



AgVetLink

ISSN 1174 - 3735 ISSUE NO 54 FEB 2006

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From the Director

Welcome to our first issue of AgVetLink for 2006! Since the new year, all staff have been working to keep up with 'business as usual' while making contributions to the strategic initiatives of the organisation. Two of these, the Imported Food Review and the Domestic Food Review, are highlighted on page 2.

Application numbers have been unusually high for the past three months (see graphs on page 4), putting pressure on the system. Therefore, filling staff vacancies has been a priority. Lucy Johnston (page 5) has already started work and several other people will join the Group in March.

In the compliance area, we are pleased to note that our efforts to inform and educate are paying off (see page 5). We have also reached an operational agreement with Biosecurity NZ for compliance relating to new organisms in veterinary medicines (page 8).



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.

General enquiries: Mary Alexander
Approvals and ACVM Group, New Zealand Food Safety Authority, PO Box 2835, Wellington, New Zealand
Phone: 04 463 2550, fax: 04 463 2566, email: mary.alexander@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

Products not updated to ACVM Act

Under the Agricultural Compounds and Veterinary Medicines (Transitional Provisions) Regulations 2002, applicable products were deemed to be ACVM registrations until 1 July 2004. At that time, they would cease to be registered unless the registrant's application to update the registration had been approved by the ACVM Group.

This period was extended to mid-December 2005. After this, it was decided that if a registrant had made no substantial effort to update his/her product(s), they would be removed from the register. Registrants were advised by letter of this policy.

Products affected are:

AOO1493	Penstrep LA
AOO2178	Millophyline-V Tablets
AOO5889	Bomastrep
AOO6454	Cloverfield Teat Spray
AOO6569	Magnetol
AOO7491	Relex Time Capsule
AOO7650	Prime Zinc Sulphate Heptahydrate
AOO7831	Exelpet Ezy-Dose Intestinal All-Wormer for Dogs
AOO8029	Genestran
POO0351	Tomset
POO2794	Saprene
POO2871	Mortein House & Garden Insect Killer
POO3271	Galben M 8-65
POO4781	Carboxin Technical Seed Dressing Fungicide
POO5039	Tomato Quik
POO5337	McGregor's Snail & Slug Pellets
POO5338	McGregor's Derris Dust

If the registrant has had ongoing dialogue with the ACVM Group regarding non-updated products where the applications cannot be resolved expediently, it is likely that those products will be removed from the register in the near future.

Food reviews – Impact on the Approvals and ACVM Group

Domestic Food Review (DFR)

The New Zealand Food Safety Authority (NZFSA) is in the public consultation phase of a Domestic Food Review with Position Paper 8 in the series just released for public discussion. This Position Paper invites public comment on a comprehensive package of proposals for the future food regulatory programme, as might be recommended to the Government by NZFSA. There are currently nine projects concerned with the process of DFR consultation and the results of that consultation.

This is only the second time in the last 30 years that the Government's role in the New Zealand domestic food sector has been critically examined at an official level. The last review was in the late 1980s, and led to the Food Amendment Act 1996 and eventually the establishment of NZFSA.

Imported Food Review (IFR)

New Zealand imports about 19 per cent of food by value and that proportion is increasing. In 2003 an external review of the NZFSA regime for imported food and food-related products was commissioned. This was the first such review since 1997 and during that time the responsibility for food safety shifted from the split MAF/Ministry of Health model to NZFSA.

The report of the review, which was to recommend cost-effective ways to improve the regime that regulates the importation of food into New Zealand with the focus on reducing illness, deaths and the other costs associated with unsafe food, was released in December 2004. Government's response to the recommendations include two main projects with associated subprojects to be carried out during 2006/2007.

Impact on the NZFSA Approvals and ACVM Group

NZFSA Approvals and ACVM staff are involved in the approvals part of the DFR and IFR projects. Although these reviews are not concerned with the ACVM Act, our rationalisation and staff multiskilling approach has enabled some of our previously ACVM-dedicated staff to assist in this project work.

MRL update

Consultation on the last amendment of 2005, and the second amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) 2005 No 2, has been completed. This amendment, which consists of four new MRLs, is due to be gazetted within the next few weeks.

The next amendment to the MRL standard is likely to contain a total of nine new MRLs, seven exemptions and one removal of an obsolete compound. In addition, there are a number of administrative tidy-up changes that aim to make the standard more user-friendly. This will comprise amendment number three to the New Zealand (Maximum Residue Limits of Agricultural Compounds) 2005 No. 2.

Following consultation, the consolidated standard for 2006 will be issued later in the year.

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Responses, residues and all that jazz...

A speaker at the 2005 NZFSA conference stimulated discussions about regulatory and food issues that continued long after the event. **Patrick Wall**, former chief executive of the Irish Food Safety Authority and now adjunct professor of Food Safety at University College Dublin and board member of the European Food Safety Authority, presented some serious messages in a hilarious, irreverent package. Some of his 'food for thought' follows...*



Proportionality of response

Proportionality of response is a key message from Dr Wall, a qualified veterinarian and medical doctor, who also has an MSc in infectious diseases and an MBA.

In the initial stages of Britain's BSE epidemic, the British MAF tried to walk a fine line between simultaneously protecting consumers and protecting the beef industry and succeeded in neither. Dr Wall says it was perceived to be suffering from CJD: 'conflicting job description'. Consumer confidence was damaged in the commitment and ability of the regulatory agencies and the government scientists to protect public health. Since then there exists a risk that being seen as too close to industry can affect a regulator's credibility with consumers. However, if a regulator's response to a crisis is not proportionate to the health risk, then unnecessary commercial damage can result. "The public won't thank you for damaging national brands – and the economy – by taking action that is unnecessary and out of proportion to the risk."

Dioxin disaster

To support the point he recounts the disaster that befell the Belgian food industry, and the country's economy, in 1999. A small quantity of dioxins had been found in a batch of animal feed. Though highly toxic, by the time the

feed would have been consumed by animals or poultry which were subsequently processed into human food, any dioxin that remained would have been "a few parts per million" and of very little risk to human health. But the combination of a tardy response by the Belgian Government, lack of traceability and misinformation being fed to consumers led to a national catastrophe, ultimately resulting in the fall of the Government.

Industry responsibility

It is extremely challenging for food safety agencies to manage technical breaches in legislation that do not pose a health risk. The recent recall of all products containing Sudan 1 is another case in point. While the health risks were extremely low, one can't allow genotoxic carcinogens into the food chain and industry has a responsibility to know the source and quality of all of the ingredients, however small the quantity it uses in its products.

"Industry must look after its own interests and not cry bad luck when something untoward occurs and its reputation and brand is damaged." It is, says Dr Wall, rarely a case of bad luck. Rather, it is bad management on their part.

Adverse publicity

Dr Wall says you may not always be able to control adverse publicity associated with your products or reputation. He

highlighted an example of how a crisis in a foreign market impacted on Ireland's reputation as a producer of quality food: an Irish pharmaceutical company exported waste from a facility manufacturing the 'morning after' pill for incineration in Belgium. When herds of pigs in Holland, the world's third-largest pork exporting country developed fertility problems, the progesterone residue was found in their kidney fat and subsequently in the feed they were consuming. The feed was tracked back, and illegal and fraudulent practices were identified in the waste management company in Belgium. 'Ireland the Food Island' was portrayed as the source of the problem though it had nothing to do with Irish food. But the adverse publicity was outside Ireland's control. The media had a field day with a fried breakfast being equated to the morning-after pill.

The media is often accused of generating food scares but they are the professional communicators and agencies must interact with them in an open and transparent fashion, he says.

"The media are quick to recognise spin and will be unforgiving of the spin merchants. Corporate giants are a fair cop, followed by government bureaucrats, so building a relationship in peace time can come in very useful in assisting in the management of a crisis."

Dr Wall has high praise for New Zealand's attitude to food production, commending both the New Zealand Food Safety Authority which he says is in the lucky position of "having experts on just about everything", to the country's food-producing industries which are "match fit" as a result of the removal of farm subsidies in the 1970s and because of New Zealand's strong emphasis on free trade. NZFSA has an excellent reputation worldwide, he says.

To view Dr Wall's presentation, visit www.nzfsa.govt.nz

* excerpts from NZFSA's Food Focus, November 2005 issue

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Applications update

ANNUAL FEES

The first phase of the ACVM Annual Fee process for the 2006/2007 financial year will commence in March. At this time a list of your organisation's products that are ACVM registered will be posted to you.

Required:

1. Ensure that all products have been listed and categorised correctly.
2. Sign and return the list after noting any cancellations, amendments or changes on the product list. You will be contacted by an ACVM Advisor (Operations) if the indicated change requires an application to be submitted.

You may post or fax the completed product list – my contact details are below.

In May invoices for your annual fees will be sent. Payment will be due by 1 July 2006.

Please Note:

Annual Fee Charges
(per product)

Food Product:
\$405.50 +GST

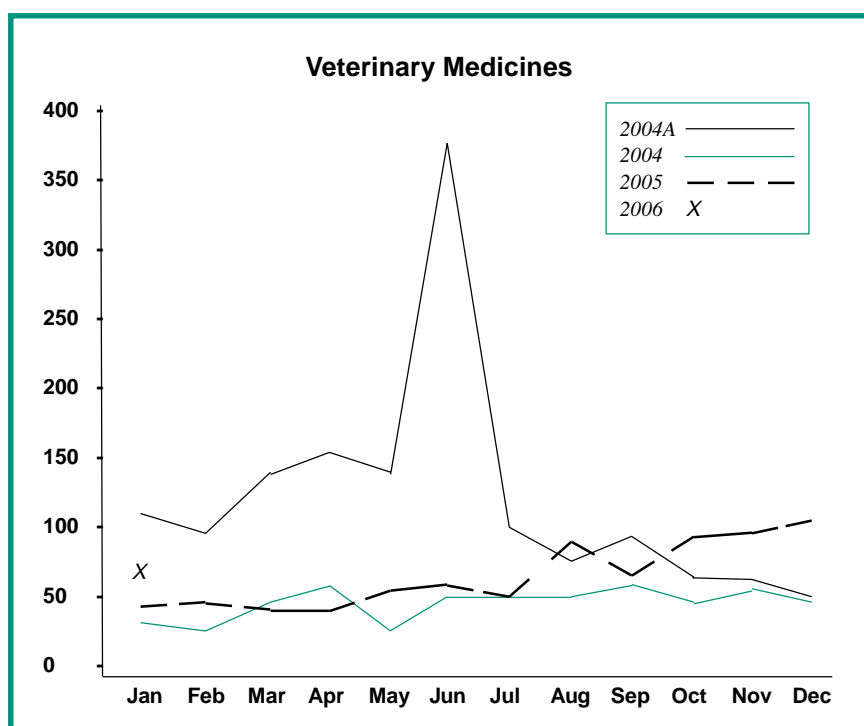
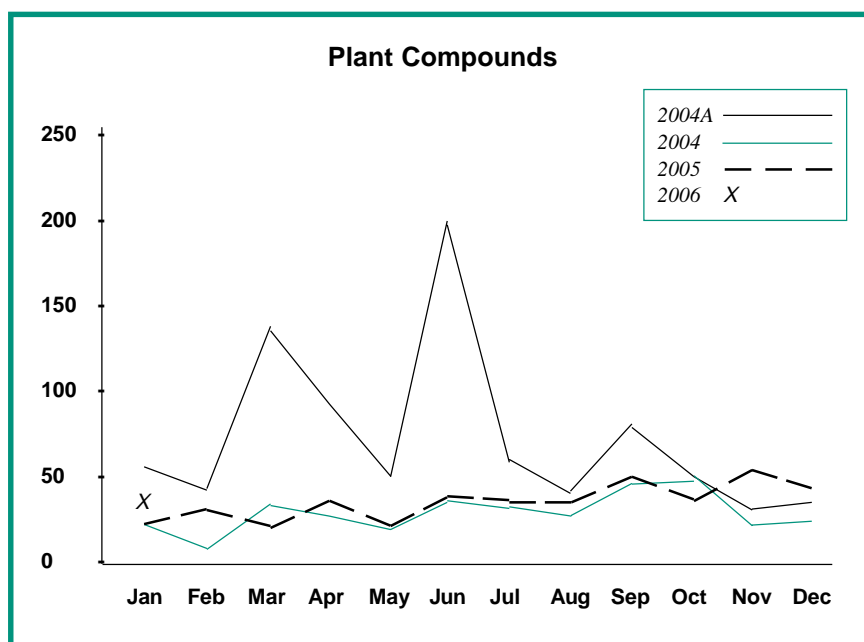
Non-Food Product:
\$335.56 +GST

If you have any queries please do not hesitate to contact me.

Hine Van Leeuwen
Advisor (Business Services)
Approvals & ACVM Group
PO Box 2835, Wellington
Tel: 04 463 2553
Fax: 04 463 2566
Email:
hine.vanleeuwen@nzfsa.govt.nz

The graphs below illustrate the applications received in the regulatory system (i.e. excludes data assessment service [DAS] applications) for the period 1 January 2004 to 31 January 2006 for plant compounds and veterinary medicines. The 2004A series includes ACVM update applications, while the 2004 series does not.

The number of applications the ACVM Group has received over the last three months has been significantly higher than for the same period in previous years. This has placed pressure on the Group.



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Compliance update

It has been quiet in the compliance area since Christmas. Most work at the moment involves education for 'first time offenders'. Efforts to inform registrants about advertising requirements also seem to be working. There has been a noticeable improvement in compliance with the advertising policy.

NZFSA has recently brought successful prosecutions under the Animal Products Act 1999 against two dairy farmers who sent bobby calves for slaughter which subsequently tested positive for sulphonamide drug residues. They were

fined for failing to comply with a notice (made under the Animal Products Act 1999) that prohibits suppliers of farmed mammals from presenting animal material for primary processing if it has been treated with or exposed to a registered agricultural compound and is within the withholding period. In both instances the animals were found to have been exposed to compounds used in the treatment of calf scours. The compounds contained sulphonamide drugs.

Breaches of the notice can carry a fine of up to \$20,000. In these cases the fines

were \$500 - \$1000 plus costs.

Geoff Allen, NZFSA's Director of Compliance and Investigation, said, "I am pleased with these results. It serves as further evidence that farmers who choose to jeopardise our animal products markets by misusing veterinary medicines stand a very good chance of being caught and publicly punished. I urge all farmers to scrupulously observe the dosage rates and withholding times provided on the labels and by the prescribing veterinarian and ensure that their farming practices protect against inadvertent contaminations".

Brian's farewell



On 15 February NZFSA farewelled **Brian Bidford** who has retired from his '9 to 5' job with the Approvals and ACVM Group (see December 2005 issue).

Work colleagues, past and present, joined with Brian's industry friends from across the country to share some memories and take the opportunity to thank Brian for his efforts over the years. Long after the party was scheduled to end, many people were still 'catching up' and swapping stories. About 85 people attended the function, and more than 170 others emailed their good wishes.

Since his retirement, Brian has been spending long hours working on his boat and enjoying every minute of it.

**If you have any
GMP enquiries, contact
LinleyThorburn,
Advisor
(Compliance and
Monitoring)**

**linley.thorburn@nzfsa.govt.nz
or phone 04 463 2569**

Staff update

Jennie Moran, whose first child is due in March, will be on maternity leave for 12 months. Her replacement is **Lucy Johnston** (see article at right).

Sally Eyre's beautiful baby, Kathryn Edith, arrived on New Year's Day. Congratulations to Sally and Simon.

Several staff vacancies are being filled, and new team members will be starting soon.



**Lucy Johnston, Advisor
(ACVM Standards-Animals)**

"I completed my veterinary degree in 1997 at Massey University. I spent the next eight years working as a practising vet in England and Australia, including two years working on the sunny gold coast. Opportunitites arose in Wellington, so my husband and I arrived in September last year. We are thoroughly enjoying our time in Wellington – being Cantabrians, we were slightly apprehensive about the weather here!

I joined the Group in December. I am enjoying the new challenges presented and look forward to working within this friendly and supportive group."

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Codex*

Following analysis of submissions on a discussion document, NZFSA published *New Zealand's Strategic Objectives in Codex*, the international food standards setting agency, in October 2005.

The agency, known as the Codex Alimentarius Commission (CAC), plays a pivotal role in the development of international standards for health protection and ensuring fair practices in food trade. Its job is to create a single food code that can be used by all countries.

New Zealand's interests

As a major producer and exporter of foods, New Zealand has a strong interest in ensuring that Codex standards and related texts are based on sound science and that the CAC is efficient and responsive to its members' needs. Our participation in its processes reflects our interests: New Zealand chairs the Codex committees on Meat Hygiene and Milk and Milk Products and sits on a wide range of others.

The Codex publication lists five key objectives, each consistent with the strategic directions of NZFSA, and suggests rationales and strategies for achieving them. These are:

- to promote the application of sound science and risk assessment in Codex standards development
- to promote fair trade principles in

Codex standards and recommendations

- to strengthen the Codex system
- to promote effective representation of New Zealand's interests in Codex
- consultation and communication.

What is Codex?

The CAC was set up in 1962 by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) as part of a Joint FAO/WHO Food Standards Programme. Its international standards and related texts are known as the Codex Alimentarius (Latin for 'food code'). They cover individual commodities, maximum limits for pesticide residues, veterinary drugs in foods, food hygiene, nutrition, additives and contaminants and labelling.

The Commission also acts as an important forum in which to discuss contemporary and emerging food safety issues.

International non-governmental organisations, such as consumer, academic or industry bodies can attend Codex meetings as observers. Membership stands at more than 170 countries, with developing countries now representing the majority.

How does it work?

Much of the detailed work of the CAC is done by subsidiary bodies grouped along the lines of commodity committees, general subject committees (these cover issues that are applied to all foods, such as food hygiene), ad hoc task forces and regional coordinating committees.

The standards are developed through a formal procedure which involves eight stages or 'steps'. Each step relies on consensus for its progress. If that can't be reached, then decisions can be put to

a vote (only member countries can vote). However, once agreed, the standards are voluntary and their implementation by member countries is not necessarily automatic.

The standards now come in for a lot of scrutiny and, as a member-driven organisation, the CAC needs the support and commitment of its members to fulfil its mandate to develop them.

How does Codex aid international trade?

Food standards are becoming more important as international trade in food opens up and consumers become more concerned about safety. Standards must reflect a high level of consumer protection and not unnecessarily restrict trade.

If a trade dispute arises, Codex standards are accepted reference documents for settlement, which underlines their increasing importance in international law.

Agreements

In 1994 several important international agreements that allow groups of World Trade Organization member countries to set up arrangements among themselves to liberalise trade were established. Two of these agreements are particularly important to New Zealand and Codex: the Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) Agreements.

Essentially, SPS measures are human (food safety), animal and plant health measures. The TBT Agreement is an undertaking by member states not to create unnecessary obstacles to trade by imposing packaging, marking and labelling requirements and analytical procedures for assessing conformity with technical regulations and standards. New Zealand is a significant contributor to the development of the international

ACVM Amendment Bill

The ACVM Amendment Bill is ready and should begin its passage through the Parliamentary process shortly.

* excerpts from NZFSA's Food Focus, August 2005 issue

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standards for the food the world's population consumes. This food code – the Codex Alimentarius – is as vital to New Zealand as work done in any of our other better known trade arenas and is helping reduce trade barriers and strengthen our reputation as a producer of foods in the global market.

It is a programme this country takes extremely seriously because, as well as helping safeguard consumers' health, the risk- and science-based approach that underpins it provides great advantages for our export sector.



Codex in New Zealand

New Zealand Codex project manager **Raj Rajaseker** says Codex provides the framework for New Zealand to emphasise on a world stage the importance of science in establishing food standards over the traditional rules-based approach and, crucially, allows New Zealand to use scientific arguments to resist attempts by other countries to impose new standards that could severely impact our exports.

There are several instances where New Zealand has been able to draw on Codex standards to support New Zealand positions, e.g. we successfully forestalled plans by Mediterranean countries to lower the permitted levels of linolenic acid, an essential fatty acid, in olive oil from 1.5 per cent to 1 per cent. This would have caused problems for producers in southern hemisphere countries such as New Zealand,

Australia and Argentina, whose climates, among other factors, tend to result in higher levels of the fatty acid.

Protecting our interests

“We were able to argue successfully that Codex standards need to capture the full range of variations that naturally occur around the world, and managed to protect our trading interests by ensuring that the standard was not modified,” Raj says. He says the plan, had it gone ahead, would have been a major obstacle to New Zealand's blossoming olive oil export industry.

New Zealand has also been able to promote international thinking on meat and milk-based product standards – two trade areas vital for this country – through chairing relevant Codex committees.

International standard

Work led by NZFSA Executive Director Andrew McKenzie and Science Group Director Steve Hathaway on meat hygiene is expected to become an international standard after consideration by the Codex Alimentarius Commission in Rome in July.

The Meat Hygiene Committee has developed a scientific, risk-based code of practice, processes and procedures for meat hygiene for meat producers to use to promote safe products, Raj says. “We have a very significant meat industry and a well recognised reputation for producing safe, sound products, so we have been able to get greater international buy-in to a way to do things that largely encompasses the New Zealand approach.”

The work is also key because the framework reinforces New Zealand's commitment to a risk-based approach to food safety.

“It's not prescriptive. The standards do not set out how abattoirs should be constructed, what materials should go

in, how many times they should be inspected, as they used to be. It is about making sure the product is safe. It is not about imposing one country's system for processing, handling and production on everyone else.”

New way of working

Raj says that one of the big issues facing Codex is how to speed up the way it introduces new standards.

“It's been too slow... too many meetings, too many committees, 160-170 countries not all thinking the same way. That makes the job of getting international standards adopted a major challenge.”

Work has started to reform the current system and take a more pragmatic approach that will speed up the process, he says. And there's been an encouraging start, thanks in part to New Zealand.

New Zealand's Strategic Objectives in Codex is available at www.nzfsa.govt.nz/policy-law/codex/publications/nz-objectives-and-strategy/codex-book.pdf

For more information on Codex, visit the website: www.codexalimentarius.net

Importation of veterinary medicines for own use

The new policy on importation of veterinary medicines for own use has been implemented and is working well.

Quarantine officials are able to speed up the clearance process by making decisions about exempt products that are clearly for own use.

Agreement with Biosecurity NZ

The Approvals and ACVM Group has signed an operational agreement with Biosecurity New Zealand (BNZ) for compliance and enforcement activities regarding release of new organisms that are, or are contained in, veterinary medicines. This agreement clarifies the roles of the two agencies in confirming that the controls imposed under the Hazardous Substances and New Organisms (HSNO) Act 1996 on the approval of a new organism are complied with when that organism is being used as a veterinary medicine. For example, a new organism may be contained in an animal vaccine that is registered with conditions under the ACVM Act. These conditions are in addition to the controls imposed under the HSNO Act.

The Biosecurity Authority is the primary compliance body in this area and the one charged with investigating suspicions or allegations of non-compliance and, subsequently, taking enforcement action.

The Group has agreed that, when NZFSA carries out its investigations for compliance with ACVM conditions on the registration of a veterinary medicine containing a new organism, it will also investigate compliance with the HSNO controls at the same time, reporting any non-compliance to BNZ. The Group will maintain a list of registered veterinary medicines that are or contain new organisms. This list will form the basis for the cooperative activity.

At this stage there are no registered veterinary medicine products that are or contain new organisms.

Submissions on the report of the Antibiotic Resistance Expert Panel

The Approvals and ACVM Group received two submissions on the 2005 *Antibiotic Resistance Expert Panel Report*. One described New Zealand's present regulatory regime as prudent and conservative relative to those of its trading partners. Both respondents expressed caution to ensure that regulatory action is not overly conservative and restrictive to the detriment of animal health and welfare. Both respondents were concerned about the potential to limit therapeutic options available to protect the health and welfare of animals.

Submissions

One respondent, who was opposed to any further intervention (particularly in regard to public health objectives about antimicrobial resistance) that might limit therapeutic options, said, "To achieve the desired control over animal diseases it is imperative that New Zealand maintains the availability of a comprehensive range of antimicrobials for animal use and the ability for veterinarians to prescribe antibiotics for therapeutic and prophylactic use". It was considered that regulatory decisions must be based on sound scientific evidence and should not be restrictive, if there is no scientific evidence that the use of antimicrobials in New Zealand's pastoral farming systems will lead to antimicrobial resistance. The recommendation to develop and document 'best practice' guidelines for veterinarians in the appropriate use of antimicrobials was supported.

The other respondent made more specific recommendations. While supporting the recommendation for an antimicrobial resistance surveillance programme for meat and milk, the respondent considered that the resistance risk from greater use of intramammary antimicrobials is low because of pasteurisation and milk discard. It was considered that technology may allow for centralised recording of statistics and practices, and a disciplined survey of prescribing veterinarians in regard to prescribing practices was recommended. It was pointed out that, even though there has been considerable investigation and research carried out on this subject, there is still limited understanding on quantifiable risks, in epidemiological terms, posed by antimicrobial use in animals.

The submission recommended that a technical group be established to help collate the information gathered from local and world research, New Zealand database and surveillance data to identify the important risk pathways for antimicrobial resistance threat to humans to support MedSafe and NZFSA regulatory decisions. It was recommended that New Zealand follow guidelines from world organisations such as WHO, OIE and FAO that promulgate safety with food and antimicrobial use. Regulatory decisions should be made on a product specific basis rather than depend on generalities about antimicrobial families.

Response

The Expert Panel report and submissions received indicate that, while refinements could be made, the regulatory control in New Zealand is set at an appropriate level and consistent with international guidelines. The Group will continue to make decisions on a product basis, working with MedSafe to apply scientifically sound principles. The Approvals and ACVM Group will prepare a response to the recommendations of the Antimicrobial Resistance Steering Group and the Expert Panel report, focussing on what needs to be done to respond to the recommendation concerning ongoing surveillance.