

10 July 2008

Policy Group  
New Zealand Food Safety Authority  
PO Box 2835  
Wellington

**Submission on: - Implementation of the ACVM Act: Regulatory changes**

Agcarm welcomes the opportunity to comment on discussion document number 03/08, May 2008, "Implementation of the ACVM Act: Regulatory changes".

Agcarm is an industry association of companies which manufacture, distribute and sell veterinary medicines and agricultural compounds. Member companies are committed to ensuring that these products are used safely, effectively and sustainably. Agcarm represents 30 member companies ranging from global enterprises to small New Zealand owned companies.

This submission follows three separate meetings between NZFSA representatives and Agcarm members: NZFSA and Agcarm's crop protection subcommittee (June 11, nine members present, Auckland); ACVM and Agcarm's animal health subcommittee (June 11, five members present, Auckland), and NZFSA and a range of Agcarm member companies (July 3, 11 members present, Wellington).

We should like to express our appreciation to NZFSA for its presentations and attendance at the meetings. The discussions improved our members' understanding of the proposed changes, and allowed Agcarm to prepare this written submission.

Our comments are set out below, in the order of topics in the document, and result from consultation between Agcarm technical director Jan Quay and Agcarm member companies.

**2. Manufacturing regulations**

Agcarm supports the requirement for manufacturers to have operating plans that cover all aspects of the manufacture of a product, and would expect that Agcarm member manufacturers already have such operating plans in place.

We understand that the proposed changes merely formalise the existing ACVM Standard for Good Manufacturing Practice and the ACVM guideline for labelling and

advertising into regulations. That said there is a shift in the responsibility for some registrants and responsible manufacturers for operating plans

### **2.3.2 Overseas manufacturers**

Under the proposals, ACVM will require that responsible manufacturers must have confidence in their suppliers through a contractual arrangement that is reviewed and kept up to date. In other words, the “responsible manufacturer” should have confidence in the quality (compliance with ACVMG approved specifications) of product or active ingredient sourced from outside New Zealand. This is fair but there is doubt about what is seen as an acceptable level of confidence. Agcarm members believe that NZFSA should provide guidance about the documentation needed within operating plans to satisfy NZFSA expectations.

Agcarm encourages the NZFSA planned ‘slice-of-life’ audits of “responsible manufacturers” to determine that there is an acceptable level of compliance with the proposed regulations.

### **2.3.5 Linking products to manufacturers**

The registrant of a product (“the responsible manufacturer”) and the actual manufacturer of a product can be two different entities. Where this is the case, the identification of the actual manufacturer may be commercially sensitive. Agcarm therefore asks that only the registrant’s details should be listed on any public register. The details of the actual manufacturer should be kept confidential within NZFSA.

## **3. Labelling**

Agcarm supports the proposal that labelling information requirements and labelling specifications are transferred into the manufacturing regulations.

## **4. Advertising and promotion of products**

NZFSA is proposing regulations that will, among other things, allow information to be communicated by third parties about off-label uses, with a prescribed obligation to warn potential users of the uncertainty, potential risks and consequential liability. Agcarm members would like a clear definition of “third parties” in this context.

### **4.3.1 Warning information.**

The discussion document does not make clear what warning information will be required in advertisements and promotional material. Agcarm would like more clarity on what warnings are required. Its members believe that any mandatory warnings should be succinct, specified as a registration condition, and be easily applied over all forms of advertising and promotion.

Registered products have labels and safety data sheets which provide product information. These should provide adequate consumer information.

Defining ‘adequate’ would be useful for managing those products which currently do not require registration.

#### **4.3.2 Obligation to represent the product as authorised**

Agcarm supports this proposal and would point out that it is already active in this area. An obligation to represent a product as authorised is supported by the industry initiated code for the promotion of agricultural compounds and veterinary medicines – FairAd (section 1.3). The FairAd Code states the basic principles and sets standards of behaviour (conduct) for the promotion of agricultural compounds and veterinary medicines) by members of FairAd.

#### **4.3.3 Information transfer versus advertising/promotion**

The boundaries between information transfer and advertising are blurred in many instances, and can depend on who is the audience. Information transfer is an important vehicle in advising professionals like veterinarians and producer groups about the availability and safe use of products. Information transfer can be a means to signal the development of new products overseas not yet registered in New Zealand.

Any regulations need clarity on what is and what is not information transfer versus promotion.

#### **4.3.4 Obligations on parties with no vested interest in the products**

We would expect an obligation on parties with no vested interest in products to have similar obligations as registrants, and therefore should be required to meet similar codes of behaviour and liability when imparting information. Agcarm expects that the NZFSA will ensure that there are clear guidelines to ensure parties are aware of their responsibilities.

#### **4.3.5 Communication about off-label uses**

Agcarm corporate company members do not, as a matter of policy, advise any off-label uses for their products. Communication about off-label uses by third parties containing information about a use that is not specifically approved in a product's registration raises liability issues for our members. That said, we acknowledge that promotion and information exchange about off-label use is a grey area. In reality, people ("third parties") do talk about products which could be suitable for off-label uses.

Agcarm believe that the NZFSA needs to provide guidance on where the boundaries are regarding these communications to ensure that registrants are not disadvantaged if there are any adverse events involving off-label use of their product, as a result of a communication by third party.

This may involve writing clear guidelines on what is acceptable "information transfer", and what is unacceptable "promotion" of products for off-label uses. We believe this could be distilled down to several key bullet point principles.

#### **5. Own use/off-label regulations**

Similarly, any regulations on own use/off-label uses of registered product must clearly reflect the responsibilities on the user in the event of any adverse outcome.

When considering conditions for registration we believe that NZFSA should be mindful of the restrictions of use placed on some product registrations under the HSNO Act, which would prohibit any off label use.

Thank you for the opportunity to comment on the discussion document and we look forward to receiving the draft regulations when they become available.

We also look forward to reading the summary of submissions.

Yours sincerely,

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