Imported food risk assessment

How FSANZ assesses food safety risks from imported foods

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About this document

This document describes how Food Standards Australia New Zealand (FSANZ) assesses food safety risks in foods imported into Australia. It also outlines how FSANZ works closely with the Australian Government Department of Agriculture and Water Resources to enhance the safety of imported foods. Food imported into New Zealand is considered via a separate process.

This is a living document. Minor amendments, updates and additions will be made from time-to-time. This version focusses on the assessment of microbiological hazards. The next version of this document will include specific guidance for the assessment of chemical hazards in imported foods.
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Introduction

The role of Food Standards Australia New Zealand (FSANZ) in relation to imported food is described in the *Food Standards Australia New Zealand Act 1991* as ‘to develop assessment policies in relation to food imported into Australia’. In practical terms, this role is performed by providing risk assessment advice to the Department of Agriculture and Water Resources (DAWR).

For imported foods, risk assessment advice is prepared by reviewing a particular food commodity for potential hazards using a single food:hazard pairing approach, e.g. bivalve molluscs and norovirus. This document details how FSANZ’s risk assessment advice is prepared. It includes the types of information and data considered, and the methodology used to determine the level of risk.

Imported food legislation

All food imported into Australia must first meet Australia’s biosecurity requirements (under the *Biosecurity Act 2015*) and is then subject to the requirements of the *Imported Food Control Act 1992* (the Act). Under the Act, DAWR is responsible for ensuring food imported into Australia complies with the Australia New Zealand Food Standards Code and the requirements of public health and safety. The Act also establishes the Imported Food Inspection Scheme (IFIS) as a risk-based mechanism for inspection and control applied to imported food. The *Imported Food Control Regulations 1993* (the Regulations) describe the classification of foods (these may be: risk, compliance agreement or surveillance foods), rates of inspection and other management measures that may be applied. Under the Regulations, the Minister for Agriculture and Water Resources may only classify food as ‘risk food’ when advised by FSANZ that the food has the potential to pose a high or medium risk to public health. The *Imported Food Control Order 2001* lists those commodities that are considered ‘risk food’ and are required to be inspected, or inspected and analysed, under the IFIS as risk food.

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Risk analysis

Risk analysis is an internationally accepted process for assessing, managing and communicating risk. The Codex Alimentarius Commission (Codex) risk analysis framework sets out an approach for evaluating the potential risk associated with food-related hazards, and for assessing ways to manage any identified risk. It separates the scientific process of risk assessment from the broad range of factors that affect risk management decisions. It also takes into account the need for communication between those involved in risk analysis as well as communication with stakeholders, such as consumers, public health professionals and government agencies, including enforcement agencies. The Codex risk analysis process is comprised of three interrelated components: risk assessment, risk management and risk communication (FSANZ 2013). Refer to Figure 1.

Figure 1: Codex risk analysis framework (FSANZ 2013)

The FSANZ document Risk analysis in food regulation provides a broad overview of how FSANZ uses risk analysis for standards development work and managing other food-related health risks in the domestic food supply. A similar approach is employed for imported foods with FSANZ undertaking the risk assessment component and DAWR undertaking risk management. Risk communication is a joint responsibility and is conducted throughout the process. The roles of FSANZ and DAWR are formalised in the imported food Schedule to the Memorandum of Understanding between DAWR and the Department of Health.

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Assessing risk in imported foods

The concept of risk analysis recognises that a risk assessment can take a variety of forms depending upon the end purpose and the availability of relevant information.

Importantly though, a risk assessment, regardless of the format used, provides risk managers with a rational and objective picture of what is known about food safety risks associated with a food at a particular point in time. There is no one size fits all approach as the assessment depends on the questions to be answered. For example, the risk manager may ask ‘what is the risk of illness from consumption of a particular food?’ which is quite a different question to ‘what are the types and effectiveness of particular interventions on reducing risk of illness from a food?’. The risk assessment response will depend upon the extent and quality of data available, as well as resources and timeframes.

Codex describes three approaches typically employed for risk assessment: estimating an unrestricted or baseline risk, comparing risk intervention strategies and research-related studies or models. An ‘unrestricted risk’ estimate is the level of risk that would be present if there were no safeguards, or no additional safeguards, in place and is most widely used in import risk analysis (FAO/WHO 2009).

Unrestricted risk can also be referred to as inherent risk. That is, the current level of risk that applies to the food if no deliberate actions are taken to control the risk. For imported foods, this refers to the inherent risk of the food when it arrives at the border and would incorporate any risks and controls associated with the manufacture and supply of the food in the exporting country. However, often this information may be unknown for foods produced in other countries.

The concept of unrestricted risk is also used to assess the biosecurity risks in Australia’s animal and animal product import-risk analysis methodology. For the biosecurity assessment, the risk evaluation follows a semi-quantitative approach using a table format that considers the likelihood and impact of an exotic disease entry. Further information on Australia’s biosecurity import risk analysis process can be found on the DAWR website11.

FSANZ provides risk assessment advice on imported foods to DAWR in the form of a risk statement (see below). The purpose of the risk statement is to determine whether the inherent risk of a single food:hazard pair presents a potential high or medium risk to public health. Whilst the evaluation follows internationally agreed approaches and uses international data, Australian food consumption data12 is used to determine the level of exposure. Once DAWR receives FSANZ advice it may then apply appropriate risk management controls.

12 Food consumption data used by FSANZ in dietary exposure assessments http://www.foodstandards.gov.au/science/exposure/Pages/foodconsumptiondatau4440.aspx
DAWR’s risk management role

Under imported food legislation, food that has been assessed by FSANZ as posing a potential high or medium risk to public health can be classified by the Minister for Agriculture and Water Resources as a risk food and can then be subject to more stringent border controls. One hundred percent of risk classified food is initially referred for inspection and analysis at the border. This inspection rate reduces when a history of compliance is established. DAWR determines appropriate risk management measures for risk food. These measures include border verification testing for identified hazards of concern. Foreign government certification may also be required where government oversight is needed in the exporting country to assure the safety of the food.

Imported food that is assessed as not posing a potential high or medium risk to public health is classified as a surveillance food, under imported food legislation. Five percent of surveillance food is randomly selected for border inspection and analysis to verify compliance with the Australia New Zealand Food Standards Code and its safety. The inspection includes a visual check and label assessment. Samples may also be taken for analyses against a range of microbiological and chemical hazards.

DAWR, through recent and future legislative changes, will also soon have the ability to require certain foods to be covered by a recognised food safety management certificate. These foods will be listed in imported food legislation and will include foods where additional assurances are needed about how the safety of the food has been managed, during its production. This requirement can be met by the importer providing documentary evidence that the overseas producer of the food is operating under an internationally recognised food safety certification scheme.

Risk statement

Purpose

Codex, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have produced guidelines on undertaking risk assessments. These texts establish that the purpose of risk assessment is to meet the needs of risk managers. For an imported food risk assessment, the risk managers (DAWR) need to determine whether food is classified as risk food or another category according to the Imported Food Control Act. ‘Risk food’ is defined as posing a potentially high or medium risk to public health.

FSANZ’s approach to how it undertakes these risk assessment has evolved over time. FSANZ has developed a style of written risk assessment called an Imported Food Risk Statement. The scope of the risk statements are determined jointly between DAWR and FSANZ at the beginning of the assessment process. The risk statements contain a concise summary of information to advise on the level of risk of a specified food for a specified hazard. In addition to determining key risk factors, the statements also address additional

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15 WHO publications on chemical risks http://www.who.int/foodsafety/publications/chemical-risks/en/
overarching questions such as: ‘what controls are in place?’, ‘where in the food chain could controls/steps be taken to manage the risk?’ and ‘who is responsible for implementing these controls?’.

**Approach**

The Codex risk assessment framework considers four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation (refer to Figure 2).

Hazard identification identifies the hazard capable of causing adverse health effects which may be present in a particular food, and describes the characteristics of that hazard. Hazard characterisation is the evaluation of the nature of the adverse health effects associated with the hazard and if there is a dose-response relationship. The exposure assessment estimates the likely intake of the hazard. Risk characterisation, the last step in risk assessment, seeks to combine information from the hazard and exposure assessments to generate a risk estimate. The term ‘risk’ in relation to food relates to the likelihood and severity of an adverse health effect from exposure to a hazard (FSANZ 2013).

![Figure 2: The four key steps in risk assessment (FSANZ 2013)](image)

FSANZ’s risk statements describe the nature of the hazards, epidemiological data and other information to determine whether hazards are likely to pose a potentially high or medium risk to public health, and to identify where in the supply chain controls may exist or be applied.
Variability and uncertainty

Generally, information on hazards and the adverse health effects resulting from that hazard are well documented. However, not everything is known in all circumstances and variability and uncertainties also need to be considered. This is particularly relevant when information is related to conditions occurring in other countries. For example, limited published information may exist on the prevalence and levels of the hazard in the food of concern, how that food is grown and manufactured and the controls that may be in place along the production chain in the country, or countries, being considered. In some cases there may be no data available.

Variability refers to the differences in values of a particular property of a population, where the population can refer to people, units of food, or species of foodborne pathogen. Some examples of variable factors that may influence the assessment include: concentration of a chemical analyte in a food, toxicological endpoints, differences in virulence between bacterial/virus strains, susceptibility across sub-populations and product handling processes between different producers (FAO/WHO 2009; FSANZ 2013).

Uncertainty is the lack of perfect knowledge (i.e. data) to define the true value of a parameter. Uncertainty can be reduced (though never completely eliminated) through additional and more accurate data. An understanding of uncertainty is important because it provides insight into how lack of knowledge can influence decisions. In a risk assessment, uncertainty is commonly dealt with by making conservative assumptions. It is important that the level and nature of uncertainty, and any assumptions are described in the risk assessment (FAO/WHO 2009; FSANZ 2013). In terms of imported food risk assessments, uncertainty can exist due to limited or absence of data, e.g. infectivity, prevalence data, or limited knowledge on production methods used in different countries.
Chapter 1: Microbiological hazards

Examples of microbiological hazards include bacteria, bacterial toxins, viruses and parasites. Depending on the strain, bacteria cause illness either via infection, intoxication, or infection-intoxication. In the case of intoxication, some bacterial strains produce toxins in the food and it is consumption of the pre-formed toxin that causes illness. Other strains first infect and colonise the host and then produce toxins inside the host (i.e. infection-intoxication). Unlike bacteria, viruses need to enter living host cells in order to be able to multiply. Although viruses cannot replicate in food, many viruses can persist in food for varying times, some up to several months. Parasites are also able to multiply in host cells. Depending on the parasite, humans may be part of the ongoing parasitic life cycle or may be an end point of infection (Codex 2012; FSANZ 2017).

There are some unique complexities associated with assessing microbiological risks in food that don’t apply to chemicals. For example, the distribution of bacteria in a food may not be homogenous because of clumping and aggregation, or the concentration of bacteria in a food can change as a result of growth or death. Furthermore, infection through secondary transmission (via person-to-person contact instead of directly through food) may be important for certain pathogens and confound the assessment of food vehicles. Finally, there is the possibility that some consumers may be asymptomatic or develop immunity to some pathogenic microorganisms.

Consequently, slightly different approaches to assessing risk have been adopted for assessing microbiological versus chemical hazards in imported foods.

The assessment of microbiological food safety risks in imported food follows a semi-qualitative approach using a table format to estimate risk that is consistent with the approach taken in Australia’s Biosecurity Import Risk Analysis process.

Risk characterisation matrix

For microbiological assessments a three-tier risk characterisation matrix is used to generate a risk characterisation estimate of low, medium or high.

FSANZ uses four key steps in risk assessment: hazard identification, hazard characterisation, exposure assessment and risk characterisation. The risk characterisation matrix considers the impact of a hazard (hazard identification and characterisation combined) and an assessment of the likelihood of exposure to the hazard (exposure assessment) to provide an estimation of risk (risk characterisation). The inputs for the variables are determined using slightly different approaches due to the different data and information requirements.
Hazard impact assessment

The hazard impact assessment considers the effects of exposure to a hazard on an individual. The assessment takes into account the infectivity, i.e. the dose likely to cause illness (Table 1), and the severity of the consequences of that illness (Table 2). The results of these two components are then applied in a matrix and expressed as a hazard impact score (Table 3).

In the absence of data on the level of infectivity a determination using the inputs from Table 1 may not be possible. Instead other descriptive information may be used to inform the hazard impact score and the level of uncertainty taken into account. For example, descriptive terminology can be used such as a higher viral load is associated with infection. If comparisons can be drawn between the microorganism of interest and a microorganism of known infectivity, this can assist the determination. There can be a high degree of uncertainty with this type of estimate which should be documented in the risk assessment, and estimates should be on the conservative side. This may be the case for emerging foodborne pathogens or pathogens not typically associated with foodborne exposure where infectivity data may not be available. The absence of data on foodborne infectivity does not however preclude the progression of the risk assessment as other factors influence the level of impact and ultimately the risk characterisation, including severity and exposure.

Dose response models may be either an infection or an illness endpoint model depending on the organism or model used. Dose response is represented as a probability (expressed as either the proportion of a population that become infected or the proportion of a population that become ill after exposure to a specific quantity of the pathogen). Microorganisms may produce a variety of effects in the host ranging from no effect (asymptomatic), to acute illness and sometimes even death. This depends on the virulence of the microorganism and the susceptibility of the host. Thus instead of a single dose response relationship there may be a range of dose responses that describe the relationship between the various biological effects and the magnitude of the dose, depending on host susceptibility. For new, or less well understood microbiological hazards, establishing a dose response relationship may be difficult as little data may be available.

For the purposes of the hazard impact assessment it is assumed that infection results in illness. Different outcomes amongst different individuals may be caused by a variety of factors including, but not limited to, strain specific virulence, dose and viability of microorganisms consumed, and age-related susceptibility or immune status.

Consideration of the food matrix and target population (i.e. susceptibility of the consumer) may also be required when considering the severity of an illness. For example, the severity of illness from *Listeria monocytogenes* contamination of ready-to-eat meat is more severe in the elderly and other vulnerable populations than in normal healthy adults.

The categories and descriptors used in Tables 1 and 2 have been developed based on published data, elements of Risk Ranger (Ross and Sumner 2002; Sumner and Ross 2002) and ICMSF (ICMSF 2002), combined with expert elicitation and information from epidemiological investigations.
### Table 1: Microbiological infectivity

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Highly infectious. Very small quantities likely to cause infection. Very low infective doses (generally &lt; 10 infectious units, but could be as few as 1 infectious unit).</td>
</tr>
<tr>
<td>Medium</td>
<td>Very infectious. Small quantities likely to cause infection. For example, illness generally associated with consumption of between 10-100 infectious units for most of the population.</td>
</tr>
<tr>
<td>Low</td>
<td>Moderately infectious. Large quantities ($10^2 – 10^4$ infectious units) likely to cause infection, or growth of organism to large numbers ($10^2 – 10^4$ infectious particles) required to produce sufficient toxin to cause illness.</td>
</tr>
<tr>
<td>Very Low</td>
<td>Mildly infectious. Very large quantities (i.e. $10^5 – 10^6$ infectious units) likely to cause infection, or growth of organism to very large numbers (&gt;10^5 infectious particles) required to produce sufficient toxin to cause illness.</td>
</tr>
</tbody>
</table>

### Table 2: Disease severity

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe</td>
<td>Potentially life threatening, illness of long duration or with substantial chronic sequelae. Requires medical intervention and/or hospitalisation.</td>
</tr>
<tr>
<td>Serious</td>
<td>Incapacitating and rarely life threatening, illness of moderate duration, with or without sequelae. Often requires medical intervention and/or hospitalisation.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Incapacitating but not life threatening, illness of moderate duration and sequelae infrequent. Medical intervention not usually required.</td>
</tr>
<tr>
<td>Mild</td>
<td>Self-limiting symptoms that may cause severe discomfort but not life threatening, illness of short duration with no sequelae. Patient rarely seeks medical intervention.</td>
</tr>
</tbody>
</table>
Table 3: Hazard impact matrix

<table>
<thead>
<tr>
<th>Infectivity</th>
<th>Mild Impact</th>
<th>Moderate Impact</th>
<th>Serious Impact</th>
<th>Severe Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
<tr>
<td>Medium</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
</tr>
<tr>
<td>Low</td>
<td>Very Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Very low</td>
<td>Very Low</td>
<td>Very Low</td>
<td>Low</td>
<td>Medium</td>
</tr>
</tbody>
</table>

The output of the hazard impact matrix (Table 3) is entered into the risk characterisation matrix (Table 5).

Exposure assessment

The exposure module can be the most complex component of a risk assessment. It considers a range of data and information in order to estimate the likelihood that a person (or population) will be exposed to a hazard and the number of microbial cells (dose) likely to be consumed. Assessing exposure to microbiological hazards is quite complex because it needs to take into account that pathogens may be introduced, grow, die or survive (without death but able to grow later) in the food throughout the food production chain.

Qualitative exposure assessments can be used when there is insufficient quantitative data available or where information may be unknown or missing. Descriptive or general terms, such as ‘low’, ‘medium’ or ‘high’, are assigned as ratings for factors such as pathogen levels, amount of food consumed, extent of growth or the effects of manufacturing. When using a qualitative approach it is important that specific definitions of the assigned ranges for each rating are clearly described and justified to avoid misinterpretation (FAO/WHO 2008).

Various factors need to be considered to estimate exposure including frequency and level of contamination of the food, food consumption patterns, characteristics of the pathogen, and the impact of the food matrix and the processing and handling on the pathogen, as well as the possibility that the food may become re-contaminated. The likelihood of consumption of the food by susceptible populations should also be taken into account.

The exposure assessment for imported foods considers five likelihood categories ranging from very high to very low (Table 4). Within each category, graded descriptors allow a determination of the type and level of evidence required to allocate a likelihood estimate.
These descriptors are based on:

- evidence that supports the hazard has caused foodborne illness
- evidence that supports the hazard is present in the food and at levels sufficient to cause illness
- evidence that supports the food is consumed
- effects of food processing on the hazard (increase, reduce, no effect)
- post-processing contamination
- whether the characteristics of the food will support the growth of any contaminating pathogen.

The graded descriptors are assessed together as a collective and are not weighted. Using Table 4, the relevant level of likelihood for each attribute is assessed. This allows an overall estimate of likelihood of exposure to be determined, which can then be entered into the risk characterisation matrix (Table 5).

Information and data are drawn from published literature including prevalence and incidence surveys, epidemiological and foodborne illness reports, food consumption and production data, other risk assessments and published information. Additional uncertainty may exist in exposure assessments due to limited available data such as prevalence data in the food in the originating country, or limited knowledge on production methods used in different countries. Any uncertainty should be documented in the risk assessment along with the evidence used and any assumptions made.
Table 4: Likelihood of exposure to microbiological hazards

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Very high likelihood</th>
<th>High likelihood</th>
<th>Medium likelihood</th>
<th>Low likelihood</th>
<th>Very low likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence that the hazard has caused foodborne illness associated with the food</td>
<td>Very strong evidence</td>
<td>Strong evidence</td>
<td>Some evidence</td>
<td>Limited evidence</td>
<td>No outbreaks reported</td>
</tr>
<tr>
<td>Evidence demonstrating the presence of the hazard in the food</td>
<td>Very strong evidence</td>
<td>Strong evidence</td>
<td>Some evidence</td>
<td>Limited evidence</td>
<td>Hazard not detected in food</td>
</tr>
<tr>
<td>Effect of processing on level of hazard in the food</td>
<td>No pathogen elimination step, processing method likely to introduce contamination</td>
<td>No pathogen elimination step, processing method likely to introduce contamination</td>
<td>No effect</td>
<td>Processing method is likely to reduce but not eliminate contamination</td>
<td>Effective pathogen elimination/inactivation step</td>
</tr>
<tr>
<td>Food supports the growth of contaminating organism</td>
<td>Yes</td>
<td>Some growth</td>
<td>Possible/limited growth</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Potential for post-processing contamination</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Limited</td>
<td>No</td>
</tr>
</tbody>
</table>
Estimating risk

The risk characterisation matrix combines the hazard impact assessment (Table 3) and the exposure assessment (Table 4) to provide an estimation of risk (Table 5).

The risk characterisation matrix (Table 5) uses a table format with a five-by-five matrix which reflects a similar matrix used by DAWR for biosecurity import risk analyses and is described in FAO/WHO guidelines. This type of matrix approach has also been adopted in previous FSANZ risk assessments such as the risk assessments undertaken for seafood\textsuperscript{17} and raw milk products\textsuperscript{18}.

Table 5: Risk characterisation matrix

<table>
<thead>
<tr>
<th>Impact</th>
<th>Very low Likelihood</th>
<th>Low Likelihood</th>
<th>Medium Likelihood</th>
<th>High Likelihood</th>
<th>Very High Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High Impact</td>
<td>Medium Risk</td>
<td>High Risk</td>
<td>High Risk</td>
<td>High Risk</td>
<td>High Risk</td>
</tr>
<tr>
<td>High Impact</td>
<td>Low Risk</td>
<td>Medium Risk</td>
<td>Medium Risk</td>
<td>High Risk</td>
<td>High Risk</td>
</tr>
<tr>
<td>Medium Impact</td>
<td>Low Risk</td>
<td>Low Risk</td>
<td>Medium Risk</td>
<td>Medium Risk</td>
<td>High Risk</td>
</tr>
<tr>
<td>Low Impact</td>
<td>Low Risk</td>
<td>Low Risk</td>
<td>Low Risk</td>
<td>Medium Risk</td>
<td>Medium Risk</td>
</tr>
<tr>
<td>Very Low Impact</td>
<td>Low Risk</td>
<td>Low Risk</td>
<td>Low Risk</td>
<td>Low Risk</td>
<td>Medium Risk</td>
</tr>
</tbody>
</table>

Conclusion

The approach taken to assess microbiological risks in foods imported into Australia follows a semi-quantitative approach to determine the level of risk in a way that is useful for DAWR to implement any necessary risk management measures at the border. The format and identification of the variables used allows a clear rationale and understanding of the basis for any risk decision. Using a transparent and robust approach also allows the risk assessment to be readily scrutinised, validated and updated when needed or when more data are available.

\textsuperscript{17}Final assessment report for the primary production and processing standards for seafood
\url{http://www.foodstandards.gov.au/code/proposals/documents/P265_Seafood_PPPS_FAR.pdf}

\textsuperscript{18}Microbiological risk assessment of raw goat milk
Recommended reading and useful links

https://www.fda.gov/food/foodborneillnesscontaminants/causesofillnessbadbugbook/

FSANZ (2017) Agents of foodborne illness, Food Standards Australia New Zealand, Canberra

References


