



AgVetLink

ISSN 1174 - 3735 ISSUE NO 48 FEB 2005

What's coming up

- The ACVM Group has been invited to address the **Agcarm Special General Meeting**, which will be held on 16 February at Waipuna, Auckland.
- The annual **Food Safety Quadrilateral Meeting**, consisting of representatives from Canada, US, Australia and New Zealand, will be held this year from 21-25 February in Australia. The ACVM Group will be represented by two staff members.
- The next **AVMAC and Industry Liaison Group** meetings will be held on 10 March 2005 in Wellington.
- The ACVM Group is planning a series of **workshops for veterinarians** to update issues such as residues in velvet, induction drugs, selenium, discretionary use and compounding, antibiotic resistance, labelling, advertising, approved trader implementation, oral nutritional compounds and herbal/homeopathic medicines. The workshops are likely to be held in early April. Information will be available on the website in the near future.

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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.

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ACVM Regulations Amendment 2005

The ACVM Regulations 2001 provide exemptions from the requirement to be registered for certain groups of agricultural compounds. The groups are defined by the intended purpose; that is, if a trade name product is sold for a use that is specified in one of the first three Schedules of the Regulations, then the product may be imported, manufactured, sold or used without registration as long as the product complies with the conditions prescribed in the Regulations and Schedules.

Amendments to the ACVM Regulations are being drafted by the Parliamentary Counsel Office. They should be promulgated around April 2005. The amendments make some changes in existing exemptions and add new exemptions.

Risk analysis

It should be noted that, in deciding if a group of agricultural compound products could be exempted from registration and how the exemptions should be worded, the ACVM Group carries out a general risk analysis for the whole group. If the risks posed by all the products in the group can be

managed by prescribing conditions common to the whole group, then registration is not considered necessary. However, the group must be defined carefully and the conditions must be simple and not ambiguous. Otherwise, products posing unique risks that should be assessed individually may inadvertently be included in an exempt group. With that in mind, the following are the specific provisions in the Amendment.

Application of more than one exemption

The Regulations are being amended to make it clear that more than one exemption and the associated conditions may apply to multi-purpose products. For example, an animal feed that is exempt from registration as an oral nutritional compound may also make claims as a urinary tract modifier, which is also exempt from registration. The animal feed would be exempt from registration in regard to both the nutritional claims and the urinary tract modification claims. However, the feed would be subject to all the prescribed conditions for *both* oral nutritional compounds and urinary tract modifiers.

Amendments to Schedule 1

Listings in Schedule 1 are exempt from registration with no conditions other than to comply with an approved code of practice if one exists. If there is no approved code of practice, then there are no conditions that must be met.

The first entry in Schedule 1 regarding **agricultural compounds prepared for own use** (i.e. not sold or supplied to someone else) will be qualified to exclude the following kinds of active ingredients:

- antibiotics
- hormones
- substances that are prescription medicines or restricted medicines as defined in the Medicines Act 1981
- substances that are prohibited by countries importing New Zealand primary produce
- vertebrate toxic agents.

New entries in Schedule 1 are:

- homeopathic plant compounds that are offered for sale (as opposed to ones prepared for a person's own use, which are already exempt from registration)
- compounds used in the production of tissue cultures
- compounds used to protect plant grafts by mechanical means (i.e. do not contain biologically active ingredients).

The **unqualified plant material** entry in Schedule 1 will be revoked. This means that plant material sold or supplied to someone as an agricultural compound must be registered unless the particular use corresponds with an agricultural compound that is exempt from registration in its own right. As examples, herbal preparations (i.e. made from plant material) for managing plants must be registered, but oral and topical herbal preparations that are veterinary medicines are exempt from registration in Schedule 2.

HSNO labelling and ACVM requirements

The ACVM Group has received many enquiries regarding our requirements for companies changing their labels to ensure they are HSNO compliant.

Registrants will be required to send us an electronic copy and a hard copy of their marketed label(s), inclusive of all the HSNO controls, and a covering letter stating that nothing in the current ACVM-approved label in regards to the ACVM risk areas has changed. These labels will not be approved as such but a copy will be placed on the file and an electronic copy will be placed on the website. There will no charge for this. However, if it is seen that labels have been changed in regards to the ACVM risk areas, then the registrant will be contacted and the appropriate application will be required.

GENERAL INTEREST

Plant material (feed commodities such as standing grass, hay, silage, grain, horticultural produce etc.) used as **animal feed** must comply with the standards in Schedule 4 (see below).

Removal of obligation to report agricultural compounds in Schedule 3

Regulation 7 will be revoked. This Regulation imposed an obligation on persons importing or manufacturing agricultural compounds listed in Schedule 3 to report (initially and annually) that importation or manufacture. Because knowledge of the importation or manufacture reaches the ACVM Group by other means, the obligation to report is unnecessary.

With revocation of Regulation 7, the obligations imposed on agricultural compounds listed in Schedule 3 are the same as those in Schedule 2. Consequently, **the entries in Schedule 3 will be placed in Schedule 2.**

Amendments to Schedule 2

In addition to relocating all the entries in Schedule 3 into Schedule 2, the entries for the following products will be adjusted.

The entry for **topical skin preparations** will be adjusted to read “used solely to treat minor injuries or to prevent dermatological abnormalities”. This will allow specific treatment products used to treat minor cuts and abrasions to be exempt from registration. (General first aid products are already exempt from registration.)

However, there will be a new Schedule listing active ingredients or groups of active ingredients that would prompt registration if they were included in a formulation. At this stage, the only active ingredients that will be included in the new Schedule will be **antibiotics**. This is because topical preparations containing antibiotics require special consideration

that can be achieved only via the registration process.

The entry for **cauterising preparations** will be qualified to limit the use to superficial application to make it clear that it does not include preparations designed to control blood loss in serious wounds or major surgery.

All the entries for **agricultural compounds used to manage plants that refer to Part B of Schedule 7** will be amended to delete that reference and impose an alternative condition that they “must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment”. This amendment will make Part B of Schedule 7 superfluous and it will be revoked.

The ACVM Group will maintain an administrative list of substances that are generally recognised as safe (**GRAS**) when included in agricultural compounds used to manage plants, but there will be no need to have the substances prescribed in the Regulations because residues (the only relevant ACVM risk to be managed) can be managed via the new condition.

Amendment to Schedule 4

The standards for **oral nutritional compounds** in Schedule 4 will be amended to add a criterion of ‘fit for purpose’ that is related to possible physical harm that could be caused by foreign objects such as broken glass.

To make sure that **feed commodities** that are sold as animal feeds are not subject to unnecessary labelling requirements, Schedule 4 will make reference to feed commodities and state that they are not subject to the labelling requirements in clause 1 of the Schedule.

Amendment to Schedule 7

As stated above, **Part B of Schedule 7 will be revoked** because it is now superfluous with the new reference to food residue standards.

A similar action is not appropriate for Part A of Schedule 7 because the inclusion into oral nutritional compounds of the substances listed in Part A has animal welfare implications as well as residue implications. Therefore, the amendment will also include a list of substances that have been assessed as generally recognised as safe (**GRAS**) for inclusion into oral nutritional compounds.

In the interim, until the amended Regulations are promulgated, the ACVM Group will give advice on products in anticipation of the changes. This should avoid the need for unnecessary short-term registration decisions.

Annual Fees

1 July 2005-30 June 2006

All registrants will receive a letter in March outlining the coming year's annual fees for all registered plant compounds and veterinary medicines. Included in this mailout will be a detailed list of your products. Any changes, updates or cancellations to this list must be submitted to the ACVM Group no later than Friday, 8 April 2005.

If you have queries contact:
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GENERAL INTEREST

Staff changes

The ACVM Group has started the year with the departure of three team members.

As reported in the December *AgVetLink*, **Catherine Alford**, Advisor (Operations) has left after 11 years. We are reviewing the tasks within the Advisor team and have not yet replaced Catherine.

Vanessa Philp has left the Group after one year as a member of the Advisor team. She was a very welcome resource during our extremely busy year of updating products to the ACVM Act.

Melanie Pero, Co-Ordinator (Operations), left the Group in January. This position is also being reviewed, but it is unlikely that a replacement appointment will be made in the immediate future.

The workloads and duties that were normally undertaken by departing staff have been allocated to **Linley Thorburn**, **Rachel Green** and **Claire Truscott**. We also have the assistance of **Chris Scott** who is completing a university degree and has been with the ACVM Group for two years in a part-time capacity. Chris is already familiar with our systems and is being trained in all aspects of the Advisor's role.

Although we do not believe there will be too many delays in the processing of work, we ask that you be patient with matters that you bring to our attention – staff members may need to get 'up to speed' with the history of your query. However, if you do experience long delays, please do not hesitate to contact Maree Zinzley, Programme Manager (Operations) by email: maree.zinzley@nzfsa.govt.nz.

Compliance confusion

It has become apparent that a number of companies are confusing audit programmes, reality checks and compliance investigations.

Audits

An audit is a planned examination of persons, places, products, systems and/or activities to confirm compliance with regulatory requirements. The ACVM Group has a comprehensive compliance programme that includes audits. At this point, however, the only official audits are for manufacturers.

'Slice of life' or reality check reviews

The ACVM Group's compliance programme also includes 'slice of life' or reality check reviews. (When first implemented last year these were referred to as 'audits', and that added to the confusion.) These reviews provide information on control of use programmes and their performance. They also determine in broad terms where gaps in ACVM Group policy, standards and procedures might lead to a lower than desirable level of risk management under the Act, or where regulatory intervention is excessive. Reality checks might also indicate that a formal audit is warranted.

Reality checks are not necessarily undertaken as a result of reported non-compliance but priority is likely to be given on the basis of identified concerns or of existing information gaps. These reviews are carried out by the NZFSA Compliance and Investigation Group (CIG) on behalf of the ACVM Group. The output of such a review is a report with recommendations to the ACVM Group Director. Responses to the recommendations are incorporated into the ACVM Group's work programme.

Investigation

An investigation is a process initiated by the ACVM Group after having received information of possible non-compliance. Every suspicion or allegation of non-compliance is investigated.

If there is a need to visit premises, this may involve an Inspector appointed under section 65 of the ACVM Act who could be a staff member of the CIG or of the ACVM Group. Information gained from these visits is then 'pieced' together to compile a file, and to enable the ACVM Group to take any appropriate action.

One area of investigation that takes a considerable amount of time concerns unapproved products, especially those that require registration. Because such products have not undergone ACVM Group evaluation for relevant risk areas, they have the potential to create problems for international trade, to cause unacceptable residues in food or to harm animals.

The compliance process is designed to ensure that responsibilities in the supply chain are met and that all of the products in the New Zealand marketplace satisfy the approved conditions of the ACVM Act and related legislation.

GENERAL INTEREST

Maximum Residue Limit (MRL) update for the new year

Last year's MRL process resulted in the smooth setting of many MRLs, including some high profile chemicals. We hope to build on this success in 2005 with a number of changes to be made to the MRL standard. Some brief information on what is planned for this year follows.

New look

The MRL table will receive a makeover to make it easier to reference and to understand. This will be done by including two new columns: one for Chemical Abstract Service (CAS) numbers and the other for a detailed residue definition. We hope this will come into effect by the middle of the year.

MRLs to be removed?

In reformatting the MRL standard, we identified three active ingredients (Demeton-S-methyl, Isazophos and Vinclozolin) that have not been registered in New Zealand for five years. We will be consulting on removing the MRLs for these chemicals.

Review

To bring the MRL table into line with our new policy on the use of the default MRL (see October 2004 *AgVetLink*), we have reviewed the MRLs for 40 pesticide active ingredients where no formal MRL was set (and therefore relied on the default MRL).

We have determined that 39 of these compounds can have MRLs set at the Limit of Quantification and one can be exempted. We hope to consult upon our proposed changes to these MRLs during April. We will also contact affected registrants to notify them of our proposed changes.

In addition, another 40 plant compounds with no formal MRLs will be reviewed with the intention of consulting on specific MRLs in the second half of 2005.

More MRL setting

With the ease that MRLs were set in 2004, we now feel that the process is well established. Twenty-eight new MRLs or MRL exemptions were included in our standard last year. In 2005 we hope to replicate the success of this process. We will again consult on our new MRL or exemption proposals four times during the year. We expect the first of these regular MRL amendment rounds to start in late February. Approximately ten changes to the MRL standard are likely to be included in that round.

Dietary Intake Project

In the October 2004 *AgVetLink*, we referred to the start of a project to manage dietary intake of plant compounds so that they would comply with potential daily exposures (PDEs) through food. PDEs may be set by ERMA under the HSNO Act midway through 2005, and will take the place of

the acceptable daily intake (ADI) figures that we have used in the past.

Soon after the October *AgVetLink* article was released, we consulted with all affected registrants on the project and asked them to provide us with relevant data. We received many replies to our letter and we wish to thank those registrants for the large amount of support they have provided.

The responses we received, plus a significant amount of research and development, have enabled us to refine our estimates of dietary intakes of plant compounds through food. We have whittled an original list of 17 chemicals that appeared to exceed the PDE_(food) down to nine. This project will continue throughout 2005 and we are confident that, of these nine remaining compounds, all will fit within the likely ERMA PDEs.

TNP status under HSNO Act

Processing registration applications for trade name products

The ACVM Registration Product Data Sheet requests the applicant to supply the TNP's status under the HSNO Act. Instead, some applicants have been referencing similar TNPs approved under the HSNO Act. This is not acceptable. The HSNO approval is based on the entire formulation and uses, not just the active ingredient (AI). Consequently, even if the proposed TNP has the same formulation type, AI and AI concentration for a TNP approved under the HSNO Act, it cannot be assumed that they have the same hazardous profile.

In addition, if the proposed TNP (even if the formulation is the same) has different uses that may not have been considered before (e.g. aerial application as opposed to ground application), then this may also mean a new approval is required under the HSNO Act.

Under such circumstances, the applicant must obtain advice from ERMA on the product's status. Once this has been determined, the ACVM Group can consider issuing the certificate of registration. This may also apply to variations to registrations such as changes in formulation.

Where the proposed TNP has the same formulation and uses as that in the TNP approved under the HSNO Act, the ACVM Group normally considers the proposed TNP to have the same hazard profile and no determination is required by ERMA.

GENERAL INTEREST

GRAS changes

We wish to notify all parties that the substances **Apple flavour**, **Butterscotch flavour**, **Raspberry flavour**, **Smokey bacon flavour** and **Strawberry flavour** are being removed from the GRAS list and their status as GRAS substances in New Zealand has been revoked.

The ACVM Group has become aware that the term present for each of the flavours on the GRAS list is not relevant to the large number of different artificial flavours and different formulations of these that are available, and some of these formulations for a flavour may not be suitable for GRAS listing.

In future we will require the composition of any flavour present in an oral nutritional compound to be declared to determine if all of the chemicals present within the flavour are on the GRAS list. If we determine that certain compositional ingredients do not appear on the GRAS list, applicants will be required to submit a formal application to include the compound on the GRAS list. We also wish to remind all applicants that trade names or mixture names will not be accepted for addition to the GRAS list, which will be reserved for distinct chemical names.

If, on applying for a class determination, a flavouring or other additive mixture does not appear to be GRAS listed, a composition of this mixture should be provided to reference against the New Zealand GRAS list. This may prevent an unnecessary decline.

NOTE: Natural flavours that are unrefined extracts of plant or animal origin are considered to be foods and are irrelevant to GRAS listings.

Nonyl phenol review

Over the past years there has been a large amount of media and public attention on the nonyl phenol chemical classes because of their potential as anti-androgenic endocrine disruptors within the environment and in relation to human health. These chemicals are currently heavily used as either active or inert ingredients in the formulations of plant compounds, veterinary medicines and oral nutritional compounds. Outside of the scope of the ACVM Act, they are also regularly used as cleaning agents.

In early 2003 many restrictions were placed on the use of nonyl phenols and nonyl phenol ethoxylates within the EU by the European Parliament's Environment Commission. In light of these restrictions overseas and predicting a future ERMA New Zealand assessment of this chemical family, we wish to notify all parties that we will soon be reconsidering the status of nonyl phenol ethoxylates as a GRAS-listed compound within New Zealand, with the possibility of revoking this listing. Depending on the outcome of an ERMA New Zealand assessment, further restrictions in the use of nonyl phenols in agricultural compounds may be introduced. At this time no action has been taken regarding the registration of products containing nonyl phenols. However, the ACVM Group wishes all affected parties to be aware of the possibility of future restrictions on the use of these products. We will strive to keep all affected registrants notified on any changes to the status of nonyl phenols within New Zealand.

Conference on Food Safety and Dietary Risk Assessment

Warren Hughes presented a paper at the 3rd International Fresenius Conference on Food Safety and Dietary Risk Assessment held in Mainz, Germany, 13-14 December 2004. The conference provided an opportunity for the ACVM Group to explain the New Zealand regulatory system, especially the MRL process, to European regulators and industry. It also provided an opportunity to keep abreast of developments in the European regulatory environment, particularly management of pesticide residues.

A speech given at the Conference detailed the newly passed Regulation that consolidates and simplifies the four framework directives covering MRLs in the EU. This Regulation:

- defines the European Food Safety Authority (EFSA) as risk assessor and the Commission as risk manager
- extends the cover of foods to animal feeds
- establishes a default MRL of 0.01mg/kg for non-authorized uses
- provides the ability for member states to recover costs for the

MRL setting process

- synchronises with EU procedures for the control of pesticide residues in food and feed
- creates a uniform EU procedure for establishing import tolerances from third countries
- provides the ability to set MRLs based on monitoring data (for exceptional cases, e.g. spices)
- establishes temporary MRLs for active ingredients that are not yet harmonised.

In addition to attending this conference, Warren visited the German regulatory authorities (BBA) to meet key personnel and discuss in some detail the regulatory system in Germany. He also visited the Bayer Cropscience manufacturing site in Dormagen, Germany, which provided an insight into the scale and processes involved in the manufacture of both active ingredients and end-use formulations.

GENERAL INTEREST

Feed commodities: fit for purpose standards

The amendment to the ACVM Regulations 2001 (see page 2) will impose a condition that feed commodities must comply with the fit for purpose standards in Schedule 4 of those Regulations.

Before the amendment, Schedule 4 related to oral nutritional preparations such as commercially compounded (manufactured) animal feeds and animal products/byproducts to be fed to animals. The amendment will place an obligation on any person who offers for sale any plant material (i.e. plant origin feed commodity) as a feed for animals to comply with the same fit for purpose criteria that apply to compounded feeds or animal products/byproducts.

Plant material feed commodities include standing grass, edible food crops or other forage crops, hay, silage, grain or other arable or horticultural products that are offered for sale or supplied for use as a feed for animals. To be fit for purpose for the species, type and class of animal to be fed the feed commodities must not:

- produce residues in products harvested from the animal(s) fed that fail to comply with applicable food residue standards set in or under any enactment;
- result in toxic reactions causing pain or distress in the animal(s);
- result in malnutrition causing pain or distress in the animal(s); or
- contain pathogenic micro-organisms at levels that could cause disease resulting in pain or distress in the animal(s).

The amendment will also add a criterion that the feed must not result in physical harm causing pain or distress in the animal(s).

Reasons

There were two main reasons for imposing this obligation. The first was to establish a level playing field for all parties selling animal feeds so that they all have to take due care to ensure their products are fit for purpose.

The second reason was to give effect to the recently endorsed Codex *Code of Practice for Good Animal Feeding*. The Code highlights an international expectation that all classes of animal feeds (compounded feeds and feed commodities) should be managed to bring the level of food safety risks down to an acceptable level.

New Zealand is a firm supporter of internationally recognised standards and codes of practice because they provide a common measure to judge appropriate trading practices. The New Zealand Food Safety Authority participated in the development of the *Code of Practice for Good Animal Feeding* to ensure that it was no more restrictive than was technically justifiable. The amendment to the ACVM Regulations 2001 was a necessary prerequisite to aligning New Zealand animal feeding practices to the Codex Code.

Fair Trading Act or ACVM Act?

During consultation on the amendment to the Regulations some parties suggested that obligations imposed under the Fair Trading Act 1986 were already sufficient to ensure that feed commodities would be fit for purpose. However, the Fair Trading Act does not provide guidance on what would constitute animal feed that is fit for the purpose. While the Fair Trading Act was relevant, fit for purpose standards would have to be prescribed.

The appropriate standards already existed in Schedule 4 of the ACVM Regulations for all other animal feeds. By measuring all feed commodities with the ACVM standard, the first objective

of a level playing field governing quality and safety of animal feeds would be achieved. Providing the fit for purpose standards in the ACVM Regulations meant the regulated parties were more likely to be aware of them through the proactive communications of the ACVM Group such as this *AgVetLink* article.

The offence and penalty provision of the two Acts were similar but the wording in the ACVM Act more closely reflects current practices, particularly in regard to knowingly committing an offence. With these advantages it was decided that the appropriate course of action was to amend the ACVM Regulations.

Practical implications

As stated above, the wording of the offence and penalty provisions of the ACVM Act reflects current practices in relation to the manufacture and sale of agricultural compounds. There has to be an element of foreknowledge before an offence is committed. This is relevant to the practical implications of the new obligation.

Presently in New Zealand the risks posed by feed commodities are relatively well managed by common production practices. Feed quality from a nutritional perspective may vary significantly and still not produce any of the negative effects specified in fit for purpose criteria, so selling surplus feed that is less than first grade is not going to result in an offence.

The amendment introduces an obligation to confirm fitness for purpose for feed commodities only in those cases where existing knowledge and common practice would make a producer conclude that the commodity is likely to cause one of the prescribed negative effects (i.e. the feed commodity grown and processed in the usual manner is likely to be contaminated or damaged

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Transfer update: veterinary medicines

(Article provided by ERMA)

The Transfer of Substances Group is currently working on the transfer of veterinary medicines (formerly licensed animal remedies) to HSNO. Consultation on the classifications and controls for most types of veterinary medicines has been completed.

To date, ERMA has approved the transfer of parasiticides (such as ivermectin drenches) and other large volume products (such as bloat remedies), and small-dose form, finished-product veterinary medicines (such as vaccines and antibiotics). The main types of veterinary products still requiring consultation are the dietary modifiers and electrolytes. We are on

track to meet the scheduled transfer date of 1 July 2005.

Concerns

From the consultation undertaken on veterinary medicines over the past 12 months, it has become apparent that there is some confusion over certain HSNO controls. Concern has been expressed about the intent of some controls and what is required to be compliant with them.

Labelling

One of the concerns relates to labelling and problems that may arise for products imported from overseas. These matters can be worked through, and a number of options are available for meeting the requirements, including the use of product inserts.

Storage

The requirements that apply to the storage of large volume products on farms and in veterinary clinics are also an issue of concern. We are continuing to discuss these matters through meetings with interested parties, such as the New Zealand Veterinary Association, and at farm visits organised by Federated Farmers.

Transition period

As was the case when pesticides were transferred, there will be a period of transition before the controls are required to be implemented, providing more opportunity to discuss and communicate workable solutions to the issues raised.

Avoiding duplication

Other controls have been varied considerably to avoid regulatory duplication with the Agricultural Compounds and Veterinary Medicines (ACVM) requirements. For example, the approved handler and tracking controls for many products have been

removed, particularly if the products have prescription animal remedy (PAR) status under ACVM.

Matters to be resolved

Two matters are yet to be resolved. Firstly, a final decision needs to be taken on whether an approved handler should be required when ecotoxic veterinary medicines are sprayed. This relates mostly to ectoparasiticides. ERMA New Zealand has made it clear that the final decision is yet to be reached.

Another matter that requires further work is the processing of veterinary medicines that were not notified under the Toxic Substances Act. Because the transitional provisions of HSNO did not include veterinary medicines, these substances were required to be notified.

A strict view would be that if a product was not notified, it cannot be transferred and we have advised all manufacturers with non-notified products of the situation. There are a number of options available to bring these products under the HSNO regime, and we are currently working with companies on this.

No fundamental problems

The concerns being raised now with veterinary medicines are not dissimilar to the concerns expressed in the lead-up to the transfer of pesticides that, nine months on, have not resulted in any fundamental problems. New Zealand's agricultural sector continues to operate in much the same way that it has in the past. ERMA New Zealand is committed to ensuring that veterinary medicines are transferred with minimal disruption to manufacturers and end users.

Contact

If you have any queries, please do not hesitate to contact Jim Waters:
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FEED COMMODITIES concluded

to the point that residues would result, or animals would be poisoned or physically harmed, or become malnourished or infected with pathogens). Examples would be intentionally selling hay that has deteriorated to such an extent that common practice would exclude it as an acceptable animal feed, or selling grain that has been stored in damp conditions.

The purpose of the obligation is to make it an offence for a person to sell feed commodities that are known not to be fit (or are very likely not to be fit) to feed to animals, and to make it clear what constitutes feed commodities that are fit for purpose.

Producers will not have to introduce any additional practices to comply with the standards. In the vast majority of cases, no additional production or testing practices will be required and no regulatory approvals or audits will be imposed.

VETERINARY MEDICINES

Manufacturing register updated

The register of manufacturers of veterinary medicines for which approval of good manufacturing practice (GMP) has been provided has been updated on the website (<http://www.nzfsa.govt.nz/acvm/registers-lists/manu-approved.htm>). It would be appreciated if you would check and notify us of any errors or omissions.

The main change to the register has occurred as a result of the implementation of the ACVM Act and our continuing efforts to reduce the costs of compliance.

Previously all registered veterinary products could be produced only by GMP approved manufacturers. Now some veterinary medicines (generally in the oral nutritional category) still require registration but are considered to be in a lesser risk category. These products are assessed and defined as 'specified requirements products' (SRPs).

CATEGORIES OF MANUFACTURE

The categories of manufacture now being used by the ACVM Group are:

- Cat 1 (a) Immunobiologicals
(b) Sterile veterinary preparations
- Cat 2 Non-sterile veterinary medicines
- Cat 3 Ectoparasiticides (large volume)
- Cat 4 Plant compounds
- Cat 5 Agricultural compounds and veterinary medicines in Schedule 3
- Cat 6 Repackers/Labellers
- Cat 7 (a) Contract testing
(b) Contract sterilising organizations
- Cat 8 Registrants/Distributors of HGPs
- Cat 9 Vertebrate toxic agents

It has been determined that the appropriate level of regulatory control of SRPs can be achieved by assessment of less data than that required for pharmaceutical or biologically effective products, and that GMP assessment of manufacturers producing only SRPs is not required for their registration. As a result, manufacturers of SRPs have been

removed from the register.

New category

A new category, manufacturers of vertebrate toxic agents, has been added to the register. Previously, vertebrate pest control products were regulated under the Pesticides Act and no GMP assessments were carried out of manufacturers of pesticides.

With the implementation of the ACVM Act it has been necessary to reclassify these products as vertebrate toxic agents. Because they are applied to animals, the animal welfare and residue risks must be managed.

Therefore, it has been determined that GMP approval is necessary for these manufacturers and they are now in the inspection programme to facilitate regulatory control of these products from manufacture to end use.

External communications – GMP

The ACVM Group continues to investigate ways to improve the performance of the GMP programme consistent with the requirements of the ACVM Act and international agreements. In December Debbie Morris and Brian Pidford visited the **Therapeutic Goods Agency (TGA)**, Canberra, to obtain an understanding of how the TGA perceives GMP for human pharmaceutical products will be managed under the Australia/New Zealand Joint Scheme for the Regulation of Therapeutic Products as it becomes fully implemented.

Another meeting, the **Veterinary International Conference on Harmonisation** (May 2005), will provide the opportunity for talks with Canadian regulators on the management of GMP for veterinary products by Health Canada.

Advertising and promoting prescription animal remedies

After further discussion with interested and affected parties, the ACVM Group has amended its standard for prescription animal remedies in regard to advertising and promoting such products to end users.

Direct toward veterinarians

Advertising or promotion activities (i.e. activities that encourage the sale of a particular trade name product) for PAR veterinary medicines should be directed toward veterinarians who can legitimately prescribe the products. Advertisers should provide accurate and technically supportable information about the products to allow prescribing veterinarians to make informed judgements regarding their use.

Approved traders

An approved trader may advertise the types of PAR veterinary medicines they stock. PAR products must not be displayed in public view, prompting the interest of purchasers.

Technical information

It is appropriate for traders to provide technical information on products and to foster awareness and understanding of disease conditions or health and production management options. (Such information transfer is not considered advertising in this context.) In doing this it is reasonable to identify themselves with the information and to inform that they market a product or products that could be used to treat a particular disease condition or contribute to the management of health or production.

Role of veterinarian

A trader may advertise or promote (including offering purchasing incentives) PAR products to end users where advertising or promotion is not likely to jeopardise the risk management role of the prescribing veterinarian. For example, advertising would be acceptable if the veterinarian's risk management involvement is in relation

to *how* or *when* a PAR product should be used (e.g. oestrus synchrony products) rather than deciding *if* a particular product should be used (e.g. disease treatment products).

In all cases, the person must emphasise that end users should discuss treatment options with their veterinarian. This distinction will require discretionary judgement from the person based on the type of product. If in doubt, the ACVM Group will offer its opinion.

Prohibition

For trade name PAR products that must not be advertised to end users (e.g. antibiotic products and anabolic steroids), the ACVM Group will expressly state that prohibition in a condition on the registration.

This means that there is no discretionary judgement to be made. The products must not be advertised or promoted, and no purchase incentives may be offered.

VERTEBRATE TOXIC AGENTS

The ACVM Group is in the final stages of finalising the registration conditions for vertebrate toxic agents (VTAs) after two rounds of consultation with relevant parties.

Because information requirements for VTAs are different than requirements for veterinary medicines (and plant compounds), the ACVM Group is also finalising separate VTA registration requirement documents and standards.

It is hoped to have the above completed by the end of February 2005. This means that a number of VTAs will have significant changes to their registration conditions and labelling requirements.

However, with the delay in transfer of 1080 by ERMA affecting the replacement of the old VPC licensing scheme with the new one, VTAs subject to this old licensing requirement cannot be updated with the new conditions of registration. Their updating will occur once the 1080 review has been completed.