

ACVM GROUP OPERATIONAL POLICY

REGISTRATION OF SOMATOTROPINS

1 BACKGROUND

The purpose of this policy is to describe issues that are to be considered when assessing applications to license somatotropins in New Zealand.

Somatotropins, when used as growth hormones, are used to increase production by making a young animal grow larger or by increasing the amount of meat and reducing the amount of fat on the carcass of an older animal. In the case of dairy cows, they are also used to increase the amount of milk produced during lactation.

These products, or artificial products working on the same hormonal pathway, act as hormonal growth promotants, and could pose similar risks to trade as currently licensed hormonal growth promotants.

If these products are to be used purely for growth promotion, with no significant benefits to the animal, there must be little or no adverse effect of the product on the treated animal. If these products are to be used therapeutically, the benefits to the treated animal might outweigh minor adverse effects.

Regulatory control is required to ensure that products are used only in an appropriate manner, as these products have well-recognised potential for misuse.

In formulating the policy regarding the use and licensing of somatotropins, various risk areas impacting on licensing have been considered in accordance with the *ACVM Group Operational Policy on Operational Definitions of Agricultural Compounds and Prescribed Risk Areas*.

These risk areas include the following:

- Risks to trade;
- Risks to animal welfare; and
- Risks to agricultural security.

2 POLICY

2.1 General

Somatotropin trade name products may be registered if:

- there is no Ministerial direction or Ministry of Agriculture and Forestry (MAF) policies excluding registration;
- they do not breach any of the risk thresholds specified in the risk policy, including risks to trade, animal welfare and agricultural security; and
- any hazards posed can be adequately managed by imposing any or all of the following conditions on registration:
 - a) use under prescription of a registered veterinarian according to registration conditions; and
 - b) use subject to a control programme involving identification of treated animals, recording and reconciliation of distribution of product, and verification of the programme.

2.2 Specific somatotropins

Bovine somatotropin (BST) is not allowed in the European Union, a major trading partner with New Zealand. There is no effective mechanism for separating milk from treated and untreated animals in New Zealand, and no analytical method of detection, therefore, BST will not be licensed in New Zealand. Provisional registration (for trial activity) may be given on the condition that the produce from any experimental animals does not enter the food chain. If the EU ban is removed, if methods of detection are improved, or if milk collection methods are altered, the licensing of BST may be reconsidered.

Other somatotropins may be licensed for use in New Zealand if the associated risks can be adequately mitigated through the usual licensing process.

All somatotropins will be classified and treated as hormonal growth promotants even if they are registered for other uses.

Should future Ministerial directions indicate that specific somatotropins are not to be licensed in New Zealand, then those somatotropins specified will not be licensed. Existing licences for those somatotropins will be revoked.

3 REFERENCES

ACVM Group Operational Policy on Operational Definitions of Agricultural Compounds and Prescribed Risk Areas.