



AgVetLink

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From the Director

In addition to updates, the theme of this issue of AgVetLink seems to be change – changes in legislation, staff, even the website.

We have been asked about developments in ACVM legislation, and we bring you up to date with the process on page 2.

Some of our staff members have changed roles, so we explain their new jobs and introduce our new Programme Manager (Performance), Trish Whitaker, on page 3.

Changes in the NZFSA website have meant that ACVM information is no longer accessed in the old, familiar way – check out page 5 for the new system.

The 'slice of life' review of PAR traders has been completed and a report will feature in the next issue. Watch this space.



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.

NZFSA conference

'Prospering With Safe Food' is the theme of NZFSA's fourth annual conference to be held Wednesday and Thursday, 1-2 November 2006, at the Heritage Hotel, Auckland.

Topics to be covered include progress on the Domestic Food Review plus more general issues around export standards, imported food and market access. Recent trade issues and a Codex update will be presented on the second day.

Various workshops are planned. These will be based on NZFSA's core business of policy-setting, market access, domestic and exported food standards, and science-based research and decision making.

The Minister for Food Safety, Hon Annette King, will address the conference. International speakers will include:

- John O'Brien, CEO, Food Safety Authority of Ireland
- Bill Reilly, Board Member, United Kingdom Food Standards Authority
- George Davey, CEO, New South Wales Food Authority
- Graeme Peachy, Chief Executive, Food Standards Australia New Zealand

For more information and details of the programme, visit the NZFSA website (<http://www.nzfsa.govt.nz/events/nzfsa-conf-2006/programme.htm>).

LEGISLATION

What's happening with changes to the ACVM Act?

The ACVM Amendment Bill has been drafted and is ready for introduction to Parliament.

Process

Once introduced, it will receive its first reading when MPs debate the merits of the Bill. It will next proceed to Select Committee and public submissions will be called. The Select Committee may recommend changes as a result of submissions received. The Bill then will have its second reading, and MPs will debate the Bill with the changes recommended by Select Committee. Following the second reading, the Bill will be debated clause by clause (or part by part) and given its third reading. It comes into law once given assent by the Governor General. The timing of the Bill's introduction and progress through the House is dependant on the priority it's given by the Government. However, we expect it is likely to be introduced sooner rather than later.

Cost recovery

In 2005/2006 NZFSA has been appropriated \$81.540 million (Vote Food Safety). Of the appropriation, Crown revenue is \$25.629 million (31 per cent) and the remaining \$55.911 million (69 per cent) is to be cost recovered from industry.

Review of funding

In 2003, NZFSA undertook a review of Crown/other funding across NZFSA and a review of the implications of harmonisation of cost recovery across the various groups involved in this activity in NZFSA. The review found the public/private funding mix varies markedly:

- Agricultural compounds and veterinary medicines – over 80 per cent privately funded;
- Animal products (including meat, fish and dairy) – over 80 per cent privately funded;
- Organics and plants – 60-70 per cent privately funded;
- Wine, domestic food and imports – less than 20 per cent privately funded.

In addition, the degree of differences in the charging structures for similar services across NZFSA's directorates/sectors is notable. These variations are being addressed through a programme of harmonisation of cost recovery policy and methods throughout NZFSA.

Over the next 12 months major cost recovery projects under the Animal Products Act 1999 and the progression of the Domestic Food Review will provide a model that will have broader applicability across other areas of NZFSA subject to cost recovery. Amendments will also be made to existing cost recovery regulations, including the ACVM Fees and Charges Regulations 2002.

GENERAL INTEREST

Staff update (change, change, change...)

New Programme Manager (Performance) Trish Whitaker

Trish takes over from **Brian Pidford**, who retired earlier this year. The role, which covered the area of Good Manufacturing Practice (GMP) and trade in prescription animal remedies (PARs) and vertebrate toxic agents (VTAs), has been expanded. A major component of Trish's new job will be reviewing programmes across the entire Approvals and ACVM spectrum to make certain they are working as intended (and as needed). For example, she will look at conditions on registration to ensure that they are appropriate to manage the relevant risks and not more or less restrictive than needed.

She is supported by **Linley Thorburn**, Advisor (Compliance and Monitoring), who is spending about 50% of her time in this area. The other half of Linley's time is spent in operations, particularly border compliance.

New Programme Manager (Process and Performance, ACVM and Non-food Assessment) Neil Kennington



Neil's previous position within the ACVM Group was Senior Advisor (Animals). For several years he has been a veterinary technical advisor with the Group. His new role as Programme Manager will not affect his relationship with registrants—it will be 'business as usual' for them.

Neil's key priority is to manage the high levels of applications currently being received for both plant and veterinary products. There will be a focus on ensuring internal systems are efficient as well as robust, and on the quality of submissions and data assessments.

Trish introduces herself: "I have worked in the pharmaceutical industry for over 20 years, primarily in veterinary biological manufacturing but also have had experience in Good Laboratory Practice (GLP), residue testing and human cytotoxin manufacture for use in early phase clinical trials. I was educated and trained as a chemist but over the years my experience has centered on Quality Assurance and compliance. I have been a contract NZFSA auditor for Category 1 manufacturers and therefore have a working knowledge of the New Zealand industry."



Linley Thorburn (left) and Trish Whitaker

New Programme Manager (Approvals and ACVM Standards) Warren Hughes



Warren, who is known to many of you, has been with the ACVM Group for a number of years. He has moved from his position as Programme Manager (ACVM and Non-Food Assessment) to Programme Manager (Approvals and ACVM Standards).

Warren's initial priorities for ACVM standards development will focus on the following key

areas:

- management of antibiotic resistance in relation to the 2005 report produced by the Expert Panel on Antibiotic Resistance;
- the recently signed MOU with APVMA (see June 2005 *AgVetLink*, page 2) on working closer together will mean a significant collaboration between the two regulators. The work plan will mean reviewing requirements and standards in wide range of areas over the next five years;
- development of a number of standards and operational policies, with focus on residues/MRL and manufacturing-related areas;
- implementation of the ACVM Amendment Bill; and
- NZ's input into international standard setting.

GENERAL INTEREST

MRL update

We have recently completed public consultation on *The New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006*. This standard, as mentioned in the previous *AgVetLink*, proposed to amend several errors within the standards, as well as consolidate *The New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005* with the amendments made to it over the previous year. In addition to this, the following MRLs were to be included as part of the amendment:

Compound Common Name	Food	MRL (mg/kg)
Azoxystrobin	Onions	0.01*
	Peas (without pods)	0.02*
	Potatoes	0.02
Fipronil	Onions	0.01
Fluoxastrobin	Cereal grains	0.01*
Imidacloprid	Lettuce	1
Iprovalicarb	Onions	0.05*
	Potatoes	0.05*
Prothioconazole	Cereal grains	0.02
Spinosad	Citrus fruits	0.05*
Thiacloprid	Stone fruits (except cherries)	0.02*
NOTE: * indicates that the maximum residue limit has been proposed at or about the limit of analytical quantification		

The following exemptions from the requirements for MRLs have been included in the standard, which is now in the process of being gazetted:

Compound Common Name	Condition
Agrobacterium radiobacter Strains K84 and K1026	When used as a beneficial bacterium in the treatment of crown gall infections for food producing plant species
Bacillus subtilis Strain: QST 713	When used as a fungicide or bactericide for food producing plant species
Beauveria bassiana (Strains indigenous to NZ)	When used as a beneficial insecticide for the control of aphids, thrips and whitefly for food producing plant species
Cydia pomonella granulosis virus (Mexican strain)	Used to control codling moth larvae for food producing plant species
Fish oil	For use as a plant compound
Bronopol	Salmonids and salmonid eggs

We are currently preparing another round of MRLs for public consultation as part of the annual MRL process. This round, which is likely to propose the setting of MRLs for five compounds and two MRL exemptions, should be submitted for public consultation in September.

Applications Update: Backlog

In comparison with the same period last year, we continue to have significantly more applications to process. In particular, we advise that the backlog in the plants area is extremely high and processing is taking the full 40 working days at this stage.

GENERAL INTEREST

WEBSITE

The NZFSA website has been given a new structure and a new look.

For those of you who haven't been able to find the ACVM part of the website since the change:

- go to the NZFSA home page
- go to the menu at left
- click on 'Industry'.

ERMA/ACVM Liaison Group

The Approvals and ACVM Group and ERMA New Zealand had a 'meet and greet' staff workshop where both parties gave presentations on the different approval areas in which they work. Following this, ACVM staff attended ERMA's celebration of the end of the transfer of hazardous substances to the HSNO Act.

The ERMA/ACVM Liaison Group will meet next at the end of August.

PLANT COMPOUNDS

11th IUPAC International Congress of Pesticide Chemistry

Warren Tully, Senior Advisor (Chemicals), attended the 11th International Union of Pure and Applied Chemistry (IUPAC) Congress in Kobe, Japan, from August 6 - 11.

'Evolution for Crop Protection, Public Health and Environmental Safety' was the focus of the Congress. Kobe City provided an excellent venue for the presentations. The scientific programme gave an overview of agriculture, agrochemicals, and environmental health issues of the near future from different points of view (i.e. academia, industries, and regulatory agencies). There were many opportunities to exchange information and technology on chemistry, biology, biotechnology, toxicology, and environmental science on agrochemicals as well as its related novel technology among the scientists.

VETERINARY MEDICINES

Codex Update

The 29th session of the Codex Alimentarius Commission was held in Geneva, Switzerland, in early July.

The Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) draft guidelines for the design and implementation of a national regulatory food safety assurance programme associated with the use of veterinary drugs in food-producing animals, which New Zealand has been leading, was adopted at step 5.

Task Force on Antimicrobial Resistance

It has been agreed to establish a new Task Force on Antimicrobial Resistance with Korea as host country. The terms of reference and objectives were abridged from those originally proposed. Details of work proposals will be considered at the first meeting, likely to be held in late 2007. New Zealand has provided extensive comment on the formation of the Task Force and will continue to be involved.

New Work on Animal Feeding

A proposal to establish a new Task Force was opposed by a number of countries. As a result, the proposal has been deferred until 2008, which will give time for comments on the implementation of the recently introduced *Code of Practice on Good Animal Feeding* to be considered.

VETERINARY MEDICINES

Labelling Guide Changes

Radio advertising

The *ACVM Labelling and Advertising Guide for Veterinary Medicines Requiring Registration* has been amended in Section 3.10, Registration Statement. The section now reads:

Every advertisement for a registered trade name product must contain the registration phrase: “Registered pursuant to the ACVM Act 1997 No....” with the registration number to be included in the phrase.

In the case of radio advertisements, where it is difficult for the listener to retain a letter/number sequence, it is considered acceptable to exclude the registration number from the above statement so it will read:

“Registered pursuant to the ACVM Act 1997”.

Advertisements in print must include the full registration statement with the registration number. Advertisements in all other media (television, website etc.) that contain a visual component must include the full registration statement, including the registration number.

This change has been made because it is considered that reading a list of registration numbers rapidly does not provide the consumer with retainable, useful information, especially in circumstances where a number of products are being advertised together. The requirement for providing registration numbers has not changed for any other advertising media.

Hormonal growth promotants (HGPs)

The *ACVM Standard for Distributors of Hormonal Growth Promotants* is currently undergoing review. A draft version will be available for consultation shortly.

In the meantime, the annex of the labelling guide (Section 9: Hormonal Growth Promotants) has been amended to include an additional labelling statement requirement for the labels or package inserts of HGPs. The new statement is:

“This product must not be used in cattle producing or intended to produce milk for human consumption”.

The statement has been added to make it clear that these products must not be used in cattle producing milk for human consumption. This is an important requirement because such use could jeopardise New Zealand’s trade in dairy products.

The labelling guide is available on the website (<http://www.nzfsa.govt.nz/acvm/publications/labelling-guides/vet-medicines/index.htm>).

Bee Products

Products used to manage bees or used in bee hives and hive components are considered to be agricultural compounds and are subject to registration or management under the ACVM Act. The introduction of the Varroa mite resulted in an increased recognition that there were regulatory obligations to manage residues from the use of products for the purposes of the ACVM Act as well as other legislation.

If products or chemicals are used in a producing hive, there is likely to be direct contamination of honey and resulting problems with meeting acceptable residue limits for both domestic and trade purposes. Any product used on frames, supers or wax has potential to contaminate honey when production commences. Chemicals that are lipophilic may be residual in the wax and accumulate, resulting in contamination of honey through the unavoidable wax content or direct contact. Bee’s wax used in combs is a food product and should be treated as such during storage and reprocessing.

If any product is being marketed or sold for use on bees or in and around hives during production or storage, the regulatory requirements under the ACVM Act, Animal Products Act 1999 and Hazardous Substances and New Organisms Act 1996 must be met.