# Imported Food Control Order 2019: Proposed changes to the food safety requirements for dates, enoki mushrooms, melons, pufferfish and kava

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We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment, and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

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## Summary

Food Standards Australia New Zealand (FSANZ) has published [new risk advice](https://www.foodstandards.gov.au/consumer/importedfoods/Pages/default.aspx) for imported dates, enoki mushrooms, melons and pufferfish. These foods have the potential to pose a medium to high risk to public health for one or more foodborne pathogens.

In response, the Australian Government Department of Agriculture, Fisheries and Forestry is proposing new food safety risk management measures for the importation of these foods. Legislative amendments are also proposed for kava to align with definitions in the Australia New Zealand Food Standards Code.

This paper provides detail on the upcoming new requirements and invites comments on the proposed changes. A summary of proposed changes is in (Table 1).

Table 1 Proposed changes to food safety requirements and implementation timing

| Food | Proposed new requirement | Implementation |
| --- | --- | --- |
| [Proposal for dates](#_Imported_Food_Inspection_1): classify fresh dates that are ready-to-eat (RTE) as a risk food | Imports of this food will need a valid mandatory food safety management certificate (FSMC). A food safety management system will provide assurance of effective foodborne pathogen management. | Commence new requirements 12 months after amendment to the Order. |
| [Proposal for enoki mushrooms](#_Proposal_for_enoki): classify fresh enoki mushrooms as a risk food | Assessment for clear and adequate storage and cooking instructions will continue. Inspection and analytical testing for Listeria monocytogenes will provide assurance the pathogen is not present. Detection of the pathogen in any sample is not permitted. | Commence on registration of the amendment to the Order. |
| [Proposal for melons](#_Toc160010529): classify melons that are whole or RTE cut and are fresh or frozen as a risk food. | Imports of this food will need a valid mandatory food safety management certificate (FSMC). A food safety management system will provide assurance of effective foodborne pathogen management. Verification testing for Listeria monocytogenes and Salmonella spp. to RTE cut melon. | Commence new requirements 12 months after amendment to the Order. |
| [Proposal for pufferfish](#_Proposal_for_pufferfish): classify pufferfish as a risk food. | Imports of this food will need a valid mandatory foreign government certificate. The department negotiates these arrangements with the exporting country. The exporting country must have regulatory controls and oversight in place. This provides assurance that the competent authority manages the food safety risk of pufferfish. | Commence new requirements 24 months after amendment to the Order. |
| [Proposal for kava](#_Proposal_for_kava): classify kava as risk food that is New Zealand product. Make consequential amendments to align with the updated definitions in the code. | As New Zealand (NZ) has not adopted changes made to kava in the code, the list of risk food from NZ needs updating. Inspection of this food will verify it meets the code, including kava of a noble variety. | Commence on registration of the amendment to the Order. |

## Introduction

The department has prepared this paper to inform stakeholders of proposed changes to the Imported Food Control Order 2019. These changes will affect how some imported foods are inspected and analysed under the risk-based [Imported Food Inspection Scheme](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis) (the IFIS).

The primary goal of the IFIS is to protect public health and safety.

The department’s role is to monitor the compliance of imported food through the IFIS. The department has a range of risk management measures it can apply at the border for an imported food. This depends on the level and nature of the food safety risk. The department applies the appropriate risk management strategy to have assurance, or to verify, that specific risks in a food have been controlled. The provision of science-based risk advice provided by FSANZ supports this.

The proposed new food safety import requirements are for:

* [dates](#_Proposed_risk_management)
* [enoki mushrooms](#_Proposed_risk_management_1)
* [melons](#_Proposed_risk_management_2)
* [pufferfish](#_Proposed_risk_management_3)
* [kava](#_Proposed_risk_management_4).

This public consultation allows the department to receive submissions that will form part of its process for considering the [inspection and testing of imported food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing). The department cannot consider submissions on the proposed risk status of a food as that is the purview of FSANZ risk advice.

The department will consider submissions on the proposed food safety risk management requirements and their implementation. To this view, the paper poses questions at relevant sections throughout.

Any changes recommended will be subject to government consideration and agreement.

## Background

The department, as part of the [national food regulatory system](https://www.foodregulation.gov.au/about-the-system), is one of many government agencies responsible for regulating food in Australia.

We administer 2 sets of legislative requirements for imported food. These requirements:

* protect Australia against biosecurity risks, under the [Biosecurity Act 2015](https://www.legislation.gov.au/C2015A00061/latest/text)
* manage imported food safety risks, as set out in the [Imported Food Control Act 1992](https://www.legislation.gov.au/C2004A04512/latest/text).

All imported food must meet biosecurity import conditions before allowed into the country.

Imported food legislation requires all imported food to be safe and compliant with Australia’s food standards. The legislation also sets out how the IFIS operates including the rates that foods are referred and inspected. The Imported Food Control Order lists food classified as risk food. Further information on the operation of the IFIS is available from the department’s [Imported Food Inspection Scheme webpage](http://www.agriculture.gov.au/import/goods/food/inspection-compliance/inspection-scheme#what-happens-during-an-inspection) and in [Appendix A](#_Appendix_A:_Imported).

Under the Imported Food Control Act 1992 and subordinate legislation, food imported from New Zealand is exempt from the IFIS, except for some risk food listed in Schedule 2 of the Order.

Once food is for sale in the domestic market, state and territory governments and local governments have the responsibility for enforcing food legislation, including the Australia New Zealand Food Standards Code. All food businesses, including food importers, have obligations to meet these requirements.

### The Imported Food Inspection Scheme

The IFIS is a risk-based system for monitoring the safety and compliance of imported food with Australia’s food standards. For the operation of the IFIS, foods are either classified as [risk food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis) or [surveillance food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis).

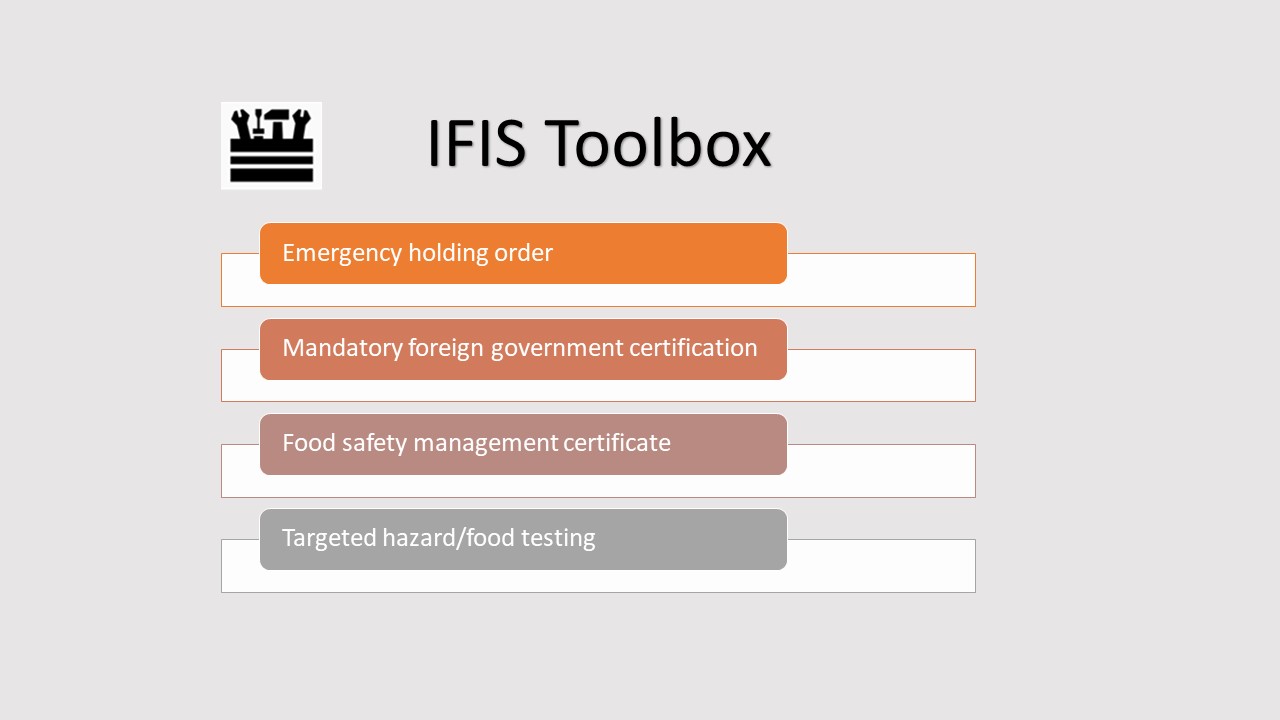
FSANZ provides risk advice to the department based on a specific food hazard combination (FSANZ 2018). If FSANZ has advised that a food has the potential to pose a medium or high risk to public health, our minister can classify food as risk.

Where imported food is risk classified, we can implement various tools to manage that risk at the border.

### Risk management tools

The department applies different risk management tools for imported food under the IFIS. This depends on the nature of the risk and the level of assurance that significant hazards are controlled, shown in Figure 1. These range from an inspection-based approach, relying on targeted testing of the food at the border, to a systems-based approach requiring certification at a country level. Where an imported food may pose a serious risk to human health, emergency holding order provisions can apply.

Figure 1 Risk management tools that can be applied to imported food referred to the IFIS



All consignments of risk food are referred to the IFIS. The food’s history of compliance is the basis for the rate of inspection. A history of compliance develops based on the producer, country of origin, and tariff code.

The rate of inspection starts at 100% and then:

* is reduced to 25% of consignments following 5 consecutive passes
* is reduced to 5% following a further 20 consecutive passes
* is increased back to 100% if a risk food fails inspection.

When food is analysed for chemical (including maximum residue limits (MRLs)) or microbiological hazards, the department applies the limits established in the food standards code as pass or fail criteria. Where there is no limit for a particular hazard in the code, the basis for permitted levels is FSANZ risk assessment advice or internationally agreed criteria established by the Codex Alimentarius Commission or the [International Commission on Microbiological Specifications for Food (ICMSF)](https://www.icmsf.org/).

Direct testing for a microbiological hazard in a food may not always be appropriate. This could be because of sampling limitations, lack of a reliable method, or where the nature of the food and production requires a higher level of control. In this instance, other risk management measures may be applied such as:

* [food safety management certificate](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/certification/safety-management-certificates), or
* [mandatory foreign government certification](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/mandatory-government-certification).

We apply verification testing for food that requires certification to assure us that controls in place are meeting the required food safety outcome.

All risk and surveillance food referred under the IFIS has a visual assessment for suitability. This includes checks for obvious signs of damage, deterioration, infestation, or contamination of the food. It will also have a label inspection to check compliance with labelling standards in the code. Country of origin labelling is also verified for compliance with the [Country of Origin Food Labelling Information Standard 2016](https://www.legislation.gov.au/Details/F2017C00920).

[Appendix A](#_Appendix_A:_Imported) provides further information on our imported food risk management.

## Proposal for dates

The proposed changes for dates are:

* Classify fresh dates that are RTE as a risk food.
* Mandate a valid recognised food safety management certificate (FSMC). Consignments will have a referral rate of 100% for documentation assessment.
* As a fruit, dates are also subject to the fruit and vegetable MRL screen (analytical testing) and a label and visual check (referral rate 5%).

### Current import requirements for dates into Australia

Under the Biosecurity Act 2015, [biosecurity import conditions](https://bicon.agriculture.gov.au/) apply depending on the country of origin of the dates. Fresh dates of the species Phoenix dactylifera (date palm) are a currently permitted import from Egypt, Islamic Republic of Iran, Israel, Morocco, and the United States of America (USA). Fresh dates of the species Ziziphus jujuba (red date) are not permitted as there are no biosecurity import conditions permitting this specific commodity.

Under the Imported Food Control Act 1992, dates are currently classified as surveillance foods under the category ‘fruits and vegetables’. Consignments are referred at 5% to the IFIS for inspection and testing. If referred, samples taken for analysis must comply with maximum residue limits in the food standards code [(Standard 1.4.2 Agvet chemicals)](https://www.legislation.gov.au/Details/F2016C00168). We also conduct a visual and labelling assessment.

#### Current import data

On average 12,000 tonnes of fresh date per year (2021 to 2023) are imported from those countries with current biosecurity import condition permissions.

### Domestic requirements for dates in Australia

The general food safety requirements for dates in Australia include:

* they should be free from harmful microorganisms that can cause foodborne illnesses
* they must be handled, stored, and transported in a manner that prevents contamination
* proper labelling, including the country of origin, packaging date, best-before date, storage instructions, and any allergen information if applicable
* they must not contain harmful chemical residues or exceed the MRLs set by the food standards code.

### Requirements for dates in New Zealand regulations

In New Zealand, the Ministry for Primary Industries (MPI) allows import of fresh dates (Phoenix dactylifera) only from the USA under the New Zealand biosecurity import health standards.

Import conditions are available through the [PIER Search](https://piersearch.mpi.govt.nz/importing-commodities-to-new-zealand/) which is similar to Australia’s BICON.

New Zealand has also identified HAV in dates as a potential issue for risk management consideration.

### Risk advice from FSANZ

FSANZ has provided [imported food risk advice](https://www.foodstandards.gov.au/consumer/imported-foods) on Hepatitis A virus (HAV) and Salmonella spp. for fresh dates that are RTE. The advice states that imported dates pose a medium to high risk to public health for HAV and may require additional management measures for these reasons:

* HAV causes incapacitating illness of moderate duration that, in rare cases, can be life threatening. It is very infectious, with small quantities likely to cause infection.
* There is strong evidence that HAV has caused foodborne illness from consumption of contaminated fresh dates.
* The method of primary production and processing can introduce contamination through manual handling, and there is also the potential for post-processing contamination of the food. No processing steps used are likely to reduce or eliminate HAV contamination for fresh RTE whole dates that are typically eaten raw.
* Although HAV cannot replicate in food, it is a robust virus and is likely to survive for extended periods of time on the surface of fresh dates that are RTE, therefore, HAV could be present at the time of consumption.
* In Australia, HAV is uncommon and, whilst vaccination is available, there is a low overall seroprevalence in the population. As a result of this, a significant proportion of the Australian population are susceptible to foodborne transmission of HAV.

There are currently no effective, realistic, and validated options to eliminate viral contamination of fresh produce before consumption without changing the normally desired characteristics of the food.

The advice states that to minimise contamination of dates with HAV, effective control measures are necessary during primary production and processing, e.g. through application of Good Agricultural Practices (GAP) on farm and Good Hygienic Practices (GHP) at critical points in the supply chain.

FSANZ risk advice for Salmonella spp. in imported fresh dates is that it poses a low risk to public health.

#### International requirements for dates

Information on the management approaches used by overseas countries is also included in the advice provided by FSANZ.

The European Food Safety Authority (EFSA) recommends good hygiene, manufacturing and agricultural practices in food producing countries. The European Commission’s Regulation (EC) No 852/2004 – Annex 1 Part A outlines general provisions for the hygienic production of food, including fresh produce (EU 2004). This includes:

* requirements on water use
* health and hygiene of food handlers
* cleaning and sanitising of facilities, equipment and vehicles
* animal and pest exclusion
* storage of waste; and the use of biocides.

Fresh fruit or vegetables imported into Canada must meet Canadian requirements set out in the Safe Food for Canadian Regulations as well as the Food and Drug Regulations. Some horticultural produce associated with elevated food safety risks have specific import requirements to minimise potential hazards (CFIA 2019a). Food that is imported, exported or inter-provincially traded must not be contaminated; must be edible; must not consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; and must have been manufactured, prepared, stored, packaged and labelled under sanitary conditions (CFIA 2019b).

In the USA, the Produce Safety Rule of the Food Safety Modernization Act established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruit and vegetables grown for human consumption. This includes requirements for:

* water quality; biological soil amendments; sprouts
* domesticated and wild animals
* worker training and health and hygiene
* equipment, tools and buildings (FDA 2019b).

The United States Department of Agriculture (USDA) has aligned the Harmonized Good Agricultural Practices Audit Program (USDA H-GAP) with the requirements of the USA Food and Drug Administration (FDA) Food Safety Modernization Act’s Produce Safety Rule. While the requirements of both programs are not identical, the relevant technical components in the FDA Produce Safety Rule covers the USDA H-GAP Audit Program.

### Proposed risk management strategy

As FSANZ has advised imported fresh dates that are RTE pose a medium or high risk to public health, the department is proposing that these dates are risk classified under the Order.

Dates mean fruit of Phoenix dactylifera (common name date palms), of which there are over 400 cultivars all producing edible fruits. The most common varieties are the Medjool, Noor Deglet, Hayani, and Bahri.

The scope is RTE fresh dates. This includes Medjool dates.

To avoid doubt, we have clarified that this excludes:

* dried dates
* product that is not ready-to-eat (intended for further processing)
* processed date products, for example date pastes, date vinegars
* mixed RTE food containing dates as an ingredient.

[Appendix A](#Appendix_A) sets out principles to support the department in developing an appropriate risk management strategy. Consistent with these principles, we are proposing to mandate that these dates import with a valid recognised food safety management certificate (FSMC). This provides assurance of the safe production of the food.

According to Codex guidance (Codex 2012), testing food for HAV is challenging, requiring matrix-dependent extraction and concentration techniques. HAV contamination of food is difficult to detect through cell culture techniques and the detection of HAV RNA can also be difficult. The HAV virus may not be homogenously spread through the food. There may be low levels of contamination, and the food may contain material that inhibits the amplification process (used for viral detection).

Certification provides assurance that date producers in the exporting country have implemented effective food safety management systems, including GAP, GHP and GMP, as identified by FSANZ as necessary to manage the hazards of concern.

A recognised food safety management certificate will meet our requirements. A recognised certificate can be issued by an accredited body certified to:

1. a Global Food Safety Initiative (GFSI) recognised programme that is appropriate for production of the food, or
2. a relevant standard, for example ISO 22000:2018 food safety management systems, which is accredited by one of the bodies recognised by the [International Accreditation Forum](https://iaf.nu/en/recognised-abs/).

[Read the guidelines](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/certification/safety-management-certificates#guideline) to find out how we determine what is a recognised food safety management certificate.

We do not propose verification testing of food for HAV due to testing complexities and no reference limit provided in the FSANZ risk advice.

As New Zealand has also identified HAV in dates as a potential issue for risk management consideration, we are not proposing to add dates to [Schedule 2-Risk food that is New Zealand product](https://www.legislation.gov.au/F2019L01233/latest/text) of the Order.

### Implementation

We propose requirements for mandatory FSMC apply 12 months after amendment to the Order. This will allow importers time to source product with the required certification. In the transition period, importers may lodge a FSMC, but it will not be mandatory. After the transition period, dates without a valid FSMC are not permitted import into Australia.

As a fruit, 5% of consignments will continue to be subject to a fruit and vegetable MRL screen. A label and visual assessment will check compliance with labelling requirements.

## Proposal for enoki mushrooms

The proposed changes for enoki are:

* Classify fresh enoki mushrooms as a risk food.
* Verify that labels on enoki mushrooms have appropriate storage and cooking instructions. For example – ‘Must be refrigerated at or below 5°C’ and ‘Cook thoroughly at a minimum of 70°C for at least 2 min’.
* Apply analytical testing to check that L. monocytogenes is not detected in five 25 g samples from a lot.
* A new rate of inspection which starts at 100% and reduces with a demonstrated history of compliance.

### Current import requirements for enoki mushroom into Australia

Under the Biosecurity Act 2015, [biosecurity import conditions](https://bicon.agriculture.gov.au/) apply to the importation of fresh enoki mushroom (Flammulina filiformis) also known as golden mushrooms or golden needle mushrooms to Australia. This commodity is eligible for risk-based inspection as part of the [Compliance-Based Intervention Scheme](https://www.agriculture.gov.au/biosecurity-trade/import/goods/plant-products/risk-return).

Under the Imported Food Control Act 1992, enoki mushrooms are currently classified as surveillance foods under the category ‘fruits and vegetables’. Consignments are referred at 5% to the IFIS for inspection and testing. If referred, samples taken for analysis must comply with maximum residue limits in the food standards code [(Standard 1.4.2 Agvet chemicals)](https://www.legislation.gov.au/Details/F2016C00168) and maximum levels for lead in [Schedule 19](https://www.legislation.gov.au/Series/F2015L00454) of the code. We also conduct a visual and labelling assessment.

#### Current import data

Our data shows approximately 2,000 tonnes per year of fresh enoki imported into Australia in the past 3 years (2021 to 2023).

### Domestic requirements for enoki mushroom in Australia

There are general food safety requirements for enoki mushroom in Australia. These include:

* It is an offence sell food in Australia that is unsafe.
* Enoki mushrooms should be free from harmful microorganisms that can cause foodborne illnesses.
* Enoki mushrooms must be handled, stored, and transported in a manner that prevents contamination.
* Proper labelling is required including the country of origin, packaging date, best-before date, as well as appropriate directions for use and storage to maintain the safety of the food.
* Enoki mushrooms must not contain harmful chemical residues or exceed the MRLs set by the code.

### Requirements for enoki mushrooms in New Zealand regulations

In New Zealand, MPI does not allow import of fresh enoki mushrooms.

Enoki producers (growers) or packers of horticultural produce must be registered with New Zealand MPI and are subject to the [National Programme](https://www.mpi.govt.nz/food-business/running-a-food-business/national-programmes-steps/#:~:text=National%20Programme%201%20will%20apply%20to%20businesses%20such,retailers%20of%20manufacturer-packaged%20ice%20cream%20and%20iced%20confectionery.) Level 1. There is limited primary production of enoki mushrooms in New Zealand.

### Risk advice from FSANZ

FSANZ has provided [imported food risk advice](https://www.foodstandards.gov.au/consumer/imported-foods) for fresh enoki mushrooms and [Listeria monocytogenes](https://www.foodstandards.gov.au/sites/default/files/2024-03/Lmono-on-enoki-mushroom.pdf). The advice states that imported fresh enoki poses a medium to high risk to public health and may require additional management measures because:

* L. monocytogenes is a moderately infectious pathogen that can cause severe disease in susceptible populations, with a case fatality rate of 15 to 30%
* there is strong evidence that L. monocytogenes can be present in enoki mushrooms and foodborne illness outbreaks reported associated with the consumption of enoki mushrooms, including in Australia
* the method of production and processing can introduce microbial contamination. There is also the potential for post-processing contamination to occur
* growth of L. monocytogenes can occur on enoki mushrooms, including when stored at refrigeration temperatures
* a cooking step such as boiling enoki mushroom should eliminate the hazard. However, there is evidence of enoki mushrooms consumed raw or without adequate cooking
* available evidence indicates that the prevalence and level of L. monocytogenes in enoki mushrooms is sufficient to be a public health risk.

The outcomes of the risk assessment showed that:

* labelling for storage conditions and directions for use is required to reduce risk but alone is insufficient to reduce the public health and safety risk posed by imported enoki under reasonably foreseeable conditions of use
* to reduce the risk of illness, once packaged, enoki must have through-chain refrigeration. Product labelling must include instructions for refrigeration and thorough cooking. For example, 'Refrigerate below 5°C’ and ‘Cook thoroughly at 70°C for at least 2 minutes’. risk increases with a longer shelf life
* cooking is generally a pathogen reduction step but cooking of this product may not be 100% effective. The time and temperature required to achieve an appropriate reduction is not reflected in available recipe methodology and consumption advice. It is reasonable to assume that some enoki is consumed raw or lightly cooked
* applying a performance objective of L. monocytogenes not detected in five 25 g samples of enoki from a lot contributes to reducing risk to an appropriate level.

FSANZ modelling identified that multifaceted risk mitigation strategies at the border would lower the public health and safety risk to an appropriate level.

#### International requirements for enoki mushrooms

Information on the management approaches used by overseas countries is also included in the advice provided by FSANZ.

Codex general principles of food hygiene CAC/RCP 1 – 1969 follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage (Codex 2020). The Codex code of hygienic practice for fresh fruit and vegetables CXC 53-2003 addresses Good Agricultural Practices and Good Hygienic Practices that help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables, from primary production to consumption (Codex 2017).

The European Commission (EC) regulations, Canadian regulatory requirements (Safe Food for Canadian Regulations) and the US Food Safety Modernization Act all have provisions for the hygienic production of food, including fresh produce.

In response to foodborne illness outbreaks, both Canada and the US have applied additional requirements for testing of imported enoki for L. monocytogenes:

* Shipments of fresh enoki mushrooms arriving in Canada on or after March 15, 2023, from the Republic of Korea and/or the People's Republic of China must be held and tested (CFIA 2023). Currently, enoki is on hold until tests confirm L. monocytogenes is not detected in a lot.
* The US Food and Drug Administration (FDA) has issued an Import Alert (IA) for enoki mushrooms from Republic of South Korea (July 2022). The alert extended to China (March 2023). Currently, to secure release of an individual shipment subject to detention without physical examination under this import alert, the owner, consignee, and/or other responsible party for the affected goods would provide evidence that the product does not bear or contain L. monocytogenes. The FDA issues these alerts to help prevent potential violative products from distribution in the US.

### Proposed risk management strategy

As FSANZ has advised imported fresh enoki mushroom food poses a medium or high risk to public health, the department is proposing that these mushrooms are risk classified under the Order.

Enoki mushroom means Flammulina filiformis also known as enokitake mushrooms, golden mushrooms, or golden needle mushrooms.

The scope is fresh enoki mushrooms, including vacuum packed but excluding canned/retorted, dried and frozen.

We propose to:

* verify product labelling meets the requirements of the food standards code. Standard 1.2.1 outlines requirements to label food. Standard 1.2.6 outlines requirements for storage directions and directions for use.
* apply border testing for the presence of L. monocytogenes – there must be no detectable L. monocytogenes in tested samples.

Both the label and visual assessment and the analytical testing will apply at an initial referral rate of 100% for this risk food. The food’s history of compliance is the basis for the ongoing rate of inspection of these consignments. A history of compliance develops based on the producer, country of origin, and tariff code.

We are not proposing to add enoki to [Schedule 2-Risk food that is New Zealand product](https://www.legislation.gov.au/F2019L01233/latest/text) of the Order as New Zealand:

* biosecurity restrictions do not allow imports of fresh enoki
* has limited domestic production.

### Implementation

We recommend the new food safety requirements take effect immediately after registration of the proposed Order amendments. As a vegetable, 5% of consignments will continue to have a fruit and vegetable MRL screen. A visual and label assessment will check compliance with labelling requirements.

## Proposal for melons

The proposed changes for melons are:

* Classify melons that are whole or ready-to-eat (RTE) cut and are fresh or frozen as a risk food.
* Mandate a valid recognised food safety management certificate (FSMC). Consignments will have a referral rate of 100% for documentation assessment.
* Apply verification analytical testing (L. monocytogenes; Salmonella spp) to RTE cut melons (referral rate 5%).
* There will be no verification analytical testing for whole melons as there are no applicable limits in the food standards code or in other relevant guidelines.
* As a fruit, melons are also subject to the fruit and vegetable MRL screen (analytical testing) and a label and visual check (referral rate 5%).

### Current import requirements for melons into Australia

Under the Biosecurity Act 2015, [biosecurity import conditions](https://bicon.agriculture.gov.au/) apply to the importation of melons to Australia. Currently melons can be imported from the United States, New Zealand, European countries and, recently, the Republic of Korea (Korea), subject to conditions. Different conditions may apply, depending on the country of origin. Requirements for an import permit may apply. This is to manage identified biosecurity risks.

Under the Imported Food Control Act 1992, melons are currently classified as surveillance foods under the category ‘fruits and vegetables’. Consignments are referred at 5% to the IFIS for inspection and testing. If referred, samples taken for analysis must comply with maximum residue limits in the food standards code [(Standard 1.4.2 Agvet chemicals)](https://www.legislation.gov.au/Details/F2016C00168). We also conduct a visual and labelling assessment.

#### Current import data

From 1 December 2023, changes to biosecurity import conditions permit commercial imports of greenhouse grown fresh oriental melon and rockmelon fruit from the Republic of Korea. Imports commenced early 2024. We are also finalising a market access request from Japan to export melons to Australia.

Our data is not able to differentiate between highly processed melon and cut fresh/frozen melon and there is high variability in the volume of imports of products under this tariff code coming into Australia over the past 3 years.

### Domestic requirements for melons in Australia

In 2022, [Standard 4.2.9 - Primary Production and Processing Standard for Melons](https://www.legislation.gov.au/Details/F2022L01063) (PPP standard for melons) was introduced. To strengthen food safety and traceability throughout the food supply chain, the standard requires growers and primary processors in Australia to identify and control food safety hazards associated with the growing and primary processing of melons. An approved food safety management statement is also required. The new standard commences in February 2025. This allows industry enough time to meet the new requirements.

Chapter 3 of the food standards code outlines food hygiene controls that apply to cut RTE melon as a risk-based preventative approach to producing safe and suitable food. These controls apply to the handling of food for sale during food receipt, storage, processing, display, packaging, transportation, disposal, and recall. It also outlines controls during cleaning and sanitising and maintenance of food equipment. There are also requirements that apply to ensure the health and hygiene of food handlers.

### Requirements for melons in New Zealand regulations

In New Zealand, MPI allows import of certain melons products under the New Zealand biosecurity import health standards from permitted source countries. The main source of imported melons to New Zealand is Australia.

Import conditions are available through the [PIER Search](https://piersearch.mpi.govt.nz/importing-commodities-to-new-zealand/), which is similar to Australia’s BICON.

New Zealand does not have a specific food safety primary production standard for melons. All horticultural producers (growers) or packers of horticultural produce registered with New Zealand MPI are subject to the [National Programme](https://www.mpi.govt.nz/food-business/running-a-food-business/national-programmes-steps/#:~:text=National%20Programme%201%20will%20apply%20to%20businesses%20such,retailers%20of%20manufacturer-packaged%20ice%20cream%20and%20iced%20confectionery.) Level 1. Growers and packers of horticultural produce who export their products or supply New Zealand’s major supermarkets, operate under third-party schemes (e.g. NZ GAP, GLOBALGAP) to meet their customer/market requirements. Section 40 of the Food Act 2014 provides for approval of third-party schemes.

New Zealand does not currently export melons to Australia.

#### Risk advice from FSANZ

FSANZ has provided [imported food advice](https://www.foodstandards.gov.au/consumer/imported-foods) on whole and cut, ready-to-eat melons. This advice states that imported melons pose a medium to high risk to public health for Listeria monocytogenes and Salmonella spp. because:

* L. monocytogenes can cause severe disease in susceptible populations, with a case fatality rate of 15–30%. Salmonella spp. can be very infectious and cause incapacitating but not usually life-threatening illness. Sequelae can occur but are rare
* there is evidence that both L. monocytogenes and Salmonella spp. have caused foodborne illness associated with consumption of whole and cut, RTE melons (melons with a netted or rough surface; and those grown on the ground)
* the method of production (e.g. growth on ground) and handling of the fruit can introduce surface contamination, and there is the potential for post-processing contamination to occur. As melons pose a medium-high risk, a through-chain, multi-hurdle management approach minimises risk. Whole and cut, RTE melons do not undergo a pathogen elimination step before consumption
* growth of L. monocytogenes and Salmonella spp. can occur on both smooth and netted melon rind, i.e. on the outside of whole melon, and in melon flesh
* growth of L. monocytogenes can occur when stored at refrigeration temperatures

The FSANZ risk advice identifies that all melons are susceptible to contamination with these pathogens during primary production and processing and can support the growth of Salmonella spp. at ambient temperature and L. monocytogenes at both ambient and refrigeration temperatures.

To minimise contamination of melons with pathogens of concern, effective control measures are necessary during primary production and processing. This involves the application of Good Agricultural Practices (GAP) on-farm, and Good Hygienic Practices (GHP) throughout the supply chain, and Good Manufacturing Practices (GMP) during processing, as well as controlling inputs through-chain.

#### International requirements for melons

Information on the management approaches used by overseas countries is also included in the advice provided by FSANZ.

In Canada, the Canadian Food Inspection Agency (CFIA) sets regulations and guidelines for importing fresh fruits, including melons, to ensure food safety. Imported fresh fruit or vegetables must meet Canadian requirements as set out in the Safe Food for Canadian Regulations and the Food and Drug Regulations. Canada has established a list of approved countries and suppliers that can export melons to Canada to ensure that the melons come from an approved country and a registered supplier (CFIA 2023).

In the United States, the industry guidelines [Commodity Specific Food Safety Guidelines for Cantaloupes and Netted Melons](https://ucfoodsafety.ucdavis.edu/produce-pre-post-harvest/commodity-specific-food-safety-information) have been available for several years to minimise Salmonella contamination on rockmelons imported into the US. In this document, all individuals in the cantaloupe supply chain are encouraged to develop specific food safety programs.

### Proposed risk management strategy

As FSANZ has advised that imported melons pose a medium or high risk to public health, the department is proposing that these melons are risk classified under the Order.

Melons includes but is not limited to, watermelon, rockmelon (cantaloupe), honeydew melons, oriental melon and piel de sapo.

The scope is whole or RTE melon that has been pre-cut and is fresh, chilled, or frozen, excluding further processed melons.

To avoid doubt, we clarified that this excludes:

* product that is not ready-to-eat (intended for further processing)
* processed product – for example, dried, pulp, puree, concentrate, or juice
* mixed ready-to-eat food containing melon as an ingredient.

[Appendix A](#_Appendix_A:_Imported) sets out principles to support the department in developing an appropriate risk management strategy. We are proposing to mandate that melons import with a valid recognised food safety management certificate (FSMC). This provides assurance of the safe production of the food.

While at border testing can apply for L. monocytogenes and Salmonella spp., the lack of a processing step to eliminate these hazards means this risk management alone is insufficient.

Certification provides assurance that the melon producers in the exporting country have implemented effective food safety management systems, including GAP, GHP and GMP, as identified by FSANZ as necessary to manage hazards of concern. Border testing can then apply to verify these control systems are effective.

A recognised food safety management certificate will meet our requirements. A recognised certificate can be issued by an accredited body certified to:

1. a Global Food Safety Initiative (GFSI) recognised programme that is appropriate for production of the food, or
2. a relevant standard, for example ISO 22000:2018 food safety management systems, which is accredited by one of the bodies recognised by the [International Accreditation Forum](https://iaf.nu/en/recognised-abs/).

[Read the guidelines](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/certification/safety-management-certificates#guideline) to find out how we determine what is a recognised food safety management certificate.

Requiring a FSMC for imported melons is also consistent with the new domestic PPP standard for melons, thereby achieving an equivalent food safety outcome.

As New Zealand do not export melons to Australia, we do not propose adding melons to [Schedule 2-Risk food that is New Zealand product](https://www.legislation.gov.au/F2019L01233/latest/text) of the Order.

### Implementation

We propose requirements for mandatory FSMC apply 12 months after amendment to the Order. This will allow importers to source product with the required certification. In the transition period, importers may lodge a FSMC, but it will not be mandatory. After the transition period, melons without a valid FSMC are not permitted import into Australia. To verify the effectiveness of FSMCs, 5% of imports of cut RTE melons will be referred for analytical testing for L. monocytogenes and Salmonella spp. As a fruit, 5% of consignments of both whole and cut RTE melons will continue to be subject to a fruit and vegetable MRL screen. A label and visual assessment will check compliance with labelling requirements.

## Proposal for pufferfish

The proposed changes for pufferfish are:

* Classify pufferfish as a risk food.
* Mandate a recognised foreign government certificate (FGC). Consignments will have a referral rate of 100% for documentation assessment.
* As ‘seafood,’ pufferfish are also subject to a label and visual check (referral rate 5%).

### Current import requirements for pufferfish into Australia

Under the Biosecurity Act 2015 [biosecurity import conditions](https://bicon.agriculture.gov.au/) apply to fish processed into a consumer ready form, including pufferfish (fish families within the order Tetradontiformes).

Under the Imported Food Control Act 1992, pufferfish is currently classified as a surveillance food. Consignments are referred at 5% to the IFIS for a visual and labelling assessment. Imports are not currently tested for Tetrodotoxin (TTX).

#### Current import data

Our data shows a small quantity of pufferfish (fugu) for human consumption imported into Australia from Japan in the previous 3 years (2021 to 2023).

### Domestic requirements for pufferfish in Australia

There is no commercial domestic production of pufferfish currently. While the food standards code does not specify a maximum level (ML) for TTX, food for sale in Australia must be safe and suitable. This means that food will not cause illness or other physical harm to a person eating it when used according to its reasonable intended use.

Standard 3.2.2 of the food standards code outlines controls that ensure the safe handling of food (including making, manufacturing, processing, preparing, transporting, serving, or displaying of food). Anyone undertaking or supervising food handling must have the appropriate skills and knowledge required to produce safe food. There are many ways for food handlers to get the appropriate skills and knowledge. Recent changes to the code (through a new Standard 3.2.2A) mandates formal training for food handlers and supervisors handling potentially hazardous food.

### Requirements for pufferfish in New Zealand regulations

New Zealand categorises imported pufferfish as a [high regulatory interest](https://www.mpi.govt.nz/import/food/imported-foods-that-require-food-safety-clearance/importing-puffer-fish-a-high-regulatory-interest-food/) food. An official certificate from an exporting country accompanies imported product requiring border clearance. MPI and the country’s Competent Authority agree on the certificate. Currently New Zealand only has an official certification arrangement with Korea.

New Zealand does not currently export pufferfish to Australia.

### Risk advice from FSANZ

FSANZ has provided [imported food risk advice](https://www.foodstandards.gov.au/consumer/imported-foods) indicating whole or portions of pufferfish pose a medium to high risk to public health for Tetrodotoxin (TTX) for these reasons:

* tetrodotoxin (TTX) is an extremely potent hydrophilic neurotoxin that accumulates in pufferfish species
* TTX is odourless and heat-stable, and is not diminished by cooking, rinsing, cleaning, or freezing
* significant training is necessary to enable an individual to remove the toxic organs from pufferfish without contaminating the edible portions with TTX
* TTX ingestion in once health adults reportedly resulted in serious illness and deaths
* TTX intoxications have occurred in Australia. These occurred where recreation caught pufferfish was consumed.

There are no Codex Standards available that establish a ML for TTX in pufferfish for human consumption. International testing exists, but no tests are currently in place in Australia. Testing does not provide assurance of the safety of the product.

#### International requirements

Information on the management approaches used by overseas countries is also in the advice provided by FSANZ.

Pufferfish flesh or fugu is a food delicacy in Japan. Select pufferfish species requires government certifications for commercial sale. Only select pufferfish species are permitted for sale. A chef must have formal training and hold a government issued permit before they can prepare fugu. Even so, TTX intoxications still result in serious food poisoning and death in Japan.

Commercial importation of pufferfish into the US is heavily restricted by the FDA. An agreement reached between the Japanese Ministry of Health and Welfare and the FDA to permit importation of a single species of pufferfish, Takifugu rubripes, for special occasions and subject to specific criteria. Currently, the only acceptable source of imported puffer fish is from a company that imports the product from processing facilities licensed by the Japanese government to prepare this product using fish cutters with special training.

The EU has regulations banning the placing of fishery products on the market if derived from poisonous fish of the families: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.

### Proposed risk management strategy

As FSANZ has advised imported pufferfish poses a medium or high risk to public health, we are proposing that pufferfish is risk classified under the Order.

Pufferfish means fish families within the order Tetradontiformes. It is also known by other common names such as globefish, blowfish, balloonfish, swellfish, toadfish, and porcupine fish.

The scope is whole or portions that are fresh, frozen, dried, or canned.

Consistent with the department’s principles in [Appendix A](#Appendix_A), we are proposing to mandate foreign government certification to provide assurance of the safe production of the food.

Limitations in methods for testing TTX in seafood means that batch testing imported product may be of limited value to safeguard against TTX contamination. For that reason, testing is not an acceptable risk management strategy for pufferfish.

The careful processing of an individual fish is the primary method of eliminating TTX from consumed product. The FSANZ advice states that to minimise contamination of pufferfish for human consumption with TTX, it must be prepared by careful removal of the organs where TTX has accumulated. This is a specialist process, where product intended for consumption can become contaminated with TTX or confused with tissue abundant in TTX.

Given the:

* high risk and potency of TTX
* challenges of testing product at the border to verify safety
* need for persons with special training to prepare fugu

we propose assurance of the safety of the food via certification. It is also recommended that this be government certification as regulatory requirements and oversight provide the level of assurance needed.

As New Zealand already requires certification for imports of pufferfish and is not currently exporting product to Australia, we are not proposing to add pufferfish to [Schedule 2-Risk food that is New Zealand product](https://www.legislation.gov.au/F2019L01233/latest/text) of the Order.

### Implementation

Countries wishing to continue exporting pufferfish to Australia will need to apply for [foreign government certification](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/mandatory-government-certification). To allow importers to source product with the required certification, we propose that the FGC requirements apply 24 months after the amendment to the Order. This will allow time for certification arrangements to finalise. After the transition period, imports of pufferfish will need a valid FGC.

## Proposal for kava

The proposed changes for kava are:

* Add kava to the list of risk food that is New Zealand product and subject to inspection under the IFIS.
* A new rate of inspection for kava from New Zealand. The rate of inspection starts at 100% and reduces with a demonstrated history of compliance.
* New definitions of kava in imported food legislation to align with amendments to the food standards code.

### Domestic requirements for kava in Australia

In March 2022, the FSANZ Board agreed on amendments to the code as part of an urgent [Proposal P1057 - Review of the kava standard](https://www.foodstandards.gov.au/food-standards-code/proposals/Proposal-P1057-Review-of-the-kava-standard) to:

* ensure kava beverages are prepared and consumed in line with historically safe practices
* clarify the current prohibition on the use of processing aids and food additives in the manufacture or processing of dried or raw kava root and kava beverages
* require that kava be sourced from noble varieties of the kava plant, which have a history of safe use.

The changes:

* allow for continued use of kava in historically safe and culturally appropriate ways
* ensure protection of public health and safety will continue after commencement of commercial importation of kava into Australia under the Pacific Step-up kava [pilot](https://www.dfat.gov.au/geo/pacific/economic-prosperity-in-the-pacific/australia-kava-pilot#:~:text=On%2011%20October%202019%2c%20Prime%2cand%20across%20the%20Pacific%20region) (FSANZ 2023).

These amendments came into effect immediately in Australia. New Zealand did not adopt the amendments to the kava Standard into New Zealand law. The kava Standard that existed before March 2022 remains in effect in New Zealand.

### Current import requirements for kava into Australia

Australia and New Zealand have joint food standards and recognise each other’s food safety standards and import control systems. This allows most food imports between the countries without border inspection.

Under the Imported Food Control Act 1992 and subordinate legislation, food imported from New Zealand is exempt, except for some food classified as risk food. This exemption recognises the Trans-Tasman Mutual Recognition Arrangement (TTMRA). In 1996, the governments of Australia and New Zealand agreed that goods that can be legally sold in one country can be legally sold in the other country. Enactment of the principles of this arrangement is through the Trans-Tasman Mutual Recognition Act 1997 (TTMR Act 1997).

Section 5 of the Imported Food Control Order 2019 allows food imported from New Zealand to be risk food and inspected under the IFIS. This can occur when food imported from New Zealand does not meet the Trans-Tasman mutual recognition principle set out in Part 2 of the TTMR Act. Matters affecting the health and safety of persons meet the exemption principle of the TTMR Act. Schedule 2 of the Order lists these foods. Foods currently listed are beef, beef products, cassava chips and brown seaweed.

#### Current import data

Our data shows approximately 20,000 kg of kava imported from New Zealand to Australia over the past 3 years (2021 to 2023).

### Proposed risk management strategy

Consistent with the code, permitted kava (plants of the species Piper methysticum) and kava root means the peeled root or peeled rootstock of a Noble variety of kava named in section 3.1 of the [Regional Standard for Kava Products for use as a Beverage When Mixed with Water (CXS 336R-2020)](https://www.fao.org/fao-who-codexalimentarius/committees/codex-regions/ccnaswp/reg-stan/en/) as adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020). Defined terms are in [Standard 1.1.2](https://www.legislation.gov.au/F2015L00385/latest/text) section 3 of the food standards code.

An Order amendment will make sure the definition of kava as a risk food .

The scope includes dried or raw kava root, including powdered root, or beverage obtained by aqueous suspension of kava root, with no processing aids used in its production, as currently permitted for sale under [Standard 2.6.3](https://www.legislation.gov.au/F2015L00466/latest/text).

As the regulatory approach will no longer be consistent for kava, given the potential for non-noble varieties of kava imports from or via New Zealand, we propose that the Order is also amended to list kava in [Schedule 2-Risk food that is New Zealand product](https://www.legislation.gov.au/F2019L01233/latest/text).

This will ensure kava imported from New Zealand can be checked for safety and compliance with the new requirements.

### Implementation

We recommend this change takes effect immediately after the Order is amended.

## Make a submission

We invite industry, business, and the community to share support and/or provide feedback on the proposed changes to the imported food safety requirements for some imported food.

### Have your say

The deadline for receipt of all submissions is by 5 pm (Canberra time) Friday 6 December 2024.

The department will consider all relevant material provided within submissions. Go to <https://haveyoursay.agriculture.gov.au/new-food-safety-requirements>.

Or your submission can be made in writing and include:

* your name and title
* your organisation’s name if submitting on behalf of an organisation
* your contact details.

Mark your submission: New food safety import requirements for dates, enoki mushrooms, melons, pufferfish, and kava 2024

Post to:

Mail Imported Food Section

Department of Agriculture, Fisheries and Forestry

GPO Box 858

Canberra ACT 2601 Australia

Submissions received after the deadline will not be considered unless an extension had been given before the closing date.

### Next steps

After the consultation period has closed, the department will assess all submissions and consider whether further amendments are required while still achieving the objectives of the Imported Food Control Act 1992.

The finalised amendments to the Order will then be recommended to the Minister for Agriculture, Fisheries and Forestry.

Table 2 Key dates for making amendments to the Order

| Date | Action |
| --- | --- |
| October 2024 | Public consultation on proposed changes to the imported food safety requirements for dates, enoki mushrooms, melons, pufferfish, and kava |
| June 2025 | Potential commencement of proposed changes to the imported food safety requirements for enoki and kava |
| June 2026 | Potential commencement of mandatory certification for dates and melons |
| June 2027 | Potential commencement of mandatory certification for pufferfish |

#### Contacts

For information about changes to the Imported food safety requirements for some imported foods, email [ifis-certification@aff.gov.au](mailto:ifis-certification@aff.gov.au).

## Appendix A: Imported food risk management policy

The department is one of many government agencies responsible for regulating food in Australia. The department administers 2 sets of requirements with which imported food must comply.

[Foods imported into Australia](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/how) are subject to requirements under the Biosecurity Act 2015 to address biosecurity concerns and the Imported Food Control Act 1992 for compliance with Australian food standards and public health and safety.

The department’s Biosecurity Import Conditions ([BICON](http://www.agriculture.gov.au/import/online-services/bicon)) system determines if a commodity intended for import to Australia requires a permit or treatment or if there are any other biosecurity conditions. Importers must be sure that food complies with biosecurity requirements. Entry into Australia is not permitted if food does not meet biosecurity requirements. For further enquiries on Australian biosecurity or import permit requirements contact [biosecurity imports](https://www.agriculture.gov.au/about/contact).

Once food meets all biosecurity requirements, it must meet Australia’s imported food legislation. This legislation comprises of the:

* [Imported Food Control Act 1992](https://www.legislation.gov.au/C2004A04512/latest/text)
* [Imported Food Control Regulations 2019](https://www.legislation.gov.au/Details/F2019L01006)
* [Imported Food Control Order 2019](https://www.legislation.gov.au/F2019L01233/latest/text)

The Act requires all imported food to be safe and compliant with Australia’s food standards. The Regulations set out how the Imported Food Inspection Scheme (the IFIS) operates, including the rates that foods are referred and inspected. For the operation of the IFIS, foods are either classified as [risk food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis) or are classified as a [surveillance food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis). Foods that are classified as risk food are scheduled in the Order.

The department is responsible for administering the Act and, in doing so, monitoring imported food for compliance with the [Australia and New Zealand Food Standards Code](https://www.foodstandards.gov.au/code/Pages/default.aspx). The code lists Australia’s food standards requirements, including for contaminants such as microbiological and chemical, additives, labelling, and genetically modified food, as well as production and processing standards.

Post border, the state and territory governments and local governments have the responsibility for enforcing food legislation (including the code), on food businesses. Food importers, as food businesses, are also obligated to meet these requirements.

### The Imported Food Inspection Scheme

The IFIS is a risk-based system for monitoring the safety and compliance of imported food with Australia’s food standards. Food is referred for inspection under the IFIS based on agreed international tariff codes and classification of goods within the [Integrated Cargo System (ICS)](https://www.abf.gov.au/help-and-support/ics/integrated-cargo-system-(ics)). The rate of referral depends on whether the food is a risk or surveillance food and its history of compliance. The rate of referral from Customs via the ICS is 100% for risk food and 5% for surveillance food, except for food excluded from the IFIS. For example, imported under a food safety recognition agreement. Once referred, the rate of inspection changes via the Agriculture Import Management System (AIMS).

FSANZ provides risk advice to the department on foods that have the potential to pose a medium or high risk to public health. In the Regulations, the minister can make an order classifying food as risk, if FSANZ has advised the department that a food has the potential to pose a medium or high risk to public health.

#### Risk food

Food classified as risk is inspected at a rate of 100 % of consignments. A compliance history is then developed for consignments based upon a specific combination of producer, country of origin and tariff code. When 5 consecutive consignments have passed, the inspection rate can be reduced to 25% and then to 5% after a further 20 consecutive passes. If a consignment fails inspection or analysis the rate is tightened again to 100% of consignments for that food from the same producer and country of origin. Risk food is subject to a ‘test and hold’ direction. It must be held and not distributed for sale until analytical test results are assessed and the food is released by the department. Risk food that is perishable (for example, fresh seafood) may be released by the department before test results are reported, if the food has a history of compliance and was referred at the normal 25% or reduced 5% referral rate.

#### Surveillance food

Food that is not risk or [compliance agreement food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/how/fica) is classified as surveillance food. Surveillance food is referred to the IFIS randomly using electronic profiles in the ICS. Five percent of a food, based on the first 4 digits of its tariff code, is referred for inspection irrespective of the importer, producer, or the country of origin of the food. When a surveillance food fails inspection or analysis, a holding order is applied. Under a holding order, all future comparable consignments of a failed food (for example same product, producer, country of origin, and importer) are referred for inspection until a history of compliance is re-established.

#### Risk management tools

A risk-based approach to managing food safety in Australia uses a range of risk management tools. The department applies different risk management tools for imported food under the IFIS. This depends on the nature of the risk and the level of assurance required for effective control of significant hazards. These range from an inspection-based approach, relying on targeted testing of the food, to a systems-based approach requiring certification at a country level. In the case of a food safety incident where an imported food may pose a serious risk to human health, emergency holding order provisions can be applied.

The risk management approach used by the department reflects these considerations:

* Testing of food can have limitations. For some hazards there may not be reliable methods, or the hazard may only be present at very low levels or localised within a batch. In these cases, it is unlikely that taking limited samples would provide the required degree of confidence that the hazard is absent, or at a safe level, in the entire lot of food.
* Food safety is best ensured through implementing good hygiene practices at each stage of food handling throughout the food chain (a preventative through chain approach). A Hazard Analysis Critical Control Point (HACCP) based approach to food safety provides greater confidence that verifiable food safety controls are in place at each stage as appropriate. HACCP systems are recognised internationally as the foundation for demonstrating food safety and provide the basis for [The Codex General Principles for Food Hygiene.](https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-standards/en/?committee=CCFH)
* Management of certain hazards may involve oversight by competent authorities within a country. For example, the safety of bivalve molluscs is best managed by national shellfish sanitation programs which include classification of shellfish growing areas, sanitary surveys and biotoxin monitoring programs. For hazards associated with animals and animal products, certification, if needed, by a veterinary authority can verify control of a hazard.

Food safety incidents can arise which need an immediate response to protect public health. Further distribution of implicated food may need to be prevented while further investigation occurs, and assurances as to its safety.

The risk management tool applied is commensurate with the level of food safety risk and the level of assurance required to assure management of significant hazards at each stage of the production and supply chain as appropriate.

The limits established in the food standards code for chemical or microbiological hazards apply as pass or fail criteria. Where there is no limit for a particular hazard in the code, permitted levels are based on FSANZ risk assessment advice or internationally agreed criteria established by the Codex Alimentarius Commission or the [International Commission on Microbiological Specifications for Food (ICMSF)](https://www.icmsf.org/).

When direct testing for a microbiological hazard in a food is not appropriate because of sampling limitations, lack of a reliable method, or where the nature of the food and production requires a higher level of control, other risk management measures apply such as [food safety management certificate](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/certification/safety-management-certificates) or [mandatory foreign government certification](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/mandatory-government-certification).

We apply verification testing for food that requires certification for assurance that controls in place are meeting the required food safety outcome.

#### Food safety management certification

A FSMC is a document that demonstrates that a food produced through a food safety management system that has appropriate controls in place to manage food safety hazards of concern. The food safety management system must be consistent with internationally agreed food safety principles as set out by the [Codex Alimentarius Commission](http://www.fao.org/fao-who-codexalimentarius/home/en/).

An accredited certification body must issue the FSMC. [Read the guidelines](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/certification/safety-management-certificates#guideline) to find out how we determine what is a recognised food safety management certificate. A food safety management certificate for a risk food may be required when:

* the hazards of concern causes serious illness and there is strong evidence of foodborne illness associated with the food
* analytical testing cannot provide an acceptable level of assurance that the hazard is not present because of sampling limitations and or the lack of a reliable method
* there are no processing steps that will eliminate the hazards of concern and management of the hazard must be ensured through implementing through-chain controls

Each lodgement of a consignment of a food requiring a FSMC must include a valid certificate. FSMC are currently required for berries and pomegranate arils.

#### Mandatory foreign government certification

Some foods classified as a risk need a recognised FGC for import into Australia. Mandatory FGC require the relevant government competent authority in the exporting country to attest management of the food safety risks with a particular food. A certification arrangement is only negotiated with a country that can demonstrate it has regulatory systems in place to certify the management of those risks. This includes, where relevant, equivalent food safety outcomes to those required in Australia for that food.

Where FGC is mandated for a particular food, a country wanting to export that food to Australia must apply to the department for an equivalence assessment and provide the department with information that demonstrates it has equivalent regulatory systems to those required in Australia, where applicable, for the domestic production of that food. This is to ensure a level playing field exists for both imported and domestic produced food, where relevant. In the case where there is no domestic production of a food, an equivalence assessment assesses whether the measures in the exporting country can ensure the food is safe and suitable.

Mandatory foreign government certification for a risk food may be required when:

* the hazards of concern causes serious illness and there is strong evidence of foodborne illness associated with the food
* analytical testing cannot provide an acceptable level of assurance that the hazard is not present because of sampling limitations and or the lack of a reliable method
* management of the hazards ensured through implementing through-chain controls which include government oversight and verification by a competent authority.

FGC is currently required for raw milk cheese, raw and cooked beef and beef products, human milk and human milk products and bivalves molluscs and bivalve mollusc products.

#### Emergency powers

Subsection 15(3) of the Act allows for the Secretary to make [holding orders for imported food](https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/holding-orders) where they are satisfied that there are reasonable grounds for believing that a particular food may pose a serious risk to human health. This enables the department to immediately prevent further import and distribution of a potentially unsafe food at the border. A holding order cannot prevent post-border distribution.

Holding orders improve responsiveness to food safety incidents by allowing earlier intervention where there are reasonable grounds to believe that food my pose a serious risk to human health, and that the food safety issue is unconfirmed and or there is no reliable test available to detect the food safety hazard. This is achieved by enabling the Secretary to make a holding order for a limited period to gather sufficient information to determine ongoing risk management measures.

#### Inspection and testing

The minister may, in an order under Section 10, classify food of a particular kind as surveillance food if food of that kind is not risk food; and is not compliance agreement food; and is not the subject of a holding order. Food monitoring for compliance with the food standards code and public health requirements comes under the IFIS. Monitoring may include testing for chemical or microbiological hazards as appropriate. Inspection of all risk and surveillance food referred under the IFIS includes a visual assessment for suitability and a label inspection to check compliance with labelling standards in the code. Country of origin labelling is also verified for compliance with the [Country of Origin Food Labelling Information Standard 2016](https://www.legislation.gov.au/Details/F2017C00920).

## Glossary

| Term | Definition |
| --- | --- |
| Code | Australia New Zealand Food Standards Code. |
| Competent Authority | The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement ([Codex, 2020](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf)). |
| CP question | Community Protection question, sometimes known as a lodgement question. |
| Dates | Plants of the species *Phoenix dactylifera* (date palm) |
| Enoki mushroom | Fungi of the species Flammulina filiformis also known as golden mushrooms or golden needle mushrooms |
| Food Safety Management Certificate | * a recognised foreign government certificate, or * a certificate issued by a third party and covered by a determination in force under subsection 18A(1) of the *Imported Food Control Act 1992*. |
| Food Safety Management System | A systematic and documented approach to identifying and controlling food safety hazards reasonably expected to occur during primary production and processing of food. |
| Foreign government certificate | A certificate issued by an instrumentality of a specified foreign government stating that food of a specified kind meets applicable standards and does not pose a risk to human health. |
| FSANZ | Food Standards Australia New Zealand. An independent statutory agency established by the *Food Standards Australia New Zealand Act 1991*(FSANZ Act). FSANZ is part of the Australian Government's Health portfolio. |
| HACCP | Hazard Analysis Critical Control Points. A science-based and systematic method of identifying hazards and measures for their control to ensure the safety of food. |
| Hazard | A biological, chemical, or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans. |
| Holding order | A legal document provided for in the *Imported Food Control Act 1992*. Use of a holding order increases the rate of inspection of a failing food until subsequent imports demonstrate compliance with the requirements of the Act. |
| Imported Food Inspection Scheme | The imported food inspection scheme. Provided for in the *Imported Food Control Act 1992* and set out in the Imported Food Control Regulations 1993. The inspection of food at the border to assess compliance with Australian food standards and that it does not pose a risk to human health. |
| Inspection | Includes physical inspection (visual and label assessment), or inspection and analysis (samples taken and sent for analysis), as the case requires. |
| Kava | Plants of the species *Piper methysticum*. |
| Kava root | The peeled root or peeled rootstock of a Noble variety of kava that is named in section 3.1 of the *Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) as adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020). |
| Melons | Means horticultural product that is covered by Australia New Zealand Food Standards Code Standard 4.2.9 and includes (but is not limited to) watermelon, rockmelon (cantaloupe), honeydew melons, and piel de sapo. |
| Pufferfish | Fish families within the order Tetradontiformes |
| Recognised foreign government certificate | A certificate issued by an instrumentality of a specified foreign government stating that food of a specified kind meets applicable standards and does not pose a risk to human health that is covered by a determination in force under subsection 18(1) of the Act. |
| Ready-to-eat | Food is ready‑to‑eat if it is ordinarily consumed in the same state as that in which it is sold.  To avoid doubt, food is not ordinarily consumed in the same state as that in which it is sold if, before it is consumed, it requires further processing (such as cooking) in order to reduce any pathogenic microorganisms potentially present in the food to safe levels. |
| Risk food | Food included in Schedule 1 of the Imported Food Control Order 2019. |
| Surveillance food | All other food that is not: classified as risk food; the subject of a holding order; or compliance agreement food. |
| The Codex Alimentarius Commission (CAC) | International food standards setting body established in 1962 by the Food and Agriculture Organization and the World Health Organization of the United Nations. Codex adopted text, including principles and standards, have defined terms and processes used by governments internationally. |

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