

9 June 2008

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Dear Sir or Madam

Progress on implementing the NZFSA's Animal Feeds Review and 'ACVM Act: regulatory changes under the ACVM Act' discussion paper

The purpose of this letter is to:

- update you on progress with implementation of the outcome of the NZFSA's Animal Feeds Review that has occurred since my letter dated 30 October 2007; and
- advise you of related work NZFSA is undertaking under the Agricultural Compounds and Veterinary Medicines Act, namely the recently released discussion paper titled "Implementation of the ACVM Act: Regulatory changes, No 03/08, May 2008".

Progress on implementing the outcome of NZFSA's Animal Feeds Review

Background

As outlined in my letter dated 30 October 2007 the Government has agreed to a number of changes to the way certain secondary processors of pet food are regulated. Pet food means any material prepared and traded as food for cats or dogs, and includes any such product intended for cats or dogs but fed to other pets or captive animals.

The decision to change the requirement was made following a public consultation process undertaken by the New Zealand Food Safety Authority (NZFSA) between August and October 2006. Information relating to NZFSA's review of regulation of animal feed, including pet food is available on the NZFSA web site at <http://www.nzfsa.govt.nz/policy-law/consultation/animal-feeds/index.htm>, where you will find the discussion document and associated information paper.

The outcome of this review was that, in general, secondary processors of pet food that is raw meat or other animal material or animal product that results from the death of the source animal (e.g. red meat, offal, poultry or fish), that are:

- regulated under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act 1997); and
- currently exempted from additional control mechanisms under the Animal Products Act 1999 (Animal Products Act)

no longer be exempt from additional control mechanisms of the Animal Products Act. This exemption would be replaced by specifications, issued by NZFSA, which would require processors to maintain prescribed documentation to demonstrate that animal material has been procured from regulated sources and to list annually with NZFSA.

The only group of the above secondary processors that are not affected by this change, and hence will continue to be regulated under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act 1997), are those processors that handle:

- raw meat or animal material or animal product that has been rendered; or
- raw meat or animal material or animal product that:
 - is acquired in a ready-for sale state; and
 - been subject to primary processing in accordance with a registered risk management programme by an earlier processor.

These changes do not affect secondary processors who are required to have a risk management programme.

Are you affected by these changes?

My previous letter provided information on both who would be affected by these changes and who wouldn't be affected. Since that time the affected secondary processors of pet food have been defined in the Animal Products (Exemptions and Inclusions) Order 2000, by an amendment issued on 10 March 2008. **The Order requires operators who are secondary processing pet food that is raw meat or other animal material or animal product that results from the death of the source animal comply with any applicable requirements of Parts 2 to 4 of the Act.** It should be noted that the Animal Products Act definition of process is "includes kill, slaughter, dress, cut, extract, manufacture, pack, preserve, transport, and store", which is comparatively broad.

Examples of secondary pet food processors that are affected by the new requirements are operators who:

- manufacture dog rolls;
- manufacture baked biscuits using any animal product other than rendered product;
- operators who receive bulk raw products that are not in retail ready packaging and then package it for retail sale. This may include slicing and/or dicing the product prior to packaging.

Requirements on operators affected by the Animal Feeds Review

The two significant requirements that will apply to affected pet food operators relate to:

- demonstrating that animal material has been procured from regulated sources; and
- listing annually with NZFSA, for which there will be a cost imposed on operators.

NZFSA is currently consulting on these requirements. Refer to page 13 of the 'Proposed amendment to the Animal Products (Specifications for Products Intended for Animal Consumption) Notice 2006'.

A copy of the proposed amendment has been enclosed for your information. Submissions on this proposal close on **20 June 2008**. If you wish to make a submission refer to the document for the NZFSA contact details.

To be able to demonstrate that animal material has been procured from regulated sources the operator must be able to trace this animal material through to animal products that have been produced.

Operators will also be subject to verification to ensure they are complying with the requirements. The verification frequency is still to be confirmed. NZFSA is still currently establishing the appropriate verification regime. Consideration is being given to verification frequencies ranging from 6 monthly to once every 5 years depending on the complexity and size of the operation, and hence potential impact. Industry will be consulted on this shortly. Operators will be charged for these verification visits, with a charge in the vicinity for \$300 plus verifier travel costs.

If you have any queries regarding the implementing the NZFSA's Animal Feeds Review including the proposed amendment to the Animal Products (Specifications for Products Intended for Animal Consumption) Notice 2006 please contact:

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Implementation of the ACVM Act: Regulatory changes, NZFSA Public Discussion Paper no 03/08, May 2008

ACVM Act background

The Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act) controls how these products are used in association with animals and plants. The ACVM Act's purpose is to:

- prevent or manage risks to public health, trade in primary produce, animal welfare, and agricultural security associated with the use of agricultural compounds;
- ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards; and
- ensure the provision of sufficient consumer information about agricultural compounds.

Existing requirements on pet food under the ACVM Act

Under the ACVM Act **pet food for cats and dogs** is considered to be an “**oral nutritional compound**” (**ONC**), which is defined under the ACVM Act regime as meaning a substance ingested by an animal as feed, or a nutritional preparation intended for oral administration to an animal to achieve a nutritional benefit. A very broad range of products fall into the ONC category including feeds for sheep and cattle such as grass and silage through to pet foods for cats and dogs.

Certain ONC products are required to be registered. The reasons for registration being required include that the product is medicated or makes therapeutic or pharmacological claims other than general health claims. An example would be the inclusion of glucosamine into a pet food at a level higher than expected to be present in the natural diet and making therapeutic or pharmacological claims relating to glucosamine on the label.

Under the ACVM Act regime ONCs that are not required to be registered may be manufactured and sold if the conditions in Schedule 4 of the ACVM Regulations 2001 are complied with (a copy of this schedule has been enclosed for your information). **A large number of pet foods would fall into this category.** This schedule includes requirements relating to:

- label information, including (but not limited to):
 - trade name;
 - ingredients;
 - the name and address of the producer or manufacturer;
 - directions for use, including the species, type, and class of animal intended to be used for;
 - manufacturing date, if applicable.
- the product being fit for the purpose of feeding to the species, type, and class of animal.

If you are processing a product that is an ONC that does not require registration you are already required to comply with Schedule 4. There is no intention to remove this requirement.

Operators producing pet food for cats and dogs under a registered risk management programme under the Animal Products Act also need to comply with the requirements in Schedule 4 if the product is an ONC that does not require registration.

Background to the discussion paper

NZFSA has begun a reform of the administration of the ACVM Act. One of the main reasons for this is that some items need to be updated to reflect changes that were made to the ACVM Act in 2007. The reform is also an opportunity to reconsider the way that the ACVM Act is implemented and to seek feedback from stakeholders. The discussion paper is the first in a series that will be released for public consultation as part of the reform process. **A copy of the discussion paper has been enclosed for your information.**

Purpose of the discussion paper and proposed changes

The document focuses on the areas of manufacturing, labelling, advertising and promotion, and own use and covers the broad classes of agricultural compounds:

- veterinary medicines;
- agricultural chemicals;
- oral nutritional compounds;
- fertilisers; and
- vertebrate toxic agents.

Most of the proposed changes relate to putting existing obligations that are currently to be found in a number of places into regulations under the ACVM Act. NZFSA is also revising its standards and information requirements at the same time.

Section 2.2.1 of the discussion paper outlines the current regulatory control of manufacture of oral nutritional compounds, including animal feeds. This notes that:

- manufacturers aren't approved by NZFSA and are not subject to a formal compliance programme;
- Suspicions and allegations of non-compliance are investigated, and manufacturers are expected to be able to provide evidence that they have taken due care to comply with the ACVM Regulations;
- NZFSA does not have a register of who is manufacturing oral nutritional compounds.

The recurrence of cases of contaminated, mislabelled and fraudulent product has convinced NZFSA that the regulation of the manufacture of agricultural compound products should be more rigorous. Section 2.3 of the discussion paper outlines the proposed changes to the regulatory regime to address these concerns. The proposals include that the:

- manufacturing process must be:
 - clearly defined and shown to be capable of consistently producing product that meets product specifications and is fit for purpose;
 - described in an operating plan that specifies procedures and instructions;
- premises and equipment must be suitable for the manufacturing process undertaken;
- personnel involved in the manufacturing process must be appropriately qualified and trained.

Section 2.3.1 of the discussion paper discusses the status of manufacturers. It states that NZFSA is considering whether manufacturers of all other classes of agricultural compounds (agricultural chemicals, oral nutritional compounds, fertilisers and the remaining vertebrate toxic agents) should be listed with NZFSA. If so, name and contact details should be sufficient in most cases. Such a list, which would not be published on the NZFSA website, could be used to facilitate investigations of non-compliance or product recall.

NZFSA is **not** proposing to recognise manufacturers of ONCs, or to require operating plans to be approved. The existing occasional compliance checking programmes ("slice of life" reviews) to check whether a sector is performing as expected would continue to be undertaken by NZFSA.

What happens next under the ACVM Act?

Submissions on the discussion paper close on **11 July 2008**. If you wish to make a submission refer to the document for the NZFSA contact details.

Once submissions close NZFSA will consider feedback received on the discussion paper. The outcome will provide the basis for making regulations under the ACVM Act.

Information on the overall reform process will be placed on the NZFSA website at <http://www.nzfsa.govt.nz/acvm/subject/acvm-act>.

If you have any queries that you would like clarified after reading the discussion paper to please contact:

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Yours faithfully

[Signed]

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