Australian Government
Department of Agriculture and Water Resources

Imported food reforms

Consultation regulation impact statement

Compliance Arrangements Branch

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The department thanks those importers that participated in the Food Importer Research to inform the regulatory analysis and those that kindly responded to our additional requests for further information.

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Have your say

This consultation process considers how improvements can be made to the management of imported food safety risks without imposing undue costs on businesses importing food and consumers, or disrupting state and territory food safety regulation. Targeted consultation has been undertaken with government, businesses and trading partners and feedback received to date has been valuable to inform the policy options being considered.

Recent food safety issues associated with imported food have drawn significant media and subsequent community attention to Australia's food safety system and highlighted some limitations in the management of imported food safety risks. With the increase in globalisation of the food supply chain and associated increase in the volume of food imported to Australia, consumers and government have become more concerned about the safety of Australia's food supply.

The proposed reform options seek to address the limitations of the current system by providing more flexible and targeted ways to prevent and respond to food safety risk to better protect the health of consumers.

This consultation Regulation Impact Statement (RIS) acknowledges that the proposed options for reform are likely to have an impact on businesses importing food, state and territory food safety regulators, consumers and our trading partners.

The paper is seeking information about the nature and extent of the impacts from affected stakeholders and interested parties.

To assist respondents, questions are posed throughout the paper and a summary provided at Appendix A. While questions are designed to elicit feedback, comments are welcome on the issues these questions raise and any other aspects associated with the proposed options for reform to the management of imported food safety risks.

It would assist the department to understand the impacts of the proposed options for reform on stakeholders and interested parties if, wherever possible, submissions could include supporting evidence and examples, including costs.

The department is also interested in respondents' views on possible ways to alleviate negative impacts, if any, for themselves or their business.

To ensure clarity in terminology, this paper interprets reference to regulation to mean provisions in Acts, Regulations, Codes of Practice and all other supporting materials for which substantial compliance is expected.

Consultation

The content of the consultation RIS includes:

- background to the regulation of imported food in Australia
- an outline of the problem highlighting the issues government, businesses and consumers have with the current imported food regulation
- discussion on improving the management of imported food safety
- a proposed response by the Australian Government to address the problem
- a series of questions to guide your feedback about the considerations and proposed response.

Making the submission

The department welcomes submissions from food importers and businesses involved in the imported food industry, food safety regulators, government agencies, trading partners and members of the public.

Respondents may address some or all of the questions raised throughout this consultation RIS, or can raise a matter not explicitly addressed, as long as it is pertinent to the proposed options for reforms to the management of imported food safety risks.

Submissions are sought by 5:30pm AEST, 30 September 2016.

Submissions can be either made online at agriculture.gov.au/imported-food-reform, by email to foodimp@agriculture.gov.au or by post to Imported Food Reforms, Compliance Division, Department of Agriculture and Water Resources, GPO Box 858, Canberra, ACT, 2601.

Respondents may elect not to have their submission published online.

Summary

The Department of Agriculture and Water Resources is responsible for administering the *Imported Food Control Act 1992*, and in doing so, monitoring imported food for compliance to the Australia New Zealand Food Standards Code. Under the Act, importers are also legally responsible for complying with the standards that apply to their products to ensure they are safe for their intended use. As food businesses in Australia, food importers are also obligated under state and territory food law to only sell safe and suitable foods.

Australia is a net exporter of food. In 2015, Australia exported food to the value of $42.0 billion. By comparison, in the same year, imported food products were worth $17.5 billion (DFAT 2016). The value of food being imported is increasing with a 5 year trend growth rate of 10.3 per cent for processed food and 7.9 per cent for unprocessed food. Between 2013-2015 there were, on average, 16 000 businesses that imported food into Australia. Of these, approximately 11 per cent were frequent importers of food.

Internationally, many countries have moved towards requiring preventative approaches to manage food safety risk associated with imported food. For example, it is understood that the new US Food and Drug Administration's Food Safety Modernization Act places responsibility on importers to verify that their foreign suppliers have adequate preventive controls in place to ensure the food they produce is safe. This approach recognises the limitations of inspection and testing alone to ensure the safety of some foods.

Foodborne illness is a serious public health and safety issue in Australia. In 2010, it was estimated there were 4.1 million episodes of gastrointestinal foodborne illness in Australia and 86 deaths (Kirk et al. 2014). Recent food safety issues with imported food such as the outbreak of hepatitis A associated with imported frozen berries in 2015, have exposed limitations with the current food safety management of imported food, particularly the ability of the system to:

- make importers responsible and accountable for the safety of food being imported
- detect food safety issues in imported food at the border
- monitor new and emerging food safety risks from imported food
- respond quickly and effectively when food safety issues are identified.

As such, the department is proposing a package of legislative and non-legislative reforms to better align the imported food inspection program with contemporary and preventative risk management approaches.

This consultation RIS discusses a number of issues to be considered when addressing this problem, including the estimated costs and benefits of proposed reform options. The policy objective is to strengthen the current system to provide more flexible and targeted ways to prevent and respond to food safety risks, to better protect the health of consumers while reducing the regulatory burden for compliant food importers and upholding our international obligations. This includes:

- increasing importer accountability

  - holding importers accountable for the safety and suitability of food being imported
- increasing importers sourcing safe food
  - recognition of food safety management approaches of compliant imported food business
  - increasing the proportion of food imported that have assurance about its safety (such as government or third party certified food safety schemes)
- improved monitoring and managing of new and emerging risks
  - ability to monitor and manage new and emerging risks to address areas of non-compliance
- improved incident response
  - broaden emergency powers to take precautionary action whilst hazards are unknown or uncertain.

The proposed reform measures also seek to align with state and territory food legislation where relevant and consistent with the policy objective.

Three policy options are presented to address the policy objective. The proposed reforms do not represent a complete overhaul of the current system, rather they are a set of practical options for reform that aim to strengthen the existing system.

Option 1 is non-legislative, option 2 involves minimal legislative change and option 3 includes more comprehensive legislative changes. Each option builds on the previous option with option 3 providing the most comprehensive improvement to the overall imported food regulatory system to address the current limitations and the policy objective.

Under option 1 there would be no legislative changes to the current system and no additional costs to businesses. This option includes initiatives already commenced to address identified limitations not requiring legislative change, including improved government communication during a food incident and increasing the number of importers on a Food Import Compliance Agreement (FICA). Assuming an additional fifty food importing businesses take up a tiered FICA over the next ten years, the regulatory savings are estimated to be $667 000 per year, across these businesses (i.e. $13 340 per year to each business). However, the system will still largely rely on existing border inspection and testing to monitor compliance with food safety requirements and lack flexibility to rapidly respond to food safety issues.

Option 2 includes the initiatives already commenced under option 1 plus more improvements including proactive compliance and enforcement activities, food surveys and increased use of foreign government certification. Foreign government certification offers an alternative to inspection and testing at the border to manage the safety for specific foods, providing savings to importers. Soft or surface ripened cheese are some of the most frequently tested foods under the Imported Food Inspection Scheme. If imports of these products from France and Italy were accompanied by foreign government certificates, the regulatory savings to the 82 food importing businesses currently importing these cheeses, is estimated to be an overall average of $168 000 per year over a ten year period. This equates to a savings of $2 048 per year to each business.

Taking into account the measures proposed under option 1, the net benefit of option 2 is calculated to be an annual saving of $835 000 over ten years to the food importing businesses benefited by these measures. This option does not address all policy objectives, particularly the ability to respond effectively to new and emerging food safety issues and increasing importer accountability for food safety more broadly, not just for those with access to government certification.

Option 3 includes the initiatives outlined in options 1 and 2 plus the following changes to primary (and consequential subordinate) legislation to:

- mandate evidence of supply chain assurance for certain foods
- broaden emergency powers
- increase powers to monitor for new and emerging risks
- recognise a foreign country's food safety regulatory system
- harmonise the *Imported Food Control Act 1992* with domestic food legislation where applicable–including requiring traceability.

The estimated annual net cost to businesses to implement option 3–the most comprehensive reform package–is $545 000 per year across the approximately 16 000 businesses importing food, averaged over ten years. This equates to a cost of approximately $34 per food importing business per year. This option includes legislative measures to effectively respond to potential food safety issues with imported food, requirements for supply chain assurance for certain foods, and recognition of foreign country food safety systems in addition to the measures proposed under options 1 and 2.

Option 3 is the preferred option, as it is the only option to fully address the policy objective and does not impose significant costs on industry. It provides the greatest benefits to consumers by placing more responsibility on importers to source safe food and enabling effective emergency response to be taken on potentially unsafe imported food. Option 3 also provides indirect benefits to importers, as it decreases the likelihood of an imported food safety incident occurring and consequently the costs to industry from such an incident.

The trade implications of the preferred option have been assessed to be minimal on the basis that many importers are already seeking assurance on the safety of the food being imported and have traceability systems in place to enable food to be effectively and efficiently recalled from the supply chain if a food safety issue arises. The proposed reforms also align with those of some of our major trading partners.

Feedback is sought on this analysis, particularly on the underlying assumptions for the costings, as well as the overall approach to address the identified issues.

Background

1.1 Imported food statistics

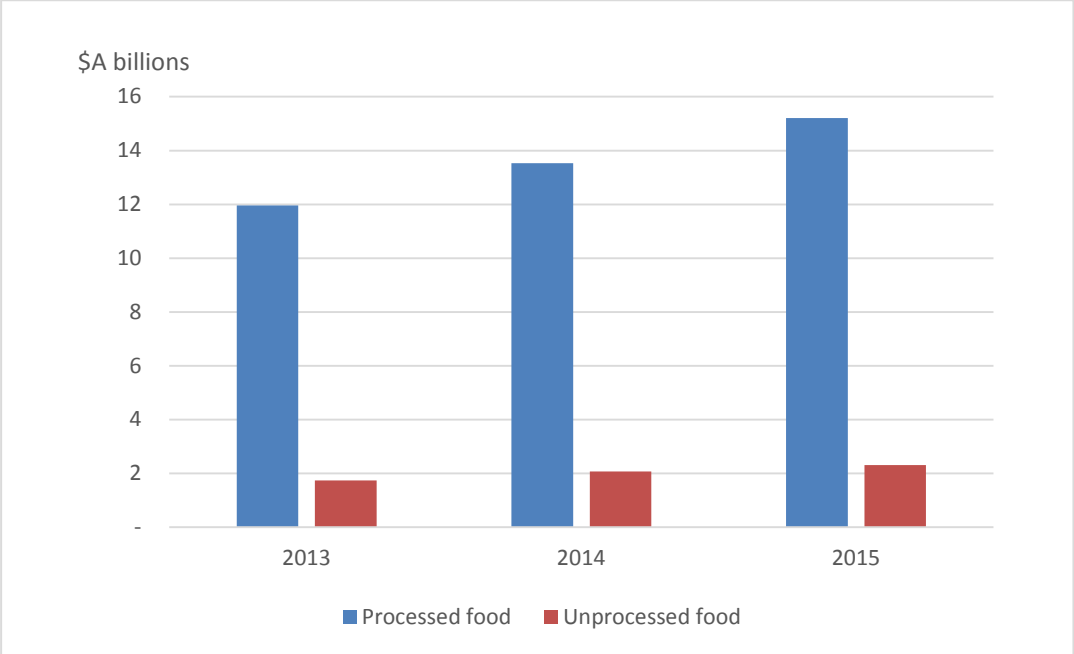
Australia is a net exporter of food. In 2015, Australia exported food to the value of $42.0 billion. By comparison, in the same year, imported food products were worth $17.5 billion (DFAT 2016). Imported food was comprised mainly of processed food ($15.2 billion) and the remainder unprocessed food ($2.3 billion).

The value of food being imported is increasing with a 5 year trend growth rate of 10.3 per cent for processed food and 7.9 per cent for unprocessed food (Figure 1). For unprocessed food, Australia mainly imports food within the Trade Import and Export Classification (TRIEC) of 'vegetables, fruit & nuts, fresh, chilled or provisionally preserved' and for processed food, 'preparations of food, beverages & tobacco not elsewhere specified'. This includes highly processed dairy products, beverages and sauces and condiments.

New Zealand is the major source of Australia's food imports, followed by United States and China (Figure 2).

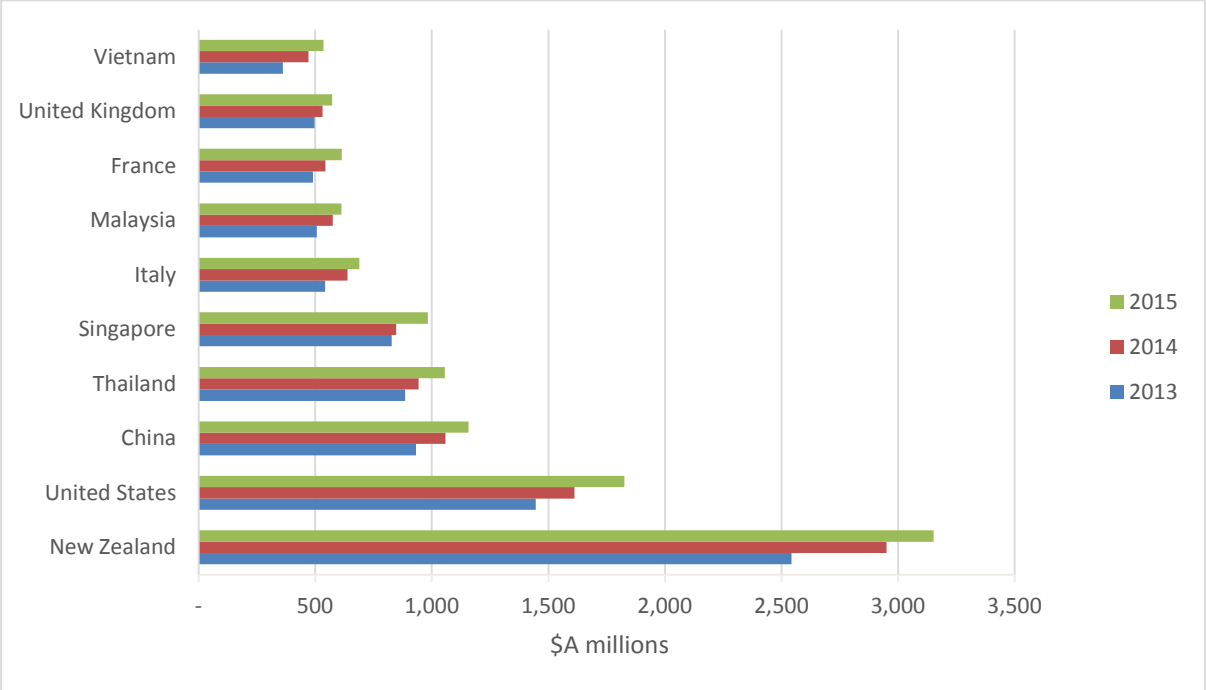
In 2015, there were approximately 17 000 food importers, with an average of 16 000 from 2013-2015 (data sourced from the Integrated Cargo System (ICS)–the electronic recording system for recording movement of goods across Australia's borders). A food importer is considered to be any business that imported food from 2013-2015. This includes businesses where the importation of food only formed part of their business. From 2013-15, approximately 11 per cent of importers were frequent importers (importing more than 20 consignments of food per year), 12 per cent imported between 6-20 consignments and the majority (77 per cent) imported five or less consignments. This indicates that only 11 per cent of the 16 000 importers were fundamentally in the business of importing food.

Figure 1 Value of food imports from 2013-2016



Source: DFAT 2016

Figure 2 Top 10 countries for food imports



Source: DFAT 2016

1.2 Food regulatory system in Australia

The food regulation system is a cooperative bi-national arrangement involving the Australian Government, states and territories and New Zealand (Department of Health 2016). Figure 3 provides a pictorial representation of the food regulatory system.

The food regulatory system in Australia is established through an intergovernmental agreement with the States and Territories and a treaty between Australia and New Zealand (Department of Health 2016). Additionally, Food Standards Australia New Zealand (FSANZ), the joint Australia and New Zealand standards setting body, is established under Commonwealth legislation, the *Food Standards Australia New Zealand Act 1991*. Each state and territory in Australia has its own laws to implement and enforce the food standards developed by FSANZ.

Food policy is set by the Australia and New Zealand Ministerial Forum on Food Regulation which consists of health and agriculture ministers from the states and territories, and the Australian and New Zealand governments. Food standards are developed to reflect this policy framework (FSANZ 2015a).

The Code includes standards for:

- the use of ingredients, processing aids, colourings, additives, vitamins and minerals
- the composition of some foods, such as dairy, meat and beverages as well as new technologies such as novel foods
- labelling requirements for both packaged and unpackaged food, including specific mandatory warnings or advisory labels
- safe food handling practices for food businesses
- primary production and processing.

Food imported into Australia must comply with the *Imported Food Control Act 1992* (*IFC Act 1992*) which also requires imported food to comply with the Code.

Figure 3 The food regulatory system

Source: FSANZ 2015a

1.3 Current regulation of imported food

Foods imported into Australia are subject to requirements under the Biosecurity Act 2015 to address biosecurity concerns and the IFC Act 1992 for compliance with Australian food standards and the requirements of public health and safety. Under the IFC Act 1992, importers are legally responsible for complying with the standards that apply to their products to ensure they are safe and suitable for their intended use.

To monitor compliance with Australia's imported food requirements, the department operates a risk based border inspection scheme, the Imported Food Inspection Scheme (IFIS), under the IFC Act 1992. Food is referred for inspection under the IFIS by the Department of Immigration and Border Protection based on internationally agreed tariff codes. The rate at which food is referred for inspection depends on its risk. Under the IFIS, food is classified as:

- risk food
- surveillance food; or
- compliance agreement food.

Risk food is the type of food that has the potential to pose a high or medium risk to public health. FSANZ provides advice to the Minister for Agriculture and Water Resources on the foods that pose such a risk. Risk food is initially referred for inspection and testing at a rate of 100 per cent against a published list of potential hazards (specific to the food), but is decreased if a history of compliance is established. However, any fail will return the inspection rate to 100 per cent.

Surveillance food is considered to pose a low risk to human health and safety. Each consignment (or lot) of surveillance food has a 5 per cent chance of being referred for inspection. All surveillance foods referred are visually inspected for obvious signs of contamination or deterioration and the labels of the food are also assessed for compliance against labelling standards. Samples of surveillance food may also be analysed for pesticides and antibiotics, microbiological and chemical contaminants and food additives. If a surveillance food fails an inspection, the inspection rate is increased to 100 per cent until a history of compliance is established. The inspection rate for a surveillance food can also be increased by placing a 'holding order' on the food, if there are reasonable grounds for believing the food may fail an inspection or analysis. This effectively increases the inspection rate for the food to 100 per cent until compliance is established (clause 15 of the IFC Act 1992).

Figure 4 provides a summary of the rate at which risk and surveillance food is referred for inspection under the IFIS and how this rate varies, depending on compliance. The arrows indicate a reduction in the rate of referral or an increase in the rate of referral based on compliance.

Figure 4 Overview of rate of referral of risk and surveillance food for inspection under the Imported Food Inspection Scheme, depending on compliance

FOOD CATEGORY	RATE OF REFERRAL FOR INSPECTION	
Risk (Medium – High Risk)	Start	100%
	5 consecutive passes	25%
	Further 20 consecutive passes	5%
	Any failure	100%
Surveillance	Start or return after 5 consecutive passes	5%
	Any failure	100%

Note: Compliance is based on the combination of specific food, from a specific producer in a specific country.

Compliance agreement food, is food that is imported by a business under a Food Import Compliance Agreement (FICA). FICAs offer food importers an alternative regulatory arrangement to inspection and testing of their products under the IFIS by recognising an importer's existing documented food safety management system. This provides these businesses with a streamlined process for importing food, which represents a substantial cost saving. It is optional for food importers to enter into a FICA. Currently, fifteen importers operate under a FICA.

Food may also be imported under a foreign government certification arrangement. The department can enter into a government-to-government certification arrangement with the national competent authority of a country exporting food to Australia, providing confidence that the food has been produced safely. While this certification can be developed for any imported food, this is only currently used for risk food because the Regulations only provide for a reduction in inspection rates for risk foods. Consignments of imported food accompanied by a recognised foreign government certificate may be inspected and tested at a reduced rate (5 per cent). Such arrangements are in place for certain risk classified seafood from Thailand and Canada and a risk classified cheese from France. Use of a recognised foreign government certificate in the clearance of food imported to Australia is normally voluntary but an Order made by the Minister may mandate a foreign government certificate for a food. Recognised government certification is currently mandatory for beef and beef products and raw milk cheese.

Under the IFC Act 1992, food may also be imported under a recognised quality assurance certificate, if approved by the Secretary of the department. However, importers and overseas food processing operations have never sought to obtain such an approval and therefore no food is currently imported under this kind of certification.

Special arrangements apply to food imported from New Zealand. Under the Trans-Tasman Mutual Recognition Act 1997, any good that may be legally sold in New Zealand may be sold in Australia. The Act provides for all food that is either produced in, or imported into and cleared for sale in New Zealand, to be imported without being inspected and/or analysed, with the exception of some foods where Australia and New Zealand do not have agreed food safety controls. Currently the only foods that Australia and New Zealand do not have agreed food safety

controls for are beef and beef products (for Bovine spongiform encephalopathy (BSE) certification), cassava chips and seaweed.

When food subject to the IFC Act 1992 is found to be a failing food, on the basis that it does not meet the applicable standards, or it poses a risk to human health through the operation of the IFIS, it may be required to be treated, destroyed or exported.

When imported food has cleared the border, it is subject to state and territory food legislation. All food sold in Australia must comply with the state and territory food legislation. The state and territory food legislation include offences for the sale of food that is unsafe or unsuitable, including non-compliance with the requirements of the Code. State and territory and local government food regulatory agencies are responsible for ensuring that all food available for sale within their jurisdiction, both imported and domestically produced food, meets the requirements of the Code.

1.3.1 Responding to food incidents

Food safety incidents associated with food, including imported food are managed by multiple Australian Government agencies and state and territory food safety regulators using a range of generic and sector-specific agreements, protocols, networks and committees. When a food incident occurs the regulatory response is coordinated through the Bi-National Food Safety Network (BFSN) which is made up of Australian Government agencies (including a representative from the department), FSANZ, state and territory and New Zealand food regulators. FSANZ's role is to coordinate information sharing between the regulators. Where there are cases of illness associated with a contaminated food, OzFoodNet –the Australian Government's enhanced foodborne disease surveillance system comprising of members from all states and territories and coordinated by the Commonwealth Department of Health, conducts the epidemiological investigation and reports findings to the BFSN.

Incidents being managed under the BFSN, may trigger activation of the National Food Incident Response Protocol (NFIRP). The NFIRP provides a formal mechanism for managing national food incidents with FSANZ being responsible for the key coordination roles of National Food Incident Coordinator, Risk Assessment Coordinator and Communications Controller.

1.4 Previous imported food reviews

1.4.1 National Competition Policy Review of the Imported Food Control Act 1992

The Imported Food Control Act Review (the Review) was completed in 1998 as part of the comprehensive examination of legislation by the Commonwealth Government to ensure compliance with the National Competition Policy (Tanner et al. 1998).

The Review identified that food safety regulation and food safety practices in Australia and overseas were undergoing major change. At the same time, there was rapid growth in world food trade, Australian food consumption patterns were changing and there was increasing consumer concern about food safety.

The Review noted that much of the food being consumed by Australians is relatively underprepared or "fresh" compared to the traditional thoroughly cooked or salted foods. Such foods come with higher inherent risk if not prepared under adequate safety systems. In that

regard, the development and application of preventive safety programs, such as those based on a Hazard Analysis Critical Control Point (HACCP) approach, have been found to be more effective in producing safe food than traditional end-product inspection and testing.

The Review examined the costs and benefits of the IFC Act 1992 and, where possible, attempted to quantify them. The costs of the scheme were estimated to be in the order of $9 million annually, representing 0.25 per cent of the value of food imported into Australia. These costs are largely borne by the importing industry and consumers.

Where imported foods are used as ingredients for further processing, export competitiveness may be affected. Benefits related mainly to the reduction in costs of illness. The estimate of the benefits was considered conservative because it did not take into account all failures detected by the program or the educative and deterrent effects of the scheme. In the absence of such a scheme, it was considered likely that the incidence of sub-standard or unsafe food entering the Australian market would increase.

The Review was cognisant of the need for the IFC Act 1992 to be consistent with Australia's international obligations and trade objectives, and for it to be compatible with advances in food processing and food safety. The Review's recommendations reinforced the conformity of Australia's controls on imported foods with the principles of the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade. The Review recommended that in order to maintain the relevance and effectiveness of the IFC Act 1992, it is important that the IFC Act 1992 allows the delivery of a program that adheres to scientific risk-management principles, and is performance-based, transparent and flexible, consultative, efficient and effective.

The Review concluded that the best way to ensure that imported food complies with Australian public health and safety standards is to develop a partnership (or co-regulatory) approach between industry and government. The partnership approach will encourage industry to take greater responsibility for ensuring food safety while, at the same time, retaining government control over the food importing system through regular government-controlled audits.

This was achieved by providing food importers with the opportunity to enter into FICAs. Under option 1 in section 5.1.3, it is recommended that more be done to increase the number of importers on a FICA, as current uptake is low.

1.4.2 Australian National Audit Office Report–Administration of the Imported Food Inspection Scheme, 2015

In 2015, the Australian National Audit Office (ANAO) published its findings into an independent performance audit on the effectiveness of the department's administration of the IFIS (ANAO 2015). The ANAO Report noted that the importation of food from countries with varying production and processing practices has the potential to expose Australian consumers to a broad range of food-borne illnesses if food safety risks are not effectively managed.

The ANAO Report found that in the context of the legislative framework established for the regulation of imported food, the department's administration of its responsibilities under the IFIS has been generally effective. In particular: planning for compliance monitoring is informed by food risk assessments prepared by FSANZ; regulatory activity takes into account the compliance history of producers; and actions taken are proportionate to the level of risk

presented. Further, inspections are underpinned by a staff capability program, a broad range of procedural guidance material, regular management verification of activities, and food testing is conducted by independently accredited laboratories. The department has also recently commenced initiatives to make its regulatory activities more client-focused and consistent through the re-organisation of business processes and deployment of new technologies.

The ANAO Report noted that in light of recent imported food incidents, the department has given preliminary consideration to legislative reforms that would better assist in the management of food incidents and also provide for systemic improvements in the regulation of imported food. The reforms under consideration would, if adopted, allow the department to: hold food at the border pending the preparation of a risk assessment by FSANZ; conduct compliance campaigns and intelligence gathering activities beyond risk and surveillance food inspections; and apply holding orders to allow for the establishment of new testing requirements, among other things.

1.5 International approaches to imported food control

In light of international guidance and best practice, many overseas countries have, or are moving towards, preventative approaches to managing food safety risks associated with imported food. Following is a summary of the regulatory approaches by some of Australia's key trading partners to manage risks associated with imported food.

1.5.1 United States

In 2011, the United States (US) Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) was signed into law, representing the most sweeping reform of food safety laws in the US in more than 70 years (FDA 2016). It aims to take a more preventative approach to food safety, by shifting the focus from responding to contamination to preventing it (FDA 2016). The law includes new tools to hold imported foods to the same standards as domestic foods. New powers include:

- **Importer accountability**: Importers will have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.
- **Third Party Certification**: The FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with US food safety standards. This certification may be used to facilitate the entry of imports.
- **Certification for high risk foods**: FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the US.
- **Voluntary qualified importer program**: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.
- **Authority to deny entry**: FDA can refuse entry into the US of food from a foreign facility if the FDA is denied access by the facility, or the country in which the facility is located (FDA 2015).

The rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals has been finalised, and compliance dates for some businesses begin in May 2017. It places obligations on importers to verify that imported food is compliant with US food safety laws across the supply chain.

For most foods, FSVP includes activities for the identification of hazards and documentation of assurances (e.g. testing and audits to verify that their foreign suppliers have adequate preventive controls in place to ensure safety and corrective actions). The FDA can also accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards, although the policy/guidance for this is still in development. The FSVP is to be re-evaluated every 3 years, or when a new risk emerges, and applies to each supplier and food. For high risk food, third party certification by a private company or government authority, and inspection of the overseas facility by US officers may be required.

Exemptions to the FSVP include food imported for research or personal consumption, food imported for further processing, low acid canned foods, juice and fish products covered by more extensive FDA HACCP regulations and meat, poultry and egg products which are regulated by US Department of Agriculture (USDA). Exemptions to the rule are also provided for small businesses such as farms averaging less than $500 000 sales during the previous three years, although these businesses must still meet reduced requirements.

1.5.2 Canada

In 2012, Canada passed the *Safe Food for Canadians Act 2012*. This Act:

- makes food as safe as possible for Canadian families
- protects consumers by targeting unsafe practices
- implements tougher penalties for activities that put health and safety at risk
- provides better control over imports
- institutes a more consistent inspection regime across all food commodities, and
- strengthens food traceability.

The Act includes powers to register or license importers, and prohibits the importation of unsafe food commodities. It also holds importers accountable for the safety of imported products – that is, that they meet domestic requirements for food safety.

Importers in Canada must verify the suitability and safety of their suppliers. Guidance on how importers can meet this is provided in the Canadian Food Inspection Agency (CFIA) Good Importing Practices (GIP) for Food (CFIA 2014). The GIP informs the decision of CFIA as to whether the food complies with Canadian food safety legislation. The GIP requires importers to have the ability to produce, on request, information about the critical steps of production and the food safety controls put in place to manage the risks, an evaluation of the supplier and have accurate records of distribution for traceability and recall. For some higher risk products an import licence is required which assures food safety along the supply chain (e.g. cheese), or it is produced in an approved country and establishment (e.g. meat and meat products).

1.5.3 European Union

Article 3 to 6 of *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs* defines specific hygiene requirements for food imported into the European Union, which includes:

- a general obligation to monitor the food safety and processes under their own responsibility
- general hygiene provisions for primary production
- a HACCP based procedure for post primary production
- microbiological requirements for certain products
- registration or approval of establishments along the supply chain.

EU importers must ensure that the food businesses they are supplied by adhere to these requirements. In addition, Annex I to Regulation (EC) No 669/2009 lists food and feed of non-animal origin that are subject to an increased level of official control for imports. The enhanced control mechanism means that competent authorities will:

- carry out systematic checks on documents accompanying the consignments,
- conduct physical checks, including laboratory analysis, at a frequency related to the risk identified.

This list is regularly updated by the EC Standing Committee on the Food Chain and Animal Health based on information from various sources such as the Rapid Alert System for Food and Feed, reports from the EU Food and Veterinary Office, and EU Member States and non-EU countries.

1.5.4 New Zealand

New Zealand passed a new food act in 2014, the *Food Act 2014* to make fundamental changes to New Zealand's domestic food regulatory system. It also incorporated changes to improve the control of imported food, including the compulsory registration of importers and a border system responsive to the risk of the food being imported (NZFSA 2009). All importers of food in New Zealand must now register with NZ Ministry of Primary Industries (NZ MPI) as a food importer (or use a registered importer), safely source and handle food before export, and meet specific requirements for foods identified as presenting a higher risk to consumers.

Importers must have accurate records to show how food has been produced, stored and transported, have records of product purchased for traceability and maintain a list of suppliers with accurate contact information.

Foods that pose a greater risk to consumers and public health are classified as 'foods of high regulatory interest' or 'foods of increased regulatory interest'.

A food safety clearance is required to import any foods of regulatory interest into New Zealand. These foods include a range of dairy, seafood, meat, nuts and processed foods including frozen berry fruit.

A food safety clearance is required to import any foods of regulatory interest and importers of foods of regulatory interest are required to demonstrate the food's safety in one of four ways in order to obtain a food safety clearance.

1) A registered food importer that's is verified by the NZ MPI can be issued with a NZ Importer Assurance. This is a certificate issued by the Chief Executive based on an audit of the registered importers business.

2) Bovine meat and products containing bovine meat that are imported from Australia must be accompanied by a manufacturer's declaration that the meat is of Australian or New Zealand origin.

3) For some countries, NZ MPI will accept official certificates (from the appropriate government agency) as assurance the food is safe. The certificate must be from the country of origin for New Zealand.

4) In some cases, food will have to be sampled and tested by an approved laboratory.

2 Statement of the problem

Foodborne illness is a serious public health and safety issue in Australia. In 2010, it was estimated there were 4.1 million episodes of gastrointestinal foodborne illness in Australia and 86 deaths (Kirk et al. 2014).

Recalls and food safety incidents are likely occurrences in a risk-based food safety system. However, recent food safety issues with imported food such as the outbreak of hepatitis A associated with imported frozen berries in 2015 have exposed limitations with the current regulatory system (Box 1), particularly the ability of the system to:

- make importers responsible and accountable for the safety of food being imported
- detect food safety issues in imported food at the border
- monitor new and emerging food safety risks from imported food
- respond quickly and effectively when food safety issues are identified.

Internationally, many countries have moved towards requiring preventative approaches to manage food safety risk associated with imported food. For example, it is understood that the new US Food and Drug Administration's Food Safety Modernization Act places responsibility on importers to verify that their foreign suppliers have adequate preventive controls in place to ensure the food they produce is safe. This approach recognises the limitations of inspection and testing alone to ensure the safety of some foods.

The department's imported food safety incident management experience indicates that there is increased awareness of both domestic and international food safety incidents. This has driven a shift in the expectations of consumers that government should be able to respond quickly to new and emerging food safety risks by controlling the entry of potentially unsafe food from entering the domestic market place.

Additionally there has been an increase in the globalisation of food supply that has seen a change in consumer demands for fresh minimally processed food where end-point testing for foodborne pathogens is of limited value.

These shifts have indicated that the current regulatory system under the *IFC Act 1992* has not kept pace with the changing circumstances and approaches of contemporary food safety risk management systems that have emerged from the globalisation of supply chains and subsequent complexity of food production systems. The complexity of these food production systems has seen a growth in the number of points within and across a supply chain which presents opportunities for error and challenges for trace-back investigations.

While Australia is a net exporter of food, the amount of food Australia imports is increasing, with a 5 year trend growth rate of 10.3 per cent for processed food and 7.9 per cent for unprocessed food per cent. This imposes greater challenges on our food importers to have confidence in the safety of this food and to have the ability to trace the source of the food.

At-border assessment of imported food needs to rely less on testing of the food and more on assurance that preventative controls are in place through the supply chain and that food is traceable and can be recalled efficiently and effectively. It is also essential that the system can readily monitor new and emerging risks and provide flexible and targeted ways to prevent and respond to food safety risks. The current regulatory system focuses on known issues and lacks the ability to identify and respond to potential food safety threats.

There are also some differences in approach to the regulation of food at-border and post-border as a result of the *IFC Act 1992* not being harmonised with state and territory government updates to domestic food legislation in 2000.

Box 1 Recalls and food safety incidents associated with imported food

In 2013-14 the IFIS referred 29 102 lines of imported food for inspection resulting in 95 058 tests being undertaken, including label and visual checks as well as laboratory testing for microbiological and chemical contamination. Overall compliance rate was 98.5 per cent based on tests completed. This high compliance suggests there are minimal food safety concerns with imported food that is referred through the system.

Data on recalls and food safety incidents provides another perspective. For food safety incidents requiring management under national frameworks and recalls, imported food is over represented compared to domestically produced food, given that imported food comprises approximately 20 per cent of the total household expenditure on food.

From data compiled by FSANZ on food recalls and the department on incidents, in the last five years, 34 per cent of recalls involved imported foods (mainly because of undeclared allergens–48 per cent) and since 2006, 63 per cent of the food safety incidents requiring management under a national framework were associated with imported food. These incidents were associated with 244 illnesses and two deaths (including allergic reactions). It is important to note that this data about food safety incidents does not include those that concern domestically produced food and do not require a national response. The national responses to imported food safety incidents deal with the additional complexity of both the on and off-shore supply chains.

In February 2015, there was a highly publicised outbreak of hepatitis A associated with imported frozen mixed berries. Thirty three cases of hepatitis A resulted from this outbreak. In December 2013, a ten year old boy died following an allergic reaction from consuming an imported coconut drink that contain undeclared milk content. In 2015 another child was reported to have had an anaphylactic reaction to another brand of imported coconut drink with undeclared milk content.

A recently published report (2014) by the Australian National University on foodborne illness in Australia has estimated that the annual incidence in 2010 was 4.1 million (90 per cent credible interval (CrI): 2.3–6.4 million) cases of foodborne gastroenteritis occurring each year, along with 5 140 (90 per cent CrI: 3 530–7 980) cases of non-gastrointestinal foodborne illness and 35,840 (90 per cent CrI: 25 000–54 000) cases of sequelae (Kirk et al. 2014). The cost of foodborne illness in Australia has been calculated to be approximately $1.2 billion/annum using estimates of foodborne illness in 2000 (Abelson et al. 2006).

The estimates of foodborne illness in the report above do not include allergic reactions to foods. However, allergic reactions to food are an increasing issue in Australia–the rate of admission to hospital with food anaphylaxis increased significantly in the years between 1995 and 2006, most dramatically in the 0–4 year age group (University of Sydney 2014). It is estimated that one in ten babies born in Australia today will develop a food allergy (ascia 2014).

2.1 Importer accountability

The *IFC Act 1992* primarily regulates the food being imported and not the business that is importing the food. While the *IFC Act 1992* includes an offence for a person who ***knowingly*** imports food that does not meet applicable standards or poses a risk to human health, it places no direct obligations on the food importing business, at the border, to take reasonable measures to ensure food being imported is safe and suitable.

By contrast, state and territory food legislation includes many more offences for selling unsafe and unsuitable food and handling food in a way that would render food unsafe or unsuitable. This is supported by measures in the Code that require food businesses to notify their business to the relevant authority, handle food safely and have information available to assist with traceback and recall activities.

Food businesses in Australia that import food may be registered or licensed by state and territory food regulators and therefore subject to the food business requirements in the Code through the state and territory food legislation. However, not all businesses that import food are regulated by states and territories and state and territory enforcement agencies can only enforce legislation post border.

There is therefore inconsistency in the obligations placed on food businesses at border and post border, with more obligations applying post border. If greater consistency could be achieved, all businesses importing food would be required to take reasonable measures to ensure the safety and suitability of food being imported.

2.2 Ability to detect food safety issues at the border

For some food risks, preventative controls through the supply chain are essential for producing safe food. Australia's current at-border inspection and testing approach that underpins the risk-based IFIS, while providing some level of protection, does not always provide an adequate level of assurance about the safety of imported food. This is particularly the case when food is tested for the presence of foodborne pathogens and certain kinds of chemical hazards that may not be evenly distributed throughout a food lot or consignment, as this testing has the following limitations:

- only a small portion of food in a lot can be tested and a negative result will not guarantee that the entire lot is safe
- for some foodborne pathogens and hazards, there are no reliable effective tests that can be applied at the border (e.g. it is difficult to test for viruses in foods such as norovirus and hepatitis A virus or some biotoxins)
- foodborne pathogens and some chemical hazards are challenging to isolate when the prevalence and/or concentration of the pathogen is low in a food (e.g. pathogenic strains of *Escherichia coli* such as *E. coli* O157 can cause serious illness in low numbers, below the level that can be reliably detected in food).

While, statistically based sampling can be an effective tool to verify compliance with food standards, it is impractical to test all imported food for hazards of concern at the border to assess safety.

The safety of foods is best ensured through the effective implementation of validated control measures throughout the food chain to minimise contamination and assure food safety. As food importers have no direct control over the production of the food they are importing and because testing for safety is limited, assurance of the food's safety should be demonstrated by proof that the food has been produced under an effective food safety management system. This is particularly important for foods where food safety controls throughout the supply chain are essential for producing this food safely.

For example, the safety of ready-to-eat produce is dependent on it being grown, harvested, processed and packaged in accordance with good agricultural and good hygiene practices. This is because if the produce is contaminated with a foodborne pathogen, there may be no further step, such as cooking, to destroy the pathogen before the produce is eaten. As this food cannot be reliably tested at the border for possible microbial contamination, importers of such foods should ensure the supply chains they use have effective food safety management systems in place.

2.3 Emergency response

Current emergency powers are limited to food safety issues and/or hazards that have already been, or can be, identified. These powers do not adequately address the management of food safety risks that are reasonably suspected of being present but cannot be analysed (for example, viruses). This is particularly challenging at the beginning of an incident where regulatory action to prevent potentially unsafe food from entering the domestic market is delayed whilst the food safety hazard and risk is identified and confirmed and the appropriate response is established.

If there is a known or suspected food safety issue with an imported food, it is critical that the department can:

- temporarily suspend the importation of the implicated food
- identify importers of the unsafe food and where in the supply chain unsafe food has been distributed
- work cooperatively and effectively with other relevant government agencies and industry to manage the food safety risk and communicate the risk to the public.

Prevent further importation of the implicated food

If there are reasonable grounds for believing that an imported food would, on inspection, or inspection and analysis, pose a risk to human health, the Secretary of the department can issue a holding order for the food (section 15 of the *IFC Act 1992*). This means the food can be held at the border and not released, until the conditions of the holding order have been met.

A holding order must also only be placed on a food if there are reasonable grounds to believe that a food, on inspection, or inspection and analysis would fail. The holding order must also specify the circumstances in which the order will be revoked. This is effective if the food safety issue is known and can be detected in the food, thereby allowing the food to be inspected and/or analysed and passed or failed. However, this is problematic where there is an unconfirmed food safety issue or the issue cannot be easily detected in the food.

The department is therefore currently constrained from taking urgent action when there is a known or suspected food safety issue due to the limitations of a holding order when there is an unconfirmed food safety issue or the issue cannot be easily detected in the food.

Identify importers of the unsafe food and where in the supply chain unsafe food has been distributed

Until recently the department had difficulty accessing and analysing import data to identify producers of foods and therefore importers of potentially unsafe food during an incident. These issues have now been rectified by improving access to import data contained within the ICS and requiring producer information to be lodged for all imported food (discussed under option 1). However, there are still challenges with confirming with these importers if they have sourced implicated batches of the food and if they have, where this food has been distributed, as not all importers have effective traceability systems. Traceability systems enable the importer to trace food one step backwards and one step forwards.

While state and territory food legislation includes traceability requirements not all importers are regulated by state and territory food legislation. For example, in Western Australia food importers are exempted from being registered, if they handle packaged foods only.

Any delay in confirming importers of a potentially unsafe food and its distribution in the supply chain, means there will be a delay in taking appropriate risk management action, such as a food recall. This increases the likelihood that more consumers could become ill.

Work cooperatively and effectively with other relevant government agencies to manage the food safety risk and communicate the risk to the public

Food safety issues that require coordination by more than one food regulatory agency or between Australia and New Zealand are currently managed under the BFSN which is coordinated by FSANZ. The Department of Agriculture and Waters Resources and the Department of Health are both active participants of the BFSN, sharing information about imported food safety issues, providing epidemiological updates, participating in teleconferences and providing advice on action items.

Any food regulatory agency with legislative responsibility for food safety can activate the NFIRP, which provides a formal framework for the coordination of Australian, and where appropriate New Zealand, government agencies responsible for food safety and food issues in the event of a national food incident. The department can therefore activate the NFIRP when an imported food is associated with illness, injury or death and national coordination is needed under a formal framework between the state and territory food regulators and/or with New Zealand.

While there are existing networks and protocols for the coordination of food safety issues between agencies, the hepatitis A outbreak associated with imported frozen berries, highlighted issues with coordination between Australian government agencies. Following this outbreak, an Australian Government inter-departmental committee considered areas for improvement when responding to a food safety incident. The key area for improvement was about better quality communication from the Australian Government, especially in the early stages of an incident. Work to improve Australian Government communication has already been progressed and is discussed under option 1.

2.4 Monitoring new and emerging risks

The imported food regulations currently require the restrictive classification of food into 'risk' and 'surveillance' food with prescribed rates of inspection for each classification. This lack of flexibility makes investigation of new and emerging risks challenging.

The department receives a range of information about new and emerging food safety risks from domestic and international sources. To respond the department needs to identify whether the risk is present in imported food, assess the risk and then, if needed, take appropriate risk management action. To obtain data on a new or emerging risk, the department can currently apply a new test to the food at the border or undertake a survey. When data is available, FSANZ can be approached to provide risk advice.

However, these options have limitations. While the department can already subject an imported food to a new test, the Regulation currently authorises 5 per cent of the consignments of a surveillance food to be referred for this new test. This low referral rate is unlikely to provide sufficient data quickly enough to make an assessment of a food's safety. The department could also obtain the data needed by submitting a new survey proposal to domestic food regulators. However, there can be long delays in obtaining the funding and commitment from food regulators for a new survey, particularly when there are competing proposals that are considered higher priority.

2.5 Removing compliant food from border intervention

The *IFC Act 1992* currently has some mechanisms to recognise imported food certified by foreign governments and food importers that operate under food safety management systems that manage the risks with the food they are importing. These mechanisms have the effect of removing food from the IFIS where there is confidence about its safety. However, more needs to be done to increase the amount of food and food importers that are recognised so there can be less compliance intervention at the border.

The Act enables the department to enter into a government-to-government certification arrangement with the national competent authority of a country exporting food to Australia, providing confidence that the food has been produced safely. Currently consignments of imported food accompanied by a recognised foreign government certificate may be inspected and tested at a reduced rate (5 per cent). Foreign government certification arrangements are currently in place for certain risk categorised foods but this could be increased by promoting the advantages of these arrangements to countries exporting a high volume of a risk food to Australia. Importers choosing to source foods from suppliers with this certification would then benefit from reduced border intervention as they would incur less compliance costs.

Food importing businesses that have documented food safety management systems in place can apply for a FICA to recognise this system. Food imported by a business with a FICA is not subject to the IFIS, thereby streamlining the importation process and providing considerable savings to these businesses from costs associated with inventory control, delays and service fees. If more importers enter into a FICA, it would focus inspection activity on potentially non-compliant imported food.

However, while importers have been able to operate under a FICA since 2010, there has been a low uptake. The likely reasons for the low uptake and options to make this arrangement more attractive to food importers are discussed in section 5.1.3.

Currently the only country with reduced border inspection for exports from that country is New Zealand, as the *IFC Act 1992* only provides for food from New Zealand to be exempted from the application of the Act. New Zealand is exempted under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). Section 5.3.4 discusses allowing foreign government equivalence for other countries.

2.6 Consistency of domestic and imported food legislation

State and territory governments updated domestic food legislation in 2000 to align with food provisions contained in the Inter-Government Food Regulation Agreement. The *IFC Act 1992* was not aligned and as a result has inconsistencies with key components of the domestic legislation such as offences, definitions, emergency powers and the ability to enforce traceability of food and ensure effective and efficient recall of food. Consequently, food at the border is not regulated in a consistent way to food post border.

2.7 Summary of the problem

Food safety issues with imported food have highlighted limitations with the existing regulatory system's ability to make importers accountable for the safety of the food being imported and to identify and respond to food safety risks with imported food. The *IFC Act 1992* regulates the food being imported and does not place specific obligations on the importing food business. This makes enforcement challenging at the border, particularly when no test can be applied to assess an imported food's safety. Instead, the focus needs to be on importing businesses seeking food safety assurance from suppliers on the safety of the food.

The restrictive classification of food into 'risk' and 'surveillance' does not enable new and emerging risks to be easily investigated, as there is no flexibility to vary referral rates for inspection unless the risk has already been established. The emergency powers are also too restrictive as they are limited to food safety issues that have already been, or can be, identified leaving a gap for those that are reasonably suspected of being present. The *IFC Act 1992* has also not kept pace with domestic food regulation in Australia or international approaches to the control of imported food. Work has commenced on addressing some of these issues and this is discussed under option 1. However, more action needs to be considered to fully address the problem outlined.

Australia experiences relatively few food safety incidents related to imported food. However, recent incidents have exposed some limitations with the current risk-based system for the management of imported food safety risks. The key areas of concern are that the system has:

- limited ability to hold importers accountable for the safety of imported food
- narrow powers to address and respond to unknown and emerging risks
- limited options for compliant importers to reduce their regulatory burden

- inconsistencies with the state and territory food legislation in the areas of offences, definitions, emergency response and the ability to trace food
- limited ability to utilise importer details for compliance analysis, consultation and education purposes.

It is important that our food safety system continues to take a risk-based approach that enables intervention where the risks are highest whilst recognising existing industry food safety systems that manage the risks effectively and that are consistent with our international obligations.

3 Need for government action

Foodborne illness is a serious public health and safety issue in Australia. In 2010, it was estimated there were 4.1 million episodes of gastrointestinal foodborne illness in Australia and 86 deaths (Kirk et al. 2014). The economic costs of foodborne illness in Australia are substantial from medical practitioner visits, antibiotic prescriptions and days of work lost each year, costing $1.2 billion/annum (Abelson et al. 2006). This, largely preventable, burden of foodborne illness to the Australian community highlights the need to continue to improve food safety in Australia (Kirk et al. 2014).

Importers of food in Australia are currently subject to regulatory control under the *IFC Act 1992* and state and territory food legislation. Market forces are also likely to motivate food importers to take steps to ensure food being imported is safe and suitable as there are negative consequences if an importer is found to be supplying unsafe or unsuitable food. For example, businesses and consumers will not buy a product associated with illness. A business also runs the risk of having to pay compensation if found liable for supplying a consumer good that has caused harm and/or being prosecuted under existing food legislation.

Consumers of imported food are generally unable to assess, when purchasing this food, if it is safe and suitable for consumption. For example, purchasers of the imported frozen berries associated with the hepatitis A outbreak in 2015, were unaware the product was contaminated as foodborne pathogens do not alter the appearance or taste of food. The exception to this is persons who suffer allergic reactions to foods, who rely on compulsory declarations on food labelling to assess whether it can be safely consumed. However, this does not work when labelling information is incorrect or missing. The imported coconut drink associated with the death of a child in 2013 did not have a declaration on the label that the product contained milk products.

Consumers are therefore reliant on existing food regulation and market forces to compel importers of food to ensure food is safe and suitable. However, there is evidence that this is not working effectively to minimise foodborne illness and death from imported food. While it is unknown what percentage of foodborne illness in Australia each year is attributable to imported food, since 2006, 63 per cent of food safety incidents requiring management under a national framework were associated with imported food (data compiled by the department in consultation with FSANZ and OzFoodNet). These incidents were linked to 244 cases of illness (including allergic reactions to food) and two deaths.

If government takes no action to address the identified problem, food safety issues with imported food will continue.

4 Policy objective

This consultation RIS raises a range of concerns in relation to the management of imported food safety risks. These include that the current system has limited ability to provide flexible and targeted ways to prevent and respond to food safety risks.

The policy objective is to strengthen the current system to provide more flexible and targeted ways to prevent and respond to food safety risks, to better protect the health of consumers while reducing the regulatory burden for compliant food importers and upholding our international obligations. This includes:

- Increasing importer accountability
  - holding importers accountable for the safety and suitability of food being imported
- Increasing importers sourcing safe food
  - recognition of food safety management approaches of compliant imported food business
  - increasing the proportion of food imported that have assurance about its safety (such as government or third party certified food safety schemes)
- Improved monitoring and managing of new and emerging risks
  - providing the ability to monitor and manage new and emerging risks to address areas of non-compliance
- Improved incident response
  - broaden emergency powers to take precautionary action where hazards are unknown or uncertain.

The proposed reform measures also seek to align with state and territory food legislation where relevant and consistent with the policy objective.

The proposed reforms do not represent a complete overhaul of the current system, rather they are a set of practical options for reform that aim to strengthen the existing system.

To ensure that these proposed options for reform will be effective and practical, the department consulted with industry, state and territory food regulators and other stakeholders to inform the analysis in the consultation RIS.

5 Proposed options for reform

Three policy options for reform are proposed (Figure 5). Option 1 is non-legislative, option 2 involves minimal legislative change and option three includes more comprehensive legislative changes. Each option builds on the previous option. Therefore option 3 provides the most comprehensive improvement to the overall imported food regulatory system to address the current limitations and the policy objective.

Figure 5 Proposed options and objectives to improve the safety of imported food

Policy Objectives / Reform Measures	Increase importer accountability	Increase importers sourcing safe food	Improved monitoring and management of new and emerging risks	Improved incident response	Options
1. Importer declaration of producer information				✓	Option 1
2. Improved Australian government communications during a food incident				✓	
3. Increase number of importers on an approved arrangement		✓			
4. Proactive compliance and enforcement activities	✓		✓	✓	Option 2 (plus option 1)
5. Non-regulatory surveys of new and emerging food safety risks			✓		
6. Increase amount of high risk food imported under foreign government certification arrangements		✓			
7. Mandatory supply chain assurance for certain foods	✓				Option 3 (plus options 1 & 2)
8. Broader emergency powers				✓	
9. Additional powers to monitor for new and emerging risks			✓		
10. Recognition of foreign country's food safety regulatory system		✓			
11. Harmonisation of the *Imported Food Control Act 1992* with state and territory food legislation – including traceability	✓			✓	

5.1 Option 1—status quo including non-legislative improvements underway

Option 1 represents the status quo but includes three initiatives that have already commenced to address the limitations identified following the hepatitis A outbreak associated with imported frozen berries. These initiatives commenced in 2015 as they did not require any legislative change. These initiatives are discussed below.

5.1.1 Importer declaration of producer information

As of 1 June 2016, lodgements of imported food will commence being required to include a declaration of the name, locality and country of the producer (a phased approach is being taken). The producer is the commercial or individual's premises or area in the country of origin where the goods were grown, caught, manufactured or processed. This requirement was introduced to assist the department's IFIS and Australia's other food regulators, such as state and territory regulators, to respond effectively to incidents linked to imported food. During an imported food incident, it is critical to identify the overseas producer of a potentially contaminated food quickly, to determine which importers in Australia have sourced the product.

Previously, importers and customs brokers only had to declare the overseas producer of the food if the food was classified as 'risk food'. During the hepatitis A outbreak, there were significant delays in determining how many importers had sourced frozen berries from the implicated overseas producer. Frozen berries are classified as 'surveillance foods' and brokers were therefore not, at the time, required to declare the overseas producer when the goods were lodged into the ICS.

5.1.2 Improved Australian government communications during a food incident

Following the hepatitis A outbreak associated with imported frozen berries, a cross government department working group was established to identify areas for improvement.

The working group concluded that the food safety response to the outbreak was prompt and effective but improvements could be made to how the outbreak was communicated to the public, as there was a fragmented approach in Australian Government communications activity. For example, there were three separate media statements about the issue and improved coordination between government agencies may have provided a coordinated, single message to the public during the incident. The nature of the media cycle in Australia can also lead to speculative reporting about the handling of an incident and raise concerns amongst consumers. Earlier and better quality communication, especially in the early stages of an incident, can assist with managing this.

The improvements identified were to:

- identify a lead Minister to manage food safety incidents quickly but recognising that as the incident progresses, the lead Minister may change
- develop a better and more coordinated approach to whole of government communications
- review the Memorandum of Understanding between the Department of Health, the Department of Agriculture and Water Resource and FSANZ

- test these new arrangements through a multi-jurisdictional (and industry) imported food incident exercise.

The above recommendations have been progressed through an inter-departmental working group, led by the Department of Agriculture and Water Resources with representatives from the Departments of Health, Prime Minister and Cabinet, the Attorney General's Department and FSANZ. This group has developed new Commonwealth communication arrangements that identify:

- a lead minister responsible for communicating to the general public during a national food incident (and how roles may change as the incident progresses)
- roles and responsibilities of agencies when managing a national food incident.

These new communication arrangements were tested successfully during a food safety incident exercise on 27 May 2016 with relevant government agencies participating. Representatives from the food industry and state and territory food regulators were also present to observe and provide feedback. All participants provided positive feedback on the new arrangements and work is now progressing to finalise the reference materials.

5.1.3 Increase number of importers with food safety management systems

Food importers that have documented food safety management systems in place can apply for a FICA to recognise this system. Food products imported under a FICA are not subject to potential delay and costs associated with inspection and testing under the IFIS. Instead, food products imported under a FICA are handled by the importer's food safety management system which is audited by the department. If more importers enter into a FICA, inspection activity at the border can be focussed on imported food more likely to pose a risk to consumers, as food more likely to be compliant will be removed from the IFIS.

However, while importers have been able to operate under a FICA since 2010, there has been a low uptake. Currently only fifteen importers are operating under a FICA.

In the food importer survey, respondents were asked if they had heard of a FICA prior to the survey and what the main barriers were to applying for FICA. Of the 41 respondents to the survey, 54 per cent had not heard of a FICA. The most common barrier identified was 'not knowing enough about what a FICA is and how they work' (24 per cent), followed by the agreement being 'too expensive/not worth the implementation and/or maintenance cost' (12 per cent).

The department has also received feedback from importers that they would be more likely to enter into a FICA if the arrangement could be for a particular imported food, food type or brand– currently it must be for the entire business. In the food importer survey, respondents were asked if this change to FICA arrangements would influence interest in applying for a FICA. Some 28 per cent of those without a FICA said they would be more likely to apply for one if this change was made.

The department is currently considering options to make this possible and has commenced development of a pilot of the proposed 'tiered' FICA with a key food retailer. If this pilot is successful, the department will need to actively communicate the new FICA arrangements and advantages to importers to encourage increased participation. It is important to note that regardless of the outcome of this pilot, importers will continue to be able to apply for a FICA to recognise their documented food safety management system.

5.1.4 Costs of option 1

Under this option, the risk based IFIS would continue, relying on food safety issues being detected at the border via inspection and analysis of the food. Foods with hazards that are difficult to detect at the border may therefore be imported. Importers would be encouraged to have food safety management systems as a way to meet their regulatory obligations to import safe food, but having such a systems approach would not be mandatory. There would be no flexibility to vary referral rates to assess new and emerging food safety risks with imported food. There would be no new emergency powers, potentially delaying urgent action needed at the border to stop further importation of potentially unsafe food during a food safety incident.

As this option only partially meets the policy objective, consumers will continue to be exposed to food safety issues with imported food as potential food safety issues will not be effectively identified or managed. There is also the potential for importers entering into FICAs to pass on the costs incurred to establish and maintain these FICAs, to consumers. However, given FICAs provide a net benefit to importers (section 5.1.6), this is unlikely.

As part of costing the regulatory burden of options 1 and 2, the cost of businesses complying with IFIS has been calculated in the Regulatory Burden Measure (RBM). The RBM is a tool developed by the Australian government to calculate the compliance costs of regulatory proposals.

Importers would continue to incur costs when risk and surveillance food is referred under the IFIS for inspection/analysis. Three substantive compliance costs have been identified: the cost to a businesses to attend the inspection of food referred to the IFIS, to have this food analysed (when required) and the cost of having food delayed at the border (see Box 2). The department charges fees to process imported food referred for inspection/analysis under IFIS, however these direct costs are excluded from the RBM framework.

Box 2 Delay costs

It is assumed that businesses importing food into Australia have financed the purchase of those goods using a business overdraft loan, and that the loan is paid back once the goods have been cleared at the border and are sold in Australia. The lost income associated with border clearance of imported food is calculated as interest paid on the value of the goods during the time between goods arriving at the border and being released into the country. An interest rate of 8 per cent is used in the calculations based on the average of business overdraft interest rates for the four major banks as at 5 July 2016.

The delay for surveillance food is calculated as the difference in days between the arrival date of the goods and the inspection date recorded in the Agriculture Import Management System (AIMS) (test and release). The average delay for surveillance foods is calculated to be 14 days. The average value of goods per line of surveillance food is $14 800, resulting in a delay cost of $40.70 per line of surveillance food referred for inspection.

The delay for risk food is calculated as the difference in days between the arrival of the goods and the final imported food inspection advice in AIMS (test and hold). This is calculated as an average of 18 days. The average values of goods per line of risk food is $18 600, resulting in a delay cost of $41.35 per line of risk food referred for inspection.

An importer entering into a FICA will incur administrative and compliance costs, including initial set up and maintenance of the agreement, and yearly audit costs. Based on the results from the food importer research it is estimated, over a ten year period, that 50 importers will enter into a FICA (representing five new FICAs per year). Based on the profile of businesses already on a FICA, it is assumed that they will be large scale importers as the more the business imports, the greater the benefits. Based on an increase of five new FICAs every year, the average cost over a ten year period is estimated to be $238 000 per year, assuming:

- a total of 80 hours for an importer to set up an agreement
- an average of 110 hours per year for ongoing maintenance of the agreement, including annual audit
- a default RBM labour cost of $65.45 per hour.

5.1.5 Benefits of option 1

The main benefit of option 1 is it does not introduce any new costs for importers currently operating under IFIS. It also partly addresses the policy objectives, as it includes initiatives already underway to improve imported food safety. These are:

- improved traceability during a food safety incident by requiring mandatory declaration of the overseas producer for all imported food
- improved government communication during a food safety incident due to the development of new arrangements
- providing greater incentives to business to operate under a documented food safety system by enabling more food importers to enter into a FICA for a particular imported food, food type or brand.

Consultation with importers on a FICA indicates there are many benefits to participating in this arrangement including:

- not relying on the department's booking inspections and related activity
- not having goods waiting under test and hold directions
- not waiting for consignments to be released
- better negotiation and planning for laboratory testing, resulting in significant cost savings
- improved planning of stock holdings
- providing prestige to their reputation as an importer and customer of large international suppliers and retail customers.

Based on the scenario outlined in Box 3, the regulatory savings of 50 additional FICAs over a 10 year period (at a rate of five additional FICAs each year) is estimated to be an average of $905 000 per year.

Box 3 Increased number of Food Import Compliance Agreements

Modelled scenario

For the modelled scenario, it is assumed an additional 50 importers operating will operate under a tiered FICA over a 10 year period. It is also assumed that large scale importers are more likely to enter a Food Import Compliance Agreements (FICA).

Results of the food importers survey showed the median number of consignments imported by FICA holders was 700 per year. Based on data from ICS, there is an average of nine lines of food per consignment, equating to 6 300 individual lines of food per FICA importer per year.

If it is assumed that a tiered FICA would cover 25 per cent of an importer's goods, the average number of lines per FICA importer per year would be 1 575. Based on data from ICS, it is assumed that 66.7 per cent of lines are surveillance foods and 33.3 per cent risk foods.

Under the existing IFIS, there is a 5 per cent chance of surveillance foods being referred for inspection and testing. This equates to 52 lines. For risk food, it was estimated that on average, 25 per cent of lines would be referred for inspection (based on the assumption that the remaining lines are on a reduced inspection rate due to a previous compliance history), equating to 131 lines. Under a FICA, these goods would not be referred for inspection and testing.

Regulatory savings

Based on the scenario above, importers operating on a FICA would avoid 183 lines of food being delayed at the border for inspection and testing. Using the delay costs calculated for surveillance and risk foods (see Box 2) the total savings due to reduced delay costs were estimated to be $203 000 per year on average over a 10 year period. Importers would also not be required to attend inspections for referred goods, resulting in a saving of $162 000 per year (an average of 30 minutes per line inspected at a base labour cost of $65.45).

As part of the FICA, importers are required to undertake their own sampling and testing of foods at an equivalent rate as the IFIS. The random nature of referrals under IFIS means that a business will not be able to predict when their food will be referred and cannot budget for the additional costs. Under a FICA, importers are able to plan analytical testing and negotiate competitive laboratory fees. Feedback from FICA holders estimate the cost savings from reduced laboratory fees is $20 000 per year per FICA holder.

5.1.6 Net impact of option 1

This option only partially meets the objectives of government action. It partially improves tracing activities during a food safety incident, improves whole of government communications during a food safety incident and has the potential to increase the number of importers recognised for operating under effective food safety management systems. However, the main cost of this option is it still relies on inspection and analysis of most food and therefore it is more likely that unsafe imported food may not be detected at the border, with potential adverse consequences. An additional uptake of 50 importers operating under a tiered FICA over 10 years would result in an average net savings of $667 000 per year, across the fifty businesses. This equates to a savings of $13 340 per year to each business on a FICA.

Questions

Option 1 – Food Import Compliance Agreements

Question 1 If you are a food importer and would be interested in entering into a tiered FICA, what proportion (%) of foods you currently import would you most likely want covered in the agreement?

5.2 Option 2–option 1 plus further non-legislative improvement

This option includes the initiatives already commenced in option 1 plus the following mainly non-legislative improvements:

- proactive compliance and enforcement activities (minimal legislative change)
- non-regulatory surveys of new and emerging food safety risks (no legislative change)
- increasing high risk food imported under foreign government certification arrangements (no legislative change).

5.2.1 Proactive compliance and enforcement activities

This initiative proposes to improve the use of imported food data to enable proactive compliance and enforcement activities to:

- identify first time importers to inform them of legal obligations when importing food
- communicate with importers
  - on compliance issues
  - on new or emerging food safety risks
  - during a food safety incident
- provide importer details to state and territory government food regulators to support their regulatory activities.

To achieve this, some legislative changes may need to be made to the *IFC Act 1992*.

Importers of all goods into Australia are required to lodge details about the imported goods into an electronic management system – the ICS, which is managed by the Department of Immigration and Border Protection. Information about food lodgements are profiled, and depending on the outcome of this profiling, referred to the IFIS for inspection/analysis. For example, in 2013-14, 820 000 lines of food within the scope of IFIS were lodged in the ICS. Of these, 101 000 lines were referred to IFIS i.e. 12 per cent of all lines of food in the scope of the IFIS were referred to IFIS for inspection/analysis.

The information on food lines referred to the department is transferred into the AIMS. This electronic system is used to manage foods referred for inspection and analysis under IFIS but does not provide a complete database of food importers to enable proactive compliance and enforcement activities.

While the department can access information on importers directly from the ICS, the *IFC Act 1992* appears to limit the use of this data to the operation of the IFIS as it does not expressly provide for powers to communicate directly with importers. To address this concern, the department is seeking legal advice on what, if any, legislative changes are needed to enable the department to more proactively use data on food importers contained within the ICS.

If the department was able to more proactively use this data, it would assist with addressing three of the reform objectives:

- increasing importer accountability
- improving emergency response
- monitoring of new and emerging food safety risks.

Identifying first time importers would enable the department to proactively communicate imported food obligations i.e. that the importer is responsible for ensuring imported food is safe and compliant with the *IFC Act 1992* and the Code. Having the ability to communicate with all food importers would enable the department to communicate food safety issues concerning imported food. For example, the importance of declaring all allergens on labels. In an emergency, it is also critical that the department can easily and quickly communicate with importers who may have imported potentially unsafe food to confirm if this food is in the supply chain and if so, the need for the importer to consider recalling it. This information could then be shared with relevant state and territory regulators to enable appropriate risk management activities to be undertaken.

5.2.2 Non-regulatory surveys of new and emerging food safety risks

The department currently receives intelligence via national and international food safety networks on potential food safety issues with imported food. To assess whether a new or emerging food safety risk exists with imported food, it may need to be tested for the hazard of concern. Samples of imported food can be taken for testing at the border prior and/or post border once it is in the supply chain. Imported food can already be sampled at the border but as discussed under section 2.4, for surveillance foods, the current legislated referral rate of 5 per cent does not provide sufficient data to enable an assessment of a new or emerging food safety risk, and is an ineffective means of sampling products from a representative range of importers.

Non-regulatory options for surveying imported food for new and emerging food safety risks post border are:

- submitting a proposal to the Implementation Sub-committee for Food Regulation (ISFR) for inclusion in its Coordinated Food Survey Plan
- liaising directly with FSANZ for a survey to be undertaken.

ISFR coordinates survey activities of national and bi-national (Australia and New Zealand) significance. Proposals for surveys are submitted to ISFR for consideration and if they are consistent with ISFR's priorities, supported by ISFR members and funding is available, will be included on ISFR's Coordinated Food Survey Plan. This plan, over a three year time frame, prioritises, plans and implements the agreed survey activities. One of the priorities of the survey plan is to contribute to knowledge, in support of scientific assessments and the management, of microbiological and chemical emerging issues, including outbreaks and food incidents.

ISFR surveys have been conducted in the past to obtain data to inform risk assessment activities on potential food safety issues with imported food. However, they have mainly been used to obtain data in response to an imported food safety incident rather than obtaining data on a food safety risk that may occur in the future. For example, in 2011 a national coordinated survey of iodine levels and seaweed and seaweed containing products was conducted in response to a national food incident due to an increased number of reported human thyroid dysfunction cases linked to high iodine intake. (FSANZ 2013a). The high iodine intake was linked to the consumption of an Australian produced soy milk that contained imported seaweed. The results of this survey were used to inform risk management activities with imported seaweed.

Surveys conducted under the ISFR framework can successfully provide data on new or emerging food safety risks but may not be accepted if there are higher priorities and/or if funding is not available. Additionally, unless the data is needed urgently in response to a food safety incident, it is unlikely that results will be available quickly. It can take many months for a survey proposal to be accepted and as the survey plan spans a three year period, depending on priorities, results may not be available for some time.

Another option is to liaise with FSANZ on conducting a survey. While FSANZ may coordinate or participate in surveys under ISFR, it also independently undertakes surveys as part of its work on the Code or in response to emerging risks and national food incidents. For example, in 2015, FSANZ tested canned and bottled fruit products (both domestic and imported product) following reports that found arsenic was present in some imported canned peaches as well as levels of lead and tin above allowable limits in the Code (FSANZ 2015c). However, the ability of FSANZ to undertake surveys, like those coordinated under ISFR, will be subject to the availability of funding and priorities.

While recognising the limitations of conducting surveys under the ISFR framework or directly with FSANZ, the department will continue to actively seek opportunities to use these mechanisms, particularly where a regulatory approach is not appropriate.

5.2.3 Increasing high risk foods imported under foreign government certification arrangements

Under the existing *IFC Act 1992*, food can be imported under a foreign government certification arrangement. The Act enables the department to enter into a government-to-government certification arrangement with the national competent authority of a country exporting food to Australia, providing confidence that the food has been produced safely. Consignments of imported food accompanied by a recognised foreign government certificate may be inspected and tested at a reduced rate (five per cent).

Foreign government certification arrangements are currently in place for certain risk classified seafood from Thailand (fish, crustaceans and bivalve molluscs) and Canada (fish and crustaceans) and Roquefort cheese from France. Use of a foreign government certificate in the clearance of food imported to Australia is normally voluntary but under an order may be mandated. Recognised government certification is currently mandatory for raw milk cheese and beef and beef products for Bovine Spongiform Encephalopathy (BSE) food safety requirements.

Foreign government certification arrangements benefit the exporting country, the importer and also potentially the consumers of these foods. The exporting country benefits as it is exposed to less trade and reputational risk from non-compliant food being exported. The importer of risk foods benefits as consignments of these foods are inspected and tested at a reduced rate (five per cent) representing financial savings to the importer. The consumer benefits from potentially safer food, as the exporting country's competent authority has provided assurance that the food complies with Australia's food safety standards. In comparison, no such government assurance is provided for other risk foods imported into Australia. However, importers may request non-government assurances from suppliers under commercial arrangements.

To increase the amount of risk food that is imported under a foreign government certification arrangement and therefore certified as being compliant with Australia's food safety standards, the department could actively seek to increase the number of arrangements in place. This could be achieved by promoting the advantages of these arrangements to countries exporting a high volume of a risk food to Australia. Importers choosing to source foods from suppliers with this certification will benefit from reduced border intervention.

Table 1 summarises the countries that had the most 'risk food' lines referred to the department for inspection and analysis under IFIS from 2013-2015 by commodity type (excluding New Zealand).

Table 1 Lines referred as risk by commodity type and country of origin, excluding New Zealand, 2015

Commodity types	Thailand	France	Korea	Japan	China	Italy	Grand total
Beverages	139		18		4	2	163
Cereals					1		1
Dairy		6 394				1 935	8 329
Horticulture	337	66	1 298	1 479	1 530	66	4 776
Meat	244	212	133	1	52	319	961
Other	431	18	1 400	412	648	84	2 993
Seafood	12 807	29	434	1 347	784	99	15 500
Grand total	13 958	6 719	3 283	3 239	3 019	2 505	32 723

Source: Integrated Cargo System

The most number of lines referred as 'risk food' is seafood from Thailand, followed by dairy from France. Foreign government certification arrangements are already in place for risk foods within the seafood commodity from Thailand and Roquefort cheese from France. However, based on the quantity of imports and referrals for inspection, foreign government certification arrangements could be explored for other 'risk' cheeses from France and Italy. The 'risk food' being exported from these countries within this commodity is soft or surface ripened cheese, due to the risk associated with foodborne pathogen *Listeria monocytogenes*.

5.2.4 Benefits of option 2

This option, which includes the initiatives already underway (as outlined in option 1), further addresses the reform objectives:

- improving importer accountability by communicating to importers about their legal obligations
- improved incident response by communicating with importers when there are food safety issues with imported food and having the ability to share information with state and territory food regulators
- monitoring of new and emerging risks by working with ISFR and FSANZ to conduct non-regulatory surveys
- increasing importers sourcing safe food by increasing the amount of that can be imported under a foreign government certificate.

This main benefits to importers by increased foreign government certification is the reduced intervention at the border, including inspection and analysis. An example of these costs are outlined in Box 4.

Box 4 Increased foreign government certification

Scenario

As presented in Table 1, dairy from France and Italy was the second most frequently imported risk food in 2015. Of these, there were a total of 930 lines of soft or surface ripened cheese inspected at the border. There were 82 unique importers of soft or surface ripened cheese from France and Italy in 2015, with an average of two suppliers per importer (range one to ten).

Costs

Based on feedback from food importers, it is estimated that the time for an importer to source from suppliers with foreign government certificate and obtain evidence of certification is two hours per supplier. Using data from AIMS, there is an average of two suppliers per importer. Using a base labour cost of $65.45 per hour, the one-off cost to importers is estimated to be $2 100 per year averaged over 10 years.

Regulatory savings

Food imported with a government certificate would have a 5 per cent chance of being inspected and tested. The reduced delay costs is estimated to be an average of $37 000 per year. Other savings include reduced inspections costs of $29 000 and laboratory testing costs of $104 000, resulting in a total regulatory savings of $170 000 per year averaged over 10 years.

Net savings

The net savings to importers for this scenario is estimated to be $167 900 per year averaged over 10 years. This equates to a savings of $2 048 per year to each business importing these products, based on the assumption that 82 importers of soft or surface ripened cheese from France and Italy source from suppliers with foreign government certification (when this option becomes available).

This option introduces minimal cost for food importers. However, there are resource implications for the department to:

- identify and proactively communicate imported food obligations to first time importers
- communicate with importers on food safety issues concerning imported food
- work with ISFR and FSANZ to conduct surveys on new and emerging food safety risks, which could include a financial contribution either 'in kind' or directly
- promoting foreign government certification arrangements with countries that are exporting a significant amount of 'risk food' to Australia such as China, Japan and Korea.

The above resource implications for the department can be absorbed within existing budget processes.

5.2.5 Costs of option 2

The main disadvantage of this option is that it does not fully address the reform objectives. It does not address the issue of the department being unable to take immediate action when a potential food safety issue is identified with imported food. It also does not increase the traceability capability of importers. This may result in a delay with responding to a food safety issue, resulting in more people being exposed to a food safety hazard.

The ability to monitor new and emerging food safety risks through non-regulatory surveys is dependent on both ISFR and FSANZ supporting such a survey and finances being available. Non-regulatory surveys are also more appropriate for where data does not need to be collected quickly due to the time it takes to obtain agreement to proceed. The department may therefore be restrained in its ability to respond to evidence of a new of emerging risk with imported food, potentially exposing consumers to unsafe food.

While this option potentially increases the number of importers sourcing safe food through foreign government certificates, the increase will only be small as these arrangements are only suitable for certain country/risk food combinations. The majority of food will continue to be imported under IFIS with the focus being on testing a percentage of this food at the border, which has a limited ability to detect hazards in food. The safety of foods is best ensured through the effective implementation of validated control measures throughout the food chain to minimise contamination and assure food safety, particularly for foods where food safety controls throughout the supply chain are essential for producing this food safely.

5.2.6 Net impact of option 2

This option provides a net regulatory saving to importers of $835 000 per year over a ten year period. It includes the $667 000 savings from option 1. It has resource implications for the department but these can be absorbed within existing budgets. It addresses the reform objectives to a greater extent that option 1 by:

- improving communication with importers and state and territory regulators to assist with incident response
- addressing new and emerging risks through ISFR/FSANZ coordinated surveys
- increasing the amount of risk food imported under foreign government certification arrangements.

However, it does not improve the ability of the department to take a precautionary approach when food safety issues are identified with imported food or to ensure importers have the ability to trace food. New and emerging risks may not be assessed in a timely and responsive way. It also largely relies on at border testing to detect food safety hazards at the border. This limits the department's ability to reduce the risk of foodborne illness from imported food from occurring.

5.3 Option 3–option 1 and 2 plus changes to primary and consequential subordinate legislation

Option 3 includes the initiatives outlined in options 1 and 2 plus the following changes to primary (and consequential subordinate) legislation to:

- mandate evidence of supply chain assurance for certain foods
- broaden emergency powers
- increase powers to monitor for new and emerging risks
- recognise a foreign country's food safety regulatory system
- align the *IFC Act 1992* with domestic food legislation where applicable–including requiring traceability.

5.3.1 Mandate evidence of supply chain assurance for prescribed foods

The existing IFIS relies on inspecting and, where relevant, testing food at the border to assess the safety of imported food. Foods that pose a medium or high risk to public health ('risk food') are inspected and tested at a higher rate than lower risk food ('surveillance food').

Testing food to assess safety has its limitations as only a sample of food can be tested and a negative result does not mean the entire batch of food or other batches not subject to testing are also negative. In recognition of the limitations of testing, international food standards recommend that food businesses produce and process food under documented food safety management systems. These systems identify the food safety hazards likely to be associated with the primary production and processing of the food and the controls that need to be followed to manage these hazards. Under these systems, testing is used to verify that the controls are working and is not used on its own to assess food safety.

In Australia, domestic food laws require businesses that produce or manufacture high risk food or prepare food for vulnerable people to have food safety management systems. This includes businesses that: prepare food for vulnerable people (such as for patients in hospitals); grow bivalve molluscs (such as oysters); or produce manufactured and fermented meats (such as salamis). Food safety management systems are also required for primary producers of produce such as poultry, meat, dairy, eggs and seed sprouts.

Comparable countries to Australia commonly require food safety supply chain assurance for imports, particularly high risk foods. The US places the responsibility on importers to verify that their foreign suppliers have adequate food safety controls in place. High-risk foods can be required to be accompanied by credible third party certification as a condition of entry. In New Zealand all importers must take all reasonable steps to document how the food has been produced and managed in a manner that ensures the food is safe for human consumption. Foods of high regulatory interest may require a higher level of evidence of supply chain assurance, as a condition of import. Canadian importers must be able to supply traceability and food safety assurance documentation on request. However, some high risk products have to prove supply chain assurance, for example meat and meat products have to be from an approved country and establishment with safety controls in place.

To address the limitations of testing food at the border and in line with domestic and international approaches, it is recommended that importers of prescribed foods be required to provide evidence that food safety hazards have been controlled throughout the primary production and processing of these foods. These foods would be prescribed in the imported food legislation.

The department, in consultation with FSANZ, would determine what foods should be prescribed foods based on:

- evidence of their association with causing foodborne illness
- the necessity for evidence of through-chain controls to demonstrate identified food safety hazards have been effectively managed
- border testing alone being insufficient to provide assurance of the food's safety.

While the foods to be prescribed would be formalised following policy agreement to this approach, the department has prepared an indicative list of these foods to enable trade and costing impacts to be estimated. These foods are:

- ready-to-eat raw or minimally processed produce associated with foodborne disease
- ready-to-eat raw or minimally processed nuts (i.e. shelled and unroasted)
- beef and beef products
- ready-to-eat uncooked meats associated with foodborne disease
- raw meat and meat products (other than beef and poultry)
- raw poultry
- eggs (whole eggs, unprocessed egg products)
- raw milk cheese
- ready-to-eat raw or minimally processed bivalve molluscs
- ready-to-eat minimally processed finfish.

Due to biosecurity restrictions, Australia does not currently import many foods that are likely to be in the 'prescribed food' category. In the above list, Australia does not import raw poultry, eggs or raw meat, with the exception of pork for further processing. Australia imports some ready-to-eat raw or minimally processed produce, of which, some have been associated with foodborne disease such as frozen berries, semi-dried tomatoes, snow peas and sugar snap peas.

It is important that the *IFC Act 1992* has the ability to manage the food safety risks associated with the broader range of 'prescribed' foods, as biosecurity restrictions may change in the future. For example, the department is currently reviewing the importation of beef and beef products from certain countries. Appendix B provides more detail on foods that may be 'prescribed', the main food safety hazards of concern with these foods and the foods Australia currently imports under the above groupings.

Importers would be able to demonstrate that the food safety hazards associated with a 'prescribed foods' have been controlled by:

- providing a recognised government certificate; or
- providing a recognised non-government certificate, such as certification against internationally recognised food safety schemes e.g. GLOBALG.A.P. or BRC Global Standards; or
- importing the food under a FICA.

Whichever type of evidence is provided, it will be verified on a document assessment, or a system verification or audit basis. This could be done either on a consignment by consignment basis (i.e. transactional) or on a pre-import basis (i.e. pre-requisite requirement).

Government certification is supported by an equivalence determination and agreement between Australia and the exporting country competent authority.

Non-government certification will be supported by recognition of food safety management systems that have been certified as meeting globally accepted food safety standards.

Some 'prescribed foods' may only be able to be imported with a government certificate. This is likely to occur where the safety of the food is dependent on competent authority controls in the exporting country, such as for animal health (e.g. brucellosis), or environmental health (e.g. human viruses in waterways growing bivalve molluscs) and will be based on risk assessment advice from FSANZ. This currently occurs with beef and beef products that can only be imported with a government certificate to provide assurance that these products are free from BSE.

Costs

This option is likely to impose new costs on a small proportion of importers as well as government and increased importers costs may be passed on to consumers. To avoid new costs, importers of prescribed foods may also decide to no longer import these foods, reducing the availability of these foods to consumers. However many food importers already require these assurances so the predicted impact on consumers is expected to be minimal.

This option impacts on importers of foods within the 'prescribed food' category, who do not already request evidence of supply chain assurance from their suppliers. It does not impact on importers that already obtain such evidence or importers of non 'prescribed food'. An analysis of import data from 1 March 2013 to 29 February 2016, indicates that 623 importers out of a total of approximately 16 000 (4 per cent) import foods within the 'prescribed food category', with the main food imported being raw pork (Appendix B).

In the food importers survey, between 2 per cent and 12 per cent of respondents indicated they had imported food types within the 'prescribed food' category in the past three years. Twelve percent had imported ready-to-eat minimally processed finfish and only 2 per cent had imported semi-dried tomatoes. Of the respondents that indicated they had imported 'prescribed foods', the only products being sourced from suppliers without food safety management certification were raw or frozen bivalve molluscs (5 suppliers out of 25) and raw ready-to-eat nuts (5 suppliers out of 83). While the number of respondents to the survey was too low to draw conclusions more broadly, it indicates that some importers of 'prescribed foods' are already obtaining food safety management system certification from suppliers of these foods.

Respondents to the food importer survey with at least one supplier providing food safety management certification, were asked to estimate how many hours it takes annually to maintain food safety management system records for all certified suppliers. Estimates varied widely, from one hour to 2080 hours (for a business with 200+ employees) and 25 per cent of respondents were unable to provide an estimate.

The costs to importers of 'prescribed food' to obtain evidence of supply chain assurance are estimated in Box 5.

Box 5 Supply chain assurance

Data from ICS shows there were 623 unique importers of foods that would fit the scope of 'prescribed foods', as detailed in Appendix B. More than 95 per cent of respondents in the food importers survey indicated they had supply chain assurances with their suppliers, although given the limited number of respondents this may be over representative for all importers. For the purposes of the RBM, it was conservatively assumed that 50 per cent of importers of 'prescribed foods' would need to gain supply chain assurance for an average of two suppliers each (based on data from ICS).

Additional information was sought from food importers on the time required to source suppliers with these assurances, with an average time of two hours per supplier.

Based on an average labour rate of $65.45 per hour, the total one off cost for importers of prescribed food to establish supply chain assurance (where such assurance is not already obtained) would be an average of $8 100 per year over ten years.

The median annual time required by importers to maintain and verify supply chain assurance was 50 hours, resulting in an average total cost of $1.02 million per year over ten years.

The net average cost for supply chain assurance for importers of prescribed foods was therefore estimated to be $1.022 million per year over 10 years.

The department will bear the initial costs associated with establishing the foods requiring supply chain assurance and the certification that will be accepted for these foods. Departmental staff will also be required to undertake document assessment of the foods at the border to ensure they are being imported with adequate certification. However, these costs are expected to be absorbed within existing financial allocations.

This option may also have a cost for consumers, if importers of foods within the 'prescribed food' category pass on any increases in the cost to import these foods from suppliers who can provide certification. However, additional feedback from importers that participated in the food importer research, indicated that this is likely to be minimal as these costs are largely absorbed by importers due to market competition.

Benefits

The main benefit of this reform is that it addresses the limitations of at border-inspection to a greater extent than options 1 and 2, by making importers of 'prescribed foods' more accountable for the safety of food being imported. These foods could not be imported without the importers obtaining documented assurance that these foods have been produced safely i.e. under good agriculture and manufacturing practices, as applicable to the food. This forces importers to take a more proactive approach to food safety. There is evidence from the food importer survey, that importers of these foods are already obtaining such assurance voluntarily, recognising the importance of taking a preventative approach to food safety.

There may also be indirect benefits to importers from being required to seek this assurance. This is on the basis that food that has been produced and processed under documented food safety management systems is less likely to be the cause of a food safety incident. Subsequently, importers would have less costs associated with recalls and paying compensation to consumers affected by unsafe food.

Consumers will benefit from this approach, as foods within the 'prescribed food' category should be safer, due to importers having to go to greater efforts to obtain assurance from suppliers that these foods have been produced safely.

Questions

Option 3 – Supply chain assurance

Question 2 (a) If you are a food importer, what assurances do you gain from your suppliers to ensure the food has been produced, manufactured and handled safely? What costs do you incur to obtain this assurance?

(b) If the food you import comes with some form of food safety certification, do you verify compliance with the certification and if so, how? What costs do you incur in undertaking this verification?

(c) Are the kinds of foods likely to require supply chain assurance clearly defined? If you are an importer of these kinds of foods, do you already require certification for supply chain assurance, such as a recognised food safety management scheme? If so, do you pass on any associated costs to consumers?

5.3.2 Broaden emergency powers

Under the *IFC Act 1992* a holding order may only be placed on a food if there are reasonable grounds to believe that a food, on inspection, or inspection and analysis would fail. The holding order must specify the circumstances in which the order will be revoked.

This is problematic when the food safety issue is unconfirmed and/or there is no reliable test that can be applied to detect the food safety hazard. For example, while the food safety hazard with the frozen berries associated with illness was known (i.e. hepatitis A), there was no reliable test that could be applied at the border to detect it in the food.

To enable the department to be more responsive when there is a potential food safety issue with imported food, it is recommended the *IFC Act 1992* be amended to enable the department to place a holding order on a food reasonably suspected of posing a serious danger to public health (based on the scientific evidence available at the time). For example, there may be strong epidemiological evidence that an imported food is causing illness, but the causative agent may not be known.

While the food is subject to this initial holding order, risk assessment advice could be sought from FSANZ and pass/fail criteria established. The main advantage of this approach is that action can be taken immediately to hold food at the border. The main disadvantage of this approach is that a wider range of foods may be caught in the initial holding order until the risk can be properly assessed and then narrowed if supported by the risk advice.

This approach is consistent with emergency powers under state and territory food acts. Under these acts, the relevant authority has emergency powers to take action if the authority has reasonable grounds to believe these actions are necessary to prevent or reduce the possibility of a serious danger to public health or to mitigate the adverse consequences of a serious danger to public health i.e. the states/territories can act on a 'reasonable belief'.

This approach appears to be consistent with international approaches and aligns with Codex Alimentarius' *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) which recommends that the responsible authority have procedures to respond appropriately to emergency situations, including holding suspect product upon arrival. The following is what is understood about how the US, Canada, New Zealand and the EU can all respond to food safety emergencies and emerging incidents based on reasonable beliefs.

- The US can issue an import alert, without inspection, on suspicion that the food would be non-compliant. The onus is then on the importer to prove the food is safe and compliant.
- Canada can also enact import alerts to prevent the importation of food if there are reasonable grounds it is unsafe or non-compliant.
- In New Zealand, if there is reasonable belief a product is unsafe or non-compliant, actions can be taken by the officers to prevent distribution in New Zealand and an importer's registration can be suspended if there is reasonable belief that the imported food will pose a high risk to public health or there is a serious failure in food safety operations.
- The EU food safety laws include the requirement to take into account the "Precautionary Principle" in risk management i.e. where there is a possibility of harmful effects but scientific uncertainty persists, risk management measures may be adopted, pending further scientific information for a more comprehensive risk assessment.

Costs

Increasing emergency response powers in the *IFC Act 1992*, to take a more precautionary approach, will impact on importers of foods deemed potentially unsafe. This approach is likely to impact more importers initially until FSANZ can complete a risk assessment to confirm or allay the suspected risk. Following receipt of this advice, the department may be able to narrow the scope of food subject to a holding order.

Australia manages between three and four serious imported food safety issues per year. Therefore, the likelihood of imported food being restricted at the border in response to a food safety incident is small. However, if it is, the cost to these importers will be primarily associated with having food held at the border. This delay could be days or weeks. When the hepatitis A outbreak was identified, the department issued a holding order nine days after a link was made between the cases and a particular brand of frozen berries. If the department had issued a holding order, prior to the receipt of risk assessment advice from FSANZ, the order may have included a wider range of berry products resulting in delay costs to more importers.

Taking a more precautionary approach also increases the impact on consumers, as more foods are likely to be subject to the initial holding order, until the risk can be properly assessed. For example, if this approach had been taken with the hepatitis A outbreak associated with imported berries, more (but not all) imported frozen berries could have been initially held at the border. This temporarily restricts the range of imported food available to consumers.

To minimise the impact of increasing the emergency powers in the *IFC Act 1992*, it is recommended that:

- a holding order only be issued for a food for which there is sound scientific evidence that it poses a serious risk to public health and safety

- the holdings order be reconsidered on receipt of risk advice from FSANZ and/or if the importer or overseas producer of the food provides sound scientific evidence that the food does not pose a serious risk to public health and safety.

Based on the case study presented in Box 6, the delay costs for four food safety incidents requiring use of the proposed emergency powers is estimated to be an average of $8 000 per year.

Box 6 Emergency powers case study

Scenario

Raw cashews imported from a single country are suspected as the cause of salmonellosis cases in Australia. Product is withheld at the border for two weeks as further evidence is gathered and appropriate safety assurances can be gained.

Data

In 2015 there were a total of 1 100 lines of cashews imported from a single country (approximately 42 lines every two weeks).

Based on the average delay costs calculated for surveillance food ($40.70 per line for a delay of 14 days) the total delay cost for such a scenario would be $2 000.

Benefits

The main benefit of this option is that it is the only option that can legally restrict the importation of potentially unsafe food at the border. It therefore provides the greatest benefit to consumers, as it minimises the exposure to potentially unsafe food.

Under option 2, with improved communication with importers, importers can be contacted about potentially unsafe food and advised not to import it or if they have, not to distribute it in the supply chain until further information about the risk is known. While many importers may be willing to voluntarily comply with this advice, there is a risk that some will not and unsafe food could be sold to consumers.

Questions

Option 3–Emergency response

Question 3 Often at the beginning of a food safety issue being identified, there is incomplete information on the cause of the issue. However, depending on the level of risk it may be necessary to take immediate action. What would be the impact to your business if imports of a specific food were restricted (held) at the border for a period to gain additional assurances on the safety of the product?

5.3.3 Increase powers to monitor for new and emerging risks

When the department becomes aware of evidence related to a new or emerging food safety risks it can apply a new test to the food at the border or approach ISFR or FSANZ with a proposal for a survey. The option to conduct a survey with ISFR or FSANZ is discussed under option 2, where it is concluded that this option is more appropriate for surveys where data does not need to be collected quickly due to the time it takes to obtain agreement to proceed. These surveys are also dependent on ISFR and FSANZ priorities and funding.

The ability to apply a new test to a food also has its limitations, as under the current Regulations only 5 per cent of the consignments of a surveillance food will be referred for this new test, which is unlikely to provide sufficient data quickly enough to determine the extent of the presence of the risk and make an assessment of a food's safety. In addition, this rate of inspection means that the higher volume imports are inspected and analysed the most and the data does not provide sufficient detail of all the different individual sources of an imported food. While these issues do not exist for 'risk food' as it is referred at 100 per cent, new and emerging risks with imported food have been associated with surveillance foods and not risk foods.

To address these concerns, it is proposed that foods suspected of posing a new food safety risk be temporarily referred for border inspection at a higher rate. This would require the introduction of a new inspection category into the *Imported Food Control Regulations 1993* with the authority to apply a higher variable referral rate. The rate at which the food would be referred would be dependent on a number of variables such as current volumes of the food imported and likely prevalence of the hazard in the food – food imported in low volumes with an emerging hazard of likely low prevalence would need referring at a higher rate.

An 'active surveillance category' was included in the Regulations but removed following the 'Tanner review' of the Act in 1998 (see Background). Under this category, 10 percent of shipments of active surveillance foods were tested to enable the, then Australian New Zealand Food Authority (now FSANZ), to provide advice on the risk to human health of a food. During the review, the Food and Beverage Importers Association raised concerns with this category stating:

> … the active surveillance classification, as currently operating, is inflexible, leads to over testing and not in line with risk analysis principles. There might be need for a classification for emergency or special testing, but the current scheme is an unnecessary cost for importers, which is passed on to consumers.

To overcome concerns with the previous 'active surveillance category', it is recommended that:

- an evidence based approach be used to determine foods requiring more active surveillance including consideration of the regulatory impact
- consultation with industry take place on any proposed increased surveillance and potential impacts
- the time the food is referred at a higher rate be specified and reflect the minimum time needed to obtain the data needed to assess the potential risk
- following an assessment of the potential risk, the increased rate of inspection be either ceased or appropriate risk management measures taken.

The US, NZ and Canada all operate risk based border inspection systems that incorporate emerging knowledge on risks. The US allocates a risk score to imports that takes into account compliance history and other factors. New Zealand food imports that pose a greater risk to consumers and public health are considered 'foods of regulatory interest' and require food safety clearances to be imported. Canada's inspection program adjusts the inspection rate according to a history of compliance and intelligence about emerging risks.

Costs

This option will have cost implications for importers of foods subject to 'active surveillance' and these costs may be passed on to consumers. These importers will incur costs associated with having a higher percentage of the food referred for inspection and analysis. This will include increased costs associated with managing the imports, inspection and analytical fees and delay costs. It is recommended delay costs be minimised by allowing foods under 'active surveillance' to be on a 'test and release' system, as currently applies to 'surveillance foods'. The cost, generally, should also be minimised by applying strict criteria to determining what foods are subjected to 'active surveillance', at what increased rate and for how long – as discussed above.

To estimate the costs, the department has assumed that, on average, no more than four types of foods per year would be placed under this 'enhanced surveillance', based on an analysis of the frequency of new and emerging risks that have arisen with imported foods in recent years. Based on the case study provided in Box 7, the average delay costs to businesses associated with an increased rate of inspection of 25 per cent for six months is estimated to be $2 500 and laboratory costs of $6 900 for each incident. If this was to occur four times a year, the total cost is estimated to be an average of $38 000 per year across those businesses importing food subject to 'enhanced surveillance'.

Box 7 Case study – monitoring for new or emerging issue

Scenario

There have been reports internationally of elevated *E. coli* levels in coriander powder, including suspicion of causing illness. Coriander powder is placed on an elevated inspection rate of 25 per cent for six months to gather data on *E. coli* levels to inform an assessment of process hygiene.

Costs

On average there are 250 lines of coriander powder imported into Australia over a three month period.

If 25 per cent of these were inspected, tested and released, there would be an associated delay cost (based on surveillance food) to businesses of $2 500.

Costs for laboratory testing would be $6 900.

Benefits

The main benefit of this option is that it enables evidence of new or emerging risks in food to be investigated promptly. Under option 2, surveys may be able to be conducted under ISFR or FSANZ but it takes time to get agreement to a survey and agreement is dependent on priorities and availability of funding. Under option 2, improved communication with importers will also enable more information to be provided on new and emerging risks but unless importers have undertaken their own testing which can be shared with the department, data will not be available for assessment of the risk. The quicker the department can act on evidence of a new or emerging risk by placing food of concern under 'active surveillance', the quicker this risk can be assessed and appropriate risk management action taken. Any delay potentially exposes consumers to unsafe imported food.

Questions

Option 3 – Monitoring and responding to emerging food safety issues

Question 4 (a) If you are a food importer, can you describe how you monitor and respond to emerging food safety issues (e.g. receive information from suppliers, industry associations, government alerts).

(b) What do you consider would be the most effective mechanism to communicate emerging food safety issues to importers?

5.3.4 Recognise a foreign country's food safety regulatory system

Currently the only country with reduced border inspection for exports from that country is New Zealand, as the *IFC Act 1992* only provides for food from New Zealand to be exempted from the application of the Act. New Zealand is exempted under the TTMRA, which aims to remove regulatory barriers to the movement of goods and services providers between Australia and New Zealand. The *IFC Act 1992* therefore does not generally apply to food imported from New Zealand unless a 'risk food' is deemed to require border inspection/analysis. Currently this means the Act only applies to beef and beef products (for BSE certification), seaweed and cassava chips from New Zealand.

The *IFC Act 1992* does allow for foreign government certification of risk foods, which under the Regulations means the referral rate of these foods is 5 per cent instead of the normal 100 per cent. However, it is currently only applied on a risk food/country basis. A foreign country is therefore currently unable to have all its foods recognised as being produced under an equivalent food safety regulatory system to Australia's, to reduce border inspection/testing.

The Codex Alimentarius Commission's *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013) and its *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) (internationally agreed guidelines), recommend that these systems include provisions for recognition, as appropriate, of the food control system applied by an exporting country's competent authority (Codex Alimentarius 2003, 2013).

In 2015, Australia completed an assessment of comparability between the Australian and US FDA food regulatory systems based on the Codex Alimentarius Commission's principles for food control systems. The comparability assessment consisted of a thorough desk audit of materials submitted by the US FDA, the trade history recorded under the IFIS and an in-country review to verify implementation of the food regulatory system. Australia is in the late stages of assessment and development of a mutual recognition arrangement with the US.

While the US's system has been deemed equivalent, the *IFC Act 1992* limits the ability to reduce border intervention from an entire country. It is therefore recommended that the Act be amended to give the authority to recognise foreign country equivalence, exempting all imports from border intervention except where there is evidence of non-compliance or a food safety risk.

Costs

This option does not impose any significant new costs to importers or consumers. Importers can benefit by sourcing food from countries that have foreign country equivalence. This may result in importers changing suppliers and there may be some costs associated with making this change.

The main costs associated with this proposed change will be to the department to assess whether a foreign country's food regulatory system is comparable to that of Australia. It is expected that the countries sought for equivalence would be identified based on imported food data, compliance behaviour, trade priorities and consultation with key stakeholders including trading partners and industry representatives. The number of potential opportunities for these types of arrangements is therefore likely to be small but achievable. It is estimated that an additional two countries would be considered for such an assessment over the next ten years.

Benefits

Importers of foods from countries that have been assessed as having a food regulatory system comparable to Australia's will benefit from having no border intervention for these foods. There may be some risk foods where equivalence is not determined, such as currently occurs with some foods from New Zealand. The cost savings to an individual importer will depend on the volume of food being imported from the recognised country. Such recognition may also benefit our exporters as it is usual for these arrangements to be reciprocal.

Recognising three foreign government food safety systems over a ten year period is estimated to produce annual savings over the ten year period of $807 500. This is based on data for foods imported from the US, as outlined in Box 8. The actual savings would depend on the volume of imports from the countries for which equivalence has been determined.

Box 8 Recognition of foreign government systems

Data

Over the last 3 years, the number of lines of food imported from the US have increased from approximately 63 000 imports in 2013, to 73 000 in 2015. Of these lines, approximately 10 per cent of risk and surveillance foods are referred to AIMS for possible inspection. There were 2 183 lines of food inspected from the US in 2015, with 562 analytical tests applied to risk foods, and 918 tests applied to surveillance foods.

Costs

If all food imported from the US was exempted from border intervention on the basis of being produced under an equivalent food safety system, an average savings of $425 000 per year, over ten years, is estimated due to reduce delay costs and laboratory testing. This was calculated using the baseline costs outlined in Appendix C.

For the RBM, it was proposed that food safety equivalence determinations could be carried out for three countries over the ten year costing period – the US in Year 1, a second country in Year 4 and a third country in Year 7. Based on this scenario, and using the savings calculated for the US as a baseline, the annual savings over the ten year period is estimated to be $807 500 per year.

5.3.5 Align the *Imported Food Control Act 1992* with domestic food legislation where applicable–including traceability

The Council of Australian Governments signed an Inter-Governmental Food Regulation Agreement in 2000 to give effect to a nationally consistent food regulatory system. One of the objectives of this agreement was providing a consistent regulatory approach across Australia through nationally agreed policies, standards and enforcement procedures. It included agreement to the adoption of Model Food Provisions (often referred to as the 'Model Food Act') to provide for the effective and consistent administration of the Code, including new food safety standards.

The Model Food Provisions have now been adopted into state and territory food legislation. This means every jurisdiction in Australia has the same definitions for key components of food legislation such as:

- definitions for 'food', 'unsafe food', 'unsuitable food'
- offences relating to food
- emergency powers.

As the Inter-Governmental Food Regulation Agreement provided for consistency between the states and territories on food regulation, it did not include aligning Commonwealth food legislation such as the *IFC Act 1992*. There are therefore inconsistencies between the *IFC Act 1992* and state and territory food legislation. A comparison of the definitions, offences and emergency powers between the Model Food Provisions and the *IFC Act 1992* is provided at Appendix D and a summary follows.

Another key difference is food businesses are regulated under state and territory food legislation and must meet specific obligations placed on them in Chapter 3 of the Code, relating to:

- notification (notifying details about the business to the appropriate enforcement agency before commencing operation such as contact details, the nature of the food business and the location)
- traceability (having the ability to provide information about what food it has on the premises and where it came from (trace-back)
- for certain businesses (including importers) having a fully documented food recall system in place (trace-forward)
- food handling controls
- health and hygiene requirements
- cleaning, sanitising and maintenance
- food premises and equipment.

The above obligations can currently be enforced on businesses that import food, post border, by the state and territory and local government food enforcement agencies. However, they are not enforceable at the border on food importers. While many of the requirements have limited relevance on food importers at the border due to the minimal handling of the food, it is critical that importers are able to trace food for effective food incident response. It is therefore recommended this obligation be placed on all importers in the *IFC Act 1992*. This is discussed further below under 'Traceability'.

Definitions

State and territory food legislation includes definitions for 'unsafe food' and 'unsuitable food', whereas the *IFC Act 1992* includes elements within these definitions under 'failing food' but there are inconsistencies. For example, the definition of 'unsafe food' excludes food being considered unsafe because it may cause allergic reactions or other reactions in persons due to sensitivities. Such foods are not specifically excluded under the definition of 'failing food' under the *IFC Act 1992*. This means, for example, an imported food containing an allergen could be failed at the border as it may be dangerous to human health.

The definition of 'food' within the state and territory food legislation provides greater clarity around what can be considered food. For example, the state and territory food legislation definition includes any substance or thing declared to be a food under the *FSANZ Act 1991*. This is not included in the *IFC Act 1992*.

Offences

State and territory food legislation, as detailed in the Model Food Provisions, include many more offences than the *IFC Act 1992* including for selling unsafe and unsuitable food, handling food in a way that would render food unsafe or unsuitable, selling falsely prescribed food and engaging in misleading conduct relating to the sale of food.

By comparison the *IFC Act 1992*, only has offences in relation to **knowingly** importing food that poses a risk to human health, labelling and dealing offences.

As per the *IFC Act 1992*, the state and territory food legislation provide that it is an offence to **knowingly** sell food that is unsafe. However, the state and territory food legislation also includes an offence (albeit a lesser offence) for a person to sell food that is unsafe. For this lesser offence, proof that the person knew the food was unsafe is not required.

The state and territory food legislation also includes additional offences related to handling food in a manner that will render, or is likely to render, the food unsafe. There is a more serious offence if a person knowingly does this.

Similar offences apply in the state and territory food legislation in relation to 'unsuitable food'.

If these offences were included in the *IFC Act 1992*, this would have the effect of, indirectly, placing responsibility on the business to take reasonable steps to ensure the food being imported is safe and suitable and once the importing business takes responsibility for this food, handling it responsibly so it does not become unsafe or unsuitable. It would also create a more seamless food regulatory system by aligning Commonwealth and state and territory food laws.

Since the *IFC Act 1992* was written, many provisions in the Code that relate to false and misleading descriptions and sale of food have been deleted and 'replaced' with general offences in the state and territory food legislation (as included in the Model Food Provisions). As the *IFC Act 1992* does not contain these offences, it limits the ability of the department to take enforcement action at the border where food may be falsely described or adulterated but not necessarily unsafe or unsuitable. Australia, like other countries, is vulnerable to the emerging and growing threat of food fraud and substitution, with economic gain being a significant motivating factor. Examples include beef substituted with horse meat, substitution of olive oil with unknown oils and honey adulterated with water and sugars.

The department, under the IFIS, can test food for authenticity at the border if the composition of the food is specified in the Code. For example, honey is currently tested for sugars and moisture content as there is a standard for honey specifying that it must be honey and contain not less than 60 per cent reducing sugars and no more than 21 per cent moisture (FSANZ 2015b). However, the composition of many foods are no longer specified in the Code, as the general provisions in state and territory food legislation and fair trading legislation provide a more efficient means of dealing with misleading conduct.

Post border regulatory action may be able to be taken under state and territory food legislation and the Australian Consumer Law (Schedule 2 of the *Competition and Consumer Act 2010*) to address misleading and deceptive conduct in relation to food. However, these regulatory activities would be more effective if they were supported by the ability to also take action at the border. This could be achieved by including the general offences in the Model Food Provisions related to false and misleading descriptions and sale of food in the *IFC Act 1992*. Without this ability, action can only be taken against imported fraudulent and adulterated food post border when it is already in the supply chain.

Emergency powers

As discussed in section 5.3.2, it is recommended that the emergency powers under the *IFC Act 1992* be expanded to enable a precautionary approach if there are reasonable grounds for believing imported food is unsafe.

This approach is consistent with state and territory food legislation, where food can be prevented from being advertised, sold, cultivated or harvested if there are reasonable grounds to believe such restrictions are necessary to prevent or reduce the possibility of a serious danger to public health.

The emergency powers in the *IFC Act 1992* restrict the placing of a holding order to food that fails an inspection or analysis or where there are reasonable grounds to believe a food would fail an inspection or analysis. This does not enable a precautionary approach to be taken if an imported food is associated with illness and the hazard is not known and/or cannot be easily detected in the food.

To improve consistency between the regulation of imported and domestically produced food, it is proposed that the IFC Act 1992 be aligned with the core definitions, offences and emergency powers in state and territory food legislation to:

- align the definition of 'food'
- separate the definition of 'failing food' into food that has failed because it is unsafe and food that has failed because it is unsuitable and include the definitions of 'unsafe food' and 'unsuitable food'
- include offences to sell food that is 'unsafe' or 'unsuitable' and to handle food in a way that renders, or is likely to render, the food 'unsafe' or 'unsuitable'
- include offences related to the false description of food and misleading conduct relating to sale of food
- have the ability to restrict the importation of food if there are reasonable grounds to believe the food needs to be restricted to protect public health and safety.

Traceability and food recall

Under state and territory food legislation, food businesses must be able to provide information about what food it has on the premises and where it came from (trace-back) and certain businesses (including certain importers) must have a fully documented food recall system in place. While a food recall is focused on retrieving potentially unsafe food from the supply chain, as part of business preparedness, it should also include the ability to trace food along the chain from suppliers through to customers (i.e. tracing both forward and backwards). This is outlined in FSANZ's Food Recall Plan Template, which food businesses can use to develop their own food recall systems (FSANZ 2016).

As food traceability requirements only apply to food businesses post border, there is a gap for those food importers that only operate at the border. To close this gap, it is recommended, that importers be required to have the ability to trace food imported one step forwards and step backwards under the *IFC Act 1992*. This means that for every consignment of food imported, the importer must have the ability to identify the immediate supplier and the immediate customer.

This might be achieved through providing in the IFC Act 1992 that the regulations may prescribe requirements for the traceability of food and for the recall of food. A similar approach is used in New Zealand legislation.

Costs

The recommended changes to the *IFC Act 1992* to align it to state and territory food legislation, where applicable, are not expected to impose new costs to industry, government or consumers. Aligning definitions should not have any impact and including the offences will only impact non-compliant importers, as these offences already apply post border.

The recommended change most likely to have an impact on food importers, is introducing a requirement to trace food imported one step backwards and one step forward. This will mainly impact those importers not already actively regulated by state/territory food enforcement agencies to have effective tracing systems in place. In the food importer survey, 80 per cent of respondents indicated they were licensed or registered as a food business and 73 per cent indicated that they had a food recall system in place. Twelve per cent of respondents did not know if they had a documented food recall system. Of those respondents that had a food recall system, nearly all said their system enables them to identify suppliers (100 per cent) and customers (97 per cent). Encouragingly, most also indicated that this information could be identified within one hour (77 per cent to identify the supplier and 67 per cent to identify the customer).

Respondents were also asked what the main barriers or challenges were to establishing a documented food recall system. Two common themes were the challenge of dealing with multiple government stakeholders at the federal and state level and a perceived lack of guidance on the process of establishing such a system.

As mentioned earlier, FSANZ has a food recall plan template available on its website. While this has only recently become available it should now be providing a valuable tool for businesses to develop their own food recall system. The NSW Food Authority also developed a simple Food Recall Action Plan earlier this year to assist food businesses develop a plan for removing unsafe product from the market (NSW Food Authority 2016).

Box 9 Traceability

Data

There were insufficient respondents to the food importer survey to have confidence that the responses were indicative of importers more broadly, however, the department has estimated that 50 per cent of importers that are not licensed or registered as a food business would need to improve their record keeping systems to ensure they have the ability to identify suppliers and customers of food being imported. Results of the survey indicated 20 per cent of importers were not registered with their state or territory. Of those businesses with food recall systems, respondents indicated that the length of time to establish the system was between two hours and 180 hours, with a median of ten hours. Half were unable to provide an estimate of the time required. Respondents were also asked to indicate how long it takes to maintain a food recall system. Responses ranged from one to 60 hours, with a median of 15 hours. Due to the availability of new tools to assist businesses establish traceability systems, the department reduced the time for set up and maintenance to seven and ten hours respectively.

Costs

The total cost of increased traceability was estimated to be $1.12 million. This included:

- 1 600 importers required to improve traceability systems
- 7 hours per importer to set up a traceability system (one-off cost)
- 10 hours per annum to maintain the traceability system
- labour cost of $65.45 per hour.

Benefits

Providing greater consistency between state and territory food legislation and the *IFC Act 1992* not only makes good sense but also addresses two of the reform objectives, increasing importer accountability and improved incident response.

Greater importer accountability is achieved by amending the *IFC Act 1992* to mirror the offences in the state and territory food legislation for a person to import food that is unsafe or unsuitable and also to handle food in a way that would render it unsafe or unsuitable. These offences, indirectly, have the effect of placing responsibility on the business to take reasonable steps to ensure the food being imported is safe and suitable and once the importing business takes responsibility for this food, handling it responsibly so it does not become unsafe or unsuitable.

Improved incident response is achieved by broadening the emergency powers and also requiring importers to have the ability to trace food.

Questions

Option 3 – Traceability

Question 5 (a) Is it reasonable to assume that importers registered as food businesses with their local authority already have the ability to trace food one step forward and back in compliance with current state and territory legislation?

(b) Are you aware of other supporting material available to food business to establish food recall plans, including templates and tools?

(c) Do you agree that these systems would largely address the ability to trace produces one step forward and back?

5.3.6 Net benefits of Option 3

Option 3 is the only option that fully addresses the policy objective. It includes the benefits of options 1 and 2 but additionally:

- provides greater certainty on the safety of food where evidence of through-chain controls is needed to demonstrate management of food safety hazards
- enables immediate action to be taken at the border to respond to a potential food safety issue with imported food
- enables evidence of a new or emerging risk with imported food to be investigated immediately by including the ability to temporarily refer this food at a higher rate for border inspection to assess the risk
- includes the ability to recognise foreign country equivalence, exempting all imports from border intervention except where there is evidence of non-compliance or a food safety risk
- provides greater consistency between domestic and imported food legislation.

Option 3 provides the greatest benefits to consumers. It increases the safety of imported food by placing greater responsibility on importers to source safe food. It also enables more effective emergency response to potentially unsafe imported food, thereby minimising exposure to consumers.

Option 3 also provides indirect benefits to importers, as it decreases the likelihood of an imported food safety incident occurring and consequently the costs to industry from such an incident.

The net annual cost of option 3 is estimated to be $545 000 per year averaged over ten years across the approximately 16 000 businesses importing food, equating to approximately $34 per business per year. This is mainly driven by the costs to businesses to implement and maintain traceability systems as well as supply chain assurance for 'prescribed foods', at $1.022 million and $1.120 million per year respectively. These costs are offset by the estimated savings of $835 000 per year from option 2.

Questions

Option 3 – Implications for stakeholders

Question 6 (a) What impact will business size have on the costs and benefits outlined in option 3, in particular small businesses? Please provide the reasons and if possible cost estimates of any impacts.

(b) Will the proposed measures in this option result in a change in the range of products available to consumers or on the price of imported food? If so, please provide the reasons for these changes and estimation of the impacts.

(c) Do you consider that the proposed reforms will have an effect on competition within Australia? Please provide the reasons and if possible cost estimates of any impacts.

(d) Will the proposed reforms to imported food have any impact on primary producers and suppliers in Australia?

(e) Do you consider the measures in this option will improve the safety of imported food?

5.4 Regulatory Burden Measure Table

Figure 6 presents the regulatory burden and cost offset estimates that have been calculated using the Commonwealth RBM, as required under the Australian Government Guide to Regulation.

Figure 6 Regulatory burden measurement and cost offset estimate table

Average annual regulatory costs	
Change in costs ($ million)	Business
Policy Option 1—Status quo and non-legislative improvements underway	**- 0.667**
Status quo (current inspection scheme)	**Nil**
Increased FICA participation (improvement underway)	**- 0.667**
Administrative costs	+ 0.238
Delay costs	- 0.203
Inspection and laboratory costs	- 0.702
Policy Option 2—Non legislative change	**- 0.835**
Costs from Policy Option 1	**- 0.667**
Increased foreign government certification	**- 0.168**
Administrative costs	+ 0.002
Delay costs	- 0.037
Inspection and laboratory costs	- 0.133
Policy Option 3—Legislative change	**+ 0.545**
Costs from Policy Option 2	**- 0.835**
Supply chain assurance	**+ 1.022**
Broader emergency powers	**+ 0.008**
Monitoring new and emerging risk	**+ 0.038**
Traceability requirements	**+ 1.120**
Country system equivalence	**- 0.808**
Cost offset ($ million) for Implementation of Option 3	
–	Business
Agency	N/A
Are all new costs offset?	N/A
Total (Change in costs – Cost offset) = + $0.545	

6 Trade implications

The proposed reforms that will require legislative change as outlined in option 3 will likely have implications for Australia's trading partners.

Whilst the proposed reforms aim to ensure that food imported into Australia meets Australian food standards and public health and safety requirements they must also be consistent with Australia's international obligations such as under the WTO agreements including *the Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement). In addition, the proposed reforms must be consistent with the international standards for food safety as set by Codex Alimentarius.

6.1 Supply chain assurance

An analysis of imports of prescribed foods over the past three years indicates which of Australia's key trading partners will be most likely affected by the proposed reforms. These countries have been approached directly to seek information about how food producers and manufacturers operate in their country.

Under option 3, importers will be required to make a declaration that they have records that provide supply chain assurance for 'prescribed' foods, where border inspection alone would be insufficient to assure the safety of the food. These foods require preventative controls to be in place during their production to ensure safety as border testing alone is insufficient to provide this assurance.

Australian importers will be able to demonstrate that the food safety hazards associated with 'prescribed foods' have been subjected to preventative controls in a food safety management system by providing a:

- recognised government certificate or
- recognised non-government certificate, such as certification of a HACCP based food safety management scheme.

Government certification will be supported by a food safety management system equivalence determination, and agreement between Australia and the exporting country competent authority. Non-government certification must be supported by food safety management systems that have been certified as meeting globally accepted food safety standards consistent with Codex Alimentarius.

This appears to be in line with the EU and Canada's supply chain assurance requirements for what is determined to be higher risk foods. Australia's proposal is less stringent than the US that requires supply chain assurance for a wider range of foods. It is also in line with New Zealand, which requires all importers to keep records on how products have been produced, transported and stored with more stringent requirements applied to foods of high regulatory interest.

In the US, it appears that importers are required to provide supply chain assurance for all foods, either to the Food and Drug Authority or the USDA. For meat, meat products, eggs, egg products and poultry the USDA manages the imports and only allows importations from registered countries and establishments that have been certified by the competent authority of that country.

In the EU, it is understood that importers are required to ensure that their suppliers comply with HACCP as a systematic approach to food safety and good hygiene practices (GHP) through the supply chain. In addition, EU importers are required at the point of import to ensure food that is higher risk such as sprouts and products of animal origin is from registered establishments.

In Canada, it appears that importers are required to have the ability to demonstrate supply chain assurance on request, but some high risk products (prescribed) have to prove supply chain assurance. For example, meat and meat products have to be from an approved country and establishment with safety controls in place.

In New Zealand, it is understood that all importers must take all reasonable steps to document how the food has been produced and managed in a manner that ensures the food is safe for human consumption. Foods of high regulatory interest may require a higher level of evidence of supply chain assurance, as a condition of import.

Prescribed foods–Case studies

'Prescribed foods' are those foods that require a higher level of food safety assurance to be demonstrated at the border due to their potential public health and safety risk and border testing alone is insufficient to provide this assurance.

To assist with assessing the potential impacts, analysis has been undertaken of the main countries that Australia currently imports 'prescribed foods' from. This analysis also identifies the Pacific Island Countries (PICs) Australia currently imports 'prescribed foods' from due to the economic importance of trade with Australia for these countries. The findings overall found that:

- prescribed foods were imported from 73 countries over a three year period from 1 March 2013 to 29 February 2016
- the top five countries from which the greatest volume of prescribed food (tonnes) was imported during the review period was the United States (191 790), Denmark (157 410), Canada (80 810), Viet Nam (52 550) and the Netherlands (41 266)
- Fiji was the only PIC country from which prescribed foods were imported
- on each prescribed food category only one or two countries imported the majority of the product, by volume

Further information about the analysis of trade data is provided at Appendix E, based on the 'prescribed food' type.

Questions

Trade implications–supply chain assurance

Question 7 (a) Do food producers in your country generally have food safety management systems (HACCP based systems) in place for the foods listed in Table B1 (for example, GLOBALG.A.P, BRC Global Standards, SQF, ISO 9000, ISO 22000)?

(b) How far back in the supply chain are these systems in place i.e. primary production, primary processing and manufacturing? Indicate all that apply.

(c) Are food safety management systems usually government certified or industry certified?

(d) What documentation can be provided by suppliers in your country to satisfy Australian importers about the safety of these foods?

(e) How easily can this documentation be obtained? Is there an associated cost?

(f) If your country imports any of the foods at Table B1 from Australia, what food safety assurances (either industry or government driven) do you require from Australian exporters or your importers?

6.2 Broaden emergency powers to allow precautionary action where there is uncertainty about the safety of a particular food

On average, Australia manages between three and four serious imported food safety issues per year. Therefore, the likelihood of imported food being restricted at the border in response to a food safety incident is low.

It is understood that the US, Canada and New Zealand all can impose import controls on food on a reasonable belief or reasonable grounds that the food could pose a risk to public health. This can include a detainment of the consignment, exportation back to the country of origin, suspension of trade, or release subject to special controls.

It appears that the EU food safety laws include the requirement to take into account the "Precautionary Principle" in risk management i.e. where there is a possibility of harmful effects but scientific uncertainty persists, risk management measures may be adopted, pending further scientific information for a more comprehensive risk assessment.

The proposed imported food reforms will extend the use of holding orders to restrict imported food to enable application on reasonable grounds that the food poses a serious danger to public health, while the full extent of the actual risk is established. This appears to be consistent with what is understood about the EU, US, Canada and New Zealand's emergency powers.

Questions

Trade implications – emergency powers

Question 8 (a) Does your government have the ability to take precautionary action when faced with a food that poses serious danger to public health?

(b) If so, what type of information is considered reasonable?

(c) What are the potential implications and how have these been managed?

6.3 Additional powers to monitor for new and emerging risks

It appears that some of Australia's trading partners conduct risk-based inspection systems for managing food safety risks in imported foods, and are able to be more flexible with the settings of the risk and inspection frequency. In Canada and the US, inspection frequency looks like it is based on food safety risk, and takes into account compliance history. New Zealand appears to have flexibility in the use of the high regulatory interest food category as well as the use of information from the Imported Food Monitoring Program used to determine at border inspections.

In the EU, the European Food Safety Authority provides scientific risk advice on foods and import requirements. However, it appears that the Member States can also consider societal, traditional, economic, ethical, environmental issues and the feasibility of border controls in categorising foods in a higher risk category for enhanced surveillance. In addition, Annex I to Regulation (EC) No 669/2009 lists food and feed of non-animal origin that are subject to an increased level of official control for imports. This list is regularly updated by the EC Standing Committee on the Food Chain and Animal Health based on information from various sources such as the Rapid Alert System for Food and Feed (RASFF), reports from the EU Food and Veterinary Office, and EU Member States and non-EU countries.

Questions

Trade implications – monitoring new and emerging issues

Question 9 If Australia applied a more flexible rate of inspection for a designated period of time or number of consignments for the purposes of assessing the potential exposure to an emerging risk based on the food type and producer/supplier, what might be the implications for your exporters?

6.4 Recognise an entire foreign country's food safety regulatory system where there is equivalence with Australia's food safety system

It is expected that the countries sought for equivalence would be determined based on imported food data, compliance behaviour, trade priorities and consultation with key stakeholders including trading partners and industry representatives. It is important to note that the number of potential opportunities for these types of arrangements are likely to be relatively small and therefore achievable.

Canada, New Zealand and the EU imported food regulations also appear to enable the recognition of other countries' food safety management regulations with exemptions for particular goods that require more stringent controls due to the risk.

Equivalence would be assessed on the basis that the foreign country's food safety regulatory system achieves the same level of protection as that of Australia's food safety regulatory system.

Recognition of a foreign country's food safety regulatory system would likely result in Australia's exporters receiving reduced regulatory intervention associated with food safety clearance of their food exports in the foreign country.

6.5 Align the Imported Food Control Act 1992 with domestic food legislation where applicable including traceability

It is proposed that for each consignment of food imported, importers in Australia will need to have accessible records that show who they bought it from and who they sold it to. This facilitates effective traceability of food during a food safety incident. Each consignment of food will be required to have documentation to identify the food, batch, supplier name and supplier location.

This appears to be consistent with the US, NZ, Canada and the EU who all make importers legally responsible for the safety and compliance of the food they are importing to be safe and compliant.

Questions

Trade implications–alignment with domestic food safety legislation

Question 10 (a) Is each consignment of food exported from your country accompanied with documentation identifying the food, batch, supplier name and supplier contact details?

(b) If not, what information is currently provided?

(c) Is this documentation required by your government?

6.6 International approaches

Countries with similar imported food safety systems

It is understood that trading partners such as the US, the EU, Canada and New Zealand have or are soon to implement similar imported food safety measures that are being proposed by Australia. The majority of the proposed reform measures for Australia are equivalent or less stringent than these overseas systems, particularly when compared with the US.

In the time since the introduction of the *IFC Act 1992*, a number of key trading partners have undertaken reviews and reforms in response to emerging food safety issues and risk management systems. Based on the following examples, the global shift in food safety regulation appears to demonstrate that our proposed reforms are well aligned to some of our key trading partners:

- United States (US): Food Safety Modernisation Act introduced in November 2015 was sweeping reform that sought to ensure food safety by shifting the focus from responding to contamination to preventing it.
- China: October 2015 update of its Food Safety Law and associated regulations aimed at strengthening regulation of food companies and encouraging confidence in the China food industry.
- New Zealand: 2014 reform of the Food Act 1981 took effect in March 2016. This provides greater flexibility to apply food safety requirements on a sliding scale depending on the level of risk with a focus on food production processes rather than premises.
- Canada: following the report into the 2008 listeriosis outbreak (the Weatherill Report), the Safe Food for Canadians Act was introduced in late 2012. This legislation consolidates the authorities of four related food Acts aimed at strengthening Canada's food safety system based on key features of international food safety systems – identification of food businesses, ability to trace food one step forward and one step back, and establish preventative food safety controls.
- European Union (EU): following a series of food incidents in late 1990 and the outcomes of its White Paper on Food Safety in 2000, established general food law regulations in 2002 that established the general principles and requirements of food law organised into functions of risk assessment, risk management and risk communication.

International Standards

Codex Alimentarius has produced principles and guidelines for food import and export inspection and certification systems. The guiding principles are set out in *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995). The guideline document of most relevant to the measures being proposed for imported food reform is *Guidelines for Food Import Control Systems* (CAC/GL 47-2003).

In the guiding principles document, it states that 'in both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.' These principles include ensuring these systems are:

- risk based
- non-discriminatory

- cost effective and no more restrictive of trade than is necessary to achieve the level of protection needed
- harmonised with international standards
- recognise equivalence
- transparent
- able to take into account the capabilities of developing countries to provide the necessary safeguards.

The proposed reforms in option 3 have been developed and will be implemented in a manner that is consistent with Australia's international obligations. To ensure consistency, advice will be sought from the Attorney-General's Department, Office of International Law, the Department of Foreign Affairs and Trade as well as from relevant Commonwealth agencies. In addition, Australia will continue to consult informally with key trading partners and formally with WTO members.

6.7 Implications for Australian Exporters

Australian exporters are not expected to be materially affected, if at all, by the introduction of the proposed imported food reforms. Currently export certification of a range of prescribed food products from Australia is underpinned by a regulatory framework that requires registration of food preparation establishments and participation in a commodity-specific approved arrangement scheme.

7 Consultation

7.1 Objective

This consultation RIS provides the first opportunity for the public to comment on the proposed options for reform. It also provides the public with the opportunity to assist the department to test its assumptions and to understand the potential risks and impacts of the proposed reforms.

7.2 Key stakeholders

The following are key stakeholders that the department has consulted with in developing the proposed reforms:

- Department of Agriculture and Water Resources Imported Food Consultative Committee
- Food and Beverage Importers Association
- Australian Food and Grocery Council
- food importers
- Australian food retailers
- customs brokers and freight forwarders
- relevant Commonwealth agencies
- domestic food regulators
- trading partners.

These groups will continue to be consulted throughout the progress of the proposed reforms.

7.3 Previous consultation

Consultation that has occurred for the development of the proposed reform options and this RIS included:

- meetings with food importers in Sydney and Melbourne in June 2015, 14 industry representatives attended
- discussions with the department's Imported Food Consultative Committee at the May 2015, November 2015, and May 2016 meetings as well as out of session updates.

Consultation with states, territories and New Zealand has occurred through existing bi-national food regulatory forums.

Trading partners have been consulted about the proposed reforms that are more likely to impact them. Trading partners consulted include Turkey, China, Brazil, the European Union, Canada, Chile, Fiji, United States, New Zealand, Papua New Guinea and Viet Nam.

Since May 2015, the department has undertaken a range of consultation activities to help inform the development of the proposed options for reform.

These activities have included targeted discussions with representatives of relevant Australian Government agencies, state and territory food safety regulators, food importers, industry associations and trading partners. In addition, the department has undertaken information gathering activities including imported food consignment data analysis, comparative analysis of international food safety regulation and a survey of food importers to assess current practices.

The focus of this consultation process is to gather information from industry and interested parties about the nature and extent of the impacts of the proposed options for reform. Trading partner views are also welcome.

A range of communication and consultation channels will be used to bring this discussion paper to the attention of industry and interested parties. The department will use its own website and social media channels as well as business.gov.au and state and territory websites.

Electronic mail out will also be sent to several subscribers lists to promote the consultation RIS. These include the department's Imported Food Notices and Import Industry Advice Notices with approximately 2 850 subscribers.

The department will also engage relevant Australian Government agencies through an interdepartmental committee, industry associations through the Imported Food Consultative Committee, and State and Territory food safety regulators through the ISFR.

Additionally the department will utilise the ICS's electronic messages. The department will also work with industry organisations and associations to promote the consultation process on their respective websites and through their contact lists.

7.3.1 Food importer research

The department engaged Colmar Brunton Social Research to conduct research into food importer compliance, awareness and importer behaviour. The key component of this research was a food importer survey which was undertaken from 18 April to 3 May 2016. A total of 41 surveys were completed in this period. Given the very small number of completed surveys achieved, these findings should be viewed as representative of the experiences of this small number of respondents only.

Objectives

The objectives of the research project were to:

- establish a database of food importer information that enables segmentation by specific criteria such as demographics, size/turnover, food types, source countries, use of food safety systems or other systems for compliance, costs of compliance, and state or territory food business registration/licence
- provide a summary report of the research analysis including food importer segmentation, national footprint, costs of compliance, extent of food safety systems, and key statistical conclusions and relevance
- obtain sufficient information regarding the type and level of involvement of importers in the food recall process, their ability to trace imported food back one step to the supplier and one step forward to the customer, and how food importers understand and meet their food recall obligations

- understand importer consideration of, and interest in, entering into a FICA with the department, the perceived barriers and benefits of doing so.

Methodology

The department circulated the draft questionnaire within the department's Imported Food Consultative Committee (comprising a range of members, including food importers, nationally) for feedback.

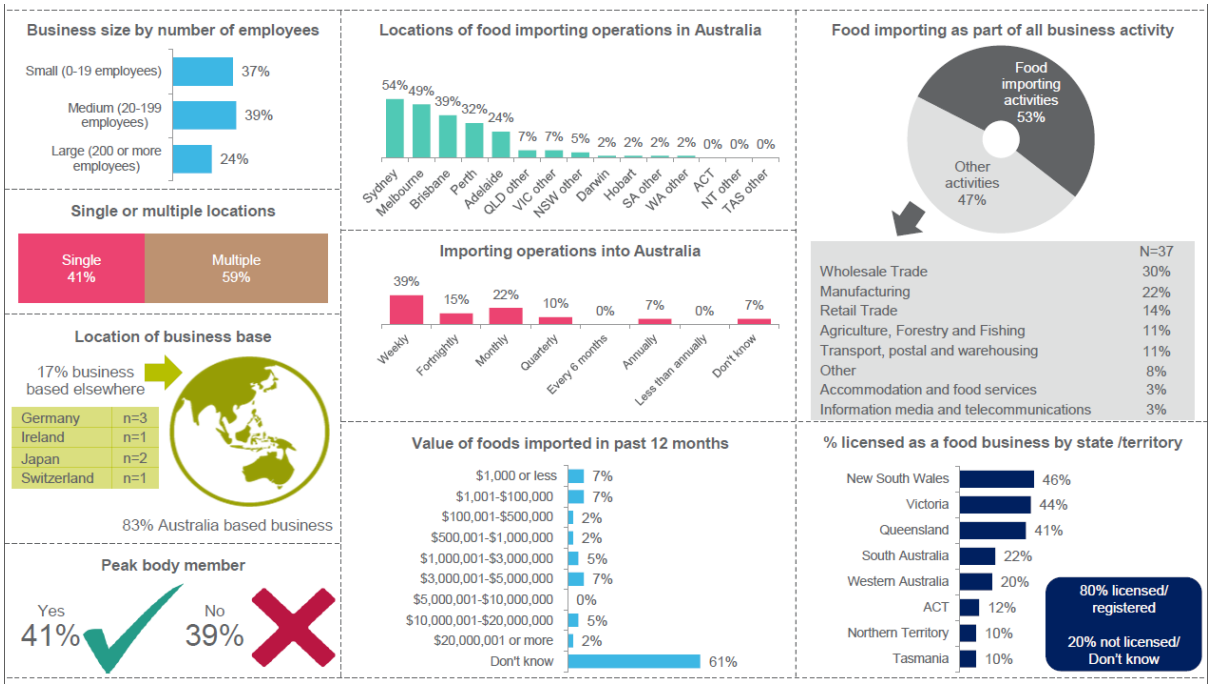
To further test the planned food importer survey, a series of nine cognitive interviews were conducted from 6-9 April 2016 with food importers ranging from small importers through to very large food importers. Feedback obtained through these interviews was used in further refining the questionnaire.

The online food importer survey was conducted on a self-select basis and was promoted via a number of channels including government websites, the department's Import Clearance Industry Advice Notice and Imported Food Industry Advice Notices, and ICS Notices. The survey was also promoted in partnership with key industry consultation and stakeholder groups and via the department's social media channels.

Sample profile of respondents to the food importer survey

The following figure provides an overview of the 41 respondents to the survey.

Figure 7 Sample profile



Key findings

The research concluded the below findings.

Accuracy of estimated hours

The ability to accurately estimate hours spent was a challenge for many. The high proportion of 'don't know' responses to hours spent undertaking specific food import tasks makes modelling of hours and the associated cost impact on a business importing food quite challenging.

Compliance effort

Broadly speaking, the compliance effort required by food operators reflects the size of the business and the volume of food importing activity. Hours reported for undertaking key compliance activities were generally higher for both medium and larger businesses and those where food importing makes up a major part of their overall business activities.

State and territory licensing and registration

Four in five respondents were licenced and/or registered as a food business at the state and territory level. One of the objectives of the study was to build a database of food importers that could be used as a future channel to engage the sector on potential reforms. While the low response rate did not allow for this to be realised, it was recommended to explore engagement through state and territory governments through food business licensing and regulation.

Knowledge of regulations

Self-rated knowledge of food safety regulation governing food importing and confidence in ability to comply was both high. Among at least the respondents of the survey, there was little evidence that food importers are lacking knowledge of the regulations governing their activities or have difficulty in complying with these. Given the self-select nature of the survey and the channels through which it was promoted, it is likely more reflective of more frequent food importers than those doing importing on a smaller or less frequent scale.

Food Import Compliance Agreements (FICAs)

Awareness of FICAs was reasonably low. More than half of respondents indicated they had not heard of a FICA, and among these one of the main barriers to not considering establishing one is a lack of knowledge about what they are. It is proposed that better promotion of FICAs may serve to stimulate growth in those entering into such arrangements.

The proposed reform to FICAs not covering all import activities is likely to stimulate greater take-up of these arrangements. The findings showed that at least a quarter of those not currently on a FICA would be more likely to apply for one if an importer could apply for only part of its importing activities.

Food safety management accreditation

The majority of importers source foods from suppliers that have food safety management system accreditation. The overall proportion of suppliers with food safety management systems in place was high, and only a small proportion of suppliers of higher risk foods were identified not to have such systems in place. Together, these findings provide a reasonable level of

assurance that food safety risk is being managed appropriately by food importer survey respondents.

Traceability

Traceability appears strong for those with documented food recall system. Those that have invested in developing a documented food recall system have the ability to readily trace one step forward or back in their supply chain, with the majority confident they could provide such information within one hour if needed.

Examine barriers to ensuring all importers meet their traceability obligations. The key challenges identified by those who had established a food recall system were the challenges of dealing with multiple stakeholders at the federal and state level and the lack of a template companies could access and use for this purpose.

7.4 Next steps

Stakeholder feedback on the consultation RIS will be reviewed and will inform the detail of a Decision RIS. The Decision RIS will inform the government's consideration of the imported food reform policy proposal.

Pending the government's decision there will continue to be opportunities for stakeholders to engage with the department during the process of developing the imported food reforms. This includes implementation and communication strategies.

Trading partners are being formally consulted through a WTO sanitary and phytosanitary (SPS) notification with the standard 60 day consultation period. Trading partners will be consulted again via another WTO SPS notification during the development of draft legislation.

The department will continue to engage with stakeholders through consultations with established stakeholder groups and more broadly.

8 Implementation

The key activity necessary to implement the proposed imported food reforms is the amendment of the IFC Act 1992 and subordinate legislation. Administrative procedures and requirements will also be updated to reflect the proposed changes.

8.1 Legislation

The proposed reforms will require some legislative changes. The department is responsible for preparing drafting instructions, with the Office of Parliamentary Counsel responsible for drafting the changes to the legislation.

8.2 Transition

It is proposed that transitional arrangements will apply in some instances such as for supply chain assurance measure and traceability systems. Transitional arrangements will be a matter for consultation with stakeholders to seek to understand the impacts on industry and how long transition arrangements are needed to ensure compliance.

Question

Transitional arrangements

Question 11 If you are a food importer, what do you consider to be a reasonable time period to meet the new requirements proposed in these reforms such as supply chain assurance and traceability systems?

8.3 Stakeholder education

An educational program will be implemented to ensure that food importers are aware of the new requirements and how to ensure that they comply.

8.4 Evaluation

The evaluation of the effectiveness and efficiency of the implementation of the proposed options for reform to the management of imported food safety risks will occur as part of the department's business as usual management of the imported food program. This involves regular monitoring of and reporting on the effectiveness of the Imported Food Inspect Scheme to stakeholders through the Imported Food Consultative Committee (IFCC).

The department also undertakes regular engagement with FSANZ to ensure the communication, coordination, development and effectiveness of risk assessment and risk management activities. Further the department contributes and participates in food safety incident management activities through the BFSN and the ISFR. These arrangements include ongoing monitoring and evaluation of the effectiveness of food safety regulation domestically.

Appendix A: Consolidated list of questions

Option 1–Food Import Compliance Agreements

Question 1 If you are a food importer and would be interested in entering into a tiered FICA, what proportion (%) of foods you currently import would you most likely want covered in the agreement?

Option 3–Supply chain assurance

Question 2 (a) If you are a food importer, what assurances do you gain from your suppliers to ensure the food has been produced, manufactured and handled safely? What costs do you incur to obtain this assurance?

(b) If the food you import comes with some form of food safety certification, do you verify compliance with the certification and if so, how? What costs do you incur in undertaking this verification?

(c) Are the kinds of foods likely to require supply chain assurance clearly defined? If you are an importer of these kinds of foods, do you already require certification for supply chain assurance, such as a recognised food safety management scheme? If so, do you pass on any associated costs to consumers?

Option 3–Emergency response

Question 3 Often at the beginning of a food safety issue being identified, there is incomplete information on the cause of the issue. However, depending on the level of risk it may be necessary to take immediate action. What would be the impact to your business if imports of a specific food were restricted (held) at the border to gain additional assurances on the safety of the product?

Option 3–Monitoring and responding to emerging food safety issues

Question 4 (a) If you are a food importer, can you describe how you monitor and respond to emerging food safety issues (e.g. receive information from suppliers, industry associations, government alerts).

(b) What do you consider would be the most effective mechanism to communicate emerging food safety issues to importers?

Option 3–Traceability

Question 5 (a) Is it reasonable to assume that importers registered as food businesses with their local authority already have the ability to trace food one step forward and back in compliance with current state and territory legislation?

(b) Are you aware of other supporting material available to food business to establish food recall plans, including templates and tools?

(c) Do you agree that these systems would largely address the ability to trace produces one step forward and back?

Option 3–Implications for stakeholders

Question 6 (a) What impact will business size have on the costs and benefits outlined in option 3, in particular small businesses? Please provide the reasons and if possible cost estimates of any impacts.

(b) Will the proposed measures in this option result in a change in the range of products available to consumers or on the price of imported food? If so, please provide the reasons for these changes and estimation of the impacts.

(c) Do you consider that the proposed reforms will have an effect on competition within Australia? Please provide the reasons and if possible cost estimates of any impacts.

(d) Will the proposed reforms to imported food have any impact on primary producers and suppliers in Australia?

(e) Do you consider the measures in this option will improve the safety of imported food?

Trade implications–supply chain assurance

Question 7 (a) Do food producers in your country generally have food safety management systems (HACCP based systems) in place for the foods listed in Table B1 (for example, GLOBALG.A.P, BRC Global Standards, SQF, ISO 9000, ISO 22000)?

(b) How far back in the supply chain are these systems in place i.e. primary production, primary processing and manufacturing? Indicate all that apply.

(c) Are food safety management systems usually government certified or industry certified?

(d) What documentation can be provided by suppliers in your country to satisfy Australian importers about the safety of these foods?

(e) How easily can this documentation be obtained? Is there an associated cost?

(f) If your country imports any of the foods at Table B1 from Australia, what food safety assurances (either industry or government driven) do you require from Australian exporters or your importers?

Trade implications–emergency powers

Question 8 (a) Does your government have the ability to take precautionary action when faced with a food that poses serious danger to public health?

(b) If so, what type of information is considered reasonable?

(c) What are the potential implications and how have these been managed?

Trade implications–monitoring new and emerging issues

Question 9 If Australia applied a more flexible rate of inspection for a designated period of time or number of consignments for the purposes of assessing the potential exposure to an emerging risk based on the food type and producer/supplier, what might be the implications for your exporters?

Trade implications–alignment with domestic food safety legislation

Question 10 (a) Is each consignment of food exported from your country accompanied with documentation identifying the food, batch, supplier name and supplier contact details?

(b) If not, what information is currently provided?

(c) Is this documentation required by your government?

Transitional arrangements

Question 11 If you are a food importer, what do you consider to be a reasonable time period to meet the new requirements proposed in these reforms such as supply chain assurance and traceability systems?

Appendix B: Prescribed foods overview

Within option 3, it is recommended that importers of certain foods be required to provide evidence that food safety hazards have been controlled throughout the primary production and processing of these foods and that these foods would be prescribed in the imported food legislation. An indicative list of food that may be prescribed is outlined in Table B1 including the main food safety hazards of concern with these foods and the foods currently imported.

From 2013-2015, prescribed foods were imported by a total of 623 importers (based on Australian Business Number).

A total of 636 672 tonnes of prescribed foods were imported during the three year period of 1 March 2013 to 29 February 2016 (Table B2). Over this period the top prescribed food group imported (by tonnes) was 'Raw meat and meat products (pork only) of which 461 759 tonnes were imported. This was followed by 'Ready-to-eat raw or minimally processed nuts' (87 497 tonnes), 'Ready-to-eat raw or minimally processed produce associated with foodborne disease' (63 413 tonnes), 'Ready-to-eat raw or minimally processed bivalve molluscs' (16 132 tonnes) and 'Ready-to-eat minimally processed finfish' (7 871 tonnes) (Figure B1).

Table B1 Indicative list of 'prescribed foods'

Indicative list of 'Prescribed foods'	Main food safety hazards of concern with these foods	Foods currently imported
Ready-to-eat[a] raw or minimally processed produce associated with foodborne disease such as fresh and frozen berries, bagged leafy greens, cut packaged fruit, sprouted seeds, fresh herbs	*Listeria monocytogenes*, Shiga toxin-producing *Escherichia coli* (STEC), foodborne viruses (such as hepatitis A virus and norovirus), protozoan parasites, *Shigella* spp.	Fresh and frozen berries Frozen mango Fresh sugar snap peas and snow peas Semi-dried tomatoes
Ready-to-eat[a] raw or minimally processed nuts (i.e. shelled and unroasted)	*Salmonella* spp.	Pistachios, almonds, cashew nuts
Beef and beef products#	Bovine spongiform encephalopathy (BSE)	No products can be imported without a recognised foreign government certificate. Review currently underway to consider importation of fresh (chilled or frozen) beef and beef products from US, Japan, the Netherlands and Vanuatu.
Ready-to-eat[a] uncooked meats associated with foodborne disease (salami, mettwurst, jerky, biltong)	Shiga toxin-producing *Escherichia coli* (STEC)	Jerky, biltong, mettwurst
Raw meat and meat products (other than beef and poultry)	Shiga toxin-producing *Escherichia coli* (STEC), *Salmonella*	Pork only for further processing under quarantine approved premises.
Raw poultry	*Campylobacter* spp., *Salmonella* spp.	None imported due to

Indicative list of 'Prescribed foods'	Main food safety hazards of concern with these foods	Foods currently imported
		biosecurity restrictions.
Eggs (whole eggs, unprocessed egg products)	*Salmonella* spp.	None imported due to biosecurity restrictions.
Raw milk cheese#	Shiga toxin-producing *Escherichia coli* (STEC), *Listeria monocytogenes*	No products can be imported without a recognised foreign government certificate, with the exception of raw milk cheese from New Zealand. Roquefort is currently the only raw milk cheese being imported from France.
Ready-to-eat[a] raw or minimally processed bivalve molluscs	Biotoxins, foodborne viruses, *Vibrio cholerae, Vibrio parahaemolyticus*	Fresh or frozen clams, cockles, mussels, oysters, pipi and scallops
Ready-to-eat[a] minimally processed finfish	*Listeria monocytogenes*	Cold smoked salmon

a: is expected to be eaten without being cooked

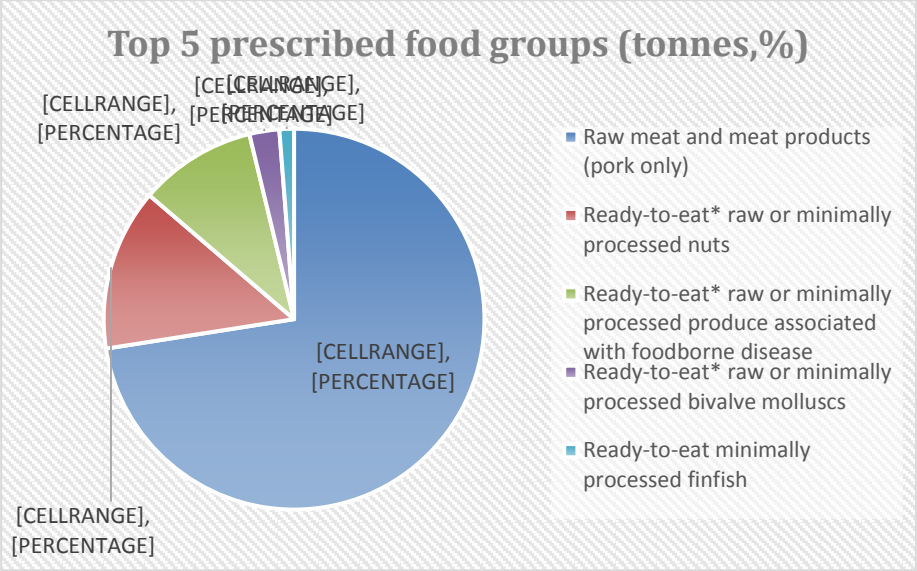
Table B2 Top five prescribed food groups imported over a three year period, by tonnes

Position	Prescribed Food Group	Total (tonnes)
1	Raw meat and meat products (pork only)	461,759
2	Ready-to-eat[a] raw or minimally processed nuts	87,497
3	Ready-to-eat[a] raw or minimally processed produce associated with foodborne disease	63,413
4	Ready-to-eat[a] raw or minimally processed bivalve molluscs	16,132
5	Ready-to-eat[a] minimally processed finfish	7,871
Total		**636,672**

Source: ICS data

a: is expected to be eaten without being cooked

Figure B1 Top five prescribed food groups imported over a three year period, by tonnes



Source: ICS data

Appendix C: Costing methodology and assumptions

The Commonwealth RBM was used for this analysis. Consistent with the Regulatory Burden Measurement Guidance Note published by the Office of Best Practice Regulation (OBPR), the analysis included consideration of the following regulatory costs to businesses from the proposed options:

- Compliance costs
  - administrative costs
    - costs incurred by regulated entities primarily to demonstrate compliance with the regulation (usually record keeping an reporting costs)
  - substantive compliance costs
    - costs incurred to deliver the regulated outcomes being sought (usually purchase and maintenance costs)
- Delay costs
  - expenses and loss of income incurred by a regulated entity through:
    - an application delay
    - an approval delay.

Direct financial costs attached to a regulation that are payable to government, such as administrative charges and fees were excluded from the RBM calculation.

The regulatory cost of the current IFIS was calculated to determine the baseline costs to businesses. The main costs to businesses under the existing scheme included:

- the cost to business for a staff member or appointed delegate attend the inspection of the food referred to the IFIS.
  - estimated time for inspection of 30 minutes per line
- the cost to business for analytical tests applied to referred food
  - an average cost of $220 per test for surveillance foods
  - an average cost of $140 per test for risk foods
- the costs associated with having food delayed at the border while it is inspected (delay cost)
  - average of 14 day delay for surveillance foods inspected and released at the border, resulting in an average delay cost of $40.70 per line inspected
  - average delay of 18 days for risk food inspected and held at the border, resulting in an average delay costs of $41.35 per line inspected
- The base labour rate of $65.45 per hour was used for all relevant calculations.

These data were used when costing the proposed options, including determining regulatory savings from reduced inspection, testing and delay costs, where relevant.

Appendix D: Comparison of *Imported Food Control Act 1992* to the Model Food Provisions

Following is a comparison of the *IFC Act 1992* with the Model Food Provisions. In 2000, the Council of Australian Governments signed an Inter-Governmental Agreement to give effect to a nationally consistent food regulatory system. This included agreement to the adoption of Model Food Provisions (often referred to as the 'Model Food Act') to provide for the effective and consistent administration of the Australia New Zealand Food Standards Code, including new food safety standards. The Model Food Provisions have now been adopted into state and territory food legislation.

The Model Food Provisions are contained within two Annex's–Annex A and Annex B. This comparison is with the provisions within Annex A only, as this Annex contain the core definitions, offences and emergency powers.

	Imported Food Control Act 1992	**Model Food Provisions (Annex A)**	**Differences**
Key definitions			
Food	*food* includes: any substance or thing of a kind used or capable of being used as food or drink by human beings; or any substance or thing of a kind used or capable of being used as an ingredient or additive in, or substance used in the preparation of, a substance or thing referred to in paragraph (a); or any other substance or thing that is prescribed; whether or not it is in a condition fit for human consumption, but does not include a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*. Clause 3 Interpretation	In this Act, *food* includes: any substance or thing of a kind used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared), or any substance or thing of a kind used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a), or any substance used in preparing a substance or thing referred to in paragraph (a) (other than a substance used in preparing a living thing) if it comes into direct contact with the substance or thing referred to in that paragraph, such as a processing aid, or	The Model Food Provisions expand on the definition of 'food' to include: substances or things that are live, raw, prepared or partly prepared (which may include live animals and plants) substances used in preparing substances or things used, or represented as being for use, for human consumption, such as a processing aid chewing gum and any ingredients and additives in chewing gum and substances used in preparing chewing gum any substances or thing declared to be a food under the *ANZFA Act 1991* (now the *FSANZ Act 1991*)

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
		chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum, or any substance or thing declared to be a food under a declaration in force under section 3B of the *Australia New Zealand Food* *AuthorityAct1991* of the Commonwealth [and prescribed by the regulations for the purposes of this paragraph], whether or not the substance, thing or chewing gum is in a condition fit for human consumption. (2) However, *food* does not include a therapeutic good within the meaning of the *Therapeutic Goods Act 1989* of the Commonwealth. (3) To avoid doubt, *food* may include live animals and plants. Clause 3	
Unsafe food	Not defined. However, *IFC Act 1992* includes a definition for 'failing food'. *failing food* means examinable food, that: as a result of an inspection, or inspection and analysis, under the Food Inspection Scheme, is found to be: food that does not meet the applicable standards for that food; or food that poses a risk to human health; or	For the purposes of this Act, food is *unsafe* at a particular time if it would be likely to cause physical harm to a person who might later consume it, assuming: it was, after that particular time and before being consumed by the person, properly subjected to all processes (if any) that are relevant to its reasonable intended use, and nothing happened to it after that particular time and before being consumed by the	The main differences are: imported food is only considered unsafe if it has been examined and meets the definition of a 'failing food' – under the Model Food Provisions, it is an offence to sell unsafe food at any time definition of 'failing food' includes food safety and suitability issues the Model Food Provisions make assumptions that the food has been processed and consumed according to its reasonable

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
	is taken, under the provisions of the Scheme, to be such food. Clause 3 Interpretation It also expands on the circumstances where food poses a risk to human health under clause (2), as below. (2) For the purposes of this Act, food poses a risk to human health if: it contains: pathogenic micro-organisms or their toxins; or micro-organisms indicating poor handling; or non-approved chemicals or chemical residues; or approved chemicals, or chemical residues, at greater levels than permitted; or non-approved additives; or approved additives at greater levels than permitted; or any other contaminant or constituent that may be dangerous to human health; or it has been manufactured or transported under conditions which render it dangerous or unfit for human consumption. Clause (3) clarifies that the references to approved chemicals, chemical residues or additives is a reference to these substances being permitted in the Australia New Zealand Food Standards Code (the Code) and that the reference to non-approved chemicals, residues and additives are those	person that would prevent it being used for its reasonable intended use, and it was consumed by the person according to its reasonable intended use. (2) However, food is not unsafe for the purposes of this Act merely because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions only in persons with allergies or sensitivities that are not common to the majority of persons. (3) In subsection (1), *processes* include processes involving storage and preparation. Clause 6	intended use and nothing happened to it to prevent the food being used for its reasonable intended use – for example, raw poultry is cooked before it is eaten, according to the instructions on the label. the Model Food Provisions exclude foods being considered unsafe because they may cause allergic reactions or other reactions in persons due to sensitivities.

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
	not permitted in the Code.		
Unsuitable food	Not defined but elements of unsuitability are included under definition of 'failing food'. These elements are: micro-organisms indicating poor handling; or non-approved chemicals or chemical residues; or approved chemicals, or chemical residues, at greater levels than permitted; or non-approved additives; or approved additives at greater levels than permitted; or it has been manufactured or transported under conditions which render it dangerous or unfit for human consumption.	(1) For the purposes of this Act, food is *unsuitable* if it is food that: (a) is damaged, deteriorated or perished to an extent that affects its reasonable intended use, or (b) contains any damaged, deteriorated or perished substance that affects its reasonable intended use, or (c) is the product of a diseased animal, or an animal that has died otherwise than by slaughter, and has not been declared by or under another Act to be safe for human consumption, or (d) contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food. (2) However, food is not unsuitable for the purposes of this Act merely because: (a) at any particular time before it is sold for human consumption it contains an agricultural or veterinary chemical, or (b) when it is sold for human consumption it contains an agricultural or veterinary chemical, so long as it does not contain the chemical in an amount that contravenes the Food Standards Code, or (c) it contains a metal or non-metal contaminant (within the meaning of the Food Standards Code) in an amount that does not contravene the permitted level for the contaminant as specified in	The Model Food Provisions clarify what can be considered to be 'unfit for human consumption' and does not restrict it to the manufacturing or transporting conditions rendering it unfit. The parts of the definition that relate to food being unfit are food that: is damaged, deteriorated or perished or contains any damaged, deteriorated or perished substances and limits this to circumstances where this affects the reasonable intended use of the food. For example, it may be acceptable to sell broken biscuits for manufacturing purposes contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food (for example metal shavings in a meat pie) is the product of a diseased animal, or an animal that has died otherwise than by slaughter. The Model Food Provisions do not automatically consider food that contains microorganisms indicating poor handling as 'unsuitable food'. To be considered 'unsuitable', the food would need to be deteriorated or perished or exceed microbiological limits specified in the Code for that food.

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
		the Food Standards Code, or (d) it contains any matter or substance that is permitted by the Food Standards Code. (3) In this section, *slaughter* of an animal includes the killing of an animal in the process of capturing, taking or harvesting it for the purposes of preparing it for use as food.	
Food business	A business that imports food is not defined under the IFC Act.	In this Act, *food business* means a business, enterprise or activity (other than a business, enterprise or activity that is primary food production) that involves: (a) the handling of food intended for sale, or the sale of food, (b) regardless of whether the business, enterprise or activity concerned is of a commercial, charitable or community nature or whether it involves the handling or sale of food on one occasion only. Clause 3 *handling* of food includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food (clause 2 Definitions)	In the Model Food Provisions a person must comply with any requirement imposed on the person by a provision of the code in relation to the conduct of a food business or to food intended for sale or food for sale. In the Code, there are specific obligations placed on food businesses in Chapter 3, relating to notifying particulars about the business to the relevant enforcement agency, food safety practices and food premises and equipment. The IFIS, set out in the regulations to the IFC Act, regulates the food that is imported. Persons who import food regulated under the Scheme must comply with the requirements on the food.
Key offences			
Offence to sell food that is unsafe	8 Importation offence A person must not import into Australia	Division 1 Serious offences relating to food 9 Handling of food in unsafe manner	In the IFC Act, it is an offence for a person to knowingly import food that poses a risk to human health. Similarly in the Model Food

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
	food to which this Act applies that the person knows: does not meet applicable standards; or poses a risk to human health. Penalty: Imprisonment for 10 years. (1A) Paragraph (1)(a) does not apply to applicable standards relating to information on labels for packages containing food. (2) For the purposes of establishing a contravention of subsection (1), if, having regard to: a person's abilities, experience, qualifications and other attributes; and all the circumstances surrounding the alleged contravention of that subsection; the person ought reasonably to have known that the food did not meet applicable standards or posed a risk to human health, the person is taken to have known that the food did not meet those standards or posed that risk.	A person must not handle food intended for sale in a manner that the person knows will render, or is likely to render, the food unsafe. Maximum penalty: $100,000 or imprisonment for 2 years, or both, in the case of an individual and $500,000 in the case of a corporation. 10 Sale of unsafe food A person must not sell food that the person knows is unsafe. Maximum penalty: $100,000 or imprisonment for 2 years, or both, in the case of an individual and $500,000 in the case of a corporation. Division 2 Other offences relating to food 12 Handling and sale of unsafe food (1) A person must not handle food intended for sale in a manner that will render, or is likely to render, the food unsafe. Maximum penalty: $50,000 in the case of an individual and $250,000 in the case of a corporation. (2) A person must not sell food that is unsafe. Maximum penalty: $50,000 in the case of an individual and $250,000 in the case of a corporation.	Provisions, it is an offence to knowingly sell food that is unsafe. However, the Model Food Provisions also includes an offence (albeit a lesser offence) for a person to sell food that is unsafe. For this lesser offence, proof that the person knew the food was unsafe is not required. The Model Food Provisions also includes additional offences related to handling food in a manner that will render, or is likely to render, the food unsafe. There is a more serious offence if a person knowingly does this.
Offence to sell food that is unsuitable	There is no offence for a person to import food that is unsuitable but some elements are included under the offence above to knowingly import food that does not meet	13 Handling and sale of unsuitable food A person must not handle food intended for sale in a manner that will render, or is	Under the IFC, it is an offence for a person to knowingly import food that is non-compliant with the Code. However, there is no offence to knowingly import food for other elements of

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
	applicable standards. Food referred for inspection under the IFIS, is considered 'failing food' if it does not comply with the Code or is considered unfit for human consumption (see definition of 'failing food' above).	likely to render, the food unsuitable. Maximum penalty: $40,000 in the case of an individual and $200,000 in the case of a corporation. A person must not sell food that is unsuitable. Maximum penalty: $40,000 in the case of an individual and $200,000 in the case of a corporation. For the purposes of this section, it is immaterial whether the food concerned is safe.	unsuitability such as food that is damaged, deteriorated or perished. However, such food could be failed at the border, if referred for inspection. In the Model Food Provisions, the offence to sell unsuitable food does not require proof that the person knows that the food is unsuitable. There is also an offence to handle food in a manner that will render, or is likely to render, the food unsuitable. For example, storing perishable foods at incorrect temperatures.
Other offences	The IFC has a separate offence related to food labelling, as it is exempted from the importation offence discussed above. The labelling offence is dealt with separately to allow a person to import food that does not meet the labelling requirements in the Code, provided the food is correctly labelled when it arrives in the country.	The Model Food Provisions has additional offences for: False descriptions of food Misleading conduct relating to sale of food Sale of food not complying with the purchaser's demand Sale of unfit equipment or packaging or labelling material Compliance with the Code.	The Model Food Provisions have more offences than the IFC Act. It may be appropriate to include some of these in the IFC Act, particularly those that relate to false and misleading descriptions and sale of food.
Emergency powers			
Powers to restrict the importation or sale of food	15 Holding orders for certain food If: an inspection, or inspection and analysis, of examinable food of a particular kind indicates the food, or a part of the food, to be failing food; or the Secretary is satisfied that there are reasonable grounds for believing that food	26 Making of order An order may be made under this Part by the relevant authority if the relevant authority has reasonable grounds to believe that the making of the order is necessary to prevent or reduce the possibility of a serious danger to public health or to mitigate the adverse	Under the *IFC Act 1992* a holding order, preventing the importation of a food, can be made if the food fails an inspection or analysis or there are reasonable grounds to believe a food would fail an inspection or analysis. This restricts a holding order to a hazard in a food that can be detected via inspection or analysis. However, an imported food may be associated with illness and the hazard is not known

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
	of a particular kind would, on inspection, or inspection and analysis, be so identified; the Secretary may, by writing, make a holding order: stating that, until the revocation of the order, food of that kind that is imported into Australia after the making of the order must be held in a place to be approved by an authorised officer, until an inspection, or inspection and analysis, required under the Food Inspection Scheme, has been completed; and specifying the circumstances in which the order will be revoked. If the Secretary is satisfied, in respect of a holding order, that the circumstances specified for its revocation have occurred, the Secretary must, by writing, immediately revoke the holding order. Making an order Clause 16 of the *IFC Act 1992* allows regulations to set out particulars of a food inspection scheme for imported food. The Act also specifies what regulations can be set out under the Scheme. This includes the power for the Minister to make orders identifying the food that is required to be inspected and analysed under the scheme and the rate of such inspection. However,	consequences of a serious danger to public health. 27 Nature of order (1) An order under this Part may do any one or more of the following: require the publication of warnings, in a form approved by the relevant authority, that a particular food or type of food is unsafe, prohibit the cultivation, taking, harvesting or obtaining, from a specified area, of a particular food or type of food or other primary produce intended to be used for human consumption, prohibit a particular food or type of food from being advertised or sold, direct that a particular food or type of food consigned or distributed for sale or sold be recalled and specify the manner in which, and the period within which, there call is to be conducted, direct that a particular food or type of food or other primary produce intended to be used for human consumption be impounded, isolated, destroyed or otherwise disposed of and specify the manner in which the impounding, isolation, destruction or disposal is to be conducted, prohibit absolutely the carrying on of an activity in relation to a particular food or type of food, or permit the carrying on of the activity in accordance with conditions specified in the order,without limiting the	and/or cannot be easily detected in the food. In response to intelligence that imported food may pose a potential medium to high risk, the department could, on the advice of FSANZ, classify the food as a 'risk food', which means it would be referred under the IFIS at a 100 per cent rate until compliance is established. Under the Model Food Provisions, food can be prevented from being advertised, sold, cultivated or harvested if there are reasonable grounds to believe such restrictions are necessary to prevent or reduce the possibility of a serious danger to public health. While the powers under the Model Food Provisions are not restricted to a food that has failed, or would fail, an inspection or analysis, they are limited to food safety. The *IFC Act 1992* can restrict the importation of food for non-safety reasons under the definition of a 'failing food'. For example, a non-safety related breach of the Code.

	Imported Food Control Act 1992	Model Food Provisions (Annex A)	Differences
	the Minister must not make or vary an order under clause 16 unless the Minister has first consulted with FSANZ. Under the regulations, food may be considered 'risk food', if FSANZ advises the Minister that the food has the potential to pose a high or medium risk to public health. This means foods of potential food safety concerns can, on the advice of FSANZ, be classified by the Minister as risk foods and thereby referred for inspection at a rate of 100 per cent until compliance is established.	generality of paragraph (f), impose conditions relating to the taking and analysis of samples of the food or of water or soil or any other thing that is part of the environment in which that activity is carried on in relation to the food, specify methods of analysis (not inconsistent with any methods prescribed by the Food Standards Code) of any samples required to be taken in accordance with the order.	

Appendix E: Prescribed foods analysis of trade implications

Methodology and limitations

The analysis within the document reviews import data of prescribed foods and the country and associated volume of the imports. The following analysis is based upon information recorded in the ICS managed by the Department of Immigration and Border Protection. The ICS is a software system into which all goods imported to or exported from Australia must be reported.

Imported food data was collected from the ICS for a three year period from 01 March 2013 to 29 February 2016. This three year period was used to reduce data anomalies which may appear due to seasonal demands or fluctuations (e.g. poor yields due to environmental factors).

Tariff codes were used to search the ICS to identify countries from which Australia is importing 'prescribed foods'. This worked well when a tariff code matched a food within a 'prescribed food category'. For example, frozen strawberries has its own tariff code and only certain types of frozen strawberry products were out of scope such as pulped, pureed and candied. However, it did not work well when the tariff code contained multiple types of foods and only a subset of these were 'prescribed foods'. For example, fresh snow and sugar snap peas are in a tariff code which includes all fresh peas. In these circumstances, the 'Goods Description' field was used to isolate the relevant food. The 'Goods Description' field is a free text field which is entered by a customs broker. Keywords were included or excluded as necessary to locate relevant foods and improve the quality of the results. However, as it is a free text field, the description entered can be of poor quality (i.e. grammatical errors, imprecise or incorrect entries). Information regarding specific keyword selection criteria used can be found in each section of this document.

While the tariff codes and 'Goods Description' fields assisted with identifying the foods likely to be considered a 'prescribed food', there is no information in the ICS that specifies the intended use of the food. This is important when a food is only considered a 'prescribed food' if it is raw or minimally processed and 'ready-to-eat'. For example, many of the raw nuts being imported are likely to be going for further processing. However, as these nuts could not be separated from those being imported ready-to-eat the results will overestimate the imports of these foods.

Countries which had imported under a total of 10kg of a food category were excluded from the summary as the importation of such small amounts is more likely to be for personal use rather than for commercial sale.

Outcome of analysis

Below, for each category of 'prescribed foods', is summary of the outcome of the analysis conducted to identify the main countries Australia imports 'prescribed food' from. A summary has also been included for the Pacific Island Countries (PICS) due to the economic importance of trade with Australia for these countries.

Ready-to-eat raw or minimally processed produce associated with foodborne disease

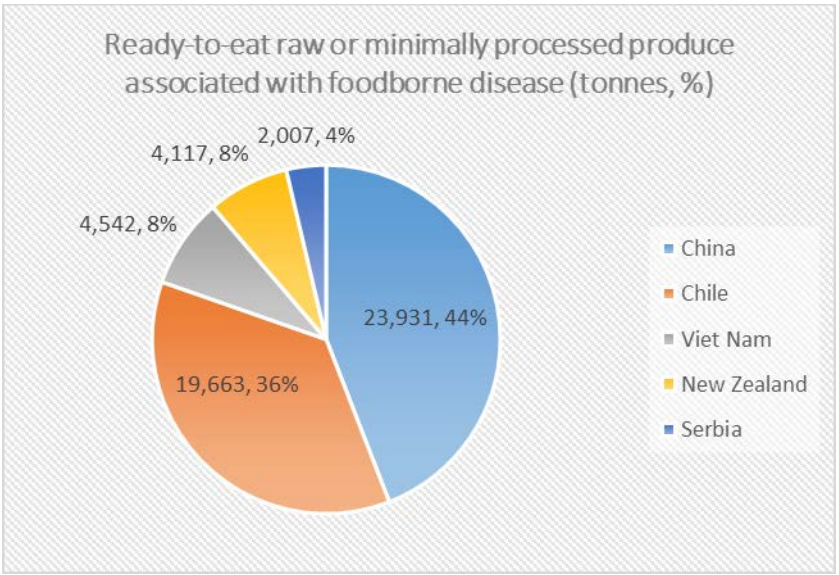
A list of imported ready-to-eat raw or minimally processed produce associated with foodborne disease was identified. This list included fresh and frozen berries, mango, semi-dried tomatoes and snow and sugar snap peas. All countries these foods had been imported from were identified and volumes per tariff and total volume were calculated. The top five countries for total import volume (tonnes) were China (23 931), Chile (19 663), Viet Nam (4 542), New Zealand (4 117) and Serbia (2 007) (see Table E1). Keywords excluded were 'pulp', 'puree', 'smoothie' and 'candied' as such imports are likely to have been subjected to some form of heat treatment.

Table E1 Top five prescribed food groups imported over a three year period, by tonnes

Position	Country	Total (tonnes)	Primary item imported
1	China	23 931	Frozen strawberries
2	Chile	19 663	Frozen berries (excluding strawberries)
3	Viet Nam	4 542	Frozen mango
4	New Zealand	4 117	Fresh berries
5	Serbia	2 007	Frozen berries (excluding strawberries)

Source: ICS data

Figure E1 Top five countries from which ready-to-eat or minimally processed produce is imported over a three year period



Source: ICS data

Ready-to-eat raw or minimally processed nuts

A list of relevant ready-to-eat raw or minimally processed nuts (shelled and unroasted) was identified, which included cashew nuts, Brazil nuts, walnuts, hazelnuts (including filberts), almonds and pistachios. All countries which these foods had been imported from were identified and volumes per tariff and total volume were calculated. The top five countries for total import volume (tonnes) were Viet Nam (4 338), the US (21 165), Turkey (7 911), Bolivia (2 331) and Brazil (1 922) (see Table E2). The country of origin for the majority (59 per cent) of the product was imported from Viet Nam (see Source: ICS data

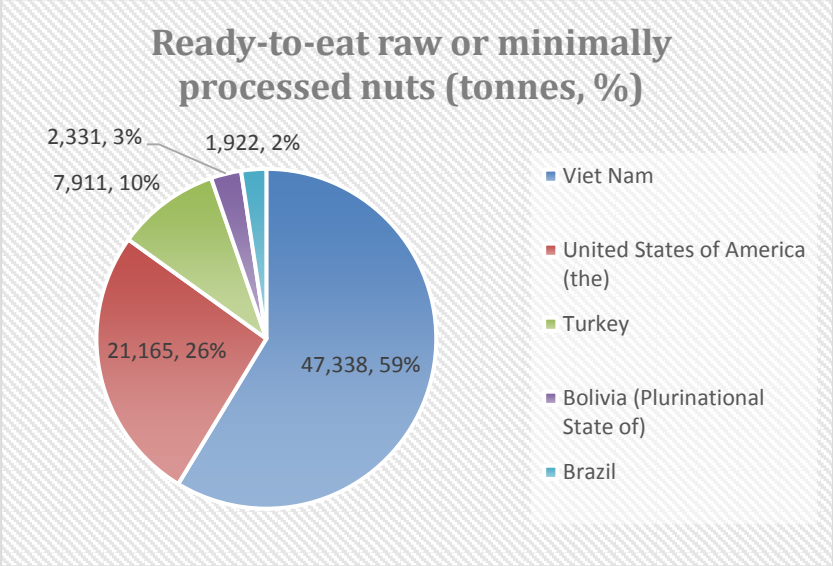
Figure E2). Keywords excluded were 'roast', 'blanch', 'sugar', 'dried' and 'cooked', as these processes are likely to reduce associated risk with this category of foods.

Table E2 Top five countries from which ready-to-eat or minimally processed nuts were imported over a three year period

Position	Country	Total (tonnes)	Primary item imported
1	Viet Nam	47 338	Cashew nuts
2	United States	21 165	Walnuts
3	Turkey	7 911	Hazelnuts (including filberts)
4	Bolivia (Plurinational State of)	2 331	Brazil nuts
5	Brazil	1 922	Brazil nuts

Source: ICS data

Figure E2 Top five countries from which ready-to-eat or minimally processed nuts were imported over a three year period



Source: ICS data

Beef and beef products

Due to biosecurity restrictions to beef and beef products, New Zealand is the only country Australia imports these products within the prescribed foods criteria. Over the three year period 6 078 tonnes of beef and beef products were imported from New Zealand (see Table E3). The primary item imported under this category was frozen meat of bovine animals. A keyword included was 'beef', to isolate all relevant foods, and a word excluded was 'return', to exclude all product being returned to Australia.

Table E3 Top five countries from which beef and beef products are imported over a three year period

Position	Country	Total (tonnes)	Primary item imported
1	New Zealand	6 078	Frozen bovine animal meat

Source: ICS data

Ready-to-eat uncooked meats associated with foodborne disease

Salami, mettwurst, jerky and biltong were identified as relevant ready-to-eat uncooked meats associated with foodborne disease. Of these, Australia is currently only importing biltong from New Zealand (17 tonnes). Cooked jerky is being imported from the US and Denmark but due to the cooking process, is out of scope. No other country imported more than a total of 10kg of the category over the three year period. Keywords included were, 'salami', 'mettwurst', 'jerky' and 'biltong'.

Raw meat and meat products

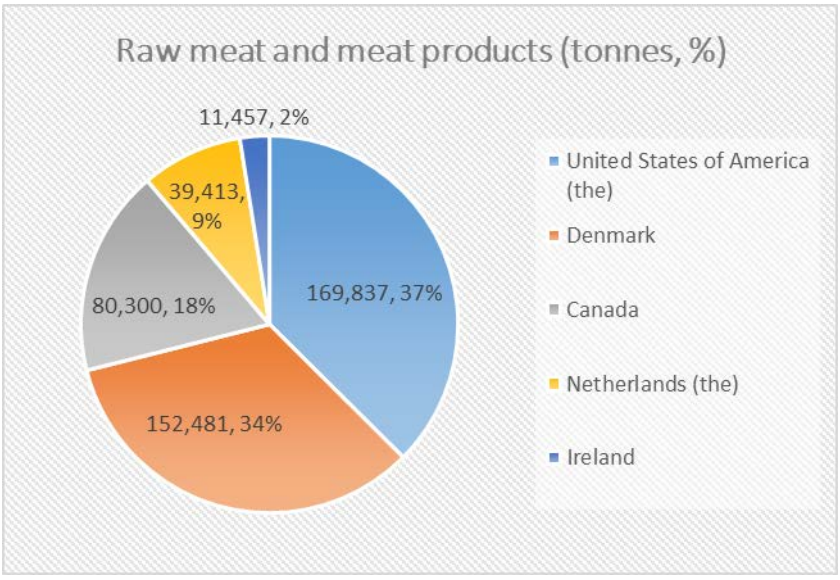
Pork is the only meat currently imported under the prescribed foods 'Raw meat and meat products' category (excluding beef as identified in a separate category above). All countries which these foods had been imported from were identified and volumes per tariff and total volume were calculated. The top 5 countries for total import volume (tonnes) were the US (169 837), Denmark (152 837), Canada (80 300), the Netherlands (39 413) and Ireland (11 457) (see Table E4). Keywords excluded were 'cured', 'salted' and 'terrine', in order to remove foods which had undergone a level of processing which reduced the risk to foods of this category.

Table E4 Top five countries from which raw meat and meat products are imported over a three year period

Position	Country	Total (tonnes)	Primary item imported
1	United States	169 837	Fresh, chilled or frozen swine meat
2	Denmark	152 481	Fresh, chilled or frozen swine meat
3	Canada	80 300	Fresh, chilled or frozen swine meat
4	Netherlands (the)	39 413	Fresh, chilled or frozen swine meat
5	Ireland	11 457	Fresh, chilled or frozen swine meat

Source: ICS data

Figure E3 Top five countries from which raw meat and meat products were imported over a three year period



Source: ICS data

Raw milk cheese

Raw milk cheese can only currently be imported from France under a foreign government certificate, specifically for the Roquefort cheese type. Over the three year period 111 tonnes was imported (see Table E5). The only keyword included was 'Roquefort'.

Table E5 Countries from which raw milk cheese (Roquefort) was imported over a three year period

Position	Country	Total (tonnes)
1	France	111

Source: ICS data

Ready-to-eat raw or minimally processed bivalve molluscs

A list of ready-to-eat raw or minimally processed bivalve molluscs was created using the prescribed foods criteria, which included oysters, clams, cockles, mussels, pipi and scallops. All countries which these foods had been imported from were identified and volumes per tariff and total volume were calculated. The top 5 countries for total import volume (tonnes) were New Zealand (7 135), China (4 404), Japan (970), Chile (775) and Peru (688) (see Table E6**Error! Reference source not found.**).

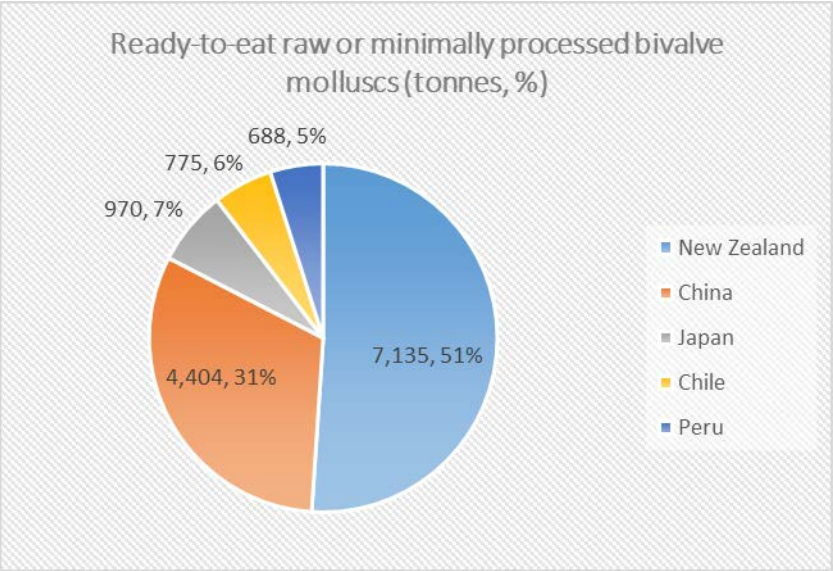
Keywords included, 'oyster', 'clam', 'cockle', 'mussel', 'pipi' and 'scallop', to isolate relevant food types, and excluded 'dried', 'dry', 'cooked', 'boiled' and 'blanch', to remove foods which have undergone processing. The keyword 'off' was also excluded to remove scallops with the roe removed as it is the part of a scallop most associated with foodborne illness.

Table E6 Top five countries from which ready-to-eat raw or minimally processed bivalve molluscs were imported over a three year period

Position	Country	Total (tonnes)	Primary item imported
1	New Zealand	7 135	Mussels
2	China	4 404	Scallops
3	Japan	970	Scallops
4	Chile	775	Mussels
5	Peru	688	Scallops

Source: ICS data

Figure E4 Top five countries from which ready-to-eat raw or minimally processed bivalve molluscs were imported over a three year period



Source: ICS data

Ready-to-eat minimally processed finfish

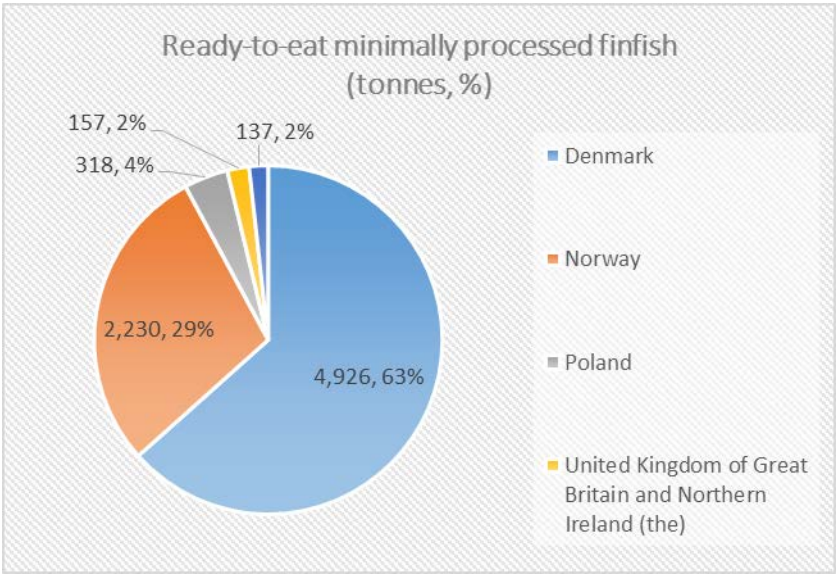
Cold smoked salmon is the only currently imported food under the prescribed food category of ready-to-eat minimally processed finfish. All countries these foods had been imported from were identified and volumes per tariff and total volume were calculated. The top 5 countries for total import volume (tonnes) were Denmark (4 926), Norway (2 230), Poland (318), the United Kingdom of Great Britain and Northern Ireland (157) and New Zealand (137) (see Table E7). Keywords included were 'smoked', 'salmon', to isolate relevant foods, and the only excluded keyword was 'hot', in order to exclude hot smoked salmon which undergoes heat treatment.

Table E7 Top five countries from which ready-to-eat minimally processed finfish were imported over a three year period

Position	Country	Total (tonnes)
1	Denmark	4 926
2	Norway	2 230
3	Poland	318
4	United Kingdom of Great Britain and Northern Ireland (the)	157
5	New Zealand	137

Source: ICS data

Figure E5 Top five countries from which ready-to-eat minimally processed finfish were imported over a three year period



Source: ICS data

Pacific Island Countries

Fiji was identified as the only country within PICS to import foods within the prescribed food categories. Fiji imported a total of 1.4 tonnes in only one of the categories with mussels being the only food imported (see Table E8).

Table E8 Prescribed foods imported by Fiji by volume (tonnes) over the three year period

English short name	Total (tonnes)	Primary item imported
Fiji	1.4	Mussels

Source: ICS data

Glossary

AIMS	Agriculture Import Management System
ANAO	Australian National Audit Office
Approved Arrangement	Voluntary arrangements (previously Quarantine Approved Premises and Compliance Agreements) entered into with the department
BFSN/the network	Bi-National Food Safety Network
BSE	Bovine spongiform encephalopathy - a transmissible and fatal neurodegenerative disease that affects cattle. Variant Creutzfeldt - Jakob disease (vCJD), a rare and fatal human neurodegenerative condition, results from exposure to BSE through eating contaminated beef or beef products.
CFIA	Canadian Food Inspection Agency
Codex Alimentarius	the International Food Standards
CrI	Credible interval - represents a range of values where the most likely estimate might lie using a posterior probability distribution. It may be interpreted similar to confidence intervals (Kirk et al. 2014)
FDA	The Food Drug Administration (United States)
FICA	Food Import Compliance Agreement
Foreign government certification arrangement	A government-to government certification arrangement that the department can enter into with the national competent authority of a country exporting food to Australia. These arrangements provide further assurance that certain food imported into Australia complies with Australia's food safety standards
FSANZ	Food Standards Australia New Zealand
FSMA	Food Safety Modernisation Act (United States)
FSVP	Foreign Supplier Verification Programs (United States)
HACCP	Hazard Analysis Critical Control Point–a management system in which food safety is addressed through the analysis and control of biological, chemical and physical hazards
Holding order	A legal mechanism under the Imported Food Control Act 1992 which ensures that future comparable consignments of a failed food are referred to the department to ensure the reason that the food failed has been rectified
IFC Act 1992	The *Imported Food Control Act 1992*
IFIS	Imported Food Inspection Scheme

ICS	Integrated Cargo System–electronic system for recording movement of goods across Australia's borders
ISFR	Implementation Sub-committee for Food Regulation
NFIRP	National Food Incident Response Protocol
NZ MPI	New Zealand Ministry for Primary Industries
OzFoodNet	Located within the Australian Department of Health, OzFoodNet undertakes surveillance and investigations of foodborne disease in Australia in conjunction with the states and territories
PICS	Pacific Island Countries
Prescribed Foods	Foods that require a higher level of food safety assurance to be demonstrated at the border due to their potential public health and safety risk. Border testing alone is insufficient to provide this assurance
RBM	Regulatory Burden Measure–a tool developed by the Australian government to calculate the compliance costs of regulatory proposals
RIS	Regulation Impact Statement
Risk Food	Initially referred for inspection and testing at a rate of 100 per cent against a published list of potential hazards (specific to the food), but is decreased if a history of compliance is established
Supply chain assurance	Assurance that the food safety hazards of a food have been controlled throughout its production
Surveillance food	Assurance that the food safety hazards of a food have been controlled throughout its production
Traceability	The ability to trace food along the supply chain from suppliers through to customers (i.e. tracing both forward and backwards)
TTMRA	Trans-Tasman Mutual Recognition Arrangement – is a non-treaty agreement between the Australian government, state and territory governments and the government of New Zealand to remove regulatory barriers to the movement of goods and services providers between Australia and New Zealand
USDA	United States Department of Agriculture
WTO	World Trade Organization

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