



AgVetLink

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**please respond to
the request for
contact information
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From the Director

In this issue we announce the review of regulatory control of ACVM products (page 2). We will be producing discussion papers and would appreciate your input into the proposed changes to help NZFSA adjust its regulatory control to be as efficient and effective as possible from a whole of government perspective.

AgVetLink will be the main vehicle used to update you on the review and other changes, so please ensure that the right people in your organisation are receiving (and reading!) this publication. See page 7 for details about updating your contacts.

The staff update this issue (page 6) includes a notice of upcoming vacancies for veterinarians. Expressions of interest are welcome.

The interim results of the Animal Feeds Review are presented on page 7. Our thanks to all those who made submissions.



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

Review of Regulatory Control

Background

NZFSa has begun a review of its policies for the administration of the Agricultural Compounds and Veterinary Medicines Act 1997. The purpose of this review is to update its operational policies to ensure that the implementation of the ACVM Act manages the risks posed by the use of agricultural compounds and veterinary medicines while remaining within the powers and scope of the Act. It is also to ensure that the implementation is consistent with the principles and objectives of NZFSa and other regulatory authorities such as Biosecurity New Zealand, ERMA New Zealand, the Ministry of Health and the Department of Labour.

There is an amendment to the ACVM Act that is in Select Committee. The public consultation period for the Amendment Bill closed 23 February and

the Select Committee should begin considering the Bill in March.

While the amendment includes provisions that will affect the purpose of the Act, such as introducing public health as a relevant risk, the operational policies being reviewed do not directly relate to the provisions of the Amendment Bill. They relate to the interpretation of existing provisions. These include:

- the definition of an agricultural compound;
- the scope of products that are included under that definition;
- the definition of the relevant risk areas; and
- the thresholds and criteria for determining whether or not a risk is acceptable.

Policies

Interpretations for these areas were

formulated into operational policies via public consultation when the ACVM Act was passed but before it came into effect (because of the delay in the commencement of the hazardous substances provisions of the Hazardous Substances and New Organisms [HSNO] Act 1996). At that time, it was uncertain what the operational policies of the Environmental Risk Management Authority (ERMA) would be and how the two regulatory regimes would complement each other to achieve comprehensive regulatory control of veterinary medicines and products used in the agricultural and horticulture sectors.

Predictions were made about the future regulatory environment. Operational policies that would be appropriate to guide the administration of the ACVM Act through this formative period were promulgated. These have been the foundation for decisions as to what products were considered to be agricultural compounds and what would constitute an unacceptable risk that needed to be managed. The principle applied was that there should be no more regulatory intervention, using the full range of statutes, than was necessary to provide adequate management of risks posed by the importation, manufacture, sale and use of agricultural compounds and veterinary medicines.

Risk management gaps

Since the operational policies were initially formulated, the implications and effects of the interface between the ACVM and HSNO Acts have become more obvious. Risk management gaps have appeared as a result of:

- the differences between placing controls on substances because of the presence of hazards under the HSNO regime and imposing conditions on trade name products to manage certain risks under the ACVM regime;
- the differences in the focus of the two Acts (trade in primary produce,

Pending Files

Because it has been taking some companies an unreasonably long time to supply basic information, the ACVM Group has decided to change the way 'pending/hold files' are managed.

We are developing a system to manage this facility on a monthly basis, and timeframes will be put in place for various outstanding matters. For example, an audit of pending files shows that many appear to be waiting for ERMA approvals. We will discuss the situation with ERMA to ascertain if the applications for ERMA approval are being made and timeframes. If the ERMA application has not been made, we will set in place a process for cancellation of the application.

These timeframes will be announced in *AgVetLink* and will be communicated through letters of request for information.

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agricultural security, animal welfare and residues in food under the ACVM Act, and health and safety of people and the environment under the HSNO Act); and

- ACVM risks that must be managed when there are no substances with a hazard classification that would prompt regulatory control under the HSNO Act.

Expanded focus

In addition, in the same period, Government has consolidated the regulatory control of food and food-related products, and placed the responsibility for it with NZFSA. In addition to commercial food production, this control includes home grown produce and recreational collection of wild foods. Therefore, the area of interest of the ACVM Group of NZFSA relative to home garden products and possibly products used for initial processing of primary produce has expanded.

Issues have also arisen in regard to the interface between the ACVM Act and the Animal Products and Food Acts. While risks to food may occur because of the use of chemicals, that use may or may not be relevant to the definition of an agricultural compound, e.g. the use of disinfectants in pre-slaughter facilities.

Because of these clarifications or changes in the regulatory environment, the ACVM Group has made ad hoc changes in its operational policies over the last few years to cater for the revised focus.

Comprehensive review

This current review of the policy base is intended to be comprehensive, restating all the changes that have been made since the interpretation of the ACVM Act was first considered. NZFSA considers that it is essential to re-establish a sound operational policy basis for regulatory control of

agricultural compounds and veterinary medicines to gain the full benefit from the amendment to the ACVM Act, and to get agreement from interested and affected parties as to a reasonable interpretation of the Act to ensure its administration will be fair, transparent and predictable.

It is intended to address the review in a step-by-step process to build up a comprehensive policy foundation for the administration of the ACVM Act. Initially reviews will be carried out within the ACVM Group with consultation with other NZFSA business groups. However, it is anticipated that the interpretations and policy proposals will be fundamental, requiring extensive external consultation.

Public consultation

The ACVM Group will ask for advice from external experts, and position papers and proposals will be prepared for industry and public consideration. It is expected that the interpretation and policy are going to have a significant impact on many regulated parties, making it likely that Government approval for consultation will be necessary.

Two areas of interpretation and policy areas for review have been identified:

- definition of 'agricultural compound' and other crucial terms
- definition of relevant risk areas and the thresholds at which intervention is warranted.

Definition of terms

The following terms have been identified as being crucial to the administration of the ACVM Act and the interface between that Act and other Acts administered by NZFSA:

- agricultural compound (veterinary medicine)
- animal
- direct management
- harvest (and an equivalent term for

the collection of animal produce from live animals)

- pest
- processing.

Definition of relevant risk areas

Exactly what is meant by risks to trade in primary produce, animal welfare and agricultural security will be reviewed; and new thresholds that recognise the crucial role NZFSA plays as the primary 'hands on' regulatory agency for the importation, manufacture sale and use of agricultural compound trade name products will be set.

Public health risks area

It is likely that the amendment of the Act will introduce a new public health risks area. This is not intended to detract from or duplicate the public health activities of ERMA, the Ministry of Health or the Department of Labour.

It is intended to fill the gaps in the present regulatory arrangements to ensure that issues such as antibiotic resistance and the use of agricultural compounds and veterinary medicines to enhance public health objectives can be addressed. It is also intended to ensure that there is adequate mandate to carry out effective approval and compliance activities.

Risk management

Once the new policy foundation has been agreed upon, NZFSA will consider how it will use the new regulatory provisions that may be available as a result of the amendment to the Act to bring the risks posed by agricultural compounds down to an acceptable level and to encourage sustainable and responsible use of such products.

Readers are advised to watch *AgVetLink* for notification of discussion papers and to participate in those discussions to help NZFSA adjust its regulatory control to be as efficient and effective as possible from a whole of government regulatory control perspective.

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Annual Fees

The first phase of the ACVM annual fee process for the 2007/2008 financial year will commence in March 2007. At this time you will be sent a list of your organisation's products that are ACVM registered.

Required of registrants

1. Ensure that all products have been listed and categorised correctly.
2. Sign the list, noting any cancellations, amendments or changes on the product list. When requesting a cancellation, include the last batch number and approximate amount of stock in trade. You will be contacted by an ACVM Advisor (Operations) if the indicated change requires an application to be submitted.
3. Post or fax the completed product list. Contact details are listed below.

When the second phase of the process begins in May 2007, you will be sent an invoice for your annual fees. Payment for this will be due by **1 July 2007**.

Annual fee charges (per product)

Food Product: \$405.50+GST
Non-Food Product: \$335.56+GST

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Regulatory Control Alignment

Progress is being made on aligning the regulatory control of agricultural compounds and veterinary medicines in Australia and New Zealand. While the alignment was being progressed initially by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and NZFSA, at the Alignment Steering Group meeting in December, ERMA NZ agreed to be an active participant in the work. This has created the opportunity to align on a country to country basis because the collective areas of responsibility of NZFSA and ERMA more closely parallel those of APVMA.

A work plan has been agreed to by all three Authorities. It is divided into two projects:

1. alignment of standards and requirements
2. alignment of approval processes and related matters.

The first step in project one is to develop a first order comparison of the documents that describe or set the standards and requirements of the three Authorities. With this in hand, each of the requirements areas can be compared in detail to identify similarities and differences. Working parties will develop proposals to resolve differences to either eliminate them or to establish equivalence. The requirements areas are:

- chemistry and manufacturing
- public health
- occupational safety and health
- environmental protection
- crop and animal safety, including animal welfare
- efficacy
- biosecurity/agricultural security
- trade
- labelling.

While the overall alignment programme will run for five years, the Authorities have set a goal to align the regulatory systems as much as is practical by 2010.

From NZFSA's perspective, its alignment with ERMA NZ will be as important an outcome as the larger Australian/New Zealand alignment. It should facilitate a seamless regulatory environment that is effective in managing the risks posed by agricultural compounds and veterinary medicines and, at the same time, simplify the bureaucracy for regulated parties. Fortunately, much of the work for NZFSA will parallel the work it is already doing in reviewing its operational policies for the administration of the ACVM Act (see article on page 2).

ACVM Amendment Bill

Submissions to Select Committee on the Agricultural Compounds and Veterinary Medicines Amendment Bill have closed. NZFSA anticipates that Select Committee hearings will commence in March. If the Bill proceeds to plan, we expect it to be passed by July.

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Applications

Applications are showing a steady trend upwards following a low in early 2005 (see tables). The indications are activity will be strong in 2007.

The 'ACVM Registration' category in the tables represents the updating of product registrations to the ACVM Act. Following the transition of registrations there has been a large increase in some variations and administrative applications. In part, the administrative application increase was expected and reflects the renewal of registrations on a three-yearly cycle. It is probable increased awareness of registration requirements has led to more formulation/manufacturing and administrative variations being submitted.

There has been a large increase in new generic plant compound registrations in the last two years. In addition, there are more new product registrations including significant new actives and formulation types. The indications are that this trend is likely to extend into the near future.

Veterinary Medicines

Application Type	2004	2005	2006
A1 - New active	5	8	11
A2 - Known active	6	7	16
ACVM Registration	768	74	20
B1 - Identical	5	5	12
B2 - Similar	52	45	64
B3 - Spec requirements	50	24	29
C1 - Formulation	13	53	51
C2 - Manufacturing	129	165	218
C3 - Shelf life	69	80	94
C4 - Target host	4	2	3
C5 - Pest/disease	9	6	11
C6 - Dose/rate	5	7	4
C7 - Admin method	2	2	3
C8 - WHP	1	3	4
C9 - Admin	90	161	412
Provisional	11	12	18
Research Approval	29	34	31
Total	1248	688	1001

Vertebrate Toxic Agents

Application Type	2004	2005	2006
A1 - New active	0	3	0
A2 - Known active	0	0	1
ACVM Registration	22	18	3
B2 - Similar	2	1	2
C1 - Formulation	0	0	4
C2 - Manufacturing	4	1	6
C3 - Shelf life	2	1	4
C4 - Target host	0	0	1
C7 - Admin method	0	1	1
C9 - Admin	8	7	9
C10- Reassessment	0	8	0
Provisional	2	6	3
Total	40	46	34

Plant Compounds

Application Type	2004	2005	2006
A1 - New active	4	7	10
A2 - Known active	8	7	13
ACVM Registration	409	47	10
B1 - Identical	19	3	5
B2 - Similar	39	78	114
C1 - Formulation	11	28	52
C2 - Manufacturing	43	49	73
C3 - Shelf life	27	28	37
C4 - Target host	10	22	18
C5 - Pest/disease	3	9	14
C6 - Dose/rate	2	8	9
C7 - Admin method	0	5	3
C8 - WHP	1	1	0
C9 - Admin	74	77	212
Provisional	35	32	45
Research Approval	7	11	4
Total	692	412	619

Review of Application Processes

In an effort to reduce paperwork, time and costs, the Group is reviewing its application processes. Administrative changes and minor technical changes are likely to become simpler.

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Amendment to the ACVM Act

Proposals for change to the ACVM Act were the subject of public consultation 18 months ago. Most of the proposals were designed to improve the efficiency of administration of the Act and to ensure that there were sufficient, clear statutory powers to achieve the intent of the Act.

As mentioned on page 4, Select Committee will soon begin to consider the ACVM Act Amendment Bill and submissions received. Select Committee will be considering, among other things, such matters as:

- introducing a relevant public health risk area into the purpose of the Act to ensure that issues such as antibiotic resistance and the use of agricultural compounds to enhance the health and health status of people in New Zealand can be addressed effectively;
- simplifying declarations at the border so that they can be made valid without recourse to a Notary Public;
- introducing two new mechanisms to regulate agricultural compounds that do not have the characteristics of trade name product that should be registered;
- introducing a power to set standards, via a transparent and predictable process, to make it clear what is expected of persons and systems in regard to statutory obligations and that can be used to assess the appropriateness of codes of practice; and
- introducing powers to suspend registration in the face of serious non-compliance and the recall of product if necessary to address an immediate threat of harm.

The Select Committee will also be considering the introduction of the following new offences:

- concerning importing or manufacturing practices that are in contravention of the Act;
- withholding information;
- increasing the severity of providing false information;
- concerning the new mechanism for regulatory control mentioned above; and
- concerning non-compliant activities while registrations are suspended or during a product recall or after a registration or other approval has been revoked.

It is anticipated that Select Committee deliberations will progress relatively smoothly and the Bill will be reported back to Parliament and possibly passed by the third quarter of this year.

Staff Update – Musical Chairs

Helen Simpson and Emma Miles-Butler (correct name?)

Helen Simpson, Executive Assistant to Director Debbie Morris, will assume responsibilities in the HR and website areas in March. The new Executive Assistant, Emma Miles-Butler, has just been appointed and will be profiled in the next *AgVetLink*.

Alice Palmer and Mary Alexander

As part of the Group's commitment to multiskilling, Alice Palmer, who is an Advisor (ACVM and Non-Food Products), will be seconded to the Food Service, Sale and Imports section of the Group for three months. Her ACVM role will be filled by Mary Alexander, who is the Group's ACVM and Non-Food Products Coordinator. A contractor will be hired to cover for Mary during this period.

Chris Scott

Chris Scott, who is also an Advisor (ACVM and Non-Food Products), will leave the Group in June for an OE and new career direction. Chris began working with the Group part time as a university student and has been a valued full-time employee since graduation. He will be missed, not only for his excellent contribution to the work of the Group but also for his participation in the Group's social life!

Jennie Moran

Jennie Moran has been on maternity leave for the past year and has decided to tender her resignation from NZFSA. Jennie started as a Veterinary Technical Advisor with the ACVM Group in 2001. Over that time she has made a significant contribution to the Group and will be missed by all. We are sure that, like us, you wish Jennie all the best for her new direction in life.

Lucy Johnston

Continuing with this theme, Lucy Johnston will be going on maternity leave in the middle of this year. This will be her first child and we extend our congratulations and best wishes to Lucy and her husband.

Positions Available

With the above changes, the Approvals and ACVM Group will be advertising in the near future for a replacement for Jennie and a fixed term contract position to cover for Lucy while she is on maternity leave. For further information on these upcoming vacancies, contact Maree Zinzley, Programme Manager (Operations) (phone 04 894 2564 or email maree.zinzley@nzfsa.govt.nz).

Interim Outcome: Review of Animal Feeds

In the December 2006 issue of *AgVetLink* NZFSA advised that it was considering submissions on its proposals to modify the regulatory control of animal feeds. The article described the two proposals.

Proposal One

Proposal One would require manufacturers of feed containing animal material resulting from the death of the source animal to list with NZFSA by supplying information such as manufacturer's name, address and type of feed being manufactured.

Submissions received expressed two major concerns.

1. There are hazards such as naturally occurring and chemical/biological contaminants associated with plant material that may be of equal significance as those in meat and offal. The proposed listing would not facilitate investigations involving those hazards.

2. The second concern related to the practicality and appropriateness of the proposed listing. The listing would not reflect the true composition of the feed manufacturing industry. In addition, some respondents pointed out that there may already be ways for NZFSA to obtain the information it needs to investigate adverse events involving animal feeds. It was also pointed out that there are other initiatives to gather the information that should be explored before an additional requirement to be listed is imposed.

Given these concerns, proposal one will be reconsidered. The NZFSA Science Group will develop a more comprehensive risk profile for animal feeds under New Zealand conditions to give a better picture of what hazards are significant, what risks should be managed and whether an NZFSA listing of feed manufacturers would help manage those risks.

Proposal Two

Proposal Two would require manufacturers of petfood (cat/dog food) containing animal material resulting from the death of the source animal to procure material only from regulated sources and to maintain a documented system that demonstrates such things as source of process inputs, suitability for intended purpose, sufficient labelling to enable traceback, and inventory control to identify substitution and security during transport.

There was qualified support for Proposal Two from the larger manufacturers in the petfood industry. A number of concerns were raised regarding the nature of the documented system, particularly for those manufacturers who were not already operating under NZFSA registered risk management programmes. However, there was sufficient agreement with and support to progress it to the next and more detailed stage, with the hope of introducing changes later this year.

International visits

Debbie Morris and Warren Hughes visited the US FDA and EPA in Washington, DC in early December. Issues discussed ranged from information requirements to operate in the regulatory environment to technical matters such as product stability requirements, animal welfare issues and residues (including trade aspects of MRLs).

In addition, Warren Hughes attended the 5th International Fresenius Conference on Food Safety and Dietary Risk Assessment held in Koln, Germany, 11 and 12 December 2006. Topics of note were:

- the continued work on probabilistic modelling, in particular in the area of acute dietary intake risk assessment;

- the work of the OECD in harmonising residue information requirements;
- progress of updating MRLs in EU and related issues; and
- use of an MRL calculator to assist regulators in determining an appropriate MRL for active ingredient/crop combination.

Prior to attending this conference, Warren visited Boehringer Ingelheim, which is located near Frankfurt, Germany. This visit provided an opportunity to view the operation of a major international company in manufacture of pharmaceuticals. It also allowed for discussion on the regulatory environment in Europe and New Zealand with respect to registration of veterinary medicines.

Right person, right format

It is expected that many changes will result when the ACVM Act Amendment is implemented. *AgVetLink* will be our main vehicle for notifying you of these changes, and we need to know who should be receiving the publication in your organisation.

Please let us know who to send it to and whether you want a hard copy or prefer to download each issue from our website. Email Mary Alexander with your preferences:
(mary.alexander@nzfsa.govt.nz).

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The Group has a new phone system – please note new numbers.

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