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# Report Name: Food and Agricultural Import Regulations and Standards **Country Report**

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### **Report Highlights:**

All foods sold in Australia must comply with a range of laws designed to protect consumer, plant, and animal health. These laws apply equally to imported and locally produced foods. All imported food must comply with quarantine and imported food requirements, and then with food safety requirements. DISCLAIMER: This report has been prepared by the Office of Agricultural Affairs, USDA/Foreign Agricultural Service in Canberra, Australia for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation or because clear and consistent information about these policies was unavailable. It is highly recommended that U.S. exporters verify the full set of import requirements with their Australian partners, who are normally best equipped to research such matters with local authorities, <u>before</u> any goods are shipped.

#### FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO AUSTRALIA'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Please contact this office if you have any comments, corrections or suggestions about the material contained in this report.

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# **Executive Summary**

Australia is a large and stable market for U.S. agricultural and related products, especially consumer-oriented products. In 2019, Australia imported \$1.7 billion worth of U.S. agricultural products of which \$1.2 billion was consumer oriented. Since 2005, Australia and the United States have had a free trade agreement, which means nearly all products can come in tariff-free.

Australia, however, has very strict quarantine regulations. All food imported into Australia must first comply with quarantine and imported food requirements and then with food safety requirements. Quarantine requirements are the first barrier that must be cleared for all imported food. These include strict sanitary and phytosanitary requirements.

Australian labeling and advertising laws are different from the United States. This means that U.S. labels are not acceptable and may need to undergo changes before entering this market. By far the largest issues for U.S. products being held up at the border are because of incorrect nutrition information panel (Australia's is substantially different to the U.S. panel), and products containing additives which are not approved for that particular use in Australia. New Zealand and Australia share the same food standards and labeling laws, allowing food packaged and labelled for Australia to also be able to be sold in New Zealand.

Information on various sectors of the Australian market is available from the FAS Attaché Reports web site.

## Section I: Food Laws

The Australia and New Zealand <u>food regulation system</u> is a cooperative arrangement between the Commonwealth of Australia, New Zealand, and Australian states and territories that has developed and implemented uniform food standards. This system was jointly developed under a treaty between Australia and New Zealand signed in December 1995.

Food Standards Australia New Zealand (FSANZ – <u>www.foodstandards.gov.au</u>) is a statutory authority operating under the *Food Standards Australia New Zealand Act 1991*. The Act provides a focus for cooperation between governments, industry, and the community to establish and maintain uniform food regulations in Australia and New Zealand.

The food standards development system is implemented by separate food legislation in each Australian State and Territory, and in New Zealand as well as by the *Australia New Zealand Food Authority Act 1991* (the ANZFA Act) of the Commonwealth of Australia. The ANZFA Act establishes the mechanisms for the development of joint food regulatory measures (a food standard or a code of practice) and creates Food Standards Australia New Zealand as the agency responsible for the development and maintenance of the joint Australia New Zealand Food Standards Code (ANZFSC). In 2005 and 2006, the Australia New Zealand Food Regulation Legislative and Governance Forum on Food Regulation agreed to a number of measures to expedite FSANZ's assessment and approval processes and better protect commercially valuable information. As a result, the *Food Standards Australia New Zealand Amendment Bill 2007* was passed on June 20, 2007. Since October 1, 2007, all applications received are assessed under the reform assessment process. This harmonizes, as much as possible, the processes for assessing applications and proposals and aligns the processes for the Australian Pesticides and Veterinary Medicines Authority (APVMA) and FSANZ when establishing Maximum Residue Limits. The reforms also enable the development of urgent standards due to unforeseen negative impacts on trade.

Although FSANZ develops food standards, responsibility for enforcing and policing food standards rests with the respective States and Territories in Australia and the New Zealand government. Each government has one or more agencies responsible for food surveillance, which are tasked with ensuring the requirements of the ANZFSC are met.

The ANZFSC is a collection of individual food standards. Standards on related matters are grouped into Parts, which in turn are combined into four Chapters. Chapter 1 deals with standards that apply to all foods; however, New Zealand regulates its own Maximum Residue Limits (MRLs) for food, thus, Standard 1.4.2 regulates MRLs in Australia only. Chapter 2 deals with standards affecting particular classes of foods. Chapter 3 deals with food hygiene issues in Australia only – New Zealand has its own food hygiene arrangements, and food hygiene is not part of the joint food standards system. Chapter 4 deals with Primary Production Standards in Australia only.

Food standards have the force of law. It is a criminal offence in Australia to supply food that does not comply with relevant food standards. Notwithstanding food standards, it is also an offense to sell food which is damaged, deteriorated, perished, adulterated or unfit for human consumption. Because food standards are given legal standing under Australian State, Territory, and New Zealand laws, it is important to read the ANZFSC in conjunction with the relevant State food legislation.

The ANZFSC should also be read in conjunction with other applicable laws such as the *Australian Competition & Consumer Act 2010, particularly* provisions relating to false, misleading, and deceptive conduct as it applies to the supply of food in trade and commerce. An overview of the legislation is available on the <u>Australian</u> <u>Competition and Consumer Commission</u> (ACCC) web site. The ACCC has produced a number of guides to assist people involved in the food industry to meet their obligations under the Act. For example, there are guides

available on the use of <u>food descriptors</u>, <u>Country of Origin Claims and the Australian Consumer Law</u>, and an <u>Advertising and Selling Guide</u>.

Food standards are developed or varied by FSANZ either by application from any individual, agency or body or by a proposal of its own initiative. Notices are published by FSANZ via media release in Australia and New Zealand seeking comment from the public on applications and proposals.

When assessing a food regulatory matter, FSANZ is required to take into account:

- any submissions received from the public in response to its public notices;
- three statutory objectives listed in order of priority:
  - a. the protection of public health and safety;
  - b. the provision of adequate information relating to food to enable consumers to make informed choices;
  - c. the prevention of misleading or deceptive conduct;
- other factors include:
  - a. the need for standards to be based on risk analysis using the best available scientific evidence;
  - b. consistency between domestic and international food standards;
  - c. the desirability of an efficient and internationally competitive food industry; and
  - d. the promotion of fair trade in food.
- relevant New Zealand standards; and
- any other relevant matters.

The most recent version of the ANZFSC is available at the following site: <u>http://www.foodstandards.gov.au/code/Pages/default.aspx</u>.

#### Food Standards Australia New Zealand

FSANZ protects the health and safety of the people in Australia and New Zealand by maintaining a safe food supply. FSANZ is a bi-national independent statutory authority that develops food standards for composition, labeling, and contaminants, including microbiological limits, that apply to all foods produced domestically or imported for sale in Australia and New Zealand. FSANZ works in partnership with Australia's Commonwealth, State and Territory governments, and the New Zealand government.

In Australia, FSANZ develops food standards to cover the entire food supply chain from the paddock [field] to plate. These measures apply to the food manufacturing industry and primary producers.

FSANZ's responsibilities include:

- Developing standards for food manufacturing, labeling, processing, and primary production;
- Providing information to consumers to enable better consumer choice;
- Coordinating national food surveillance, enforcement, and food recalls;
- Conducting consumer and industry research;
- Undertaking dietary exposure modeling and scientific risk assessments; and
- Providing risk assessment advice on imported food.

The Australia and New Zealand Legislative and Governance Forum on Food Regulation develops policy guidance, which is then used by FSANZ to guide the development of standards for the Australia and New Zealand Food Standards Code. The Australian government, States and Territories, and the New Zealand government are represented by their Health Ministers on this Forum. Health ministers are joined by ministers from other relevant portfolios such as agriculture and consumer affairs, to ensure a whole-of-government approach to food safety regulation.

The Food Standards Code is adopted under the Food Acts of the respective Australian States and Territories, and New Zealand. The Food Standards Code is enforced through the various designated government agencies. It is a criminal offence in Australia to supply food that does not comply with the relevant food standard.

Foods available for sale in Australia and New Zealand must also comply with laws pertaining to trade practices and other food related matters such as environmental protection and the control of poisons.

Food standards can be varied through processes which start either by receipt of an application (which may be initiated by individuals, companies or bodies representing an industry or consumer group) or a proposal (initiated by FSANZ and usually covering more complex public health and safety issues). Manufacturers introducing a new food product, producing food using a new process or using a new additive should first check to see whether the ANZFSC already has suitable standards. Where it doesn't, FSANZ can be asked to develop a new standard or modify an existing measure. All applications are required to include certain minimum information as detailed in the *FSANZ Act* and in the <u>Application Handbook</u>.

Detailed information on the process of applications and proposals is available on the Information for Applicants page on the FSANZ web site at: <u>http://www.foodstandards.gov.au/code/changes/Pages/default.aspx</u>.

If you wish to apply for the development of a new standard or variation of an existing standard, FSANZ has a page on their website dealing with providing <u>pre-application assistance</u> relating to potential new applications.

In Australia, FSANZ also:

- Coordinates food product recalls in cooperation with the States and Territories;
- Conducts research on matters that may be included in a food standard;
- Undertakes food safety education initiatives in cooperation with the States and Territories;
- Develops Codes of Practice for industry on any matter that may be included in a food standard; and
- Develops risk assessment policies for foods imported into Australia.

FSANZ can be contacted at the following address:

Food Standards Australia New Zealand P.O. Box 5423 Kingston, ACT 2604 Australia Tel: +61 2 6271 2222 E-mail: info@foodstandards.gov.au Web: http://www.foodstandards.gov.au

# **Section II: Labeling Requirements**

<u>Food Standards Australia New Zealand</u> (FSANZ) has responsibility for the administration of the Australia New Zealand Food Standards Code (ANZFSC), which is subject to frequent amendments. The labeling requirements stated below are subject to change, so the ANZFSC should be consulted for definitive information on current food labeling requirements. The most up-to-date version of the ANZFSC is available on the FSANZ website at: <u>http://www.foodstandards.gov.au/code/Pages/default.aspx</u>.

<u>Chapter 1</u> of the ANZFSC covers the general standards that apply to all foods.

- Part 1.1 Preliminary (structure & definitions)
- Part 1.2 Labeling & Other Information Requirements
- Part 1.3 Substances Added to or Present in Food
- Part 1.4 Contaminants & Residues
- Part 1.5 Foods requiring pre-market clearance
- Part 1.6 Microbiological limits & processing requirements

<u>Chapter 2</u> contains standards for a number of specific commodity groups.

- Part 2.1 Cereals
- Part 2.2 Meat, Eggs & Fish
- Part 2.3 Fruit & Vegetables
- Part 2.4 Edible Oils
- Part 2.5 Dairy Products
- Part 2.6 Non-alcoholic Beverages
- Part 2.7 Alcoholic Beverages
- Part 2.8 Sugars & Honey
- Part 2.9 Special Purpose Foods
- Part 2.10 Standards for Other Foods (salt, vinegar, chewing gum & miscellaneous)

<u>Chapter 3</u> relates to food safety standards that apply to Australia only.

<u>Chapter 4</u> relates to primary production standards which also apply to Australia only.

There is also a <u>Schedules</u> section which contains all the schedules relating to the standards throughout the various chapters of the Code.

FSANZ has also developed <u>User Guides</u> for various parts of the ANZFSC to assist with interpretation and provide examples. These User Guides are not legally binding. Companies should seek legal advice if there are questions about the standards.

## **General Labeling Standard**

*There is a <u>User Guide</u> available which gives an overview for labeling of food for retail sale & for catering purposes.* 

<u>Part 1.2</u> of the ANZFSC sets out the application of general labeling and other information requirements, and labeling and information requirements specific to certain foods in Chapter 2 of the ANZFSC. This Part sets out the labeling requirements for food for sale and information that must be provided in conjunction with the sale of

certain foods, where labeling is not required. Food Product Standards in Chapter 2 may impose additional labeling and information requirements for specific classes of food.

Unless specifically exempted, the label on a package of food for retail sale or catering purposes must include the following core information:

- **Prescribed name** or where no name is prescribed, a name or a description of the food sufficient to indicate the true nature of the food;
- Lot identification;
- Name and business address in Australia or New Zealand of the supplier;
- Mandatory warning and advisory statements and declarations, specified in Standard 1.2.3 and any other warning and advisory statements specified elsewhere in the ANZFSC;
- Ingredient listing;
- Date marking;
- Nutrition information panel;
- Percentage labeling (characterizing ingredient/s and component/s);
- Directions for use or storage where, for reasons of public health and safety, consumers need appropriate directions for use or storage of the food; and
- **Country of Origin** must be stated on products made and sold in Australia, other than food products from New Zealand.

#### The Name of the Food

The label on a package of food must include:

- the prescribed name of the food, where the name is declared in the ANZFSC to be a prescribed name; and,
- in any other case, a name or a description of the food sufficient to indicate its true nature.

The name or description of the food should be sufficiently specific to differentiate it from other foods and reflect its true nature. There is no specific requirement as to where this information should appear on a label.

There are a few *prescribed names* in the ANZFSC. A prescribed name is a name by which a food is defined or described in a standard and is declared to be a prescribed name in that Standard. Examples include: honey; formulated supplementary food; and formulated supplementary food for young children.

In accordance with the food and fair trade laws, suppliers must not represent foods in a false, misleading or deceptive manner.

#### Lot Identification

Lot marking is required on packaged food to assist in the event of a food recall. A lot mark identifies the 'lot' a food comes from as well as the premises from where the food was packed or prepared. A date mark and address details can help satisfy the requirements of a lot mark.

There are some specific exemptions from lot identification. These exemptions cover:

- Individual portions of ice cream or ice confection; and
- Food in small packages when the bulk packages and the bulk container in which the food is stored or displayed for sale includes lot identification.

#### Name and Business Address of Supplier

The label on a package of food must include the name and business address of the food supplier in Australia. The term 'supplier' includes the packer, manufacturer, the vendor or importer of the food. Business address means a description of the location of the premises from which the business in question is being operated, but <u>does not include a postal address</u>.

Mandatory Warning & Advisory Statements and Declarations (Standard 1.2.3; Schedule 9)

There is a <u>User Guide</u> available for this Standard.

The ANZFSC requires that certain information be provided to consumers on labels on packaged food. This information may be in the form of a **warning statement**, which includes prescribed wording, an **advisory statement** or a specific **declaration**, depending on the degree of risk to the health and safety of consumers. Some of these statements and declarations are set out in general standards and some are set out in commodity standards. U.S. exporters should make certain that they understand the requirements and have all the required statements on their labels.

**Mandatory warning statements:** A warning statement is a prescribed labeling statement that must be expressed on the package label in the <u>exact</u> words and in the format specified in the ANZFSC. Warning Statements are defined in <u>Standard 1.1.1</u>.

A prescribed <u>warning statement</u> is required on:

• Royal jelly presented as a food and food containing royal jelly (<u>Standard 1.2.3</u>). This is the only mandatory warning statement which is applicable *across the food supply*.

Warning statements applicable to specific foods are for:

- Kava (<u>Standard 2.6.3</u>);
- Infant Formula Products (<u>Standard 2.9.1</u>);
- Infant foods (<u>Standard 2.9.2</u>);
- Formulated Supplementary Sports Foods (Standard 2.9.4); and
- Food for Special Medical Purposes (<u>Standard 2.9.5</u>).

**Mandatory advisory statements:** Mandatory advisory statements do not need to be expressed in the exact words set out in the ANZFSC. Manufacturers are able to use their own words for advisory statements as long as the words are to the effect of the statement in the ANZFSC.

Mandatory advisory statements are required on certain foods or when certain substances are present in foods. Standard 1.2.3 lists the foods required to bear mandatory advisory statements. Such statements must be 'set out legibly and prominently such as to afford a distinct contrast to the background' as required in Standard 1.2.9.

**Other prescribed statements** are required in standards throughout the Code. Please refer to the <u>User Guide</u> for guidance on which parts of the Code require other prescribed statements.

**Mandatory declarations** of certain substances in food: Certain substances, in the form of an ingredient, ingredient of a compound ingredient or component of a food additive or a processing aid or component of a processing aid, must be declared when present in a final food. This must be done as outlined in <u>Standard 1.2.3</u>. The requirement to declare certain substances may be satisfied by the declarations in the ingredient list.

#### Ingredient Listing (Standard 1.2.4)

#### There is a <u>User Guide</u> available for this standard.

Unless specifically exempted, packaged foods are required to list all the ingredients and compound ingredients used in the manufacture of that food. An ingredient means any substance, including food additives, used in the preparation of food. A compound ingredient means an ingredient of a food, which is itself made up of two or more ingredients, e.g. spaghetti, which is made up of flour, egg and water.

Ingredients and compound ingredients must be declared in a statement of ingredients in descending order of ingoing weight subject to limited exceptions. Ingredients must be declared in the statement of ingredients using the common name of the ingredient; or, a name that describes the true nature of the ingredient; or, where applicable, a generic name set out in Standard 1.2.4. It should be sufficiently detailed to describe the ingredient, and accurate to ensure they are not false, misleading or deceptive, or likely to mislead or deceive.

#### Date Marking (Standard 1.2.5)

#### There is a <u>User Guide</u> available for this standard.

Packaged food is generally required to be date-marked, usually in the form of a 'best-before' or 'use-by' date. Food with a 'best-before' date of two or more years is exempt from date marking (except for infant formula, which must be labelled with a date mark - see <u>Standard 2.9.1</u>). Additional exemptions, including those for small packages, are set out in <u>Standard 1.2.5</u>.

When, for health and safety reasons, a food should not be consumed after a certain date, a 'use-by' date is required. There is information in the User Guide to assist with deciding whether a product needs a 'use-by' or 'best-before' date.

There are also prescribed forms for date marks and dates, and requirements to include statements of specific storage conditions on labels of packaged food. Packaged food must not include a date marking system other than that prescribed by this Standard.

#### Nutrition Labeling (Standard 1.2.8)

#### There is a <u>User Guide</u> available for this standard.

Subject to specific exemptions, food required to bear a label *must* display a nutrition information panel setting out the energy, protein, fat, saturated fat, carbohydrate, sugars and sodium content of the food. A nutrition information panel must be set out in the prescribed format and must include the number of servings in the package and the average quantity of the food in a serving. This standard does not apply to infant formula (see <u>Standard 2.9.1</u> for specific nutrition labeling requirements for infant formula).

Additional nutrition labeling requirements generally apply if a specific <u>nutrition claim</u> is made (see Section VII below).

This Standard also lists exemptions from nutrition information requirements.

U.S. exporters should work closely with their importer to get the nutritional panel correct, as this is an area where problems often occur. *The U.S. style nutrition panel is not acceptable for the Australian market.* 

A Nutrition Panel Calculator is available to assist with calculating amounts for the Nutrition Panel.

Percentage labeling (characterizing ingredients and components) (Standard 1.2.10)

#### There is a <u>User Guide</u> available for this standard.

Foods that have a characterizing ingredient(s) and/or component(s) must be labeled with a percentage declaration of the characterizing ingredient or component. The percentage declaration is calculated on the weight of the characterizing ingredient or component. The percentage declaration may be an actual amount or a minimum amount, provided that a minimum declaration is clearly labeled. Placement of the declaration on the label is not prescribed.

#### Instructions for Use and Storage (Standard 1.2.6)

Mandatory date, use, and storage requirements are listed in Standard 1.2.6 to ensure public health and safety.

#### Country of Origin Labeling

All packaged and some unpackaged food sold in Australia must be accompanied by country of origin information. For packaged food, the information must be included on the label of the food. For unpackaged food, the information can be written on a sign nearby the food. Some unpackaged foods may also have labels such as a piece of fruit, which may have a sticker on it.

In July 2016 regulation of country of origin claims was moved out of the Food Standards Code to the <u>Australian</u> <u>Competition and Consumer Commission</u> (ACCC) under the <u>Competition and Consumer Act</u>, Australian Consumer Law (ACL). The transition period between the two pieces of legislation ended on June 30, 2018 so anyone selling or supplying food for retail sale in stores, markets, online or from vending machines is required to comply with the <u>Country of Origin Food Labelling Information Standard 2016</u> (the Standard). There is a <u>Country of Origin Food Labeling guide</u> available to assist businesses to comply with the standard.

U.S. suppliers should pay close attention to the requirements of the ACCC Standard to ensure they do not breach the principles of ACL.

### Weights and Measures Requirements

Package weight is governed under the administration and regulatory oversight of the <u>National Measurement</u> <u>Institute</u>. Please check this website for details on weights and measurements requirements.

Prepackaged products must be marked with:

- 1) the name and address of the person who packed the product in a clear, conspicuous and legible manner on the main display panel; and
- 2) a statement of the net measurement in a clear, conspicuous, and legible manner. The measurement must be declared in metric terms.

Pre-packed goods, including food, must be labeled with a mark that states the measurement of the package (weight, volume, length, area, or number). Measurement markings must:

- be clear, conspicuous, readily seen and easily read when the article is exposed for sale;
- appear on the main part of the package and close to any name or brand of the article to which it relates;

- be at least 2 millimeters (mm) from the limits of the package and separated by at least 2 mm in all directions from other graphic matter or copy; and
- be in <u>metric</u> measurement system and written in the English language.

### Labeling of Genetically Modified Foods (Standard 1.5.2)

Mandatory labeling of foods of agricultural biotechnology ('genetically modified') came into force in December 2001.

Under the Standard, food or ingredients that contain new genetic material or protein as a result of the genetic modification or have altered characteristics must be labeled. Some flavorings may also be labeled if they are in a concentration of more than 1 gram per kilogram (0.1 percent). Food additives and processing aids do not need to be labeled unless the introduced genetic material is present in the final food.

The words 'genetically modified' must be used in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list on packaged food. For unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.

Food prepared for immediate consumption – for example, in restaurants and take-outs – does not need to have genetically modified ingredients identified.

Claims about foods not produced using gene technology - for example, "GM-free", must be consistent with the provisions of the overarching consumer protection laws in the <u>Competition & Consumer Act</u> in Australia (see information below) and the Fair Trading Act in New Zealand, as well as food legislation in both countries.

## **Additional User Guides**

In addition to the User Guides mentioned throughout the sections of this report, Guides are also available for:

<u>Compendium of Microbiological Criteria for Food</u>: This guide explains information in Standard 1.6.1 and presents additional microbiological guideline criteria which are not mandatory.

Methods of Analysis for Foods: This guide will help analysts to choose appropriate methods of analysis for food when they are not specified in the Code.

<u>Generally Expected Levels (GELs) for Metal Contaminants</u>: This guide helps to identify a range of contaminant levels that would normally be expected in particular foods. The information should be read in conjunction to Standard 1.4.1

<u>Labeling of Alcoholic Beverages</u> This guide will help interpret the requirements of the Code as they relate to the labeling of alcoholic beverages.

## **Other Specific Labeling Requirements**

### **Competition & Consumer Act**

As mentioned throughout this report, the *Competition & Consumer Act 2010* should be taken into account as it pertains to false, misleading or deceptive conduct relating to labeling or advertising of food products. The Australian Competition and Consumer Commission (ACCC - <u>www.accc.gov.au</u>) is the body which administers

the Act. An overview of the legislation can be found at: <u>https://www.accc.gov.au/about-us/australian-competition-consumer-commission/legislation</u>

The ACCC produced a number of guides to assist those involved in the food industry to meet their obligations under the Trade Practices Act, which are still relevant under the new legislation (Competition and Consumer Act). These guides are:

- <u>Food Descriptors Guideline</u> provides a trade practices perspective on industry representations about food and beverage products. The guideline is to assist food and beverage businesses in understanding the law with examples of the types of claims businesses can and cannot make about their products.
- <u>Country of Origin Claims</u> this guide helps the food and beverage industry understand the provisions of the Act that relate to making country of origin representations. It contains information to help businesses and industry groups develop strategies to improve compliance with the Act.
- <u>Advertising and selling guide</u> this guide educates businesses on their legal rights and obligations in selling and promoting products and services; and explains how the Australian Consumer Law applies to their activities. The guide also includes tips for using social media, online reviews, and online purchases.

#### Advertising

Labeling rules also apply to advertising of the product whether print, audio or television advertisements.

It is an offence to label or to advertise food in a manner that is false, misleading or deceptive. This is spelled out in the State and Territory Food Acts and the Competition and Consumer Act of the Federal Government. See Advertising and Selling Guide above.

# **Section III: Packaging and Container Regulations**

## **Packaging Size**

There are no packaging or container size regulations for food products in Australia. Manufacturers may pack food in any size container.

The Australia New Zealand Food Standards Code (ANZFSC) does not regulate the manufacture of packaging materials. Consequently, the ANZFSC does not specify which materials may be added to or used to produce food packaging materials or any articles and materials in contact with food. It is the responsibility of food manufacturers and retailers to ensure that the products used in association with food are safe and that the food complies with the general requirements in the Australian and New Zealand Food Acts and with the specific requirements in the ANZFSC which relate to contaminants - <u>Standard 1.4.1</u>, Contaminants and natural toxicants.

## Legibility Requirements (Standard 1.2.1)

#### There is a <u>User Guide</u> available.

Any information required in or on a food label needs to comply with legibility requirements as set out in Standard 1.2.1. The ANZFSC requires that all food labels must present information so that it is:

- legible
- prominent (such as to afford a distinct contrast to the background), and
- in English.

This approach allows manufacturers flexibility in label presentation, but requires them to ensure that the information is clear and readily accessible to the consumer. Additional legibility requirements apply to warning statements. These are discussed below.

In order to be legible, information on food labels should be:

- **Indelible**—Printing that under normal conditions of use and storage fades, runs, or is rubbed off would no longer be legible or prominent would not comply with Standard 1.2.9.
- **Distinct**—Decorations and embellishments such as logos should not interfere with the legibility of the words on the label. Text printed on complex or pictorial or otherwise multicolored backgrounds is unlikely to be adequately legible in many cases.
- Easy to read—The use of all lower case or all capitals is not prescribed in the Code. However, statements in sentence or title case are usually easier to read than statements in upper case or in mixed case.

A minimum size of type is not required for most information required on food labels (except warning statements - see below). It is up to the manufacturer to determine which type size is best for such information, provided the label is legible.

National trade measurement laws control the measurement of pre-packed articles by <u>quantity</u>. The National Measurement Institute (NMI) web pages contain details of the requirements for businesses in relation to <u>pre-packaged goods</u>, including details of the position, size, etc., for where the measurement information must appear on a label. Other regulations may also be downloaded from the NMI <u>Measurement Legislation</u> page.

All the labeling information required by the ANZFSC must be in English. Information in other languages is permitted on a label of a package of food or in association with a display of food, so long as the information does not negate or contradict the information on the label in English.

#### Further legibility requirements for mandatory warning and other statements

**Warning statements:** Certain warning statements are required to be expressed on the label of packages of specific foods. The words for each warning statement are prescribed and **must** be written on the label using the text required under the ANZFSC. For most packages, each letter or numeral must be at least 3 mm in size when measured from the base to the top of the letter or numeral. Separate requirements apply to small packages. Manufacturers may choose the type and style of lettering of a warning statement, ensuring that the statement is legible and prominent so as to afford a distinct contrast to the background.

Advisory statements or mandatory declarations: The ANZFSC also requires information to be provided about certain foods and substances in the form of mandatory declarations or advisory statements. The Code does not prescribe exact wording or a minimum type size for these statements. Where such statements are required, manufacturers must comply only with the general legibility requirements of <u>Standard 1.2.1</u>.

#### Legibility requirements for mandatory warning statements on small packages

Because of their small size, small packages are permitted to have warning statements written in a minimum type size of 1.5 mm. A small package is a package with a surface area of less than 100<sup>cm2</sup>.

# **Section IV: Food Additives Regulations**

Unless expressly permitted in <u>Standard 1.3.1</u>, food additives must not be added to food.

A food additive may only be used where permitted by Standard 1.3.1 and only where it performs a technological function. The following criteria are guiding principles that FSANZ uses in assessing whether a food additive is listed in Standard 1.3.1 and therefore permitted for use in foods:

- it poses no unacceptable risk to health when used in amounts up to the specified permitted limits;
- there is a demonstrable need for the substance and it fulfils a technological function that benefits consumers; and
- it is used in food only up to the level that achieves the technological function, even if higher levels might pose no threat to health.

Food additives should always be used in accordance with Good Manufacturing Practice (GMP). Manufacturers are responsible for justifying the use of additives. The Codex Alimentarius Commissions Procedural Manual sets out the following relevant criteria for use in assessing compliance with GMP:

- the quantity of additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacture, processing or packaging of a food and which is not intended to accomplish any physical or other technical effect in the food itself, is reduced to the extent reasonably possible; and
- the additive is prepared and handled in the same way as a food ingredient.

For the purposes of ingredient labeling, food additives are treated the same as other ingredients in a food. <u>Schedule 7</u> of the Code lists class names for additives based on their technical function. <u>Schedule 8</u> of the Code lists all permitted additives by their prescribed name and code number. An additive must be declared in the ingredient list in its correct place by using its appropriate class name as identified in Schedule 7, followed by the additive's specific name or code number (from Schedule 8). One exception to this rule is that enzymes need only be declared by the class name "enzyme" and not by specifically declaring the name of the enzyme.

Where a food additive is capable of being classified in more than one class, the class name used must best reflect the function of the additive in the food. A food additive that cannot be classified in one of the classes specified in Schedule 7 must be declared by using its prescribed name from Schedule 8.

The technological purposes performed by substances used as food additives are listed in <u>Schedule 14</u> of the Code. Substances that may be used as food additives are set out in <u>Schedule 15</u>. <u>Schedule 16</u> lists the types of substances that may be used as food additives.

Special note should be taken for additives that are genetically modified. For more information on the declaration of genetically modified ingredients see Section V of this report on Labeling of Genetically Modified Foods.

# **Section V: Pesticides and Other Contaminants**

The Australian Pesticide & Veterinary Medicines Authority (APVMA) – <u>www.apvma.gov.au</u> - is the Australian government authority responsible for assessing and registering agricultural and veterinary chemicals in Australia; regulating such chemicals up to and including the point of retail sale; and establishing MRLs. The APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) in partnership with the States and Territories and with the involvement of other Australian government agencies.

MRLs are listed in the Food Standards Code and apply to both imported and domestic food. FSANZ's role is to protect public health and safety by ensuring consumption of agricultural and veterinary chemical residues in food is within appropriate safety limits. FSANZ has overall responsibility to assess dietary exposure to residues in the diet as part of the MRL setting process.

In addition, FSANZ is responsible for addressing anomalies between the Food Standards Code and international standards that may result in adverse trade impacts. To do this, FSANZ raises an annual <u>Proposal</u> to consider requests for harmonization of Australian MRLs with international standards. There are no fees or charges associated with the requests considered under these annual Proposals. FSANZ aims to complete MRL proposals within nine months, but there is no guarantee that this will occur as there are no statutory time limit on Proposals. An organization, company or individual may also submit their own <u>Application</u> to FSANZ for a MRL variation. FSANZ may charge for the assessment of such applications, but statutory time limits would apply and an assessment would be completed within six to nine months. In its assessment, FSANZ will consider dietary exposure to the particular agricultural and veterinary chemicals in the context of the Australian diet.

All MRLs (those set by either APVMA or FSANZ) must be adopted into the Food Standards Code before they are considered in effect. If a MRL is not listed in the Food Standards Code, then the tolerance is zero.

<u>Standard 1.4.2</u> (AgVet Chemicals), <u>Schedule 20</u> (maximum residue limits), and <u>Schedule 21</u> (extraneous residue limits) establish the maximum permissible limits for agricultural and veterinary chemical residues present in food. Schedule 20 lists all of the agricultural and veterinary chemical limits in particular foods. If a maximum residue limit for an agricultural or veterinary chemical in a food is not listed in Schedule 20, there must be no detectable residues of that agricultural or veterinary chemical in that food. Schedule 21 lists all extraneous agricultural chemical limits in particular foods. If an extraneous residue limit for an agricultural chemical in a food is not listed in Schedule 21, there must be no detectable residues of that agricultural chemical in that food. Schedule 21, there must be no detectable residues of that agricultural chemical in that food. Schedule 22 sets out the foods and classes of foods to which the maximum or extraneous residue limit refers.

*Maximum residue limits are constantly being reviewed and updated.* New Zealand has its own standards for chemical residues and <u>Standard 1.4.2 does not apply in New Zealand</u>. It should also be noted that Australia does not automatically default to CODEX MRLs if a tolerance is not listed in the Food Standards Code.

# Section VI: Other Requirements, Regulations, and Registration Measures

## **Facility and Product Registration Requirements**

Eligible meat or poultry products must originate from Australian-approved establishments. Details of eligible products and establishments are available in the Food Safety and Inspection Service <u>Export Library</u>.

Other food processing facilities do not require registration to be eligible to export to Australia. There are, however, strict quarantine requirements for many products. The Department of Agriculture, Water and the Environment maintains an online searchable database of these requirements called <u>BICON</u> (Biosecurity Import Conditions). Examples of some product-specific export certification requirements are available in the FAIRS Export Certification report for Australia. This report can be downloaded from the FAS reports website at: <u>https://gain.fas.usda.gov/#/</u>. Search in the Food and Agriculture Import Regulations and Standards Report category.

### **Testing Requirements**

Imported food is inspected based on two inspection categories. These categories determine the frequency with which the food will be inspected and the appropriate testing regime. The categories are: (1) risk, and (2) surveillance. These food inspection categories are regularly reviewed by FSANZ.

**Risk category food:** FSANZ categorizes food as 'risk' if it has the potential to pose a medium to high risk to public health. Risk food is referred to DAWE Biosecurity by the Department of Home Affairs and has a 100 percent inspection rate.

Risk food is tested against a published list of potential hazards—including micro-organisms and contaminants. Once five consecutive consignments have passed inspection, the inspection rate is reduced to 25 percent; after a further 20 consecutive passes, the inspection rate is reduced to five percent.

Risk foods are subject to 'test and hold' and are not released for sale until test results are known. Consignments of risk food which fail inspection and do not meet Australian standards cannot be imported. These foods must be brought into compliance otherwise the food will be re-exported or destroyed.

If a consignment fails, it will then be subjected to 100 percent testing until a history of compliance is reestablished for the producer of the food.

The list of risk-categorized foods is subject to change at any time and DAWE may inspect and analyze other foods which it believes may not comply with the requirements of the ANZFSC. The latest DAWE Imported Food Notices, which includes the latest notice relating to the tests applied to risk category foods, are available at: <a href="http://www.agriculture.gov.au/import/goods/food/inspection-compliance/risk-food">http://www.agriculture.gov.au/import/goods/food/inspection-compliance/risk-food</a>.

**Surveillance category food:** All other foods considered to pose a low risk to human health and safety and are classified as 'surveillance food.' Each consignment of surveillance food has a five percent chance of being referred for inspection.

The selection of surveillance food consignments is random and the referral of those consignments is done using electronic profiles in the Department of Immigration and Border Protection's Integrated Cargo System. Information such as the importer, producer or the country of origin of the goods does not affect the random selection and referral of a surveillance food.

Samples of surveillance food may be analyzed for pesticides, antibiotics, microbiological contaminants, natural toxicants, metal contaminants, and food additives.

As surveillance foods are considered low risk, they are subject to a 'test and release' direction and can be distributed for sale before test results have been received.

If there are adverse test results, the relevant state or territory food regulatory authority is advised so it can determine if a recall is required. Any expenses resulting from a recall or withdrawal involving imported goods will be borne by the importer.

Surveillance food that fails inspection is subject 100 percent testing until a history of compliance is established. The process for increasing inspection of surveillance food is referred to as applying a 'holding order.' A holding order remains in place until favorable test results are received. Following five consecutive passes the rate of referral returns to five percent of consignments.

The latest Department of Agriculture, Water and the Environment Imported Food Notices are available at: <u>http://www.agriculture.gov.au/import/goods/food/inspection-compliance/tests-applied-to-surveillance-category-foods</u>.

## **Holding Orders**

In the event of a risk or surveillance food not complying with the ANZFSC, a Holding Order may be issued. A Holding Order effectively means that the inspection category of the food has been raised to "risk" status. This means that **all** future shipments of that food from the offending supplier will be automatically detained and held until compliance with Australia's requirements is confirmed. After five clear inspections, the food reverts back to its prior surveillance category. Further details on the Holding Order process are available at: <a href="http://www.agriculture.gov.au/import/goods/food/inspection-compliance/what-happens-if-my-food-fails-inspection">http://www.agriculture.gov.au/import/goods/food/inspection-compliance/what-happens-if-my-food-fails-inspection.</a>

## Quarantine

When any food is imported into Australia it must first comply with quarantine requirements.

Australia has strictly controlled import conditions that require various treatments (e.g., fumigation, time/temperature controls) that must be supported by import permits and attestations on export certificates from authorities in the country of origin. <u>Examples</u> of products for which Australia requires attestations from authorities in the country of origin are:

- chicken meat and chicken meat products;
- pork and pork products;
- beef and beef products;
- egg and egg products;
- fresh fruits and vegetables;
- dairy products; and
- salmon (fresh)

All of these products are either not permitted or are permitted under strict conditions.

U.S. exporters need to determine exactly what restrictions exist on the foods they wish to export to Australia. In some cases, a prohibition exists simply because an import risk analysis from which appropriate control measures can be determined has not been requested. In this case, import would not be permitted until an import risk analysis has been undertaken.

The Australian government has a formal mechanism in place for evaluating the degree of risk associated with the importation of certain products or produce from foreign countries. The evaluation procedure involves other governments, industry groups, academia, and consumers. The evaluation is often a protracted exercise and can take some years to complete, particularly for foods that are unprocessed or only partially processed as these are perceived to represent the greatest danger of carrying pests and diseases into Australia.

DAWE maintains a searchable Biosecurity Import Conditions Database for agricultural products entering Australia (known as BICON) at the following site: <u>http://www.agriculture.gov.au/import/bicon</u>.

# Section VII: Other Specific Standards

## **Specific Commodity Standards**

<u>Chapter 2</u> of the ANZFSC contains standards for a number of specific commodity groups. These are:

- Part 2.1 Cereals
- Part 2.2 Meat, Eggs & Fish
- Part 2.3 Fruit & Vegetables
- Part 2.4 Edible Oils
- Part 2.5 Dairy Products
- Part 2.6 Non-alcoholic beverages
- Part 2.7 Alcoholic Beverages
- Part 2.8 Sugars & Honey
- Part 2.9 Special Purpose Foods
- Part 2.10 Standards for other Foods

## Nutrition Claims (Standard 1.2.8)

#### There is a <u>User Guide</u> available for this standard.

Where a nutrition claim is made, the Nutrition Information Panel must be provided and must include energy, protein, fat, saturated fat, carbohydrate, sugars, and sodium. The Panel must also include any claimed nutrient or biologically active substance, or any other nutrients that may be triggered.

Information regarding the type of nutrition claims that can and cannot be made, as well as examples of Nutritional Information Panels for each type of claim, is contained in the <u>User Guide</u> to <u>Standard 1.2.8</u>. There is also an additional guide on <u>Getting Your Claims Right</u>, which applies to both nutrition and health claims.

A <u>Nutrition Panel Calculator</u> is also available to assist in calculating mandatory nutrition information for the panels.

## Permitted Health Claims (Standard 1.2.7)

#### *There is a <u>User Guide</u> available for this standard.*

In January 2013 a standard governing nutrition content claims and health claims on food labels and in advertising became law in Australia and New Zealand. <u>Standard 1.2.7</u> – Nutrition, Health and Related Claims gives consumers confidence about the nutrition content and health benefits on food labels and in advertising. These claims should be supported by scientific evidence. These standards aim to:

- reduce the risk of misleading and deceptive claims about food;
- expand the range of permitted health claims;
- encourage industry to innovate, giving consumers a wider range of healthy food choices; and
- provide clarity for the jurisdictions enforcing the Standard.

Health claims must be based on food-health relationships that have been substantiated according to <u>Standard 1.2.7</u> and associated schedules 4, <u>5</u> and <u>6</u>. See FSANZ <u>Nutrition, health and related claims web page</u> for full details. **Nutrition content claims** are claims about the presence and the amount of certain nutrients or substances in a food, such as 'low in fat' or 'good source of calcium.' These claims need to meet certain criteria set out in the

Standard. For example, any food that carries 'a good source of calcium' claim will need to contain more than the amount of calcium which is specified in the Standard.

Health claims refer to a relationship between a food and health rather than a statement of content. There are two types of health claims:

- **General level health claims** refer to a nutrient or substance in a food and its effect on a health function. Under the standard, health claims must not refer to a serious disease or to a biomarker of a serious disease. For example: *'calcium is good for bones and teeth'* is an example of an acceptable general level claim under the new standard.
- **High level health claims** refer to a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. For example: *Diets high in calcium may reduce the risk of osteoporosis in people 65 years and over*. An example of a biomarker health claim is: *Phytosterols may reduce blood cholesterol*.

Food businesses wanting to make **general level health claims** are able to base their claims on one of the more than 200 pre-approved food-health relationships in the Standard or self-substantiate a food-health relationship in accordance with detailed requirements set out in the Standard. Read more about the <u>notification process</u>. <u>Guidance is available</u> on establishing food-health relationships for general level health claims.

**High level health claims** must be based on a food-health relationship pre-approved by FSANZ. Pre-approved food-health relationships for high level health claims are listed in the <u>Schedule 4</u> of the Standard.

All health claims are required to be supported by scientific evidence to the same degree of certainty, whether they are pre-approved by FSANZ or self-substantiated by food businesses. Food-health relationships derived from health claims approved in the European Union, Canada, and the United States have been considered for inclusion in the Standard.

Health claims will only be permitted on foods that meet the nutrient profiling scoring criterion (NPSC) set out in the standard. For example, health claims will not be allowed on foods high in saturated fat, sugar or salt. Food businesses will be required to ensure its products meet a certain nutrient profiling score in order to make a health claim. An <u>online calculator</u> is available to help food businesses determine a food's nutrient profiling score.

**Endorsements** that are nutrition content claims or health claims will be permitted provided the endorsing body meets requirements set out in the Standard.

## **Fortification of Food with Vitamins & Minerals**

<u>Standard 1.3.2</u> limits the claims that can be made about the vitamin and mineral content of foods. <u>Standard 1.2.7</u> relates to the claims that can be made about nutrition content, including the presence of vitamins and minerals in food. There are also provisions in other standards that affect claims about specific foods. See for example:

- <u>Standard 2.1.1</u> cereal and cereal products;
- <u>Standard 2.4.2</u> edible oil spreads;
- <u>Standard 2.9.1</u> infant formula products;
- <u>Standard 2.9.2</u> food for infants;
- <u>Standard 2.9.3</u> formulated meal replacements and formulated supplementary foods;
- <u>Standard 2.9.4</u> formulated supplementary sports foods; and
- <u>Standard 2.9.5</u> food for special medical purposes.

## Words and Expressions

The use of certain words and expressions are restricted. Words such as polyunsaturated, pure, natural, organic, low alcohol, non-alcoholic, health vitamin enriched, etc., are restricted and guidance should be sought from the relevant product standard and from the ACCC guidelines mentioned elsewhere in this report.

### **Pictures and Designs**

Manufacturers should ensure that their pictorial representations do not give a misleading overall impression about their products.

Pictures or designs may be prohibited on certain foods and manufacturers and importers should familiarize themselves with the restrictions in the ANZFSC. The Australian Competition & Consumer Commission (ACCC) <u>Food Descriptors Guideline</u> also provides some guidance on the acceptable use of pictures and designs as they relate to the Competition & Consumer Act.

## **Foods Requiring Pre-Market Clearance**

#### Novel Foods (Standard 1.5.1)

This Standard regulates the sale of novel food and novel food ingredients. This Standard prohibits the sale of these foods unless they are listed in the <u>Schedule 25</u> of the Code. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, warning statements or other advice, or the need to meet specific requirements of composition or purity.

FSANZ will assess the safety of the novel food for human consumption prior to its inclusion in Schedule 25. The safety assessment will be performed in accordance with the Authority's safety assessment guidelines.

Novel food includes novel foods used as ingredients in another food. Categories of novel foods may include, but are not limited to plants or animals and their components; plant or animal extracts; herbs, including extracts; dietary macro-components; single chemical entities; micro-organisms, including probiotics; foods produced from new sources, or by a process not previously applied to food.

Information regarding applying for approval for a novel food is available in Section 3.5.2 of the FSANZ Application Handbook.

#### Genetically Modified Foods (Standard 1.5.2)

Section 1.5.2-3 addresses when a food produced using gene technology is subsequently permitted for sale. The Standard prohibits the sale and use of these foods unless they are included in Section S26-3 of <u>Schedule 26</u>.

Additives and processing aids which are produced using gene technology are not regulated this Standard. Other Standards in the Code regulate additives and processing aids and require pre-market approval for these substances.

Section 1.5.2-4 specifies labeling and other information requirements for foods, including food additives and processing aids, produced using gene technology.

Information for those wishing to apply to FSANZ to introduce a new food produced using gene technology as provided for in the ANZFSC is available on the <u>Standards Development</u> page of the FSANZ web site and/or Section 3.5.1 of the <u>Applications Handbook</u>.

#### Irradiated Food (Standard 1.5.3)

This Standard prohibits the irradiation of food or ingredients or components of food, unless specific permission is given. FSANZ provides permission to sell irradiated foods, but may impose conditions relating to matters such as dose, packaging materials, approved premises or facilities.

Food to be processed by irradiation, and the packages and packing materials used or intended for use in connection with this technology should be of suitable quality and in an acceptable hygienic condition appropriate for the purpose of such processing.

The operation of irradiation facilities and control of the irradiation process should be undertaken in accordance with any relevant State, and Territory, and New Zealand law governing radiation control. They should also be undertaken in accordance with an appropriate Code of Practice such as the 1983 Codex Alimentarius General Standard for Irradiated Foods and its associated Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods.

This Standard also sets out permitted sources of radiation, requires the keeping of certain records in relation to the irradiation of food, and the labeling of food which has been irradiated.

Information regarding applying for approval for irradiated food is available in Section 3.5.3 of the FSANZ Application Handbook.

## **Trade Samples**

The amounts of food that may be imported as trade samples for the purposes of scientific or commercial evaluation are:

- For foods in liquid form, up to 20 liters;
- For foods not in liquid form, up to 20 kilograms;
- For <u>concentrated liquid foods</u> (however packed), that are used in the preparation of other foods or are not usually consumed unless as part of a prepared food, not more than 2 liters;
- For <u>moisture reduced foods</u> (however packed), other than liquid foods, that are used in the preparation of other foods or are not usually consumed unless as part of a prepared food, not more than 2 kilograms net weight;
- For <u>spices</u> (however packed) that are used in the preparation of other foods or are not usually consumed unless as part of a prepared food, not more than 1 kilogram.

#### Note:

- Food imported as trade samples must not be consumed by any person.
- Trade samples are not exempt from quarantine requirements i.e., if a product requires an import permit for commercial shipments, then it will require a permit for samples.

## Front-of-Pack Health Star Rating System (voluntary)

After several years of discussion by Federal and State ministers about a Front-of-Pack label format, the Australian government introduced a voluntary Health Star Ratings (HSR) front-of-pack labelling system in June 2014.

Although <u>Standard 1.2.8</u> of the Australia New Zealand Food Standards Code (Code) already requires most packaged foods to display a Nutritional Information Panel (NIP) which, at a minimum, must feature most of these key food components for average quantity per serve and per 100 grams, the HSR system provides such information in interpretative form on the front of food products.

The HSR system was introduced in June 2014 on a voluntary basis for five years. The HSR system is a star rating system based on a product's nutritional value, which has been developed to help consumers understand a product's nutritional information and food labeling more generally to enable them to make better informed food choices. The system rates food products on a 1 to 5 star scale (with  $\frac{1}{2}$  star increments) based on four aspects of food associated with increasing risk factors for chronic disease – energy, saturated fat, sodium, and total sugar – as well as positive aspects, namely protein, dietary fiber, fruit, vegetables, nuts and legumes and, for some products, calcium. The overall rating of the product is determined based on an algorithm that awards stars according to the quantity of these components within the product – i.e. the more stars, the healthier the food. The Health Star Rating System website has available information on applying Health Star Ratings to products including a Guide for Industry; a Health Star Rating Calculator; a Style Guide; information on the process for assessing potential anomalies; and information on the dispute resolution process.

# Section VIII: Trademarks, Brand Names and Intellectual Property Rights

Australian law protects patents, trademarks, and copyrights. Australia is a member of the World Intellectual Property Organization, the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the Universal Copyright Convention, the Patent Cooperation Treaty, the Trans-Tasman Mutual Recognition Agreement for the Patent Attorney Profession, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, the Strasbourg Agreement Concerning the International Patent Classification, Nice Agreement for the International Classification of Goods and Services for the Purposes of the Registration of Marks, and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights.

IP Australia is the federal agency responsible for registrations of patents, trademarks and designs. IP Australia incorporates the Patent, Trade Mark and Designs Offices, which administer the *Patents Act 1990*, the *Trade Marks Act 1995*, the *Designs Act 1906* and associated regulations as well as the *Olympic Insignia Protection Act 1987* and the *Scout Association Act 1924*. More information and links to the legislation are available on the IP Australia web site.

**Patents:** Patents are available for inventions in all fields of technology and are the principle system for protecting ownership of any device, substance, and method of process that is new or inventive and they are protected under the *Patents Act, 1990*. There are two types of patents in Australia: a <u>standard patent</u> giving long-term protection and control over an invention for up to 20 years; and, an <u>innovation patent</u> - a relatively fast, inexpensive protection option, lasting a maximum of 8 years. Biotechnological methods of breeding and biotechnologically produced plants and animal products are protectable under the Patents Act (s.18). Further information is available on the <u>Patents</u> page of the IP Australia Website.

**Trademarks:** Trademarks may be protected for ten years and renewed indefinitely upon request by registration under the *Trademarks Act, 1995.* U.S. exporters intending to market a product in Australia should consider checking with the trademarks office at IP Australia to ensure that its mark or name is not already in use. Further information is available on the <u>Trademarks</u> page of the IP Australia Website.

**Designs:** A new or original design may be registered for up to ten years maximum (in five-year increments). Registration gives the owner the exclusive rights to make, use, and sell articles incorporating the registered design. Further information is available on the <u>Designs</u> page of the IP Australia Website.

**Copyrights:** Copyrights are protected under the *Copyright Act 1968*. The Attorney-General's Department administers the legislation for automatic rights to copyright and circuit layout rights. Further information is available on the <u>Copyright</u> page of the IP Australia website and from the <u>Australian Copyright Council</u>.

# **Section IX: Import Procedures**

There is no pre-market approval of either the composition or labeling of any food in Australia. Imported food must comply with all aspects of the Food Standards Code at the point of entry into Australia. DAWE performs random inspections on any food imported. High-risk foods can be targeted for inspection at a higher frequency.

All goods imported into Australia must be cleared by Customs, whether they are imported by air, sea or mail. While imports of low value will generally be released by Customs for delivery direct to consignees, importers are responsible for obtaining a formal Customs clearance for consignments of goods above set value limits (currently A\$1000).

Cost recovery charges apply for the processing of entries. The cost will depend on whether the entry is an electronic entry or a documentary (manual) entry.

The minimum documentation required to be submitted with customs import entries or informal clearance documents includes an airway bill or bill of lading, invoices, and any other papers (including packing lists, insurance documents, import permits, etc.) relating to the shipment.

Importers are required to ensure that goods entering the commerce of Australia are correctly marked. Customs administers truth in labeling provisions that makes it an offence to knowingly apply or for imported goods to carry false trade descriptions.

Customs import entry procedures are based on self-assessment by importers who should be aware of all their obligations. Penalties may be imposed for the submission of incorrect or misleading information or for the omission of information to mislead. Therefore, while it is not a requirement, it is recommended that importers use the services of a customs broker to complete customs import entries and related clearance formalities. Brokers specialize in the clearance of imported goods and are licensed by the Australian Customs Service.

More information on importing goods into Australia is available from the Australian Border Force - <u>https://www.abf.gov.au/importing-exporting-and-manufacturing/importing/how-to-import</u>.

#### Note: The use of local agent representation is highly recommended.

### **Imported Food Inspection Scheme**

The following information deals with both public health and quarantine (i.e., animal & plant health) requirements for imported foods. The requirements for each are quite different, but the import clearance of foods is the responsibility of the <u>Department of Agriculture</u>, <u>Water and the Environment</u> (DAWE) and is coordinated under the <u>Imported Food Inspection Scheme (IFIS)</u>.

All food imported into Australia must first comply with quarantine requirements stipulated in the <u>Biosecurity Act</u> <u>2015</u> and then the <u>Imported Food Control Act 1992</u> and the <u>Imported Food Control Amendment Act 2018</u>. A release issued after the <u>quarantine</u> inspection is **NOT** a clearance from the IFIS inspection.

All incoming food shipments must be declared to the Australian Border Force using the international harmonized tariff schedule. DAWE Biosecurity has a direct link to the DIBP computer network and is able to place impediments on imported foods that require clearance.

Importers of targeted foods are obliged to go to DAWE Biosecurity to secure the release of the goods. With riskcategory foods, the criterion for the release of goods and whether the food needs to be inspected or not is based on the compliance history of the producer.

DAWE Biosecurity maintains its own computer network linking inspectors in all States and Territories. The system holds records of the inspection status of all overseas suppliers of risk foods. This network allows inspectors to be notified as to whether an inspection for a particular shipment is required.

While the focus of the IFIS is on food safety, imported foods must comply with all requirements of the ANZFSC. It is the legal responsibility of the importer to ensure they do so. *U.S. exporters should not assume that because their products are accepted in other markets that they will be automatically accepted in Australia*. Often the Australian standards differ in such areas as the description of the product; its composition; the use of preservatives, and if colorings and additives are permitted.

DAWE Biosecurity inspectors check the food against the requirements of the ANZFSC. Inspectors examine all referred foods for labeling compliance and perform visual inspections. The visual inspection involves, where necessary, opening the packages and examining the food for contamination and defects.

Inspectors will ensure that the label:

- is in English;
- has an accurate trade description;
- has manufacturer/importer details;
- has declared Country of Origin;
- has batch/lot codes;
- has date marking (in the correct format);
- has net weight contents; and
- has a statement of ingredients (where appropriate).

DAWE Biosecurity has a managed process whereby importers are given the opportunity to check that it's in compliance with ANZFSC labeling requirements and, if necessary, make corrections to the labels prior to arranging an IFIS inspection. Importers must ensure that the consignment has cleared quarantine <u>before</u> undertaking any IFIS examination.

Rather than reject foods for import entry, DAWE Biosecurity will allow corrective action to be taken for significant breaches. Minor defects will generally be cleared, with an understanding that the importer will make the necessary changes to correct specified problem(s). Repeated failures could result in a Holding Order being issued (see below for details).

At the time of the inspection, the DAWE Biosecurity inspector may take samples for laboratory analysis to determine the food's microbiological status, levels of any pesticide residues, the correct use of additives, and the food's composition.

It is the importer's responsibility to ensure that the foods they import comply with the requirements of the ANZFSC. The ANZFSC requirements can be complex and if U.S. exporters are not sure if their foods will comply, they should check with their importer or seek legal advice from a consultant or food lawyer. *Having a food assessed prior to importation reduces the risk of any unnecessary delays and additional expenses if the food product is found not to be compliant.* 

If U.S. exporters are unsure about which quarantine prohibitions or restrictions may apply to their product, they are encouraged to contact DAWE Biosecurity prior to shipment - <u>http://www.agriculture.gov.au/general-inquiries?query=imports</u>.

The IFIS is jointly run by the DAWE Biosecurity and FSANZ. FSANZ advises on food risk assessment policy and DAWE Biosecurity having operational responsibility for inspection and sampling.

Authorized DAWE Biosecurity officers carry out food inspections. The standards applied are those set down in the ANZFSC and these same standards apply to foods manufactured in Australia.

# Section X: Trade Facilitation

## **Food Safety Recognition Agreements**

Under the Imported Food Control Regulations 1993, DAWE can lower the rate that food is inspected if there is a Food Safety Recognition Agreement in place. These agreements set out the food that is covered and not covered under the agreement. They may cover risk food and/or surveillance food. The purpose of a food safety recognition agreement is to reduce the rate of import inspection and analysis of a food covered by the agreement, on the basis that the food has been produced under an equivalent food safety system in the exporting country. These agreements do not cover biosecurity certification requirements for any food imported into Australia or Bovine Spongiform Encephalopathy (BSE) certification requirements.

In 2017, DAWE signed the first Food Safety Recognition Agreement with the U.S. Food and Drug Administration (FDA) with both countries recognizing each other's food safety systems as comparable/equivalent to each other.

Foods covered by this agreement include: canned food (except those containing beef); most seafood; most dairy products; fresh fruit and vegetables; fruit juices; confectionery; and, baked goods.

Foods NOT covered include: meat (except game meat); poultry; processed egg products; raw bivalve molluscan shellfish; raw milk cheese; and, dietary supplements and natural health products.

## **Government-to-Government Certification Arrangements**

DAWE Biosecurity has agreements with other countries regarding certifications. Before recognizing any certification issued by other authorities, DAWE Biosecurity must be satisfied that there is a system in place that is monitored by the relevant authorities and that they ensure that foods will comply with Australian requirements.

Foods accompanied by certificates from approved agencies are quickly cleared by IFIS, assuming quarantine requirements are met. Minimum fees apply to foods cleared under certification. Random audits and analyses are conducted on certified shipments.

If something is later found to be wrong with a food certified by a DAWE approved overseas authority, DAWE resolves the problem with the certifying agency without taking action against the importer or the supplier. The approved foreign country authority is required to resolve the problem, and if problems continue DAWE may suspend the arrangement.

Information on the current foreign government certification arrangements can be found at: <u>http://www.agriculture.gov.au/import/goods/food/inspection-compliance/foreign-government-certification</u>.

## **Food Import Compliance Agreements**

Since February 2010 Australian food *importers* have been able to enter into a Food Import Compliance Agreement (FICA) with DAWE Biosecurity under the *Imported Food Control Act 1992*.

FICAs offer food importers an alternative regulatory arrangement to inspection and testing of their products under the imported food inspection scheme (IFIS).

All food imported under a FICA will continue to be subject to quarantine import restrictions in accordance with the *Biosecurity Act 2015* and its subordinate legislation. Further information on FICAs is available at: <a href="http://www.agriculture.gov.au/import/goods/food/inspection-compliance/food-import-compliance-agreements-fica">http://www.agriculture.gov.au/import/goods/food/inspection-compliance/food-import-compliance-agreements-fica</a>.

## **Approved Arrangements**

<u>Approved Arrangements</u> are voluntary arrangements entered into with the Department of Agriculture, Water and the Environment. These arrangements allow *importers* to manage biosecurity risks and/or perform the documentary assessment of goods in accordance with departmental requirements, using their own sites, facilities, equipment and people, and without constant supervision by the department and with occasional compliance monitoring or auditing.

An approved arrangement can cover all biosecurity activities involving the physical handling of goods at one or more approved arrangement sites. An approved arrangement can also cover biosecurity activities that do not involve the physical handling of goods, such as documentary assessment for goods subject to biosecurity control by accredited persons or performing disinfection treatments on aircraft. Both physical and non-physical biosecurity activities can be grouped together under the same approved arrangement.

## **Compliance Based Intervention Scheme**

The DAWE runs a <u>Compliance-Based Intervention Scheme</u> (CBIS) for the importation of selected plant products to Australia. The scheme rewards importers of these products who demonstrate consistent compliance with Australia's biosecurity requirements with risk-based inspection rates. Compliant importers benefit from the CBIS through smoother clearance of goods at the border and reduced regulatory costs.

# **Appendix I: Government Regulatory Agency Contacts**

Local government authorities that have responsibility for administering and evaluating imported products include:

Department of Agriculture, Water and the Environment, Imported Food Program http://www.agriculture.gov.au/import/goods/food

Food Standards Australia New Zealand http://www.foodstandards.gov.au

Australian Border Force <u>https://www.abf.gov.au/</u>

Office of the Gene Technology Regulator http://www.ogtr.gov.au

IP Australia http://www.ipaustralia.gov.au

Australian Department of Health <u>http://www.health.gov.au</u>

### **SPS & TBT Contacts**

Each member government is responsible for the notification procedures associated with agreement under the World Trade Organization (WTO). Examples here relate to the Sanitary and Phytosanitary Agreement (SPS) and Technical Barriers to Trade (TBT) Agreement. WTO obligations include notifying any trade significant proposals that are not substantially the same as international standards to the WTO; providing copies of the proposed regulation upon request; allowing time for comments; and also to provide upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on the country's regulations, standards, and certification procedures can also be obtained through the Enquiry Point(s) listed below:

Australian SPS contact point Trade and Market Access Division Department of Agriculture, Water and the Environment E-mail: <u>sps.contact@agriculture.gov.au</u>

TBT Enquiry Point Office of Trade Negotiations Department of Foreign Affairs & Trade E-mail: <u>tbt.enquiry@dfat.gov.au</u>

# **Appendix II: Other Import Specialist Contacts**

Office of Agricultural Affairs U.S. Embassy Moonah Place Yarralumla, ACT 2600 Australia Tel: +61 2 6214 5854 E-Mail: <u>AgCanberra@fas.usda.gov</u>

Food & Beverage Importers Association E-mail: <u>info@fbia.org.au</u> Web: <u>http://www.fbia.org.au</u>

American Chamber of Commerce in Australia

Tel: +61 2 8031 9000

E-mail: <u>nsw@amcham.com.au</u>

Web: <u>http://www.amcham.com.au</u>

#### Attachments:

No Attachments