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Whats coming up

ACVM Act changes

MAF Policy is preparing a public discussion paper on proposed changes to the ACVM Act. The discussion paper will be advised in *AgVetLink* and will be available on the ACVM part of the website.

ACVM Fees Regulations

The long promised review of ACVM fees and charges is being worked on by the ACVM Group and MAF Policy. We expect to have a public discussion document out within the month and to discuss proposals at the next AVMAC meeting and at the workshops planned for late February (see below). The review will use the same basis and policies as were applied for the original fees and charges – details will be available on the website. It is expected that any new fees and charges will take effect on 1 July 2002.

ACVM Regulations changes

Changes to the GRAS lists, the prohibition of some substances as agricultural compounds, and additions to the exemptions list are being made. Keep watching the ACVM website for details.

ACVM Transfer Regulations

The proposal to transfer animal remedies and pesticides to the ACVM Act effective from 1 July 2002 is still on track.

ACVM Workshops

The ACVM Group will run another series of workshops on ACVM Act applications in late February. This is your opportunity to come along with any comments or queries. At this stage workshops are planned for the following dates and venues:

Christchurch	Monday 25 February	Airport Commodore
Auckland	Tuesday 26 February	Lakeside Convention Centre
Wellington	Thursday 28 February	Turnbull House

You will need to register your interest (see insert with this *AgVetLink* or registration information can be found on the website). There will be a charge to cover catering.

AgVetLink is produced at least six times annually by the MAF Food Assurance Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of animal remedies and pesticides. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

General enquiries: Gill Culliford

ACVM Group, MAF Food Assurance Authority
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Phone: 04 474 4245; fax: 04 474 4240; email: cullifordg@maf.govt.nz

Website: www.maf.govt.nz/acvm

Code of practice for own use of substances

Under Schedule 1 of the ACVM Regulations 2001 substances that are not trade name products can be used as agricultural compounds by persons treating their own animals or plants on their own land without registering the substances as trade name products. However, that use could cause harm. While those substances are not subject to registration, the person must still use them in a responsible manner, adequately managing the risks posed by the use.

Because the exemption from registration imposes a condition that the user must comply with an approved code of practice, MAF proposes the following code that states the expectation of responsible use without prescribing the manner.

1. The user must not:
 - use any substance that is prohibited for use as an agricultural compound; or
 - use any genetically modified organisms unless approved by ERMA NZ under the Hazardous Substances and New Organisms Act 1996; or
 - experiment on animals with a substance without the appropriate animal ethics committee approval under the Animal Welfare Act 1999.
2. The user must not offer for sale any animals or plants for human consumption that would breach the domestic food residue standards, and must take due care to advise anyone who may harvest animals or plants for human consumption.
3. The user must take due care to avoid unnecessary pain and distress in animals intentionally exposed to a compound and animals that may inadvertently be exposed, and seek veterinary advice if animals continue to suffer pain or distress after treatment or exposure.
4. The user must ensure that the compound is fit for its purpose. From an ACVM perspective, compounds are fit for their purpose only if they do not do any of the following:
 - produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment;
 - cause unnecessary pain or distress in animals due to toxic reactions or physical damage;
 - result in malnutrition causing pain or distress in the animal, or result in undesirable physiological side-effects;
 - contain micro-organisms at pathogenic levels or any other plant or animal pest that is likely to promote disease or pest transmission;
 - have a selenium content that would result in the application of selenium as sodium selenate at a rate exceeding 10 grams per hectare.
5. Persons are obliged to:
 - store, prepare, administer or apply, and dispose of the compound in a manner that does not expose themselves or other persons, stock or crops, or the environment in general to unnecessary hazards;
 - protect the welfare of any animals that may come into contact with the compound and mitigate any pain or distress caused by the exposure;
 - advise any likely third parties of any hazards to themselves or their property;
 - where necessary, advise the appropriate officials of the use, and the time and place of administration or application;
 - keep adequate records to show that due consideration was made of the matters above, and due care was taken to comply with them.
6. Where compounds are used by subordinate persons or employees

on behalf of a person/organisation, the responsible person/organisation must provide written instructions that direct:

- how the compound is to be stored, prepared, administered or applied, and disposed of;
- how the welfare of any animals that may come into contact with the compound is to be protected and how pain or distress is to be mitigated;
- how third parties are to be contacted or advised of the use and warned of any hazards;
- how officials are to be advised of the use, and the time and place of administration or application.

They must also ensure that the subordinate persons or employees are appropriately trained and provided with whatever is needed to carry out the instructions safely.

Apart from the ACVM Act, people who use substances are also likely to be subject to statutory obligations under other legislation (i.e. Resource Management Act 1991, Health and Safety in Employment Act 1992, Hazardous Substances and New Organisms Act 1996, Animal Welfare Act 1999, Animal Products Act 1999, Dairy Industry Act 1952 and the Food Act 1981).

Exempting compounds from registration under the ACVM Act does not exempt anyone from obligations imposed under any other legislation.

If you have any comments on the proposed code of practice please send them to:

Jenny Yee
 MAF ACVM Group
 PO Box 2526
 WELLINGTON
 phone: 04 460 8759
 email: yeej@maf.govt.nz

C1 applications –

Formulation changes to registered pesticides and licensed animal remedies under the transition provisions of the HSNO Act

Until recently, through an operational agreement between the ACVM Group and ERMA NZ, the ACVM Group processed C1 applications as they were under the previous legislation unless a potential risk to public health or the environment was identified. The ACVM Group only has delegated authority from ERMA NZ to process those variations where there is no change in hazard status.

It has become apparent, however, that although the ACVM Group can identify and manage 'risks' associated with a trade name product, it is not possible for us to make the 'hazard' classifications that are required by ERMA NZ. (Note that the HSNO Act considers the hazardous properties of **all** of the ingredients in the whole substance, not just those of the active ingredient.)

It is also possible that ERMA NZ may require information additional to the ACVM Group's Registration and Product Datasheet on any new proposed formulations to determine whether the new formulation is materially different from the existing approved product. For this reason, although a variation to a formulation can be approved by the ACVM Group as meeting the ACVM requirements, we are unable to issue the new registration/licence until confirmation from ERMA NZ has been received that the hazard status remains unchanged.

Therefore, applications to the ACVM Group for a variation to the formulation of these products (i.e. C1 applications) must be assessed by ERMA NZ to verify whether the proposed formulation changes the hazard status of the product under the Hazardous Substances and New Organisms Act.

ERMA NZ advises that this confirmation can be obtained by submitting a request for advice on the status of a substance to them, and the relevant application form (HS6) can be obtained from the ERMA NZ website (<http://www.ermanz.govt.nz/publications>). Alternatively, enquiries can be made directly to ERMA NZ (phone 04 916 2426).

If the hazard status of the trade name product is materially altered by the proposed formulation change, ERMA NZ will require an application for approval of a new substance. In that situation, the ACVM Group will be unable to issue the new registration/licence until the appropriate ERMA NZ approval has been received (if the product is hazardous).

If an ERMA NZ approval is not obtained the registration/licence for the newly formulated product cannot be effected until the product is transferred to the HSNO Act.

Applicants who obtain the confirmation of unchanged hazardous status from ERMA NZ are assured that the ACVM Group will do all within its power to ensure that processing of applications is completed within two working days of this confirmation being received. We apologise for any delay with applications. Unfortunately this is outside of the ACVM Group's control.

Vertebrate Pest Control Poisons Update

- ERMA NZ has been holding meetings with stakeholders to introduce the proposed new system for management of controlled pesticides after their transition to HSNO approvals.
- MAF is conducting an internal evaluation of what controls will be required under the ACVM Act, and the other acts that MAF administers, to ensure that those risks for which MAF is responsible are properly managed. The MAF view will be conveyed to ERMA NZ for its consideration for setting controls when these products are transferred to HSNO approvals. MAF will then finalise its controls so that where ERMA NZ controls are sufficient to manage those risks MAF will not duplicate them and potentially impose unnecessary compliance costs.
- The National Registration Authority (NRA) in Australia is undertaking a review of compound 1080 in 2002. The NRA has asked MAF ACVM Group if it will supply information for the review. This we will do provided appropriate confidentiality is maintained.
- Brodifacoum is being reviewed by MAF because residues in feral game meat being prepared for export continue to be found. A stakeholders meeting will be arranged for mid to late February. For more information contact Warren Hughes (phone 04 460 8760).

Consumer information

One of the purposes of the ACVM Act is to ensure the provision of sufficient consumer information about agricultural compounds. The term 'consumer' is not defined in the Act, so it has been interpreted to mean those people purchasing and using agricultural compounds and veterinary medicines. Therefore, the labelling requirements imposed by the ACVM Group are intended to provide the information needed by the users to use a product appropriately and safely.

Initially, it was intended to limit labelling requirements to information related to the risk areas specifically mentioned in subsection 4 (a) of the ACVM Act (risks to trade in primary produce, agricultural security and animal welfare). This was decided on the basis that other agencies, i.e. Ministry of Health, Occupational Safety and Health, Ministry of Transport, ERMA NZ and the Commerce Commission, would take responsibility for specifying consumer information requirements and approve labels in regard to matters relevant to the legislation they administer.

Presently the ACVM Group, on behalf of other agencies, approves all aspects of labels for animal remedies and pesticides. Members of the pharmaceutical and agricultural chemical industries and user groups advised that this system is practical and efficient, and more likely to produce labels that contribute to the effective management of the range of risks posed by the use of agricultural compounds or veterinary medicines.

The ACVM and HSNO Acts have now commenced and the ability of other agencies to impose practical and effective labelling controls that can be translated into useful label statements has been tested. It is clear that, to meet its statutory obligation as specified in subsection 4 (c) of the ACVM Act, the ACVM Group is the only agency in a position to impose product-specific labelling requirements and to approve label content.

Because the ACVM Act does not specify what consumer information is relevant, the ACVM Group considers

that any information that is needed to use a product appropriately and safely is relevant to its statutory responsibility.

Consequently, it will require labels to include information that assists the users to avoid or mitigate adverse effects across the full range of risks that Government expects to be managed. This includes risks to the safety of the users, other people who might be exposed, and the environment in general, as well as the targeted plants and animals. The kind of information that may be required is discussed in the article below.

The ACVM Group will approve the label content rather than necessarily approving the final label itself because it does not consider that it should take on the responsibility of an editorial check on final labels. However, since the layout of the label has an impact on the message communicated, applicants may find it more convenient to present a mock-up version or even the final label itself for approval.

Requirements for conditions on labels

Under the ACVM Act, conditions on the registration of a trade name product must be put on the public register. However, not all the conditions may be relevant to or appropriate on the label (for example, conditions on importation or manufacture are usually not relevant). In addition, most ACVM conditions will be as general as possible (unless there is a need to be specific), whereas the label will 'translate' the general conditions to the intended uses.

In the future, the ACVM Group intends to require all information that is needed to use a product appropriately and safely to be provided on the product's label (label

includes outer packaging or leaflets provided with the product). The requirement will be made under section 4 of the ACVM Act, which states that one of the purposes of the Act is to "ensure the provision of sufficient consumer information about agricultural compounds" (see above).

Users can expect to find statements on the labels about:

- any prohibitions/limitations on use;
- safety or contraindication warnings;
- any obligations on users in regard to use, disposal, record keeping or reporting; and
- any other matter that must be brought to their attention.

Registrants will be required to provide the ACVM information on use with the product.

Where necessary, registrants will be required to make it clear when there is a statutory obligation on the user or any other person to comply with a particular label statement.

Registrants will not be required to put on the label any matter that encourages a use of the product for any purpose that was not recommended by the registrant. Therefore, users may have to consult the public register to find out if a product can be used for purposes other than those stated on the label.

Update: Mutual Recognition Agreement for Good Manufacturing Practice

New Zealand and the EC propose to implement the Mutual Recognition Agreement (MRA) for Good Manufacturing Practice (GMP) of Veterinary Medicines on 1 April 2002.

Significant activity occurred on this project during November and December 2001. Following the visits to the EMEA, MCA and VMD reported in *AgVetLink* 29, return visits by two European officials were made to New Zealand for inspections and for the preparation of documentation to complete the transition period.

In November, an inspector from the MCA visited and inspected a manufacturer of veterinary medicines in Auckland, part of which was observed for MAF's ACVM Group. This was followed by an inspection of another veterinary medicines manufacturer by two AgriQuality New Zealand inspectors, which was observed by the MCA inspector.

In December, Katrin Nodop, Principal Administrator with the EMEA, made a first visit to New Zealand to prepare for the completion of the transitional period, and the implementation of the full mutual recognition agreement for veterinary medicines. Dr Nodop gave a presentation of the European system for GMP control, and held meetings with MAF and Medsafe relating to the operation of the agreement and the maintenance programme that will be implemented to keep the agreement current.

Agreement was reached on specific documentation items to be used between the parties in respect of exported goods. These include a harmonised batch certificate, a common format for a GMP certificate, and a format for notification of product recalls due to defective manufacture. Terms of reference for a Joint Sectorial Committee to administer the MRA maintenance programme were developed, and a final joint (NZ/EC) report to the Joint Committee for the MRA was prepared recommending implementation of the full agreement for veterinary medicines on 1 April 2002.

As a result of this development the ACVM Group will refine its GMP inspection processes to provide more information to manufacturers and to meet its obligations under the agreement. These refinements will include:

- the change of certification of manufacturers to the new format as inspections progress and new certificates are required to be issued;
- the provision of more specific pharmaceutical expertise for inspections of veterinary pharmaceutical manufacturing premises;
- changes to the standard to make regulatory intervention and corrective action steps and timeframes clearer for all parties;
- the adoption in New Zealand of the rapid alert system used in Europe to notify regulatory authorities of the recall of products due to faulty manufacture.

We look forward to confirming the implementation of the agreement to manufacturers in April.

Electronic copies of labels/label content

The ACVM Group clarified some time ago that a product registration would consist of three components: the registration certificate, the Product Data Sheet (PDS) and the approved label content. Recently, the ACVM Group requested that, in addition to paper copies of the PDS, an electronic copy should also be supplied. We have reviewed the effectiveness of this and are now extending the requirement to include electronic copies of the final label or the approved label content wherever possible.

Under the ACVM Act the approved label content will form part of the registration and therefore the public register. It is a major undertaking to enter all of the use patterns for products, especially for the plant compound products where the pest/species combinations can be considerable. In most cases the registration certificate will reference the label information as part of the approval so it is a logical step to provide for an electronic copy of the label (or the relevant part of the label) to go on the public register.

We also expect that the electronic versions of labels will provide for more robust checking by Border Services staff, and that it will provide a useful resource for other groups such as regional councils, contractors and consumers.

The ACVM Group believes that as more and more companies are becoming 'e-commerce' oriented it should not be difficult to supply electronic versions of labels/label content and PDSs. The ACVM Group has access to scanning equipment or digital cameras where electronic copies cannot be provided.

It is intended to make label information available on the website, under the 'Registers and Lists' pathway. If you have any comments or concerns about this proposal, please contact Maree Zinzley, Customer Services Manager (email: zinzleym@maf.govt.nz).

NZIER report

On 20 December 2001 the Hon Jim Sutton, Minister of Agriculture, released the New Zealand Institute of Economic Research (NZIER) report into the cost of compliance with the HSNO and ACVM Acts.

NZIER was contracted to help MAF gain a fuller understanding of the economic workings of the agricultural chemicals sector in New Zealand. In particular MAF wanted to understand how the implementation of the HSNO Act and the ACVM Act would, in the form of compliance costs, impact on the agricultural sector.

The report says there is a perception that there is a significant risk of a substantial increase in the cost of compliance on the industry.

It reports there is a perception amongst agricultural chemical companies that the introduction of the HSNO Act substantially increases the chances that they will introduce agricultural chemicals into New Zealand only after most other

developed countries have approved a product for use, thus denying access to agricultural users in New Zealand of that product when their competitors already have access to it.

This could lead to farmers and growers being forced to keep using more toxic 'harder' chemicals because 'softer' less toxic alternatives were not registered for use in New Zealand.

The report also says the composition of agricultural chemicals is changing over time as the market demands 'softer' and 'softer' chemicals. The application of these products is typically part of an integrated pest management approach. The changes in pesticide use over the past decade are primarily due to changes in land use, cost effectiveness, and the adoption of integrated pest management. This means more biological and less organophosphate and dicarboximide-based chemicals are used.

In world terms, the New Zealand market for agricultural chemicals is

very small – about 0.26 per cent of world demand. The pesticides and animal health markets in New Zealand are worth about \$190 million and \$170 million a year respectively.

When interpreting the report it is important to note that the report was researched and written prior to the ACVM Act and hazardous substance sections of the HSNO Act commencing on 2 July 2001. It was therefore based on stakeholders' perceptions of the HSNO Act and ACVM Act, not on any operational experience. However, the issues raised in the report, if borne out, will have significant ramifications for the agricultural sector.

MAF will use the report as a benchmark to monitor the implementation of both the HSNO and ACVM Acts against to provide early warning to Government of any unintended consequences.

The report can be found on the ACVM part of the MAF website.

Contacts List Update – IMPORTANT!!!

With the number of changes in the industry and the move by many organisations to electronic means we want to make sure that our contacts list remains up to date. We will continue to send *AgVetLink* to all registrants and licensees as it remains one of the key tools in our consultation process. For this reason we would like you to confirm that it is being sent to the correct person and address by confirming the information below. All other recipients wishing to remain on the *AgVetLink* contacts list will need to confirm the following details to Gill Culliford:

Name: _____
 Organisation: _____
 Address: _____
 Phone: _____
 Fax: _____
 Email: _____

As part of the review we will be limiting the number of *AgVetLink* copies sent to organisations because there are website copies available at the same time that hard copies are mailed. This exercise will enable us to update our records and ensure that we have the correct information for everyone. Thanks for your cooperation. For further information please contact Gill Culliford (phone: 04 474 4245, fax: 04 474 4240, or email: cullifordg@maf.govt.nz).

What's new on the website

- The ACVM homepage is undergoing a continuing upgrade process to make the site more user friendly. There is now a section entitled **Determinations/Registration/ Notification/Fees/GRAS Information**, which should make it easier to find the relevant information, forms, standards and guidelines, and fees information for applications and registrations of agricultural compounds and veterinary medicines.
 - Also added to the home page (under the Registers & Lists section) is the register for **Registered Veterinary Medicines and Plant Compounds** – the ACVM database of currently registered veterinary medicines and plant compounds. Along with this register, this section also holds the registered pesticides and licensed animal remedies registers – the ACVM database of currently registered pesticides and currently licensed animal remedies respectively.
 - There is a new section for **import approval forms** that can be found under the Publications/Forms section of the website, or at this site (<http://www.maf.govt.nz/acvm/publications/forms/import.htm>).
 - There are two new labelling guides, one for **Plant Compounds Requiring Registration**, and one for **Veterinary Medicines Requiring Registration**. These can be found under Publications/ Labelling Guides.
 - Information relating to **Notification under Regulation 7 of the ACVM Regulations**, specifically relating to exempt products (under Schedule 3) that must be notified under these regulations, can be found under the Determinations/Registration/ Notification/Fees/Gras Information section.
 - A paper entitled **Stratification of Class 1 Prescription Animal Remedies** can be found on the web in either the Forums/AVMAC/ Papers section or the Antibiotic Resistance and in-Feed Use of Antibiotics in New Zealand subject page.
 - The vertebrate pest control (**VPC frequently asked questions**) have been updated. These can be found in either the VPC section or the frequently asked questions section, which can be located easily by using the 'V' or 'F' on the site A-Z index.
 - **Variations to formulations of licensed animal remedies and registered pesticides (C1)** information has been posted under the Determinations/Registration/ Notification/Fees/Gras Information section, specifically under the subheading entitled **Information relating to preparing a variation application to an already registered pesticide and/or licensed animal remedy**.
 - Under the What's New section of the website are two articles, one a media statement entitled **Report provides useful benchmark: Minister**, dealing with a report written by the New Zealand Institute of Economic Research.
- The other article is the report itself (**Cost of Compliance – report to the Ministry of Agriculture and Forestry**), which deals with assessing the effects of implementing both the Hazardous Substances and New Organisms (HSNO) Act and the Agricultural Compounds and Veterinary Medicines (ACVM) Act (see related article on page 6).

- Under **Other ACVM Related Publications on the MAF Website**, found under the Publications/Other MAF section, are several new linkages to other MAF periodicals and newsletters. These include the following:

Food Focus

Quarterly newsletter of the MAF Food Assurance Authority – provides general information for the agriculture and seafood industries.

Dairy Connection

Quarterly newsletter informing key audiences about the issues and developments involved in the regulatory control of dairy products.

APBulletin

Animal Products Group newsletter

Biosecurity

Periodical that informs and consults on MAF Biosecurity Authority's complete biosecurity and animal welfare programmes.

Surveillance

Periodical published on behalf of the Director Animal Biosecurity – an authoritative source of information on New Zealand's animal health status.

VICH 2nd International Conference

Japan (9 - 11 October 2002)

The details of the planned agenda for the meeting covering the harmonisation of registration requirements for veterinary medicines are available at <http://vich.eudra.org/pdf/vich2.pdf>. Further details will be available in April 2002.

Recent changes in the regulatory control of antimicrobial products

The ACVM Group has completed the review of antimicrobial products in line with the September 1999 report of the expert panel to MAF and the Animal Remedies Board. There were two main conclusions from the report:

- Growth promotion is not an appropriate use for an antimicrobial substance that is used for the treatment of infections in humans; and
- While the development of resistance is possible (and proven in some cases), there was insufficient information to confirm that the problem was being exacerbated by the veterinary use of particular antimicrobials.

In the initial study it was found that present practices are not conducive to providing the information that would clarify the resistance situation in New Zealand. A few antibiotic products were not under any professional supervision at all, and those were predominantly registered for use as growth promotants. Other products were under professional supervision, but the licensing conditions did not

encourage the gathering of information that would contribute to our understanding of the problem. Actual data on prescribing and use practices, and prevalence of resistance was virtually non-existent.

In light of the review, licences are being changed:

- to limit the antimicrobial substances that can be used for growth promotion; and
- to introduce graded regulatory control of antimicrobial products, along with a requirement for reporting of some products.

Limited growth promotion claims

Growth promotion claims for any antibiotic considered important in the treatment of infection in humans will no longer be approved. Licensees of such products have been advised accordingly. At the same time it has been confirmed that certain antimicrobial substances are not relevant to the problem of antibiotic resistance in humans. These are the ionophores, quinoxalines, flavophospholipols and avilamycin. Products containing these antimicrobial substances may still make growth promotion claims, but users should note that this use may still encourage the development of resistance in animal pathogens.

Graded regulatory control for antimicrobial products

Antibiotic products will be classed into the following:

- over-the-counter; and
- prescription animal remedy (PAR) class 1, groups 1 through 4.

Over-the-counter

Coincidentally, most of the products that can still be used for growth promotion can also still be sold over-the-counter. These may also have disease treatment and prevention uses as well but, in all cases, they are not

relevant to antibiotic resistance developing in humans. Any antibiotic that is relevant and that is presently classed as an over-the-counter product will be reclassified as a prescription animal remedy. This means that some common antibiotic products, such as injectable procain penicillin, will not be able to be purchased without a veterinary prescription.

Prescription animal remedy class 1, groups 1 through 4

For antibiotics that must be sold and used only under the prescription of a veterinarian, there will be increasingly stringent conditions imposed on veterinarians to manage the resistance problem and contribute to the overall understanding of the problem. In the past the conditions on all PAR1 products were the same. Now a graduated scale of regulatory obligations for antibiotics classed as PAR1 has been introduced.

The majority of products (group 1) will have conditions that are basically the same as they were in the past. There will be no specific reference to antibiotic resistance and no increase in the statutory obligations on veterinarians.

However, there are some antibiotic substances (group 2) that are considered to require more stringent management of the resistance problem. The antibiotics in this group (e.g. enrofloxacin and orbifloxacin) are identified as essential for use in humans and are known to cause resistance to develop in bacteria. They will still be classed as PAR1 but their use will be limited to therapeutic purposes under circumstances in which the prescribing veterinarian is satisfied that the antibiotic is likely to be the only effective treatment.

Growth promotion will be a prohibited use with no veterinary discretion to prescribe for that purpose.

AVMAC and ILG meetings

The dates for meetings in 2002 have been confirmed. See the Forums section of the ACVM website for details of members and the notes from meetings or the proposed agendas. The meeting dates for this year are:

Thursday 21 February 2002
Thursday 23 May 2002
Thursday 22 August 2002
Thursday 21 November 2002

Codex Committee on Residues of Veterinary Drugs in Foods

Where necessary, other specific prohibitions on certain uses that further limit any discretionary use of the product will be applied. Other conditions may also be imposed. For example, if the antibiotic is used in an intramammary preparation, milk may not be allowed to be fed to calves until after the specified withholding period (plus four days if used in dry cow therapy product). The issue of the effect intramammary use may have on the development of resistance in human pathogens remains unresolved. It may be that use will be restricted even further in the future.

Where it is considered essential to control the overall use of an antibiotic even for therapeutic purposes, the Board will impose even more stringent controls. This level of control would be applied to products containing antibiotics (e.g. virginiamycin) that in human medicines are subject to more stringent controls than the basic prescription condition, i.e. restricted to hospital specialists etc. (group 3). The products would still be classified as PAR class 1 products with conditions similar to those imposed on group 2 but the following obligations will also be imposed:

- all discretionary use for any purpose other than that specified on the label would be prohibited; and
- the prescribing veterinarian would have to notify MAF of every case in which the antibiotic is prescribed, giving the date, species prescribed for and disease treated.

Some antibiotics (group 4) will be prohibited from use in food-producing animals and some may even be prohibited from use as a veterinary medicine.

All antibiotic products have now been reviewed and licensees contacted. Changes must be made to product labels by July 2002.

The 13th meeting of the CCRVDF was held in Charleston, South Carolina, from 4 - 7 December 2001. New Zealand was represented by Dr Bill Jolly (Leader)* and John Reeve.

There have been problems in the past with proposed MRLs being held up in the process on political grounds, and this has resulted in pressure to review all the CCRVDF procedures. For example, two of the grounds for objecting to progressing MRLs were that the objecting country had not considered that veterinary drug for registration and so had no knowledge that the suggested residues were acceptable, or that the suggested MRLs did not match the objecting country's domestic MRLs – that is, there was no scientific basis required for objecting.

However, because of the lack of scientific reasoning behind the objections, New Zealand, the USA and Australia encouraged the 12th meeting of the CCRVDF to accept a requirement that any country objecting

to an MRL being progressed had to forward supporting data to the Joint Expert Committee on Food Additives (JECFA). This had to be done in a timely manner so that the JECFA expert opinion on the objection could be considered by the next CCRVDF. Failure to get data supporting the objection to JECFA within the timeframe meant that the MRL **must** be progressed to the next appropriate step in the Codex system.

As a result, many MRLs progressed at the 13th meeting. Because this requirement is now an accepted precedent, it is hoped that future progressing of Codex MRLs will continue at a more acceptable rate.

The report of the meeting is being prepared and a debriefing meeting will be held for all those interested when the report is available.

* Dr Bill Jolly has now taken up the position of Veterinary Counsellor in Brussels following his move from Washington last year.

Registration and Product Datasheet

Some minor changes have been made to the Registration and Product Datasheet form, based on how the forms have been filled in and comments received so far from applicants. The changes include:

- whether the product is low risk;
- request to list both current and proposed formulations for Type C1 applications;
- additional explanatory notes to clarify some of the questions.

MAF's new D-G recognises the importance of agriculture



MAF's newly appointed Director-General, **Murray Sherwin**, is well aware of the importance of the primary

sectors, and consequently MAF, to New Zealand's economy.

As an economist with more than 25 years' experience in the public sector, Mr Sherwin says the huge amount of capital invested in agriculture and forestry is crucial to the state of the economy – whether that's negative or positive.

"When you've got that much capital invested you've got to be getting good returns from it," he says. "If you are, the economy's booming and if you're not, it's going to be struggling."

Murray Sherwin's career has included working for the Reserve Bank, which involved substantial work in the field of agricultural economics including

export forecasting where, he says, he was up to his ears in agriculture sector issues and policy. He was also elected to the board of the World Bank representing the interests of a number of Pacific countries.

Mr Sherwin worked at the OECD in Paris in 1979, and was a member of the Prime Minister's advisory group in the early 1980s.

Mr Sherwin says his new job represents a whole new range of issues and challenges and he's looking forward to the task with considerable pride and eagerness. The new D-G says his initial task will be to familiarise himself with the organisation, its work and its people.

Early priorities will be to look at a raft of issues including risk management, HR strategies, communications issues and overall strategic issues.

"I see an interesting question around the way MAF conceives of itself. Is it as a holding company with a number of more or less independent subsidiaries or as an integrated operational unit?" he considers. "The question is where the boundaries lie."

Murray Sherwin hails from a rural background. Born and raised on a Waikato dairy farm, near the village of Pirongia, he did his secondary schooling at Te Awamutu College before spending a year in the USA under an exchange programme. His university studies were completed at Waikato University where he majored in economics with, he says, some dabbling in politics, geography and philosophy.

"My studies were funded by working in the Te Awamutu Dairy Company – operating a milk powder plant – and later by truck driving for a rural transport company," he says.

Mr Sherwin has maintained an interest in things rural – he is a regular speaker on agricultural economics, exchange rates and broader economics matters at a variety of rural events and has been a commentator in the rural media, including lengthy debates in the pages of *The New Zealand Farmer*. He retains a small hands-on contact with the land through a half share in a 275 ha forestry block in the Wairarapa. And he has a passion for old cars, running and maintaining a 1964 Jag. "I'm a bit of a car nutter," he enthuses.

Standards and Guidelines

ACVM Standards and Guidelines are available via the MAF website: www.maf.govt.nz/acvm/index.htm

Alternatively they can be ordered directly from:

Manor House Press Ltd
PO Box 38-071, Wellington Mail Centre
Phone: 04 568 6071, Fax: 04 568 7282
Email: office@manorhouse.net.nz

An order form for this purpose is available on the MAF website.

ACVM

Application Workshop Programme

- 9.00** Tea and coffee available
- 9.30** Transition process update
- 10.00**
- Overview of application process
 - Product Data Sheets and Application Forms
- 10.30** Morning Tea
- Presentation of an application and essential elements, including the use of data package reviews and product summaries
 - Information waivers
- 12.00** Lunch
- 1.00** Data requirements divided into streams:
- Veterinary Medicines
Topics include Chemistry Standard, Efficacy Requirements, Target Animal Safety and Residues
 - Plant Compounds/Pesticides
Topics include Chemistry Standard, Efficacy Requirements and Residues
- 3.00** Afternoon Tea
- 3.30** Questions
- 4.30** Finish

ACVM Application Workshop REGISTRATION FORM

These workshops are intended for regulatory affairs personnel, consultants and others involved in the registration of agricultural compounds. The objective is to present the current ACVM perspective on the application process and to receive feedback from participants. Though the primary focus is the components of a registration package, peripheral subjects such as class determinations and import approvals can be discussed as time allows. A brief update on the transition process and ERMA NZ will be included because these are topics of immediate interest.

If there are queries, please submit these to Gill Culliford (contacts below) prior to the seminar so we can make sure they are covered adequately on the day.

We require registrations no later than **Monday 18 February 2002**.

If numbers are low sessions may be cancelled or rescheduled.

Refreshments and lunch will be provided (cost is covered by registration fee).

All sessions will start at 9.30am; coffee will be available from 9.00am.

Monday 25 February 2002

9.30am - 4.30pm

Christchurch

Commodore Christchurch Airport
449 Memorial Ave

Tuesday 26 February 2002

9.30am - 4.30pm

Auckland

Lakeside Convention Centre
Auckland International Airport

Thursday 28 February 2002

9.30am - 4.30pm

Wellington

Turnbull House
Bowen Street

Name: _____

Organisation: _____

Fax number and e-mail address: _____

City/date of session: _____

Please send any queries and post registration along with cheque for \$45.00 (made out to MAF) to Gill Culliford by Monday 18 February 2002

by post:

MAF Food: ACVM

PO Box 2526, Wellington

or fax:

04 474 4240

or send an e-mail to:

cullifordg@maf.govt.nz

