence and recall product.

## Registration numbers under the ACVM Act 1997

Under the ACVM Act, the numbering of registrations is to continue in the sequence that has been used for products licensed/registered under the Animal Remedies and Pesticides Acts. The only noticeable difference this will make to applicants is in the registration statement on label content. In order to differentiate products under the Act, the registration number will be prefixed with 'A' for veterinary medicine products and 'P' for plant compound products, e.g. 'Registered pursuant to the ACVM Act 1997, No. A1234' for a veterinary medicine or 'Registered pursuant to the ACVM Act 1997, No. P2468' for a plant compound.

A small number of products that have already been registered under the ACVM Act have not had this prefix added to the registration number on their label content. Affected registrants will be contacted in order to correct this at the next reprinting of their labels.

## Toxicology assessors

For some years now, the ACVM Group has had a relationship with the University of Surrey, England. This has seen the Group providing employment to third year students studying toxicology – enjoying increased expert resources (the students have completed the necessary subject modules to enable them to handle basic toxicology assessments) while giving the students valuable experience in the world of regulatory toxicology.

**Laura Phillips** is the fifth 'professional year' student that we have had; her term in the office finishes at the end of June. After a holiday, she will return to the University to complete her final year.

Because of an ongoing need for additional expertise to review the current MRLs listed in the NZ Mandatory Food Standard to ensure that the entries are still relevant and to rationalise definitions, we have taken on **Nicola Reeves** to replace Laura. Nicola (no relation of the National Manager Toxicology and Residues John Reeve – in fact a different surname!) will arrive in mid-June so that she can get on the job training from Laura before flying on her own for the year from 1 July.

## Compliance: 1080 substitution incident

On 8 March 2002, MAF was notified that 1080 may have been used by mistake (instead of cholecalciferol) in a pest control operation in Southland. A dog had died; postmortem examination revealed symptoms of 1080 poisoning.

Preliminary investigation carried out by staff of Southland Regional Council indicated that a pest control company contracted by the Regional Council to conduct pest control activities had subcontracted the actual bait laying operations to local licensed vertebrate pest control (VPC) operators.

The incident was investigated further by the ACVM Group to determine whether breaches of the Pesticides (Vertebrate Pest Control) Regulations had occurred, and what needed to be done to prevent a similar event happening again.

It was determined that the pest control company was operating in a professional manner with area supervisors managing subcontracts with local pest control operators in various parts of the country. The ACVM Group recommendation was that the company should develop guidelines for subcontractors relating to the receipt, storage, transportation, use and documentation of toxins. It should also provide area supervisors with additional training in risk assessment and inspection techniques.

The investigators determined that the mistake had occurred where two vertebrate pest control operators were using the same depot owned by one of them. A container of baits thought to be cholecalciferol pellets had contained 1080 pellets, and had been collected from the depot by one of the operators for transfer to another site. Significant features of the incident included:

- insufficient or mislabelling of the container,
- lack of procedures or systems for isolating 1080 in the depot,
- insufficient records to enable reconciliation of toxin stocks in the depot, and
- lack of regular communication between the two operators.

The VPC licences of both operators were suspended.

The VPC operators have since responded to the investigation with detailed remedial actions that are being implemented.

Following a review by the ACVM Decision Making Committee, the VPC licences have been reinstated, but the operators will be audited to ensure ongoing compliance.

## Residue standards review

The biennial review of the ACVM residue standards has commenced. Major content changes are not contemplated at this time although some changes are proposed.

The Standard and Guidelines for Plant Compounds will be merged into one document.

The Standard for Veterinary Medicines will be split into two separate (but related) standards. One of these will address requirements for new active ingredients and uses where the MRL is not gazetted in the NZ Mandatory Food Standard and where both an MRL and a WHP are sought. The second standard will address requirements for registration where the MRL is gazetted and only a WHP is required. Guidelines will be incorporated into each of these standards.

Some other potential changes are signalled for veterinary medicine registration requirements: the removal of the 20 ml upper limit restriction on parenteral products and the expanded options of stratification of WHP by dose.

Consultation on the proposed changes to the ACVM residue standards with stakeholders and interested parties will be subsequent to the issuing of the first draft of the new standards.

If you have any queries, contact:  
Mike Clear, National Manager,  
Veterinary Residues  
(04 460 8734, [clearm@maf.govt.nz](mailto:clearm@maf.govt.nz))  
or  
Dave Lunn, National Manager,  
Plant Residues  
(04 460 8735, [lunnd@maf.govt.nz](mailto:lunnd@maf.govt.nz)).

## Application costs under the ACVM Act

Although the ACVM Act commenced on 2 July 2001, the majority of the ACVM Group's work since the commencement has been to process applications made under the Pesticides and Animal Remedies Acts.

However, when products are transferred to the ACVM Act on **1 July 2002**, it should be noted that all applications made after that date will be processed under the ACVM regime.

The administrative system under the ACVM Act differs from that under the previous legislation in that applicants are charged on a *time* basis as opposed to a *modular* basis. From 1 July 2002, all applications for registration (or to vary a registration) submitted to the ACVM Group will be 'time tracked' throughout the process.

Once the application process has been completed, the actual cost will be

calculated and any difference refunded or invoiced to the applicant.

For this reason, applicants should take the processing time of their applications into account when preparing applications for submission. Applications that do not adhere to ACVM requirements may bear significant and unnecessary costs.

Some of the things that applicants can do to reduce their costs are:

- Ensure that all forms are filled out correctly and all declarations are signed;
- Use data package reviews and application summaries wherever possible;
- Submit requests for information waivers at the time of application or (where possible) prior to applications.

Advice on the most effective way to make an application is provided in the appropriate 'Information Requirements' documents on the ACVM Group's website (<http://www.maf.govt.nz/acvm/subject/registration/index.htm>).

Further information on the fees coming into effect in July 2002 can be obtained from the MAF discussion paper, *Proposed Amendments to the Agricultural Compounds and Veterinary Medicines (Fees) Regulations 2001* (<http://www.maf.govt.nz/acvm/archive/draft/amendments/index.htm>).

If in doubt, applicants should also discuss requirements with Customer Service Officers prior to submitting an application.

## We are moving

With the proposed establishment of the New Zealand Food Safety Authority (NZFSA) on 1 July 2002, the ACVM Group will be moving to a new location. In addition to the name change, we will be changing phone and fax numbers, box numbers, email addresses, as well as the street address. Keep an eye out for a special edition of *AgVetLink* containing all of the new contact information.