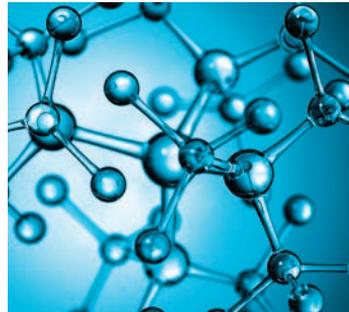
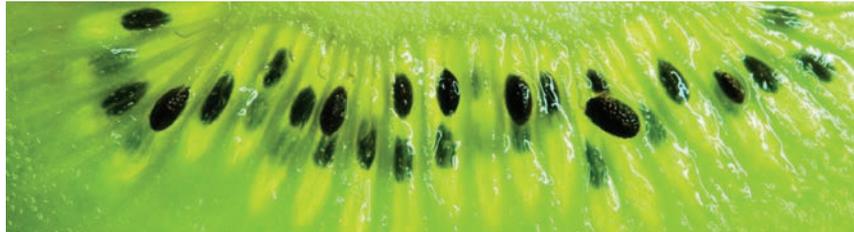


Case studies



8 Case studies

Risk analysis provides a structured framework for examining and assessing public health and safety risks associated with food. However, the broad range of potential risks in different types of food requires that the risk analysis approach be sufficiently flexible in identifying and managing such risks. This is illustrated in the following case studies.

8.1 Approval to use the food additive Advantame

Assessing an application for a new food additive

8.1.1 The regulatory problem

In 2009, an application was received to amend Standard 1.3.1 – Food Additives in the Code. The Applicant sought approval to use Advantame, a new intense sweetener, in a range of foods and beverages. These included table top sugar substitutes (powdered only) and a range of powdered beverages including fruit flavoured drinks, milks and flavoured milk drinks, instant tea and coffee, and protein drinks. The Applicant advised FSANZ that the purpose of using Advantame as a food additive would be to provide assistance to people as part of their weight management or weight loss regime by lowering the calories in foods while maintaining flavour.

FSANZ was required to conduct a pre-market safety assessment under Standard 1.3.1 of the Code, before Advantame could be sold in Australia or New Zealand. At the time the application was received, no other country had completed a toxicological assessment. Therefore no acceptable daily intake (ADI) for Advantame had been established.

8.1.2 The risk

FSANZ conducted a comprehensive risk assessment. This included an independent evaluation of more than 50 detailed toxicity studies, including studies on kinetics, metabolism, acute toxicity, repeat-dose toxicity, genotoxicity, immunotoxicity, reproductive toxicity and developmental toxicity. Four human studies were also evaluated. The toxicity of Advantame was well characterised based on the extensive database. An ADI of 5 milligrams per kilogram of body weight per day (mg/kg bw/day) was established.

FSANZ sought an external peer review of the toxicological report. The reviewer concurred with FSANZ's conclusions and commented that FSANZ's evaluation was scientifically defensible.



Food additive permissions in the Code apply to food produced or sold in both Australia and New Zealand. Therefore a dietary exposure assessment was conducted for both countries using food consumption data reported in the 1995 Australian National Nutrition Survey, the 1997 New Zealand National Nutrition Survey and the 2007 Australian National Children's Nutrition and Physical Activity Survey.

To enable the dietary exposure assessment to be conducted, the Applicant provided proposed maximum levels of Advantame likely to be used as a sugar replacement in the range of food products requested. Where permission to add Advantame at certain concentrations to specific foods was proposed, the whole group of foods to which the specific food belongs was included in the dietary exposure assessment and assumed to contain Advantame at that concentration. For example, while permission was requested to add Advantame to 'powdered flavoured milk drinks' the category of 'liquid milk products and flavoured liquid milks' was included in the assessment. Overall, this resulted in a much broader range of foods being included in the assessment than had been requested and consequently a highly conservative estimate of dietary exposure was made.

Despite the conservative nature of the dietary exposure assessment, the estimated dietary exposures were well below the ADI of 5 mg/kg bw for all groups of Australian and New Zealand consumers assessed (including children). On this basis, FSANZ concluded that there were no public health and safety issues for Australian and New Zealand consumers associated with the proposed addition of Advantame to food.

8.1.3 The response

Although there were no public health and safety issues associated with the proposed addition of Advantame to food, FSANZ considered two options to ensure its appropriate use. The first option involved establishing maximum permitted levels in Schedule 1 of Standard 1.3.1 of the Code. The second option was to give approval for Advantame use according to Good Manufacturing Practice (GMP) in Schedule 2 of Standard 1.3.1.

Schedule 1 permissions usually apply when the risk assessment determines that an exceedance of the ADI could be possible for a population group and it would be appropriate to restrict levels of the food additive in foods. However, FSANZ calculated that a 60 kg person would have to consume 300 mg Advantame/day to exceed the ADI of 5 mg/kg bw. As Advantame is 20,000 times sweeter than sucrose, this would be equivalent to a consumption of 6 kg of sucrose per day. A 19 kg child would have to consume the equivalent of 1.9 kg of sucrose per day, which is unrealistic in the context of a normal diet.



Therefore, FSANZ concluded that the second option, to recommend GMP permissions for Advantame in Schedule 2 of Standard 1.3.1, would be the most appropriate option because:

- the risk assessment found there was no specific risk that needed to be managed by setting maximum permitted levels in foods
- it would allow Advantame to be used in a wider range of food preparations to suit a variety of broader food applications
- due to the intense sweetness of Advantame, which means that only minimal amounts are needed to sweeten foods, the use of Advantame is self-limiting
- when used at the levels proposed by the Applicant, the dietary exposure for the highest consumer was well below the ADI.

General labelling requirements in the Code, including the mandatory declaration of food additives, would ensure that adequate information regarding foods containing Advantame would be provided to consumers. Advantame would need to be declared in the ingredient list by its food additive class name 'sweetener' followed by its specific name or food additive number.

8.1.4 Communication

The application was assessed as a Major Procedure, requiring a minimum of two rounds of public comment. Public submissions were invited on each of the two assessment reports. FSANZ took all submitters' comments into consideration in completing the assessment and reaching its conclusions.

On gazettal of the new food regulatory measure, FSANZ notified the public through its food standards notification circular, public notices and publication in newspapers.

Due to intermittent media and consumer interest on sweeteners generally, FSANZ continues to publish and update information about the use of intense sweeteners in the food supply.



8.2 Cyanogenic glycosides in cassava-based snacks

Responding to an incident of a naturally occurring toxicant in food

8.2.1 The regulatory problem

Cassava (*Manihot esculenta* Crantz) is a hardy plant that is an important food source in some developing countries. Cassava contains compounds called cyanogenic glycosides, which can cause potential health risks to consumers. These are naturally occurring sugars that have cyanide in their structure. The main cyanogenic glycoside in cassava is linamarin (93%). A small amount of lotaustralin (7%) is also present.

In January 2008, Japanese authorities notified Australia that the cyanogenic glycoside concentrations in a cassava-based snack food manufactured in New South Wales were higher than normal and 'a danger to damage human health' (translation). At the time this issue emerged, a standard for cassava-based snack food did not exist in Australia. Within 24 hours of notification being received from Japan, the National Food Incident Response Protocol was activated. This case study demonstrates that the general principles of risk analysis can still apply in responding to rapidly emerging issues, although time constraints may affect the sequence of events and depth of information that can be obtained and assessed.

8.2.2 The risk

It is important to process cassava appropriately before consumption to reduce the levels of cyanogenic glycosides. If it is not adequately processed, it can retain high levels of cyanogenic glycosides which are broken down by gut microflora in humans to form hydrogen cyanide (or hydrocyanic acid, HCN). Processing methods include peeling, grating, soaking in water and mild heat treatment. Processing allows the natural conversion of linamarin to HCN, which due to its volatility, is released into the air.

Symptoms of acute toxicity include headaches, dizziness, stomach pain or mental confusion. In developing countries where cassava is a staple food, toxicity has also been implicated in the aetiology of several chronic diseases including Konzo, a motor neuron disease affecting legs, arms and speech and tropical ataxic neuropathy (TAN), characterised by symptoms affecting the mouth, eyesight, hearing or gait, mainly of older people.

Using available toxicity studies on linamarin, FSANZ was able to establish an acute reference dose (ARfD) for linamarin of 0.7 mg/kg bw. This was based on death in hamsters at doses greater than 70 mg/kg bw. A 100-fold inter and intra-species safety factor was applied. This ARfD was converted to an ARfD for total HCN of 0.08 mg/kg bw.



As a follow-up to the testing of Australian-made products done by Japan, Australia sampled and analysed a total of 300 samples of domestically produced and imported cassava-based snack foods (i.e. ready-to-eat cassava chips). While there were equally high levels of total HCN found, results also showed significant variation in the levels (<10–145 mg/kg).

A dietary exposure assessment was conducted using the concentration data obtained from the 300 products surveyed and consumption data reported in the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey. As consumption of ready-to-eat cassava chips was not reported separately, consumption data for equivalent salty snacks was used, assuming that consumption amounts for cassava-based snacks would be similar.

Two types of dietary exposure assessment were conducted: deterministic and probabilistic. The results of the deterministic dietary exposure assessment were compared with the ARfD. The mean concentration of total HCN of 63 mg/kg could result in dietary exposures above the ARfD for all groups assessed. Children 2–4 years of age showed the highest risk of exceeding the ARfD. At the minimum concentration of 10 mg/kg, 2–4 year old children remained at risk.

When compared to the ARfD, the results of the probabilistic exposure assessment indicated that, at the mean concentration of total HCN of 63 mg/kg, the likelihood of 2–4 year old children exceeding the ARfD was 56%. At the minimum concentration of 10 mg/kg, the likelihood decreased to 2–4%.

As HCN has a short half-life, there was an additional consideration whereby the consequences of exceeding the ARfD was also dependent on whether exposure occurs in one sitting or over the course of a day. However, the 97.5th percentile consumption of salty snacks for 2–4 year olds was estimated at around 100 g. It was reasonable to assume that this quantity could be easily consumed in one sitting.

The results of the assessment indicated that inadequate processing of raw cassava could result in there being detectable levels of total HCN remaining in ready-to-eat cassava chips. Even the lower end of the total HCN concentrations detected in a range of products available in Australia might present a public health risk, with children of 2–4 years of age being at most risk.



8.2.3 The response

The National Food Incident Response Protocol provides a framework for coordinating timely and appropriate action in Australia, in response to a national food incident. Preliminary toxicological expert advice indicated that at the levels detected by Japan, consumption of between 100–200 g might manifest in mild symptoms. The manufacturer of the product was informed and agreed to voluntarily recall the product in question.

In February 2008, a preliminary risk assessment was completed by FSANZ using a guidance level of 25 mg/kg (this risk assessment was later refined as described in Section 8.2.2 above). Manufacturers and importers of products found to have concentrations above 25 mg/kg were advised that these levels were not acceptable and asked to consider a course of remedial action. Most companies responded by voluntarily withdrawing their product.

Significant variability in levels of total HCN in ready-to-eat cassava chips had been observed, even between different batches of the same product. Stronger controls over ingredients and processing practices would help to ensure levels of total HCN were maintained as low as reasonably achievable.

FSANZ prepared Proposal P1002 – Hydrocyanic acid in ready-to-eat cassava chips to assess the public health risks associated with HCN in these products. In June 2009, and following a balanced consideration of public submissions received, an ML of 10 mg/kg for total HCN in ready-to-eat cassava chips was established in Standard 1.4.1 of the Code. In addition, upon risk assessment advice from FSANZ, the Department of Agriculture instituted testing of imported products at the border.

8.2.4 Communication

Initial risk communication messages to the public were in the form of media releases issued by jurisdictions across Australia. Messages were formulated based on the analytical results for total HCN in cassava chip products available at that stage of the incident. Consumers, especially children, were advised to avoid eating large quantities of cassava-based chips/crackers.

Follow up materials were produced for the FSANZ website with more of a focus on advice regarding cooking raw cassava and advice about the limits set in the Code for cassava chips.



8.3 Methylmercury in fish

Monitoring contaminants and re-evaluating our risk assessment as new data becomes available

8.3.1 The regulatory problem

Mercury is a heavy metal released into the environment from a range of natural and man-made sources. Methylmercury (an organic form of mercury) is formed from inorganic mercury by microbial action in aquatic systems (both fresh and marine water), sediments and soils. Methylmercury enters and accumulates in the aquatic food chain, with predatory and long living species higher up the food chain accumulating higher levels. These species include marlin, swordfish and shark.

The consumption of fish and seafood is the major source of human exposure to methylmercury in most populations. Methylmercury levels will differ significantly across different fish species. Typical levels in some types of fish can cause potential health risks to consumers. The developing foetus is thought to be at particular risk from methylmercury exposure due to the toxic effects of methylmercury on foetal brain development.

At its 61st meeting in June 2003, JECFA re-assessed mercury and revised the PTWI for methylmercury from a level of 3.3 micrograms per kilogram of body weight per week ($\mu\text{g}/\text{kg}$ bw/week) to 1.6 $\mu\text{g}/\text{kg}$ bw/week. The new level was considered safe for the developing foetus. This prompted FSANZ in 2003 to re-evaluate its risk assessment for mercury. FSANZ had evaluated mercury in 2000 as part of Proposal P157 – Metal contaminants in food. At that time, FSANZ determined that the most effective risk management strategy would be to provide advice to pregnant women and women intending to become pregnant on the amounts and types of fish that could be safely consumed. This advice needed to be updated based on the revised PTWI, and this formed the basis of the updated risk assessment.

8.3.2 The risk

The toxic effects of methylmercury in humans are well documented. Methylmercury is readily absorbed following ingestion and can induce toxic effects in several organ systems. However, the nervous system (central and peripheral) is the most sensitive to methylmercury toxicity, with the developing nervous system the most vulnerable.

In 2003, following the JECFA review, FSANZ re-evaluated its risk assessment for mercury. A dietary exposure assessment was undertaken using more recent analytical data on mercury concentrations in fish, which had become available subsequent to Proposal P157, and consumption data reported in the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey. The revised risk assessment also considered



specific mercury concentrations and consumption levels for specific types of fish and other seafood, whereas for the previous assessment, there were two concentrations used for two groups of fish determined as predatory and non-predatory.

Various scenarios were assessed to estimate dietary exposure to methylmercury. The first scenario used all of the analytical data on mercury concentrations, including concentrations exceeding MLs in the Code. This scenario assessed the assumption that strict enforcement of fish exceeding MLs did not take place. Other scenarios were run to assist in determining whether lowering the MLs in the Code could decrease the dietary exposure. For example, one scenario excluded concentration data points above 1 mg/kg (the higher ML for fish in the Code). Another scenario excluded concentration data points above 0.5 mg/kg (the lower ML for fish in the Code)²⁷.

For this assessment, two PTWI levels were used to reflect different sensitivities in the population to the toxic effects of methylmercury. The lower level of 1.6 µg/kg bw was applied to women of childbearing age (as a proxy for pregnant women and women intending to become pregnant). A FSANZ review of the toxicological data determined that a PTWI of 3.3 µg/kg bw was applicable for use for the rest of the population including children.

The potential risk to public health of methylmercury exposure was established by comparing the dietary exposure estimates for the Australian and New Zealand populations to their respective PTWIs. For most population groups in Australia and New Zealand, the estimated dietary exposures were below the PTWI, and only exceeded the PTWI in the worst case scenario i.e. where concentrations below the level of detection ('Not Detected') are assigned a concentration equal to the Limit of Reporting (LoR). For those with high exposures to methylmercury (i.e. those at the top 5% of exposures), the estimated dietary exposures exceeded the PTWI for all Australian population groups assessed but none of the New Zealand population groups. This is due to differences in the types of fish consumed in the two countries. There were similar results when concentration data above 1 mg/kg or 0.5 mg/kg were excluded from the exposure assessment.

Based on these results, it was determined that some risk management was still needed and the number of serves of each species of fish that could be consumed without exceeding the HBGV was calculated per week, fortnight or month for each relevant population group. Revised consumption advice was generated for each specific type of fish using specific concentrations, as opposed to the advice based on two types of fish given previously.

²⁷ FSANZ sets maximum levels for mercury in fish in Standard 1.4.1 of the Code. An ML of 0.5 mg/kg has been set for most fish excluding the following: gemfish; billfish (including marlin); southern bluefin tuna; barramundi; ling; orange roughy; rays and all species of shark, for which an ML of 1 mg/kg has been set. The ML can be used to restrict the sale and consumption of fish that does not fall within the established limit.



8.3.3 The response

The risk management of methylmercury exposure is complex as the risks associated with exposure to methylmercury through the consumption of certain types of fish must be considered noting also the benefits of consuming fish as part of a healthy diet.

Fish consumption has many nutritional benefits. Fish are considered a good source of protein, omega 3 fatty acids and iodine. Fish are also low in saturated fat. As a result, fish consumption is often encouraged by health professionals. In considering the risks and benefits, the aim was to restrict the level of methylmercury in fish to protect public health and safety, while not setting the levels so low so as to restrict the availability of fish in the marketplace (and their concomitant nutritional benefits).

In relation to risk management options following the revised risk assessment, it was noted that the level of mercury in the fish is difficult to control in their natural environment, and MLs for mercury were already in place in the Code. It was determined that providing revised advice to the population (and, in particular pregnant women and women intending to become pregnant) on fish consumption would be the best way of managing potential health risks of methylmercury in fish.

Methylmercury in fish has been a known hazard for many years and is the subject of previously completed risk analyses at the international level. In 2010, a Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption was held to examine the health risks associated with methylmercury and other chemical contaminants in fish and the health benefits of fish consumption. The work outlined in this case study precedes this expert consultation and further consideration of the HBGVs by the Codex Committee on Contaminants in Food (CCCF). This case study illustrates that risk management responses need to be reviewed and updated as new scientific evidence becomes available, particularly for vulnerable population sub-groups such as pregnant women, children and consumers with high levels of fish consumption. It further illustrates the cyclic nature of the risk analysis process and also demonstrates that food-related health risks may be addressed through a mix of regulatory and non-regulatory interventions.

8.3.4 Communication

An advisory statement on mercury in fish, detailing the number of serves of different types of fish pregnant women and women planning pregnancy could safely consume was first issued by FSANZ in 2001.



Following the re-evaluation in 2003, the risk management approach included revised consumer information. The advisory statement again targeted pregnant women and women intending to become pregnant, providing advice on four specific species of fish that should be consumed in limited quantities only, while also highlighting the nutritional benefits from eating fish. Advice was also added at this time for the general population, including children. The advice was published on the FSANZ website and was distributed to key health professionals (e.g. doctors, dietitians) and the fishing industry for their information. In addition, FSANZ developed a fact sheet targeted to health professionals and others requiring further technical information on mercury, the risk assessment and the development of the consumer advice brochure.

A number of jurisdictions in Australia have also provided advice on fish and mercury.

8.4 Approval to add calcium to several non-dairy foods

Assessing the risks and benefits associated with voluntary nutrient fortification

8.4.1 The regulatory problem

In 2001, an application was received to amend Standard 1.3.2 – Vitamins and Minerals. The applicant sought permission for the voluntary addition of calcium to: fruit- and vegetable juices; fruit- and vegetable drinks; fruit cordial (later withdrawn); soups; and savoury biscuits. The applicant sought permission to add calcium at a level that would allow a claim of good source of calcium, that is, 25% of the calcium RDI per reference quantity²⁸ (similar to a serving) of the food.

Vitamins and minerals are not permitted to be added to general purpose foods unless the addition of the specific vitamin or mineral is permitted in Standard 1.3.2. At the time, Standard 1.3.2 permitted the voluntary addition of calcium to breakfast cereals and most dairy products but not to non-dairy foods.

8.4.2 The risk

The identified public health and safety risks associated with calcium addition to the requested range of foods included:

- over-consumption of the nutrient in multiple foods
- the displacement of other more nutritious foods already in the food supply
- other behavioural changes.

28 As defined in clause 1 of Standard 1.3.2.



At the time the application was received, nutritional risk analysis, incorporating an assessment of both the risks and benefits associated with the addition of a nutrient, was still a developing area of work. Specifically, our assessment considered the:

- suitability of the nutrient for potential fortification
- existing inadequacy of calcium intakes of the total population and population sub-groups
- risk of excess calcium intake for the total population and population sub-groups
- suitability of the foods proposed to be fortified
- risk of dietary displacement (i.e. increased consumption of fortified foods in place of natural sources of calcium, such as milk)
- risk of nutrient deficits or imbalances resulting from milk substitution, specifically in relation to riboflavin and zinc
- potential for increase in sugar consumption, specifically risk of dental caries and over-nutrition
- risk of calcium not being bioavailable in the requested foods.

FSANZ assessed the inadequacy of calcium intakes of the total population and population sub-groups and found that about one third of the Australian and New Zealand populations had inadequate calcium intakes, in particular Australian and New Zealand adolescent and adult females, non-dairy consumers and New Zealand Maori.

The risk of people consuming excessive amounts of calcium from a diet containing calcium-fortified foods was considered minimal. The main concern about dietary displacement was whether calcium-fortified fruit- and vegetable juices and drinks would displace milk in the diet. However, an independent survey of 1200 Australians as well as overseas data indicated minimum risk of long-term substitution of calcium-fortified beverages for milk, because these beverages were considered to be sufficiently different from milk in nutrient profile, taste and usage. In addition, FSANZ modelled a 'worst-case' scenario assuming a 50% reduction in milk consumption due to substitution with calcium-fortified non-dairy beverages, which showed only a small decrease in the intake of nutrients obtained from milk such as riboflavin and zinc.



8.4.3 The response

FSANZ approved draft variations to Standard 1.3.2 to permit the voluntary addition of calcium to fruit- and vegetable juices and drinks, soups and savoury biscuits, up to a maximum claim per reference quantity of 25% RDI, equivalent to a 'good source' claim.

During the assessment of this application, a new policy guideline on the *Fortification of Food with Vitamins and Minerals*²⁹ was developed by the then Australian and New Zealand Food Regulation Ministerial Council. The release of the guideline prompted further consideration of whether the proposed fortification would:

- promote consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand (i.e. reduce milk consumption and increase fruit juice consumption)
- promote increased consumption of foods high in sugar, salt and fat.

Stakeholders had particular concerns about: the suitability of the foods proposed to be fortified; their potential to displace other foods and nutrients in the diet; and that the fortification itself could mislead consumers as to the foods' nutritional quality. FSANZ addressed these issues by seeking additional information from key stakeholders, undertaking further assessments and engaging expertise to assist in examining the likely impact of the proposed calcium-fortified foods on food consumption patterns.

Further work was also undertaken to address the concern that calcium claims on the label could mislead consumers about the nutritional quality of fortified foods. The potential risk of consumers perceiving fortified foods to be 'healthier' than unfortified counterparts was acknowledged. Labelling requirements at the time were considered sufficient to provide consumers with adequate information on the presence and total amount of calcium in foods. Any possible risk of consumers being misled from label claims was considered to be outweighed by the potential benefit derived from additional sources of calcium in the diet.

8.4.4 Communication

There were two calls for public comment during the assessment of this Application. Submissions were received from a variety of stakeholders including government enforcement agencies, food manufacturers and health professionals. The comments raised in submissions were taken into consideration in completing the assessment and reaching its conclusions.

²⁹ Ministerial Policy Guideline on the *Fortification of Food with Vitamins and Minerals* is available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines#5>



Initial messages were targeted to dietetic and health professionals. FSANZ also notified the public of its decision to permit calcium to be added to the requested foods through its food standards notification circular, public notices and through the media. Follow up materials were produced for the website to support education initiatives to help raise awareness of general labelling information and the role of fortified food in the diet.

8.5 Raw milk products

Using risk analysis to develop a regulatory framework to support the safe production of raw milk products

8.5.1 The regulatory problem

Requirements for the primary production of milk and processing of dairy products specified in the Code essentially specify that dairy products sold in Australia must be pasteurised. In recent years, however, permissions have been given for a small number of raw milk cheeses following risk assessment work that demonstrated that these products would present a low risk to public health and safety with implementation of appropriate milk production and processing controls.

Rather than continue with a case-by-case assessment of specific raw milk cheeses, a risk analysis approach was taken to develop a through-chain regulatory framework that would support the safe production of raw milk products.

8.5.2 The risk

A wide range of microbiological hazards may be associated with raw milk. If these hazards are not managed, all raw milk products can present a high level of risk to public health and safety. The level of risk posed can be reduced by implementing production and processing controls. A number of qualitative and quantitative risk assessments identified the:

- milk production factors that impact on the prevalence of pathogens in raw milk
- factors that have the greatest contribution to pathogen control during cheese manufacture (the primary raw milk product)
- key parameters for determining pathogen reduction, and conditions for growth and no growth
- level of risk associated with each category.



Product	Process and product criteria	Performance criteria	Level of risk
Category 1	<p>Process and product criteria contribute to elimination of pathogens.</p> <p>For cheese:</p> <ul style="list-style-type: none"> • curd cooking at >48°C • extended ripening (≥120 days) at ≥10°C • moisture content ≤39% 	Combination of control measures used during manufacture must provide for a net 5 log reduction of pathogens.	Very low
Category 2*	<p>Process and product criteria must not support pathogen survival and growth.</p> <p>For cheese:</p> <ul style="list-style-type: none"> • rapid acidification • minimum ripening period and temperature • inhibitory pH/salt in moisture profile 	Combination of control measures used during manufacture must ensure no net increase of pathogens.	Low
Category 3	Processing factors do not prevent pathogen survival and intrinsic characteristics of the final product do not inhibit pathogen growth.	Not established.	Medium to high

* The potential pathogen load of raw milk used for the manufacture of Category 2 products is a critical factor. The raw milk needs to meet a stringent level of microbiological quality, achieved through additional on farm controls and verification testing.

8.5.3 The response

Three categories of raw milk products were defined based on the effect that processing factors and final product properties have on pathogen survival and growth.

Category 3	Pathogens survive production process. Final product supports growth.	 <p>Increasing level of risk</p>
Category 2	No net increase of pathogens during production. Final product does not support growth.	
Category 1	Pathogens are essentially eliminated during production (net 5 log reduction).	



Given the increased potential for pathogens to be present, the food safety risk associated with each category increases from Category 1 to Category 3. This category approach provides the basis to determine what raw milk products could be permitted ('approved raw milk products') and what on farm and processing control measures need to be implemented to support their safe production.

8.5.4 Communication

There is strong consumer, industry and regulatory interest in potential permissions for raw milk products. There is a balance between protecting public health and safety, facilitating trade and addressing consumer demand which must be founded on robust scientific assessment. Communicating the approach being taken for assessing raw milk products and the decisions made requires the ongoing provision of clear messages which explain the science, generally delivered in materials such as fact sheets.

FSANZ has provided website information and regular updates about its work. Social media is also one of a suite of tools, which includes FSANZ publications, used to communicate this work. Media releases and regular contact with the media about the issue have also been valuable in confirming the messages about this proposal.

FSANZ's assessment of raw milk products has been progressed through Proposal P1007 – Primary Production and Processing Requirements for Raw Milk Products and Proposal P1022 – Primary Production and Processing Requirements for Approved Raw Milk Products. This work is available on the FSANZ website:

<http://www.foodstandards.gov.au/code/primaryproduction/Pages/default.aspx>.

