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Compliance under the ACVM Act

Anything legally being used as an animal remedy, stock food, fertiliser or pesticide prior to 2 July 2001 when the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 commenced can be legally used for the three years of the transfer period to the new legislation (see page 2).

Any products that are required to be registered but were not registered or licensed prior to the July start date are illegal under the ACVM Act as of the date of commencement of that Act. The penalties for non-compliance have increased considerably under the ACVM Act – they are up to \$30,000 for an individual and up to \$150,000 for companies. Offences relate to illegal importation, manufacture, sale, advertising and use (including using a product other than as allowed for in the conditions).

If you are unsure of the status of your product, the ACVM Group offers a 'class determination' service to confirm that the product is:

- not an agricultural compound; or
- exempt from the requirement for registration subject to applicable codes of practice; or
- exempt from the requirement for registration subject to the prescribed standards (oral nutritional compounds and fertilisers); or
- exempt from the requirement for registration subject to conditions and reporting (partial annual fees are applicable to this group as specified in schedule 3 of the Agricultural Compounds and Veterinary Medicines Regulations 2001); or
- required to be registered but likely to fit the low risk requirements; or
- required to be registered.

Details of the information requirements, forms and the costs are available on the ACVM website (www.maf.govt.nz/ACVM).

Readers should be aware that:

- the report of the Royal Commission on Genetic Modification has been presented to Parliament, and government departments are examining how to carry out Government's directions;
- the second MAF Food conference will be held in Auckland in October.

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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Transfer of trade name products to new legislation

On 2 July 2001 the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the hazardous substances provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996 commenced.

Trade name products (TNPs) that are currently registered/licensed under the Pesticides Act 1979 and the Animal Remedies Act 1967 have up to three years to be transferred to registrations under the new legislation.

Some trade name products will be exempt from the requirement to be registered. However, this article is about those products that require registration.

Transfer processes

There are two separate processes required to transfer relevant registered/licensed TNPs to the new legislation, and these must be carried out within the specified transition period. If trade name products are not transferred within this period, they

will become illegal. (The ACVM Group will advise proprietors who have not initiated the transfer of their products as the end of the transition period draws closer.)

These two processes are:

1. classification of TNP under the HSNO Act; and
2. transfer of TNP (animal remedies and pesticides) to the ACVM Act.

Classification under HSNO Act

Under the HSNO legislation ERMA New Zealand will classify substances as 'hazardous substances' when they trigger any of the hazard thresholds set under the Act. Substances that are not hazardous will not be regulated under the HSNO Act. After classification, ERMA New Zealand will assign controls and transfer them to the main framework of the HSNO Act. In some cases the substance will be a single chemical entity, but in other cases the substance will be defined by the total formulation of a trade name product. It is up to the applicant to define the substance.

Transfer of TNP (animal remedies and pesticides) to the ACVM Act

The ACVM Group will transfer those currently registered/licensed TNPs that are agricultural compounds to the new legislation. Existing licences/registrations will be adjusted to reflect the requirements under the ACVM Act, and new registrations will be issued.

These processes are separate but ERMA New Zealand staff will be working closely with ACVM staff to ensure the transfer to both Acts is coordinated. For those TNPs that are not hazardous substances, the ACVM Group will process the transfers but will notify ERMA New Zealand of its intention. If a TNP is a hazardous substance, the ACVM Group cannot transfer the licence or registration until the appropriate approvals have been issued by ERMA New Zealand.

Registration and Product Datasheet

The ACVM Group and ERMA New Zealand require similar information in order to transfer TNPs under their respective legislation. To avoid unnecessary duplication of information during the transfer process a Registration and Product Datasheet has been designed to summarise this information for both parties (see box at right).

It is proposed that this Registration and Product Datasheet be completed by holders of all currently registered/licensed TNPs for each product and returned to the ACVM Group as soon as possible. This will allow:

- accurate details of each product to be agreed upon by the registrant/licensee and the ACVM Group;
- information to be assembled for the public register;
- information to be collated to permit the hazard classification of that product under the HSNO Act; and
- non-hazardous products to be transferred without ERMA New Zealand approval.

Inappropriate contact person

Recently an applicant company's regulatory affairs person knowingly contacted an ex-employee of the ACVM Group to request information on a product application. Needless to say, the ACVM Group considers this behaviour to be extremely inappropriate and treats such incidents very seriously.

Any queries on applications for the registration of products must be directed through the designated Customer Services Officer (CSO) who will liaise with the ACVM staff concerned to get a response as soon as possible. It is important that direct contact with technical staff is kept to a minimum to ensure that the bulk of applications are processed as quickly and efficiently as possible. In addition, some ACVM staff members are not contracted full time to the Group and have obligations to other parts of MAF.

If you are not satisfied with the response from the CSO, then your concern should be directed to Maree Zinzley (Customer Service & Approvals Manager), or escalated to Brian O'Sullivan (National Manager, ACVM Approvals) or Debbie Morris (Director, ACVM Group).

Receipt of a Registration and Product Datasheet will be the prompt to transfer a TNP. Datasheets received by the ACVM Group will be shared with ERMA New Zealand to facilitate the transfer process.

A proprietor who considers a product not to be a hazardous substance may make a declaration to that effect and the ACVM Group will process the application (unless the proprietor is obviously mistaken about the hazard classification). However, only ERMA New Zealand can issue a definitive statement about the hazard classification of a substance so, if in doubt, contact ERMA New Zealand directly to discuss the matter.

In summary, to initiate the transfer of a TNP, send a completed Registration and Product Datasheet and *either* a declaration as to the hazardous or non-hazardous status of the product *or* advice from ERMA New Zealand as to that status.

The Registration and Product Datasheet package replaces the current application form for new applications made after 2 July 2001. Applications for variations to an existing registration can still be made under the Pesticides Act 1979 and Animal Remedies Act 1967 before a product is transferred by using the original forms.

A separate Registration and Product Datasheet must be completed for each TNP and parts A, B and D must be fully completed in all cases. Part C is required only for new applications for registration, or applications for variations made at or after the time of transfer. There will be no charge for transfer.

Allow sufficient time

As TNPs must be transferred from the old legislation to the ACVM/ HSNO legislation by regulation it is essential that Registration and Product

REGISTRATION AND PRODUCT DATASHEET

The Registration and Product Datasheet consists of four parts:

- **Part A** Product characteristics (general information)
- **Part B** Product characteristics (commercially sensitive information)
- **Part C** Additional information for registration, or applications for variations made at or after the time of transfer
- **Part D** Declaration that the information provided is true and correct

Part A – General information
Part A contains product characteristics and particulars of a TNP that are not considered to be commercially sensitive (i.e. trade name, registrant details etc.). The ACVM Group proposes to use this information for the public register developed under the ACVM Act.

Part B – Commercially sensitive information
Part B contains product characteristics and particulars of a TNP that are considered to be commercially sensitive. Information in this section will be used only to fulfill requirements under the legislation (hazard classifications etc.) and will not be made available to the public.

Where a company does not have direct access to the information required, it can be supplied directly to the ACVM Group. In such a situation, companies should arrange for the manufacturer/supplier of the product to provide the information and/or fill in the appropriate part of the form on their behalf.

Part C – Application details
Part C contains the additional information that is required only for new registrations or variations to existing registrations made at or after the time of transfer.

Part D – Declaration
Part D is a declaration that must be signed for each TNP stating that the information provided is true and correct.

Datasheets are returned within sufficient time to be processed and included in the legislative transfer. If the Registration and Product Datasheets are not returned within sufficient time there is a possibility that the transfer may not occur within the transition period and those products may become illegal. A new registration, which would attract the appropriate fees, would then be required.

We therefore advise all registrants and licensees to complete Parts A, B and D of the Registration and Product Datasheet package and return the completed form as soon as possible.

Copies of the Registration and Product Datasheet have been posted to licensees and registrants. However, a copy can also be found on the ACVM Group website or obtained directly from the ACVM Group.

Commencement of the hazardous substances provisions of the HSNO Act 1996

The following article has been provided by ERMA New Zealand

Many substances commonly used by farmers, growers and others in the agricultural sector have come under new management with the commencement of the hazardous substances part of the Hazardous Substances and New Organisms Act (HSNO) 1996 and the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

As of 2 July 2001, all registered pesticides and licensed animal remedies with hazardous properties have become part of a comprehensive new regime covering hazardous substances from the time they are imported or manufactured right through to disposal of residues.

The HSNO Act also applies to many other substances used by the agricultural, horticultural and related communities. These include things as diverse as diesel, explosives and the cleaning compounds used in dairy sheds. In fact, if it is a hazardous chemical it will probably be covered by the new Act.

The HSNO Act represents a major step forward in protecting people's health and the environment from the harmful effects of many substances essential in our daily lives. Across the community these range from household bleach to fireworks, petrol, pesticides and major industrial chemicals. Without good management, they can explode, catch fire, poison us, or pollute the environment.

This country has already notched up too many cases of careless or ill-informed use of chemicals. We have seen people being left with ongoing health concerns. We have seen landowners or the Government left with expensive problems, such as the contaminated site at Mapua, to clean up.

One central agency, the Environmental Risk Management Authority (ERMA), now makes decisions on which new hazardous substances can be introduced to New Zealand and will set a range of controls, in conjunction with the ACVM Group of MAF to ensure that they are used safely.

A key feature of the new system is that New Zealanders will now have input into the process of assessing and setting controls on hazardous substances new to the country. This was not possible under previous laws.

So, what will all of this mean for farmers and growers? The answer is not a lot in the short term. Those manufacturing, using or transporting hazardous substances such as registered pesticides already legally present in this country can expect pretty much business as usual for awhile.

The 2 July commencement date is of most immediate relevance to importers and manufacturers of new hazardous substances. They will now need ERMA New Zealand approval before they can introduce new substances. However, most major players are already well aware of the new controls and have been acting to make sure that their house is order.

Meanwhile ERMA New Zealand (and the ACVM Group for agricultural compounds and veterinary medicines) need to work through the process of transferring many thousands of existing substances to the new system before any changes in the way they are controlled will take effect.

The first transfers are expected to take place over the next two years and will cover dangerous goods, explosives and pesticides. However, once

ERMA New Zealand starts approving applications to introduce new substances, it will impose controls on these substances under the HSNO Act, with which people must comply.

A series of agencies, led by the Occupational Safety and Health Service, Ministry of Health and territorial authorities, with oversight from ERMA New Zealand, will work together to ensure effective enforcement of the new controls. It should mean there is no duplication, overlap or gap in enforcement.

The transfer period will provide an opportunity for many large and small businesses to get up to speed with the new system.

There will be plenty of ways people can do this, ranging from a website at www.hsno.govt.nz, to seminars and workshops, to guidance material developed by the Ministry for the Environment and ERMA New Zealand, and advice from the agencies that already have experts in this field. For farmers, planning is underway for a special set of seminars on the HSNO Act and Resource Management Act. Watch for one of these in your area.

The Ministry for the Environment administers the HSNO Act and should therefore be a primary contact for information about the Act itself, including details of the Act and amendments) as well as general policy direction.

The HSNO Act is fundamentally different from the laws it replaces, such as the Dangerous Goods Act, the Explosives Act and the Toxic Substances Act. It has more in common with the Resource Management, Building, and the Health & Safety in Employment Acts. ➔

Changes to the fee structure for gaining a Vertebrate Pest Control licence

With the commencement of the ACVM Act and the HSNO Act, there has been a change in the fee structure for gaining a Vertebrate Pest Control (VPC) licence.

The work will continue to be carried out by the ACVM Group under delegated authority from ERMA New Zealand under the HSNO Act. The fee structure will be as follows:

The \$295 (including GST) fee covers the ACVM Group administrative function plus the examination fee. In addition to this fee there will be a cost of \$200 (including GST) per person for the provision of training. Therefore, the total fee charged for the application, training and examination is \$495 (including GST).

The above fee covers 1-5 controlled poisons where the application is made at any one time. These controlled poisons are:

- Sodium Fluoroacetate (1080)
- Phosphorus
- Cyanide
- 3-Chloro-P-Toluidine Hydrochloride (DRC 1339) and
- Alphachloralose (in concentrations greater than 2.5%).

For groups of over 10 people there would be a maximum of \$2950 (including GST) for **examinations** (if all done as a single group at the same time and place) and a maximum of \$2000 (including GST) for **training** (if all done as a single group at the same time and place).

AgriQuality, working on contract to the ACVM Group, will provide examination functions in most cases.

However, training could be provided via other reputable service providers, such as polytechs or pest control organisations.

Where AgriQuality provide the training function, the fee will be collected by the ACVM Group.

Applicants must travel to the AgriQuality site nominated by the ACVM Group. This will be the closest AgriQuality site to the applicant unless the applicant requests to sit at a specific site (this site should be noted on the bottom right of the application form).

HSNO concluded

The basic difference is that it is effects-based rather than assuming that 'one size fits all'. As a result, over the long term it will not be business as usual. The HSNO Act is not about telling people exactly how to do everything. Instead, it is about setting standards and expecting people to live up to those standards. Over the longer term this means that controls on hazardous substances will set the objectives to be met but not limit how they are met. This will allow all those who manage hazardous substances to use new and improved methods of compliance without having to wait for law changes or get special permissions from a government official.

If you wish to know more about when and how existing hazardous substances will be transferred to the HSNO framework you should contact ERMA New Zealand or monitor the website (www.hsno.govt.nz).

Agreements with ERMA New Zealand

The ACVM Group and ERMA New Zealand have signed operational agreements covering:

- the parallel processing of applications under the ACVM and HSNO Acts,
- the processing of Vertebrate Pest Control (VPC) operator approvals in the transfer period.

For applicants the VPC process will remain the same as it has been – applications will be made to the ACVM Group and the approval process will be the same as that run by the Pesticides Board in the past. There are some changes to fees (see above). The ACVM Group will be operating under delegated authority for the period until the VPC products are transferred to the HSNO and ACVM Acts.

The agreement on parallel processing of applications under the ACVM Act outlines the intention to work together with ERMA New Zealand staff, and to keep any duplication to an absolute minimum (providing that the application is being dealt with by both organisations at the same time). There is provision for each organisation to advise the other on receipt of applications and to share as much information as possible.

Both agreements form part of an overarching memorandum of understanding between MAF and ERMA New Zealand.

Registration for limited periods for further data collection

A number of applications to use vaccines in farm animals have been made using the 'Application For Approval To Import Animal Remedies Or Pesticides For Special Use' mechanism. The use of an unregistered product in food animals for domestic consumption, or for export, creates a very real problem for the verification of New Zealand's primary produce. This is not an option that can be considered because of the risks it poses to trade in particular, and to the whole philosophy of the need for registration to manage identified risks.

The intent of the 'special use' import approval mechanism is to provide a mechanism for people to import products for the following purposes:

- repacking/relabelling of a licensed/registered product;
- importation under a provisional licence or experimental use permit;
- re-export;
- analysis only;
- other research;
- use in quarantine;
- veterinary discretionary use.

In each of these cases use of product is very limited, risks can be managed adequately by means other than registration, and the treated animals do not enter the food chain. It was never the intention that the mechanism be used as an alternative to registration.

However, there are occasions in which products that have no New Zealand equivalent need to be used on a larger scale than the special use mechanism was designed to manage. It is considered that these products would have to be registered before they could be used to combat a disease problem because registering the product ensures proper product stewardship. Ongoing assessment of the risks associated with the use of the product in food producing animals is also covered.

While registration is possible, there is usually limited data available concerning the specific New Zealand details of the disease to be treated (e.g. farming practices, bacterial strains etc.).

One possible solution is to provide for a registration with strict conditions, including in this instance registration for a limited period of time, and with a limited quantity to enable the collection of data while still limiting the risk to the appropriate level. Registration would be reviewed and the conditions relaxed to reflect the additional data if available.

Alternately, if there are products registered in the interim with more robust and complete data, the registration of the original product would lapse unless the equivalent data were supplied to support the continuation of registration.

Therefore it is proposed that registration can be issued based on the following:

1. The disease being treated must be characterised by *severe* pain or distress using the welfare thresholds, as outlined in the Guidelines For Risk Assessment And Hazard Analysis Under The Agricultural Compounds And Veterinary Medicines Act 1997 section 5.2.
2. No alternative therapy and or/ preventative treatment exists that adequately manages the risks to welfare.
3. The registration will be issued for a specific and restricted period.
4. During the period of registration data for full and permanent registration must be sought.
5. There must be a full data package (minus the New Zealand specific information) available for the product to allow registration.
6. The product will be supplied only to veterinarians as a PAR.

7. Data collected must be supplied to the ACVM Group prior to the review of the registration.
8. The registration will be issued on the condition that if another similar product with more robust and complete data becomes available, then the registration will be reviewed.
9. The licensed remedy could not be advertised or promoted in any way until the data deficiencies were addressed.

Code of practice condition in schedule 1

Schedule 1 of the Agricultural Compounds and Veterinary Medicines Regulations 2001 lists groups of agricultural compounds that are exempt from the requirement to be registered. Even though they do not have to be registered, trade name products that fit the definition of any of these groups must comply with an applicable code of practice, i.e. one that relates to that group of agricultural compounds and that has been approved under section 28 of the Agricultural Compounds and Veterinary Medicines Act 1997.

At this stage there are no codes of practice approved. Consequently, there are no codes that require compliance. In effect, until there is a relevant code, these trade name products do not have to be registered and do not have to comply with any particular condition.

The ACVM Group is aware of development of only one code of practice that would affect any agricultural compounds in schedule 1. If the code is ever approved it may place limitations on fertilisers and fertiliser additives that are raw or composted biological wastes if they are used on agricultural land.

Green light for the New Zealand Food Safety Authority

On Tuesday 15 May, the Government announced its decision to create the New Zealand Food Safety Authority. The Authority will integrate the food regulatory functions of the Ministry of Agriculture and Forestry (MAF) with those of the Ministry of Health. It will be a semi-autonomous body attached to MAF.

At present, the Ministry of Health is responsible for administering regulations covering food sold within New Zealand, while MAF is responsible for primary production and export food. The new Authority will take on both responsibilities.

“We are really pleased to have this opportunity to create a food safety programme that meets the needs of New Zealand consumers and

producers as well as those of our overseas trading partners. At a time of increasing emphasis on food safety everywhere, it has the potential to become a model for the rest of the world,” said Andrew McKenzie, current Group Director of MAF Food Assurance Authority.

“Ensuring the safety of New Zealand food has always been MAF Food’s primary objective, although our focus until now has been on primary production up to the point of retail sale, and on exports. The reputation of New Zealand’s primary produce and exported food is without equal and we are looking forward to using the experience we have gained in some of the world’s most discerning markets for all New Zealand food.”

MAF Food and the Ministry of Health have been working together for some time to integrate their approach to food safety regulation, so we are expecting the transition to the new Authority to be a smooth one. The Authority will bring together an impressive pool of expertise from both MAF and the Ministry of Health.

The Authority will have its own Vote, a new Ministerial portfolio and an advisory board.

A Food Implementation Team has been established to set up the new organisation, which is expected to be launched within the next twelve months. *Food Focus* will keep you in touch with developments over that period.

MRLS and the New Zealand Food Standard

Prospective applicants wishing to register trade name products under the ACVM Act are reminded that active ingredients in trade name products used as agricultural compounds may need an assessment for a maximum residue limit (MRL) to be determined. Once an MRL is determined it must be notified in the *New Zealand Gazette* and entered into the Mandatory Food Standard Table of MRLs prior to the registration of any product containing that ingredient.

MRLs in the New Zealand Food Standard should not to be confused with those gazetted by the Australian and New Zealand Food Authority (ANZFA). The latter apply only in Australia. Applications for an MRL are made to the ACVM Group, Food Assurance Authority of MAF.

The New Zealand Food Standard may be viewed through the Ministry of Health website (see instructions below). Not all active ingredients approved for use in agricultural compounds used in New Zealand are currently entered into the Food Standard Table of MRLs. If you have any queries in this regard contact John Reeve, National Manager, Toxicology and Residues.

www.moh.govt.nz

- go to **Search**, enter **Mandatory Food Standard**
- click **New and Issues-Regulation of Food in New Zealand**
- go to heading **The New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999**
- open **PDF file nzmrlmfs1999.PDF**

Information waiver process

The ACVM Group will be starting the information waiver process **in advance** of product applications in the very near future. Applicants wanting an information waiver will need to apply to the ACVM Group **prior** to lodging an application for registration. Details will be advised on the ACVM website (use the facility provided to request notification when the ACVM part of the website is updated – it can be found at the left bottom of the menu bar) and in future issues of *AgVetLink*.

The information requirements documents have been updated and the forms are on the website.

Policy development on prescription animal remedies (veterinary medicines) status

Under the ACVM Act all products used to manage animals are veterinary medicines. Veterinary medicines that are medicines or drugs will be known as animal remedies to distinguish them from non-medicinal products such as feeds or dietary supplements. If animal remedies are subject to prescription, they will be classified as prescription animal remedies (PAR).

Recent issues involving the control and sale of prescription animal remedies have prompted a review of the criteria and rationale that places products into the 'prescription' category. The existing criteria have been reviewed and the following has been adopted.

An animal remedy will be required to be under prescription if:

- the formulation includes a drug that is a controlled drug within the meaning of the Misuse of Drugs Act 1975, e.g. morphine, pethidine;
- there is the possibility of acute or long-term toxic effects or development of hypersensitivity in humans, e.g. streptomycin, DMSO;
- animal safety or welfare may be threatened, e.g. succinyl choline;
- the remedy could mask disease, e.g. *Brucella ovis* vaccine;
- use demands a veterinary diagnosis and or monitoring of the animal's response, e.g. iodine, copper, corticosteroid, anaesthetics;
- the administration 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 remedy contains a human medicine, or a pro-drug of that human medicine that 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;
- a remedy is to be used under a national scheme to monitor, control

or eradicate disease;

- indiscriminate use of a remedy is a threat to trade, and market access requirements require prescription use and control, e.g. hormonal growth promotants, antibiotics.

Workloads

We wish to advise you that all staff of the ACVM Group are currently 'snowed under' with applications lodged before the implementation of the ACVM Act. There has been an enormous increase on individual workloads, and there may be some time delays in advising you about your applications. We ask that you be patient at this time of legislation change. We are devoting as much time to application work as possible, including evenings and weekends. We do appreciate your cooperation.