



# AgVetLink

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## In this issue...

### GENERAL INTEREST

From the Director .....	1
New ACVM fees and charges .....	2
ACVM fee for border clearance .....	2
Application quality .....	2
Staff update .....	3
Workload update .....	3
AVMAC and ILG meetings .....	4

### AGRI-CHEMICALS

Food Residue Surveillance Programme	4
OECD work on pesticides .....	5

### COMPLIANCE

Audit of research, testing and teaching organisations .....	6
Border clearance .....	6
Mystery Creek Fielddays .....	7
Incorrect labelling .....	7

### REGULATORY CHANGES

AGCARM meetings .....	8
-----------------------	---

### VETERINARY MEDICINES

VICH update .....	9
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## From the Director

*Changes to application fees, annual fees and border clearance fees will take effect on 1 July 2008. See page 2 for details.*

*Also on page 2 is a reminder about how to put an application together to make it easier for us to assess. To make things easier for you, we are in the process of rewriting our information requirements documents and application forms. Any comments or suggestions you have would be appreciated. Send them to Kate Hartley (see contact details below) ASAP.*

*This month's OECD meeting on pesticides covered many areas of interest to New Zealand registrants, from spray drift to labelling (page 5).*

*Compliance activities are highlighted in this issue – formal audits, border clearance, and our annual 'education exercise' at Fielddays (pages 6-7).*



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.

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

## GENERAL INTEREST

### New ACVM Fees and Charges

New fees and charges come into force from 1 July 2008.

#### Application fees

- The hourly rate for application assessment increases from **\$121.50** (incl GST) per hour to **\$149.62** (incl GST) per hour.
- The pre-screen fee for applications increases from **\$364.50** (incl GST) to **\$545.60** (incl GST).

A revised estimate of fees and charges will be available on the website.

#### Annual fees

The annual fee will increase to **\$545.62** (incl GST) for every 12 month period.

However, to enable registrations to get into the new annual fee due date cycle, this year registrants will be charged for the period 1 July 2008 - 30 September 2009 (15 months). This equates to a fee of **\$682.03** (incl GST).

#### Adjustments

For applications received and paid for prior to 1 July 2008 (at the old

rates), NZFSA will record the hours done at the new rate and invoice applicants for any material difference.

#### Product lists

The initial product lists of the ACVM annual fee process for the 2008/2009 financial year have already been sent out. If you have not received your initial product list or you would like to discuss the new fees and charges, please contact:

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### Application Quality

Just a reminder -- the presentation of an application makes a considerable difference when it is reviewed. The estimated fees are based on a 'good' application, so if applications take more time they will incur increased charges. Advice in the information requirements documents can be used as a guide.

Key areas for improvement:

- Make sure supporting documents and data volumes are indexed and preferably organised logically.
- Provide summary documents where there are several studies or papers in a submission. Be sure to address the key points in an application.
- In electronic submissions provide indexes and ensure file names give an indication as to the content.
- Provide all relevant data. This is particularly important for new actives and uses. If there is doubt that data is needed, indicate the availability in the application letter.
- Data package reviews can be useful to assist in locating key pieces of information. They also act as a checklist for the applicant.
- List supporting documents in the covering letter.

### Border Clearance Fee

*The fee for clearance of imported product at the border will increase from 1 July 2008. This fee is enforced by and payable to MAF Biosecurity border staff. The new fee will be \$100 (incl GST) per hour for an inspector to give authority or clearance of the imported product, which is the same as under the Biosecurity Act 1993.*

*Note: if NZFSA is required to get involved in product clearance, the time is charged to the importer at \$149.62 per hour.*

## GENERAL INTEREST

### Staff Update

#### Going, going, gone...

**Eve Menzies**, Advisor (Operations), will be leaving in July for the wine country, Blenheim, where she will be joining her partner who has taken up a position with his family law practice. We wish her well and hope she'll have some good hints for us on Marlborough wines. Her replacement is **Caroline Strack** who introduces herself at right.

**Simon Ellery**, who was an ACVM Advisor before moving to the food side of the Approvals and ACVM Group, will be taking 12 months' leave of absence from early July to embark on his OE. Simon is going to take on the role of a 'Roady' as he supports his partner in the music field. We wish him well on his travels.



#### **Caroline Strack Advisor (Operations)**

*"I am originally from Christchurch. I moved to Wellington 5 years ago to study at Victoria University and graduated last year with a double degree in Marketing and Art History.*

*After graduating, I worked in Lower Hutt at The New Dowse Art Gallery for about 9 months. I quickly got tired of the commute to the Hutt every day and decided to find a job right here in town. I have been working with the ACVM Group since the end of April.*

*Outside of work I love shopping, hanging out with friends and looking at expensive art works, dreaming of the day that I can afford them..."*

### Workload Update

Application numbers have remained steady this year after a record peak of applications from September - December 2007.

The agricultural chemical applications this year are up by 33% for the first six months of 2008, largely due to a spike of administrative applications in February. Veterinary medicine applications are also up by nearly a third, but the increased workload resulted from technical variations and new registrations over April/May. Currently there are no major hold-ups in processing applications, and we are generally maintaining timeframes.

As the financial year draws to a close it is an opportunity to take stock of the numbers of new products being registered. The totals in the box below cover the current ACVM financial year except for the last week of June. The overall application activity is up, and this trend is also reflected in the numbers of innovative and generic products receiving approval.

The veterinary medicine generic approvals are overstated due to the inclusion of 46 B3 applications. These are mainly animal feeds containing additives and other compounds that do not comply with the exemption from registration. With these removed from the picture, the numbers of new registrations for agricultural chemicals and veterinary medicines in New Zealand are similar.

new product approvals					
Application type	Ag chems	VTAs	Vet meds	Total 2007-2008	Total 2006 - 2007
A - new (active, use, formulation type)	18	1	17	36	20
B - similar	51	1	95	147	70
Total 2007-8	69	2	112		
Total 2006-7	28	3	59		

## GENERAL INTEREST

### AVMAC and ILG meetings

The Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC) and the Industry Liaison Group (ILG) met this month. Topics covered included the following:

- release of information in regard to Official Information Act queries
- purpose of the Food Bill – a complete review of all foods imported or sold in New Zealand
- ACVM Act implementation – it was noted that the intention is to ensure that the legal requirements are met and only approve operating plans when needed.
- ACVM Act fundamentals – definitions etc
- 'slice of life' checks – some are scheduled and some are reactive
- reported MRL breaches – NZFSA takes action in each and every instance and tries to make sure it doesn't happen again
- antimicrobial resistance management update
- next priorities in regulatory change:
  - oral nutritional compounds – policy discussion document within the next two months
  - information requirements – next two-three months.

Check the website for complete details.

### ACVM Act Regulatory Changes

#### Reminder to Stakeholders:

The deadline for submissions on the regulatory changes discussion document ([www.nzfsa.govt.nz/consultation](http://www.nzfsa.govt.nz/consultation)) is 11 July 2008.

Please take time to read the document and provide comment on it. Feedback is very helpful to the ACVM Group.

## Food Residue Surveillance Programme (FRSP)

### Season 1 and 2 (07-08) results

The FRSP for the 07-08 period has now been completed. The results from the first season indicated a number of non-compliances. The results from the second season had a lower level of non-compliance (see table below).

The non-compliance residues were all from New Zealand produce. The relevant industry sector and growers were

advised of these results. Growers were reminded of their responsibilities where off-label use was involved to ensure they manage the residue situation.

NZFSA is currently working on the next round of the FRSP. It is anticipated that there will be sampling of imported produce and a revisit of crops where non-compliant results were found in the past.

Season	Produce	# samples	Non-compliances	Chemical(s)
1	Strawberries	36	4	Cyprodinil, Fludioxinil
	Capsicum	24	3	Iprodione, Protham, Methamidophos
	Fancy lettuce	24	2	Permethrin
	Mushrooms	24	1	Prochloraz
2	Fancy lettuce	24	1	Acephate
	Capsicum	24	1	Iprodione
	Mushrooms	24	1	Prochloraz
	Courgettes	24	0	
	Strawberries	12	0	

## AGRI-CHEMICALS

### OECD Work on Pesticides

Warren Hughes, Programme Manager (Approvals and ACVM Standards), attended several meetings on the OECD's (Organisation for Economic Co-operation and Development) work on pesticides in early June in Paris.

These meetings covered a range of areas including minor use, joint reviews, harmonisation of information requirements, risk reduction and spray drift. Progress was given on a number of guidance documents in the areas of toxicology, ecotoxicity, and environmental fate. Some highlights from the meeting follow.

#### Residue chemistry

An update on the work of the Expert Group on Residue Chemistry was presented. Of interest is the latest work on guidelines on residue trial protocols, including number of trials required for a crop/compound combination.

The latter was of particular interest as various countries differ significantly over the number of trials. The Expert Group believes the minimum number of trials should be three for a crop/compound combination.

Other areas of work include extrapolating residue data within a crop grouping and extrapolation of residue data from different geographical locations.

The ACVM Group will consider these matters once they are adopted to decide if we need to update our information requirements to align with OECD guidance and guideline documents.

#### Minor crops/minor uses

A meeting of the Expert Group on Minor Crops/Minor Uses was held. New Zealand is a member of this group which has been tasked to explore options to facilitate minor crops/minor uses in countries.

Discussions covered:

- collating baseline information on what resources, such as databases on data sets, are available
- examining liability and data protection issues
- sharing data among regulators and industry
- defining minor crops/minor uses.

#### Joint reviews for new chemistry

Over the past few years OECD countries have been working on joint reviews for new chemistry. Various regulators collaborate with each other to review parts of a global data package submitted by a chemical company. The intentions are:

- to reduce regulatory timeframes (and hence reduce costs) and
- to have the new chemistry approved in countries approximately at the same time.

A workshop on the lessons learned from the first few joint reviews is planned for December. Part of this workshop is to develop some guidelines for chemical companies and regulators on procedures for managing joint reviews. At this stage New Zealand has not participated in any joint reviews.

#### Information technology

Current information technology work involves development of templates (XML format) for chemical companies to use for reporting on studies and the ability

of regulators to use these templates for developing monographs. In addition, work is being undertaken to allow for electronic data exchange among regulators and between regulators and industry.

#### Spray drift

A one day seminar was held on spray drift and mechanisms to reduce spray drift. A number of countries gave presentations on their requirements to reduce spray drift. A common theme among the presentations was the use of spray buffer zones.

An outcome from the seminar was a proposal for countries:

- to work together more closely on exchanging information on spray drift incidents and
- to encourage new technologies such as spray nozzles to reduce spray drift.

#### Labelling

An interesting presentation was made by the US Environmental Protection Agency on some labelling proposals. These included:

- submission of electronic labels rather than hard copies to assist in the regulatory assessment process and
- a website for end users to obtain information on directions and precautions for a product rather than obtaining this information from the label affixed to the container.

This would mean the information on the physical label could be reduced significantly and any changes to directions or precautions would be more up-to-date as this information is available on the website.

## COMPLIANCE

### Audit of Research, Testing and Teaching Organisations

In 2006, the NZFSA Compliance and Investigation Group carried out a 'slice of life' review of six research, testing and teaching organisations (RTTOs) in New Zealand to check compliance with ACVM legislation. (The 2006 review findings are available on the website at [www.nzfsa.govt.nz/acvm/subject/compliance/review-rttos](http://www.nzfsa.govt.nz/acvm/subject/compliance/review-rttos).)

Two of the locations visited were deemed to be compliant with the ACVM legislation. Four locations visited were not fully compliant with the legislation. These locations were audited in 2007, at the request of the Approvals and ACVM Group Director, to determine the effectiveness of any corrective actions taken after the 2006 visit.

Aims of the 2007 audit were to:

- provide relevant information on

how RTTOs are now working within the ACVM legislation

- ascertain current levels of awareness and compliance to approved codes of practice and standards
- assess the usefulness of the approved codes of practice and standards in developing operational procedures that ensure the conditions of veterinary medicine registration or exemption are met.

#### Emphasis of audit

Subsequent to findings in recent ACVM audits special emphasis was placed on:

- purchasing and storing
- prescribing, dispensing and using
- disposing of surplus

agricultural compounds, veterinary medicines and unregistered veterinary and human medicines requiring veterinary overview,

within the RTTOs' spheres of activity. Other areas, that included all of the above, were record keeping, training and auditing.

#### Results

The full summary is available on the website. In brief, the 2007 ACVM audits found a positive and proactive approach by the organisations to comply with requirements. All four locations have made considerable effort to respond adequately to the recommendations made in the 2006 review. They are well underway to becoming self-regulating in the area of the use of prescription medicines for the direct management of animals used in research, testing or teaching.

There were no serious non-compliances or non-compliances raised in the 2007 audit.

### Border Inspections

**NZFSA is confirming the scope of an agricultural compound border survey to be done by MAF Biosecurity in the near future (probably August and September).**

**For air cargo and express freight, one out of ten imports of all goods coming into New Zealand under agricultural compound tariff codes will be inspected. This includes both registered and exempt from registration products.**

**Please note that there may be some delays in releasing goods because of the increased activity during the survey period.**

#### Recommendation for NZFSA Ongoing audits in the ACVM RTTO Domain

The fact that four out of six locations visited in the 2006 ACVM RTTO review were deemed to be non-compliant and warranted a re-audit in 2007 may indicate the trend of compliance at RTTOs not as yet visited by NZFSA. Ongoing ACVM audits in the RTTO domain appear to be warranted.

#### *NZFSA response:*

An ongoing programme of audits of RTTOs will be arranged, especially to confirm compliance with recent changes to the ACVM Act which will require them to have approved operating plans.

## COMPLIANCE

### Mystery Creek Fielddays

Every year ACVM staff attend Fielddays at Mystery Creek, Hamilton, to educate people about the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) and to confirm compliance with its requirements.

To ensure compliance, the ACVM Group begins by providing education to companies who are unfamiliar with their obligations under the ACVM Act and are marketing ACVM products. Brochures are handed out to interested parties. (A copy can be downloaded from our website.)

Earlier this month, the 2008 Mystery Creek Fielddays were held and



*Taking a break from talking with exhibitors, ACVM team member Angela Waddell enjoys a 'close encounter' with an Angora goat at Fielddays.*

ACVM staff who attended were pleased to see a high degree of compliance displayed, especially by the larger veterinary medicine and agricultural chemical marketing companies.

Last year we saw a reduction in the number of non-compliances and this year was much the same.

There were a few minor non-compliance issues, mainly relating to the use of the incorrect registration statement being displayed on labels. ACVM staff will be working with these companies to ensure that this is rectified.

Members of the ACVM Group enjoyed meeting many industry people behind product marketing and helping them to become more aware of their responsibilities under the Act. Staff reported that it was a very worthwhile exercise.

### Investigations

In general, compliance with requirements of the ACVM Act has been improving.

However, NZFSA is actively investigating a number of suspected breaches of the Act relating to importations of unregistered products.

### Incorrect Labelling

Recent GMP audits have identified a number of products still being sold with label registration statements referring to the Animal Remedies and Pesticides Acts. Distribution of such product has been stopped.

The deadline for updating labels to the ACVM Act was 1 July 2007.

**USING OUTDATED REGISTRATION STATEMENTS IS ILLEGAL.**

## REGULATORY CHANGES

### AGCARM Meetings

*Meetings of the AGCARM subcommittees were held 10 June 2008 to clarify and discuss the proposed ACVM regulatory changes (see consultation document on the website). It was noted that proposed regulations will apply to all ACVM products (exempt and registered). A brief summary of the discussions follows.*

#### **Crop Protection Subcommittee Manufacturing**

For the most part, it was going to be business as usual in regard to manufacturing because the changes were primarily transferring existing requirements in ACVM standards into regulations. However, there were proposals for some fundamental changes in the areas of information transfer and own use. In particular, the proposed obligations on third parties were discussed.

#### **Clarification of the definition of 'responsible manufacturer'**

The registrant stated in the manufacturing specification would be responsible for overall quality control and product release and, therefore, should be considered the responsible manufacturer. Only the responsible manufacturer would be put on the public register.

#### **Overseas manufacturers**

The New Zealand registrant or agent would be held responsible for complying with the proposed ACVM (Manufacturing of Agricultural Compounds) Regulations, so registrants should have systems in place to have confidence in any overseas manufacturers contracted.

#### **Animal Health Subcommittee Clarification of operating plans**

The term 'operating plan' refers to approval under section 28 and would be used in a number of circumstances. Once the requirement for an operating plan is prescribed in the regulations, the ACVM Group will prepare guidance for each industry sector in regard to the terms they are already using.

#### **Approval of active ingredient (AI) manufacturers**

There was some confusion because the public discussion document was asking if AI manufacturers should be approved and the subcommittee was under the impression that AI manufacturers were already being approved as part of registration. The ACVM Group confirmed that it did not require official approval of AI manufacturers but had identified international trends and concerns that could lead to such a requirement.

#### **Labelling**

The reasons for labelling requirements being transferred from the guidelines on advertising and labelling into the regulations on manufacturing were discussed and accepted as reasonable and appropriate.

#### **Information transfer**

The subcommittee wanted clarification of the concept of primary message, and expressed concern that the requirement to include warnings in the primary message could cause considerable difficulty and uncertainty if there was no clear guidance as to the scope and detail of warning that should be included. The ACVM Group took note of this and agreed that it would have to develop adequate guidance in this area.

#### **Promoting off-label uses**

Both subcommittees noted that the most likely source of reliable information about the likely consequences of off-label use would be the registrant, who is currently prevented from promoting the product for off-label uses. They were advised that this was one of the reasons why information transfer regulations are being proposed. NZFSA would like to provide a safe and legal context in which any party, including the registrant, can disseminate information that would be helpful for users.

#### **Timeframe**

Both subcommittees asked about the timeframe for the regulations. They were advised that there was a window of opportunity to make regulations before the end of the year, but the elections could jeopardise this and the regulations might not be made until mid 2009.

#### **Restricted access policy for veterinary medicines**

After the proposals for regulations were discussed, the animal health subcommittee discussed the proposed restricted access regime for veterinary medicines. It was noted that the work on the restriction categories has progressed and resulted in the current proposal, ie unrestricted and restricted (in 3 groups). Developing the rules for grouping particular products was the next stage in the process. In the meantime, joint ACVM Group, Veterinary Council of New Zealand (VCNZ) and New Zealand Veterinary Association workshops would be held for veterinarians and registrants as soon as VCNZ developed guidance to veterinarians on product groups.

## VETERINARY MEDICINES

### VICH update

#### Background

VICH, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, is a programme aimed at harmonising technical requirements for veterinary product registration. It was officially launched in Paris in April 1996.

The organisation brings together the regulatory authorities and representatives from the USA, Japan, the EU, Australia/New Zealand and Canada. The USA, Japan and EU are principal members, while Australia/New Zealand and Canada have observer

status. Observer members participate in the work of VICH, but do not vote at VICH meetings.

#### Guidelines

VICH produces guidelines that cover topics in product quality, efficacy, safety, environmental safety and pharmacovigilance. There are specific guidelines for anthelmintics and biological products such as vaccines. Guidelines are developed by a rigorous process of initial drafting by an expert working group, public consultation and review by the VICH Steering Committee. Experts from Australia and New Zealand

participate in several of the expert working groups.

#### New Zealand endorsement

In the past New Zealand has endorsed the finalised VICH guidelines and accepted them as alternatives to New Zealand registration requirements in the appropriate areas.

Several guidelines are now ready for discussion/endorsement at the next AVMAC meeting (28 August). **Any comments you have should be sent to us before this date** (email Emma.Miles-Buckler@nzfsa.govt.nz).

**Guidelines revised with no material changes from the existing version, so we will request AVMAC endorsement:**

- GL3 Stability testing (1) New drug substances and products
- GL10 Impurities in new veterinary drug substances
- GL11 Impurities in new veterinary medicinal products
- GL28 Studies to evaluate the safety of residues of veterinary drugs in human food - carcinogenicity testing

**Guidelines signed off by the VICH Steering Committee but there is no record of consideration by AVMAC.**

**These will be for discussion and possible endorsement at the August AVMAC meeting:**

- GL38 Environmental impact assessment for veterinary medicinal products - phase II
- GL27 Guidance for pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance
- GL36 Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI
- GL37 Studies to evaluate the safety of residues of veterinary drugs in human foods: repeat dose chronic toxicity testing
- GL39 Specifications: test procedures and acceptance criteria for new veterinary drug substances and new medicinal products
- GL40 Specifications: test procedures and acceptance criteria for new biotechnological/biological veterinary medicinal products

**Guidelines at Step 4 that are being consulted on at present:**

- GL43 Target animal safety for pharmaceuticals
- GL44 Target animal safety for veterinary live and inactivated vaccines
- GL45 Quality: bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products

The text of all of the guidelines can be found on the VICH website at <http://www.vichsec.org/>