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Commencement of the ACVM Act

Cabinet has stated that the Hazardous Substances and New Organisms (HSNO) Act 1996 will commence **2 July 2001**. The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 will also commence on the same day. While there have been a number of dates set by the Minister for the Environment for commencement, this is the first time Cabinet has endorsed the date. Consequently, the ACVM Group is initiating action to give effect to the commencement on that date.

The ACVM Regulations have been finalised and are ready for Cabinet approval. They will come into effect at the same time the Act commences. There have been no material changes made since consultation comments were incorporated in late 1999. The Regulations list the trade name product groups that will be exempt from registration. The ACVM Group is now in a position to begin the transfer of animal remedy licences and pesticide registrations (see page 2). The Regulations also include two lists of generally recognised as safe (GRAS) substances for inclusion in:

- non-medicated oral nutritional compounds exempt from registration; and
- plant compounds exempt from registration.

The ACVM Group will also action the approval of the codes of practices that have been lodged with MAF for approval under section 28 of the ACVM Act.

I am confident that, with cooperation from affected parties, the ACVM Act can commence with minimal disruption. However, it is worth reminding everyone that the full range of risks posed by agricultural compounds or veterinary medicines will be managed via the ACVM Act and the HSNO Act. The ACVM Group and ERMA NZ will be working together to make their operations as compatible as possible, but the regulatory requirements of both Acts must be met.

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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.

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Licence and registration transfer project

With the commencement of the ACVM Act all animal remedy licences and pesticide registrations must be converted to ACVM registrations unless either:

- the trade name product is not an agricultural compound under the new Act (e.g. household pesticides, home gardening products, etc); or
- the trade name product fits the definition of an agricultural compound that is exempt from the requirement to be registered.

Transition period

The transition period lasts for three years from the commencement of the ACVM Act. By the end of that period the transfers must have been completed. At that time it will be illegal to import, manufacture, sell or use a trade name product that requires registration that has not received its new ACVM registration.

In the mean time, products that are presently licensed or registered will remain so until they are transferred. They will be regulated under the provisions of the Animal Remedies and Pesticides Acts, respectively.

EXTRA ISSUE

To inform readers who have many questions relating to implementation of the ACVM Act, an extra issue of *AgVetLink* will be published next month.

Meanwhile, keep checking the website (www.maf.govt.nz/ACVM) for updates.

Hazardous substance?

If a trade name product is not a hazardous substance the ACVM Group will issue its new registration. However, new registrations will not be issued for trade name products that are also hazardous substances (or where the hazardous status is uncertain) until the ACVM Group is advised that either:

- an ERMA approval has been issued; or
- an ERMA approval is not required.

The ACVM Group is working with ERMA NZ to clarify the rules that it should use to identify what is not a hazardous substance. The ACVM Group will make these rules public as soon as they are finalised, so licensees or registrants can see whether ERMA approvals are necessary for their products before an ACVM registration can be issued.

Exempt products

As stated above some trade name products may not have to be registered under the ACVM Act (see page 5 on exempt agricultural compounds).

Pesticides

All agricultural compound pesticides will have to be registered. They will all be hazardous substances as well, so they will need ERMA approvals. Pesticides that will not be agricultural compounds (see page 7) will not have to be registered under the ACVM Act, but they will need ERMA approvals.

Vertebrate pest control products

The ACVM Group has not seen the controls ERMA NZ will impose on vertebrate pest control products. If they are insufficient to:

- manage the risks to animal welfare;
- prevent residues that breach New Zealand residue limit standards;

and

- manage the risks to trade in primary product (e.g. violative residues in export game meat), then MAF will ensure that they are defined as agricultural compounds and will require them to be registered under the ACVM Act.

Prescription animal remedies

All prescription animal remedies will have to be registered. Almost all will retain their present PAR classifications. However, a few classifications may change when the PAR criteria listed on page 5 are applied.

Over-the-counter products

A number of over-the-counter animal remedies may be exempt from registration. A few, such as over-the-counter antibiotic trade name products, may be made prescription animal remedies. Information on oral nutritional compounds is provided on page 8.

Transfer request

The transfer of a trade name product will commence on receipt of a transfer request containing the information described on page 3. Because the conversion of licences and registrations must be done by Regulations (section 88 of the ACVM Act), the actual time available for processing registrations is approximately two years. Consequently, it is important that licensees or registrants start the transfer of their products as soon as possible.

The rules the ACVM Group will apply in determining the class of a trade name product can be found as an information sheet on the ACVM Group website (www.maf.govt.nz/ACVM/). If you are uncertain about the classification of your product(s) you can ask for a class determination from the ACVM Group.

Information requirement for transfer

The transfer of licences or registrations of specific trade name products (TNPs) will commence on receipt of a transfer request. The information required to process a transfer consists of a product data sheet and either:

- the content of the label, including the script and any graphic material that expresses or implies a use, claim or instruction for use (or the actual label);
- a material safety data sheet for the formulated product, if available; and
- a signed declaration that the product being transferred is the same as the product that is licensed or registered.

Labels

Note that label means any written, pictorial, or other descriptive matter under which the compound is sold or to be sold that purports to give some information about the TNP.

As stated on a number of occasions, the ACVM Group will not be approving labels *per se*. However, it will examine label content or labels to confirm that the product is being marketed in accordance with the approved product specifications and the conditions of registration. The ACVM Group will accept reference to the label content provided for any product data sheet information that is detailed on the label.

Product data sheet

The product data sheet must contain:

- trade name
- existing registration number
- details of the registrant (and New Zealand agent if applicable)
- details of approved manufacture(s)
- formulation type
- uses and instructions
- warnings or contraindications
- withholding period
- ingredients and concentrations
- shelf life
- packaging specifications
- labelling specifications.

All ingredients and their proportion, and instructions for use must be included, so that the ACVM Group can confirm that:

- the product is the same product as the one that is licensed/registered; and
- the licence/registration can be updated without reviewing any data.

Hazardous substances

The ACVM Group is working with ERMA NZ to ensure that, wherever possible, the product data sheet required by the ACVM Group contains the same information that could be used to determine if the product is hazardous or not. The information required by ERMA NZ to determine the actual hazard classification will be a matter that must be discussed between the licensee/registrant and ERMA NZ. The ACVM group is interested only in whether the trade name product does or does not require an approval from ERMA.

Confidentiality

The full product data sheet will be confidential, but a version will be extracted from what is provided and made public as part of the public register entry for the product. The ACVM Group considers that the only commercially sensitive information that it requires on the product data

sheet is the list of ingredients and their proportions. It considers that the public register should list the ingredients with biological activity, but the other ingredients can and will remain confidential.

Material discrepancies

The ACVM Group is anticipating circumstances in which, for one reason or another, the product being transferred is not exactly the same as the one licensed/registered. The information provided should specify what the product is at the time it is being transferred. Any material discrepancies between the product specifications in the existing licence/registration and the information provided will be discussed with the licensee/registrant. The ACVM Group may decide that the discrepancies are insignificant and will issue the updated registration. However, it reserves the right to require re-licensing or re-registration before the transfer if the discrepancies suggest that the transfer cannot be carried out safely.

The information should be provided in hard copy with an electronic version of any text. The ACVM Group has developed specifications for how the electronic information should be provided. These will be provided to all licensee/registrants, but can be found on the ACVM Group website (www.maf.govt.nz/ACVM/).

FREQUENTLY ASKED QUESTIONS

The ACVM Group has prepared answers to frequently asked questions such as:

- When will animal remedy and pesticide products get transferred to the ACVM registrations?
- What will happen with products under a provisional registration or an experimental use permit?
- What happens with annual fees under the Animal Remedies and Pesticides Act when licences and registrations are transferred?

These can be found on the Group's website (www.maf.govt.nz/ACVM/). The Group will add questions and answers over the next few months, so you may want to check the site regularly for updates.

Update versus review

Over the next three years the ACVM Group will be transferring licences and registrations under the old legislation to registrations under the ACVM Act. Right from the start, the Group would like to clarify the difference between updating and reviewing licences/registrations.

Updating licences/registrations

Every animal remedy licence and pesticide registration must be updated as part of the transfer process. Updating involves using existing information about a trade name product and confirming that the transfer can be made safely. Licence and registration numbers will be converted and the conditions will be adjusted to reflect the requirements of the ACVM (see article on ACVM registration conditions, page 6). New information will not have to be provided by the licensee or registrant (see page 3). The data on the trade name product will not be reviewed.

Reviewing licences/registrations

There will be a few trade name products that have over time posed new risks that were not addressed when they were originally licensed. There may be significant uncertainty about the new risks posed by a trade name product or about the appropriate conditions that would be needed to manage those risks. In those few cases the data held on the product will be reviewed and the licensee/registrant may even be asked to provide new information/data to facilitate the review.

Policy on review of information prior to transfer of licences or registrations

All present licences and registrations will be updated as they are transferred to regulatory control under the ACVM Act. Wherever possible the ACVM Group will use information it already has to transfer the licences or registrations of trade name products. In most cases it will not request the applicant to provide any new data. However, there will be circumstances in which the transfer of a licence or registration cannot be made without concerns that the risks may not be adequately managed. In such cases there will be a review carried out before the licence or registration is updated.

Where the information gaps are minor from a risk management perspective, the transfer can still be completed without new information. Concerns will be considered minor if the lack of information does not prevent the making of a technically sound registration decision

Where a registration decision could be made but there is further information that would be needed to refine the conditions, either:

- a limited registration period may be imposed, to allow the registrant to adequately address the concerns before the termination of the new registration period; or
- more stringent/limiting conditions may be imposed to manage the risks in the face of uncertainty, and could include conditions on importation, manufacture, sale and especially use.

When more restrictive conditions are applied, registrants would have to apply for a change in the registration and provide the supporting information if they wish to have the conditions modified.

There will be a few occasions in which the level of uncertainty is too great to make either of the above options appropriate. On such occasions the ACVM Group may request new information. The new information will have to be reviewed before a registration decision is made.

The following are rules for when a review of new information may be carried out:

- if the information held by the ACVM Group is inadequate to set appropriate conditions (even more stringent ones than are presently imposed on the licence/registration); and
- there may be adverse consequences if the conditions that seem appropriate (given the information held by the ACVM Group) were applied.

The potential for adverse consequences will be judged on:

- a history of adverse events; or
- scientific or public expressions of concern about the specific trade name product or products similar to the one in question.

Registrants/licensees will be advised if new information is required. It is expected that new information will not be required in most cases.

Policy on prescription animal remedies

The prescription animal remedy (PAR) classification system will continue to be used under the ACVM Act (see page 6). Such trade name products will be known as prescription animal remedies and will be the subset of veterinary medicines that are commonly considered to be drugs or medications.

The criteria used when imposing prescription status to trade name products were originally established by the Animal Remedies Board in 1983/84. These criteria will continue to be relevant under the ACVM Act but two additional criteria (last two bullet points below) have been added to manage risks that were uncommon when the Board set the original criteria.

A trade name product will be given a PAR status when:

- it includes in the formulation a drug that is a controlled drug within the

meaning of the Misuse of Drugs Act 1975, e.g. morphine, pethidine;

- there is a possibility of acute or long-term toxic effects or development of hypersensitivity in humans, e.g. *Brucella* vaccine, streptomycin, DMSO;
- animal safety or welfare may be threatened, e.g. succinyl choline;
- the trade name product could mask disease, e.g. *Brucella ovis* vaccine;
- use of the trade name product demands a veterinary diagnosis and or monitoring of the animal's response, e.g. iodine, copper, corticosteroid, anaesthetics;
- the administration of the trade name product requires the skill of a registered veterinarian to manage animal welfare concerns, e.g. intrauterine, intra-articular administration;
- there is an increased risk of development of bacterial resistance to antibacterial agents used in human or veterinary medicine;
- the trade name product contains a

human medicine, or a prodrug of that human medicine, which is available only on prescription, unless specifically exempted by the Ministry of Health;

- directions for sale and correct use of the animal remedy cannot be adequately conveyed by the product labelling and must be used by or under the control of a registered veterinarian;
- the trade name product is to be used as part of an official national scheme to monitor, control or eradicate disease;
- use of the trade name product is a threat to trade, and market access conditions require prescription use, and control e.g. hormonal growth promotants, antibiotics etc.

It must be noted that PAR status is recognised as a significant limitation on access and use of a trade name product. It will be imposed only when it is justifiable from a risk management perspective.

Agricultural compounds exempt from registration

The following groups of trade name products have been prescribed as exempt from the requirement to be registered under the ACVM Act. Only a group title has been made. The full description of the group should be used in determining if a particular trade name product fits any of the definitions in schedules 1, 2 or 3 in the Regulations. Any expansion of the uses or claims beyond what is provided for in the definitions will exclude a trade name product from exemption from registration.

Schedule 1

- Products made for own use
- Commercial compressed gases
- Non-medicated hoof preparations
- Non-medicated skin preparations for skin quality
- Masking agents for odour
- Cleaning agents
- In-vitro diagnostics
- Plant material
- Fertilisers and fertiliser additives that are raw or composted biological wastes

Schedule 2

- Non-medicated oral nutritional compounds
- Homeopathic preparations without disease specific claims
- Herbal preparations without disease specific claims
- Markers, paints and dyes
- First aid preparations
- Human medicines used by veterinarians
- Preparations compounded by veterinarians for their own use

Schedule 3

- Topical skin medications
- Non-medicated anti-diarrhoea preparations
- Oral laxatives and lubricants
- Cauterising preparations
- Urinary tract modifiers
- Respiratory tract modifiers
- Spray markers
- Plant compound adjuvants
- Repellants
- Anti-transpirants
- Frost protectants
- Sunblocks

Conditions on registered agricultural compounds

In developing the ACVM Regulations 2001 the ACVM Group has produced schedules of conditions for the following kinds of agricultural compounds:

- prescription animal remedies in classes I, II, and III;
- over-the-counter veterinary medicines; and
- over-the-counter plant products.

The schedules contain generic conditions and refer to the current approval in which the product-specific conditions are listed along with the product specifications that have been approved. The conditions are as follows.

Class III prescription animal remedy

The product must be manufactured in accordance with the *ACVM Standard for Good Manufacturing Practice* and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.

In addition to any labelling requirements specified in the current approval, labelling must comply with the *ACVM Standard and Guidelines for Labelling*.

The product must be sold or imported only according to the current approval.

The product must not be sold to any person other than a veterinarian or dealer.

The product must not be administered except following a veterinary consultation.

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

The product may be used at the discretion of a registered veterinarian:

- when acting in accordance with any applicable code of practice approved under section 28 of the ACVM Act; and
- on animals under the direct care of that veterinarian, unless that use is expressly prohibited in the current approval.

The product has been assessed only for residues and safety for use in the species, type, age, and gender of animal and manner specified in the current approval.

There are no assurances or warranties made by the registrant as to the effectiveness or appropriateness of the product when used in a manner not recommended by the registrant.

Class II prescription animal remedy

The product must be manufactured in accordance with the *ACVM Standard for Good Manufacturing Practice* and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.

In addition to any labelling requirements specified in the current approval, labelling must comply with the *ACVM Standard and Guidelines for Labelling*.

The product must be sold or imported only according to the current approval.

The product must not be sold to any person other than a veterinarian or dealer.

The product must not be administered except following a veterinary consultation.

The product must be administered to an animal only by a veterinarian, or in the presence and under the control of a veterinarian.

The product has been assessed only for residues and safety for use in the species, type, age, and gender of animal and manner specified in the current approval.

The product may be used at the discretion of a registered veterinarian:

- when acting in accordance with any applicable code of practice approved under section 28 of the ACVM Act; and
- on animals under the direct care of that veterinarian, unless that use is expressly prohibited in the current approval.

There are no assurances or warranties made by the registrant as to the effectiveness or appropriateness of the product when used in a manner not recommended by the registrant.

Class I prescription animal remedy

The product must be manufactured in accordance with the *ACVM Standard for Good Manufacturing Practice* and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.

In addition to any labelling requirements specified in the currently approval, labelling must comply with the *ACVM Standard and Guidelines for Labelling*.

The product must be sold or imported only according to the current approval.

The product must not be sold to any person other than a veterinarian or dealer, or otherwise than pursuant to the prescription of a veterinarian.

The product must not be administered, or prescribed or dispensed except following a veterinary consultation.

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

The product has been assessed only for residues and safety for use in the species, type, age, and gender of animal and manner specified in the current approval.

The product may be used at the discretion of a registered veterinarian:

- when acting in accordance with any applicable code of practice approved under section 28 of the ACVM Act; and
- on animals under the direct care of that veterinarian,

unless that use is expressly prohibited in the current approval.

There are no assurances or warranties made by the registrant as to the effectiveness or appropriateness of the product when used in a manner not recommended by the registrant.

Over-the-counter veterinary medicine

The product must be manufactured in accordance with the *ACVM Standard for Good Manufacturing Practice* and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.

In addition to any labelling requirements specified in the currently approval, labelling must comply with the *ACVM Standard and Guidelines for Labelling*.

The product must be sold or imported only according to the current approval.

The product may be sold or used by any person without a veterinary prescription.

The product has been assessed only for residues and safety for use in the species, type, age, and gender of animal and manner specified in the current approval.

The product must not be used by any person on animals or in a manner expressly prohibited in the current approval.

The product may be used at the discretion of a registered veterinarian:

- when acting in accordance with any applicable code of practice approved under section 28 of the ACVM Act; and

- on animals under the direct care of that veterinarian, unless that use is expressly prohibited in the current approval.

Use of the product by any person other than a veterinarian in any other animal or in any other manner other than those specified in the current approval must be done only after seeking veterinary advice.

There are no assurances or warranties made by the registrant as to the effectiveness or appropriateness of the product when used in a manner not recommended by the registrant.

Pesticides that will not be agricultural compounds

There are a number of pesticide trade name products registered under the Pesticides Act 1979 that will not be agricultural compounds under the ACVM Act. These products are intended for use in industrial, public health, or domestic settings in which the risks specified in the ACVM Act are not relevant. Therefore, as at commencement of the ACVM Act, the following kinds of products will not require registrations under that Act:

- household pest control products;
- public health pest control products;
- industrial pest control products;
- home garden preparations; and
- anti-fouling paints.

These products will be hazardous substances and will require ERMA approvals even though they do not require registration under the ACVM Act. If in the future some of the products are found to pose risks specified in the ACVM Act, they may be made agricultural compounds by Order in Council. No such Order is anticipated as this time.

Oral Nutritional Compounds

One of the areas of greatest uncertainty and misunderstanding in the transition to the ACVM Act is in regard to oral nutritional compounds. This is primarily because of the way some proprietors make products that have the characteristics of oral nutritional compounds but want to:

- market them as medications to prevent, control or cure conditions characterised by pain or distress; or
- include ingredients that have or purport to have therapeutic or pharmacological effects.

Proprietors want to create the expectation of a medication, but cannot or do not want to provide information to show that the products work.

Regulatory rules

Recognising the wide range of oral nutritional products, and the varied claims that are made about such products, the following regulatory rules will be applied.

Non-medicated oral nutritional compounds will be exempt from registration. If they contain therapeutic or pharmacological substances then they are medicated and must be registered. If they contain only nutrients and feed additives, but they make therapeutic or pharmacological claims, they are not just oral nutritional compounds and will have to be registered, unless they fit the definition of some other type of product that is exempt from registration.

Oral nutritional compounds can contain only:

- substances that are known to be nutrients or for which a case is made that each substance is a nutrient and has been incorporated into the product to achieve a nutritional benefit as defined in the ACVM Regulations 2001; or
- feed additives that are listed in part A, schedule 7 of the ACVM Regulations 2001.

If a substance is not a nutrient and is not in part A schedule 7, then a person can apply to the ACVM Group to have it listed in the schedule. The ACVM Group will ask for expert advice and state its intention to the public, with an opportunity for the public to comment, before recommending that the substance be listed.


If a trade name product has a substance in it that is not a nutrient or an approved feed additive, then it is not an exempt oral nutritional compound.

Claims

Oral nutritional compounds can make non-specific health claims without jeopardising the exempted status of the product. Claims would include such things as improved production or performance, enhanced flexibility or mobility, enhanced disease resistance or non-specific stimulation of the immune system if the claims can be attributed to a nutritional benefit.

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