



**CONSULTATION ON AMENDMENTS TO ANIMAL PRODUCTS REGULATIONS UNDER  
THE ANIMAL PRODUCTS ACT 1999 RELATING TO EXPORT EXEMPTIONS, OFFENCES,  
GAME ESTATES AND TERMINOLOGY**

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# 1 Purpose of the Paper

The purpose of this discussion document is to propose amendments to regulations and new specifications under the Animal Products Act 1999 (APA) relating to animal products. These proposals fall into two parts:

**Part A** proposes a new regulation under Section 60B (2) and 166 of the APA to provide for general labelling and composition export exemptions from selected food standards, and Director-General notices under section 60B (1) and 167 of the APA to exempt animal products from safety-related composition and labelling standards. These amendments aim to:

- improve regulatory consistency across all animal products in the application of export exemptions under section 60B of the APA;
- improve the transparency of criteria applied for assessing export exemptions;
- apply an exemption process that manages general and safety-related labelling and compositional requirements as separate processes.

**Part B** proposes changes to the Animal Products Regulations that include:

- the inclusion of a new Regulation relating to offences; and
- a consequential change from the Animal Products Amendment Act 2002 relating to game estates; and
- a consequential change arising from the Animal Products Amendment Act 2005 relating to terminology.

These Part B proposals do not involve policy changes but are intended to increase the clarity and functioning of the Animal Products Regulations 2000 and to update them.

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# Part A : Proposal to Review Export Exemptions

## 2 Introduction

For New Zealand to be a successful international trader of animal products it must export products in a form that meets the demands of overseas food authorities and market access requirements. Sometimes these requirements are in conflict with New Zealand standards. The APA recognises this situation and provides for exports to be exempted from New Zealand food standards where appropriate.

This power is in Section 60B of the APA. Its application is limited to exports being exempted from the requirements of Part 2A of the Food Act 1981 and from standards specified by notice under the APA. [These requirements are set out in section 3].

Part A of this discussion document considers different options for the application of export exemptions under Section 60B and proposes general criteria for assessing these options. A preferred option is identified.

Submissions are sought on the option preferred by NZFSA and on the proposed general criteria.

### 2.1 Scope

The scope of Part A of the paper covers:

- all animal products and materials to be used as food or in food ingredients for human consumption, produced under the APA, and intended for export from New Zealand.

The scope of the paper does not cover:

- animal products and materials, intended to be exported to Australia;
- animal products and materials not regulated under the APA;
- products and materials for animal consumption.

Related NZFSA paper - Domestic/export Interface paper. NZFSA. November 2006.

[[www.nzfsa.govt.nz/policy-law/publications/export-domstd](http://www.nzfsa.govt.nz/policy-law/publications/export-domstd)]

## 2.2 Outline of Approach

The work that has resulted in the preparation of this discussion document has highlighted a need to improve regulatory consistency in the application of export exemptions across all animal products. It has also highlighted a need to improve the transparency of criteria applied to applications for export exemptions.

General criteria have been developed and are used in the discussion document to assess the various approaches to export exemptions presented.

Using these criteria a preferred option for implementing section 60B of the APA has been identified.

## 2.3 Overview of Options

**Policy Option 1:** General exemption of certain animal products and materials for export from selected compositional and labelling requirements under Part 2A of the Food Act 1981 and standards specified under section 167 of the APA. This will be achieved through a regulation under sections 60B (2) and 166 of the APA.

**Policy Option 2:** Case-by-case basis exemptions of specified animal products and materials from compositional and labelling requirements under the Food Act and the standards specified under 167 of the APA. This will be achieved through Notices under sections 60B and 167 of the APA.

**Policy Option 3:** A combination of options 1 (general exemption applying primarily to broad exemptions for non-safety related labelling) and option 2 (selected on a case-by-case basis and applying primarily to safety-related composition and labelling requirements).

**Policy Option 4:** Status Quo – make no further exemptions other than the Animal Products (Exemption of Labelling Standards for Dairy Product and Dairy Material intended for Export) Notice 2006.

## 2.4 NZFSA Preferred Option

The option preferred by the NZFSA is option 3. In summary, a general exemption for certain animal products and materials from selected labelling and composition requirements through a Regulation, supported by case-by-case exemptions of specified animal products and materials from composition requirements and safety-related labelling requirements using Director-General Notices.

The key reasons why policy option 3 is the NZFSA's preferred choice are:

- It will support a flexible system that allows for safety-related labelling and composition exemptions for certain animal products or classes of animal products thereby effectively managing safety-related issues via the exemption process on a case-by-case basis;
- The combination mitigates some of the weaknesses of taking either option 1 or option 2 in isolation;
- It will deliver a harmonised and consistent approach to export exemptions across all animal products, particularly with the establishment of support systems and documented procedures;
- It will support a transparent and robust application process for general labelling exemptions.

## 3 Background

The current food regulatory environment is characterised by a series of generic and product-specific safety and labelling food standards made under food legislation administered by the NZFSA<sup>1</sup>. Accordingly, all food produced, processed, stored, transported and sold must be compliant with the requirements set out under the standards set under these Acts.

The NZFSA is responsible for regulating food safety and suitability across both the domestic and export sectors. A key objective of the APA is to ensure that all animal products produced in New Zealand are “fit for their intended purpose” irrespective of whether the food is destined for the New Zealand domestic market or export. This applies to food for human consumption and for further processing.

The APA enables the Director-General to provide a legal underpinning of importing country requirements by issuing a notice that specifies the export requirements and manner for meeting those requirements. This is empowered by section 60 of the APA. New Zealand exporters must adapt their production processes to meet these requirements in order to have their products eligible for trade to the countries concerned. In addition to these mandated requirements are marketplace specifications or commercial requirements that may need to be met by the exporter for products to enter the foreign marketplace.

In some areas, such as labelling, there are requirements that are similar in nature between countries and so it may be appropriate for a more generic approach to exemptions to be applied. For example the New Zealand requirement that products be labelled in English is not appropriate for retail ready products entering countries where English is not an official language.

In contrast, some countries' labelling requirements and compositional standards may be quite specific and therefore may need to be considered on a case-by-case basis.

### 3.1 Section 60B Export Exemptions

The mechanism of allowing for export material and product to be exempted from meeting the requirements of Part 2A of the Food Act (labelling and compositional requirements) and from standards specified by notice under the APA is section 60B of the APA.

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<sup>1</sup> NZFSA administered food legislation covers: The Food Act 1981, Animal Products Act 1999, Wine Act 2003, and Agricultural Compounds and Veterinary Medicines Act 1997.

Section 60B of the APA empowers the Director-General to exempt certain classes or descriptions of animal material or animal products from Part 2A of the Food Act 1981 and from standards specified by notice under section 167 of the APA.

To implement an exemption, the Director-General can use either regulations or a Director-General notice.

By way of justification, the Director-General needs only to have regard to the relevant overseas markets.

This provision, however, must be balanced against New Zealand's reputation as a producer of safe and suitable food. Therefore, any implementation of an export exemption needs to consider the extent to which the exemption from the New Zealand food standard or animal product specification would impact on consumer health and the overall integrity of New Zealand regulatory control over exports.

For ease of reference section 60B of the APA is reproduced below.

**Animal Products Act 1999. Section 60B. Exemption from requirements of food standards where appropriate-**

(1) The Director-General may, by notice under section 167, where satisfied that it is appropriate to do so having regard to the requirements of the relevant overseas market –

- (a) exempt from the requirements of any foods standards issued under Part 2A of the Food Act 1981 or any standards specified by notice under section 167 of this Act any 1 or more classes or descriptions of animal material or animal product that is intended for export from New Zealand to any destination other than Australia;
- (b) exempt from the requirements of any such food standards that apply only in New Zealand any 1 or more classes or descriptions of animal material or animal product that is intended for export to Australia. “

(2) Regulations made under section 166 may also provide for exemptions of a kind referred to in subsection (1)(a) or (b).

### 3.2 Part 2A of the Food Act 1981

Part 2A of the Food Act sets out a series of generic and product-specific standards that apply to all New Zealand food, and that operators must be compliant with when producing, processing, storing, transporting and selling animal products. There are five New Zealand food standards made under the Food Act 1981. In summary, these are:

### **1. New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002**

The New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 is a broad set of food labelling and composition standards for both New Zealand and Australia and is the legal instrument that incorporates FSC into New Zealand law. These standards include:

- Labelling requirements (safety related) e.g. any warning or advisory statements that may apply
- Labelling requirements (suitability related) e.g. nutrition information panels
- Composition requirements (safety related) e.g. maximum permitted levels of food additives, processing aids, vitamins and minerals
- Compositional requirements (suitability) e.g. minimum compositional requirements for defined or standardised foods such as chocolate, peanut butter, ice cream.

### **2) New Zealand (Prescribed Foods) Food Standards 2002**

Lists high risk foods and associated risks.

### **3) New Zealand (Bee Product Warning Statements - Dietary Supplements)**

Requires mandatory warning statements for bee products when sold as a dietary supplement.

### **4) New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006**

Sets standards for maximum permissible limits at which residues of an agricultural compounds may be present in specified types of foods.

### **5) New Zealand (Milk and Milk Products Processing) Food Standards 2002**

Sets processing requirements for milk and milk products.

In addition to the above there are also,

### **6) Food (Safety) Regulations 2002**

Contains regulations that cover general food safety standards and some specific permissions for fluoridated water, the sale of artificial drinks and hemp seed oil in New Zealand, and provisions for the manufacturer of low-acid canned food (e.g UHT milk).

### **7) Emergency Food Standards.**

Sections 11M and 11N of the Food Act enable the Director-General to issue an Emergency Food Standard (by issuing a food standard or amending an existing food standard) under specific conditions.

A more detailed summary of each of these standards is provided in **Part One of the Appendix**.

### 3.3 Animal Products Act Notices

There are a number of Director-General notices made under section 167 of the APA. These are not listed here, rather the NZFSA is presenting only those notices that it is likely that an export exemption (or modification) could be made.

#### **The Animal Products (Specifications for Products Intended for Human Consumption) Notice<sup>2</sup>.**

The notice sets out general and specific requirements for the production, processing and sale and export of animal products for human consumption. These include:

- Mandatory Labelling Requirements
- Labelling Requirements for Changes to Status
- Specific Labelling Requirements for Farmed Animals, Game Estate Mammal Products and Bivalve Molluscan Shellfish
- Compositional Requirements

A more detailed summary of each of these standards is provided in **Part One of the Appendix**.

### 3.4 Dairy Specifications under the APA

#### **1. The Animal Products (Exemption of Labelling Standards for Dairy Product and Dairy Material intended for Export) Notice 2006.**

This provides an interim exemption provision under the APA for dairy products and relates only to labelling.

#### **2. Animal Products (Export Requirements – Dairy Products) Notice 2005**

Sets out general requirements and responsibilities for dairy products and materials intended for export (including Australia). These requirements cover the following areas:

- Labelling and Packaging requirements (except products exported to Australia)
- Traceability
- General Requirements Responsibilities

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<sup>2</sup> The Animal Products (Specifications for Products Intended for Human Consumption) Notice excludes dairy products. However, for specifications promulgated after June 2005, animal products include dairy products (generally).

### 3. Animal Product (Dairy Processing Specifications) Notice 2006

Sets out general requirements for the processing of dairy materials and products, including risk management programmes.

4. **Approved Criteria** - Approved Criteria (including Dairy Product Criteria), are documents which set out additional criteria for the purpose of elaborating and clarifying the outcome requirements from regulations and specifications.

Approved Criteria serve as a reference for those developing, evaluating or verifying risk management programmes, or for those assessing, recognising or approving people, organisations, operations, chemicals or other areas under the APA 1999.

A more detailed summary of each of these standards is provided in **Part One of the Appendix**.

## 3.5 The Issues

There are a number of issues that have given rise to this review and the need for this discussion document to consult on the ways in which NZFSA could approach export exemptions under section 60B of the APA. These issues relate to the need to:

- improve regulatory consistency in the application of export exemptions across all animal products;
- establish general criteria for permitting export exemptions under the APA;
- ensure good regulatory practice;
- consider how best to approach labelling and composition export exemptions given the flexibility of section 60B of the APA.

### 3.5.1 Improved Regulatory Consistency

Prior to 1 June 2005 dairy export exemptions were managed under the Dairy Industry (Food Act 1981) Exemption Order 1996 (The exemption order). The exemption order exempted all exports of dairy products and material (except to Australia) from compliance with the Food Act. The exemption order was revoked on 1 June 2005, the same time as the Dairy Industry Act 1956, when the dairy sector was incorporated into the APA.

Under the APA a replacement for the exemption order was sought and this resulted in the making of the Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Export) Notice 2006. NZFSA considered this only an interim provision as it recognised the need for a more fundamental review of its approach to all animal product export exemptions. This notice is currently

the only exemption provision available to any animal products under section 60B of the Act, and it relates only to labelling.

### 3.5.2 Proposed General Criteria

This section gives consideration to the factors that need to be taken into account when making an export exemption under 60B of the APA. The NZFSA is proposing general criteria to assist decision-making processes and to ensure consistency across the animal product sector. The criteria needs to be consistent with NZFSA's commitment to food safety and suitability as well as the specific objectives of the APA.

- *“to minimise and manage risk to human and animal health from producing and processing animal material and products through measure that ensure as far as is practicable all traded animal products are fit for purpose; and*
- *to facilitate the entry of animal material and products into overseas markets through providing controls and mechanisms to give and to safeguard official assurances”. [APA 1999]*

The following criteria have been identified.

#### Fit For Its Intended Purpose

The term 'fit for its intended purpose' is a key concept in the APA and generally relates to the animal product being "suitable for the purpose for which the product specifically stated or could reasonably be presumed to be intended, having regard to its nature, packaging and identification"<sup>3</sup>.

##### **Criterion one: Fit for its Intended Purpose**

All animal material and animal products for export must be 'fit for its intended purpose'. This applies to both food exported for human consumption and for further processing.

#### Safe to Consume

The NZFSA is concerned about protecting consumers from food safety risks. This applies to food destined for the domestic market and for export. Food legislation supports food safety in the production, processing, distribution, preparation and retail. In relation to the APA, this is currently based on registered risk management programmes, regulated control schemes and the application of animal products standards.

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<sup>3</sup> NZFSA Glossary and Acronym 2006.

**Criterion two: Safe to Consume**

All animal products and material produced for export must be safe to consume.

**Suitability**

The term 'suitability' is not used in the APA but the Act does cover wholesomeness and contains offences in relation to deception (e.g. false or misleading labelling). It also covers composition. Food 'suitability' is intended to cover matters not directly related to food safety or commercial quality requirements but which are necessary for the product to be fit for intended use, such as composition, labelling and aesthetic characteristics. Clearly 'suitability' requirements can differ from country to country.

**Criterion three : Suitable**

All animal products and materials produced for export must be consistent with the suitability requirements of the importing country.

**International Obligations**

The NZFSA is committed to ensuring that all animal products and materials produced for export are consistent with New Zealand's obligations as a member of Codex Alimentarius Commission (Codex) and the World Trade Organisation (WTO).

The major objective of Codex is the development of science-based international food standards that protect the health of consumers, ensure fair trading practices, and facilitate trade through the development and harmonisation of international standards.

Codex also has in place a Code of Ethics for International Trade in Food that has an objective to promote ethical conduct in international trade in food. Codex has sought to fulfil the objectives of the Code through the development of international standards and guidelines.

New Zealand is also a member of the WTO. The two WTO agreements most relevant to Codex are the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which underpin Codex standards, guidelines and recommendations, and the WTO Technical Barriers to Trade Agreement, which ensures that the establishment of technical standards are not used as barriers to trade.

**Criterion four: International Obligations**

New Zealand will meet international food safety and suitability obligations as a member of Codex and the World Trade Organisation.

## **New Zealand's Default Position**

All animal products for export must comply with safety and suitability standard appropriate to that product. The New Zealand standards should be viewed as the framework for all food produced in New Zealand and export requirements viewed as additional to the New Zealand standards. Where a conflict between the New Zealand standard and export market requirements exists, the NZFSA has developed policy guidance<sup>4</sup> which gives consideration to a range of factors that include safety implications.

### **Criterion five: Compliance with the New Zealand standard and Export Market Requirements**

All animal products and materials produced for export must comply with relevant New Zealand standard and the export requirements of the overseas market, where these are additional to the New Zealand standard.

## **3.5.3 Good Regulatory Practice**

Beyond the exemption criteria listed above, the NZFSA also needs to ensure that its implementation approach to export exemptions under section 60B of the APA is consistent with the New Zealand Code of Good Regulatory Practice (NZCGRP). The NZCGRP is characterised by the following criteria:

### **Efficiency**

The NZFSA needs to ensure that any approach to export exemptions is administratively efficient and does not create excessive use of NZFSA staff time and other resources. The approach should also be efficient from a business compliance cost standpoint.

### **Effectiveness**

The approach to export exemptions needs to be effective, by providing for clear exemptions in accordance with policy and legal expectations. It should also be robust in regard to the application to other animal materials or products if it is intended to provide an ongoing solution.

### **Transparency**

The NZFSA wishes to provide for transparency in regard to its decision making processes.

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<sup>4</sup> Export-Domestic Standards – Policy Statement on Interface, [[www.nzfsa.govt.nz/policy-law/publications/export-domstd](http://www.nzfsa.govt.nz/policy-law/publications/export-domstd)],

## Clarity

The approach to export exemptions precisely state what is exempted from which standard and should leave industry in no doubt regarding interpretation or application.

## Equity

The preferred approach needs to treat industry stakeholders fairly and not unnecessarily advantage participants in one sector over another.

### 3.5.4 How to Approach Labelling and Composition Exemptions

This review has provided an opportunity to consider the process by which export exemptions are approved and to consider various ways that export exemptions may be approached to manage labelling and composition exemptions.

#### Labelling

Importing countries generally set their own general labelling requirements, which New Zealand exporters must meet. Some of these requirements form part of export requirements, but generally there is little reference to labelling in country specific access requirements.

Overall, general labelling requirements are considered less contentious as most countries have similar labelling requirements compared with New Zealand. However, safety-related labelling requirements, need consideration to ensure export requirements or other general requirements manage risks in these areas.

Examples of safety related labelling requirements include Directions for Use and Storage (Standard 1.2.6) of the FSC that requires either directions for use and/or directions for storage to be included on the label where, for reasons of health and safety, the consumer should be informed of specific use or storage requirements (e.g. raw meat that is joined or formed to resemble a cut of meat has the potential for bacteria to grow at the seal and needs to be cooked thoroughly).

A further example is Mandatory Warning and Advisory Statements and Declarations (Standard 1.2.3) of the FSC, i.e. royal jelly has been reported to cause severe allergic reaction and in rare cases fatalities especially in asthma and allergy sufferers.

#### Composition

A further consideration of this paper relates to compositional requirements which also vary across countries and, like labelling requirements, may form part of an export requirement, or may be similar between countries. However, in contrast to general labelling requirements, a decision to exempt

specific compositional requirements needs to be supported by a robust decision process to ensure the animal product produced under an exemption is safe and suitable to consume.

## 4 Options for Export Exemptions

As part of this review, the following policy options were considered:

### Policy Option 1

General export exemption of certain animal products and materials from selected labelling and compositional requirements under Part 2A of the Food Act and standards specified under section 167 of the APA.

This would be achieved through a Regulation under sections 60B (2) and 166 of the APA.

### Policy Option 2

Case-by-case export exemption of specified animal products and materials from compositional and labelling requirements under the Food Act and the standards specified under 167 of the Animal Products Act.

This will be achieved through Director General Notices under section 60B (1) and 167 of the APA.

### Policy Option 3

A combination of options 1 (selected general basis) and 2 (selected case-by-case basis).

### Policy Option 4

Status Quo – make no further exemptions other than the Animal Products (Exemption of Labelling Standards for Dairy Product and Dairy Material intended for Export) Notice 2006.

For each of these policy options, the following process was followed:

- underlying assumptions identified;
- options assessed against general criteria for permitting export exemptions;
- options assessed against the Code of Good Regulatory Practice (Efficiency, Effectiveness, Transparency, Clarity and Equity).

## 4.1 Policy Option One:

This is a general exemption of certain animal products and materials for export from selected labelling and compositional requirements under Part 2A of the Food Act and standards specified under section 167 of the APA.

Policy option 1 proposes a regulation under sections 60B (2) and 166 of the APA to exempt animal products produced for export from selected labelling and compositional requirements.

In relation to Part 2A of the Food Act, the following provides examples of safety and suitability standards under the FSC that may need to remain mandated for classes of products and/or specific animal products for reasons of health and safety. These are:

- Use by date marks and food identification labelling
- Directions for Use and Storage
- Mandatory Warning and Advisory Statements and Declarations
- Labelling Requirements for Changes to Status.

### **Underlying Assumptions and Considerations**

The underlying assumption of this approach is that the general requirements of the New Zealand standard and the Animal Products Regulations eg the fundamental requirement for truth in labelling, coupled with export requirements provide sufficient safeguards to managing labelling issues for animal products destined for export markets.

The following are key questions to consider when looking at the validity of the assumptions on which this option is based:

1. Is the exemption provision flexible enough to manage individual products about which the NZFSA has concern?
2. How are new and amended labelling standards considered when a blanket exemption applies and could this raise safety and suitability issues down the track?
3. Is a review process required where labelling standards are amended or new ones added?
4. Will a general labelling exemption manage issues around products produced for export that re-enter the New Zealand market?
5. Should these provisions be the same across all classes of animal products or selected on a case-by-case basis?

### Assessment of Option Against Criteria

<b>Exemption Criteria</b>	
<b>1. Consistency Across the APA</b>	Addresses inconsistencies across animal products in the application of general labelling and composition exemptions under the APA.
<b>2. Fit for its Intended Purpose</b>	There would be baseline export requirements as well as any country specific requirements that apply to labelling for exported animal products. These could potentially raise issues around how products are monitored, particularly when products produced for export re-enter the New Zealand market, but a system could be developed to cover this. If this option is implemented for selected standards only it provides reasonable assurance that a product is "fit for its intended purpose" as there would be scrutiny of export products as part of the process to assess which labelling and composition standards should apply.
<b>3. Safety</b>	Provides a mechanism for the regulator to select specific labelling and composition standards that are required for safety reasons (if any).
<b>4. Suitability</b>	Specific product labelling and composition requirements may not necessarily be covered in export requirements. For example, warning statements, directions for use, date marking, legibility etc. This could raise safety issues for specific products but if required by foreign governments then these will be advised.
<b>5. International Obligations</b>	Potentially less effective in ensuring New Zealand complies with its international labelling obligations as a general exemption provides less control over the labelling and composition process, although all applicable export requirements would need to be met.
<b>6. Compliance with an Agreed Standard or Export Market Requirements</b>	It is a requirement for export products to meet export requirements. These are general export requirements made as Director-General notices under the APA. This option does not necessarily take into account how certain labelling and composition elements are regulated by any given country, or what is considered a risk or not. Under this option the NZFSA would be making the decision for all countries.
<b>Good Regulatory Practice Criteria</b>	

<p><b>7. Efficiency</b></p>	<p>A general exemption is administratively simple and cost efficient from both the regulator's and industry's perspective as operators can apply the exemption across a broad range of products. If applied on a selective basis some efficiencies could be lost but this still provides a more cost efficient approach.</p> <p>A regulation can take time to amend and is therefore less responsive than a Director-General Notice as requirements change over time.</p>
<p><b>8. Effectiveness</b></p>	<p>New labelling/compositional amendments to the FSC and APA standards will not be given consideration under this option. This could potentially limit the effectiveness of the option as new scientific evidence will not be accommodated.</p> <p>To apply this approach on a selected basis potentially improves effectiveness.</p>
<p><b>9. Transparency</b></p>	<p>Transparency is provided through this consultation process. If applied generally there is limited transparency in the decision making process for individual classes of animal products.</p>
<p><b>10. Clarity</b></p>	<p>Consistent with 'minimum necessary intervention' to achieve objective. There would be a high degree of clarity in a general exemption i.e. everything is exempt from all of Part 2A of the Food Act and standards specified under section 167 of the APA. In contrast, selected classes and selected labelling/composition requirements exemptions may be less clearly applied as there may be grey areas open to interpretation as to what remains mandatory and what is exempted. This would make the framing of the exemption crucial to avoid or minimise any grey areas. Also, clarity would decrease over time if standards change and the exemption is not clear if they are included or not.</p>
<p><b>11. Equity</b></p>	<p>If applied generally across animal products it provides maximum equity across the application of export exemptions under the APA.</p>

## 4.2 Policy Option Two

This is a case-by-case exemption of specified animal products and materials from compositional and labelling requirements under the Food Act and the standards specified under section 167 of the Animal Products Act.

This will be achieved through Notices made by the Director-General under sections 60B (1) and 167 of the APA.

This option allows for notices at the tertiary level of law to manage exemptions from safety-related labelling requirements and/or compositional standards under Part 2A of the Food Act and the standards specified under section 167 of the APA. As such it provides for the most flexible and responsive approach and is suitable for exemptions on a case-by-case basis. It is intended that the description of the exemption will set the parameters for any specific requirements that might need to be added for safety reasons or to meet international obligations.

While compositional standards are likely to be the main application of these exemptions it is possible to also cover labelling exemptions in this way. In a general application to labelling, however, this is not the preferred approach to exemptions as it would be very time consuming and costly to grant general labelling exemptions on a case-by-case basis. A regulation is considered the more appropriate legal tool to effect general labelling exemptions because of the greater level of scrutiny and accountability given compared with a Director-General Notice. Thus this option is limited to case-by-case exemptions of safety related labelling.

Considering compositional matters the following are the type of standards that could be considered for exemption on a case-by-case basis:

- certain ingredients, including food additives and nutrients;
- macro and micro nutrient in finished product;
- processing aids;
- microbiological limits;
- and any other product characteristic that the Director-General determines to be compositional in nature and which has requirement or standards established under the relevant legislation referred to in this definition.

### **Underlying Assumption and Considerations**

The underlying assumption of this approach is that compositional standards and some safety-related labelling requirements for some countries may be quite specific and need to be considered on a case-by-case. This approach would allow the scope of the exemption to be as broad or as narrow as

considered necessary by the Regulator. For example, the exemption could apply to an individual product or to an identified class or product (e.g. all process ingredients). A Notice would provide a more immediate response to New Zealand's trading opportunities.

The following are key questions to consider when looking at this option:

- 1) If this is the only option used, will the need for case-by-case exemptions become overly burdensome on the regulator and also compliance cost issues for industry?
- 2) Will this approach to exemptions be able to manage issues around products produced for export that re-enter the NZ market?
- 3) Which safety specification type of labelling requirements should/not be exempted? Should the regulator try to provide an indicative list?
- 4) Which compositional requirements should/not be exempted? Should the regulator try to provide an indicative list?

#### Assessment of Option Against Criteria

<b>Exemption Criteria</b>	
<b>1. Consistency Across the APA</b>	The case-by-case approach could lead to a divergence in application. Guidance to ensure consistent decision-making would be required.
<b>2. Fit for its Intended Purpose</b>	<p>Because this approach requires the decision maker to give critical examination to each case, it involves a high degree of scrutiny and control, there is a risk, however, that information for the decision is limited. In the main this approach should provide greater assurance that an animal product for export meets its intended purpose compared with a general exemption.</p> <p>In general a precautionary approach would be applied - in the absence of clear evidence of safety, and acceptability (suitability) in the importing country's legislation, any application for exemption would be unlikely to succeed.</p>

<b>3. Safety</b>	<p>Provides a mechanism to identify any compositional and safety related provisions needed to ensure the safety of exported animal products.</p> <p>Consumer safety is based on an assumption that the international standard being met in place of the New Zealand standard is of equal or greater safety. This can be a difficult judgement if we are not familiar with the foreign compositional or safety standard concerned or the compounding effects of changing specific compositional elements.</p>
<b>4. Suitability</b>	This approach should deliver adequate suitability.
<b>5. International Obligations</b>	This approach should deliver against the criterion.
<b>6. Compliance with an Agreed Standard or Export Market Requirements</b>	It is a requirement for export products to meet export requirements. There are general export requirements made as Director-General Notices under the APA.
<b>Good Regulatory Practice Criteria</b>	
<b>7. Efficiency</b>	Compared with a general exemption this approach could potentially slow down the export exemption process as each animal product would need to be considered on an individual basis. In addition, efficiency could be slowed if NZFSA does not have a good knowledge of the technical impacts of the change sought. However, using a Director-General Notice is generally considered a responsive tool.
<b>8. Effectiveness</b>	<p>In the main this approach supports a robust decision-making process for assessing export exemptions because of its case-by-case nature. The risk is limited knowledge of the foreign standard concerned, the change sought and the compound impacts. Exemptions could be granted to facilitate trade that may have a food safety risk.</p> <p>This approach provides the ability to prevent products getting into the New Zealand market – i.e. as returned, imported or as an ingredient in another product.</p>
<b>9. Transparency</b>	The need for transparency is met through published criteria and the ability to correspond with the applicant seeking an exemption to fully disclose issues and decisions.
<b>10. Clarity</b>	Specific case-by-case exemptions should provide for maximum clarity.
<b>11. Equity</b>	<p>Some differentiation across the animal product sector in the application of case-by-case exemptions is possible but can be mitigated with good systems and documented procedures.</p> <p>An application for an exemption submitted by a single operator (involving potentially significant work and some cost). If successful, the exemption will become available for other operators to use and thus</p>

	other operators would benefit. Consideration may need to be given to how NZFSA costs are recovered for work on case-by-case exemptions.
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## 4.3 Policy Option Three:

### **Application of Both Options 1 and 2 (NZFSA preferred Option)**

This option combines options 1 and 2 to provide the certainty and compliance simplicity of a general labelling exemption, but with flexibility to support case-by-case exemptions for safety-related labelling and composition.

### **Underlying Assumption and Considerations**

The underlying assumption of this approach is that exemptions from safety related labelling and compositional requirements are more effectively managed as separate processes. As discussed, general labelling and composition exemptions on the whole can be managed through export requirements and generic requirements that are similar or equivalent between countries. Safety-related compositional and labelling exemptions on the other hand are viewed as requiring a more case-by case approach in order to identify any product or class specific requirements that might need to be considered. In addition, export requirements rarely contain detailed compositional requirements and if they are present they are normally additional to (rather than instead of) New Zealand requirements.

The key reasons why policy option 3 is considered the NZFSA's preferred choice are:

- The combination mitigates some of the weaknesses of taking either option 1 or option 2 in isolation;
- It will deliver a harmonised and consistent approach to export exemptions across all animal products, particularly with the establishment of support systems and documented procedures;
- It will support a transparent and robust application process for general labelling exemptions;
- It will support a flexible system that allows for safety-related labelling and composition exemptions for certain animal products or classes of animal products thereby effectively managing safety-related issues via the exemption process on a case-by-case basis.

A possible concern of this option is that it requires two separate legal approaches with associated administration costs. The NZFSA notes that the general labelling exemption to be made via regulation would be a long enduring exemption, and that making this reduces the demand on the case-by-case exemptions. Rather than increase compliance costs, the NZFSA considers that this combination approach will improve overall efficiency compared with using only case-by-case, and provide much greater effectiveness compared with only the blanket exemption.

### Assessment of Option against the Exemption Criteria and the Good Regulatory Practice Criteria

<b>Exemption Criteria</b>	
<b>1. Consistency Across the APA</b>	Provides for greater consistency than option 2 alone. Consistency can be better achieved through supporting systems and documented procedures.
<b>2. Fit for its Intended Purpose</b>	With the general exemption implemented on a selective basis and then individual case-by case exemptions possible, this option provides the best delivery against this criterion.
<b>3. Safety</b>	Safety is no stronger or weaker than option 1 or 2. Supports a robust process that provides increased assurances about the safety of animal products.
<b>4. Suitability</b>	Suitability is no stronger or weaker than option 1 or 2
<b>5. International Obligations</b>	This approach should deliver against the criterion.
<b>6. Compliance with an Agreed Standard or Export Market Requirements</b>	It is a requirement for export products to meet export requirements. There are general export requirement made as Director-General notices under the APA. This option has the same weakness as option 1 & 2.
<b>Good Regulatory Practice Criteria</b>	
<b>7. Efficiency</b>	Overall efficiency is high. This option provides the best ability for NZFSA to manage the tensions that arise from efficiency versus effectiveness. Provides greater efficiency compared with Option 2 alone.
<b>8. Effectiveness</b>	Provides a greater degree of effectiveness when compared with either option 1 or 2 alone.
<b>9. Transparency</b>	NZFSA considers that the transparency criterion can be met under option 3 supported by published criteria and procedure.
<b>10. Clarity</b>	Clarity is no stronger or weaker than option 1 or 2.
<b>11. Equity</b>	Equity is stronger than 2 alone.

## 4.4 Policy Option Four

### Status Quo

Option 4 proposes the status quo option. Currently animal products export exemptions are under sections 60B and 167 (1) (b) of the APA. However, dairy products exemptions are largely managed through the Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Export) Interim Notice 2006.

### Underlying Assumption

The status quo option reflects the 2005 incorporation of the dairy sector into the APA 1999. The rationale for this change was the need to provide a legal framework that reflected today's dairy sector and to provide a risk-based approach to food safety based on the risk management model underpinning the APA. However, due to a time constraint the dairy exemption were not fully carried over to the APA. The Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006 provides an interim provision to exempt dairy products from the labelling standards issued under Part 2A of the Food Act.

### Considerations

The following is a key question to consider when looking at this option:

- (a) Does the status quo support regulatory consistency across all animal products?

### Assessment of Option against the Exemption Criteria and the Good Regulatory Practice Criteria

<b>Exemption Criteria</b>	
<b>1. Consistency Across the APA</b>	Does not directly address inconsistencies across animal products in the application of export exemptions under the APA.
<b>2. Fit for its Intended Purpose</b>	Limited control over production processes provides some assurance that an animal product for export meets its intended purpose.
<b>3. Safety</b>	Safety is reliant on compliance with the general requirements of the Food Act and notices under the APA, any risk management programmes in place and export market requirements.
<b>4. Suitability</b>	Suitability is reliant on compliance with general suitability requirements and export market requirements.
<b>5. International Obligations</b>	This approach should deliver against the criterion.

<p><b>6. Compliance with an Agreed Standard or Export Market Requirements</b></p>	<p>The dairy export requirements notice defaults to the Food Act labelling standards in the absence of clear importing country requirements, or international (Codex) standards. Therefore, there is a built in safety net which cannot be exempted. In the absence of this fall back for other animal products there is no justification for the dairy exemption, which does not currently exist for other animal products.</p>
<p><b>Good Regulatory Practice Criteria</b></p>	
<p><b>7. Efficiency</b></p>	<p>Does not support consistency and harmonisation across all animal products.</p>
<p><b>8. Effectiveness</b></p>	<p>Exemption process not as effective in supporting a consistent and robust decision process.</p>
<p><b>9. Transparency</b></p>	<p>Some transparency in terms of the application of export exemptions.</p>
<p><b>10. Clarity</b></p>	<p>Consistent with 'minimum necessary intervention' to achieve objective.</p>
<p><b>11. Equity</b></p>	<p>Some differentiation across the animal product sector in the application of labelling and composition exemptions.</p>

## 5 Regulatory Impact Statement (Draft)

### Executive Summary

#### Problem Definition

The NZFSA has identified some inconsistencies in the application of section 60B of the Animal Products Act 1999 (APA) across all animal products, and a need to improve transparency of criteria applied to applications for export exemptions. Section 60B empowers the Director-General to exempt certain classes or descriptions of animal material and products from Part 2A of the Food Act 1981 and from standards specified by notice under section 167 of the APA.

#### Preferred Option

The NZFSA is proposing a preferred option (3) that combines policy option 1 and 2. In summary, this option supports a general exemption for certain animal products and materials from selected labelling and composition requirements through a Regulation, that is supported by case-by case exemptions from composition and safety-related labelling requirements using Director-General Notices.

Policy Option 1: General exemption of certain animal products and materials for export from selected compositional and labelling requirements under Part 2A of the Food Act and standards specified under section 167 of the APA. This will be achieved through a regulation under Sections 60B (2) and 166 of the APA.

Policy Option 2: Case-by-case basis exemptions of specified animal products and materials from compositional and labelling requirements under the Food Act and the standards specified under 167 of the APA. This will be achieved through Notices under sections 60B and 167 of the APA.

#### The key reasons why a combined approach is proposed are:

- The combination mitigates some of the weaknesses of taking either option 1 or option 2 in isolation;
- Delivers a harmonised and consistent approach to export exemptions across all animal products, particularly with the establishment of support systems and documented procedures;
- Supports a transparent and robust application process for general labelling exemptions;
- Supports a flexible system that allows for safety-related labelling and composition exemptions for certain animal products or classes of animal products thereby effectively managing safety-related issues via the exemption process on a case-by-case basis.

### **Main Impacts**

The approach requires two separate legal approaches with associated administration costs. The NZFSA notes that the general labelling exemption to be made via regulation would be a long enduring exemption, and that making this reduces the demand on the case-by-case exemptions. Rather than increase compliance costs, the NZFSA considers that this combination approach will improve overall efficiency compared with using only case-by-case, and provide much greater effectiveness compared with only the blanket exemption.

### **Status Quo and Problem**

Currently dairy products exemptions are largely managed through the Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Export) Notice 2006 and not section 60B and 167 (1) (b) of the APA. This situation reflects the 2005 incorporation of the dairy sector into the APA 1999. The rationale for this change was the need to provide a legal framework that reflected today's dairy sector and to provide a risk-based approach to food safety based on the risk management model underpinning the APA. However, due to time constraints, dairy export exemptions were not being fully carried over to the APA. The Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006 provides an interim provision to exempt dairy products from the labelling standards issued under Part 2A of the Food Act. The NZFSA is seeking to revise its approach to export exemptions to support regulatory consistency across all animal products.

### **Why action is needed**

Regulatory consistency across all animal products is a key objective of the NZFSA's strategic approach. The amendments proposed would deliver a harmonised and consistent approach to export exemptions across all animal products, including dairy.

### **Objective**

The following identifies objectives each of the options were considered against.

#### **Exemption Criteria**

- Consistency in the application of Section 60B across the APA
- Fit for its Intended Purpose
- Safety
- Suitability
- International obligations
- Compliance with an Agreed Standard or Export Market Requirements

### **Good Regulatory Practice Criteria**

- Efficiency
- Effectiveness
- Transparency
- Clarity
- Equity

### **Implementation and Review**

#### **Consultation**

While section 163 [*Consultation, Notifications, ect*] of the APA does not specifically require undertaking consultation, for the purposes of good regulatory practice, it is intended that the discussion document will be released for targeted consultation with all animal products industries/representatives, consumer organizations and interested government departments: The Ministry of Agriculture and Forestry; The Ministry of Economic Development; The Ministry of Consumer Affairs and the Ministry of Foreign Affairs and Trade.

## **Part B : Games Estates, Terminology, Offences**

### **6 Introduction**

#### **6.1 Purpose**

Part B of this discussion document proposes a number of changes to the Animal Products Regulations 2000. These proposed changes are not policy changes, but are intended to increase the clarity and functioning of the Regulations and to update them.

The discussion document is intended to inform interested parties and to invite public comment on the proposed changes.

#### **6.2 Summary**

The changes to the Animal Products Regulations proposed in this paper include:

- the inclusion of a new Regulation relating to offences; and
- a consequential change arising from the Animal Products Amendment Act 2002 relating to game estates, and
- a consequential change arising from the Animal Products Amendment Act 2005 relating to terminology.

### **7 Background**

This discussion document proposes changes to the Animal Products Regulations 2000 (the Regulations). The Regulations are made under the Animal Products Act (the APA). The APA replaced the Meat Act 1981 and the Dairy Industry Act 1952, and largely came into force on 1 November 1999 (dairy was brought under the Act in 1 July 2005). The Act aims to do two main things:

- to minimise and manage risks to human or animal health arising from the production and processing of animal material and products by instituting measures that ensure, so far as is practicable, that all traded animal products are fit for their intended purpose; and

- to facilitate the entry of animal material and products into overseas markets by providing the controls and mechanisms needed to give and to safeguard official assurances for entry into those markets.

The APA was amended in 2002. Of relevance to this paper is the inclusion of a new section (Part 5A) on Game Estates.

The APA was also amended in 2005. Of relevance to this paper is the amendment of terminology (replacement of the term 'accredited' with 'recognised').

The Regulations were made under the APA and came into force on 20 November 2000. The Regulations, among other things, allow for the setting of animal products standards, and provide for matters in relation to the making of specifications. The setting of standards include those relating to fitness for purpose; production, processing, and preparation of animal material and product; examining, sampling, and testing; packaging, storing, and handling; and standards relating to identification, labelling, and record keeping. The Regulations also provide for criteria for making certain specifications.

The Regulations also allow for the development of requirements relating to animal material for primary processing; requirements relating to suppliers of animal material for primary processing; risk management programme evaluation; recognised agencies and accredited persons; and identification, differentiation and security systems and devices.

## 8 Proposals

### 8.1 Proposed Offence Amendment

#### Problem Definition

When the Regulations were made, it was intended that failure to comply with the Regulations would constitute an offence. However, some of the Regulations were drafted with a specific reference to an offence (eg Regulations 22-26), while others were not. This inconsistency is problematic, as for those Regulations that do not state that failure to comply is an offence, it is not necessarily clear that failure to comply would constitute an offence. Additionally, the APA requires that in order for failure to comply to constitute an offence, the Regulation must specifically state that it is an offence, as below.

Section 135(1) of the APA states that a person commits an offence if they, without reasonable excuse, fail to comply with "(b) Any provision of any regulations made under this Act the failure to comply with which is specified in those regulations as an offence".

In order for failure to comply with the Regulations to constitute an offence, the Regulation must state that it is an offence to fail to comply. Currently, only Regulations 22-26 state that failure to comply is an offence.

Section 135(1) of the APA also states that a person commits an offence if they, without reasonable excuse, fail to comply with "(c) any direction, condition, notice, or requirement lawfully given, made or imposed by or under this Act". This is intended to cover non-compliance with any tertiary legislation made under the Act, such as notices or specifications.

The APA does not state that failure to comply must be specified in the tertiary legislation or the Regulation under which it is made. This means that failure to comply with any tertiary legislation is an offence, regardless of whether the Regulation that it is made under states that failure to comply is an offence or not.

Many of the Regulations that do not mention an offence allow for the making of tertiary legislation, and failure to comply with such tertiary legislation would constitute an offence under Section 135(1)(c). However, where it was anticipated that tertiary legislation would be created under Regulations (such as Regulations 5-19), in some cases it has not been created.

The net result is that, in some cases, it is not clear that failure to comply with the Regulations is an offence, when the policy intended failure to comply to be an offence. Where tertiary legislation has not been developed, failure to comply with the Regulation cannot constitute an offence either, which means that prosecutions cannot be brought against failure to comply with what was intended to be legal requirements.

## Proposal

It is proposed to create a new Regulation to indicate that it is an offence to fail to comply with most Regulations in the Animal Products Regulations. This would remove the current ambiguity and inconsistency.

Such a new Regulation would refer to the Regulations for which an offence is relevant. This type of Regulation is preferable to amending each relevant Regulation to contain an offence provision. For example, such a Regulation, modelled on the Animal Products (Dairy) Regulations, might read:

- Offences - Failure to comply with any of regulations 5(1), 5(2), 6(1), 7(1), 8, 9, 10, 11(1), 11(3), 12, 13, 14(1), 15, 16, 17, 18(1), 19(1), 19(2), 22(5), 23(3), 24(1), 25(1), 25(2), 26(2), 26(3), or with

specifications made under or for the purposes of any of those Regulations, constitutes an offence for the purposes of section 135(1)(b) of the Act.

This would make it clear that failure to comply with the nominated Regulations (and any tertiary legislation made under those Regulations) would constitute an offence.

### **Impacts on industry**

This proposed amendment would have very little material effect on industry.

It may affect those committing an offence by making prosecutions more likely to be successful, as the proposed changes would clarify that it is an offence to fail to comply with certain Regulations.

## **8.2 Consequential Amendments (Games Estates)**

### **Problem Definition**

The APA was amended in 2002. This amendment, amongst other things, added a new part (Part 5A Game Estates). As a consequence of this addition, some minor changes will be required to align the Regulations with the amended APA. These are administrative changes, and not policy changes.

The main object of Part 5A, Game Estates, is to facilitate the tracing of any animal material or product intended for human or animal consumption that is derived from animals from game estates, thus helping to ensure proper treatment of the animal material or product. A game estate is a place within which animals are kept (whether all or only some of the time), as if in the wild, for the purpose of providing opportunities for people to hunt or catch them as recreational catch. Animals that fit this description can include deer, chamois, goats, pigs, wallaby and water buffalo.

Regulation 22 (Requirements relating to animal material for primary processing) and Regulation 23 (Requirements relating to suppliers of animal material for primary processing) currently require producers and suppliers to adhere to certain conditions in relation to Parts 2-5 of the APA (Part 2 covers Risk Management Programmes, Part 3 covers Regulated Control Schemes, Part 4 covers Animal Product Standards and Specifications, and Part 5 covers Export of Animal Material and Products). Animals slaughtered on game estates should be subject to the same requirements as farmed animals in terms of processing.

The requirements for processing animals (and for supplying animals for processing) must include those from farmed and wild sources, and from game estates, if the full extent of the 2002 amendment is to be realised – if Regulations 22 and 23 are not complied with, the game estate animals can not be

accepted for processing. Regulations 22 and 23 should therefore refer to the new Part 5A, Game Estates.

## Proposal

It is proposed to alter Regulation 23(1) to refer to "Parts 2 to 5A", rather than "Parts 2 to 5".

The 2002 amendment to the APA included a new part on game estates, which then created an inconsistency in the Regulations. In order to be consistent, two of the Regulations now need to refer to the new part of the amended APA.

Regulations 22 and 23 cover animal material for primary processing and suppliers of animal material for primary processing, and Part 5A of the Act covers game estates. Regulations 22 and 23 should refer to Part 5A of the APA, as below:

Regulations 22(1) currently reads:

"The Director-General may, by specifications made for the purposes of any of Parts 2 to 5 of the Act(a) specify the obligations of primary producers... [and] (b) specify requirements as to the procurement and presentation of animals and animal material".

It is proposed to alter Regulation 22(1) to refer to "Parts 2 to 5A", rather than "Parts 2 to 5".

Regulation 23(1) currently reads:

"The Director-General may, by specifications made for the purposes of any of Parts 2 to 5 of the Act, require that specified classes of supplier of specified animal material for processing must have a specified level of competency, qualification, or experience in order to present animals or animal material for primary processing."

This is a consequential amendment, not a policy change. Tertiary legislation<sup>5</sup> already refers to animals from game estates in the same way as animals from farmed sources.

## Impacts on industry

This proposed amendment would have very little material effect on industry.

The inclusion of reference to Part 5A on game estates clarifies existing requirements, as set out in specifications, and fulfils the intent of the 2005 amendment to the APA.

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<sup>5</sup> Animal Products (Specifications for Products Intended for Human Consumption) Notice 2004

## 8.3 Consequential Amendments (Recognised)

### Problem Definition

The APA was amended in 2005. This amendment made a number of changes, including altering some terminology. The amendment altered the word 'accredited' to 'recognised'. As a consequence of this, the Regulations are now inconsistent with the APA.

### Proposal

The word 'accredited' should be replaced with the word 'recognised' wherever it occurs in the Regulations.

### Impacts on industry

This proposed amendment would have no material effect on industry. The change in terminology is from the 2005 amendment to the APA and would bring the Regulations in to line with these amendments.

### Summary of proposals

#### What is proposed?

It is proposed to

- add a new regulation to indicate that it is an offence to fail to comply with most Regulations in the Animal Products Regulations
- amend Regulations 22 and 23 to refer to Part 5A (Game Estates), and to
- replace the word 'accredited' with the word 'recognised'.

## 9 Regulatory Impact Statement (Draft)

Part B of this discussion document proposes a number of changes to the Animal Products Regulations 2000. As these proposed changes are not policy changes, but are intended to increase the clarity and functioning of the Regulations and to update them, no regulatory impact statement is considered necessary.

## 10 Submission process

### Submissions

Submissions are invited from any interested party, whether representing organisations or acting as individuals. When sent on behalf of an organisation, the submission should include the position in the organisation of the person signing the submission and the extent of internal consultation undertaken in preparing the submission.

### Process after submissions

After analysing submissions, the NZFSA will make recommendations to the Minister for Food Safety. If the Minister decides amendment to the Regulations and new specifications are desirable, she will make a recommendation for the required process to commence.

### 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, e-mail if available)

### Additional information 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:

- 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

## Send submissions to:

Please send your submission to:

Animal Products Regulations  
Policy Group  
New Zealand Food Safety Authority  
PO Box 2835  
Wellington – New Zealand

Phone: 04 894 2682  
Facsimile: 04 894 2583  
Email: [policy@nzfisa.govt.nz](mailto:policy@nzfisa.govt.nz)

## Closing date for submissions

The closing date is 28 September 2007

## Official Information Act

Please note that your submission is public information and subject to the Official Information Act (OIA) 1982. Therefore, if you consider that any or all information in your submission should be treated as confidential or is commercially sensitive, please state this clearly when making your submission.

The OIA states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are in the OIA. Submitters may wish to indicate grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

## Next Step

The next steps in this review will be to analyse submissions, provide a summary to submitters, and draw on submissions to put forward a proposal to Government. The following step will involve implementing Government's decision that results from this process.

# 11 APPENDIX

## 11.1 New Zealand Food Standards

There are five New Zealand food standards made under the Food Act 1981. The following is a summary of each of these standards.

### **New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002**

The New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 is a broad set of food labelling and composition standards for both New Zealand and Australia and is the legal instrument that incorporates the Australia New Zealand Food Standards Code into New Zealand law.

The following is a summary of labelling and compositional requirements covered by the Joint Food Standards Code. These requirements are grouped in terms of whether they relate to safety or suitability. [Note that some of these requirements could sit in one or both lists]

#### **Labelling requirements (safety related)**

- Food identification requirements, including the batch code and suppliers name and address
- Any warning or advisory statements that may apply
- Declaration of ingredients (particularly food allergens)
- Use by dates
- Directions for use and storage that affect health and safety (**Standard 1.2.6**).

#### **Labelling requirements (suitability related)**

- Best before date marks
- Characterising ingredient (%)
- Nutrition labelling – nutrition information panels and nutrition claims
- Wording, graphics and branding placed on labels to promote products may also affect suitability.

#### **Composition requirements (safety related)**

- Maximum levels of contaminants and toxins
- Microbiological limits for food
- Maximum permitted levels of food additives, vitamins and minerals (processing aids)
- Prohibited or restricted plant and fungi, novel foods
- Nutrients in special purpose foods such as infant formula.

#### **Compositional requirements (suitability)**

- Minimum compositional requirements for defined or standardised foods such as chocolate, peanut butter, ice cream.

### **Mandatory Warning and Advisory Statements and Declarations (Standard 1.2.3) FSC**

Standard 1.2.3 sets out mandatory advisory statements and declarations which must be made in relation to certain foods or foods containing certain substances as set out in the table to clause 2. For

example, an advisory statement is required for milk and beverages made from soy and cereals, where these foods contain no more than 2.5 m/m fat. The advisory statement is worded: “Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years”.

Standard 1.2.3 also sets out mandatory warning statements and declarations for foods set out in the table to clause 3. For example Royal jelly when presented as a food as an ingredient must contain a warning statement that states the product contains royal jelly which has been reported to cause severe allergic reaction and in rare cases fatalities especially in asthma and allergy sufferers.

#### **New Zealand (Prescribed Foods) Food Standards 2002**

The New Zealand (Prescribed Foods) Food Standards 2002 lists prescribed foods (high risk foods) and requires the risks associated with a prescribed food have been controlled prior to it being sold.

#### **New Zealand (Bee Product Warning Statements - Dietary Supplements)**

New Zealand (Bee Product Warning Statements - Dietary Supplements) sets a mandatory requirement for warning statements for products containing royal jelly, bee pollen and propolis when sold as a dietary supplement.

#### **New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006**

New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006 sets standards for maximum permissible limits at which residues of an agricultural compounds may be present in specified types of foods.

#### **New Zealand (Milk and Milk Products Processing) Food Standards 2002**

The New Zealand (Milk and Milk Products Processing) Food Standards 2002 sets processing requirements for milk and milk products.

#### **Directions for Use and Storage (Standard 1.2.6) FSC**

Standard 1.2.6 requires either directions for use and/or directions for storage to be included on the label where, for reasons of health and safety, the consumer should be informed of specific use or storage requirements.

In addition, food standards may contain directions for use and/or storage specific to individual products. For example raw meat that is joined or formed to resemble a cut of meat has the potential for bacteria to grow at the seal, if the meat is not cooked sufficiently. FPS 2.2.1 requires a declaration that the meat is joined or formed, in conjunction with cooking instructions indicating how the ‘microbiological safety’ of the meat product can be achieved.

## **Food (Safety) Regulations 2002**

In addition to the above, the Food (Safety) Regulations 2002 contain regulations that generally fall outside of the Joint Food Standards System and so are not covered in the Food Standards Code. In summary the regulations set out some general food safety standards and some specific permissions for fluoridated water, the sale of artificial drinks and hemp seed oil in New Zealand.

## **11.2 APA Standards**

Section 167 of the APA 1999 empowers the Director-General to make notices that set specific requirements for animal products and materials. These requirements must be met by anyone operating under the APA, including exporters.

The Animal Products (Specifications for Products Intended for Human Consumption) Notice ([attach weblink](#)) sets out general and specific requirements for the production, processing, sale and export of animal products for human consumption. Those that are most relevant to this paper are described below.

### **General Labelling Requirements**

#### **Mandatory Labelling Requirements**

Part 7 clause 32 (4) sets out mandatory labelling requirements for animal materials and products intended for human consumption. "Mandatory labelling must be clear, legible, indelible, and use terms that are commonly used in English language or other language approved by the Director-General.

#### **Labelling Requirements for Changes to Status**

Part 7 clause 32B (1) (2) (3) sets out labelling requirements for animal products and materials that have a change of status. These require that all affected labelling and documentation is amended to reflect the new status prior to its release for trade, or the packaging (including labelling) must be replaced. In case of products and materials that are downgraded and are no longer intended for trade for human consumption, the affected labelling or the accompanying documentation identifying the product as fit for human consumption must be removed or defaced at the consigning premises.

### **Specific Labelling Requirements**

**Farmed animals** - Part 12 clause 76A requires that farmed animals must not be labelled using the terms "wild" or "game" or any other term of similar meaning.

**Game Estate Mammal Products** - Part 2 clause 91 requires that game estate mammal products must not be labelled using the term “wild” or “game” or any other term of a similar meaning.

**Bivalve Molluscan Shellfish Labelling** - Part 13 clause 139 requires that containers of shellfish leaving the processing premises must be labelled with (a) the growing area lease, license, resource consent, or permit number (b) the date of harvest (c) the type and quantity (number or weight) of shellfish.

### **Compositional Requirements**

#### **Additives, Processing Aids, Vitamins and Minerals**

Part 1 Clause 17 – The identity and purity of additives, processing aids, vitamins and minerals and other added nutrients must comply with the current Australia New Zealand Food Standards Code, Part 1.3 “Substances added to Food”, and Standard 1.3.4 “Identity and Purity”.

#### Standard 1.3.1 – Food Additives

Food additives is a substance used as an ingredient of food to achieve one or more technical functions as specified in schedule 5. This standard regulates the use of food additives in the production and processing of food.

#### Standard 1.3.4 – Identity and Purity

This standard ensures that substances added to food in accordance with the joint Food Standards Code meet appropriate specifications for identity and purity of food additives, processing aids, vitamins and minerals and other added nutrients. In general terms, these specifications are those used by the international community.

The following provides a general overview of additional areas covered in this notice:

- design and construction of facilities and equipment
- water (including ice and steam) that comes into contact with animal products and materials
- gases that comes into contact with animal products and materials
- premises hygiene and maintenance
- management of animal materials and products not for human consumption
- waste management
- health and competency of personnel
- calibration
- packaging
- documenting programmes and record keeping
- movement of farm animals
- supply of animal material that has been used in experiments, trials and research.

In addition, there are some specific requirement for the supply of:

- farmed rabbits
- killed wild mammals and live possums
- killed game state mammals
- deer velvet

- fish
- honey and other bee products
- Bivalve Molluscan Shellfish labelling
- Listeria monitoring programme for fish
- Transportation.

### 11.3 Animal Products (Residue Specifications) Notice 2004

The Animal Products (Residue Specifications) Notice 2004 is issued under section 45 and 167 (1) (h) of the Animal Products Act 1999. The purpose of the notice is to set specifications in relation to the maximum permissible level at which residues of a substance may be present in specified types of animal material or products intended for human consumption.

### 11.4 Dairy Specifications under the APA

This section provides an overview of dairy specifications under the APA that are considered most relevant to this paper.

#### **Background**

##### **Dairy Industry (Food Act 1981) Exemption Order 1996 (Revoked)**

Prior to 1 June 2005 the dairy industry was regulated under the Dairy Industry Act 1952 and regulations made under that Act. Dairy export exemptions were managed under the Industry (Food Act 1981) Exemption Order 1996 (The exemption order). The exemption order recognised there were occasions where it was necessary, in the interest of trade, to exempt dairy products<sup>6</sup> produced for the export market from mandatory labelling and compositional requirements. The exemption order exempted all exports of dairy products and material (except to Australia) from compliance with the Food Act 1981.

The scope of the exemption order was broad and did not identify specific markets or classes or descriptions of dairy products. There was no provision to consider overseas requirements or to require the re-labelling of export dairy products that re-entered the domestic market. The exemption order made no distinction between labelling and compositional requirements. Export operators were not required to apply for exemptions from the Food Act 1981 as exemptions existed automatically under the provision of the exemption order.

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<sup>6</sup> For the purpose of this paper dairy products covers both dairy products and materials.

The exemption order was revoked at the same time as the Dairy Industry Act (1 June 2005).

### **Labelling**

#### **The Animal Products (Exemption of Labelling Standards for Dairy Product and Dairy Material intended for Export) Notice 2006.**

The Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Export) Notice 2006 provides an interim exemption provision under the APA for dairy products. This provision was necessary due to a time constraint that meant the need for dairy export exemption was not fully addressed under the APA regime from 1 June 2005. This notice is currently the only exemption provision available to any animal products under section 60B of the Act, and it relates only to labelling.

#### **Animal Products (Export Requirements – Dairy Products) Notice 2005**

Animal Products (Export Requirements – Dairy Products) Notice 2005 sets out general requirements and responsibilities for dairy products and materials intended for export (including Australia). These requirements cover the following areas:

#### **Labelling and Packaging requirements (except products exported to Australia)**

- All labelling information must be clearly presented and must not be removed, defaced or obliterated.
- Products must not be labelled or marked in a way that is misleading or deceptive.
- Products must comply with labelling requirements set out in the Notice and with any requirements set by the importing country.
- The outer packaging must be labelled with a product designation that complies with a standard of identity prescribed by the importing country (including words and pictures).
- Where the importing country does not prescribe a standard of identity the outer packaging must comply with the Food Standards Code or labelled and identified to comply with the relevant definition of the Act.
- The net content by weight or volume must be stated on a label affixed to its outer packaging or in documentation accompanying the product.

#### **Traceability**

- Sufficient information to ensure traceability that includes a unique identifier or the name and address of the final premises of manufacturer; lot identification and date of manufacture or date of packaging.

#### **General Requirements Responsibilities**

- Identify the export market for which the Dairy material is intended to be eligible.
- Knowledge and compliance with export requirements issued by Notice under section 60.
- Maintain a risk management programme (RMP) or documented system demonstrating compliance with relevant export requirements.

- Have a RMP or documented system evaluate and verified against the relevant export requirements by their Recognised Agency/Person.
- Recognised Agencies and Recognised Persons are responsible for evaluating and verifying that RMPs and documented systems comply with the export Notice under section 60 and with any other export requirements issued by Notice.

### **Animal Product (Dairy Processing Specifications) Notice 2006**

The Animal Product (Dairy Processing Specifications) Notice 2006 sets out general requirements for the processing of dairy materials and products, including risk management programmes. The following is a summary of these requirements:

- Procedures to identify, detain and dispose of non-conforming dairy products and materials. The procedure must also ensure any non-compliance is reported to the recognised agency for verification of the RMP (RMP) and that any testing of the product is carried out in a recognised dairy laboratory
- Records of the RMP must be kept to identify compliance (or non-compliance with the RMP) and that the product is fit for the intended purpose
- Official Assurance may only be issues where the export product meets the all notified requirements
- Approved criteria
- Hazard Analysis and Critical Point System (HACCP) requirements
- Performance Measurement of Dairy Processors (include frequency and intensity of verification process).

In addition to the above general requirements for the processing of dairy products and materials, the specification sets out specific requirements to be covered by the RMP that relate to:

- Farm dairies (ie environment, filtering and cooling of raw milk, milking healthy animals, water quality, milk withholding)
- Raw milk (ie sale/supply of impure milk, refusal of suspect milk, monitoring of raw milk, records of suppliers and traceability)
- Manufacture of dairy products (ie documentation of systems to ensure only permitted raw materials, ingredients, additives and processing aids are used, traceability, fitness of purpose of all milk received or sold for manufacture is monitored. Storage areas and equipment is maintained and cleaned)
- Dairy heat treatments (defines dairy material heat treatment requirements for thermisation for cheese-making, pasteurisation, ultra high temperature, requires an Independent Verification Programme, Pathogen Management)
- Requirements for dairy manufacturers and Stores (ie pest management)
- Requirements for dairy premises (ie environment and equipment are clean and suitable, changes to the premises to be registered as an amendment to the RMP)
- Dairy storage and transportation
- Evaluation and Verification (covers the evaluation of compliance and non-compliance).

### **Approved Criteria**

Approved Criteria (including Dairy Product Criteria), are documents which set out additional criteria for the purpose of elaborating and clarifying the outcome requirements from regulations and specifications.

Approved Criteria serve as a reference for those developing, evaluating or verifying risk management programmes, or for those assessing, recognising or approving people, organisations, operations, chemicals or other things under the APA 1999. There are currently six approved criteria<sup>7</sup>:

#### DPC1: Animal Products (Dairy) Approved Criteria for General Dairy Processing

The Approve Criteria for General Dairy Processing 2006 sets requirements that include:

- Reporting Requirements (including exemption reporting)
- Dairy Product Safety (ie Wholesomeness and Foreign Matter, sets microbial Product Safety Limits (PSLs))
- Residues of agricultural compounds and veterinary medicines (limits specified by Codex)
- Toxic Trace Metal (limits specified in the Food Standards Code)
- Nutrient Fortifications (lists fortification standards set by Codex)
- Monitoring of radionuclides levels
- Dairy HACCP Plans (including plans, team, scope, product safety outcomes, monitoring critical control plan, corrective actions, verification procedures)
- Traceback of non-conforming dairy material and products (includes sampling and testing and disposal of non-conforming products)

#### Section 18 Labelling of mislabelled and/or unsafe dairy material or dairy product (Summary)

- (1) Where dairy produce fails to meet the requirements of Animal Products (Export Requirements – Dairy Products) Notice 2005 any NZFSA devices appearing on the product must be defaced.
- (2) Where dairy material and dairy product fails to meet “Dairy Product Safety”, the following are to be completed:
  - (a) any NZFSA devices appearing on the product are defaced, and
  - (b) all packages and associated documentation bear the words “Not for Human Consumption”.
- (3) Where dairy raw materials fail to meet the requirements any NZFSA devices appearing on the raw materials are to be defaced.
- (4) The HACCP plan for maintaining the safety of dairy material during collection and transportation is to be developed in compliance with Animal Products (Dairy Risk Management Programme Specifications) Notice.

#### DPC 2: Animal Products (Dairy) Approved Criteria for Farm Dairies

The Animal Products (Dairy) Approved Criteria for Farm Dairies sets out additional requirements for the processing of raw milk in farm dairies that include:

- premises and equipment design, maintenance, housekeeping and hygiene, cleaning and usage, clean udders and teats, separation of colostrums and speciality milks
- filtration and cooling
- milking animal health, management of agricultural compounds and veterinary medicines, management of withheld milk
- water quality, water management plan
- raw milk acceptance
- records and reporting

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<sup>7</sup> Alternatives to the ‘approved criteria’ may also be recognised as valid by the Director-General.

- farm dairy assessment systems.

### DPC 3: Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Products

The Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Products sets out additional criteria for the general dairy processing of dairy materials or dairy products that include:

- Integrity and Labelling of Dairy Material or Dairy Product ( maintaining the integrity of the product and ensuring that labelling of dairy products is in compliance with NZFSA Animal Products (Export Requirements – Dairy Products) Notice 2005, truthful labelling of sampling and testing
- storage of dairy material
- transport of dairy material
- manufacturing premises cleaning
- product safety and HACCP
- pathogen management
- pest management
- control of foreign matter
- raw milk
- ingredient control (ie storage, protection from contaminants, handling)
- packaging
- water quality criteria
- water management plan (reticulation, testing, monitoring, non-complying)
- dairy heat treatments
- independent verification programme
- non-operating registered manufacturing premises
- starting a non-operating registered manufacturing premises
- performance measurement of dairy manufacture
- demonstration of compliance
- assessment requirements.

### DPC4: Animal Products (Dairy) Animal Products (Dairy) Approved Criteria for Storage and Transportation of Dairy Material and Products

The Animal Products (Dairy) Approved Criteria for Storage and Transportation of Dairy Material and Products sets out additional requirements for general dairy processing of dairy material or dairy products that include:

- labelling of dairy material and dairy products - the procedures to ensure dairy material and dairy products are labelled in a manner that enables traceability to be maintained.
- hygiene criteria for premises that include location, design and layout of premises, internal structures and fittings
- food control and monitoring equipment (ie equipment used to cook, heat treat, cool, store, freeze)
- facilities (ie temperature control, air quality and ventilation, lighting, storage)
- requirements of transport operators (ie procedures to assess and ensure suitability and cleanliness)
- HACCP and product fitness for purpose
- transport of dairy material (ie procedures to ensure hygienic standards are equipment are maintained, regular assessments are made by suitably qualified persons, documentation of deficiencies, appropriate corrective action)
- requirements of store operators.

#### Animal Products (Dairy) Conditions for Recognition

The Animal Products (Dairy) Conditions for Recognition set out the conditions for recognition of agencies and persons under the Animal Products Act 1999 for the dairy industry. Recognised agencies include laboratories and also persons who are recognised by NZFSA to perform evaluation and verification of registered Risk Management programmes for the dairy industry.

#### Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Person

The Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Person sets out the requirements to be met by a recognised agency or person to maintain recognition under the Animal Products Act 1999 for the dairy industry.

## 11.5 Glossary

**Animal** means any member of the animal kingdom, and includes-

(a) any mammal, bird, finfish, shellfish, reptile, amphibian, insect or invertebrate:

(b) any other creature or entity that is declared by the Minister by notice in the *Gazette* to be an animal for the purpose of this Act; -

but does not include a human being.

**Animal product** means any animal material that has been processed (other than simply transported or stored in such a way as not to involve any alteration to its nature) for the purpose, or ultimate purpose, of consumption by other use by human or animals. [APA 4 (1)]

**Animal material** means any live or dead animal or any tissue or other material taken or derived from an animal. [APA 4 (1)]

**Compositional standards** refers to standards established under Parts 2A of the Food Act 1981, or by notice under section 167 of the Act, and includes additives, ingredients, macro and micro nutrient in finished product; processing aids; microbiological limits; and any other product characteristic that the Director-General determines to be compositional in nature and which has requirement or standards established under the legislation referred to in this definition.

**Fit for its intended purpose** is used in relation to animal products that has been processed in accordance with requirements set out under the APA and is suitable for the purpose for which the product is specifically stated or could reasonably be presumed to intended having regard to its nature, packaging, and identification. [APA 4 (1) abridged]

**New Zealand standard** - There are five New Zealand Food Standards made under the Food Act. These are the Australia New Zealand Food Standards Code; Bee Product Warning Statements – Dietary Supplements; Maximum Residue Limits of Agricultural Compounds; Milk and Milk Products Processing; and Prescribed Foods. The New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 is the legal instrument that incorporates the Australia New Zealand Food Standards Code into New Zealand law.