



What's coming up

■ NZFSA talk to dieticians on toxins in foods

On 2 August 2003 John Reeve, the NZFSA Programme Manager (Toxicology and Residues), will present a talk on toxins (both natural and those arising from human activities) in New Zealand foods. The talk will attempt to put the relative importance of both sources of toxins into perspective, and enable dieticians to inform the public properly on this issue.

■ Veterinary Council of New Zealand

A follow-up meeting with the Veterinary Council of New Zealand (VCNZ) is planned. The objective of setting up a Memorandum of Understanding on compliance cooperation has been extended to discuss complementary standards setting.

■ International animal health conference

The Drug Information Association (DIA) is planning the first conference on veterinary topics for 23-24 October in Nice, France. A broad range of themes and a diversity of speakers from around the world will cover regulatory activities and related scientific issues. Many of the speakers are experts from the VICH process. Details and the conference programme are on the DIA website (http://www.diahome.org/docs/events/events_search_detail.cfm).

■ Coordination meetings

Coordination meetings with ERMA NZ staff and with MAF Biosecurity staff (including the Animal Welfare Group) are planned for August. We are also giving

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presentations for MAF Verification Agency as well as the Biosecurity and Policy Groups on the prescription animal remedy (PAR) policy implementation.

- The next **AVMAC** and **Industry Liaison Group** meetings will be held in Wellington on Thursday, 21 August 2003.

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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Recent events

- On 16 July 2003 the NZFSA held another **Consumers Forum** (which is designed to give consumers direct input into NZFSA activities). The major topic discussed was the way in which maximum residue limits (MRLs) are set in New Zealand. The purpose of the presentation was to inform consumers as to the assurance of safety that this process provides. John Reeve from the ACVM Group was one of the keynote speakers and covered the MRL setting process prior to the public consultation step.
- Debbie Morris recently addressed the New Zealand **Feed Manufacturers Association AGM**. Issues discussed included the development of the oral nutritional compounds standard (see page 7) and the recent audit of the system.
- The ACVM Group met with the **Taranaki Branch of the New Zealand Veterinary Association** to discuss the prescription animal remedy (PAR) operational policy development. The 22 July meeting was held in Stratford.
- Debbie Morris and Maree Zinzley (ACVM Operations Manager) addressed the **Agcarm AGM** on 24 July in Wellington.
- The ACVM Group has contacted all registrants of products used for **deer delevetting** to advise that any updates under the ACVM Act will be required to address the issue of potential residues, and that the current MRL is the default level in the food standard of 0.1ppm. For a number of years NZFSA and MAF business groups have discussed the need for the development of a code or practice to replace the deer delevetting regulations made under the Animal Remedies Act. There must be an approved code of practice in place under the ACVM Act prior to the end of the transition period on 2 July 2004 if the practice of delevetting is to continue.
- The ACVM Group has been in contact with the **bee industry** and affected marketers to remind them of the need to have products that were not covered by previous legislation, but that come under the ACVM Act, registered prior to 1 July 2004 to enable continued importation, manufacture, sale and use. We will write to other industries and marketers in the short term to remind them of this same requirement.
- The ACVM Group's response to submissions on the discussion document *Regulatory Control of Prescription Animal Remedies* is now available on the ACVM **website**. We also have new proposed changes to the GRAS list plus new and revised standards for the efficacy of some veterinary medicine products.

Fielddays activities



Paul Dansted of the ACVM Group on the NZFSA stand at 2003 Fielddays in Hamilton

The ACVM Group was represented on the NZFSA stand at the Hamilton Fielddays in June, but the main area of focus was on compliance activity in the field.

The aim of the visit was to:

- assess the marketplace in veterinary medicines and plant compounds
- confirm compliance of approved products with the conditions of their approval
- provide education to people marketing agricultural compounds who were unfamiliar with their obligations under the Agricultural Compounds and Veterinary Medicines Act 1997.

It was necessary for the Group to issue two prohibition notices to registrants at the Fielddays – one for a product requiring registration that was being marketed with a label bearing the registration number of a different registered product, the other for a range of products previously determined as requiring registration.

It was apparent that the main area of non-compliance with the Act was in the area of herbal and homeopathic veterinary medicines, with a high degree of compliance evident for the larger veterinary medicine and plant compound marketing companies.

The ACVM Group will investigate non-compliant products identified at the Fielddays over the following months and will consider how best to increase awareness within the herbal and homeopathic remedy marketplace of the requirements for veterinary medicines under the ACVM Act.

'Slice of life' audits – 2003/2004 year

The ACVM Group has agreed a programme outline with the Compliance and Investigation Group (CIG) for the current year for 'slice of life' audits. These audits are additional to any investigative work carried out by CIG.

Some of the areas that are to be covered (in no particular order of priority) are:

1. Veterinary compounding

A number of comments in the consultation on the draft prescription animal remedy (PAR) policy related to compounding by veterinarians. We need to find out what is being done and why, how important it is, and if there are any specific skills or standards that need development. The initial audit would be against the approved code of practice (Appendix 1 of the veterinarians' *Code of Professional Conduct*).

2. Vertebrate pest control (VPC)

It has been suggested that further controls on VPC substances are needed. The ACVM Group is developing standards in this area, so we need a substantial look at what is happening at present – of special interest is the use of anti-coagulant products by farmers.

3. Prescribing standard and approved code of practice

We need to look at compliance generally in this area to build an idea of the need for a regular programme.

4. Bee industry drug use

Exemptions in place under the ACVM Act are subject to compliance with certain criteria. Also, antibiotics are used in this industry without veterinary involvement, so we need to see what is being done and if there are any potential problems that need regulatory intervention.

5. Codes of practice for the use of PAR products by non-veterinarians in research, testing and teaching organisations

We need to confirm the level of

compliance with the approved codes of practice in this area.

6. Minor industry drug use

This is likely to be a series of smaller audits to look at what is happening with 'off label' use in fish, deer, emu, goats, horses, etc.

7. Pesticide use

This will be a check of what is happening in some horticultural areas with a special look at glyphosate and some of the older chemicals. It will also look at minor use crops to see how well the current system is working.

8. Trading of PAR products

When we have the standard in place, we want to check how well it is being used throughout the supply chain for PAR products.

9. Fertiliser code of practice

This will be a look at what is happening against this approved code.

10. Grooms code of practice

This will check for compliance (should

be fairly small) and may be combined with item 6.

11. Border

Late in the year we want to have another look at what is happening at the border with ACVM products as a follow-up to the previous audits in this area.

These audits are in addition to those already undertaken or programmed from the last year covering areas such as antibiotic use in the intensive industries, compliance at the border, and the use of human medicines by veterinarians.

The ACVM Group continues to run (via third party agencies) programmes for GMP approvals, HGP distributors and VPC approvals of users.

Any regular programmes that are identified as being required from the CIG audits and investigations will be done in accordance with the regulatory model as much as possible, where the bulk of the work is undertaken by third party agencies on a user pays/performance-based basis.

ERMA audit of ACVM registrations

On 17 June 2003 an ERMA NZ consultant undertook the annual audit of ACVM registrations. This consisted of 20 approvals made up of two cancelled products, five VPC licences and 13 general approvals. The application forms, secure storage of records and the public register were reviewed.

The outcome and findings were very positive. The review revealed that:

- 1. The decision making process being followed is consistent with the HSNO Act and associated documents.**
- 2. Appropriate application, registration, licensing and other forms are being used.**
- 3. The ACVM Group has carried out delegated powers and functions with reasonable due diligence and promptness.**
- 4. Records and confidential data are being kept secure.**

Purpose of withholding periods

Registrants are reminded that regulatory withholding periods (WHPs) are set by the ACVM Group purely to manage the risk of violative residues occurring in treated produce at the time of collection. It is not a tool to manage any other concerns the registrant may hold for the product (e.g. product quality).

A critical consideration in setting the WHP for plant compounds is the time that harvesting of treated crops must occur. The same is not true for veterinary medicines where the WHP for milk, egg and meat harvested for human consumption can be set at any point after residues fall below the allowable limit.

Consideration of good veterinary practice (GVP), good agricultural practice (GAP) and the desirability for the least WHP possible has meant that the periods requested by registrants for veterinary medicines are at or close to the time at which edible products are first eligible for human consumption.

Some registrants have elected WHPs significantly longer than necessary to manage the risk of residues. This has been accepted as being the registrant's prerogative in the past. However, the ACVM Act requires that conditions placed on product registrations (such as the withholding period) be sufficient to

manage risks but also impose least cost to the public. In consequence, where a conservative WHP has been requested despite the availability of data supporting a reduced time and the approval of the prolonged WHP is considered likely to impose a cost on the public, the ACVM Group may not approve it.

Registrants with data that support a shorter WHP are encouraged to apply for a reduction in the approved WHP, particularly if the current WHP is significantly longer than is necessary and where the additional time may lead to restrictions in GVP or GAP.

Australian workshops

Two workshops (to be hosted by Avcare and VMDA) will be held in Sydney and in Melbourne in late August/early September. They will be based on the programmes run in New Zealand in November last year, but will be updated with recent information.

There will be 'breakout sessions' for veterinary medicines and plant compounds in the afternoon. Keep a watch on the website if you are interested in attending.

Default withholding periods for veterinary medicines

Registrants are reminded that the default withholding periods applied to provisional registrations are now a recognised option for products fully registered under the ACVM Act. Although the preferred withholding periods remain those approved following assessment of a residue package, the ACVM Group recognises that it is not economically viable for registrants to produce a residue package for all potential food uses of a veterinary medicine, and that default withholding periods are useful in such circumstances.

Default withholding periods are necessarily conservative and have been agreed upon by the Animal Products and Dairy Groups of the NZFSA. Some historical registrations were approved with withholding periods that were not approved following assessment of residue data. Such periods are variable; however, most were set at 28 days.

Any historical products with a withholding period that was not approved as the result of data assessment or consideration of technical argument will be expected to change to the current default withholding period (e.g. 63 days horse meat). This change will be enforced when products are updated or an application is made to alter an already updated label.

Should registrants wish to supply data and/or technical argument to reduce the 'default' withholding period, they may be provided at the time of update. A separate application will not be required; however, the ACVM Group will charge the standard hourly rate (\$108.00 plus GST) for the time taken to complete the assessment.

The current default withholding periods are included as Appendix A in *ACVM Registration Information Requirements for Provisional Registration*. They will be included in the veterinary medicine residue standard at the next update.

Default milk withholding period for long-acting veterinary medicines

The ACVM Group no longer permits 'Do not use' statements in place of a withholding period (WHP) where no data or technical argument have been supplied to enable an assessed or allocated WHP to be approved where good agricultural practice (GAP) requires a WHP to be established. For short-acting veterinary medicines, the default milk withholding period of 35 days will apply in such circumstances. This withholding period was never intended for application to long-acting products.

Although the use of long-acting products with extended milk withholding periods in lactating animals producing milk for human consumption is not considered GAP, the use of such products may be GAP during the dry period. The continued application of 'Do not use' statements for these products is no longer considered consistent with the principles of good risk management.

The ACVM Group holds sufficient data to be confident that, regardless of the product type, violative milk residues will occur only while violative meat residues are present. However, insufficient data are held to enable a 'one fits all' default to be set for long-acting preparations with approved meat withholding periods longer than 35 days.

In consequence, the ACVM Group has adopted the following policy: For any long-acting product with an approved meat withholding period in excess of 35 days for which no milk residue data is supplied, the default milk withholding period approved will be the same period approved as the meat withholding period.

This change will be enforced when products are updated or an application is made to alter an already updated label. Should registrants wish to supply data and/or technical argument to reduce the 'default' withholding period, they may be provided at the time of update. A separate application will not be required; however, the ACVM Group will charge the standard hourly rate (\$108.00 plus GST) for the time taken to complete the assessment.

MRL UPDATE

The second MRL consultation round in 2003, which proposed a MRL for pymetrozine in lettuce and an exemption for 9,10-anthraquinone in grapes, started on 15 May and finished on 13 June.

The permission for pymetrozine in lettuce was gazetted on 17 July but submissions on the exemption for 9,10-anthraquinone are still being considered.

Compliance

There has been a big increase in the number of compliance incidents reported over the last quarter.

In general, it appears that most of those reported are for products that fall within the oral nutritional compound category. This has always been an area where marketers have confusion on what should or shouldn't require registration. It is timely to remind you that ingredients such as chondroitin and glucosamine require registration. This is in addition to shark cartilage and green lip mussel. However, it is not just the ingredients that determine whether a product requires registration or not.

A number of incidents concerning advertising and the claims that have been made have been reported. We can assure you that these complaints and all complaints are thoroughly investigated, and the offenders are advised of the appropriate action to rectify the non-compliance.

If your company is unsure about what you can or can't say in marketing your products, then we strongly suggest that you consult our assessment team. This will avoid complaints against your products.

The ACVM Group has been working closely with the Compliance and Investigation Group on breaches of the ACVM Act and advise that we will, if necessary, take further prosecution action.

PAR Class II conditions and label wording

As per section 28 of the ACVM Act, codes of practice may be approved by the Director-General as a risk management tool to control the use of any agricultural compound. Codes that have a sufficient degree of risk management to enable the use of Class II PARs by non-veterinarians when a veterinarian is not present at the time of administration have been approved.

The current PAR Class II condition reads as follows:

- The product must not be sold to any person other than a veterinarian or dealer.
- The product must not be administered except following a veterinary consultation.
- The product must be administered to an animal only by a veterinarian, or in the presence and under the control of a veterinarian, unless specified otherwise in the current approval.

The first two sentences of the condition are still applicable for PAR Class II veterinary medicines. However, in order to accommodate the use of this class of veterinary medicine within the bounds of a code of practice or under a set of operational instructions from a supervising veterinarian, the ACVM Group has modified the wording of the third sentence of this condition to read as follows:

- The product must be administered to an animal only by, in the presence of, or under the direct control of a veterinarian, unless specified otherwise in the current approval.

Where a PAR Class II condition is considered appropriate for a particular veterinary medicine but the risks associated with the product are such that they could be managed only by a veterinarian, the use of the medicine by a non-veterinarian when a veterinarian

is not present will be specifically contraindicated in the current approval.

Consequent to this rewording of the condition, the PAR Class II statement used on product labels must also change. Currently PAR Class II veterinary medicines have the following statement:

“For use only in the presence of a veterinarian”.

The ACVM Group proposes changing the mandatory statement to the following:

“For use only by, in the presence of, or under the direct control of a veterinarian”.

Comments are invited on the proposed statement and should be sent in writing to:

Jennie Yee, ACVM Group
New Zealand Food Safety Authority
PO Box 2835, WELLINGTON
Email: jennie.yee@nzfsa.govt.nz.

PAR Class I Label Statement

An error is present in the current version of the ACVM New Zealand Labelling Guide for Veterinary Medicines Requiring Registration with respect to the mandatory label statement required for Class I Prescription Animal Remedies.

The statement that is required is provided in section 3.2.6 and reads:

"Prescription Animal Remedy (P.A.R) Class I

For use only under the authority or prescription of a veterinarian".

The wording provided in section 2 of the annex is incorrect and should not be used. The labelling guide will be revised in the near future at which time the error will be rectified.

The ACVM Group apologises for any inconvenience this error may have caused.

Antibiotic resistance: Reporting on sales

We are collating the information that has been supplied for 2002 and, while the information is still in draft form and the support rationale is still being checked with the industries, we can advise that there appears to be an increase in sales in the region of 0.7% over last year. This is too small a difference to be of any significance.

Indications from the report are that no antibiotics of human health significance were sold for growth promotion purposes in the calendar year 2002 (although a recent 'slice of life' audit has shown that some were used in that way). There was a general trend in sales towards therapeutic use of products of greater significance – this was expected as treatment regimes were adjusted to minimise prophylactic treatment and with the removal of products like avoparcin. We are checking the figures with a number of groups and hope to publish the report shortly.

Proposed list of allowable levels of nutrients with known therapeutic uses

The ACVM Group has had continued compliance problems with oral nutritional compounds that contain substances that at certain levels can be considered nutrients and, at other levels, therapeutic substances. Most problematic was the 'neutraceutical' group that includes glucosamine, chondroitin sulphate, shark cartilage, deer velvet and green lipped mussel extract. Such products were being marketed as treatments for a range of diseases, predominantly arthritis and joint disease.

Under the ACVM Act any veterinary medicine making claims to treat or prevent diseases of pain and distress are registered and the claims assessed. In order to manage the claims being made for these products it was necessary to deal with these as therapeutic substances or non-nutritional such that all products

containing them at any level currently require registration. This policy was notified in the October 2002 *AgVetLink*.

It is recognised that at low levels some of these substances may have nutritional properties and their inclusion at those levels in veterinary medicines could be considered to be purely to achieve the provision of a 'normal' diet. The ACVM Group attempted in the past to accommodate this recognition by providing the opportunity for registrants to supply information to demonstrate the appropriate nutritional levels so that they could be included on the GRAS list. It is now recognised that the GRAS list is not the most appropriate tool to manage this issue.

In consequence, the ACVM Group intends to establish a list of allowable levels of nutrients with known

therapeutic uses in exempt oral nutritional compounds. The list will facilitate the inclusion of non-therapeutic levels of such substances in animal feeds including pet food so that, provided no therapeutic claims are made in relation to the inclusion of the substances, they will be considered exempt from the requirement for registration.

The details of the format and construction of the list are yet to be finalised. However, the ACVM Group will take the lead in setting the nutritional levels. An opportunity will be provided for set levels to be challenged, but such challenges will be considered only if supportable by data. Any veterinary medicine containing quantities of the listed substances in excess of the determined levels will continue to require registration.

2003/04 New Zealand Total Diet Survey

The 2003/04 New Zealand Total Diet Survey is underway. Collection of food samples commenced the week beginning 28 July 2003.

Additional resources committed to the survey have allowed a number of enhancements over the previous survey. These include:

- increasing the number of samples from 2440 in the 1997/98 survey to 4400;
- analysis of sodium and iron across all foods tested;
- for the arsenic, cadmium, iodine, iron, lead and sodium analyses and the multi-residue pesticide screen, all foods will be analysed as individual regional foods (i.e., there will be analytical results for each region over two seasons) or as individual brands (i.e., there will be analytical results for each of the four national

- brands over two seasons);
- dithiocarbamate fungicides (DTCs), mercury and selenium will also be analysed as individual regions or brands for the foods that are analysed (e.g. grains and cereals are not analysed for mercury or DTCs and margarine oil and salad dressing are not analysed for selenium);
- a mix of individual samples and some composite samples will be analysed using the acid herbicides screen.

The NZFSA has created a page on its website for the Total Diet Survey (www.nzfsa.govt.nz/science-technology/research-projects/total-diet-survey/index.htm). Quarterly raw data reports will be posted on the website and interested parties notified. The first quarterly report is expected to be released around mid November and the second report around mid March 2004.

Public consultation on ONC standard

Comments on the *Draft Standard for Oral Nutritional Compounds* are requested. It is available on the website (www.nzfsa.govt.nz/acvm/publications/discussion/standards-guidelines/) now.

Public discussion will close **15 September 2003**.

All comments should be sent to:
Chris Boland
ACVM Group
New Zealand Food
Safety Authority
PO Box 2835
WELLINGTON
Email: christopher.boland@nzfsa.govt.nz

Food residue coordination

Review of EU banned chemicals

The ACVM Group is currently reviewing the registration of a number of veterinary medicines that are still registered for use on food-producing animals in New Zealand, but have been banned in the European Union.

Principally, the anticoccidial drugs containing nitrofurans derivatives are under the spotlight. They have been banned in the EU because they are mutagenic and possibly carcinogenic. Their continued use in New Zealand is based on the fact that they are very rapidly metabolised in the animals for which they are licensed (pigs and poultry), no residues are likely in human foods and, where there is no exposure, the residues cannot harm consumers.

Already the drugs are not permitted for use in New Zealand on any food-producing animal that is used in the production of produce destined for the European market (because EU bans directly apply to countries supplying that market). While their use may well be able to be justified on scientific grounds, it is increasingly difficult to maintain current use. A restriction on use is likely to lead to problems for ostrich breeders who claim that there are no alternatives and there are animal welfare difficulties if coccidiosis takes hold of the birds.

All of these issues are to be dealt with in the review. Once the consultation has been undertaken internally and with MAF and ERMA NZ, we will confer with all of the interested and affected parties on the issues and options.

Accidental intramuscular administration of long-acting veterinary medicines

The nature of long-acting injectable products is such that intramuscular administration is likely to result in a prolonged period of residue persistence compared to subcutaneous administration. The consideration of intramuscular administration data for long-acting injectable products with subcutaneous administration claims only is now a mandatory and enforced requirement for any residue package assessed by the ACVM Group for such products. However, this requirement has not been consistently applied to residue assessments in the past.

In consequence, the ACVM Group has adopted the following policy:

For any injectable long-acting product intended for subcutaneous administration only and for which intramuscular residue data has not been assessed by the ACVM Group and factored into the calculation of the withholding period the following label statements will be required.

**“Ensure injection is subcutaneous.
Intramuscular injection will result in
prolonged residues.**

Where intramuscular injection may have occurred, animals producing meat and offal for human consumption must not be slaughtered within 91 days of the last treatment.”

Unless registrants of currently registered products can demonstrate that the approved withholding period includes consideration of accidental intramuscular data, this statement will be enforced when products are updated or an application is made to alter an already updated label.

Should registrants wish to supply data and/or technical argument to demonstrate that the statements are not required for any particular product or to reduce the ‘default’ withholding period of 91 days for accidental intramuscular injection, they may be provided at the time of update. A separate application will not be required; however, the ACVM Group will charge the standard hourly rate (\$108.00 plus GST) for the time taken to complete the assessment.

Annual fees

Invoices and accompanying product lists were sent out in July. We are now operating under the ACVM Act and would like to remind registrants that the due date for the payment of annual fees is **20 August 2003**. 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 obviously 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 2003;
- 50% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 October to 31 December 2003;
- 25% waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 January to 31 March 2004;
- No waiver for all products cancelled by registrant and accepted by the ACVM Group in the period 1 April to 30 June 2004.

Newly registered products

All 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:

- 75% annual fee payable for all veterinary medicine and plant compound products registered with the ACVM Group in the period 2 July to 30 September;
- 50% annual fee payable for all veterinary medicine and plant compound products registered with the ACVM Group in the period 1 October to 31 December 2003;
- 25% annual fee payable for all veterinary medicine and plant compound products registered with the ACVM Group in the period 1 January to 31 March 2004;
- No annual fee payable for all veterinary medicine and plant compound products registered with the ACVM Group in the period 1 April to 30 June 2004.

Equine products

We have received a number of queries from registrants of equine products with regards to the product being classified as FOOD for annual fees purposes. Because horses have the potential to go into the human or animal food chain, any equine products are classified as FOOD products under the ACVM Act.

Queries

If you have any annual fee or account queries, please contact:

Sarah Smyth
Coordinator (Business Services)
ACVM Group
PO Box 2835
WELLINGTON
Tel: 04 463 2553
Fax: 04 463 2566
Email: sarah.smyth@nzfsa.govt.nz

Adverse event reports (AERs)

The ACVM Group would like to take this opportunity to remind you that, as one of the ongoing obligations of the registrant, an annual summary of adverse events for each veterinary medicine/plant compound product must be reported to the ACVM Group at the time the registration is renewed.

These should be sent in with payment of the annual fees.

The summary does not need to contain all the details of the adverse event set out in the Registration Requirements documents, but should include a brief description of the event type. If no adverse events have been reported to the registrant, the summary should state 'nil'.

These reports should be sent to:

ACVM Group
New Zealand Food
Safety Authority
PO Box 2835
WELLINGTON
Tel: 04 463 2550
Fax: 04 463 2566
Email:
acvm@nzfsa.govt.nz

REMINDER TO APPROVED CREDITORS

All approved creditors are required to pay their invoices by the 20th of the month following the invoice or risk losing their approved creditor status.

International scene

Development of a Memorandum of Understanding with Australia

The ACVM Group is developing a Memorandum of Understanding (MoU) on good manufacturing practice (GMP) with the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The harmonisation of regulatory control on agricultural compounds and veterinary medicines is excluded from the Trans-Tasman Mutual Recognition Agreement (MRA). However, in spite of the exclusion, for a number of years the ACVM Group and the APVMA have operated an informal agreement to recognise the competence of each other's manufacturers of veterinary medicines, and their compliance with GMP standards. This arrangement has been possible because of the development of a close relationship between the two regulatory authorities and regular visits during which issues of mutual interest are addressed.

Now that the APVMA has fully implemented its GMP inspection programme and is moving to adopt the single GMP standard used by New Zealand and the EC under the MRA for GMP, it is appropriate that the arrangements in place with Australia should be formalised within a MoU.

Progress:

There is agreement in principle from both parties. The ACVM Group has developed a draft MoU which is with the APVMA for comment.

Labelling Guide requirements

The ACVM Group's requirements for the label content of veterinary medicines and plant compounds are stated in the respective Labelling Guides. Every effort is made by the ACVM Group to ensure the label content of registered agricultural compounds complies with the requirements of the Labelling Guide during the approval process.

However, registrants are reminded that ultimately it is their responsibility, and not the ACVM Group's, to ensure all product labels comply with the Guide. Where the ACVM Group or registrant detects non-compliance with the Labelling Guide for any registered product, it is expected that labels be brought into compliance at the next reprint, regardless of any prior approval.

Technical Agreement for Official Batch Release – Veterinary Vaccines

The ACVM Group is collaborating with the Veterinary Medicines Directorate (VMD), United Kingdom, to enter into a technical agreement under which the ACVM Group would perform Quality Assurance/Quality Control (QA/QC) inspections for official batch release of veterinary vaccines on behalf of the VMD.

The process for the release of each batch of veterinary vaccine onto the market by a regulatory authority in the European Community is called 'official batch release'. All the European regulatory authorities, with the exception of the VMD, enable batch release of veterinary vaccines through sampling and testing provisions in the European Directives. The VMD operates a different system in the UK under which a system of QA/QC inspections of manufacturers of veterinary vaccines, carried out annually, replaces batch sampling and testing. These annual visits by UK inspectors for QA/QC inspections are expensive for New Zealand manufacturers exporting vaccines to the UK.

The ACVM Group and the VMD have reached agreement in principle that it is possible for New Zealand inspectors to perform QA/QC inspections of veterinary vaccine manufacturers' quality systems on behalf of the VMD after an appropriate transitional period for mutual confidence of both regulators. It is agreed that the 2003 cycle of inspections will be carried out jointly and collaboratively by both regulatory authorities. It is also agreed that the next cycle of inspections (due in March 2004) will be carried out by the New Zealand inspector and observed by the VMD inspector. Successful completion of this programme will form the basis of a technical agreement between the VMD and the ACVM Group for the conduct of future QA/QC inspections by the ACVM Group on behalf of the VMD.

Progress:

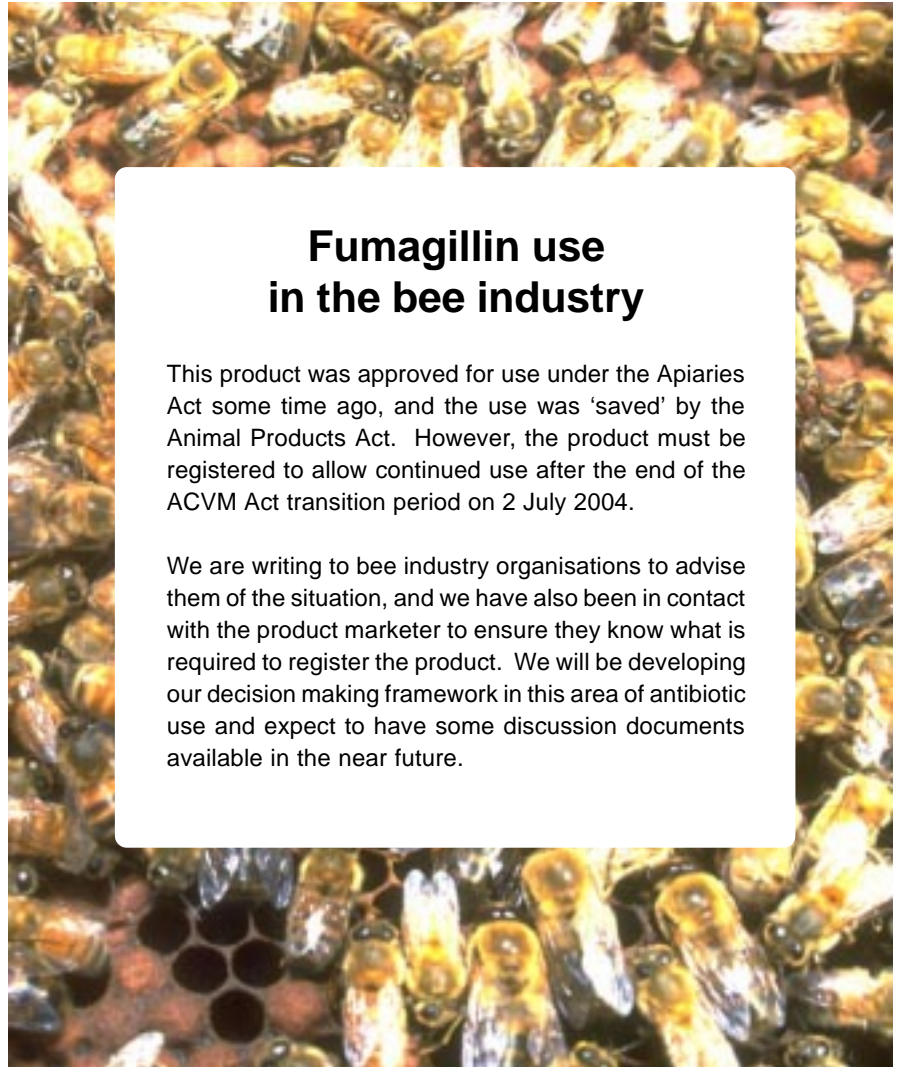
The 2003 cycle of inspections has been completed successfully, and the ACVM Group and VMD are both confident that the programme should be completed on schedule in April 2004.

OECD Risk Reduction Steering Group workshop on minor (off-label) uses of pesticides

This working group set up under the OECD Working Group on Pesticides (which in turn is a part of the OECD Environment Programme) intends to hold a one-day workshop on how regulatory agencies should deal with the issue of the use of pesticides on minor crops (for which no registration is likely), in the context of risk reduction. New Zealand is represented at the Working Group on Pesticides by the NZFSA, and the Ministry for the Environment represents New Zealand on the Risk Reduction Steering Group.

The workshop is to be held in Canberra on 4 November, and it is planned for New Zealand (NZFSA) to present its modus operandi for dealing with this off-label issue during the day. The New Zealand approach is to allow registration of uses of pesticides by third parties (such as the growers needing the pesticides in their crop production) who are required to generate the residues data to enable maximum residue limits (MRLs) to be set to ensure the safety and legality of the food produced.

NZFSA involves the pesticide registrants in the process and, to date, they have gone on to formally register the 'new' use for their products. This is a transparent process and quite different from that generally used by overseas regulators who usually issue permits for off-label uses without formally making any changes to the registration status of the pesticides.



Fumagillin use in the bee industry

This product was approved for use under the Apiaries Act some time ago, and the use was 'saved' by the Animal Products Act. However, the product must be registered to allow continued use after the end of the ACVM Act transition period on 2 July 2004.

We are writing to bee industry organisations to advise them of the situation, and we have also been in contact with the product marketer to ensure they know what is required to register the product. We will be developing our decision making framework in this area of antibiotic use and expect to have some discussion documents available in the near future.

Limited period registrations

The ACVM Group is expecting a significant number of 'updates' of products in the coming 12 months, and we are aware that there is still significant development being under-taken on the wording of conditions under the ACVM Act. Refinements are being made in light of investigations, audits, and registrant feedback as implementation occurs.

For this reason, the Group is considering making registrations valid for a limited period rather than being indefinite.

The period we are considering is three to five years (although this will be considered case by case if there is a specific reason), with no costs to the registrant for updates if no changes are required.

Staff update

Claire Truscott heading overseas

We are about to farewell one of our Advisors on her OE. Claire Truscott's last day with the ACVM Group is 15 August. We will miss her – Claire has been the life and soul entertainer of the Group and always manages to lift the spirits when things are a bit dull and gloomy. We wish her well in her endeavours.

Claire is currently training her replacement, Kylie Edwards (see her profile below). After 15 August, Kylie will be responsible for accounts formerly managed by Claire.

Kylie Edwards, Advisor (Operations)



Although Kylie was born in Tauranga, she has spent the majority of her life in Wellington and is a Wellingtonian through and through.

Kylie attended Victoria University for five years and has just completed a Bachelor of Commerce Degree in Commercial Law and Marketing. She has also studied towards a Bachelor of Tourism and Services Management Degree. As well as studying, Kylie spent the last two years working at the Wellington Racing Club as the Marquee Co-ordinator for the Wellington Cup Carnival.

Kylie is a keen netballer and enjoys going to the gym (when motivation kicks in). She loves socialising and travelling – last year she spent two months in Peniscola on the coast of Spain before travelling around the rest of Europe.

Kylie is excited about the opportunity she has been given to work at NZFSA and is looking forward to being part of the ACVM Group.

Richard Dickson - Lowe



Richard is currently undertaking a BSc Microbiology (Medical) degree at Surrey University. As a part of this four year 'sandwich' course he has come to the ACVM Group for his third year, which is his industrial placement year.

Richard has a disturbing obsession for sport and loves to travel– hence the reason why he came to New Zealand. Hopefully, with the Kiwis being as amicable and freakishly sport-loving as they are, he should have a fine 12 months in and around this most southern part of the hemisphere.

REMINDER

When lodging an application for registration or variation to an existing registration, ensure that you use the correct version of the Registration and Product Datasheet.

The ACVM website (www.nzfsa.govt.nz/acvm/publications/forms/reg.htm) has the latest version for your convenience.

Operational update

The ACVM Group has had an influx of applications, mainly for updates to the ACVM Act.

During the period 1 June to 18 July, there have been five A1 (new active ingredient) type applications submitted to the ACVM Group – three for veterinary medicines and two for plant compounds.

Some veterinary medicine applicants may be experiencing delays as queues have been building in this area. We are in the process of employing part-time staff to assist, but in the interim you should contact Maree Zinzley or your advisor if you have any queries about the progress of your application.