

the use of animal remedies on minor species March 2001

Products that are not animal remedies under the Animal Remedies Act (1967)

There are a number of substances such as copper sulphate that are purchased for a range of uses, many of them without any agricultural context. **In order for a product to be considered an animal remedy in terms of the Animal Remedies Act (1967) it must be imported, manufactured, advertised for sale or sold as an animal remedy, not simply used on an animal.** The definition from the Animal Remedies Act is:

“Animal remedy”, or “remedy”, means any drug, medicine, remedy, or therapeutic preparation, or any biochemical substance, which is manufactured, imported, or advertised for sale or is sold for any of the following purposes:

- (a) Curing, diagnosing, treating, controlling, or preventing any disease in animals; or
- [(aa) Testing any animals in relation to any disease; or]
- (b) Destroying or preventing parasites on or in animals; or
- (c) Maintaining or improving the health, condition, [or productivity] of any animal; or]
- [(d) Capturing or immobilising any animal,—] but does not include any preparation, substance, or product which is used primarily as a food for animals”.

MAF and the Animal Remedies Board (‘the Board’) have taken this to mean that farmers can make up preparations for use on their own animals without being in breach of the Animal Remedies Act.

Concerns with regards to residues in food are covered by the residue monitoring programmes that are in place.

Violative residues are in breach of the Meat (Residues) Regulations and the New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.

Therefore, while copper sulphate is an ingredient in a number of licensed animal remedies, copper sulphate is in itself not an animal remedy unless it is imported, manufactured, advertised or sold as one.

Off-label use of licensed animal remedies

The term ‘off-label’ is used widely (in New Zealand and in other countries) to cover the use of a licensed product on

species that do not appear on the label. There are few licensed animal remedies with label claims for deer, goats, emu, etc. as these are ‘minor species’ from an international perspective. The drug companies concerned consider they do not merit the cost of the research and development required to add the species to the label claims.

In most cases farmers of these minor species take expert (veterinary) advice on the product/s that should be used on their animals to prevent or to treat conditions of concern. It is part of veterinarians’ training to ensure that animal welfare and food residue concerns are addressed. Failure to do so would result in legal liability under the Veterinarians Act and under other commercial legislation.

It is important to note that MAF and the Board consider that using a licensed product off-label is vastly different to using an unlicensed product. Any licensed product has gone through the full assessment process required by the Board. **The application for a licence is**

required to show that the product is efficacious regarding the claims that it makes.

There is also information required on the chemistry and manufacturing in order to demonstrate that the product is made consistently and safely, that it is stable and that no risks are introduced during the manufacture.

Data are required on target animal safety (animal welfare), and on toxicology and residues (to demonstrate that the product is safe in terms of public health and the environment as well as ensuring that there are no domestic food standard or trade residue problems).

The Board applies conditions to the licence to manage the risks identified down to a reasonable level and to advise users on safe use.

In the policy development for the Meat (Residues) Regulations MAF considered that the Animal Remedies Act allowed for the off-label use of licensed products. It was not intended that Director-General approval for this practice was required.

Director-General approval was to cover the eventuality of an unlicensed product being used (for example on an experimental animal as is allowed under the Animal Remedies Act) where a specific approval would be required before any produce could safely enter the food chain.

The default maximum residue level (MRL) in the food standard and residue levels in the

Meat (Residue) Regulations ensure food safety and compliance with any importing country requirements if they are applicable.

Situations allowed for in the Animal Remedies Act

The Animal Remedies Act specifically provides for two situations where MAF also considers there is no need for Director-General approval under the Meat (Residues) Regulations.

The first of these is the **exemption of veterinarians**, enabling them to use either human medicines or to compound remedies to treat animals under their direct control.

The second is the **provision enabling products to be exempted from the requirement to be registered following the approval of the Minister.**

In the case of veterinarians, as was stated earlier, it is expected that they have the expertise to ensure that there are no food safety issues in terms of either the Food Regulations or the Meat (Residues) Regulations.

In the case of products exempted by the Minister, they have been demonstrated to be of low regulatory interest in that they are low risk, particularly in terms of the potential for residues.

In both instances these products are exempted from the

requirement to be licensed and are not in the same category as remedies that are required to be licensed but which are not licensed.

Unlicensed animal remedies

The use of unlicensed animal remedies, except as provided for in the Animal Remedies Act 1967, is not allowed. Animals treated with unlicensed animal remedies may not be submitted for slaughter unless approved by the Director-General.

In the consideration of the application to license an animal remedy, data are required to demonstrate that the residues are acceptable (in terms of the Food Act and standards) and that the use of the product does not leave residues. One of the concerns over the use of unlicensed animal remedies in food producing animals is that the food safety aspects of the active ingredient and any excipients in the product have not been assessed.

Changes under the ACVM Act

It is expected that the Agricultural Compounds and Veterinary Medicines Act 1997 will commence later in 2001. Under that Act conditions on the registration of veterinary medicines will be worded to ensure that safe 'off-label' use can continue as it does at present.

Disclaimer:

This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.

A Guide to Animal Remedies and the Animal Status Declaration

Please refer to labels of treatments used on the animals
or ask your veterinarian to help you answer these questions

