



AgVetLink

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From the Director

Since the last issue, several topics have generated rumours and speculation. You may have heard tales about the possible split of NZFSA and MAF. See page 2 for the latest information.

The deadline for updating labels is fast approaching (page 2). The rumour that ERMA and the ACVM Group will be doing spot compliance checks is TRUE!

The North American pet food recall has also given rise to speculation as scientists try to identify the cause of the problem. Background and the New Zealand situation are presented on page 4.

Staff took note of a suggestion in the last customer survey to get 'out and about' more, and the result was a very worthwhile field trip to Auckland (page 3). Our thanks to Nufarm and Elliott Technologies for the well organised day.



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

Possible split: NZFSA and MAF*

The New Zealand Food Safety Authority (NZFSA), which was established on 1 July 2002, is a semi-autonomous body attached to the Ministry of Agriculture and Forestry (MAF). The functions and powers exercised by NZFSA are vested in the MAF Director-General who delegates to the NZFSA Executive Director.

The Minister of State Services is seeking to separate NZFSA from MAF and create a new department to administer food safety. She has asked the State Services Commissioner to provide advice on such a separation.

The State Services Commission (SSC) has engaged an external contractor to evaluate the situation, working closely with the SSC, Treasury, NZFSA and MAF staff to determine the financial,

legal and human resource implications of separation. The contractor will advise the SSC of possible structural options arising from the separation of NZFSA from MAF. This advice will include the scope and range of functions for each organisation and a discussion of the relative merits of each option.

The SSC will consider the advice and provide recommendations to the Ministers of Food Safety and Agriculture and Forestry. Based upon this advice, the Ministers will indicate their preferred structural option(s).

The SSC is expected to provide the Minister of State Services with detailed advice on the implications of separating NZFSA from MAF by May 2007. The State Services Commissioner's report will contain:

- a description of a potential new Food Safety department, including its scope and range of functions
- a description of the consequential new scope and range of functions of MAF
- a suggested model for sharing services between the two departments
- a report on the legal, financial and human resource implications of separating NZFSA from MAF
- a suggested work programme for implementing the separation of NZFSA from MAF.

Following receipt of the State Services Commissioner's advice, Cabinet will decide whether or not to proceed with the separation of NZFSA from MAF.

* This information is taken from the State Services Commission's website (<http://www.ssc.govt.nz>).

Labels: ACVM and ERMA Reminder

1 July 2007 is the deadline for HSNO compliance and for updating old labels that say "Approved under the Animal Remedies Act..."

At the ERMA and ACVM Group operations meeting held on 13 April, it was brought to the members' attention that a huge number of labels in the marketplace have not been updated with HSNO requirements. As a follow-on, ACVM registration statements have not been updated to meet the requirements of the ACVM Act, and are therefore NOT approved. ERMA also advised that the Department of Labour has been informed of this situation.

We remind you again that use of these labels will be illegal in the marketplace from 1 July 2007 except for product already in the distribution chain on this date. Further manufacture, sale or use of labels with an old regulatory statement on them will be in breach of the ACVM Act. The ACVM Group (and ERMA) will monitor compliance by doing spot checks on labels.

The ACVM Group advises you that once changes have been made to the labels, these changes must be submitted to us for approval. There is no cost for the approval of the label for this registration statement updating exercise. However, if other changes to the label have been made, an appropriate application will be required.

By now you should have received a letter about providing us with the batch numbers when you update labels. **This is a requirement.** Please contact Trish Whitaker if you did not receive your letter (trish.whitaker@nzfsa.govt.nz).

GENERAL INTEREST

‘Out and About’

A point raised in last year’s customer survey was that ACVM Group staff should get ‘out and about’ more. With this in mind, several members of the Group recently accepted an offer from Nufarm and Elliot Technologies to tour their Auckland production sites, and to visit some local growers and a working trial site.

After lunch the group visited Young Wah Chong Ltd, a well known and large grower who supplies KFC with the bulk of their cabbage. Mr Howe Young showed the group summer squash and pumpkins in the field and the machinery used for spraying large plantings of these types of crops. He talked about challenges growers face, especially with

- local government regulations
- meeting the chemistry standard in terms of parameters such as stability (ie many products have a shelf life of more than two years but problems arise due to the legislation that states the two-year shelf life statement is to be used on the label)
- the cost/time involved in some



Approvals and ACVM Group staff members (from left) Neil Kennington, Bruce Nalder, Andrew Pearson, Rebecca Fisher, John Bongiovanni, Warren Tully and Maree Zinzley meet with Rebecca Bush, Pukekohe Growers Supplies Agronomist, and Howe Young of Young Wah Chong Ltd.

Nufarm’s Allan Cliffe and Brian Smith from Elliott Technologies took the group from the airport to Nufarm’s head office in Manuwera where they met Emma Wilson (regulatory affairs) and toured the Nufarm production site.

meeting supermarket requirements, increasing costs for vegetable growers, sourcing labour for harvesting crops, compliance with the HSNO Act and, in particular, the approved handler regime.

- assessments (eg simple C2, 3, 4/5)
- whether efficacy is an ACVM Group concern or should it be left up to the registrant
- ‘not to be used on animals’ statement to be incorporated onto the label.

Next was a visit to the mesclun salad production site in Mangere with Gary Graham, Pukekohe Growers Supplies Limited (Elliot Technologies). The group talked with Gary about the challenges faced with using product, off-label uses, the effects of weather on this fast growing crop, meeting supply and demand etc. They moved on to the Pukekohe Growers Supplies Boardroom for further discussions and a presentation by Brian Smith. Brian provided an overview of the business units involved in the handling and use of agricultural compounds through the food chain, and the hoops that a grower/farmer has to jump through to ensure compliance with various pieces of legislation.

At Alpha Research the group saw trials (residues and efficacy) on plots of brassicas etc, and were shown equipment used. The advantages of using independent researchers over CRIs were also explained.

In discussions it was determined that all of the above issues are already on the ‘work list’ to be reviewed during the ACVM Group’s current review of the ACVM Act and procedures to make things more simple.

Nearing the end of the day, the last visit was a quick look around a seed treatment plant and the equipment used to coat various types of cropping seeds.

Discussion topics

The field trip reinforced some of the messages the ACVM Group has been receiving or has been discussing with registrants, including:

- the impact of ERMA and HSNO changes
- the rationale behind Government and

All in all, the group found the day very informative and interesting. It provided a clear look at some of the hurdles that growers/registrants/importers face in their day to day efforts to ensure compliance with various pieces of legislation, local government bodies and international sectors.

The ACVM Group would like to thank Allan and Brian for their time and efforts in organising the field trip.

GENERAL INTEREST

Pet Food Recall

Background

In March 2007 the US Food and Drug Administration became aware of the illness and death of cats and dogs associated with certain pet food. The main effect reported was acute renal failure, primarily in cats. Signs of kidney illness reported include loss of appetite, lethargy and vomiting.

All the suspect pet food contained wheat gluten sourced from a single supplier,

Xuzhou AnYing Biologic Technology Development Co. Ltd of China. A voluntary recall of 95 brands of pet food (mainly gravy type foods) was initiated. In April, twelve more brands were added to the list.

Initially, the chemical aminopterin (a form of rat poison) was implicated because it was found in some of the cat foods. Since then, this theory has been discounted. At the time of writing, samples of the implicated pet food and the wheat gluten had been analysed and found to contain melamine, a chemical used as a fertiliser and in the production of plastics. Melamine was also identified in urine and tissue samples taken from some sick cats.

While there appears to be a clear correlation between the kidney damage seen in cats and the consumption of contaminated wheat gluten, scientists investigating the situation are concerned that the levels of melamine detected in pet food are lower than they would expect to cause the toxic effects that have been seen in pets and that melamine may not be the cause of kidney failure. It is possible that there is another, as yet unidentified, contaminant that is present alongside the melamine that is the primary causative agent. Studies continue.

New Zealand situation: pet food

NZFSA is aware of three brands of pet food available in New Zealand that were affected in the US. However, shipping delays to New Zealand mean that none of the product in question was distributed here. Some product was shipped to New Zealand but was

reshipped or destroyed. Hills has advised that they are voluntarily recalling their product even though it is now clear that product imported into New Zealand is not in the batches of concern. They have decided to continue the recall so as not to lead to any confusion.

NZFSA has been monitoring the situation, but has not taken an active role because there is no known affected product here. Distributors involved have been very responsible, keeping NZFSA up to date.

New Zealand situation: wheat gluten

Given the concerns of the US scientists that the primary cause of illness and death following consumption of contaminated wheat gluten has not yet been identified, NZFSA is currently unable to provide assurance as to the safety of any wheat gluten sourced from Xuzhou AnYing Biologic Technology Development Co. Ltd of China. Until the contaminant in the wheat gluten that is the cause of illness and death is positively identified, the presence or absence of that contaminant remains unknown.

For further information, see the following websites:

http://www.fda.gov/ora/fiars/ora_import_ia9926.html
http://www.nlm.nih.gov/medlineplus/news/fullstory_47329.html
<http://www.fda.gov/oc/opacom/hottopics/petfood/transcript040507.pdf>
<http://www.vet.cornell.edu/news/FoodRecall/prApril5.htm>

Legislation Update

ACVM Act Amendment Bill

The Bill is with the Primary Production Select Committee, and the submission procedure (written and oral) has been completed. NZFSA is now working with the Parliamentary Counsel Office to make amendments to the Bill. The Select Committee is expected to report back to Parliament in June.

ACVM Regulations

Parliamentary Counsel Office is drafting changes to the exemption regulations and the Cabinet process should be completed for signing by the Governor-General in late May. The legislation will then be notified in the *Gazette* and will come into force 28 days after this notification.

updating the website – labels

As you know, the ACVM Group uploads finally approved text drafts or full labels onto the public website. We do not have electronic PDF copies of all labels yet. If you haven't supplied your electronic PDF copy for a registered product, please do so ASAP. Email them to your Advisor or to Emma Lester (emma.lester@nzfsa.govt.nz).

GENERAL INTEREST

Staff Update



Emma Miles-Buckler, Executive Assistant to Director Approvals and ACVM Group

Emma joined NZFSA mid-April after spending the last seven years with the Ministry of Justice as Executive Assistant to the General Manager of Collections and then Human Resources. Emma's main interest is gardening, as many of her new colleagues have found out. She would like to say that she is very interested in tramping, hiking and other vigorous outdoor pursuits – but her garden calls and she just can't find the time, or the inclination. And although she may not be the most active person around, she will actively and loudly support anyone else's sporting feats. She does fish, mainly land-based sea

fishing and is learning to catch very elusive trout, but this can be difficult when a big bite comes and she has just reached a really good part of a book....

Changing roles

The Approvals and ACVM Group has made two appointments since the last issue of *AgVetLink*:

- **Mary Alexander** has been appointed to Advisor, replacing **Chris Scott** who is going on his OE in June
- **Simon Ellery** has been appointed to Advisor in the Food Service, Sales and Imports area (as of June).

Streamlined Approvals

There is a recognised need to improve the way applications are handled to make it quicker, easier (and cheaper) to process simple variations to registrations. The original focus on technical type variations where there is little impact on the registration or those that are easily assessed has been broadened to include a review of the C9 and B1 applications. We are trialling the new streamlined system prior to launching revised application forms and information on the process. The intention is to process suitable technical applications during the pre-screen process to avoid unnecessary handling. There will also be increased flexibility as to when documentation such as product data sheets need to be updated.

Food Safety Quadrilateral Meeting – Food Safety and Animal Health

This yearly meeting was hosted by New Zealand at Paihia in conjunction with the Animal Health Quadrilateral Meeting. The meeting provides for regulators from Australia, USA, Canada and New Zealand to discuss topics of mutual interest.

Annual Fees

The first part of the annual fee process has been completed. Most product lists, which were sent out to all registrants in March, were checked, signed and returned promptly. We are currently updating our system to reflect any necessary changes indicated on the returned lists. In mid-May, the annual fee invoices for the period 1 July 2007 to 30 June 2008 will be posted. **Please note that these invoices are due for payment by 1 July 2007.**

Late payment procedure

- 1 If payment is not received **prior** to 1 July 2007, 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) are prohibited from importation and/or manufacture under section 82 of the ACVM Act. Removal of the prohibition will occur only after payment on all outstanding debts and any penalty fees have been received.

If you have any queries please contact:

Jane Chuang, Coordinator (Business Services)

Tel: 04 8942563, fax: 04 8942566, email: jane.chuang@nzfsa.govt.nz

In the ACVM area of interest, topics this year included discussion of:

- private standards (those set by non-government bodies such as supermarket chains that exporters need to meet to sell their produce) with respect to their current and future impacts
- Codex Committees, their funding and setup
- risk management of low level chemicals in the environment.

The other topic of interest was the weather – a number of delegates had an unscheduled stopover due to closure of roads and airports after rain caused widespread flooding.

Global Minor Use Summit: Rome 2007

The Food and Agriculture Organisation, US Food and Drug Administration and US Environmental Protection Agency are organising a summit on minor use in early December 2007 in Rome, Italy.

The purpose of the summit is to bring interested parties together to address challenges in specialty crops and minor uses. In particular, the summit will look at residue requirements that can be accepted nationally and internationally, and discuss approaches to harmonise data generation to support national and international maximum residue limits (MRLs).

New Zealand, along with most other countries, struggles to balance the regulatory requirements against the disincentives to pesticide registration and development in the minor use area. In addition to regulators, this summit should be of interest to producer groups and agricultural companies.

For further information on the summit go to the IR-4 website (<http://www.ir4.rutgers.edu/GMUS/index.html>).

MRL Update

The New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007 came into effect on 8 March. It consolidated the 2006 standard with the following list of MRLs proposed as part of the amendment round.

| Compound | Crop/animal tissue/milk | MRL(mg/kg) |
|-----------------|---|------------|
| Closantel | Cattle fat | 3 |
| | Cattle kidney | 3 |
| | Cattle liver | 1 |
| | Cattle muscle | 1 |
| Doramectin | Milk | 0.015 |
| Fenpropidin | Wheat | 0.02* |
| | Maize | 0.02* |
| Mesotrione | Maize grains | 0.01* |
| Pinoxaden | Cereal grains | 0.01* |
| Ractopamine | Pig fat | 0.01 |
| | Pig kidney | 0.09 |
| | Pig liver | 0.04 |
| | Pig muscle | 0.01 |
| Trifloxystrobin | Citrus fruits (except clementine and Satsuma mandarins) | 0.3 |
| | Grapes | 0.02* |
| | Mandarins (clementine/Satsuma) | 0.02* |
| | 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 first amendment to the 2007 standard proposes to set MRLs for eleven active ingredients. Consultation for this amendment has begun, and the consultation document for the proposed MRLs is available on the NZFSA website (<http://www.nzfsa.govt.nz/policy-law/consultation/index.htm>).

Codex Committee on Pesticide Residues (CCPR) – China 2007

The 39th session of CCPR will be held in China from 7 - 12 May. This will be the first session held by the new secretariat (China) for this committee, which has taken over from The Netherlands.

Approximately 60 countries belong to CCPR. One of its main roles is to establish maximum residue limits (MRLs) for pesticides in various commodities, thus facilitating trade between countries. In addition, the CCPR develops risk assessment and risk management procedures associated with pesticide residues in food in international trade. As in previous years, New Zealand will be represented at the meeting.

VETERINARY MEDICINES

Aflatoxins and Animal Feed

In 2006 the dairy National Chemical Contaminants Programme (NCCP) identified raw milk supplies that contained aflatoxin. These levels did not represent a food safety issue but were of interest and some concern as the residues are caused by contaminated feed, and New Zealand milk would normally be free of any trace of aflatoxin. The results are of some concern from a trade perspective as they were close to the limit imposed by the EU for raw milk at the farm vat.

The findings of the investigations into the levels of aflatoxin in imported copra meal found batches that were elevated and might result in milk at the farm vat failing to meet the requirement of 0.05 µg/kg (micrograms per kilogram or parts per billion) depending upon feed rates. This is the subject of ongoing review by NZFSA. Individual dairy companies are likely to place restriction on the use of copra by suppliers until there are adequate assurances that feed

will not cause residues in milk. The same concerns do not exist for meat.

This case serves as a reminder that there is a requirement under the ACVM Act Regulations exempting animal feed that the feed must be fit for purpose, which requires it does not produce residues in primary produce or result in toxic reactions causing pain or distress in animals.

Currently the primary concern is with copra as this material is an ideal substrate for the production of aflatoxins. Other imported feeds such as palm kernel have not been implicated to date.

Storage in New Zealand cannot be ignored with a requirement to keep feeds dry and cool both prior to sale and on farm.

Although there are no formal levels set for aflatoxins in animal feed in New

Zealand, levels used internationally are relevant guides. The EU has a limit of 5 µg/kg for lactating dairy cows, which is required to achieve the 0.5 µg/kg in milk. Higher levels can be fed to other classes of stock because there is not the same residue constraint. (Aflatoxins will cause toxicity to animals depending on age and species.)

The following levels used in the US by the FDA are a guide:

- finishing beef cattle – 300 µg/kg
- finishing pigs over 40 kg – 200 µg/kg
- breeding beef cattle, breeding swine, or mature poultry – 100 µg/kg
- immature animals – 20 µg/kg
- animal species or uses not specified above, or when the intended use is not known – 20 µg/kg

The NZ Feed Manufacturers Association is developing a code of practice for animal feeds to address this issue.

Invitation to comment on draft VICH residue guidelines

A VICH Expert Working Group on Metabolism and Residue Kinetics is developing guidance documents on the following topics:

- Topic 1: Study requirements to identify the nature and quantity of residues
- Topic 2: Study requirements to demonstrate comparative metabolism
- Topic 3: Study requirements to demonstrate residue depletion and to establish withdrawal periods
- Topic 4: Validation requirements for analytical methods used in residue trials
- Topic 5: Harmonisation of scientific model assumptions (withdrawal time calculations)

First drafts of the guidance documents for topics 1, 3, 4 and 5 are available on the VICH section of the NZFSA website. Comments on these draft documents are welcome and should be emailed to Warren Hughes (warren.hughes@nzfsa.govt.nz) by **25 May 2007**.

Labelling and Packaging: GMP

Labelling and packaging product are both part of the manufacturing process. **All the relevant GMP standards and guidelines also apply to these steps.** For example, manufacturing must be carried out in approved premises. This means that all steps in the process, including labelling and packaging, must be carried out in approved premises. Packaging in unapproved site(s), which has come to light in recent audits, is not permitted.

DoC Procedure to Manage PARs for Research Use

The Approvals and ACVM Group was pleased to see the procedure the Department of Conservation (DoC) has developed for using prescription animal remedies (PARs) while meeting their obligations under the ACVM Act.

The veterinarian responsible for overseeing the use of drugs has developed an excellent system of control that includes a comprehensive web-based training programme and resource for researchers and an auditable way of providing PAR II drugs to researchers. DoC has researchers working in remote locations on feral species such as cats, ferrets and rodents. The programme developed has meant these researchers

can safely handle wild animals, thus reducing the risk of being bitten and causing minimal stress to the animals.

Because of the difficulties in managing the use of PARs in remote locations, the programme developed has required some flexible thinking but has resulted in an auditable and controlled system. The system achieves the goals of managing animal welfare, providing adequate veterinary control of drugs, preventing diversion of drugs for inappropriate use and allowing researchers to work in a safer way. The responsible way DoC has approached their obligations under the ACVM Act is to be commended.

PAR Review Reports

Reports on the 2006 'slice of life' reviews of prescription animal remedy (PAR) use in veterinary practices and in research, teaching and testing organisations are available on the NZFSA website.

You will find them at: <http://www.nzfsa.govt.nz/acvm/subject/compliance/review-rttos-0307.htm> and <http://www.nzfsa.govt.nz/acvm/subject/compliance/review-vet-par-traders-0307.htm>

Change to VM Labelling Guide

The Annex in the *Labelling/Advertising Guide for Veterinary Medicines Requiring Registration* has been altered.

Section 13 In-water and in-feed medications now reads:

The labels of in-feed and in-water veterinary medicines must carry a sufficient amount of information to ensure animals undergoing treatment receive the required daily dose. Minimum information to be included is:

- a dose rate for each label species, eg in mg/kg, and
- where feed or water inclusion rates are recommended a statement that they are based on the notion that animals have a certain assumed intake, and should be adjusted as necessary to achieve the required dose rate where intakes vary from that assumed.

Where sufficient information is provided to show the product is not absorbed significantly and efficacy is based only on the concentration in ingesta not on a mg/kg dose rate, an in-feed inclusion rate alone may be considered sufficient information to provide accurate dosing. This will be considered on a case by case basis for individual products.

Antimicrobial Resistance Steering Group

The Antimicrobial Resistance Steering Group met on 15 March 2007 to discuss, among other things, progress being made on the various recommendations made in the *Expert Panel Working Group Report on Antimicrobial Resistance*. The Steering Group was advised that a number of the recommendations are currently being undertaken.

The ACVM Group reported on the Codex Alimentarius Commission's establishment of an ad hoc task force to consider antimicrobial resistance with a focus on human health (for further details on this refer to *AgVetLink* Number 56, June 2006).

The various sector groups at the meeting also provided updates on antimicrobial resistance activities in their areas.