Business Sector
Food Safety Risk Priority Classification Framework

Endorsed by the Food Regulation Standing Committee on 16 March 2007
Introduction

In April 2005, the Department of Health and Ageing, on behalf of the Food Regulation Standing Committee, called for tenders for the development of a Risk Profiling Tool (“the Framework”) for Australian Food Business Sectors. This document introduces the Framework developed and demonstrates its use.

The Framework was developed by a multi-disciplinary group from private enterprise, academia and government, including consultation with and oversight from the Food Regulation Standing Committee Policy Working Group - Developing Options for Food Safety Management in Australia.

What the Framework is intended to do

This risk profiling Framework has been developed to provide guidance on the allocation of Australian food business sectors into categories based on their likelihood of contributing to foodborne disease and the potential magnitude of that contribution. That categorisation is required to enable appropriate risk management regimes to be assigned to those business sectors. In addition, the Framework will be used to guide future policy decisions on food safety management in Australia. In its current form the Framework assumes that the user has high level understanding of food safety issues, and approaches to their management, and is not intended for general use by food businesses.

The Framework is designed to:
- be science-based and transparent;
- be applicable to the whole food supply chain both “before, and after, the farm gate”;
- consider relevant biological, chemical and physical hazards associated with particular foods/processes; and,
- reflect;
  - risks inherent to the product/process;
  - the potential of controlling the risks; and,
  - a measure of their association with past foodborne illness outbreak information.

What the Framework cannot do

The Framework cannot be, and is not intended to be, a substitute for food safety risk assessment. Food safety risk encompasses the probability of a hazard being present in a food and the severity of the consequences if it is. Clearly, the true food safety risk is based on many factors which can vary in time, location, and circumstances specific to individual businesses within a sector. Methods for full risk assessments are described in various publications being developed under the auspices of the ‘Codex Alimentarius Commission’.

The correct use of the Framework requires that the following sections are read and understood before commencing.

Continue
About the Framework: Format of the Framework and Navigation

The Framework itself is a series of decision trees, with extensive documentation to assist in its correct application, as well as instructions for use. The Framework is presented in a Microsoft® PowerPoint file that opens automatically as a PowerPoint ‘show’, so that is has the appearance and functions of an internet web-site. This means that you can click on various objects to get more information, or go to different parts of the Framework.

Menu bars, such as the one opposite, contains ‘hyperlinks’ to assist in navigation around the Framework. In many parts of the Framework, the menu is at the bottom of the page and looks like this:

The nature of the links should be self-evident after reading through these introductory pages.

To view the overall architecture of the Framework, click on the “Document Map” button (e.g. on the left hand side of this page).

As you navigate through this document, and particularly when using the Framework you may choose to follow links that provide additional definitions, explanations or interpretations needed to use the Framework correctly. To facilitate this, an additional button is included on many pages that will return you to the page that you came from.

Clicking on the [UP] will return you to the page you last viewed.

Some words and terms are defined in a Glossary that forms part of the Framework. Words or terms that are underlined and in a red type can be ‘mouse-clicked’ to obtain a definition. Some links are to the ‘world wide web’. These may take several seconds to open, and require that your PowerPoint software is correctly configured to enable direct connections to the internet.

Some items in the Framework are also hyperlinked to provide additional information. You can tell that extra information is available if, when you move your cursor over an item, the cursor changes to a ‘hand with pointing finger’.

To stop using the Framework, click on ‘Quit’.

A print version of the Framework is also available.

Continue….
Business Sector Food Safety Risk Classification Framework

About the Framework: Document Layout

This document includes:
• the background to the inception of the Framework;
• description of the overall layout of the Framework and its accompanying documentation;
• the philosophy underlying the Framework;
• instructions for use of the Framework;
• the Framework itself, comprising:
  – primary level decision trees for both Primary Producers and Food Business Sectors;
  – secondary decision trees that elaborate the intent of the questions in the primary level decision trees; and,
  – supporting documents that can assist to answer the questions in the various decision trees.
• other supporting documentation and references;
• lists of examples of the use of the Framework to assess the Priority Risk of various food businesses and primary production enterprises; and
• overview diagrams of the decision tree, in the order presented above. Many of the above sections include multiple pages.

The detailed layout of the document can be seen by following the “Document Map” link from any page.

Continue …. 
About the Framework: Philosophy and Approach to Development of the Framework

Based on the initial success of a similar tool developed by the New South Wales Food Authority, the current Framework is presented as a series of decision trees. In those trees, the questions posed are intended to identify whether the food or primary production business influences the risk from the food/primary product when it is consumed. If the answer is “NO”, the decision leads the user ‘across’ the tree. A “YES” answer, however, leads the user down the tree. Thus, moving downward through the tree is always indicative of increasing risk.

The questions in this decision tree also aim to determine whether the business or primary production sector contributes to the safety of the product eaten by the consumer, and how critical that business sector’s contribution is to overall consumer safety. The tree requires the user to determine whether a business sector has or requires at least one critical control step (CCP) in the sense used in HACCP §. To help users to answer this question, classification is based on known risk-affecting factors including the need for elimination of pathogens, potential for microbial (re)contamination and growth, potential for inadvertent introduction of physical or chemical hazards that will not be detected, and the size and health status of the population served.

The approach in the decision trees is to consider:

- the nature of the potential risk that might exist or arise from products sold by the business sector and considering both the inherent risk, (i.e. in the absence of existing controls) and the reliability of existing risk management actions, i.e. managed risk,

- whether there are steps that are susceptible to introduction of hazards, or processes that are critical to the safety of the product at the time it is consumed.

Essentially, the Framework asks three key questions, that must be answered sequentially:

1. Could a hazard realistically be present in the food? (“NO” - Priority 4, “YES” go to Question 2)
2. Does the business sector have a crucial role in controlling the hazard? (“NO” - Priority 3, “YES” go to Question 3)
3. Are there known ‘high risk’ factors associated with the sector? (“NO” - Priority 2, “YES” - Priority 1).

Thus, the three basic considerations lead to four risk categories.

For businesses that handle many types of foods or undertake diverse processes, it is recommended that the classification of the business sector is that of the highest classification applicable to any of the hazards associated with any of the products that the business handles.

No categorisation based on a ‘class’ of product or business type will be completely appropriate to every product or business in that category. Rather, the aim is to provide an objective means to appropriately classify the risk presented by most of the businesses producing, or handling, a particular product type. Users should recognise that individual circumstances could affect the risk category.

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§ HACCP is system for developing, implementing and maintaining food safety management in food businesses. It is the model system on which the Food Safety Programs referred to in the Food Standards Code (S.3.2.1) are based. Useful assistance for HACCP plan development is readily available on the internet, including the Food Safety Centre’s Food Safety Toolkit (http://www.foodsafetycentre.com.au/fsToolkit/)
Business Sector Food Safety
Risk Classification Framework

Using the Framework

Background

As described previously, the Framework is a decision tree which is set up as a series of questions with “YES” or “NO” answers. All questions are contained in diamond shapes. Answering each question successively will lead the user to a new question, or a business sector risk classification on a scale of Priority 1 to 4, where Priority 1 represents the food business (or primary producer) type and/or process combination that represents the highest risk to the community. If the answer to the question is not obvious, or the intent of the question not clear, more guidance can usually be obtained by clicking on the diamond containing the question.

A “YES” answer is always associated with factors that increase risk and leads the user ‘down’ the decision tree. Thus, moving further down the decision tree corresponds to increasing risk.

Levels within the Trees

Factors in food business sectors that affect risk from a food are not necessarily those that affect the risk inherent in the original source of that food from primary producers. Consequently, two parallel decision trees were developed. The first is for primary production where the product sold by the business sector is not considered to be intended for consumption in the form sold by the business sector but where the hazard could remain in, or be transferred into, foods derived from the primary products. The second is for food business sectors, i.e. those that sell or handle foods or food ingredients.

Each tree is summarised in a Primary Level tree that involves a small number of questions which embody the basic philosophy of the Framework. The close similarity of the two trees arises because the logic behind each is similar, as described on the previous page. The trees cannot be the same, however, because the initial questions must reflect important differences in product types and processes at the different levels of the food chain.

It must be noted that the logical basis of the tree requires that the questions are answered sequentially. Each successive question in the tree applies to an increasingly narrow range of business sectors. Additionally, the answers to the primary questions are not always intuitive. For this reason it is important that the answers to the Primary Level questions are based on working through the decision sub-trees that accompany them. Arrows on the primary level trees are ‘faded’ and ‘dashed’ to reinforce this point. The decision sub-trees can be accessed by clicking on the appropriate diamonds in the Primary Level trees.

Assistance in the choice of which decision tree to use is available by clicking on the “Use the PCS Decision Tree” button on the left-hand side of this page.

Correct Use of the Decision Tree

Another consideration critical to the successful and consistent use of the Framework is to remember that questions about food relate to the food sold by, altered by or handled by the business sector, not the form of product that the business sector receives. Complementary questions address the combined influence on risk of the ingredients, or form of food received and/or handled by the business sector, and the processing and handling that the business undertakes.

Continue....
The Primary Producer business risk classification decision tree is intended for businesses involved in primary production and that do not perform processing (see below), e.g. those involved in:

- maintaining, breeding and agisting of animals, fish or birds, or
- taking or catching shellfish and crustaceans, or
- propagation, maintenance or cultivation of plants, seeds or fungi

that are intended to be processed into food, or food ingredients, for human consumption. Processing is taken to include:

- killing, dismembering, filleting, washing, cooking, peeling, packing, treating, freezing, boning, depuration, etc.

For some primary producers whose product is likely to be consumed substantially in the form presented for sale to another business or to the public, classification of the enterprise may be better addressed by the Food Business Sector Priority Classification decision tree. [It should be noted that both trees use the same decision process to achieve classification (see About the Framework: Philosophy ...), but use different language reflecting differences between primary products and foods and food ingredients.]

The Primary Producer (PP) risk classification decision tree encompasses consideration of microbial, chemical and physical hazards. It is structured to complement the Food Business Sector (FB) decision tree.

The approach in the Primary Production decision tree reflects the intent of the Food Business Sector decision tree in that the questions relate to:

- the nature of the potential risk that might exist or arise from animals, seeds etc. sold by the primary producer (and considering both the inherent risk, i.e. in the absence of existing controls, and the managed risk, i.e. reliability of existing risk management actions at other points in the farm to fork pathway); and,
- whether there are steps that are susceptible to introduction of hazards, or processes that are critical to the safety of the product at the time it is consumed.

For the purposes of the decision Framework, the term ‘on-farm’ is used to refer to activities/enterprises at any primary production level, including fishing, etc.

Example Classifications

A number of classifications of primary production systems, showing the decision tree path, are also included. Select ‘Primary Production Example Classifications’ from the menu opposite to view them.

Continue....
**Primary Producer Decision Tree (cont.)**

**Description of Priority Classification Levels**

The interpretation of the four Primary Production classification levels is similar to that of the classifications of the Food Business Sector decision tree.

**Priority 1**

A primary producer whose product could contain hazards which, if not controlled by the primary producer, could lead to “severe” illnesses and public health risk in foods derived from that product, (e.g. oysters contaminated with Hepatitis A virus).

**Priority 2**

A primary producer whose product could contain hazards which, if not controlled by the primary producer, represent a “serious” illnesses and public health risk in foods derived from that product, (e.g. Salmonella in poultry).

**Priority 3**

A primary producer whose product could contain hazards that, if not controlled at the farm, represent (at worst) a “moderate” illnesses public health risk from foods derived from that product either because:

- the safety hazards that can be controlled ‘on-farm’ induce mild illness only and would only affect a small number of consumers; or,
- the hazard is reliably controlled by normal handling or processing at a subsequent step in the food supply chain.

**Priority 4**

A primary producer whose product or a food derived from it:

- does not, or could not be anticipated to, contain any known food safety hazard; or,
- may contain a hazard that cannot be controlled by actions by the business sector but is reliably controlled by normal handling or processing of the product at a subsequent step in the food supply chain under normal conditions of use and handling.

**Example Classifications**

A number of classifications of primary producer businesses, showing the decision tree path, are also included. Select ‘Primary Producer Example Classifications’ from the menu opposite to view them.
Business Sector Food Safety
Risk Classification Framework

Food Business Sector Decision Tree

Overview
The intent, structure and philosophy of the Food Business Sector decision tree has been described in previous pages. The Food Business Sector decision tree is intended to be used to classify the Risk Priority of all food business sectors, with the exception of Primary Producers, as described previously. The following section describes the four Priority Classifications that have been adopted and the rationale for them.

Interpretation of the Food Business Sector Priority Classifications

Priority 1 and 2
Typically, a business sector that would be considered to have, or to need to implement, at least one CCP (as defined within the HACCP approach) as part of its control or manipulation of the food, is classified as a Priority 2 or Priority 1 business sector. Such business sectors will characteristically handle “high risk” foods, e.g. those that support the growth of pathogenic micro-organisms and where such pathogens are present or could, from experience or documented reports, be expected to be present and to cause “severe” illness.

Priority 1 business sectors will, typically, be characterised further by known risk-increasing factors, such as potential for inadequate/incorrect temperature control (e.g. reheating, ‘hot-holding’ of food), a consumer base that includes predominantly immunocompromised populations, and others factors identified in the National Risk Validation Project (FSA & ME, 2002) or their scale of production and potential for a hazard to be present.

Priority 3
A Priority 3 food business sector will, typically, only handle “low risk” or “medium risk” foods. A medium risk food is one that may contain harmful natural toxins or chemicals introduced at steps earlier in the food supply chain, or that:

- may contain pathogenic microorganisms but will not normally support the formation of toxins or growth of pathogenic microorganisms due to food characteristics; or,
- is unlikely to contain pathogenic microorganisms due to food type or processing but may support the formation of toxins or growth of pathogenic microorganisms.

Continue…. 
Interpretation of the Food Business Sector Priority Classifications (cont.)

Priority 4

Priority 4 business sectors are those considered to present negligible risk of causing foodborne illness. A Priority 4 business will normally handle only “low risk” foods, i.e. those that are unlikely to contain pathogenic organisms and will not support their growth, and would be extremely unlikely to introduce microbial, physical or chemical hazards to the foods they sell or handle.

Example Classifications

A number of classifications of food business sectors, showing the decision tree path, are also included. Select ‘Food Business Sector Example Classifications’ from the menu opposite to view them.

Choose from the ‘Navigation’ menu on the left to continue or to begin to use the Framework.
Is the business involved in ‘primary production’ of products that will be used as, or in, foods but not selling or serving those primary products directly to the public as foods?

**NO**
- click here to go to
  - Food Business Sector
  - Decision Tree

**YES**
- click here to go to
  - Primary Production
  - Decision Tree
The purpose of this question is to recognise the differences in sources of food safety risk relevant to businesses involved in handling plant, animal and fungal tissue that has not yet been processed or packaged into a food commodity or product. Primary Producers include those involved in:

- maintaining, breeding and agisting of animals (e.g. cows, sheep, deer etc), or birds, or fish, shellfish or crustacea (e.g. by aquaculture) or
- catching or collecting of fish, shellfish or crustaceans, or
- propagation, maintenance or cultivation of plants, seeds or fungi

that are intended to be processed into food, or food ingredients, for human consumption.

Furthermore, for the purposes of the Framework primary producers do not process the product, where processing is taken to include:

- killing, dismembering, filleting, washing, cooking, peeling, packing, treating, freezing, boning, depuration, etc.

This differentiation between types of food business is needed because some of the questions required in the Food Business Sector decision tree are difficult to interpret when applied to certain plant materials and live animals. For example, a cow is not a food, but there are some food hazards can be introduced or prevented or eliminated by actions taken on farm such as control over use of chemicals. Once the animal is slaughtered, however, the food safety risk is best assessed using the Food Business Sector decision tree because the primary product has been processed into ‘meat’, i.e. a food.

The principal distinction, consistent with other frameworks addressing farm-to-fork food safety, is that of processing (see description above). Where the primary product could be sold directly as a food direct for consumption, the Food Business Decision Tree may be more appropriate. Accordingly, the question is structured to recognise that for some primary producers who sell their product as food, the Food Business Decision Tree will be equally, or more, appropriate. In this context, it is important to note that both the Primary Producer and Food Business Decision Trees use essentially the same criteria to establish the food safety business risk classification and that the use of two decision trees is largely due to the need to differentiate food from the primary products from which it is derived.
Primary Production Decision Tree: Primary Level (Overview)

PP1. Is it likely that a food safety hazard is present on/in the primary product that could be transferred to food derived from the primary product?

YES

PP2. Is there a practical hazard control action, demonstrated to be effective, that can be implemented 'on-farm'?

NO

PP3. Is an ‘on-farm’ action critical to the safety of the product at the time of consumption?

YES

PP4. Could the hazard in the commodity cause a "severe" public health consequences in food derived from the primary product?

YES

PP2a. Could the hazard persist at or reach levels that could cause illness despite subsequent and correct processing/handling by other handlers/business sectors?

YES

Product currently unacceptable for consumption without additional risk management actions

NO

Priority Classification 1

Priority Classification 2

Priority Classification 3

Priority Classification 4
FB1. Could the business sector introduce a hazard to the food, or fail to control the level of a hazard that could be present?

FB2. Does the business sector need to take action(s) to eliminate, reduce or control a hazard critical to the safety of product when it is consumed?

FB3. Will/could the presence of the hazard lead to "severe" public health consequences?
PP1. Is it likely that a food safety hazard is present on/in the primary product that could be transferred to food derived from the primary product?

The purpose of this question is to exclude from further consideration and place in the lowest Priority Classification any primary product/commodity which is very unlikely to introduce a hazard into the food supply chain. The question encompasses chemical, physical and microbial hazards. The decision sub-tree below is provided to assist users to answer the question by asking three questions related to the potential for introduction of hazards.

Carriage of microbial foodborne pathogens (e.g. Salmonella) in the gut of food animals leads to a “YES” because they may be a source of contamination of carcase and manufactured meat products further along the food supply chain.

Chemical hazards can be introduced through feed, therapeutic administration, toxigenic infection/growth of microorganisms or environmental exposure and may include agricultural and veterinary chemical residues as well as environmental contaminants (e.g. cadmium in offal, organo-chlorines from prior land use), or plant-associated toxins (e.g. micro-algal biotoxins, pyrrolizidine alkaloids, mycotoxins etc).

Physical hazards may include broken needles arising from animal treatment or lead shot in wild animals.

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Physical hazards may include broken needles arising from animal treatment or lead shot in wild animals.
PP2. Is there a practical hazard control action demonstrated to be effective, that can be implemented ‘on-farm’?

This question relates to hazards whose control can be assured, or effectively minimised, by the application of appropriate measures (e.g. Good Agricultural Practice etc.) in the primary production sector. ‘Appropriate measures’ should also pass the criteria of technological and economic feasibility.

Examples of control steps considered to be effective and practical “on-farm” include:

- Minimum periods between application of agricultural chemicals (e.g. fungicides) and harvest;
- Measures that reduce *Salmonella* contamination of broiler flocks such as vaccination of broiler-breeder flocks;
- Inspection to remove foreign matter at the time of harvesting; and,
- Monitoring zones in which shellfish (e.g. oysters, cockles) are commercially harvested or grown for evidence of faecal contamination and algal biotoxins.

*Answer “YES” only if effective measures are available that have been validated for use “on-farm”*

A “YES” answer leads to Question PP3.

A “NO” answer leads to Question PP2a.
When an uncontrolled hazard exists it is important to determine whether that hazard is effectively controlled at a later point in the food supply chain and, if not, whether the public health risk is sufficient to require the development and implementation of actions to eliminate, minimise or reduce that hazard.

**Answer “NO” only if:**

- the hazard will be eliminated reliably either by further processing of the product later in the food supply chain or, in the case of microbes, those hazards will be reliably eliminated by a business sector further along the food supply chain prior to sale or service to consumers (e.g. by cooking or other decontamination treatment).

**Answer “YES” only if:**

- the hazard is likely to be present at a level that could cause illness and will not be eliminated by further processing, or
- there is potential for presence and growth of pathogenic microorganisms to hazardous levels (or production of hazardous levels of toxins) prior to further processing and those toxins/substances will not be eliminated by subsequent processing.

† Click here for assistance in assessing whether a particular food will permit growth of pathogens.
PP3. Is an ‘on-farm’ action critical to the safety of the product at the time of consumption?

The purpose of this question is to identify primary production processes and risk management actions that, while contributing to food safety, are not essential for assurance of the safety of foods derived from the primary product at the time of their consumption. Primary producers characterised by such steps/actions are considered to have a lower risk priority. Additional help can be obtained by clicking on the question diamonds.
PP4. Could the hazard in the commodity cause a “severe” public health consequences in food derived from the primary product?

Primary Products to which these questions are applied will be those for which:
- a hazard could be present;
- an on-farm action is critical to the safety of the product or foods derived from it; and,
- no further hazard reduction or elimination procedures can be relied upon prior to its consumption.

As such, all such products will be classified as Priority 2, at least. To better relate the level of regulatory oversight to risk, primary producers of commodities for which:
- the illness caused by the hazard is ‘severe’, i.e. likely to be life threatening or to cause chronic illness effects; and,
- there is a reasonable likelihood that the hazard could be present if the on-farm control action is not reliably implemented,

are given the highest Priority Classification (Priority 1).

The decision sub-tree below assists in the identification of such products/commodities. Additional help can be obtained by clicking on the question diamonds.
Additional HELP for Questions PP3a - d.

**PP3a At the time of consumption, is the hazard likely to be present at levels that could cause illness?**

This question is intended to address hazards which may be present in the commodity, but which could only be present in products at disease-causing levels under extremely unusual circumstances. The question will usually relate to agricultural and veterinary chemicals for which it is extremely unlikely, due to:

- contemporary usage;
- modes of contamination; or,
- dilution or degradation through subsequent processing of the commodity, that the levels present in foods derived from the product would cause human illness either in the short, or long, term. Unless the hazard is likely to be present, at the time of consumption, at levels that could cause overt illness, answer “NO”.

**PP3b Could business sectors further along the food supply chain not be expected to eliminate the hazard?**

The intent of this question is to recognise that some business sectors that sell or handle commodities that potentially contain hazards, do not have a critical responsibility for the safety of foods derived from those commodities. This applies where the commodity sold will receive further processing, including CCP steps, that will eliminate the risk from the hazard prior to the food or commodity being consumed. If business sectors further along the food supply chain cannot be relied upon or expected to eliminate the hazard, or if the business sector sells direct to the public, answer “YES”.

**PP3c If present, would the level of the hazard expected at the time of consumption cause serious or severe illness in the target consumer?**

Consideration should be given both to the seriousness of the hazard and to likely changes in the levels of the hazard from that present in the primary product sold by the producer to that likely, or realistically possible, at the time of consumption in foods derived from the primary product.

**PP3d Will the contamination lead to widespread exposure of consumers?**

This question will only be applied to primary products that could be contaminated with hazards that would only cause moderate, or less, harm to consumers. Nonetheless, if many consumers are exposed there may be a public health risk that can be prevented by appropriate actions. The magnitude of that risk depends on how many meals are derived from the contaminated batch or unit of food and the disease severity(see Quantifying Public Health Risk). Such enterprises may require regulatory oversight. This question focuses attention on such primary producers because the magnitude of exposure to a hazard is a component of food safety public health risk.
Additional HELP for Questions PP4a and b.

**PP4a**  *Does documented evidence exist that the presence of the hazard in the product is likely to cause human illness?*

Many foods could contain many different hazards. To facilitate assignment of an appropriate Priority Risk classification, this question is included to differentiate credible risks from improbable risks.

“Documented evidence” is taken to include evidence that the presence of the hazard in the product, or an analogous hazard in an analogous product, has caused foodborne illness.

In answering the question, it should also be remembered that this question is only used to assist in differentiation of Priority 2 and Priority 1 business sectors. Thus, a “YES” answer to this question identifies business sectors that could have associated with them factors that indicate “very high” risk.

**PP4b**  *Does the hazard typically cause severe illness to consumers?*

ICMSF (1986) describes severe illness as “causing life threatening illness or substantial chronic sequelae or causing an illness of long duration”.

Hazard severity, particularly hazards that can cause death, have a very high risk associated with them (see Quantifying Public Health Risk). This question highlights primary processing sectors that handle foods that may harbor severe hazards compared to business sectors that produce sell or serve foods susceptible to contamination with hazards that lead to minor discomfort for short periods of time.
FB1. Could the business sector introduce a hazard to the food, or fail to control the level of a hazard that could be present?

The purpose of this question is to exclude from further consideration and place in the lowest Priority Risk Classification business sectors that handle a product or undertakes process that:

- cannot introduce a hazard; or,
- in the case of microbial hazards, cannot lead to growth of a hazard; or,
- do not need to take action(s) to eliminate a hazard that may be present in raw ingredients.

In other words, the question seeks to exclude from further consideration business sectors or processes that do not affect the food safety risk.

The following decision tree is provided to assist users to answer the question by asking three questions related to the potential for introduction of pathogens, or other hazards, or for allowing pathogens to grow.

Additional help is available by clicking on the question diamonds.
FB2. Does the business sector need to take action(s) to eliminate, reduce or control a hazard critical to the safety of product at the time of consumption?

The intent of this question is to identify food business sectors that undertake food processing or handling steps that require specific actions to ensure the safety of the product. The question also seeks to recognise that small businesses that do not “manipulate” high risk or medium risk foods present a low risk through low potential exposure. In other words, if the business does not include or need a critical control step, it will be classed as Priority 3, unless it is a large business producing/selling medium risk foods.

Additional help is available by clicking on the question diamonds.
FB3. Will/could the presence of the hazard lead to “severe” public health consequences?

The decision support for this question, which is presented on the following pages, is provided to assist users to answer this question consistently.

All business sectors considered in this question will handle foods that could cause “serious” or “severe” foodborne illness or are business sectors that handle, produce or sell medium-risk foods for a large number of consumers.

This section firstly identifies (medium and high risk) foods for which no reliable food safety management step exists along the entire supply chain.

Foods that are in the category “medium risk” but that may pose a high risk to consumers by virtue of potentially unreliable hazard reductions steps, such as fermentation of meats, are also identified.

The final section includes questions that are structured to identify food business types, foods or processes that are known to be frequently associated with foodborne disease outbreaks and to place them into the highest risk classification, e.g. preparation of ready-to-eat foods, service to a susceptible population, potential for inadequate/incorrect storage, heating or cooling, or holding temperature, possible presence of “severe” hazard, etc.

Continue to FB3 sub-tree
Food Business Sector Decision Tree

**Question FB1a - c: Additional HELP**

**Question FB1a.**  Is the food “potentially hazardous”?

The key aspect is to determine whether the food requires temperature control such as refrigeration, for its stability, i.e. is the food ‘potentially hazardous’? If the food is stabilised by chemical means such as preservatives, acidity regulators or combination thereof, but may be refrigerated, then answer “NO”.

**Question FB1b.**  Does the business sector handle other than pre-packaged foods or does it re-package food?

This question is intended to determine whether there is potential for human intervention, or vermin/insects intrusions of the product that could allow contamination to occur. If the food is already packaged and arrives at the business sector in cartons or other sealed packages and the business sector displays those packaged items for sale without opening them or repacking into other containers for sale, the answer is NO.

**Question FB1c**  Does the business sector re-heat the food?

This question determines whether any heating of packaged items occurs that may allow pathogen growth if adequate controls are not implemented upon reheating or hold holding.
Food Business Sector Decision Tree

**Question FB2a and b: Additional HELP**

**Question FB2a. Is the product a “high risk” food?**

*High risk* foods are generally synonymous with a *potentially hazardous* food, i.e. those that allow the growth of pathogenic microorganisms. The Framework relies on existing definitions of ‘high’, ‘medium’ and ‘low’ risk. In some cases preparation and packaging of the product manage the risk to a consistently acceptable level. Thus, in such cases potentially hazardous foods, such as pasteurised milk, have been classified as *medium risk foods* because they are unlikely to contain pathogens. If the product’s risk is unclassified (as ‘high’, ‘medium’ or ‘low’), the moisture content, pH, composition, contamination risk and storage characteristics need to be considered to assess whether that food can support the growth of pathogens and/or the formation of toxins. Advice to assist in determining whether foods not currently classified can be considered as ‘high risk’ can be found at “Foods that allow pathogen growth”.

Answer “YES”:

- if the food is a defined *high risk* food, OR,
- if undefined as “high”, “medium” or “low” risk, the characteristics of the product sold by the business meet the criteria of a potentially hazardous food.

**Question FB2b. Could chemical contaminants be present at levels that could cause acute illness?**

Chemical hazards that could contaminate foods include heavy metals, agricultural and veterinary chemicals, lubricants, disinfectants and cleaning compounds, food additives etc. Some of these compounds are deliberately applied to foods and primary products, while others are accidental contaminants arising from use of such chemicals in the vicinity of food production or handling areas.

The question should be answered in the context of whether, given the expected handling of the food, hazardous levels of chemical contaminants could be present, whether due to inappropriate application of such chemicals by the business, or due to accidental introduction of such contaminants by the business.

This question is not intended to consider the risk from long term consistent exposure to chemicals that can cause chronic illness nor does it relate to adventitious contamination by naturally occurring allergens. As an example, higher than permitted levels of sulphur dioxide may lead to acute illness (noting that sulphur dioxide is classed as a food additive for the purposes of this Risk Classification Framework).

Answer “YES”:

- if the business sector could, through its normal operations, introduce chemical contaminants that could cause acute illness in the ultimate consumers of that food or product; OR,
- if the business is considered to have responsibility for elimination or removal of harmful chemicals that could be expected to be present at levels that could cause acute illness in the ultimate consumers of that food or product.
Food Business Sector Decision Tree

*Question FB2c - e: Additional HELP*

**Question FB2c**  
*Does the food produced by the business sector involve a ‘potentially unreliable’ hazard reduction process?*

The purpose of this question is to establish the integrity of pathogen intervention/reduction steps in food that do not support the growth of pathogens, such as fruit juice and lettuce but may harbour pathogens at low, but disease-causing levels.

**Question FB2d**  
*Does the business handle medium risk foods?*

Medium risk foods are defined by FSANZ as described in the glossary. This question is required to avoid overlooking the potential risk from medium risks foods that may be produced in very large quantities, i.e. where a risk may arise due to the magnitude of potential exposure rather than disease severity.

**Question FB2e**  
*Do businesses in the sector produce or serve sufficient units or servings simultaneously to pose an unacceptable risk?*

Taken together, the two questions assess the risk of a moderate hazard potentially present in a large amount of food. While businesses that handle high risk foods are immediately placed into Priority 1 or 2, a high volume producer of medium risk foods may represent a risk to public health unless adequate and reliable controls are in place. Accordingly, through these questions, high volume producers of medium risk foods are subject to a further set of assessment criteria, i.e. Questions FB3. The significance of business size, in relation to hazards that may be present, can be addressed by consideration of the Disability Adjusted Life Years (DALY) concept.
**Food Business Sector Decision Tree**

**Question FB3: Additional HELP**

**Question FB3a. Is a practical action available to control the hazard?**

This question is principally intended to identify foods or processes for which a practical strategy (i.e. technologically and economically feasible), or combination of strategies, is available to control the hazard in the product made, sold or handled by the business sector. “Control” is used in the sense used in the HACCP approach, i.e. an action taken to prevent, reduce to an acceptable level, or eliminate a food safety hazard. Thus, ‘control’ does not always mean reduction or elimination of a hazard, but can include prevention of worsening of a hazard (e.g. refrigeration) as well as hazard reduction or elimination. It is expected that there would be few hazard/product combinations for which the answer is ‘no’, and such products would be considered to be unsafe for human consumption by virtue of being likely to contain hazards at levels likely to cause **acute illness**.

**Question FB3b. Is the control action critical to the safety of the product sold by the business sector?**

The intent of this question is to identify business sectors that, while handling a medium or high risk food, do not have essential responsibility for the safety of the product at the point of consumption. The inference of a ‘NO’ answer is that processes undertaken by another business sector(s) in the food supply chain are the most important in assuring the safety of the product at the time of consumption.

Business sectors for which the answer is ‘no’ would include retailers and distributors of long shelf-life refrigerated foods, in impermeable packaging, that could harbour pathogens that grow at low temperature. A specific example is retailers or transporters of vacuum-packed processed ready-to-eat meats or fish that support the growth of *Listeria monocytogenes*. While the business sector should maintain good refrigeration, even with good refrigeration the hazard, if present, will increase slowly during storage. Thus, the critical control of this hazard is considered to be prevention of contamination at the processing plant (as reflected in so-called “zero tolerance” regulations).
Food Business Sector Decision Tree

**Question FB3c and d: Additional HELP**

Questions FB3c and d aim to identify whether, despite controls, hazards that could lead to human illness could still be present in the product sold by the business sector.

**Question FB3c. Are the Critical Control actions potentially unreliable, or unproven, or could recontamination occur prior to sale by the business sector?**

The intent of this question is to differentiate the risk from business sectors/processes for which critical food safety controls are well established and demonstrably effective when reliably implemented, (e.g. canned foods, pasteurised milk) from those which, while usually providing a safe product, are subject to failure that is not readily detected prior to release of the food for sale.

While products such as pasteurised milk and canned foods can support pathogen growth and might be considered “high risk” that risk is controlled by processes and systems that have a high margin of safety and demonstrated record of consistent safe provision of such inherently high risk foods. For this reason, FSANZ defines these products as “medium” risk. For such processes answer “NO”.

Conversely, for business sectors that rely on processes that do not achieve high levels of hazard reduction (e.g. fermentation, chlorine washes, vegetables acidified and stored in oil), or where evidence indicates that recontamination with hazards is common (e.g. sliced, long shelf life processed meat, some cheeses), or where the process can occasionally fail, without that failure being detected prior to release of the product for sale, answer “YES”.

**Question FB3d. Does documented evidence exist that the presence of the hazard in the product is likely to cause frequent or severe human illness?**

Many foods could contain many different hazards. To facilitate assignment of an appropriate Priority Risk classification, this question is included to differentiate credible risks from improbable risks.

“Documented evidence” is taken to include evidence that the hazard in the product, or an analogous hazard in an analogous product, has caused foodborne illness.

In answering the question, it should also be remembered that this question is only used to assist in differentiation of Priority 2 and Priority 1 business sectors. Thus, a “YES” answer to this question identifies business sectors that could have associated with them factors that indicate “very high” risk.

Click **CONTINUE** for help to Questions FB 3e and 3f.
Food Business Sector Decision Tree

Questions FB3e - f: Additional HELP

Questions 3e - h are intended to identify factors associated with the product sold or handled by business sector, or the nature of the business itself, that implicitly, or from available epidemiological evidence, significantly contribute to risk. These include:

- service to predominantly susceptible consumers;
- processes or practices with potential for temperature abuse leading to significant pathogen growth;
- presence of hazards that can cause severe illness; and
- exposure of a large number of consumers to a moderate hazard.

The intent of the questions is to increase regulatory attention on business sectors that produce ‘high risk’ foods and that are also subject to additional factors that increase the potential public health consequences of those hazards.

Question FB3e. Is the target consumer unusually vulnerable to the hazard?

If the population served by the business sector includes a high proportion of very young children (e.g. ≤4 y.o), elderly (e.g. > 70 y.o.) or other people known to have reduced immunity (e.g. pregnant women, liver disease, HIV, transplant recipients, cancer patients receiving chemo- or radiotherapy etc), then answer “YES”. Examples could include ‘aged care facilities’, delivered meals organisations (e.g. “meals on wheels”, child care facilities, hospitals etc.

If the target consumers of the business sector are the general population, or sub-sections of better than average health (e.g. youth market, sports players), answer ‘NO’.

Question FB3f. Does the hazard typically cause severe illness to consumers?

ICMSF (1986) describes severe illness as “causing life threatening illness or substantial chronic sequelae or causing an illness of long duration”.

Hazard severity, particularly hazards that can cause death, have a very high risk associated with them (see Quantifying Public Health Risk). This question highlights business sectors that handle foods that may harbor severe hazards compared to business sectors that produce sell or serve foods susceptible to contamination with hazards that lead to minor discomfort for short periods of time.

Continue for help to Questions FB 3g and 3h.
**Food Business Sector Decision Tree**

*Questions FB 3g and h Additional HELP*

**Question FB 3g.** Could the level of the hazard cause *acute illness* in a healthy consumer or, before eating, increase to such levels due to poor temperature control?

This question is intended to further identify business sectors that may present a high risk because they undertake processes or produce foods that are susceptible to temperature abuse that could lead to significant pathogen growth (e.g. slow reheating, protracted cooling, or ‘hot holding’ of foods prior to sale or service, inadequate refrigeration of raw foods), i.e. processes for which temperature is the principal means of assuring safety. In the case of psychrotrophic pathogens in long shelf life refrigerated foods, even proper temperature control will not eliminate or control the hazard, i.e. temperature control is not the principal risk management action.

Additionally, the question is intended to identify business sectors that employ processes that are susceptible to recontamination of the product, or susceptible to failure to eliminate hazards present at levels that could cause acute illness (e.g. toxins, low infectious dose pathogens such as enterohaemorrhagic *Escherichia coli*).

If the business sector produces or serves foods that could be contaminated at levels that could lead to acute illness, or foods that could be contaminated and during normal handling allow hazard levels to increase to those that could cause acute illness if temperature is not properly controlled, answer “YES”.

**Question FB 3h.** Do businesses in the sector produce or serve sufficient *units* or servings simultaneously to pose an *unacceptable risk*?

Through the logic embodied in the decision tree, the only food businesses that this question will be applied to are those that produce ‘high risk’ food that is unaffected by severe hazards but that relies on a *potentially unreliable* hazard reduction step. As such, hazards may occasionally be present but, even if present at low frequency, could cause a foodborne disease outbreak if that product is consumed by a large number of people. This question focuses attention on such businesses because the magnitude of exposure to a hazard is a component of food safety public health risk (see *Quantifying Public Health Risk*).
Glossary A - H

acute: (of illness) a disease with an abrupt onset and (usually) short duration (cf. ‘chronic’).

CCP: (see ‘Critical Control Point’).

chronic: (of illness) an illness that persists for a long period of time (defined by the U.S. National Center for Health Statistics as longer than 3 months). Subacute has been coined to designate the mid-ground between acute (q.v.) and chronic.

critical control point: Codex defines a critical control point as “a step [in the food supply or processing chain] at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level”. Processes critical to the safety of a product could include, for example, pasteurisation, retorting, fermentation, oxygen exclusion with acidification, refrigeration, modified atmosphere packaging, etc.

DALY (disability adjusted life years). A metric for public health risk (more...).

HACCP: (Hazard Analysis Critical Control Points). HACCP is an approach to food safety management that is almost universally endorsed as the most effective means to minimise food safety risks. The principle, derived from formal “fault analysis”, aims to identify points in a process where failures could occur that would have a critical effect on the quality/safety of the final product. Thus, food production systems are critically examined for steps where control of product safety could be lost and the safe operating limits of these steps are defined, controlled and monitored. By controlling these steps it is considered that product safety is “built in”, rather than determined retrospectively by end-product testing. The approach began to be applied to food manufacture in the 1970s after its development for the NASA moon landings program. The HACCP process is incorporated into the development of Food Safety Plans. More detail can be found at:

http://www.cfsan.fda.gov/~lrd/bghaccp.html or

food business sector: for the purposes of the Framework, a ‘food business sector’ can be defined broadly (e.g. “bakeries”) or narrowly (e.g. “retail bakeries employing less than 5 personnel, and selling from a single outlet only”). Re-definition of the business sector could change the risk classification and, in general, broader groupings will tend to characterise all businesses in that sector at the level of those businesses that have the highest risk. Conversely, more specifically defined business sectors, should result in risk classifications that are more appropriate to more businesses within that sector.

handle: for the purposes of this Framework, “handling” of food is defined as in the Food Standards Code (ANZFA, 2001a) and includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food.

high risk foods†: food that may contain pathogenic microorganisms and will support formation of toxins or growth of pathogenic microorganisms (see ‘potentially hazardous foods’ q.v.). Examples include raw meat, poultry and fish, unpasteurised milk, oysters, tofu, fresh filled pasta, meat pies, frankfurts, cooked rice and lasagne. Using the Framework, business sectors that handle high risk foods will always be classified as Priority 1 or 2.

† This definitions is based on FSANZ ([formerly ANZFA] 2001) definitions. However, whereas FSANZ’s definitions are based on risk under current risk management controls, particularly in relation to the probability of a pathogen being present, the current Framework is based on the inherent potential for pathogen outgrowth and survival, with probability of contamination considered separately.
inherent risk: in the context of this Framework, ‘inherent’ risk relates to the possibility for a food to contain a hazard that could be present at levels that could cause human illness whether due to the nature of the food itself, or the processing and handling it undergoes (more...).

low risk foods†: those that are unlikely to contain pathogenic organisms and will not support their growth (see also ‘potentially hazardous foods’) and are unlikely to contain harmful chemicals or foreign matter. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionary, dried fruit, alcohol and fats and oils.

managed risk: in the context of this Framework, ‘managed’ risk relates to the likelihood that a food contains a hazard at a level that could cause human illness given the various practices and circumstances that relate to its production (more...).

medium risk foods†: those that may contain harmful natural toxins or chemicals introduced at steps earlier in the food supply chain, or that:

- may contain pathogenic microorganisms but will not normally support the formation of toxins or growth of pathogenic microorganisms due to food characteristics; or,
- are unlikely to contain pathogenic microorganisms due to food type or processing but may support the formation of toxins or growth of pathogenic microorganisms.

Examples include fresh fruits and vegetables, orange juice, pasteurised milk, canned foods, salami, vegetables stored in oil, peanut butter, shell eggs, milk-based confectionary and hard-frozen ice cream.

moderate hazard: not usually life threatening (i.e. usually no sequelae (q.v.), illness normally of short duration, symptoms are self-limiting but can cause severe discomfort).

perishable: foods that allow microbial growth and and so will eventually deteriorate and spoil. Typically such foods require storage under refrigeration to extend their shelf life, i.e. foods that are not shelf stable (q.v.), or are potentially hazardous (q.v.).

potentially hazardous food (PHF): By definition (Australian Food Standard 3.2.2.1), “food that has to be kept at certain temperatures to minimise the growth of any pathogenic organisms that may be present in the food or to prevent the formation of toxins in the food”. The term “perishable” has also been used in the past, but PHF could include foods that have to be kept hot (Guidance on the characteristics of PHF).

† These definitions are based on FSANZ (ANZFA, 2001) definitions. However, whereas FSANZ’s definitions are based on risk under current risk management controls, particularly in relation to the probability of a pathogen being present, the current Framework is based on the inherent potential for pathogen outgrowth and survival, with probability of contamination considered separately.
ready-to-eat food: food that is normally consumed in the same state as that in which it is sold (without further cooking or preparation) but does not include nuts in the shell and whole, raw, fruits and vegetables that are intended for hulling, processing, peeling or washing by the consumer.

sequelae: a medical condition (usually chronic) that arises as a consequence of a disease after the initial (acute) symptoms have passed.

serious hazard: incapacitating but not usually life threatening illness; sequelae (q.v.) rare, and of intermediate duration.

severe hazard: causing life threatening illness, or substantial chronic sequelae (q.v.), or illness of long duration.

shelf stable: foods that by virtue of their form, formulation, or packaging can be stored for extended periods (e.g. months or greater) at ambient temperature without significant deterioration of quality.

TCS: abbreviation for “temperature controlled for safety”. This term was proposed by the US Institute of Food Technologists (IFT) in 2001 (IFT, 2003) for defining foods that require time/temperature control for safety. The term was proposed as an alternative to ‘potentially hazardous food” (q.v.) because “the term accurately describes both what is required—temperature control with time implied—and why it is required—safety”.

unit (of food): in the context of this decision tree a typical retail unit of production, or a typical serving portion of food, e.g. a can of foods, a carton of milk, a packet or a fillet of fish, a sausage, etc.
Characteristics of Foods that Allow the Growth of Pathogenic Microorganisms

High risk foods are generally synonymous with a potentially hazardous food, i.e. those that allow the growth of pathogenic microorganisms. However, in some cases preparation and packaging of the product manage the risk to a consistently acceptable level. The Framework relies on existing definitions of high, medium and low risk. Where the risk from the product is unclassified, the following can assist to determine whether growth of pathogens is possible.

Prevention of microbial growth through combinations of temperature, water activity (addition of salt or sugar), acidity and addition of organic acids, heat treatment, specialized packaging, and a relatively narrow range of permitted additives, is a quest of food producers. A goal of food producers, however, is to apply the minimum combination of inhibitory factors that will prevent microbial growth so as to minimize the effects on the sensory properties of the food. In food science, each factor that inhibits microbial growth is termed a “hurdle” and application of the science of minimum combinations of ‘hurdles’ has been termed ‘hurdle technology’. Almost all unprocessed foods are living, or recently killed, living tissue contain all the requirements to support life, including the life of pathogenic organisms.

By definition (Australian Food Standard 3.2.2.), potentially hazardous foods are those that have to “be kept at certain temperatures to minimise the growth of any pathogenic organisms that may be present in the food or to prevent the formation of toxins in the food”. The term “perishable” has also been used in the past, but PHF could include foods that have to be kept hot. In other words, for such foods, so few hurdles to microbial growth exist in the product that temperature control is required to prevent, or at least slow to an acceptable extent, the growth of microorganisms on the product (n.b. many heat-treated, shelf-stable foods, will support microbial growth. The key to shelf–stability is the elimination of microorganisms by the heat treatment, prevention of the outgrowth of survivors and prevention of recontamination through maintenance of packaging integrity).

As noted, food preservation is a fundamental goal of the food industry and the elucidation of novel methods of food preservation is enormous area of research activity. However, different organisms can grow under different environmental conditions and product that may have long shelf lives may still permit the growth of pathogens. Equally, different foodborne pathogens have different growth ranges. In other words, there is no simple set of product formulation factors that can be defined for ‘potentially hazardous foods’.

The chart below (after IFT, 2001) provides a useful first estimate advice on some combinations of pH and water activity which, taken together, are indicative of formulations that will prevent microbial growth. In the Tables, only those combinations that lead to “non-TCS” do not require temperature control for safety (TCS), i.e. pathogen growth is very unlikely. It must be stressed, however, that the presence of additional hurdles could prevent pathogen growth at conditions of pH and water activity that are less severe than those indicated in the Tables.

Tables A and B below list combinations of pH and water activity. If the combination is indicated to be ‘non-TCS’, it means that the product will not need temperature control to maintain its safety. If the combination is denoted by a “?” it indicates that the product is potentially unsafe without refrigeration (n.b. depending on the presence of other hurdles, the formulation could be safe without refrigeration).

If the product of interest has been heat-treated to destroy vegetative microbial cells and has been packaged to avoid recontamination use Table A to ascertain the need for temperature control, otherwise use Table B.

### Table A

<table>
<thead>
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<th>Critical pH values</th>
<th>4.6</th>
<th>&gt; 4.6. to 5.5 (&lt; 5.6)</th>
<th>&gt; 5.6 (&gt; 5.6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical pH value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 0.92 or less</td>
<td>non-TCS</td>
<td>non-TCS</td>
<td>non-TCS</td>
</tr>
<tr>
<td>&gt; 0.92 to 0.95</td>
<td>non-TCS</td>
<td>non-TCS</td>
<td>?</td>
</tr>
<tr>
<td>&gt; 0.95</td>
<td>non-TCS</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

### Table B

<table>
<thead>
<tr>
<th>Critical pH values</th>
<th>4.2</th>
<th>&gt; 4.2. to 5.0 (&lt; 5.0)</th>
<th>&gt; 5.0 (&gt; 5.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical pH value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 0.88</td>
<td>non-TCS</td>
<td>non-TCS</td>
<td>non-TCS</td>
</tr>
<tr>
<td>0.88 to 0.90</td>
<td>non-TCS</td>
<td>non-TCS</td>
<td>non-TCS</td>
</tr>
<tr>
<td>&gt; 0.90 to 0.92</td>
<td>non-TCS</td>
<td>non-TCS</td>
<td>?</td>
</tr>
<tr>
<td>&gt; 0.92</td>
<td>non-TCS</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
Inherent vs. Managed Risk

In the context of this Framework, ‘inherent’ risk relates to the possibility for a food to contain a hazard that could be present at levels that could cause human illness whether due to the nature of the food itself, or the processing and handling it undergoes.

Thus, potentially hazardous foods are inherently riskier than shelf stable products because, should they become contaminated with a pathogen, the potential for the pathogen to reach a disease-causing level is much greater. Similarly ready-to-eat foods could be considered inherently more ‘risky’ because contamination could occur between production and consumption. If the food were not ‘ready-to-eat’ that contamination might be eliminated by peeling, washing, cooking etc. whereas in a ready-to-eat food that additional level of protection would not exist. Equally, products such as fugu are inherently risky.

In practice, however, many local circumstances and non-specific actions can affect the inherent risk. An example would be the absence from Australia (or Australian herds) of many zoonoses, e.g. BSE. While not always specifically managed for food safety reasons, biosecurity measures can affect the risk presented by Australian-produced foods. Similarly, there appears to be a relatively low environmental incidence of type E Clostridium botulinum in Australia aquatic habitats. Another example would be that usage patterns of some agricultural and veterinary products in Australia, or that the subsequent processing (e.g dilution, heating, etc) might preclude those hazards from ever being present at levels that could cause human illness. These conditions affect the inherent risk and should not be ignored in the assessment of risk as noted in the instructions for preparation of this Framework (see P.2).

Accordingly, when prioritising food business sectors according to their contribution to food safety risk, there should be recognition of the shared risk management responsibility of all food business sectors in the “farm-to-fork” chain. Risk prioritisation of a food business sector should consider the ‘managed’ risk, i.e. when other sectors are taking appropriate responsibility for management of some of the risk.

Thus, in the context of this Framework the managed risk relates to the likelihood, under realistic scenarios, that a food contains a hazard at a level that could cause human illness given the various practices and circumstances that relate to its production including current regulatory measures required of other business sectors that handle the product sold by the business.
Descriptors of Foodborne Public Health Risk

Factors that dictate the the risk due to hazards in foods include the severity of the disease caused by the ingestion of the hazard, and also the number of consumers that are exposed to disease causing levels of the hazard in food.

Exposure is a function both of the probability that an individual unit of the food is contaminated, and the number of units of foods produced, related to the scale of production. While there is little direct evidence that the size of businesses within a sector affects the probability that it will produce contaminated food, or be the cause of a foodborne illness (FSA & ME, 2002), it is implicit that a sector that has enterprises that produce larger amounts of food will expose more consumers to harm if a hazard is present and, therefore, represents a higher risk.

The following descriptions of the severity of foodborne hazards are drawn from ICMSF (1986).

**moderate hazard**
- not usually life threatening (i.e. usually no sequelae, illness normally of short duration, symptoms are self-limiting but can cause severe discomfort).

**serious hazard**
- incapacitating but not usually life threatening illness; sequelae rare, and of intermediate duration.

**severe hazard**
- causing life threatening illness, or substantial chronic sequelae, or illness of long duration.

Hazard severity can depend on the inherent nature of the hazard, and the dose ingested. As such, when evaluating hazard severity, the usual disease symptoms associated with a recognisable case of the illness should be the basis of the hazard severity assessment. The usual symptoms could change, for example, if the risk to a specific susceptible population were being assessed. Similarly, if there is a ‘usual’ level of the hazard in the product, the usual disease severity associated with that level of the hazard can be used as the basis of the assessment. An example of this could be methyl-mercury levels in fish of less than a certain size/age.

For the purposes of this Framework, the magnitude of the public health risk will usually depend most heavily on the hazard severity and the likelihood of the hazard being present in the foods at levels that could cause disease in the normal consumers of the product. This is because, as explained elsewhere, disease severity - and in particular long term sequelae or death - can have vastly more influence on public health impact than does exposure.
Quantifying Public Health Risk - the *DALY* concept

Intuitively, we assign greater importance to one, or a few *deaths*, from foodborne illness, or a life-long ailment as a consequence of a foodborne hazard, than we might to a few hundred cases of self-limiting gastroenteritis. Equally, intuitively we are more distressed at the death of a small child from foodborne illness, than we might be by the death of an elderly person or a person already enduring some other life-threatening illness. While, superficially, this may seem an essentially subjective and emotive response, the ‘DALY’ concept offers a rational basis for comparing and balancing the severity of foodborne hazards against the number of people affected by them and which helps explain our intuitive responses.

DALY is an acronym for “Disability Adjusted Life Years”. The concept was originally developed by Murray and Lopez (1996) and adopted by the World Health Organization to inform global health planning (AIHW, 2000). The DALY is a measure of the years of healthy life lost due to illness or injury. One DALY is one year of “healthy” life lost due to sickness or, in extreme cases, death. DALYs are calculated as the sum of years of life lost due to premature death (YLL) and the equivalent years of “healthy” life lost due to poor health or disability (YLD). The YLD considers the number of years that a disability is endured weighted according to the severity of the disability.

Using the DALY concept the outrage associated with the death of babies and children can be seen to have a rational basis because, when an infant dies, their entire potential life is lost. The outrage associated with the death by foodborne disease of an elderly, or critically ill person, might be expected to be less because they are expected to have fewer years of life remaining.

In this scheme, a single infant death might have a value of 70 DALYs, while that of an elderly or severely immunocompromised, person might, for example, equate to 1 - 10 DALYs. Analogously, a case of gastroenteritis of 5 days duration, and resulting in a 50% loss of quality of life for those five days, would equate to ~0.007 DALY. Thus, the public health severity of a single infant death through food poisoning is of the order of 10,000 times greater than that of a foodborne illness that results in self-limiting gastroenteritis. Put another way, the exposure of thousands of people to *Staphylococcus aureus* intoxication might be considered to be of similar magnitude as the death a child from Haemolytic Uraemic Syndrome due to foodborne enterohaemorrhagic *Escherichia coli*.

Thus, the DALY concept provides a way to assess objectively the relative contribution of hazard severity and magnitude of exposure. While the concept has been widely used, a specific example of its use for comparison of the costs of foodborne illness can be found in:

Overview of *Primary Producer* Priority Classifications

**Priority 1**
A primary producer whose product could contain hazards which, if not controlled by the primary producer, could lead to a serious or severe public health risk in foods derived from that product – (e.g. oysters contaminated with Hepatitis A virus).

**Priority 2**
A primary producer whose product could contain hazards which, if not controlled by the primary producer, could lead to a moderate public health risk in foods derived from that product – (e.g. *Salmonella* in broiler chickens).

**Priority 3**
A primary producer whose product could contain hazards that if not controlled at the farm, or harvest site/time, could, at worst, lead to “low” public health risk from foods derived from that product either because:
- the safety hazards that can be controlled ‘on-farm’ induce mild illness only and would only affect a small number of consumers; or,
- the hazard is reliably controlled by normal handling or processing at a subsequent step in the food supply chain – (e.g. game meat harvesters).

**Priority 4**
A primary producer whose product, or a food derived from it under normal conditions of use and handling:
- does not, or could not be anticipated, to contain any known food safety hazard; or
- may contain a hazard that cannot be controlled by actions by the business sector but is reliably controlled by normal handling or processing of the product at a subsequent step in the food supply chain.
Overview of Food Business Sector Priority Classifications

Priority 1 and Priority 2
This classification relates to business sectors that will, characteristically, handle foods that support the growth of pathogenic micro-organisms and where such pathogens are present or could, from experience or literature reports, be expected to be present. Their handling of food will, characteristically, also involve at least one step at which control actions must be implemented to ensure the safety of the food.

Priority 1 business sectors are further characterised by known risk-increasing factors, such as potential for inadequate/incorrect temperature control (e.g. reheating or ‘hot-holding’ of food), a consumer base that includes predominantly immunocompromised populations, the scale of production/service and others factors identified in the *National Risk Validation Project* (FSA & ME, 2002).

Priority 3
Business sectors that will only handle “low risk” or “medium risk” foods. A medium risk food is one that may contain harmful natural toxins or chemicals introduced at steps earlier in the food supply chain, or that:

- may contain pathogenic microorganisms but will not normally support the formation of toxins or growth of pathogenic microorganisms due to food characteristics; or
- is unlikely to contain pathogenic microorganisms due to food type or processing but may support the formation of toxins or growth of pathogenic microorganisms.

Priority 4
Business sectors that will normally handle only “low risk” foods, i.e. those that are unlikely to contain pathogenic organisms and will not support their growth, and will not introduce microbial, physical or chemical hazards to the foods they sell or handle.
There are a range of food processes that, while yielding shelf stable (i.e. medium risk) foods, rely for their safety on processes that are unreliable or are not expected to completely eliminate the hazard. Additionally, there are a number of new, ‘milder’ processing technologies that do not have long history of successful and reliable use. Perhaps the best example of an ‘unreliable’ process is meat fermentation. Numerous studies (see Ross and Shadbolt (2001) for review) have shown that the process of meat fermentation, unless involving high temperature fermentation or heating steps, or extended maturation (‘ripening’) times (e.g. >3 - 4 weeks) achieves only relatively modest (e.g. < 3 log) inactivation of *Escherichia coli*, the potential pathogen of concern. Reliable inactivation of vegetative pathogens in raw milk cheeses (Boor, 2005) in the USA requires at least 60 days of maturation, for reasons similar to the factors that dictate pathogen inactivation in fermented meats.

Examples of potentially unreliable processes include:

- meat fermentation and maturation;
- raw milk fermentation (except for mature cheeses, e.g. cheddars);
- preservation of vegetables in oil;
- novel/emerging technologies without a long history of reliable application:
  - e.g. high pressure processing against *L. monocytogenes*, pulsed electric fields, bacteriophages intended to lyse pathogenic bacteria, etc
- reliance on natural acidity to inactive pathogens in fresh (unpasteurised) fruit juices;
- pathogen inactivation by chlorine rinses or dips;
- pathogen inactivation by acid rinses or dips; and
- bottling vegetables, bulbs and herbs under low acid conditions.
Risk Management Options for Potentially “Unsafe” Products

Products that fall into this category are those for which a serious or severe hazard is considered likely to exist and would not be expected to be eliminated by processes that occur further along the food supply chain and prior to consumption of the product. An example would be dispersed wild-harvested pipi’s or cockles that contain algal paralytic toxins.

As such, the acceptability of the product for sale needs to be considered by assessing the risk that the hazard present, in terms of the likelihood of its presence and the harm that it could cause, (i.e. severity of symptoms suffered by individual victims, and the total number of consumers that might be affected).

To assess that risk, the approach recommended by the CODEX Alimentarius Commission (CAC 2005; Attachment 1: CCFH 05/37/6) is to conduct a Risk Profile. This is an essential first step to guide risk management when there is uncertainty about the degree of risk and what immediate (or provisional) control actions are justified.

The product may be able to be made acceptable by modification of the product formulation or the processing step to achieve control.

Several examples of “potentially unsafe” products are described at the bottom of Table 1 (example classifications of primary production business).
References


FSA & ME (Food Science Australia and Minter Ellison) (2002). National Risk Validation Project. Food Science Australia, North Ryde, NSW, Australia. 124 pp + Appendices.


http://www.medterms.com/script/main/hp.asp for definitions of medical terms

The concept of using decision trees as the basis of a national Australian Priority Classification System was introduced by FSA (2003) in a study coordinated by the Commonwealth Department of Health and Aging with funding provided by the States and Territories. The FSA (2003) report, entitled: “Scoping Study on Food Safety Risk Profiling” took into account those factors identified in National Risk Validation Project (FSA & ME, 2002) as being most frequently associated with foodborne disease outbreaks.

Following a review of that study, the prototype decision tree was refined by the New South Wales Food Authority (NSWFA). The revised decision tree was again independently reviewed and a number of suggestions for improvement nominated.

The Commonwealth Department of Health and Ageing (DoHA) funded this project specifically to develop a high level, national Priority Classification System for ranking of the risk that food business sectors could cause to public health.

The project team includes members of the group that originally proposed the decision tree and produced the prototype, the NSW Food Authority team that developed the next iteration, and the reviewers of both proposed decision trees.
Example Classifications

On the following pages are presented numerous examples of how the Framework can be used to classify food business sectors.

The process of classification is summarised by reporting each question answered. The summary is divided into columns, with each column representing the sequence of answers for each of the four major questions in each of the decision trees.

In most cases, the answer to the question is implicit in the next question answered, but in some cases the answer is indicated by a “Y” (to indicate a “YES” answer) or “N” (to indicate that the answer is “NO”) to make clearer the decision-path to the final classification.

Comments are also provided to make more explicit some of the reasons for answers to particular questions.

A detailed example is presented below for an abattoir processing red meat.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the product intended for human consumption in the form sold by the business sector?</td>
<td>Yes</td>
<td>self evident - despite the product being raw it is in a form that could be eaten without further processing.</td>
</tr>
<tr>
<td>FB1a. Is the food “potentially hazardous”</td>
<td>Yes</td>
<td>product clearly supports microbial growth</td>
</tr>
<tr>
<td>FB2a. Is the product a “high risk” food?</td>
<td>Yes</td>
<td>by FSANZ definition</td>
</tr>
<tr>
<td>FB3a. Is a practical action available to control the hazard?</td>
<td>Yes</td>
<td>temperature control, good slaughter practice</td>
</tr>
<tr>
<td>FB3b. Is the control action(s) critical to the safety of the product sold by the business sector?</td>
<td>Yes</td>
<td>minimisation of pathogen contamination and growth is assumed by subsequent users</td>
</tr>
<tr>
<td>FB3c. Is the Critical Control action potentially unreliable, or could recontamination occur prior to sale by the business sector?</td>
<td>Yes</td>
<td>recontamination could occur, facial matter could be spilt</td>
</tr>
<tr>
<td>FB3d. Does documented evidence exist that the presence of the hazard in the path product is likely to cause frequent or severe human illness?</td>
<td>No</td>
<td>While pathogens in meat cause severe illness, failures at other stages of the farm-to-fork are usually responsible for levels reaching disease causing levels</td>
</tr>
</tbody>
</table>

Thus, in summary:
<table>
<thead>
<tr>
<th>Primary Producer Type</th>
<th>Classification</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetables</td>
<td>Microbial</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Fruits</td>
<td>Microbial</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Dairy</td>
<td>Microbial</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Honey</td>
<td>Microbial</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Fish</td>
<td>Microbial</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Pigs</td>
<td>Salmonella</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Turkeys</td>
<td>Salmonella</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Vegetables</td>
<td>Microbial</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Commercial skyline</td>
<td>Salmonella</td>
<td>a,b,1</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

Table 1. Example Classifications: Primary Producers not selling direct to the public (see P. 12)

Introduction

Food Business DT

Primary Producer DT

Document Map

References

Glossary

QUIT
<table>
<thead>
<tr>
<th>Product</th>
<th>Classification</th>
<th>E. coli</th>
<th>Y. enterocolitica</th>
<th>L. monocytogenes</th>
<th>S. aureus</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef filet</td>
<td>C. jejuni</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>ε</td>
<td>(Y)</td>
</tr>
<tr>
<td>Broilers</td>
<td>Campylobacter</td>
<td>ε</td>
<td>N</td>
<td>N</td>
<td>ε</td>
<td>(Y)</td>
</tr>
<tr>
<td>Sausage bread</td>
<td>Microbial</td>
<td>ε</td>
<td>N</td>
<td>N</td>
<td>ε</td>
<td>(Y)</td>
</tr>
<tr>
<td>Diagnosed nonbacterial endocarditis</td>
<td>MRSA</td>
<td>ε</td>
<td>N</td>
<td>N</td>
<td>ε</td>
<td>(Y)</td>
</tr>
</tbody>
</table>

Table 1. Example Classifications: Primary Producers (cont.)
Table 2. Example Classifications: Food Business Sectors (part 1)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic Red Meat</td>
<td>Microbial</td>
<td>a</td>
<td>x</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Alcoholic Poultry Meat</td>
<td>Campylobacter</td>
<td>a</td>
<td>x</td>
<td>a,b,c,d,e,f,g,h (Y)</td>
<td>a,b,c,d,e,f,g,h (Y)</td>
</tr>
<tr>
<td>Alcoholic Spirit</td>
<td>Chemical</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Baby food (pasteurized, frozen)</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Baby Formula</td>
<td>Salmonella</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Baby 1 cereal (flour only)</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Baby 2, infant formula, milk, yogurt</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Infant rice (dry)</td>
<td>Microbial and chemical</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Pasteurized milk, milk powder</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Pasteurized water</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Processed food</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Carbonated beverage</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Cider</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Conventional</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Conventional</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Conventional</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Cheddar</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Cheddar</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Crackers, sausage, cheese, meats</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
<tr>
<td>Crackers, sausage, cheese, meats</td>
<td>Microbial</td>
<td>a,b,c,d</td>
<td>a,b,c,d</td>
<td>a,b,c,d (N)</td>
<td>a,b,c,d (N)</td>
</tr>
</tbody>
</table>

If in ‘pps’ mode, click here for a larger version of the above Table.

If in ‘pps’ mode, click here for a larger version of the above Table.

more examples ...
# Table 2. Example Classifications: Food Business Sectors (part 2)

<table>
<thead>
<tr>
<th>Processor/Marshaller</th>
<th>Mammalian</th>
<th>Plant</th>
<th>Invertebrate</th>
<th>Fish</th>
<th>Microbial Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eggs, Chicken</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
<tr>
<td>Eggs, Poultry</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
<tr>
<td>Vegetables, fish</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>35°C</td>
</tr>
<tr>
<td>Milk</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
<tr>
<td>Glass</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
<tr>
<td>Paper</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
<tr>
<td>Wood</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
<tr>
<td>Plastic</td>
<td>m</td>
<td>m</td>
<td>m</td>
<td></td>
<td>n, 35°C (Y)</td>
</tr>
</tbody>
</table>

If in 'pps' mode, click here for a larger version of the above Table.
### Example Classifications: Food Business Sectors (part 3)

#### Table 2.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Example Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic Drinks</td>
<td>Malt whisky; malt beer; malt ale (6)</td>
</tr>
<tr>
<td>Beverages</td>
<td>Soft drinks; fruit juices (6)</td>
</tr>
<tr>
<td>Meat</td>
<td>Sheep meat; beef; pork (6)</td>
</tr>
<tr>
<td>Poultry</td>
<td>Chicken meat; turkey meat (6)</td>
</tr>
<tr>
<td>Seafood</td>
<td>Fish; shellfish (6)</td>
</tr>
<tr>
<td>Primary Producer</td>
<td>Wheat; rice; cotton (6)</td>
</tr>
<tr>
<td>Processed Food</td>
<td>Biscuits; cookies; candy (6)</td>
</tr>
<tr>
<td>Fresh Produce</td>
<td>Fruit; vegetables (6)</td>
</tr>
</tbody>
</table>

**Introduction**

Food business sectors encompass a wide range of activities, from primary production to distribution and marketing. Each sector requires specific knowledge and skills, and regulations vary by country and region. Understanding the dynamics within each sector is crucial for effective business operations. This table provides a snapshot of the various classifications within the food business sphere.

**Glossary**

- **Food Business DT**: Description of the food business sector.
- **Glossary**: List of terms and definitions relevant to the food business sectors.
- **References**: Sources and further reading on the topic.

**References**

For more detailed information, refer to the sources listed in the references section.

---

*If in ‘pps’ mode, click here for a larger version of the above Table.*
Table 2. Example Classifications: *Food Business Sectors* (part 4)

<table>
<thead>
<tr>
<th>Food Business Sectors</th>
<th>Category (1, 2)</th>
<th>National/Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food Safety</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary Producer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Document Map</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>References</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If in ‘pps' mode, click here for a larger version of the above Table.
# Architecture of the Framework: Contents of Pages

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<th>Page</th>
<th>Content</th>
</tr>
</thead>
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<td>Introduction</td>
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<td>3</td>
<td>About the Framework: Format and Navigation</td>
</tr>
<tr>
<td>4</td>
<td>About the Framework: Document Layout</td>
</tr>
<tr>
<td>5</td>
<td>About the Framework: Philosophy and Approach to Development of the Framework</td>
</tr>
<tr>
<td>6</td>
<td>Using the Framework</td>
</tr>
<tr>
<td>7</td>
<td>Primary Producer Decision Tree</td>
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<td>8</td>
<td>Primary Producer Decision Tree: Description of Priority Levels</td>
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<td>9 - 10</td>
<td>Food Business Sector Decision Tree</td>
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<td>Decision Tree Selection</td>
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<tr>
<td>12</td>
<td>Help for Decision Tree Selection</td>
</tr>
<tr>
<td>13</td>
<td>Primary Producer Priority Risk Classification Decision Tree</td>
</tr>
<tr>
<td>14</td>
<td>Food Business Sector Priority Risk Classification Decision Tree</td>
</tr>
<tr>
<td>15 - 21</td>
<td>Help for Primary Producers PCS Decision Tree Questions</td>
</tr>
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<td>22 - 25</td>
<td>Decision Sub-Trees for Food Business Sectors</td>
</tr>
<tr>
<td>26 - 32</td>
<td>Help for Food Business Sector PCS Decision Tree Questions</td>
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<td>33 - 35</td>
<td>Glossary</td>
</tr>
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<td>Characteristics of Foods that Allow the Growth of Pathogenic Microorganisms</td>
</tr>
<tr>
<td>37</td>
<td>Inherent vs. Managed Risk</td>
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<td>38</td>
<td>Descriptors of Foodborne Disease Severity</td>
</tr>
<tr>
<td>39</td>
<td>Quantifying Public Health Risk - the DALY Concept</td>
</tr>
<tr>
<td>40</td>
<td>Overview of Primary Producer Priority Classifications</td>
</tr>
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<td>41</td>
<td>Overview of Food Business Sector Priority Classifications</td>
</tr>
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<td>42</td>
<td>“Potentially Unreliable” Hazard Reduction Processes</td>
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<td>43</td>
<td>Risk Management Options for Potentially Unsafe Products</td>
</tr>
<tr>
<td>44</td>
<td>References</td>
</tr>
<tr>
<td>45</td>
<td>Acknowledgements</td>
</tr>
<tr>
<td>46</td>
<td>Example Classifications - Introduction</td>
</tr>
<tr>
<td>47 - 48</td>
<td>Table 1: Example Classifications: Primary Producers</td>
</tr>
<tr>
<td>49 - 52</td>
<td>Table 2: Example Classifications: Food Business Sectors</td>
</tr>
<tr>
<td>53 - 56</td>
<td>Architecture of the Framework</td>
</tr>
</tbody>
</table>
Architecture of the Framework: Complete Decision Tree

Enlarge Food Business Sector Decision Tree

Enlarge Primary Producer Decision Tree

Introduction  Food Business DT  Primary Producer DT  Document Map  References  Glossary  QUIT
Architecture of the Framework: Primary Producer Decision Tree