



## What's coming up

- An AVMAC meeting will be held in Wellington on 20 February 2004 with an Industry Liaison Group meeting planned for the same date.
- The ACVM Group is planning a series of 'roadshows' for veterinarians to address concerns and confusion over the implementation of the ACVM Act relating to PAR products. Dates will be available shortly in a special edition *AgVetLink* for veterinarians, which will be available on the website.
- The ACVM Group has been invited to address an Agcarm special general meeting being held in February in Auckland.
- An OECD registration steering group meeting will be held in Paris in February in conjunction with the meeting of the working group on pesticides and the joint meeting of the chemicals committee. John Reeve will attend these meetings.
- A VICH 'future directions' meeting will be held in March. Debbie Morris will attend this meeting to represent the views of the observer countries (Australia, New Zealand and Canada). The draft paper will be circulated to the New Zealand industry and regulatory agencies as soon as it is available. The outcomes of the meeting will be presented to the next VICH steering group meeting in April 2004.

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## Reminder : Update Products Now!!!

Registrants are reminded that products must be updated to the new legislation by 1 July 2004. Details of the process are available in the December 2003 *AgVetLink* 'Special Edition for Registrants', which is available free of charge on the ACVM Group website (<http://www.nzfsa.govt.nz/acvm>).

**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.

## HAVE YOU UPDATED YET?

In our special December registrants' edition of *AgVetLink* we urged companies to update their registered products to the ACVM Act as soon as possible, and advised that this must be undertaken before 1 July 2004.

To date, 739 products out of approximately 2500 have been updated. There is a steady flow of updates from some larger companies, but we are concerned that those who have very few products registered may not be aware of the urgency or they are going to submit updates at the last moment.

**Again, we advise that if products are not updated by 1 July 2004, it will be illegal to import, manufacture, sell or use products that have not undergone this process. They must be updated to be legally existing.**

The ACVM Group has put in place a compliance strategy to manage those registrants whose products are not updated. See the December 2003 special issue of *AgVetLink* ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)).

**SO DON'T PROCRASTINATE – CHIP AWAY and/or GET ON TO IT!**

## Products that now require registration under the ACVM Act

Some products that are covered by the ACVM Act were not covered under the previous legislation. The products now covered include groups such as plant compound adjuvants (including wetting and sticking agents), pH buffers, drift retardants, and water conditioners.

Most of these products are already covered by the exemption Regulations but, if they are not, proprietors need to be aware that the transitional provisions of the ACVM Act expire on 2 July 2004. The transitional provisions allowed for any substance that was legally existing to continue to be imported, manufactured, sold or used for a period of three years following the implementation of the ACVM Act.

The ACVM Group is using this opportunity to encourage registrants to check any non-registered products to ensure that they do not require registration under the ACVM Act. Registrations must be approved by 2 July 2004 to enable the products to continue to be imported, manufactured, sold or used (see above article).

Any registrants affected are encouraged to discuss concerns with the ACVM Group. Some of these products will also be affected by the HSNO Act and there is room for providing flexibility on labelling for an initial two year period where needed. Registration will require the usual application for registration of a new product, but there may be limited information required where the ACVM Act risks are low.

The ACVM Group has written to all parties who have undertaken class determinations for products in this category to remind them of their obligations under the ACVM Act.

## Document update

### Completed documents:

The *ACVM Standard for Oral Nutritional Compounds* has been finalised and is available on the ACVM part of the website. Updated material also available on the website includes:

- *ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*
- *ACVM New Zealand Labelling Guide for Veterinary Medicines Requiring Registration*
- *ACVM Registration Standard and Guideline for Target Animal Safety*
- *ACVM Research Standard*
- The definition of oral nutritional compounds
- Information sheet on class determination of veterinary medicines
- Information sheet on class determination of plant compounds
- GRAS process timeline & application form
- ACVM policy on compliance and operating principles

### Draft standards out for discussion:

- *ACVM Standard for Vertebrate Toxic Agents* and
- *ACVM Standard for Own Use of Agricultural Compounds.*

## DAS business rules

The Data Assessment Service (DAS) process has been in operation for six months. This has allowed applicants to use parties other than the ACVM Group to undertake DAS reports. Over this period a few issues that need clarification have arisen.

The main issues surround lack of understanding of business rules that applicants and third party assessors need to follow when undertaking DAS reports. Although these were covered in a series of ACVM workshops, we appreciate that not all applicants attended these workshops. Consequently, we have not been rigorously enforcing these business rules during the 'settling in' period for this new system but now we would like to remind applicants of the following:

1. It is preferred that DAS reports, while they may be prepared by a person in the applicant organisation, be done by someone other than the regulatory affairs personnel for reasons of independence.
2. We require the CV of the person who undertakes the DAS report. This is particularly important where specialised reports (e.g. efficacy, animal safety etc.) have been undertaken. The purpose of this is to assure the ACVM Group that the person has the relevant qualifications and/or experience. If you are unsure whether the ACVM Group already has the person's CV, check first with us before submitting the report.
3. Applications submitted into the regulatory system based on third party DAS reports will be audited. The level of auditing will depend on a number of factors, e.g. appropriateness of the report author's qualifications. Where the ACVM Group needs to seek verification of a report, such as seeking advice from its own advisors, the ACVM Group will stop

the clock until this verification is complete.

4. Persons undertaking DAS reports need to ensure that they relate the applicant's information to appropriate ACVM standards and guidelines. If the information does not conform, then this should be brought to the applicant's attention. It is then the responsibility of the applicant (not the DAS assessor) to provide extra information or request an information waiver to support the non-submission of the information.

On a related matter, it has been noted that the qualifications of some of the persons undertaking a DAS report are either not appropriate or are marginal. For example, the person may have a number of years of experience and/or qualifications (such as entomology) but

not in the area relating to the review of information (pathology) for a DAS report. This is of particular relevance to the efficacy and animal safety reports. Therefore, it is important that applicants only use persons with relevant and suitable qualifications and/or experience, otherwise the ACVM Group, as mentioned above, will undertake a detailed audit of the reports.

Finally, it should be noted that a favourable DAS report (irrespective of whether the person who undertook the writing of the report had appropriate qualifications or not) does not necessarily mean the application will be approved by the ACVM Group. This is because the ACVM Group is responsible for managing risks under the ACVM Act via the regulatory process, whereas DAS reports only identify hazards.

## New Zealand Total Diet Survey

In November, the NZFSA released the first round of results from the New Zealand Total Diet Survey (NZTDS). The foods were collected from supermarkets and shops in Auckland, Napier, Christchurch and Dunedin in July and August. They were then sent to ESR in Christchurch where they were prepared, as they would normally be consumed, before being sent for testing for chemical residues, contaminants and selected nutrients.

NZTDS Project Leader Cherie Flynn says there are no surprises in the results.

"The results so far are as we expected them to be. This is the first quarter to be completed. The other three will be completed over the next nine months," Mrs Flynn said.

The NZFSA's media release on the first results can be found on the NZFSA website (<http://www.nzfsa.govt.nz/publications/media-releases/2003/2003-11-21-nztds.htm>).

The NZTDS also has a dedicated webpage (<http://www.nzfsa.govt.nz/science-technology/research-projects/total-diet-survey/index.htm>).

## Dry cow product labelling statements

In the current *ACVM New Zealand Labelling Guide for Veterinary Medicines Requiring Registration* (21 ACVM 10/03), section 13 of the annex is entitled 'Labelling of Dry Cow Products'. The section lists four mandatory statements for dry cow products. They are as follows:

1. Dry cow therapy should be used at drying off only.
2. Lactating cow products should be used if retreatment is required during the dry period.
3. Milk (colostrum) from the first 8 milkings after calving should be prevented from directly entering the food chain.
4. Treatment to be at least 30 days before calving.

The first three statements remain current. The fourth statement is an historical requirement resulting from the Animal Remedy Board's decision to approve a standardised pre-natal treatment interval (PNTI) of 30 days for all dry cow products (where the PNTI is equivalent to the treatment to calving interval). The other standardised withholding period of 8 milkings for dry cow products coincides with the required colostrum withhold period.

Under current policy, to prevent user confusion and maintain product market viability, when conducting residue assessments the ACVM Group uses the PNTI as the variable to ensure milk compliance with the relevant MRL by the ninth milking. With the advent of more diverse active ingredients and longer acting preparations, some dry cow products have been registered with PNTIs in excess of 30 days so that the fourth mandatory statement is untrue in those cases.

In addition, a mandatory label statement has not been established to direct users on the appropriate procedure when a cow calves within the regulated PNTI. There has been a determined move away from the use of individual cow testing as milk is regulated on a bulk vat and not individual animal level. Therefore, the statement that will replace the above mentioned fourth mandatory statement is as follows:

Treatment to be at least 'x' days before calving.  
If calving occurs within 'x' days of the last treatment, milk to be sold for human consumption may be taken only after the full 'x' days from treatment and a further 8 milkings have elapsed.

(Note: 'x' is the ACVM approved treatment to calving or pre-natal treatment interval). The labelling guide has been updated to reflect this change.

## PAR condition wording

In the October 2003 issue of *AgVetLink* the ACVM Group advised that there had been changes to the wording of the PAR Class II condition to line it up with the management of PAR products. The wordings for the Class I and III conditions have now also been revised for the same reason. Changes have been made with respect to the wording regarding who may sell and buy the products but no changes have been made to the wording regarding who may use the products.

The wording that will now appear on the ACVM website and on all certificates of registration for veterinary medicines approved with the PAR Class I condition is:

### Class I Prescription Animal Remedy

The product must be sold only by an approved trader.

The product must be sold only to an approved trader, or to any person with a veterinary prescription or authorisation.

The product must be administered to an animal only by a veterinarian, or under and in accordance with the authority or prescription of a veterinarian.

The wording that will now appear on the ACVM website and on all certificates of registration for veterinary medicines approved with the PAR Class III condition is:

### Class III Prescription Animal Remedy

The product must be sold only by an approved trader.

The product must be sold only to an approved trader.

The product must be administered to an animal only by a veterinarian.

The ACVM Group is finding that for some groups of veterinary medicines it has become difficult to match the current structure of the PAR conditions with the controls necessary to achieve the management of risks as required under the ACVM Act. In consequence, the suitability of the current PAR class conditions is under review.

## Importation of Materials of Animal Origin

**The ACVM Group is requesting its inspectors to carry out specific checks of documentation concerning any materials or ingredients of veterinary medicines that have been imported and that are derived from ruminant animals. This is to confirm that no such materials or by-products have originated from countries that are known to have been exposed to BSE. It will mean that inspectors will pay special attention to raw materials of animal origin and will require to see a current MAF Biosecurity Permit for Importation in respect of every importation made. These checks will form part of all future regular GMP inspections.**

## Ministry of Health/ACVM Group meetings

The Medicines Act 1981 and Misuse of Drugs Act 1975 are extremely prescriptive with respect to who may prescribe and use human prescription medicines and controlled substances. Veterinarians are able to prescribe and use human medicines and controlled drugs in the treatment of animals by way of specific exemption written into these pieces of legislation. It should be noted, however, that the exemption applies only from the provisions of the Medicines and Misuse of Drugs Acts. As soon as any substance is used in the direct management of an animal it becomes a veterinary medicine and is

subject to the requirements of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

The ACVM Act requires that the ACVM Group obtain Ministry of Health approval before any prescription human medicine is registered as a veterinary medicine. This can be a complicated process and can require a great deal of information transfer because of the significant differences in medicine use patterns between human and animal health programmes. It is recognised that a close working relationship is required between the Ministry of Health and the

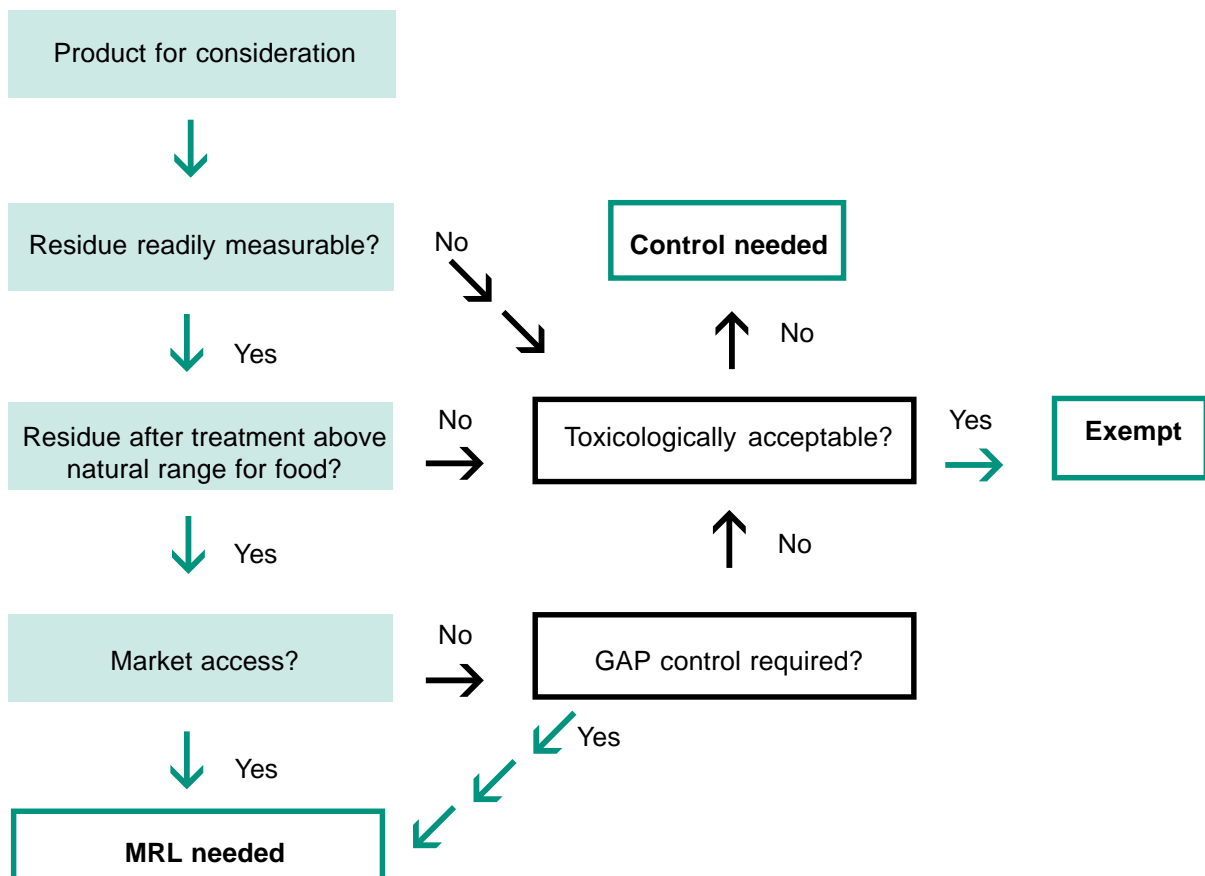
Agricultural Compounds and Veterinary Medicines Group to ensure that the work conducted by the independent Groups is complementary.

In consequence, regular liaison meetings are now held between members from Medsafe and the ACVM Group. Issues discussed to date include:

- antibiotic resistance management principles;
- compounding and repackaging; and
- the current PAR status of veterinary medicines with the potential for diversion to human use/abuse.

### Exemption of compounds from the MRL standards

As indicated in the October *AgVetLink*, the NZFSA has developed a policy for exempting compounds from the MRL standards. It is expected that the exemption for 9,10-anthraquinone will now proceed. Several other exemptions are expected to proceed in the near future. Below is the finalised version of the new process that substances must go through in order to be considered for exemption.



## INTERNATIONAL LIAISON

### FSANZ visit

In November 2003, Sarah Lester (Technical Assessor, Plant Compounds) and Paul Dansted (Senior Advisor, Technical Policy) were hosted for a week-long visit to Food Standards Australia New Zealand (FSANZ) in Canberra. Although regulation of agricultural compound residues is outside the scope of the joint food standard-setting treaty with Australia, there are many similarities between our two countries' processes.

Tracy Hambridge and Robin Gannaway of FSANZ organised a series of meetings and training sessions on topics relating to Australian legislation, the FSANZ maximum residue limit (MRL) setting process, the DIAMOND database for dietary intake assessment modelling, and the Australian Total Diet Survey (methods, uses and the 'rolling' approach proposed in future). Initial talks on probabilistic modelling of dietary intake may lead to New Zealand joining FSANZ in investigating the feasibility of using this technique in future risk assessments.

Sarah and Paul also presented a talk on the New Zealand MRL process, which initiated much discussion on the streamlined nature of our process and the use of the 0.1 mg/kg default MRL. This was well received because a 'hot' issue at present is the proposed harmonisation of the FSANZ and Australian Pesticide and Veterinary Medicine Authority (APVMA) MRL processes.

### APVMA visit

Sarah Lester, Technical Assessor in the plant compounds area, spent seven weeks at the Australian Pesticide and Veterinary Medicine Authority (APVMA) in October and November 2003, working with Raj Bhula, Trevor Doust and the residues team. As well as some concentrated time spent on pesticide residue assessments, dietary intake assessments and the Australian MRL approach, this was also a great opportunity to make valuable contacts in Australia and learn more about how the APVMA works in general.

The chemistry and residues team and the pesticides evaluators were very helpful and always willing to discuss common issues and our sometimes different approaches. The APVMA's 'minor use' seminar proved interesting, as did the field trip and discussions with various staff from other parts of the organisation.

The ACVM Group plans to reciprocate by inviting staff from APVMA to visit here in the future.

### Workshop

John Reeve (Programme Manager, Toxicology and Residues) recently attended the International Workshop on the Harmonisation of Data Requirements and Evaluation of Pesticides in Seoul, and an OECD seminar on pesticide minor uses and risk reduction in Canberra.

John took the opportunity to present a poster in Seoul and he also gave a talk in Canberra on the ACVM Group's third party registration scheme. This is the scheme in which parties other than the proprietors of pesticides can generate suitable residue data so that an MRL can be set for a pesticide on minor crops. Then the minor (e.g. off-label) use can be officially registered under the ACVM Act and, if accepted by the proprietor, added to the label of the pesticide. Two such registrations have thus far gone through the new system, with the cooperation of both the growers and the proprietors.

The scheme can also be extended to additional uses for veterinary medicine products but to date all of the interest has been with plant compounds.

The presentations on the scheme were well received at both international fora, which were attended by regulators and pesticide users and proprietors from many countries.

### Registrant's obligations to communicate changes

**Product registrants have an obligation to communicate changes to their labels and registrations to those distributors and users who practically need to know. While the user or prescriber of a product has the responsibility to be familiar with label requirements, situations arise where an unheralded change to a product's conditions of registration may not be immediately recognised. Some changes are generic and may be communicated directly by the ACVM Group; however, in general, alterations to product specific requirements (such as revised withholding periods) rely on the registrant or their distributor to ensure traders, veterinarians, advisors or users are kept informed.**

## Requirements of the 'expert panel' during the GRAS process

When the 'expert panel' receives a Generally Recognised As Safe (GRAS) application, it will have already been assessed as meeting the criteria for inclusion onto the stated GRAS list. The Assessor (Technical Standards-Toxicology) will have viewed the supporting data provided with the application and decided whether it is sufficient to support its inclusion.

The most useful supporting data is its inclusion on international GRAS lists, particularly the US and EU lists. If this has not been provided, the Assessor will search these international lists and note their inclusion when forwarding applications to the 'expert panel'. However, inclusions on international GRAS lists should not be the sole form

of supporting material. As this is a non-fee paying process, it is the job of the applicant to provide enough data for the assessor to be completely happy with the inclusion of the substance on the New Zealand GRAS list – the job of the 'expert panel' should not be time consuming.

### The job of the 'expert panel'

- To view the list of substances presented to them and, **using their knowledge and experience**, note any immediate issues that come to mind, particularly if they have knowledge that might preclude a substance from being GRAS.
- If a substance is known to them, then all aspects of safety, for the proposed

use, should be considered – still using their own knowledge.

- If a substance is not known, it should simply be noted.

Because there are nine 'experts' on the panel, it is likely that someone will have knowledge about each of the proposed GRAS substances, hopefully covering them all. The proposal document is also put out for public discussion, thus subjecting it to a wide range of opinion.

This filter system should be sufficient enough that our 'experts' at NZFSA can observe and moderate the inclusion of GRAS substances without having to use excessive resources.

## Compliance update

Since the holiday break, the ACVM Group has 'hit the ground running' in the compliance area. For the months of December 2003 and January 2004, 15 compliance matters have been reported and are under investigation. A number of these relate to advertising claims on products that have not been approved by the ACVM Group.

The ACVM Group has put together an 'active' compliance list of those companies/persons who are of ongoing concern to us in regards to non-compliance. This will mean that over the next 12 months, companies/persons on the list could be audited as a result of repeat non-compliances and/or may be included in our ongoing 'slice of life' audits carried out for specific category types (e.g. equine, homeopathic etc.) where we would be taking particular note of manufacture, sale, and use of such products in these fields.

## Imports Review Programme

The NZFSA is currently undertaking a review of the arrangements that control imports that are covered by legislation administered by the NZFSA. This includes:

- imported food and ingredients
- food-related products (e.g. tableware)
- agricultural compounds and veterinary medicines
- stock feed and pet food.

The review team is made up of non-NZFSA staff and will be led by Dr John Hellstrom, ex-chair of the Biosecurity Council. The team includes a public health expert, an economist, an animal feedstuffs specialist and a project manager. Julian Waters, who was also part of the Expert Panel for the Antibiotic Resistance Review, is one of the team members with a good understanding of the ACVM-related issues.

The review is one of a range of projects, each dealing with specific parts of the imports puzzle. The related projects that come under the scope of the main programme include:

- A Strategic Review of Arrangements Controlling the Importation of Food and Food-related Products into New Zealand
- Trans-Tasman Imports Inspection Review
- Imports Food Risk Profiling
- BSE Categorisation Process Review.

## Staff update

**Profile:**  
**Vanessa Philp**  
**Advisor, Operations Team**



I grew up in Wellington, and until recently was working for the Institute of Chartered Accountants of New Zealand.

The time came to further my career, meet new people and experience new challenges, which led me to joining the ACVM Group of the NZFSA in the role of an Advisor in the Operations team.

Even in my first week, I have found that the people are really friendly and I feel like I have known them longer.

I am excited to be working with the ACVM Group and getting to know the team even more.

In my spare time, you will find me lifting weights or running at light speed on the treadmill at the gym. I also spend a lot of time with my eight-year-old son.

I really enjoy singing (but you won't catch me on New Zealand Idol) and I have been involved in many singing groups in the past. Now I am just the karaoke queen.

## EMPLOYMENT OPPORTUNITY

### NEW ZEALAND FOOD SAFETY AUTHORITY

#### Assessor (Technical Standards – Plant Compounds) ACVM Group

The New Zealand Food Safety Authority (NZFSA), a semi-autonomous body attached to MAF, has been established by Government to administer all New Zealand food-related legislation. Its role is to protect and promote public health and safety and to facilitate access to overseas markets for New Zealand food and food related products. The ACVM Group is a business group within the NZFSA, with responsibility for administration of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

This is an outstanding opportunity to join a forward thinking organisation in our buzzing and challenging environment. This is a twelve-month fixed term position to replace a staff member taking leave and is based in Wellington. The principal purpose of this position is to provide technical input into the approval process of plant compounds.

If you have initiative and drive and the following attributes we need you:

- a degree in science, chemistry, pharmacology, agriculture, horticulture, or other relevant area;
- analytical skills, problem solving and decision-making abilities;
- organisational and time management skills, and ability to work under pressure;
- effective written and oral communication skills; interpersonal, negotiating and debating skills.

If you are keen to learn, and an enthusiastic individual with a great attitude, then we want to hear from you. This could be an opportunity for a person returning to the workforce or for a new graduate with the contract able to be negotiated in terms of hours. The ACVM Group would consider work sharing as an option. There is a very supportive and co-operative working environment with technical assistance available through the learning phase.

Visit [www.maf.govt.nz](http://www.maf.govt.nz) (click on Employment in MAF) to obtain a job description and to apply online. Alternately, contact Andrea Mackenzie by telephone 04 463 2540 or email [andrea.mackenzie@nzfsa.govt.nz](mailto:andrea.mackenzie@nzfsa.govt.nz). Applications may also be sent to Andrea Mackenzie, Acting Executive Manager (Business Services), New Zealand Food Safety Authority, P O Box 2835, Wellington.

Applications close on **Monday, 16 February 2004.**

The NZFSA is committed to equal employment opportunities.