



What's coming up

- The next **AVMAC** and **Industry Liaison Group** meetings will be held on 24 February 2005 in Wellington. The other 2005 meeting dates for both groups are 19 May, 18 August and 17 November.
- The third **VICH conference** will be held in Washington DC, USA. There is a flyer enclosed with this edition of *AgVetLink*. We would encourage you to register early and book flights if you are intending travelling to the States at this time as it is very close to a holiday period. Don't forget to check new travel arrangements with your travel agent prior to travel as a new passport may be required for some travellers.
- The **Codex Committee on Pesticide Residues** will meet in the Hague on 18 to 23 April 2005. New Zealand representatives will be Dave Lunn and Warren Hughes.
- The **2005 NZFSA conference** will be held in Wellington on 28 and 29 September at the Duxton Hotel. The proposed programme should be out early in the new year.
- The **20th International Conference of the World Association for the Advancement of Veterinary Parasitology** will be held in Christchurch from 16 to 20 October 2005.
- The **Antibiotic Resistance Expert Panel** will be contacting some registrants and other interested parties to request any new scientific data for consideration (see page 9).

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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.

General enquiries: Gill Wilson

ACVM Group, New Zealand Food Safety Authority, PO Box 2835, Wellington, New Zealand

Phone: 04 463 2539, fax: 04 463 2566, email: gill.wilson@nzfsa.govt.nz, website: www.nzfsa.govt.nz/acvm

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

GENERAL INTEREST

ACVM workshops

The workshops held in Auckland on the 4th and 5th of November had a good turnout on both days. Thursday was the busiest day with predominantly plant compound people and consultants of both plant compound and veterinary medicine interests. Friday was a shorter day with mostly veterinary medicine people. Similar comments, suggestions and queries were raised on both days.



Workshop participants

The main points were as follows:

■ Our contacts database is out of date because information, such as *AgVetLink*, is not reaching people. Consultants should be added into the database so that they may also receive *AgVetLink*. At the moment it is mainly going out to registrants. (See box page 9.)

■ *AgVetLink* should be split into veterinary medicines, plant compounds and general interest instead of being mixed up. Presently it is hard to read

because of this. (*Recommendation implemented with this issue.*) Also, it needs to be more colourful because it is boring to look at. (*Recommendation under consideration – cost of full colour production is considerably higher.*) In addition, registrants of plant compounds feel that veterinary medicines have been favoured recently.

■ Some ERMA/HSNO issues were discussed, e.g. the concern that ERMA will not release information to registrants that the ACVM Group

requires for registration, and this is holding up many applications. The ACVM Group promised to meet with ERMA to discuss these issues.

■ The Data Assessment Service (DAS) process is taking too long, and there should be a more specific timeline.

■ The fee system (specifically for C9 administration type applications) is 'out of whack' and needs to be

looked at. In registrants' opinion, some applications, e.g. C3 pack size change, should be handled by the Advisors.

The ACVM Group will work through the comments received with a view to making changes in the new year. Watch this space! In the meantime, if you have other suggestions for improvement, contact:

Maree Zinzley
phone 04 463 2546 or
email maree.zinzley@nzfsa.govt.nz

Christmas Break

The ACVM Group offices will be closed for the Christmas break from **Friday, 24 December 2004, until Monday, 10 January 2005.**

It is likely that the office will not be fully staffed for the first few weeks of 2005 because we are encouraging staff to take longer leave periods in light of the expected workloads later in the year.

GENERAL INTEREST

Processing remaining applications to update registrations

The ACVM Group advised registrants that it was unlikely that all the applications for updating registrations could be processed by 1 July 2004. Consequently, the Group would continue to recognise the existing registrations until applications could be processed.

Most trade name product registrations have now been updated and have been reissued with revised conditions. However, about 300 applications have not been processed yet. There are some applications where the data assessment parts of the applications are unacceptable. Many of the applications still to be processed are ones in which some additional information must be provided by the applicant.

Transitional registration policy

For compliance reasons unprocessed applications cannot be left open indefinitely, recognising registrations that are technically not valid. To manage this situation, the ACVM Group's Decision Making Committee (DMC) has promulgated the following transitional registration policy:

1. The ACVM Group will continue to recognise the registration that was current at 1 July 2004 for any agricultural compound or veterinary medicine that was required to be updated by the transfer date of 1 July 2004 (that has not been updated) for which an update application has been received.
2. The registration of an agricultural compound or veterinary medicine to which 1 above applies will cease to be recognised as the current registration on:
 - an ACVM Group decision to update the registration; or
 - a decision to decline the registration; or
 - the close of business 16 November 2005 (whichever occurs first).
3. Conditions or requirements imposed under the Animal Remedies, Pesticides

or ACVM Acts prior to 1 July 2004 will continue to apply to affected products in the interim period.

This means that over the next 12 months all pending applications will be sent to the DMC for a decision in time to have final decisions before 16 November 2005.

Deficient applications

Deficient applications that are sent to the DMC are likely to be declined. If this happens in regard to a product that had been registered, that product will no longer be registered and it will no longer be legal to import, manufacture, sell or use the product unless this is specifically allowed in the DMC decision. A new application to register the product will have to be lodged with the ACVM Group if a registrant wants the product to be registered in New Zealand.

If applications are deficient, applicants will be advised before their applications are sent to the DMC so that they have an opportunity to address the deficiency, thus avoiding a DMC

decision to decline the registration. The timeframe for addressing the deficiency should be discussed with ACVM Group staff.

VTA products

Special arrangements will be made for vertebrate toxic agent trade name products. In most cases, updating the registrations of these products has not been delayed because of a lack of information. They have not been updated because the ACVM Group does not want to force dual regulatory control systems as a result of the ERMA decision not to transfer 1080 along with the other vertebrate toxic agent substances into the main framework of the HSNO Act (see article on page 7).

Unless it is necessary, applications to register these products will not be sent to the DMC until all VTA products can be regulated in a coordinated manner. It is hoped that a decision on 1080 will be made in sufficient time to update registrations before 16 November 2005. However, if there are further delays, a new deadline will be set for updating the registrations of VTA products.

NEWS FLASH!!!! Departing ACVM Group

It is with sadness and deep regret that we advise of the pending resignation of one of our longest serving employees, **Catherine Alsford**. Catherine has been with the ACVM Group for 11 years and her corporate knowledge and contribution to the ACVM Group has been immensely valuable.

I am sure you will all join us in wishing Catherine good luck and best wishes in her future endeavours. Thank you, Catherine, for all your efforts with the ACVM Group, and with your many registrants and contacts. You will be sorely missed by everyone.

GENERAL INTEREST

Website update

Discussion papers/ draft policies

- Vertebrate toxic agents – registration requirements
- Proposals for GRAS register inclusions – 2004
- GRAS for Oral Nutritional Compounds, Veterinary Medicines other than Oral Nutritional Compounds and Plant Compounds (Nov 2004)

Updated document

- Register of Codes of Practice approved under the ACVM Act

New items

- ACVM customer survey graphs and comments (<http://www.nzfssa.govt.nz/acvm/publications/articles/customer-survey-2004/index.htm>)
- October *AgVetLink*
- PAR traders *AgVetLink* (September)
- Summary of submissions on the NZFSA discussion paper: Proposed Amendments to the ACVM Regulations 2001
- Area for work relating to the Antibiotic Steering Group and Expert Panel 2004
- Area for vertebrate toxic agents including criteria for test certifiers, traders and handlers
- *ACVM Specified Requirements Products Standard and Guideline Oral Nutritional Compounds with non GRAS Ingredients*
- *ACVM Specified Requirements Products Standard and Guideline Veterinary Medicines Containing Pheromones*
- *ACVM Specified Requirements Products Standard and Guideline Oral Nutritional Compounds Containing Nutrients with Known Therapeutic Uses (Functional Nutrients) +/- non GRAS Ingredients*

Imports programme review

At the end of November NZFSA received the final report of the review (by an independent review team) into New Zealand's imports programme for the imported products that come under NZFSA's management. This list includes agricultural compounds (including veterinary medicines and animal feeds), food and food containers. The review, the first since 1996, involved a ten-month investigation and consultation period. The final report includes the review team's findings, conclusions and recommendations. (Check the NZFSA website if you are interested in viewing a copy.)

Agricultural compounds

Overall, the review team found that the imports regime for agricultural compounds is generally adequate. However, the chair of the review team, Dr John Hellstrom, said that the lack of routinely collected data on import shipments made it difficult for the review team to draw any firm conclusions. Therefore, one of their main recommendations is to improve data collection and management systems.

Specific to the agricultural compounds area, other recommendations include instigating risk-based testing and targeted process audits, and ensuring that any new regulations are risk-based and efficient.

Tim Knox, Director of Domestic and Imported Food, welcomed receipt of the report. He said, 'We are very satisfied with the process that the review team went through to produce the report. They have considered all aspects of the imports regime and consulted with a wide range of stakeholders. The next step is for NZFSA to address the report's recommendations, consider their implications and plan the way forward. This review is not something that happens every day, or even every year. So we have to take the time to consider its implications carefully'.

Early in the new year, the ACVM Group will begin working through any implementation implications for our areas of responsibility, and we will be using *AgVetLink* as a key communications tool for this.

Domestic food review

The first four papers covering the domestic food review are out for consultation and the fifth, covering cost recovery principles, will also be available before Christmas. Work has begun on other aspects of the review that may directly impact on ACVM areas – there are papers being developed at the moment covering programme performance, compliance and sanctions, and 'other' approvals (such as GMP or good manufacturing practice). Consultation will take place in the New Year, and the papers should be considered by ACVM registrants and other regulated parties because there is likely to be an impact on them. We will keep you informed of progress via *AgVetLink*, and we would welcome comments from you on the proposals.

GENERAL INTEREST

Registration renewals – your thoughts, please!

As advised in our communication with registrants, a trade name product's registration expires three years after approval. So what happens on expiry? The ACVM Group proposes the following procedure:

- ACVM Group system will generate a generic letter to send to registrants whose products are expiring
- Registrant will submit a Product Data Sheet and labels to the ACVM Group
- ACVM Group will treat this as a C9 'administration type' application
- ACVM Group will have 15 working days to process the application
(time to process = approximately one hour)
- Charging will be based on actual time taken.

If a third party is involved in giving information for the registration of a product, e.g. formulations supplied by an overseas company, it will be the registrant's responsibility to source this information to ensure that the ACVM Group is fully informed.

The ACVM Group would appreciate your thoughts and input on this proposal so we can implement the requirements as soon as possible. However, if you have products that are expiring within the next month or two, we suggest you provide the above information to avoid delays. Send comments to:

Maree Zinzley
ACVM Group, NZFSA
PO Box 2835, Wellington
Email: maree.zinzley@nzfsa.govt.nz

Biosecurity Act – changes in responsibility

At the Biosecurity summit held at Waipuna Lodge in Auckland on 18 and 19 November, the newly named 'Biosecurity New Zealand' (BNZ) gave presentations and held a number of workshops of interest to the ACVM Group. There was an opportunity to work through the new responsibilities that the agency is taking on from the Ministry of Health, the Ministry of Fisheries and the Department of Conservation, as well as to look at any potential changes for the traditional areas of responsibility. The summit was attended by Debbie Morris and Warren Hughes, and a number of ACVM stakeholders were present as well.

The changes in responsibility are explained in *Biosecurity* magazine issue 55, November (<http://www.maf.govt.nz/biosecurity/publications/index.htm>). All of the presentations made at the summit are also available (<http://www.maf.govt.nz/biosecurity/biosecurity-summit/index.htm>).

In the new year, the ACVM Group will work with the new Directors of BNZ (in particular, Debbie Pearson, Pre-border; Peter Thompson, Post-border; and Douglas Birnie, Policy and Business Services) to determine what changes, if any, are needed to the currently agreed ACVM thresholds and criteria to support the altered biosecurity responsibilities.

Check out future editions of *AgVetLink* for details of any proposals.

Chemistry standards review

The *ACVM Registration Standard and Guideline for the Chemistry of Plant Compounds* is currently being updated. This is likely to be completed and available for comment by the end of January 2005. A sneak preview of some of the proposed changes can be found in the second part of the ACVM Registrants Workshop presentation on the *ACVM Registration Standard and Guideline for the Chemistry of Plant Compounds* found on our website: (<http://www.nzfsa.govt.nz/acvm/publications/workshops/nov-2004>).

The update of the *ACVM Registration Standard and Guideline for the Chemistry of Veterinary Medicines* will begin within the next few months.

Submissions on changes proposed to either standard are welcome and may be emailed to Warren Tully (warren.tully@nzfsa.govt.nz).

Sign up to the 'Notification of changes to the website' on the ACVM homepage to get email advice of changes and updates.

GENERAL INTEREST

MRL update

The following MRLs were finalised as the third amendment to the food standards in early November:

- setting an MRL for Cyprodonil in grapes
- setting MRLs for the compounds Xylazine and Lignocaine in deer velvet
- setting an MRL for Permethrin in kumara.

Exemptions from MRLs were also made for the following compounds:

- Permethrin
- Fatty acids of 8 carbons or more in their chains, and their salts
- Thiopental sodium
- Iodine (organic and inorganic forms)
- Isoxsuprine (lactate)
- Medroxyprogesterone acetate
- Oestradiol-17beta and its esters or conjugates
- Etamiphylline camsylate.

The fourth and final amendment to the

food standards for this year entered consultation on 7 October. Consultation was extended for all compounds in this amendment bar Tebuconazole as a result of a request from another country.*

The proposed new MRLs for Tebuconazole were not delayed because they have minimal impact on imports and are important for a certain industry sector. They are proceeding through the final legal stages of the MRL setting process.

The following proposed MRLs have been affected by the extended consultation period and are expected to be gazetted in late December:

- setting limit of detection MRLs for Emamectin Benzoate in kiwi and pome fruit
- setting MRLs for Methoxyfenozide in kiwi and pome fruit
- setting MRLs for Thiamethoxam in kiwi and pome fruit

- setting an MRL for Fludioxylin in grapes
- setting limit of detection MRLs for Milbemectin in apples and avocados.

The following compounds are proposed to be made exempt from MRLs:

- Dinoprost and its salts
- Salicylic Acid and its derivatives
- Demborexine
- Zinc and its salts.

* Whenever MRLs are proposed, NZFSA also notifies the proposals internationally under the World Trade Organization Agreement on Sanitary and Phytosanitary (SPS) Measures. The period of international consultation for the fourth MRL amendment has been extended to 60 days to be consistent with international guidelines. NZFSA is currently considering how to deal with SPS notifications in future.

PLANT COMPOUNDS

OECD meeting

ACVM Programme Manager (Toxicology and Residues) John Reeve has just returned from the 16th OECD Working Group on Pesticides, Registration Steering Group, and Risk Reduction Steering Group meetings in Paris. Generally the meetings were uneventful, but the strong theme of work sharing and subsequent improvements in times taken for consideration of applications for registration continue. There is to be a workshop in Washington DC for assessors to familiarise themselves with the way in which other countries carry out their assessments, and the use of electronic tools to assist in the assessment processes.

One item to note is that New Zealand was accepted to host back-to-back Risk Reduction Steering Group and Registration Steering Group meetings in late November 2005. This will involve a seminar relating to the use of new application technology and related topics in pesticide risk reduction, as well as the formal meetings of the two Groups. The meetings will bring an increased awareness in this part of the world of the valuable work that is going on in the OECD relating to pesticides and, in particular, efforts to harmonise registration systems and assessments. It should also mean a reduced cost of attendance for New Zealand delegates.

Minor use, minor species

The ACVM Group facilitated a meeting of interested parties to discuss the problem of approval of claims for minor species and for minor uses of registered products. Representatives from VegFed, ACVM Group, NZFSA Dairy & Plants Group, industry companies and several consultants attended. A number of initiatives from the meeting will be progressed, including the idea of lower data requirements for produce (such as herbs like parsley, basil, coriander and mint) that form a minute part of the New Zealand dietary intake. This follows proposals being considered internationally.

PLANT COMPOUNDS

Meeting with the US EPA

Probabilistic modelling of potential dietary intakes for pesticides used in food production

Debbie Morris and John Reeve met with David Millar and David Hrdy of the US Environmental Protection Agency (EPA), taking advantage of the EPA expertise in utilising this sophisticated technique for better modelling of dietary intakes of residues to get up to speed with the technique, its possible pitfalls, and methods of educating the public about the changes.

The New Zealand database of food intake figures (derived from the recent National Nutrition Survey that was carried out by Otago University on behalf of the Ministry of Health) was also looked at, and we were advised that it was good enough to use in probabilistic modelling.

The outcome of the meeting was a greater understanding of the technique, and greater confidence that it has a potential future for use in New Zealand.

Recent events: PC & VTA

- Paul Dansted attended a familiarisation tour for Government officials organised by the **Vegetable Growers Federation**. The tour spent the day around the Pukekohe area and proved to be extremely valuable for all of those taking part. Thanks, VegFed!
- Warren Hughes did a presentation on proposed controls for vertebrate toxic agent products for the **National Possum Control Association** in Wellington and attended their conference on 24 and 25 November.

VERTEBRATE TOXIC AGENTS

Holding pattern on VTA product registrations

The ACVM Group has been working on a standard for vertebrate toxic agents (VTAs) and the conditions of registration that are to be imposed on each VTA trade name product. Decisions have been delayed because the ACVM Group wanted to ensure that its conditions of registration were compatible with and complementary to the controls imposed under the transfer of VTA substances into the main framework of the Hazardous Substances and New Organisms Act 1996. These substances, except sodium fluoroacetate (1080), were transferred as of 1 November 2004 (ref: *New Zealand Gazette* notice, issue 141, 29 October 2004) and the controls are now clear.

It was hoped that updating the registrations of trade name products containing these substances could progress. However, the decision by ERMA not to transfer 1080 has had an effect on the ACVM registration of all VTA products.

Existing controls continue

To avoid prompting dual regulatory systems in the short term, the *NZ Gazette* notice included transitional controls specifying that the controls in place before 31 October 2004 will continue to apply until 30 April 2005. This means that the existing controls will continue and there is no obligation to comply with the new HSNO controls until at least May 2005. ERMA has indicated that this date may be extended.

Interim registrations

Consequently, the ACVM Group will have to recognise interim registrations and delay imposing any changed conditions until then (or later if there is any further delay in ERMA's timetable to process a decision about the fate of 1080 as a vertebrate toxic agent substance) unless other circumstances require earlier action.

In the meantime, products can still be used as they have been and there is no definitive advice on the medium- to long-term regulatory control of these products. The ACVM Group will complete its consultation and make it clear what conditions it will impose on each trade name product. However, any new conditions will not be imposed until ERMA has made a decision about 1080.

1080 products

Because 1080 was not transferred, trade name products containing that substance are still regulated under the transitional provisions of the HSNO Act (i.e. the old Pesticides Act registrations) and the ACVM Act. They can still be used as they have been until a decision about continued use of 1080 is made by ERMA. There is no need to recognise interim registrations as with the other VTA products. Once ERMA makes a decision on 1080, the ACVM Group will update the registrations of 1080 trade name products.

Recent events: VM

- The ACVM Group has instituted six-monthly meetings with the **Pork Industry Board** to discuss areas of mutual interest. The first of these was held 9 November.
- An ACVM staff member gave a presentation on prescription veterinary medicines to a veterinary conference organised by **The Vetservice Group**. This organisation provides business development, quality systems and marketing support to member veterinary practices. Vetservice has widespread support from major veterinary practices and owns the major veterinary marketing brands.
- Debbie Morris and Maree Zinzley were invited to speak to the **ARPPA** AGM in Auckland on 12 November. This proved a great opportunity to talk to ARPPA members about the outcomes from the recent ACVM workshops and ACVM Group plans for the 2005 year.
- The **AVMAC** meeting held on 16 November discussed more fully the role and responsibilities of AVMAC in the future and considered the make up of the council. Further work in being undertaken and will be presented to the next meeting.

Toxicology review

We have carried out a review of the veterinary medicines in the New Zealand market that are banned in the EU or USA. They are subject to restrictions on their use so as to avoid trade problems, but it was necessary to update our assessments of these various substances to see if there is any new information that would change their status in New Zealand.

The draft review was submitted to the Toxicology Peer Review Group for comment, but because there was new information on carbadox (one of the substances reviewed) from the recent Codex Committee on Veterinary Drugs in Foods meeting (see below), it was felt that a full consideration by the Group should wait until the new information and any Codex actions could be taken into account. The review is being updated and a full Peer Review Meeting will be called as soon as possible to finalise the NZFSA recommendations for action.

15th Codex Committee on Veterinary Drug Residues in Foods

The 15th Codex Committee on Veterinary Drug Residues in Foods was held in Washington DC from 26 to 29 October 2004. Some veterinary drug MRLs were considered, with mixed results as far as progressing through the Codex system.

New Zealand submitted a paper that addresses the way in which violations of MRLs on imports should be handled at the border: *Draft Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods*. It includes an appendix on the prevention and control of veterinary drug residues in milk and milk products. The document received many excellent comments that should enable this paper to progress quickly at the next meeting.

Another major paper considered by the meeting was the *Draft Code of Practice to Minimise and Contain Antimicrobial Resistance*. The draft was considered paragraph by paragraph and was finalised except for the definition of the term 'antimicrobial'. The draft definition, which was the European Union's, could not be accepted by the USA because of the definition that exists in their current law, and the USA definition could not be accepted by the Europeans. Progress on the document was on the verge of being frozen because of this stalemate until a last minute caucus of the EU, USA, JECFA and New Zealand (Debbie Morris) reached a compromise agreement, and the very valuable document advanced to all but full acceptance.

VICH – update on pharmacovigilance harmonisation

Debbie Morris represented the ANZ VICH Committee at the meeting in Berlin on 19-20 October 2004. Following this meeting, the VICH Steering Committee provided an update on the development of VICH pharmacovigilance.

The Steering Committee reaffirms its commitment to the VICH process and recommends that the Pharmacovigilance Working Group (WG) be reconvened to complete the harmonisation process to deliver mutually agreeable guidelines for adverse event reporting. The Steering Committee recommends four principles to assist the WG in coming to an agreed position:

- Flexibility by WG representatives will be required.
- There must be willingness to negotiate and compromise on five key issues:
 1. definitions on similar/identical products for expedited reporting
 2. data field requirements
 3. common dictionary
 4. timelines for expedited reporting
 5. timelines for periodic summary update (PSU) reports.
- The VICH Guidelines produced should be an improvement over the status quo.
- Regulators should not overregulate unnecessarily.

The Steering Committee is making the following proposals to the WG:

- Each product should have a single International Birth Date. This would be the first marketing authorisation (registration approval) in any of the VICH represented regions. This is necessary to synchronise the PSU to the product birth date.
- PSUs are subject to local regulatory needs; however, reports based on six-monthly data sets are considered appropriate. Some states wish to have a 12-monthly PSU cycle, provided that the product has been approved for more than two years in a VICH region.
- Clarification of the reporting issues under points 4 and 5 above is required.
- The Steering Committee is committed to seeing a resolution reached on the type of adverse event information, the way it is captured, and the time and method of its transmission to other VICH partners.
- In the data capture area, information should be divided into dispensable (non-mandatory) and indispensable (mandatory) information.
- The adoption of common terminology is seen as central to the implementation of harmonised guidelines.

Antibiotic Resistance Expert Panel

The Antibiotic Resistance Expert Panel met for the first time on Monday, 18 October 2004. The meeting went very well and centered mainly on the planning and parameters of the report. The Panel is undertaking a search and review of domestic and international literature and will commence work on the initial sections of the report before the next meeting on 9 December.

The Panel will also consult with other interested parties, and NZFSA is arranging for requests to go to registrants and organisations such as the NZ Microbiological Society and the NZ Institute of Food Science & Technology, asking if they have any technically robust information available for consideration by the Panel. (If you have information and have not been contacted, email michelle.casey@nzfsa.govt.nz)

It is expected that members will consult with the Antibiotic Resistance Steering Group in April/May 2005 and that a first 'rough' cut of the report will be available by April.

AgVetLink distribution

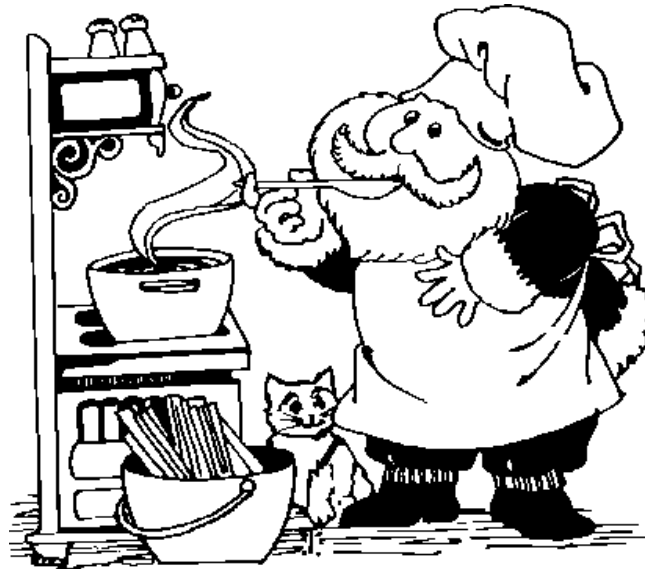
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Gill Wilson
ACVM Group
NZFSA
PO Box 2835
Wellington

Or email:
gill.wilson@nzfsa.govt.nz

Happy Holidays

***Best wishes for the holidays
from the ACVM Group***



***Don't forget the New Zealand
Foodsafe Partnership four 'Cs' –***

CLEAN hands and food preparation surfaces

COOK food thoroughly

COVER food until ready to eat, and

CHILL food correctly and quickly

And watch out for Foodsafe Freddy's advice on TV