



Animal feed

Consultation Process

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Overview

The New Zealand Food Safety Authority (NZFSA) has reviewed the regulation of animal feed for the domestic market, including petfoods, by the *Animal Products Act 1999* (APA) and the *Agricultural Compounds and Veterinary Medicines Act 1997* (ACVM Act). The review found that existing arrangements are adequate for management of risks associated with animal feed containing:

- only plant material
- products from live animals (for example dairy products, eggs and honey)
- primary processed animal material
- rendered animal material
- products containing animal material for export.

No change in regulation is proposed for animal feed that contain these materials or products.

The review found that certain manufacturing operations involving domestically processed animal feed containing animal material pose a high risk to domestic animal health, and a high *indirect* risk to New Zealand's export trade. These risks relate to certain manufacturing operations involving the *secondary processing* of animal feed containing animal material, and in particular, to the procurement of source material for secondary processing from unregulated sources.¹

In order to protect domestic animal health and to maintain confidence in New Zealand's reputation as a trusted supplier of animal feed, specific new proposals to change the regulation of certain manufacturers of animal feed are necessary. These proposals would *only* affect secondary processors exempt from the requirement to maintain a Risk Management Programme under the APA, and relate to animal feed made from animal material resulting from the death of the source animal (for example meat, offal, poultry and fish material) manufactured in New Zealand. These proposals would not apply to retailers

¹ 'Manufacturing' as used in this paper includes the preparation, production or processing of material to make animal feed. This can include primary processing and secondary processing operations. Primary processing involves the killing, slaughter and dressing of the animal. Secondary processing includes subsequent processing. Technical terms used in this paper are explained in the glossary.

that are mainly in the business of selling food for human consumption² that make food fit or originally fit for human consumption available as petfood. The changes proposed are:

Proposal 1: a requirement for manufacturers secondary processing animal feed containing animal material resulting from the death of the source animal (meat, offal, poultry and fish material), to list with NZFSA, by supplying, for example, business name, business address and type of animal feed manufactured. The reasons for this proposal are to maintain confidence in, and safeguard New Zealand's reputation and position as a trusted supplier of animal feed and to protect domestic animal health. A secondary processor not listed would be operating illegally. The listing requirement would not apply where NZFSA otherwise collects the information. This proposal would be implemented by amendment of the regulations under the ACVM Act.

Proposal 2: a requirement for secondary processors of petfood (feed intended for consumption by cats or dogs, or for animals fed cat or dog food) containing animal material resulting from the death of the source animal (for example, meat, offal, poultry and fish material), to procure material from a regulated source³ and to maintain a documented system that complies with minimum prescribed requirements.⁴ These relate to source of process inputs, suitability to meet fitness for purpose, sufficient labelling to enable traceback of the product to secondary processor, and inventory control to identify substitution and security during transportation. The reason for this proposal is to maintain confidence in New Zealand's regulatory programme for animal feed being certified for export, to manage risks to domestic animal health and welfare, and to provide for investigation of adverse events. This proposal would be implemented by creating new Standards, a Regulated Control Scheme, a modified Risk Management Programme under the APA, or Regulations under the ACVM Act.

Proposal 1 is likely to affect around 150 secondary processors of animal feed and Proposal 2 around 70 secondary processors of petfood. The cost of administering Proposal 1 is expected to be around \$100 per year for each secondary processor affected. Registration costs (including administration, compliance audit and verification) of Proposal 2 are estimated at \$250 per year for each secondary processor affected.

It is proposed 25% of the costs of both proposals are recovered from affected secondary processors (the risk makers) and 75% from the exporters of animal feed containing animal

² Subject to the Food Hygiene Regulations 1974 or a Food Safety Programme provided for by the Food Act 1981.

³ A regulated source includes from a primary processor operating under a Risk Management Programme or procurement from a retail outlet subject to the provisions of the Food Act 1981.

⁴ This proposal would not apply to secondary processors subject to a Risk Management Programme, such as those rendering animal material for petfood, and exporters of petfood.

material (the principal beneficiaries). This would result in a charge to secondary processors of animal feed affected by Proposal 1 of around \$25 per year, and a charge to secondary processors of petfood affected by Proposal 2 of around \$63 per year. The estimated costs to the export animal feed industry would be around \$24,500 per year, less than 0.03% of the value of animal feed exports.

NZFSA is reviewing controls on imports of animal feed as part of its Imported Food Review. This may result in future proposals to ensure they continue to meet the New Zealand standard.

Glossary

Animal feed: edible material that provides nourishment to an animal, in the form of energy and for building tissues; and which contributes to the normal physiological function and metabolic homeostasis of an organism, by the oral provision of nutrients to any kind or class of animal (that is, all members of the animal kingdom except humans).

Animal material: any live or dead animal, or any tissue or other material taken or derived from an animal.

Dairy material: milk extracted from a milking animal and any material derived or processed from milk.

Domestic consumption: feed consumed by animals in New Zealand.

Hazard: microbiological, chemical or physical agents in, or potentially in, animal feed capable of causing adverse human and/or animal health, and/or effects on trade.

Ingredient: any substance, including a feed additive, added to animal feed during processing.

Manufacture: preparation, production or processing of material to make animal feed. This includes primary and secondary processing.

Petfood: feed intended for consumption by cats or dogs or for animals fed cat or dog feed.

Primary processing: the killing, slaughter and dressing of an animal.

Processing: the killing, slaughter, dressing, manufacture, preserving, packing, transportation and storage of material for animal feed.

Regulated source: material from a dead animal that is made available to secondary processors from primary processors that have a Risk Management Programme or sourced from a retail outlet subject to the Food Act 1981.

Rendering: the breaking down of animal tissues into constituent fat and protein elements, by applying heat and pressure or otherwise.

Risk: as used in this paper, the probability of adverse events occurring and the severity of the impact of such events if they do occur. The *risk profile* of an animal feed is an estimation of the probability of an adverse event occurring multiplied by the severity of potential impact. To determine risk it is necessary to first identify hazards.

Secondary processing: includes the processing of material for animal feed after primary processing (including packing, preserving, transport and storage).

1 Introduction

NZFSA is required, among other things, to administer all food related legislation in New Zealand and is responsible for ensuring food safety and suitability for consumption, including animal feed. NZFSA's review of the regulation of animal feed has been prompted by concern that certain practices within parts of the animal feed industry may not now be adequately managed.

1.1 Current regulatory framework

Risks associated with the sourcing, processing, and distribution of animal feed are currently managed under the *Agricultural Compounds and Veterinary Medicines Act 1997* (ACVM Act), the *Animal Products Act 1999* (APA) and the *Biosecurity Act 1993*.

The ACVM Act regulates agricultural compounds including substances or microbiological compounds constituting 'feed' for animals. The ACVM Act also regulates imports of all feed (feed of plant origin, animal origin and chemical additives). Animal feed is currently controlled by conditions set by regulations under the Act. These conditions relate to:

- labelling
- animal feed being fit for purpose and not resulting in certain effects
- the incorporation of therapeutic or pharmacological substances and feed additives.

The APA regulates animal feed derived wholly or partly from animal material processed in New Zealand. The APA focuses on primary processing, but also covers secondary processing, and export. An interface between the APA and ACVM Act was established in 2000, allowing secondary processors of animal products for animal consumption to be regulated under the ACVM Act. This does not apply to rendering or blood drying operations or where official assurances for exports are required. In 2005, the APA was amended to include dairy processors which were previously excluded from the scope of the APA.

Primary processing includes the killing, slaughter and dressing of the animal. **Secondary processing** includes the processing of animal material beyond primary processing.

The *Biosecurity Act 1993* regulates the exclusion, eradication and management of pests and unwanted organisms. The *Biosecurity (Ruminant Protein) Regulations 1999*, among other things, prohibits the feeding of ruminant protein to ruminants, and requires operators to be subject to ruminant protein control programmes. The *Biosecurity (Meat and Food Waste for Pigs) Regulations 2005* regulates the feeding to pigs of meat and food waste that is, or contains meat. Both sets of regulations were made under the Biosecurity Act. NZFSA's

review is concerned with the ACVM Act and the APA both of which are administered by NZFSA. The Biosecurity Act is administered by Biosecurity New Zealand.

1.2 NZFSA's review of animal feed

The purpose of the review was to:

- consider the risks associated with the production, sourcing, processing, distribution and use of animal feed in New Zealand
- determine whether those risks are adequately managed under the ACVM Act and APA
- propose options for improved management of identified risks.

The review covered all animal feed produced for the domestic market. It was prompted by concern that certain practices within parts of the animal feed industry may not be adequately managed.

The variety of products affected by the review is extensive, including feed commodities and compounded feeds for both food-producing animals (animals intended for the food supply) and non-food producing animals (such as pets). Feed products may be fresh, frozen, dried, unprocessed, processed, unpackaged, packaged, or canned.

NZFSA has published a background information paper on its review of animal feed, *Review of Animal Feed*. This is available on NZFSA's website and in hard copy, on request.

1.3 Purpose of this discussion paper

The purpose of this discussion paper is to:

- set out proposals for the management of feed that differs from current arrangements and that address risks identified by the review
- invite comment on all aspects of those proposals.

2 What are the risks?

NZFSA has grouped animal feed according to risk and type of animal feed. The approach taken was to identify risks that are not adequately managed with current controls. This included an examination of sourcing, manufacture, and use of animal feed. Direct and indirect risks to human health, animal health and welfare, agricultural security (including biosecurity), and New Zealand's export trade were identified and considered. These are outlined in **Appendix 1**.

For the purposes of the review, risk was assessed in terms of probability of an adverse event occurring multiplied by the potential magnitude of impact. Risks were then categorised as high, medium or low (according to the estimated probability of an adverse event occurring and the magnitude of impact, should an adverse event occur).⁵

Previous experience and information available to NZFSA indicates that *with current risk management controls*, risks involved with the production of animal feed are low and existing arrangements are adequate, with one exception. This exception relates to secondary processing operations involving animal feed containing animal material resulting from the death of the source animal. This animal feed group includes meat, offal, poultry and fish material. NZFSA considers:

- risks to domestic animal health and welfare and indirect risks to New Zealand's export trade associated with procurement of source material for secondary processing are *high*
- where secondary processors are subject to the Risk Management Programme regime under the APA, risks are adequately managed
- additional controls are required to manage risks associated with the procurement of source material for secondary processing operations.

Table 2.1 sets out the risks associated with various animal feed types with existing controls.

⁵ Further details of NZFSA's approach to risk and determination of risk associated with animal feed is provided by the information paper *Review of Animal feed*, available on NZFSA's website and in hard copy on request.

Table 2.1 Risks⁶ associated with ingredients in animal feed with existing controls

Animal Feed Product	Risk
Only plant material	low
Only products from live animals (e.g. dairy products, honey, eggs)	low
Products containing some animal material, for export, subject to an Risk Management Programme	low
Rendered products	low
Primary processed animal products subject to a Risk Management Programme	low
Secondary processed animal products resulting in the death of the source animal, not subject to a Risk Management Programme, other than petfood	medium
Secondary processed animal products resulting in the death of the source animal, not subject to a Risk Management Programme, for petfood	high

⁶ Risks to domestic animal health and welfare and indirect risks to New Zealand's export trade in animal feed.

3 NZFSA's proposals to manage these risks

NZFSA's review of animal feed indicates that risks involved in the majority of animal feed operations are currently adequate and appropriately managed under the ACVM Act and the APA. However, the review identified high indirect risks to New Zealand's export trade and high direct risks to domestic animal health from *certain* secondary processing operations, given current regulatory controls. It is NZFSA's view that risks identified as high or medium require further management, and that the degree and cost of controls applied, will be proportionate to the risk.

3.1 What additional regulation is proposed?

Proposal 1: a requirement for secondary processors of animal feed containing animal material resulting from the death of the source animal to list with NZFSA by supplying, for example, their business name, business address and type of animal feed manufactured.

It is proposed:

- that the manufacturer be required to confirm this information on an annual basis, and notify NZFSA of changes to this information
- the requirement would be implemented through regulation under the ACVM Act
- a secondary processor not listed would be operating illegally
- the requirement would not apply to secondary processors who maintain a Risk Management Programme under the APA, or where NZFSA otherwise collects this information from secondary processors (for example where Proposal 2 applies to a secondary processor).

Why is this proposal necessary?

The key reason why NZFSA considers additional regulation is necessary is to maintain confidence in and safeguard New Zealand's reputation and position as a trusted supplier of animal feed. NZFSA considers *direct* risks to New Zealand's export trade through the export of animal feed are adequately managed by current arrangements. However, NZFSA is of the view that a serious problem involving feeds for the domestic market could show deficiencies in domestic controls.

NZFSA has a record of all primary processors and secondary processors subject to the RMP regime, but does not have this information for all secondary processors exempt from the RMP regime. Should there be an adverse occurrence involving these animal feed products, the inability of NZFSA to know the number and location of these animal feed processing operations could undermine confidence in New Zealand's arrangements for risk management, and New Zealand's reputation as a trusted supplier of feed.

NZFSA believes that the negative indirect impact to New Zealand's export trade would be significantly greater than the additional costs of these proposals. The proposal would also aid the management of the high risk to domestic animal health and welfare from these animal feed operations.

Regulatory impacts

Proposal 1 would affect an estimated 150 manufacturers of animal feed that contain animal products and involve a direct cost of listing under the ACVM Act.

- There would be an *indirect cost* to secondary processors of around half an hour to understand the requirements and provide business name, business address and type of feed manufactured.
- It is proposed that this information would be provided electronically, on-line (with an alternative hard copy 'listing' form available).
- The cost to NZFSA of administering this listing would be around \$100 per listing per year. NZFSA is required to recover these costs from the risk makers, and the beneficiaries of government intervention. The risk makers are the domestic secondary processors. The beneficiaries are primarily exporters of animal feed containing animal material. Comment is invited on the apportionment of costs between secondary processors who would be required to be listed, and exporters of animal feed containing animal material. It is proposed that 75% of the cost is recovered from these exporters of animal feed. This would mean that listing would cost around \$25 per listing per year to animal feed manufacturers required to list.
- There would be a net benefit in the minimisation of risks to New Zealand's export trade. There would also be a secondary benefit in the minimisation of risks to domestic animal health and welfare.

Proposal 2: a requirement for secondary processors of petfood (feed intended for consumption by cats or dogs or for animals fed cat or dog food) resulting from the death of the source animal (for example, meat, offal, poultry and fish material) to procure material from a regulated source and maintain a documented system that complies with minimum prescribed requirements.

It is proposed:

- the requirement would apply to secondary processors of petfood, that is cat or dog food, and also apply to feed for animals fed cat or dog food
- the requirement would not apply to retailers selling food for human consumption subject to the Food Hygiene Regulations or a Food Safety Programme under the Food Act, who secondary process animal material to be made available for sale as petfood, provided the source material for processing:
 - is fit for human consumption and is voluntarily made available for sale as petfood and/or
 - was originally fit for human consumption when it entered the premises of the retailer, but is no longer fit for human consumption, and is nevertheless fit for animal consumption
- procurement of source material must be from a primary processor subject to a Risk Management Programme or a retail outlet subject to the Food Act regime
- the documented system demonstrate:
 - the source of process inputs
 - their suitability to meet fitness for intended purpose
 - sufficient labelling to enable traceback of the product to the manufacturer
 - inventory control to identify substitution and security during transportation
- NZFSA would prescribe the type and format of the documented system and provide guidance, in order to help manufacturers meet the requirements of this proposal, and minimise compliance costs
- manufacturers would need to register their documented system with NZFSA and in so doing would satisfy the listing requirement contained in Proposal 1

- prior approval of the documented system would *not* be required before a manufacturer commenced operations. Provided the manufacturer met the requirements, minimal independent verification of the documented system would be required, once every three to five years. To minimise compliance costs, it is proposed that NZFSA arrange verification for manufacturers and include this cost in an annual registration charge
- should investigations or audits identify that the manufacturer's documented system was not complying with requirements, NZFSA could require the manufacturer to supply documentation to substantiate future compliance. This would be for monitoring purposes by NZFSA. NZFSA could also require increased frequency of independent verification, to ensure the documented system continued to meet requirements.

Retailers of petfood

It is intended that retailers whose main business is selling products for animals (for example, petfood shops) who secondary process animal material resulting from the death of the source animal (for example, raw meat, offal, poultry and fish material) will be subject to the proposals.

It is common practice for retail outlets whose main business is selling food for human consumption and who are subject to the Food Hygiene Regulations or a Food Safety Programme under the Food Act, to repackage, dice or slice animal material fit for human consumption (for example, surplus stock) and to voluntarily make this available as petfood. Material originally fit for human consumption but no longer fit (for example, because it has fallen on the floor of the premises), is also commonly made available for petfood. NZFSA considers risks involved in such activities are adequately controlled by current arrangements.

NZFSA is not aware of retailers whose premises are subject to the Food Hygiene Regulations or a Food Safety Programme under the Food Act, procuring material unfit for human consumption and importing it onto the premises for processing as petfood. To do so would likely contravene the Food Hygiene Regulations (Regulation 10(2)(b)), in that such activity would pose a risk to human health. NZFSA intends to make it a condition of registration of a Food Safety Programme that any material processed for petfood must originally be fit for human consumption. All retailers secondary processing material that is sold as petfood will continue to be subject to the conditions set by regulation under the ACVM Act relating to fitness for purpose, contents and labelling.

Why is this proposal necessary?

This proposal is necessary to maintain confidence in New Zealand's regulatory programme for animal feed certified for export, to manage risks to domestic animal health and welfare, and to allow for investigation of adverse events. This proposal would enable NZFSA to track products posing high potential risk back to origin, and for appropriate documented control

systems in place to enable effective audit. The proposal would also aid the management of an identified high risk to domestic animal health.

From information available to NZFSA, the potential for substitution of unfit for fit animal material is primarily confined to the production of petfood. This is because of its high animal material composition and potential for large gains to be made by substitution unfit for fit material into such feed. Currently manufacturers secondary processing animal feed containing animal material are not required to maintain a documented system unless they are undertaking rendering operations or exporting the product.

It is intended that the requirements apply to petfood whether it is intended to be fed to pets (cats and dogs) or fed to other animals. This is because it is not possible to be certain at the point of manufacture, whether the petfood the manufacturer claimed was for other animals, would not be fed to cats and dogs.

Implementation options

There are a number of options for implementation of this proposal on which comment is invited. This proposal may be implemented by way of:

- *Standards* under the APA
- *Regulations* under the ACVM Act
- a *Regulated Control Scheme* under the APA
- a *modified Risk Management Programme* regime under the APA.

Comments are invited on these legislative tools. **Appendix 2** contains an assessment of these options.

Regulatory impacts

Proposal 2 would affect an estimated 70 secondary processors petfood. Whichever implementation option was chosen the requirements on secondary processors would be similar. The front-end costs of developing the requirements and implementation by government would differ depending on the option chosen. These would be Crown funded.

For secondary processors, there would be an indirect cost of around one hour to understand the requirements. It is proposed that there would be an annual registration charge to cover administrative, compliance audit and verification costs (which NZFSA would arrange on a three to five year frequency).

NZFSA would need to recover these costs from the risk makers and beneficiaries of government intervention. The risk makers are domestic secondary processors. The

beneficiaries are primarily exporters of animal feed. Based on an estimated 70 manufacturers affected by this proposal, the cost of registration would be around \$250 per year per registration. Comment is invited on the apportionment of costs between secondary processors producing for the domestic market and exporters of animal feed. NZFSA proposes 75% costs of registration be recovered from the exporters of animal feed containing animal feed, as they are the principal beneficiaries of this proposal. This would result in a registration cost to manufacturers concerned of around \$63 per registration per year.

Affected businesses would be required to register the documented system with NZFSA. This registration would satisfy the listing requirements contained in Proposal 1. Affected businesses would need to make arrangements for developing and maintaining a documented system. This requirement would impose a marginal direct cost on affected businesses. Businesses are already required to keep records of purchases and sales for Inland Revenue Department audit. The ACVM Act (by which these manufacturers are currently regulated), places obligations on manufacturers in respect of labelling. NZFSA considers the additional requirements for documentation relating to source inputs, suitability to meet fitness for purpose, any additional labelling to enable traceback and inventory control to identify substitution and security during transportation, would involve an indirect cost of around half-an-hour per week to compile and maintain required records.

It is proposed to apply a requirement for independent verification at a three to five year frequency for secondary processors, unless non-compliance is identified, and that the costs of verification be included in an annual registration charge. This will reduce the cost to affected manufacturers (in the time taken to arrange the verification visit).

There would be a strong incentive for manufacturers to comply with the requirements, since those found to be non-compliant would face additional costs of compliance monitoring and increased verification. Increased verification necessary because of non-compliance would be additional to the registration charge. This is because it would be unfair for affected manufacturers compliant with the requirements and the export animal feed industry to share costs of non-compliance. In addition, the costs to NZFSA of administration associated with compliance monitoring would be recovered from non-compliant manufacturers, at \$80 per hour.

The net benefit of this proposal would be the minimisation of risks to New Zealand's export trade. There would also be a secondary benefit in the minimisation of risks to domestic animal health and welfare.

Overall cost of both proposals

Based on an estimated 220 manufacturers involved in secondary processing operations likely to be affected by the proposals, the total annual costs that NZFSA would seek to

recover from industry (apportioned between the risk makers and principal beneficiaries) would be around \$32,500 including verification, as follows:

- Proposal 1: 150X\$100. Total cost: \$15,000
- Proposal 2: 70X\$250. Total cost: \$17,500.

NZFSA considers these costs modest given the risks to the export animal feed industry. An apportionment of 75% of recovered costs (around \$24,400) to the export animal feed industry would represent less than 0.03% of animal feed exports, valued at over \$84 million in 2005.⁷

Appendix 2 provides an assessment of the costs and benefits of the proposals compared with a 'do nothing' (status quo) option against the following criteria:

- management of risks in the risk areas of animal health and welfare and New Zealand's export trade (risk areas where high unmanaged risks were identified in the review)
- achieving regulatory intervention that is equitable and at the lowest cost to business, government and society
- the feasibility of development and implementation of the option.

3.2 Transitional arrangements

It is proposed that manufacturers affected would be given three months from the date of the proposals taking effect to comply with requirements. NZFSA would provide detailed guidance on the additional requirements.

⁷ Source: Statistics New Zealand.

4 Submission process

4.1 Closing date for submissions

The closing date for submissions is **Friday 20 October 2006**.

Please submit your response by **5pm Friday 20 October, 2006** to:

John Parker
Policy Group
New Zealand Food Safety Authority
PO Box 2835
WELLINGTON

Alternatively, responses can be faxed to (04) 463 2583 or emailed to john.parker@nzfsa.govt.nz.

4.2 Guidance for submitters

Comments from all those with an interest in any aspect of the proposals presented in this document are invited. Clear and concise comments will assist in ensuring that the significance of your comments is understood.

The following points may be of assistance in preparing comments:

- some questions are included below to assist you in providing comment on this paper
- wherever possible, comments should be specific to a particular section of the document
- comments should be to the point and, where possible, give reasons and data in support
- the use of examples to illustrate particular points is encouraged
- a number of copies may be made of your comments so please ensure that your comments are clear, preferably made in black ink or typewritten.

4.3 Questions that might help

Aspect of the review	Question
Risk identification	Do you have any comment on NZFSA's identification of risks outlined in Appendix 1 of this paper?
	Do you have any comment on those activities assessed as low risk and for which no changes are proposed?
Proposal 1	Do you have any comment on the proposal to require secondary processors of animal feed resulting from the death of the source animal (for example, meat, offal, poultry and fish material) to list with NZFSA, by supplying, for example, business name, business address and type of animal feed manufactured?
	Do you have any comment on the reasons given for the proposal: to maintain confidence in and safeguard New Zealand's reputation and position as a trusted supplier of animal feed, and aid the management of the high risk to domestic animal health from these feeds?
	Do you have any comment on the proposal that this requirement be implemented through a 'listing' under the ACVM Act?
Proposal 2	Do you have any comment on the proposal to require secondary processors of petfood resulting from the death of an animal (for example, meat, offal, poultry and fish material) to procure from a regulated source, and maintain a documented system that complies with minimum prescribed requirements?
	Do you have any comment on the reasons given for the proposal: to maintain confidence in New Zealand's regulatory programme for animal feed certified for export, to manage risks to domestic animal health and welfare, and to provide for investigation of adverse events?
	Do you have any comment on the activities to which it is proposed should be documented for risk management?
	Do you have any comment on the application of this proposal to petfood (feed for cats or dogs, whether intended to be fed to cats or dogs or other animals)?
	Do you have any preference and/or comment on the options proposed for implementation (Standards or a Regulated Control Scheme or a Risk Management Programme, under the APA, or Regulations under the ACVM Act)?
Impact of the proposals	Do you have any comment on the impact of these proposals, on business, government and society in general?
	Do you have any suggestions on how compliance costs to business of these proposals may be reduced, while maintaining management of the identified risks?
Cost recovery	Do you have any comment on the apportionment of NZFSA costs to be recovered from domestic secondary processors (the risk makers) and exporters of animal feed containing animal material (the primary beneficiaries)?
Transitional arrangements	Do you have any comment on the transitional arrangements proposed (a three month transition period)?

4.4 Requirements for submissions

Submitters are asked to include the following information in submissions:

- the title of this discussion document
- name and title of submitter
- organisation's name (if applicable)
- submitter's address and contact details (phone, fax, email if available)
- the number(s) of the section(s) commented on, beside each comment.

4.5 Official Information Act

Submissions may be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available unless there are grounds for withholding it; such grounds are set out in the OIA. Submitters may wish to indicate specific grounds for withholding specific information contained in their submission, such as that the information is commercially sensitive or personal (for example, name and contact details). Any decision to withhold information requested under the OIA is reviewable by the Ombudsman.

4.6 Process following receipt of submissions

After the closing date, submissions received will be taken into account when providing advice to the Minister on the proposals. A recommendation will then be made by the Minister to the Governor General who may agree to amend legislation to give effect to resulting proposals.

Appendix 1 Risk identification

The following provides an explanation of hazards and risks for the purposes of the review of animal feed.

Hazards and risks associated with animal feed

Hazards refer to microbiological, chemical or physical agents in animal feed capable of causing adverse human and/or animal health, and/or effects on trade. Hazards can be actions or inactions of people involved in the production process as well as microbiological, chemical or physical entities. *Risk* relates to the probability of adverse events occurring and the severity of the impact of such events if they do occur. The *risk profile* of an animal feed is an estimation of the probability of an adverse event occurring multiplied by the severity of potential impact. To determine risk it is therefore necessary to first identify hazards in relation to animal feed.

Hazards in animal feed

Hazards can be present in the ingredients at source or introduced during processing and/or manufacture. They can also be introduced, amplified (or *not* reduced, as was expected) because of the way a feed is processed and/or manufactured. These might be neutral characteristics, but become hazards when they can potentially cause some adverse affect.

Hazards in animal feed ingredients at source

These are:

- microbiological contaminants that could cause infection or illness in the animal, or can be transferred to animal products destined for human consumption, or result in the spread of pests
- chemical contaminants (for example herbicides, pesticides, veterinary medicines, cadmium, or lead) that may either cause undesirable reactions, are toxic to the animal, or would produce levels in animal feed that do not comply with required standards
- physical contaminants such as foreign bodies (for example pieces of metal or broken glass) that could cause harm to the animal.

Hazards in processing animal feed

Processing includes all interventions intended to make raw materials into animal feed. Processing may be limited to the minimal preparation and packaging of the animal feed, or it may involve substantial manufacturing. Hazards in processing animal feed also include the

introduction of microbiological, chemical or physical contaminants. Processing hazards in animal feed may arise from ineffective processes, such as not managing ingredient hazards (for example, faulty cooking or heating originally intended to remove microbiological contamination), or faulty formulation processes (for example, concentrating chemical contaminants or processing chemicals, rather than reducing their concentration).

Hazards associated with use of animal feed

These hazards include the use of the product in a manner other than intended, such as consumption by a species of animal for which the feed is unsuitable. In most cases, hazards introduced at this stage, while potentially significant, are not practically managed through regulatory intervention, other than labelling of the animal feed. Non-regulatory tools, such as the provision of consumer information and raising awareness among processors, are the appropriate means of mitigating these risks.

Relation of hazards to risks of animal feed

Hazards associated with animal feed may pose significant variations in risk across the range of animal feed products and the kinds of ingredient used. Because data was not available to undertake a quantitative risk assessment, consideration of risks was based on NZFSA's perception of the hazards associated with animal feed, gained from operational experience and on information available to NZFSA.

NZFSA's risk identification was framed by its statutory mandate relating to food (including animal feed) safety and suitability. It is NZFSA's view that the relevant risks extend beyond those that are directly related to the impact of animal feed used for their intended purpose, and must also include indirect risks. In particular, the indirect risk of harm to New Zealand's export trade. This may be caused by a loss in confidence in New Zealand's ability to control risks, following an adverse occurrence in New Zealand associated with animal feed produced for the domestic market.

Summary of risk factors

Following a consideration of the hazards and risks involved in the sourcing, processing/manufacture and distribution of animal feed, the following risk factors were identified as appropriate:

- human health
- animal health
- New Zealand's export trade
- agricultural security (including biosecurity).

Direct risks identified

The following describes (in no particular order) the types of direct risks that are of concern to the NZFSA:

- source materials introducing unknown and/or uncontrolled hazards making them unfit for intended purpose
- process controls being inadequate to ensure product fitness for intended purpose, resulting in:
 - animal feed causing malnutrition resulting in unnecessary pain or distress in animals
 - animal feed causing physical harm to the animal resulting in unnecessary pain or distress
 - animal feed being a source of pathogenic organisms or other pests that either cause disease or spread pests
- animal feed containing chemical contaminants causing undesirable and unintentional reactions (toxic or pharmacological) in animals
- animal feed containing substances that are prescribed as prohibited (usually because of the possible adverse affects listed above, including being contrary to import requirements or New Zealand government policy)
- inadequate information provided to users of animal feed so as not to enable the appropriate and safe use of the product (including labelling)
- animal feed failing to meet label claims
- animal feed exported from New Zealand not complying with importing country requirements (although the review was not specifically concerned with additional requirements relating to animal feed for export).

Indirect risks identified

The following describes (in no particular order) the types of indirect risks that are of concern to the NZFSA:

- presence of substances in feed in concentrations that would result in products for human consumption causing illness, including poisoning of the consumer
- presence of substances in feed in concentrations that would result in breaches of the domestic food residue standards in animal products for human consumption

- deliberate diversion or substitution (including those in breach of existing regulatory controls) of materials and products from the animal consumption chain into the human consumption chain
- biosecurity impacts of the introduction and spread of organisms associated with animal feed
- impacts of substances, such as antibiotics, on the health of humans
- spread of organisms that would cause disease in humans (zoonotic pathogens)
- loss of overseas market access for animal feed or primary products for human consumption, due to an adverse event in New Zealand related to animal feed and/or the loss in confidence in New Zealand's regulatory management of animal feed.

Both direct and indirect risks listed above are relevant to the control of animal feed for their intended purpose, and NZFSA considers they should influence regulatory strategy and specific regulatory decisions.

There are numerous other risks that were identified and considered by the review, but which were considered either not relevant to NZFSA's current statutory mandate or specifically to the regulation of animal feed. These include:

- occupational exposure of humans to animal feed in manufacturing or feeding situations resulting in human health problems
- contamination of food in the domestic household due to inadequate hygiene practices
- inadvertent or intentional consumption of animal feed by humans
- misleading labelling in breach of the Fair Trading Act
- risks pertaining to wholesomeness
- environmental contamination (chemical or microbiological) resulting in adverse affects on ecosystems
- animal feed failing to meet claims that are not relevant to the health and welfare of the animals (for example that the feed will result in increased energy or improved skin coat condition).

Appendix 2 Options assessment

Proposal 1: a requirement for secondary processors of animal feed containing animal material resulting from the death of the source animal, to list with NZFSA

	Minimisation of risks to: human and animal health and New Zealand's export trade	Regulatory intervention that is equitable and at the lowest cost to business/government/society	Feasibility
Option 1: status quo (no change)	The status quo is that there is a high (and therefore unacceptable), indirect risk to New Zealand's export trade, and also risk to domestic animal health/welfare from identified feed manufacturers. NZFSA does not currently have the information to locate the manufacturers of these feeds to manage risks, if this were necessary.	The status quo would impose no additional compliance costs on business and government. However, unmanaged indirect risks to New Zealand's export trade in particular, and animal health/welfare risks have the potential to impose significant costs to business and government.	Given the assessment of risks as high (and therefore unacceptable) the status quo is unacceptable.
Option 2: a requirement for secondary processors of animal feed containing animal material resulting from the death of the source animal to list with NZFSA	<p>A requirement for listing would provide NZFSA with a mechanism to rapidly identify manufacturers of these feeds.</p> <p>It would contribute to the maintenance of confidence in and safeguard New Zealand's reputation and position as a trusted supplier of animal feed.</p> <p>The requirement would also aid the management of risk to domestic animal health and welfare from these animal feed operations.</p>	<p>Listing of the manufacturer's name, address and type of feed manufactured is the minimum data necessary to enable identification of manufacturers of various types of animal feed.</p> <p>The cost to NZFSA of maintaining a database would be around \$100 per registration to NZFSA. These costs would need to be recovered.</p> <p>It is proposed that 75% of the costs of listing should fall on exporters of animal feed as they are the principal beneficiaries of this proposal. Secondary processors required to list are the risk makers and there is a secondary benefit to domestic animal health/welfare. Therefore part of the cost of implementation of listing should be borne by those required to list.</p>	This could be achieved by an amendment to the ACVM regulations to provide for the listing of manufacturers of animal feed containing animal material not otherwise subject to listing or registration.

Proposal 2: a requirement for secondary processors of petfood resulting from the death the source animal, to procure from a regulated source, and to maintain a documented system that complies with minimum prescribed requirements.

	Minimisation of risks to: human and animal health and New Zealand's export trade	Regulatory intervention that is equitable and at the lowest cost to business/government/society	Feasibility
Option 1: Status quo (no change)	NZFSA's review has identified high and therefore unacceptable risks to New Zealand's export trade and animal health and welfare associated with the manufacture of petfood. NZFSA believes these risks are particularly high for petfood. The status quo would leave these risks unmanaged.	The status quo would impose no direct and indirect costs on manufacturers. However, the costs to New Zealand's export trade from a significant adverse event would be high.	Given the assessment of risks as high (and therefore unacceptable) the status quo is unacceptable.
Option 2: a requirement for secondary processors of petfood resulting from the death of an animal, to procure material from a regulated source and to maintain a documented system that complies with minimum prescribed requirements.	The principal risks to New Zealand's export trade and domestic animal health arise from the sourcing of material for petfood from unknown and unregulated sources, by secondary processors. A requirement for procurement to be only from a regulated source would significantly reduce this risk. The requirement for a documented system would enable NZFSA to monitor and detect this risky material and provide for enforcement.	This proposal provides flexibility to enable the appropriate level of regulatory intervention to be applied and ensure that unnecessary costs are not imposed on business. The requirement to procure material for secondary processing operations only from a regulated source will substantially reduce the risks to the industry from the activities of a small number of operators. The implementation options proposed offer the flexibility to apply the minimum requirements unless non-compliance is identified, and then requirements commensurate with the degree of non-compliance. Demands on non-compliant manufacturers would increase in proportion to the degree of non-compliance, by requiring the manufacturer to provide documentary evidence to substantiate compliance and/or require further independent verification.	The APA and ACVM Act provide risk management tools for the required level of risk management identified.

		<p>It is proposed that the costs involved in implementing this proposal be apportioned between the secondary processors affected and the export animal feed industry. NZFSA proposes 75% of costs be recovered from the exporters of animal feed as the principal beneficiaries of the proposal. Comment is invited on this apportionment.</p>	
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Proposal 2: Implementation options

Implementation Tools	Minimisation of risks to: human and animal health and New Zealand's export trade	Regulatory intervention that is equitable and at the lowest cost to business/government/society	Feasibility
A: Standards under the APA	<p>All implementation options could manage the risks identified.</p>	<p>Whichever implementation option was chosen, the requirements on secondary processors would be similar. The front-end costs of developing the requirements and implementation by government would differ depending on the option chosen. These would be Crown funded.</p>	As tertiary legislation, Standards may not be considered appropriate given the new obligations on manufacturers.
B: Regulations under the ACVM Act			Regulations under the ACVM Act would require amendment if this implementation option were chosen.
C: Regulated Control Scheme under the APA			Where Regulated Control Schemes have been developed they have generally worked well and implementation is not complex. The APA currently provides for Regulated Control Schemes so no new legislation would be required. There would be front-end development costs on NZFSA which are likely to be high in relation to the number of manufacturers likely to be affected.
D: Modified Risk Management Programme under the APA			The Risk Management Programme regime is generally well understood. A modified Risk Management Programme would be developed if this implementation option were chosen. There would be 'front-end' costs in this development. Specifications would need to be developed to reflect the required level of regulatory control.

