FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Imported food risk assessment

How FSANZ assesses food safety risks from imported foods

September 2022

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, Fisheries and Forestry to enhance the safety of imported foods. Food imported into New Zealand is considered via a separate process.

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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*[1] 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, Fisheries and Forestry (DAFF).

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*[2]) and is then subject to the requirements of the *Imported Food Control Act 1992*[3] (the Act). Under the Act, DAFF is responsible for ensuring food imported into Australia complies with the Australia New Zealand Food Standards Code[4] and the requirements of public health and safety. The Act also establishes the Imported Food Inspection Scheme[5] (IFIS) as a risk-based mechanism for inspection and control applied to imported food. The *Imported Food Control Regulations 2019*[6] (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, Fisheries and Forestry 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 2019*[7] lists those commodities that are considered 'risk food' and are required to be inspected, or inspected and analysed, under the IFIS as risk food.

[1] *Food Standards Australia New Zealand Act 1991* https://www.legislation.gov.au/Series/C2004A04193
[2] *Biosecurity Act 2015* https://www.legislation.gov.au/Series/C2015A00061
[3] *Imported Food Control Act 1992* https://www.legislation.gov.au/Series/C2004A04512
[4] Australia New Zealand Food Standards Code http://www.foodstandards.gov.au/code/Pages/default.aspx
[5] Imported Food Inspection Scheme https://www.awe.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis
[6] *Imported Food Control Regulations 2019* https://www.legislation.gov.au/Details/F2019L01006
[7] *Imported Food Control Order 2019* https://www.legislation.gov.au/Series/F2019L01233

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.

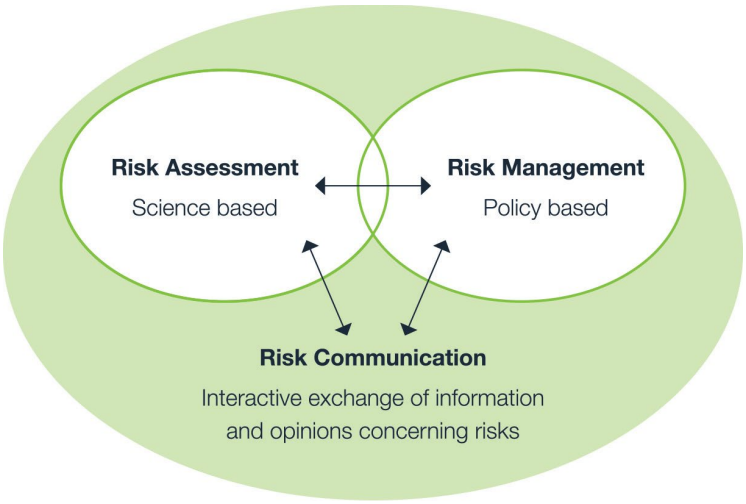

Figure 1: Codex risk analysis framework (FSANZ 2013)

The FSANZ document *Risk analysis in food regulation*[8] 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 DAFF undertaking risk management. Risk communication is a joint responsibility and is conducted throughout the process. The roles of FSANZ and DAFF are formalised in the imported food Annex[9] to the Memorandum of Understanding between DAFF and the Department of Health[10].

[8] Risk analysis in food regulation http://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx
[9] Annex Imported food: An arrangement for coordination of procedures and communication of imported food issues between FSANZ and DAWE https://www.awe.gov.au/biosecurity-trade/policy/partnerships/mou/annex-fsanz-imported-food
[10] Memorandum of Understanding between DAWE and the Department of Health https://www.awe.gov.au/biosecurity-trade/policy/partnerships/mou/mou

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, 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 DAFF website[11].

FSANZ provides risk assessment advice on imported foods to DAFF 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 data[12] is used to determine the level of exposure. Once DAFF receives FSANZ advice it may then apply appropriate risk management controls.

[11] DAFF biosecurity import risk analysis guidelines https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis/guidelines

[12] Food consumption data used by FSANZ in dietary exposure assessments http://www.foodstandards.gov.au/science/exposure/Pages/foodconsumptiondatau4440.aspx

DAFF'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, Fisheries and Forestry 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. DAFF 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.

DAFF also has 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[13,14,15]. 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 (DAFF) need to determine whether food is classified as risk food or another category according to

[13] Codex Principles and guidelines for the conduct of microbiological risk assessment CAC/GL 30-1999 https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B30-1999%252FCXG_030e_2014.pdf

[14] WHO microbiological risk assessment series:
Hazard characterization for pathogens in food and water https://www.who.int/publications/i/item/9241562374;
Exposure assessment of microbiological hazards in food https://www.fao.org/3/A0251e/A0251e00.pdf;
Risk characterization of microbiological hazards in food https://www.fao.org/3/i1134e/i1134e00.pdf

[15] FAO/WHO Principles and methods for the risk assessment of chemicals in food https://inchem.org/documents/ehc/ehc/ehc240_summary.pdf

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 assessments has evolved over time. FSANZ has developed a style of written risk assessment called an Imported Food Risk Statement[16]. The scope of the risk statements is determined jointly between DAFF 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 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).

[16] FSANZ advice on imported food http://www.foodstandards.gov.au/consumer/importedfoods/Pages/FSANZ-advice-on-imported-food.aspx

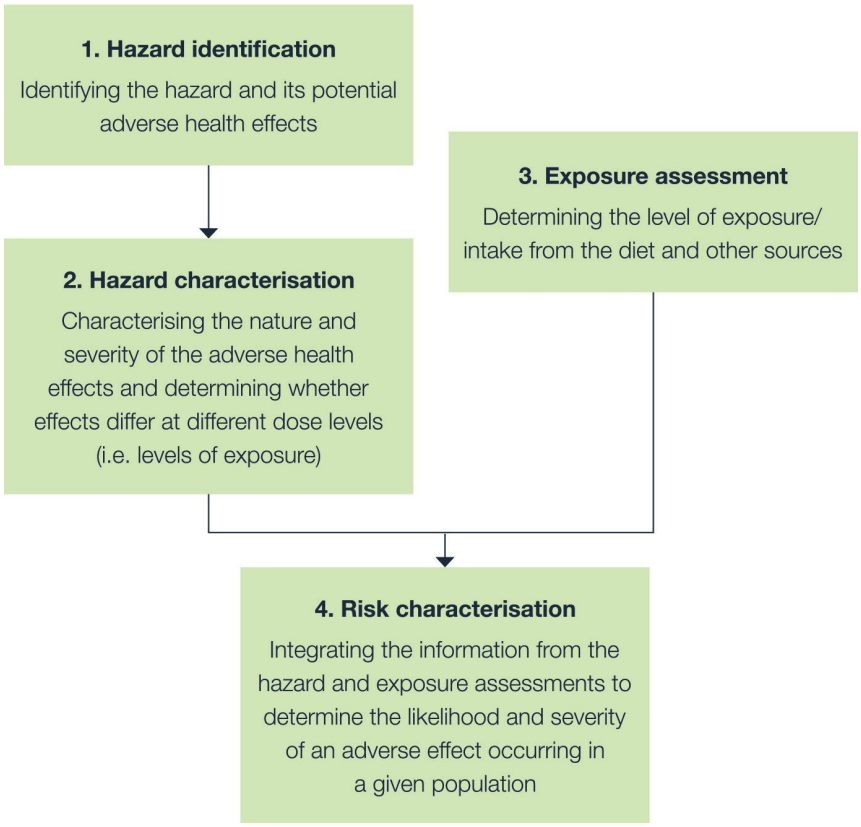

Figure 2: The four key steps in risk assessment (FSANZ 2013)

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 the 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: Chemical hazards

Food is essentially a complex mixture of chemicals. Most of these chemicals have a long history of consumption as a normal part of our diet and do not negatively impact health or safety. While all chemical substances can pose a toxicity risk if consumed in sufficiently large quantities, the toxic potential (toxicity) of the majority of chemicals in food is so low it would be impossible for a typical person to consume enough of the food to cause toxic effects.

However, there are some chemical substances that may be a concern when consumed in food, or if they were to become too abundant in our diets. FSANZ is therefore constantly monitoring and assessing the safety of chemical substances in food to ensure the health and safety of Australian and New Zealand consumers is protected.

Chemical substances in food that may require regulatory intervention take many forms, and may be:

- naturally present in foods (e.g., alcohol, cyanogenic glycosides);
- added intentionally (e.g., preservatives, colours or processing aids); or
- contaminants from the environment, spoilage or processing (e.g., metals, mycotoxins or pesticides).

The following section discusses how FSANZ applies the Codex risk assessment framework to assess chemical substances in imported foods. The methodology uses a quantitative approach when sufficient toxicity information exists, but can be adapted when the requisite safety data are incomplete.

Hazard Identification

Hazard identification for chemical substances involves an examination of the characteristics (including physical and chemical properties, method of manufacture and composition) of both the chemical substance and the associated food. Toxicity studies (in laboratory animals, for example) and relevant human studies, if available, are also considered to determine adverse health effects.

Through their ongoing monitoring activities, FSANZ and DAFF work together to identify food:hazard pairs that involve hazardous chemical substances. Import quantities, emerging trends, national or international recalls data, poisoning case reports, newly available toxicity studies or assessments undertaken by other scientific bodies (such as the Joint FAO/WHO Expert Committee on Food Additives and Contaminants [JECFA]), are all useful to identify potential chemical hazards or risk foods.

The safety of many chemical hazards is already managed through the Food Standards Code by applying various risk management measures such as the setting of maximum limits, which are informed by FSANZ's risk assessment work. Previous FSANZ assessments can guide imported food risk advice to determine if a food:hazard pair should be managed at the Australian border. However, other potential chemical hazards have not undergone the FSANZ risk assessment process, or the specific food:hazard pair is not being managed

already. In the absence of previous assessment work, a newly identified chemical hazard needs to be characterised by FSANZ in the imported food risk statement, using the best available scientific evidence, and in a way that enables DAFF to consider if a risk management response is necessary.

Hazard Characterisation

FSANZ critically considers a broad range of data when characterising a link between a chemical substance, an adverse health effect and a food of interest. In addition to traditional toxicity studies or observational data in humans, other informative evidence for hazard characterisation includes: food compositional analysis (measuring the concentration of chemical substances in the food that consumers would ordinarily be exposed to in the diet), the manufacturing process (to understand the potential for concentrating chemical substances) and any history of safe consumption in Australia, New Zealand or overseas.

Health-Based Guidance Values

Hazard characterisation of chemicals ideally seeks to characterise toxicological responses to a food:hazard pair using observations in laboratory animals and/or humans at various levels of exposure (i.e., doses). This is often referred to as a dose-response assessment. Hazard characterisation will identify the critical health effects associated with exposure and, if possible, establish a dose-response relationship.

It is generally accepted that for most chemicals there is a level of exposure, known as a threshold dose, below which adverse health effects do not occur. Hazard characterisation focuses on establishing a ‘safe’ level of exposure; that is, a level below this threshold level of exposure. This level can be used to establish what is generally referred to as a ‘health-based guidance value’ (HBGV), which reflects the level of a chemical that can be ingested over a defined time period (e.g., lifetime or 24 hours) without appreciable health risk.

For most chemicals, HBGVs are established on the basis of traditional toxicity studies in laboratory animals, which can provide information on the absorption, distribution, metabolism and excretion pathway of the chemical, possible adverse effects following a single exposure (acute toxicity) and adverse effects following long-term exposure (chronic toxicity). These studies use a range of dose levels to identify the highest dose at which adverse health effects do not occur—the no-observed-adverse-effect level (NOAEL). In some cases, and particularly for certain contaminants, agricultural chemical residues and nutritive substances, the NOAEL may be based on human studies. To establish the HBGV, ‘safety’ (or ‘uncertainty’) factors are applied to the NOAEL to account for interspecies differences in sensitivity between the experimental animals and humans, and for variability in sensitivity among members of the human population.

HBGVs that are commonly established to account for long term exposure are the acceptable daily intake (ADI) for food additives or agricultural and veterinary chemical residues, and the provisional tolerable (daily, weekly, monthly) intake (PTDI, PTWI, PTMI) for contaminants. For some chemicals, an acute reference dose (ARfD) is an appropriate HBGV, which is an established short-term exposure (a single meal or single day exposure) that does not result in appreciable risk to the consumer.

FSANZ may adopt a HBGV derived by another food safety body (such as JECFA) for the purpose of risk characterisation in an imported food risk statement. This will only occur after critical review, and where FSANZ is satisfied that the methodology is robust and that the conclusions can be suitably transferred to the Australian and New Zealand context.

Data limitations and the weight of evidence

For many chemical substances, a threshold of toxicity, and therefore a HBGV, cannot be identified as part of the hazard characterisation process. This may be due to insufficient data being available, or if the chemical substance is genotoxic and/or carcinogenic.

In some cases, such as for genotoxic carcinogens, an alternative to the NOAEL approach can be used, which involves dose-response modelling to determine a benchmark dose or BMD. This may also be expressed as the BMDL, that is the lower confidence limit of the BMD. The BMD is a level producing a low but measurable adverse response, corresponding to a pre-determined increase (usually 5 or 10%) in a defined adverse effect.

In the case of substances for which a threshold cannot be established to quantify safe consumption levels, FSANZ must still endeavour to characterise the chemical hazard. Where there is consistent scientific precedence for the food:hazard pair, the hazard characterisation may comprise of identifying the likelihood (or probability) of an adverse health effect occurring and establishing the consequences (and in some circumstances, severity) of such an event. This process may also consider adverse events associated with any current unrestricted risk that is associated with the food in Australia or overseas, or the efficacy of risk management approaches used by other food economies.

In some cases, FSANZ may be required to characterise a potential chemical substance hazard in the absence of any quantitative data, recorded adverse events, international precedence, or where conflicting evidence exists for a food:hazard relationship. Under these circumstances, FSANZ may use a weight of evidence approach to consider the total body of evidence available, including non-quantitative forms of data. A weight of evidence characterisation requires that each available data source be assessed for quality and relevance, where the hazard is characterised based on a consideration of this total body of evidence, with greater weight being placed on the results of higher quality studies. A description as to degree of certainty in the weight of evidence characterisation is then clearly articulated in the final output. The relative weighting FSANZ gives to different sources of evidence is described elsewhere (FSANZ, 2013).

Exposure assessment

The exposure assessment seeks to provide an estimate of the magnitude, frequency and duration of exposure to a chemical hazard. Exposure assessments undertaken by FSANZ for the purposes of providing imported food risk advice primarily comprise dietary exposure data, although other sources of exposure (e.g., supplements) may be considered. FSANZ dietary exposure estimates combine food consumption data with food chemical concentration data to estimate exposure to food chemicals. Food consumption data for dietary modelling purposes is commonly derived from the most recent Australian National Nutrition Survey.

The nature of the food chemical will determine whether a chronic dietary exposure estimate is required (exposure over time), or an acute estimate (exposure from a meal or over one day). Depending on the purpose of the assessment, dietary exposure to a chemical substance may be estimated for the whole population, consumers of the food only, high consumers, and/or specific population sub-groups.

Unfortunately, food consumption and chemical and nutrient concentration datasets are often incomplete, variable in quality or inadequate for use in a dietary exposure assessment. When limitations are identified during the exposure assessment, additional information can be incorporated to offer an indication of potential exposure. Examples of additional information includes market share data for foods, both across the food supply or in a specific food category, or current import quantities of a food commodity. Any assumptions used for an exposure assessment are documented in the imported food risk statement.

Risk characterisation

Chemical risk is a function of both the hazard and the level of exposure to that hazard. For this reason, both features are equally important in determining the level of risk of an adverse effect to a chemical substance in food. Risk characterisation integrates information from the hazard and exposure assessments to establish if FSANZ considers a chemical substance in imported food to be medium or high risk to public health and safety.

The risk characterisation may apply to the whole population or for a specific population sub-group, depending on the nature of the adverse health effect and the pattern of dietary exposure. Specific risk characterisation information for at risk groups—e.g., infants, pregnant or lactating women, the elderly, or immuno-compromised individuals—may need to be considered separately in establishing the health and safety risk of a chemical substance.

It is important that the level of uncertainty, any conservative assumptions, or the use of qualitative evidence to underpin FSANZ risk characterisation, is clearly articulated in the imported food risk statement. The uncertainty needs to be understood by the DAFF, so the strength of available evidence can be fully considered in any risk management decisions.

Conclusion

To assess the risk of chemical hazards in imported foods, FSANZ uses either a quantitative approach when sufficient toxicity information exists, or a weight of evidence approach if the safety data is incomplete. The imported food risk advice aims to provide a concise representation of the available safety evidence and the consequent level of risk of a food:hazard pair, allowing DAFF to implement any necessary risk management measures to ensure the health and safety of Australian consumers is protected.

Chapter 2: 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 2020).

There are some unique complexities associated with assessing microbiological risks in food that do not 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 bacterial 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.

Decision matrix

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

As described previously, FSANZ uses four key steps in risk assessment: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Initially the impact of the hazard is assessed by considering hazard identification and hazard characterisation information. This hazard impact assessment is then combined with an exposure assessment (likelihood of exposure to the hazard) to provide an overall estimate of risk (risk characterisation).

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

High	Highly infectious. Very small quantities likely to cause infection. Very low infective doses (generally <10 infectious units, but could be as few as 1 infectious unit).
Medium	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.
Low	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.
Very Low	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 (>10^5 infectious particles) required to produce sufficient toxin to cause illness.

Table 2: Disease severity

Severe	Potentially life threatening, illness of long duration or with substantial chronic sequelae. Requires medical intervention and/or hospitalisation.
Serious	Incapacitating and rarely life threatening, illness of moderate duration, with or without sequelae. Often requires medical intervention and/or hospitalisation.
Moderate	Incapacitating but not life threatening, illness of moderate duration and sequelae infrequent. Medical intervention not usually required.
Mild	Self-limiting symptoms that may cause severe discomfort but not life threatening, illness of short duration with no sequelae. Patient rarely seeks medical intervention.

Table 3: Hazard impact matrix

	Severity of adverse outcome			
Infectivity	**Mild**	**Moderate**	**Serious**	**Severe**
High	Medium Impact	High Impact	Very High Impact	Very High Impact
Medium	Low Impact	Medium Impact	High Impact	Very High Impact
Low	Very Low Impact	Low Impact	Medium Impact	High Impact
Very low	Very Low Impact	Very Low Impact	Low Impact	Medium Impact

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

Attributes	Very high likelihood	High likelihood	Medium likelihood	Low likelihood	Very low likelihood
Evidence that the hazard has caused foodborne illness associated with the food	Very strong evidence	Strong evidence	Some evidence	Limited evidence	No outbreaks reported
Evidence demonstrating the presence of the hazard in the food	Very strong evidence	Strong evidence	Some evidence	Limited evidence	Hazard not detected in food
Effect of processing on level of hazard in the food	No pathogen elimination step, processing method likely to introduce contamination	No pathogen elimination step, processing method likely to introduce contamination	No effect	Processing method is likely to reduce but not eliminate contamination	Effective pathogen elimination/inactivation step
Food supports the growth of the contaminating microorganism[17]	Yes	Some growth	Possible/limited growth	No	No
Potential for post-processing contamination	Yes	Yes	Yes	Limited	No

[17] As viruses cannot replicate in food, this attribute is not applicable to viral contaminants.

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 DAWE 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[18] and raw milk products[19].

Table 5: Risk characterisation matrix

	Exposure (likelihood)				
Impact	**Very low Likelihood**	**Low Likelihood**	**Medium Likelihood**	**High Likelihood**	**Very High Likelihood**
Very High Impact	Medium Risk	High Risk	High Risk	High Risk	High Risk
High Impact	Low Risk	Medium Risk	Medium Risk	High Risk	High Risk
Medium Impact	Low Risk	Low Risk	Medium Risk	Medium Risk	High Risk
Low Impact	Low Risk	Low Risk	Low Risk	Medium Risk	Medium Risk
Very Low Impact	Low Risk	Low Risk	Low Risk	Low Risk	Medium Risk

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 DAWE 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

[18]Final assessment report for the primary production and processing standards for seafood
http://www.foodstandards.gov.au/code/proposals/documents/P265_Seafood_PPPS_FAR.pdf
[19]Microbiological risk assessment of raw goat milk
http://www.foodstandards.gov.au/code/proposals/Documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD2%20Goat%20milk%20Risk%20Assessment.pdf

to be readily scrutinised, validated and updated when needed or when more data are available.

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