



AgVetLink

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From the Director

With the deadline looming for registrants to update labels to meet HSNO requirements (page 2), 'updating' has been a top priority since the last issue of AgVetLink. We have employed extra, temporary staff to help avoid delays. Several new permanent staff members have also joined the Group. Rebecca Fisher, our new plants advisor, is profiled on page 6.

Work on an agreement with our Australian counterpart to align registration procedures (as much as practical) should lead to access to a wider range of agricultural compounds and veterinary medicines that might not be available in New Zealand because the cost of registration would be prohibitive, given the size of the market in this country (page 4).

An investigation into the use of a plant pesticide as an animal spray, which resulted in residues in a shipment of beef to Korea, highlights the need to use agricultural compounds and veterinary medicines correctly (page 6).



Debbie Morris
Director
Approvals and
ACVM Group

AgVetLink is produced at least six times annually by the New Zealand Food Safety Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of agricultural compounds and veterinary medicines. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

General enquiries: Mary Alexander

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

Phone: 04 463 2550, fax: 04 463 2566, email: mary.alexander@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.

GENERAL INTEREST

Updating Labels for HSNO Requirements

The ACVM Group requires electronic copies and hard copies of a company's marketed label(s), inclusive of all the HSNO controls.

When a company has updated its label for HSNO requirements but has made no changes to the ACVM risk areas of the label, we have been accepting and returning a stamped, signed copy of the label at no charge. It is important to note that the ACVM Group is **not** approving the label in this instance. Therefore, registrants may use the HSNO updated label without first submitting it to the ACVM Group for acceptance.

However, if a registrant makes any label changes relating to our risk areas, he/she must submit the appropriate application to us and gain approval before placing a product into the marketplace.

We are reminding registrants of the above because we understand they are required to have HSNO-compliant labels for new stock (not stock in trade) entering the marketplace by 1 July 2006. It is also our understanding that stock in trade that is not HSNO-compliant at 1 July 2006 will be allowed to be used until 1 July 2007. If you are unsure of your obligations in this area, it is

recommended you contact ERMA New Zealand.

The ACVM Group anticipates that it will receive a significant number of HSNO-compliant labels in the lead up (particularly in June 2006) to the 1 July 2006 deadline. This will have an impact on resources within the Group. Therefore, there are likely to be delays in returning stamped, signed copies of the label to registrants. This should have no impact on labelling new stock with HSNO controls, although if the ACVM Group identifies labels of stock in trade with unapproved changes to our risk areas, then compliance action may ensue.

Annual Fees

The first part of the annual fee process has been completed. The majority of product lists, which were sent to all registrants in March, were checked, signed and returned promptly. We are currently updating our system to reflect any necessary amendments, changes or cancellations indicated on the returned product lists.

In mid-May the annual fee invoices for the period 1 July 2006 to 30 June 2007 will be sent. **Payment is due by 1 July 2006.**

Late payment procedure

1. If payment is not received **prior** to 1 July 2006, you will receive a 10% penalty invoice under section 18 of the Ministry of Agriculture and Fisheries (Restructuring) Act 1995.
2. In addition to the 10% penalty invoice, your product(s) will be prohibited from importation and/or manufacture under section 82 of the Agricultural Compounds and Veterinary Medicines Act 1997. The prohibition notice will be removed only after payment on all outstanding debts and any penalty fees has been received.

If you have any queries contact:
Hine Van Leeuwen
Advisor (Business Services)
Approvals and ACVM Group
PO Box 2835, Wellington
Tel: 04 463 2553
Fax: 04 463 2566
Email: hine.vanleeuwen@nzfsa.govt.nz

GENERAL INTEREST

Applying to Have a Feed Additive Registered as Generally Recognised as Safe (GRAS)

The GRAS Register for Oral Nutritional Compounds

The Approvals and ACVM Group maintains a GRAS register for feed additives* for use in oral nutritional compounds in order to avoid the repeated assessment of safety data for substances that are considered safe for this use and of no regulatory interest in terms of the ACVM Act. This allows regulatory interest to focus on substances that are of concern, or substances where there is insufficient evidence to determine their safety as feed additives.

The criteria for inclusion on GRAS registers are conservative so that substances are classified as GRAS only where they have a proven history of safety when used appropriately (i.e. in accordance with Good Manufacturing and Good Feeding Practices).

It must be noted that a substance declared by NZFSA to be GRAS is not necessarily recognised as safe when used for some purpose other than that specified on the GRAS register. The GRAS declaration only applies to regulation under the ACVM legislation, and the substance could still pose risks that are managed under other New Zealand legislation, such as the Hazardous Substances and New Organisms Act 1996 or the Food Act 1981.

GRAS applications

In order to obtain GRAS listing of a substance, applicants must provide a completed application form **including documented evidence of international GRAS listings**. The international references currently recognised by the Approvals and ACVM Group are the US FDA and EU GRAS lists. It is noted that there are a number of other similar lists maintained by these authorities that are not GRAS lists and, although these are useful as supporting evidence, they must be accompanied by other

documented evidence proving the appropriateness of GRAS status for the substance.

If the applicant is unable to provide references to recognised international GRAS registers, he/she must provide a rationale to support GRAS status of the additive. This rationale, with documented evidence, must clearly demonstrate:

- that the proposed GRAS substance is well known, in common use and has a history of safety in the context of use;
- the low potential for and impact of residues in food produced from exposed animals;
- that risks to the safety and welfare of animals treated or exposed will not be compromised. **This must include relevant toxicity data to enable us to determine that the proposed addition can be considered safe for its target animals;**
- that risks to international trade from the likely substance use(s) are unlikely.

In addition, a number of commonly encountered feed additives are naturally

present in food, but when added to an oral nutritional compound fall under the definition of a feed additive. In this situation, it would be useful to provide a comparison (backed up by documented evidence) between levels present naturally in food and levels resulting from the addition of the substance as a feed additive.

GRAS applications that are not clearly structured and accompanied by the relevant and necessary documented evidence will not be sent to the consultation group for consideration and will be returned to the applicant.

Please see the NZFSA website for further GRAS classification information (<http://www.nzfsa.govt.nz/acvm/subject/registration/gras.htm>).

Alternatively, contact the GRAS administrator by email: toxassessor@nzfsa.govt.nz

*A feed additive is defined as a non-nutrient substance added to a food of animals to improve the preservation, digestion, colour, palatability, texture or nutritive value of food.

Maximum Residue Limit (MRL) Update

The first amendment of 2006 is due for public consultation. The proposed amendment contains eight new MRLs and six exemptions, and is likely to be gazetted within the next few months, when the consolidation of the 2006 standard will be issued.

The MRL consultation documents are available on the website at: <http://www.nzfsa.govt.nz/policy-law/consultation/index.htm>

GENERAL INTEREST

ERMA New Zealand and ACVM Group Operational Meeting

The ACVM Group and ERMA New Zealand hold monthly meetings to discuss any operational or parallel matters. The last meeting, which was held on 11 April 2006, covered the following:

- The memorandum of understanding (MoU) concerning the interrelationship between ERMA and NZFSA has been completed and is ready for Rob Forlong and Andrew McKenzie to sign off. Once this has been completed, we will work with ERMA to update the Operational Agreement for Managing the Parallel Decision Making Process and the Vertebrate Toxic Agent MoU.
- Peter Dawson presented a report on the February 2006 meeting of the National Drugs and Poisons Schedule Committee (NDPSC). Of interest for the ACVM Group was the section reporting on a meeting held with the Chemical Standards team of the Australian Safety and Compensation Council (formerly NOHSC). This meeting discussed a workplan under the Trans-Tasman Mutual Recognition Agreement Co-operation Programme with particular initiatives to harmonise labelling requirements.
- The members were informed that the OECD is setting up a working group in regards to sharing information, putting in place some rules governing use of data, and protecting confidential data. (Some countries do not have confidentiality agreements.)

The next operational meeting will be held on 12 May 2006.

Trans-Tasman Co-operation Project

The ACVM Group recently met with the Australian Pesticides and Veterinary Medicines Authority (APVMA) to progress the development of a memorandum of understanding (MoU) that will align (as far as practical) the registration processes in both countries. The intention is to facilitate access to a wider range of veterinary medicines and plant compounds by:

- ensuring that registration requirements are only what are necessary and sufficient to assess the safety and appropriateness of trade name products; and
- making the requirements in both countries as close to the same as is practical, given the differences in circumstances.

As part of the MoU, the ACVM Group and APVMA are developing a five year workplan to progress the alignment of particular standards or processes. Already the Authorities have established an understanding in regard to recognition of each other's approvals for manufacturers of veterinary medicines. This in itself simplifies the registration process in some cases in regard to manufacturing dossiers required for an application.

Good Manufacturing Practice (GMP) approval is not required at this stage for plant compounds, but a GMP approval condition has been imposed on vertebrate toxic agent products that contain active ingredients such as 1080 and cyanide.

Another exercise that has commenced is a side-by-side comparison of the assessments of registrations. Five representative veterinary medicine products that have been registered in both countries in the last two years will be selected, and the registration processes will be compared to identify similarities and differences. The outcome of the comparison will be used to assist alignment of both standards/requirements and processes for veterinary medicines. A second exercise will be carried out on agricultural chemical products.

The scope of the alignment is comprehensive and is intended to lead to access to a wider range of veterinary medicines and plant compounds that might not be available in New Zealand because the cost of registration would be prohibitive, given the size of the market in this country.

Agricultural Compounds and Veterinary Medicines Act Amendment

An introduction copy of the Bill to amend the Agricultural Compounds and Veterinary Medicines Act will be ready to go the Cabinet Legislation Committee on 4 May 2006.

GENERAL INTEREST

International Meetings Update

Codex Committee on Pesticide Residues

Dave Lunn, Programme Manager (Residues-Plants), Export Standards Group, and Warren Hughes, Programme Manager (ACVM and Non-Food Assessment), attended the Codex Committee on Pesticide Residues (CCPR) held in Fortaleza, Brazil, between 1 and 8 April 2006.

Topics of interest included how national enforcement agencies would interpret the measurement of uncertainty associated with the residue results from laboratories (e.g. $x \text{ mg/kg} \pm y\%$), and the draft paper outlining criteria for any country or body to object to the advancement of maximum residue limits (MRLs) through CCPR.

The Chair of the Committee led an interesting discussion on the relevancy of CCPR when a number of countries do not recognise Codex MRLs for imported primary produce. A paper by the chair on this topic will be presented at next year's CCPR. It should be noted that New Zealand does recognise Codex MRLs for imported food.

OECD Pesticides Programme

John Reeve, Principal Advisor (Toxicology), was the New Zealand delegate to the OECD Pesticides Programme meetings that were held in Paris from 13-17 February. At these meetings, the main business of relevance to NZFSA is the harmonisation of support data requirements for the registration of pesticides. They also promote the use of work sharing arrangements to make more efficient use of government resources in the assessment of data submitted to regulators. Outcomes of note are:

1. The warm appreciation of New Zealand's organisation and facilitation of the meetings of the Registration Steering Group and Risk Reduction Steering Group that were held in Wellington in November/December 2005, and acknowledgement of the great success of the meetings (they attracted the largest ever attendance for these groups).
2. New Zealand has become involved in a global work sharing arrangement that involves at least six countries that will assess the data for a new product in 2007, and the drafting of guidelines and guidance documents relating to the production and assessment of residue data submitted in support of pesticide registration.
3. New Zealand is also involved in a working group that is charged with resolving issues surrounding the use of commercially confidential information in work sharing arrangements. Currently, different countries have differing laws relating to the protection of this data.
4. New Zealand has managed to get the OECD interested in reviewing the whole paradigm of current toxicology data requirements with a view to consider new ways of generating robust toxicity data (some of which do not use animals in testing), and to ensure that all data required are actually useful and not duplicating information obtained in other required tests. This has the potential to reduce the amount of data required to be submitted, and this will reduce the regulatory resources that currently have to be put in to assessing this data.

Codex Committee on Residues of Veterinary Drugs in Foods

The next (16th) Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) is to take place in Cancun, Mexico from 8-12 May.

The restructuring of NZFSA in July 2005 has led to a review of the delegations to some of the Codex meetings, and it has been agreed that NZFSA would get better use of John Reeve's toxicological expertise if he moved to taking responsibility for the contaminants part of the Codex Committee on Food Additives and Contaminants – particularly as this Committee is splitting and the contaminants will be dealt with by their own Committee. Accordingly, Neil Kennington, Senior Adviser (Animals), will take over as New Zealand's second delegate to the CCRVDF, beginning with this upcoming meeting.

Apart from the consideration of new maximum residue limits (MRLs) for colistin, erythromycin, flumequine, ractopamine and triclabendazole, the meeting will consider redrafts of the New Zealand-sponsored paper on draft guidelines for the establishment of a regulatory programme for the control of veterinary drug residues, and the French-sponsored draft risk management methodologies relating to residues of veterinary drugs in foods.

The meeting will also consider draft proposals as to what to do about residues of veterinary drugs without current acceptable daily intakes (ADIs) or Codex MRLs. A working group (which included New Zealand) has drafted these proposals in an attempt to resolve issues arising from the deletion of ADIs and the subsequent removal of Codex MRLs for 'orphaned' drugs that do not have toxicology packages that meet current regulatory requirements. These drugs are the ones that are used in third world countries that cannot afford the modern drugs, and even though no issues regarding potential human health risks have arisen from residues, these drugs are no longer acceptable in trade because of the technicality of not having anybody who is prepared to pay for an updated toxicology data package to be produced.

GENERAL INTEREST

Residue Investigation

Endosulfan, a horticultural pesticide, was found in a sample of New Zealand beef shipped to South Korea in late 2005. Korea, along with the meat company, provided valuable assistance that allowed rapid and conclusive traceback to determine the source of the residue.

Only one farm was implicated. The residue was from the non-approved use of a plant pesticide as an animal spray. Although detected at levels below those internationally allowed in a

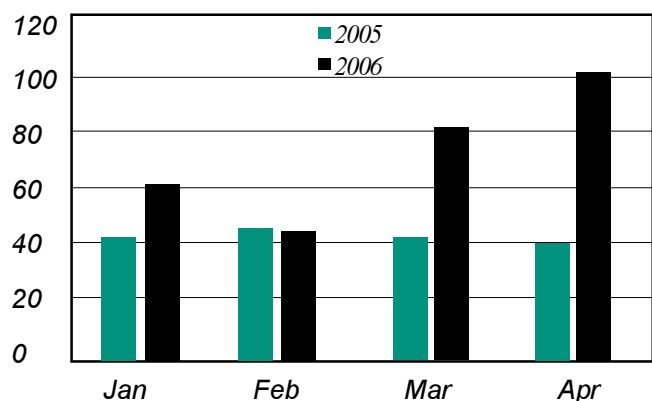
variety of fruit and vegetables for which the spray is approved (and not considered in itself to present a health risk to consumers), its use in such a way is a breach of regulations. Legal action has been taken.

This incident illustrates that alleged careless action by just one individual can have severe consequences not just for neighbours but for a whole food production and export industry.

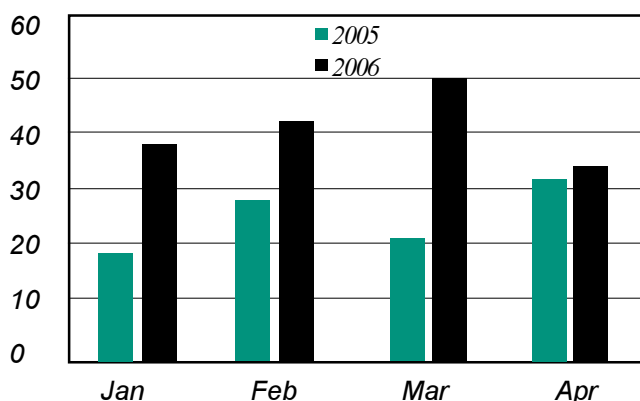
Applications Update

The ACVM Group received significant number of review and evaluation (R&E) applications for the first third of this year (the 2005 figures are provided for comparison). This trend is a continuation from last year. The average number of working days to process applications ranges from 8 days for C variation and provisional applications to 33 days for A1 and A2 applications.

R&E applications received: veterinary medicines



R&E applications received: plant compounds



**New Plants Advisor
Rebecca Fisher**

"Originally from Katikati, in the Bay of Plenty, I went to Palmerston North to attend Massey University. In 2004 I completed a BSc in horticultural science and spent the next year working for Massey in their Plant Growth Unit.

This year I moved to Wellington and I have been enjoying the 'big city' lifestyle. I have been working for the Approvals and ACVM Group since March. I'm really enjoying working with everyone in the Group and would like to thank them for their warm and friendly welcome."

NOTE TO ALL REGISTRANTS:

When requesting a product cancellation, please include the last batch number and approximate amount of stock in trade.

PLANT COMPOUNDS

Review: Diazinon Products

Because of concern over the formation of toxic degradation products, namely O,S-Tepp and S,S-Tepp, over time, Diazinon emulsifiable concentrate products have been reviewed.

The APVMA performed a similar review recently and their report, which gives a background of the issues associated with these types of product, is available at <http://www.apvma.gov.au/chemrev/diazinon.shtml>.

As a result of our review, the new requirements placed on current and new products of this type are:

1. The expiry specifications for the end-use formulation must include the following:
 - The O,S-TEPP content determined shall not be higher than $[0.22 \times \text{diazinon content (as per label claim)/specific gravity}] \text{ mg/kg}$, as indicated appropriate in the FAO Specification

15/EC/S(1988) for diazinon emulsifiable concentrates.

- The S,S-TEPP content determined shall not be higher than $[2.8 \times \text{diazinon content (as per label claim)/specific gravity}] \text{ mg/kg}$, as indicated appropriate in the FAO Specification 15/EC/S(1988) for diazinon emulsifiable concentrates
- Water content (maximum) 2 g/kg. Above this limit the formation of O,S-Tepp and S,S-Tepp are known to be favoured.

2. The release specifications for the end-use formulation must include a maximum water content of 1 g/kg or less.

3. The following statements must be included on the label:

“The toxicity of this diazinon product may increase markedly over time. DO NOT use this product if it is out-of-

date”, “Store in tightly closed original containers under cool, dry, dark conditions” and “Do not allow water to enter this container. Do not rinse the lid with water”.

4. All products and technical grade active must include an appropriate level of stabiliser, usually ethoxylated soyabean oil.

5. Non-permeable packaging such as lined metal containers should be used. Although this is not compulsory at present, the consequence of using a more permeable packaging will be a shorter shelf life.

6. Instead of a shelf life statement, an actual expiry date relating to the shelf life will be added to all of the products with the assigned shelf life reflecting the data provided, specifications and packaging used.

VETERINARY MEDICINES

Registration Liaison Committee (RLC) Meeting

Chris Boland and Maree Zinzley attended the RLC meeting in March. In addition to the operational /business as usual items on the agenda, there was a discussion about APVMA's relocation from Barton to North Symonston, which will take place later this year. CEO Joe Smith assured members that special efforts will be made to ensure a smooth transition with little disruption for staff and stakeholders.

In 2005 all the APVMA Consultative Committees were reviewed, including membership of the RLC. Joe Smith advised members at the March meeting that the APVMA is not recommending any changes to this Committee at this time. He believes it is a necessary group in regards to changes and the drivers that impact on these changes between APVMA, States/Territory representatives, and New Zealand.

Prescription Animal Remedy (PAR) Trader Audits

The ACVM Group has been working with AgriQuality in regards to the inspections of premises for those wholesale traders involved in the selling and supply of PAR products. We received seven applications from wholesalers and, of these, four have been inspected. The remaining inspections will take place over May and June 2006, or when the companies advise us that their premises are ready.

The ACVM Standard for Unregistered Veterinary Medicines Requiring Veterinary Overview will be available on the website in May (www.nzfsa.govt.nz/acvm).

Animal Feeds

For several months now the ACVM Group has been working with the New Zealand Standards and Policy Group of NZFSA to prepare a public discussion document covering the regulatory control of animal feeds. It should be noted that 'animal feeds' include all oral nutritional compounds for all kinds and classes of animals, including dog and cat foods as well as stock feeds.

Schedule 4 requirements

As you will already know, animal feeds and feed supplements are exempt from registration under the ACVM Act, but the products and their manufacture must comply with the minimum standards set out in Schedule 4 of the ACVM Regulations 2001. This means that they must comply with:

- minimum labelling requirements;
- 'fit for purpose' criteria;
- restriction to general health claims related to a nutritional benefit only; and
- restrictions on the inclusion of therapeutic or pharmacological substances and only feed additives that are 'generally regarded as safe' (GRAS).

Codes of practice

The ACVM Group has not been prescriptive about what in detail must be complied with or how compliance must be achieved. In addition, we have not imposed verification requirements, leaving the industry to establish best practices in their own codes of practice (one already approved for the New Zealand Feed Manufacturers Association and one being developed by the New Zealand Petfood Manufacturers Association).

Compliance

The ACVM Group investigates suspicions and allegation of non-compliance, and expects to see evidence of taking due care to comply with the Regulations or prosecutions may be taken. The Group's experience is that, in general, there is a high level of

compliance and very few 'adverse events' related to non-compliant animal feeds. This has given the Group a reasonable level of confidence that risks are being managed adequately.

Different regulatory control

One main reason for the review is that the dog and cat food sector of the industry is regulated under the Animal Products Act 1999, which sets quite different regulatory obligations with a higher level of regulatory intervention because of the animal products content (meat and offal) in their products.

This difference in regulatory control has raised questions such as:

- What is the appropriate level of regulatory control and intervention for animal feeds?
- Are there grounds for different levels of control for different kinds of animal feeds or should they all be regulated in the same way?

The ACVM Group (and NZFSA as a whole) considers that there are grounds for variable levels of control based on the potential risks posed by different kinds of products. However, it also considers that the level of control should be no more than what is necessary and sufficient to manage the relevant risks.

Discussion document

The public discussion document, which should be released for comment in May, will be available on the website (www.nzfsa.govt.nz/acvm). It proposes a regulatory scheme that tries to strike a balance between assuring adequate mitigation of risks and the inevitable cost of complying with any regulatory requirements. It considers the relative risk profiles of different kinds of products and suggests the kind of regulatory intervention that would be appropriate.

Comments on the proposals would be appreciated.

Exporting Trade Name Products to the EU

This is a reminder to veterinary medicine registrants and New Zealand manufacturers. If your marketing plans change and you export your products to the EU, you must notify the ACVM Group to ensure that the manufacturing premises are subject to yearly GMP audits, in accordance with the EU/NZ Mutual Recognition Agreement.

The ACVM Group provides assurances only for what we can verify. Failure to notify us so we can adjust the audit frequency to meet European requirements may jeopardise your export plans and may even jeopardise the GMP approval itself.