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Food Safety Risk   
Assessment of NSW Food   
Safety Schemes

March 2009

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Abbreviations   
aw

Water activity

ABARE

Australian Bureau of Agricultural and Resource Economics

ABS

Australian Bureau of Statistics

ACMF

Australian Chicken Meat Federation

ACMSF

Advisory Committee on the Microbiological Safety of Food (UK)

AECL

Australian Egg Corporation Limited

ANZDAC

Australia New Zealand Dairy Authorities Committee (formerly   
ADASC)

AMRA

Australian Milk Residue Analysis Survey

APL

Australian Pork Limited

APVMA

Australian Pesticide and Veterinary Medicines Authority

ASP

Amnesic Shellfish Poisoning

ASQAP

Australian Shellfish Quality Assurance Program

ATDS

Australian Total Diet Survey/Study

APVMA

Australian Pesticides and Veterinary Medicines Authority

AQIS

Australian Quarantine and Inspection Service

BSE

Bovine Spongiform Encephalopathy

BTEC

Brucellosis and Tuberculosis Eradication Campaign

CAC

Codex Alimentarius Commission

cfu

Colony forming unit

CFR

Code of Federal Regulation (US)

CJD

Creutzfeldt-Jakob Disease

DAFF

Department of Agriculture Fisheries and Forestry (Australian Government) (formerly AFFA)

DFSV

Dairy Food Safety Victoria

DSP

Diarrhoetic Shellfish Poisoning

EFSA

European Food Safety Agency

EHEC

Enterohaemorrhagic E. coli

ERL

Extraneous Residue Limit

EU

European Union

FAO

Food and Agricultural Organization of the United Nations

FDA

Food and Drug Administration (US)

FRDC

Fisheries Research and Development Corporation

FRSC

Food Regulation Standing Committee

FSA

Food Science Australia

FSAI

Food Safety Authority of Ireland

FSANZ

Food Standards Australia New Zealand (formerly ANZFA)

FSIS

Food Safety and Inspection Service (US)

GAP

Good Agricultural Practices

GBR

Geographical BSE Risk

GHP

Good Hygienic Practices

GMP

Good Manufacturing Practices

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HACCP

Hazard Analysis Critical Control Point

HAV

Hepatitis A virus

HTST

High Temperature Short Time pasteurisation

HUS

Haemolytic Uremic Syndrome

ICMSF

International Commission on Microbiological Specifications for Foods

JECFA

Joint FAO/WHO Expert Committee on Food Additives

KP

Kanagawa phenomenon

MAP

Modified atmosphere packaging

MeHg

Methylmercury

ML

Maximum Level

MLA

Meat & Livestock Australia

MMWR

Morbidity and Mortality Weekly Report

MRL

Maximum Residue Limit

NARM

National Antibacterial Residue Minimisation program

NEPSS

National Enteric Pathogen Surveillance Scheme

NGSP

National Granuloma Submission Program

NRS

National Residue Survey

NZFSA

New Zealand Food Safety Authority

OC

Organochlorine

OP

Organophosphate

PHLS

Public Health Laboratory Service, UK

PIRSA

Primary Industries and Resources South Australia

PISC

Primary Industries Standing Committee

PSP

Paralytic Shellfish Poisoning

PTWI

Provisional Tolerable Weekly Intake

REPFEDS

Refrigerated processed foods of extended durability

RIRDC

Rural Industries Research and Development Corporation

RIS

Regulatory Impact Statement

RTE

Ready-to-eat

SARDI

South Australian Research and Development Institute

SSOP

Sanitation Standard Operating Procedures

STEC

Shiga toxigenic E. coli

SWG

Sector Working Groups

TFAP

Tuberculosis freedom assurance program

TVC

Total Viable Count

UCFM

Uncooked comminuted fermented meats

UHT

Ultra Heat Treated

USDA

US Department of Agriculture

WHO

World Health Organization

YMT

Yolk Mean Time

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Executive summary   
The NSW Food Regulation 2004 contains food safety schemes that outline the regulatory requirements for dairy, meat, plant products, seafood businesses and businesses serving food to vulnerable persons in NSW. A draft egg food safety scheme is currently being finalised for inclusion in the Regulation. The regulatory requirements in the food safety schemes have been introduced over a number of years, either by the NSW Food Authority or its predecessor organisation SafeFood Production NSW. Dairy and meat food safety schemes were carried over from previous legislation. Individual risk assessments   
were carried out prior to the introduction of both the seafood and plant products food safety schemes. The development of the vulnerable persons food safety scheme occurred following the introduction of Standard 3. 3. 1 – Food Safety Programs for Food Service to Vulnerable Populations of the Australia New Zealand Food Standards Code (Food Standards Code). In respect to the egg food safety scheme, the NSW Food Authority conducted a risk assessment prior to developing requirements for the scheme. Within each sector covered by the food safety schemes there are a wide variety of hazards that may potentially be present and cause illness in the consumer. The degree of illnesses caused by these hazards can range from mild illness through to severe and life threatening disease. In general, it is the microbiological hazards associated with foods that are considered more significant, as chemical and physical hazards are rarely detected in food.

This risk assessment document summarises the known information from previous risk assessments, risk profiles and hazard assessments, and includes new or updated information where it is available and applicable to food businesses in NSW.

Dairy food safety scheme   
In 2006–2007 there were 684 million litres of milk sold in NSW and ACT, with the average person consuming in excess of 100 L of pasteurised milk each year. A wide variety of bacteria may be present in raw milk with the microbial status of milk being influenced by animal health, the farm environment and production methods. Pasteurisation was successfully introduced to eliminate tuberculosis and brucellosis from milk and nowadays the main microbiological hazards associated with milk and dairy products include Salmonella, Listeria monocytogenes, pathogenic Escherichia coli, Staphylococcus aureus, Campylobacter spp., Yersinia enterocolitica and Cronobacter sakazakii.

Between 1995 and 2008 there were fourteen Australian outbreaks attributed to dairy products, none occurring in NSW. Nine of these outbreaks were associated with consumption of unpasteurised milk. Internationally, foodborne outbreaks associated with dairy products have been attributed to   
the use of unpasteurised milk, contaminated non-dairy ingredients, faulty pasteurisation process and poor hygiene. Controlling the safety of milk and dairy products relies on using raw materials (milk and non-dairy ingredients) of good quality, ensuring correct formulation, effective processing, prevention of recontamination and maintenance of temperature throughout the cold chain. Dairy products identified as high risk include unpasteurised milk, soft cheese, dairy desserts, fresh cheeses and dairy dips, as these products may support the growth of pathogenic microorganisms. Two critical steps in controlling pathogens in milk and dairy products are effective pasteurisation, followed by good manufacturing practices to ensure postFood Safety Scheme Risk Assessment

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pasteurisation contamination does not occur. Food safety programs targeting these controls have been an effective mechanism for controlling microbial hazards in milk and dairy products.   
There are several potential sources of chemical contamination associated with milk production including agricultural and veterinary chemicals, environmental contaminants and chemicals from animal feed. The implementation of on-farm food safety programs has managed these risks, and the risk is considered low as surveys of dairy products have not detected significant levels of chemicals in Australian milk and dairy products.

Meat food safety scheme   
It has been estimated that Australians each consume 38. 2 kg of beef and veal, 11. 4 kg of lamb, 2. 7 kg of mutton and 14. 4 kg of bacon and ham products each year. Various microbiological hazards are associated with different types of meats, with Salmonella, pathogenic E. coli, Clostridium perfringens, Campylobacter jejuni and the parasite Toxoplasma gondii associated with beef and sheepmeat, while the primary pathogen of concern in pigmeat is Yersinia enterocolitica.

Livestock and poultry can serve as a reservoir for pathogenic microorganisms and within the abattoir environment these pathogens can be transferred from   
the gut to the external surfaces of the carcase and contaminate equipment and workers. Currently the risk associated with red meat is considered low, due to the control measures implemented by the meat industry, such as the Australian Standards for the hygienic production of meat and game meat. However, cross contamination of ready-to-eat (RTE) foods by raw meat is considered a potential issue of concern. It has been estimated that if the cross contamination rate of Salmonella increased from 1% to 10% there would be an extra 5000 cases of foodborne illness, while an increase to 50% would result in more than 29, 000 cases of salmonellosis across Australia each year.

Poultry is the most widely consumed meat in Australia, with each person consuming 39. 5kg of poultry each year. The primary hazards of concern in poultry meat are Salmonella and Campylobacter spp. Contamination of poultry can occur on farm through breeding stock, contaminated water, litter, insects, rodents, wild birds and farm workers. Surveys have identified poultry meat as a significant source of foodborne illness, with 46 confirmed outbreaks and 1170 cases of illness between 1995 and 2002. Due to significant under-reporting, it is estimated that cases of foodborne illness due to processed chicken products may be as high as 79, 000 cases per year. A through chain approach is the preferred option to reduce contamination of poultry meat, with estimates that this could reduce levels of poultry-related foodborne illnesses by between 74% and 93% each year.

Processed meat products have also been identified as high risk, with the pathogens of concern including pathogenic E. coli, Salmonella and L. monocytogenes. There have been a large number of recalls of processed meats due to L. monocytogenes, and a significant number of foodborne illness outbreaks. Between 1991 and 2000, 323 cases of illness and one death were attributed to consumption of processed meats with a total cost to the community estimated to be $77 million. Controlling pathogens in processed meats include effective cooking, curing or fermentation with starter culture, and implementation of good hygienic practices (GHP) to limit the potential for post-processing contamination with L. monocytogenes. Food safety programs have been widely implemented in the Food Safety Scheme Risk Assessment

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processed meat sector to ensure control measures are in place. However, it was estimated that if these programs are not complied with, and poorly controlled or unreliable processing was allowed to occur in the production of uncooked comminuted fermented meats, this could lead to a significant increase in risk, with estimates the number of foodborne illness cases in Australia due to pathogenic E. coli could be up to 604 cases per year.

Plant products food safety scheme   
Previous risk assessment work conducted on the risk associated with plant products found that fresh cut fruit and vegetables, seed spouts, vegetables in oil and unpasteurised juice present a high risk. This was due to a history of foodborne illness outbreaks in Australia, mainly due to Salmonella, in addition to a number of outbreaks overseas. Annual NSW consumption of these products has been estimated as being 11, 000 tonnes of fresh cut vegetables, 150 tonnes of fresh cut fruits, 2600 tonnes of seed sprouts, 1000 tonnes of vegetables in oil products, and 100, 000 L of unpasteurised juice.

Surveys of plant products have shown the potential for these high risk plant products to be contaminated with L. monocytogenes, Aeromonas spp., B. cereus and Salmonella.   
Contamination of fresh cut fruit and vegetables can occur during growth, harvest or processing with the main pathogens of concern being L. monocytogenes in general, and C. botulinum for modified atmosphere packaged product. These products are considered high risk when they are consumed raw.

Seed sprouts can become contaminated with B. cereus, Salmonella and pathogenic E. coli during growth and harvest of the seeds and also during the sprouting process, which provides a near perfect environment for the growth of microorganisms. The oxygen reduced environment provided by vegetables immersed in oil allows for the growth of anaerobic microorganisms including C. botulinum, the cause of botulism. To reduce the risk, the   
vegetables or fruits are usually cooked and acidified prior to placement in oil.

Unpasteurised fruit juices may become contaminated during the juicing process, either due to contamination on the exterior of the fruit or the use of damaged and mouldy fruit. Because the juice is not heat treated, any pathogenic microorganisms present are able to survive, and acid tolerant strains of pathogenic E. coli and Salmonella may grow.

Seafood safety scheme   
Annual consumption of seafood has been estimated at approximately 15. 1 kg per person. The hazards associated with seafood vary depending on the type of seafood and processing methods employed.   
Shellfish, particularly oysters, as filter feeders can accumulate contaminants from the growing environment. The hazards of concern for shellfish include pathogenic bacteria and viruses, algal toxins and chemical contaminant from the growing environment. Viral contamination of shellfish is recognised as the highest risk for all seafood and is effectively managed by the implementation of shellfish safety programs that manage the waterway and harvesting of the shellfish. Algal toxins in shellfish are generally considered low risk where harvest management programs manage the risk. Where no programs are in place, the risk associated with algal

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toxins increases to medium. Severe illness has been associated with the consumption of oysters contaminated with V. vulnificus.   
Wild caught prawns particularly those caught in estuarine waters are susceptible to contamination from the environment, such as naturally occurring Vibrio spp. present in the waterway. Prawns treated with metabisulphite may present a problem to consumers who suffer from asthma-related conditions. The on-board cooking and cooling of prawns also has the potential to introduce bacterial contamination when water from the   
waterway is used to cool the prawns.

Hazards associated with wild caught finfish include ciguatera and histamine, depending on the type of fish caught. Ciguatera poisoning is generally regarded as medium risk, with most illnesses occurring with fish caught near tropical reefs. Histamine poisoning is usually associated with certain fish such as tuna, swordfish, mahi mahi and blue grenadier and can be controlled by effective temperature control throughout the supply chain. If the fish are to be consumed raw, hazards such as parasites and Vibrio spp. become significant. Mercury in finfish presents a risk to pregnant women or women planning to become pregnant. Because mercury is naturally present in the marine environment, management strategies have relied on education of the consumer, in particular advising pregnant women to avoid consuming large predatory fish which are known to contain higher levels of mercury. Processed, RTE seafood products (including smoked seafood) can support the growth of L. monocytogenes, however contamination is thought to occur during the handling and packaging of the finished product. Strict hygiene and sanitation programs can reduce the likelihood of contamination. The packaging of smoked seafood under modified atmosphere packaging may allow the growth of C. botulinum. While botulism poisoning associated these products is rare, the illness is severe and is considered a medium risk.

Vulnerable persons food safety scheme   
Certain population sub-groups are more at risk of foodborne illness or can develop more severe conditions due to foodborne illness when compared to the general population. The degree of vulnerability depends on the susceptibility of the individual and the pathogenicity of the pathogenic microorganism. In general terms, the vulnerable population group includes children under five years of age, people over 65 years old, pregnant women and persons with depressed immunity. It is estimated that the number of meals served to vulnerable persons in NSW facilities such as hospitals, aged-care facilities, hospices, day care establishments and childcare centres is approximately 133 million meals per year. It is estimated that up to one million meals per year served at these facilities may be contaminated with a foodborne pathogen.

Since 1995 there have been 65 foodborne illness outbreaks in Australian aged-care facilities, childcare centres and hospitals with 758 illnesses and 75 fatalities. The pathogens implicated have included Salmonella, C. perfringens, L. monocytogenes and Campylobacter. The prevalence of foodborne-related illness and deaths in the elderly living in nursing homes is far greater than the baseline level of illness in general population, while children appear more at risk to Salmonella due high salmonellosis rate in children seen both in Australia and overseas. The major hazard of concern to vulnerable persons is L. monocytogenes, with some sub-groups within the vulnerable population being 100 times more susceptible to listeriosis than the general population. Other hazards of concern include infants Food Safety Scheme Risk Assessment

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exposed to C. botulinum through consumption of contaminated honey, neonatal infants consuming Cronobacter sakazakii (formerly Enterobacter sakazakii) contaminated infant formula and individuals with liver dysfunction exposed to Vibrio vulnificus via raw oysters. Other organisms that may result in more severe illness in vulnerable sub-groups include pathogenic Enterohaemorragic E. coli, S. aureus and C. perfringens.

When assessing the risk associated with foods, it is important to consider food preparation and hazardous scenarios. Businesses catering to vulnerable persons need to consider the susceptibility of their consumers when designing menus and sourcing, preparing and serving foods. Under the Food Standards Code, these establishments are required to implement a food safety program including, substitution of high risk foods with lower alternatives; effective cleaning and sanitation of fruits and vegetables to be consumed raw; limiting the storage of reconstituted infant formula; minimising storage times/temperatures for RTE foods; ensuring foods are cooked properly and effective cleaning and sanitation of equipment.

Egg food safety scheme (draft)

The average Australian consumes approximately 137 eggs per year, equating to over 800 million eggs being consumed in NSW each year. The primary hazard of concern is Salmonella, in particular Salmonella Typhimurium which may contaminate the egg shell through environmental contamination and through contact with bird faeces. Overseas foodborne illness outbreaks attributed to eggs have been predominantly due to Salmonella Enteritidis however, Australian layer flocks remain free of Salmonella Enteritidis.

While Salmonella may be present in the farm environment, surveys have found the prevalence of Salmonella on shell eggs to be very low. However, eggs and egg products can also become contaminated during the grading and processing due to improper crack detection, incorrect washing of eggs and poor hygiene and sanitation during the processing of eggs into pulp and other products. Although egg products such as liquid pulp are pasteurised, the heat treatment is only mild and therefore it is important to limit the level of microbiological contamination. There is significant epidemiological evidence to suggest that a major contributing factor of salmonellosis in Australia is the use of dirty and cracked eggs, especially in products that receive minimal or no cook step. The Food Standards Code limits the sale of cracked eggs to businesses where the egg will be further processed and receive a heat treatment.

Depending on the hygienic practices on farm and proper grading, processing and storage of eggs, the potential number of egg-related illnesses was estimated up to 1800 cases per year across Australia. Current industry practices to address these issues include strict biosecurity on farm, implementation of quality assurance systems during grading and processing and effective supply chain management. Potential sources of chemical contamination of eggs on farm include contaminated soil, insecticide spray, incorrect use of medication and inappropriate egg washing solutions and concentrations. However, in general, only low levels of chemicals have been detected in eggs and previous risk assessment has assessed the risk of chemicals in eggs as low. The exception to this are specialty eggs such as Balut, salted and century eggs, where surveys have detected the unauthorised use of lead as an additive, leading to chemical contamination of some   
products. These products Food Safety Scheme Risk Assessment

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may also become contaminated with pathogens due to the extensive handling during processing.

Conclusion   
This review has illustrated that across the food safety schemes there are many potential hazards that can impact on human health with microbiological hazards considered the most significant. It concludes that for food businesses within these schemes, mitigating food safety risks requires the development and implementation of reliable, systematic and preventative procedures. Such procedures are the core elements of food safety programs, introduced either due to regulatory requirements or through industry-sponsored codes of practice. The review acknowledges that mitigating food safety risk necessitates a multi-factorial approach extending beyond the controls implemented by a food business operating under a food safety scheme.

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Introduction   
Purpose   
Under current legislation, the NSW Food Authority (the Authority) can establish food safety schemes in respect to different type or classes of foods, food businesses or food activity (Food Act 2003). The food safety schemes aims to assist in improving the safe production and handling food by outlining the regulatory requirements for the food, food businesses or food activity (or activities) covered by the scheme. Currently food safety schemes exist for dairy, meat, plant products and seafood businesses operating in NSW, as well as businesses serving food to vulnerable persons. In addition to these schemes that have already been implemented, an egg food   
safety scheme is currently being finalised.

These commodities have been identified as containing high risk products that may potentially cause outbreaks of foodborne illness, and where the cost benefit analysis justified a regulatory presence, and the use of regulatory tools such as the implementation of food safety programs based on principles of Hazards Analysis Critical Control Point (HACCP).

Current legislation also requires a risk assessment be undertaken when establishing a new food safety scheme. The risk assessment provides the science to underpin the food safety scheme and is required to be based on national or international standards.

The Authority, or its predecessor SafeFood Production NSW, previously commissioned risk assessment prior to the introduction of food safety schemes relating to seafood and plant products. In addition, risk assessments were conducted on the proposed scheme for egg and egg products and during the review of the dairy food safety scheme. The requirements under the meat food safety scheme were carried over from a previous legislation which did not require a risk assessment to be conducted and as such the Authority has not previously conducted a risk assessment in relation to meat. The vulnerable persons food safety scheme was introduced following the gazettal of Standard 3. 3. 1 – Food Safety Programs for Food Service to Vulnerable Populations of the Australia New Zealand Food Standards Code. Food service to vulnerable populations were identified as high risk in the National Risk Validation Project (Food Science Australia and Minter Ellison, 2002) The purpose of this risk assessment document is to provide a scientific review of hazards and their associated risks for food businesses covered by the food safety schemes. This risk assessment summarises the known information from previous risk assessment and where new or updated information is available, this has been incorporated into the information.

Scope   
This risk assessment will review the hazards associated with food businesses   
regulated under the food safety schemes of the NSW Food Regulation 2004 and includes:   
•

Dairy

•

Meat

•

Plant products – fresh cut fruits and vegetables, unpasteurised juice and vegetables in oil

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•

Seafood

•

Food service to vulnerable persons

•

Eggs and egg products (draft food safety scheme currently being finalised)

Overview of risk assessment   
Risk assessment forms part of an overall process, called risk analysis. Risk analysis is used by governments and industry to assess, manage and communicate the risk associated with particular food or food groups and in   
turn aims to reduce the potential for foodborne illness. The Codex Alimentarius Commission divides risk analysis into three components (CAC, 1999):

•

Risk assessment – a process by which the potential risk posed by food safety hazard(s) is determined

•

Risk management – the process of determining alternatives for control the hazards identified in the risk assessment and

•

Risk communication – the exchange of information on risk and risk management amongst interested parties.

CAC (1999) has identified four components of risk assessment: •

Hazard identification – the process of identifying potential hazards associated with the food

•

Exposure assessment – an estimation of the potential human exposure to the hazard and includes the use of data such as the occurrence in the food and/or potential consumption rates of the food

•

Hazard characterisation – the evaluation of the potential illness associated with the hazard

•

Risk characterisation – the process of determining the probability of occurrence and severity of the adverse health effects based on the information collected in the hazard identification, exposure assessment and hazard characterisation.

Previous risk assessment work   
When developing a food safety scheme, the NSW Food Authority has previously commissioned hazard assessments, risk profiles and risk assessments or sourced information from risk assessments performed by other government and nongovernment organisations. These risk assessments have included: •

Ross, T. & Sanderson, K. (1999). A risk assessment of selected seafoods in NSW

•

Food Science Australia (2000). Final report – Scoping study on the risk of plant products

•

Food Science Australia & Minter Ellison Consulting (2002). National risk validation project. Final report

•

Miles, D. (2004). Risk assessment of the NSW dairy industry (unpublished)

•

Miles, D. and Chan, C. (2007). Risk profile and risk management of eggs and egg products in NSW (unpublished)

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In addition, risk assessments have been conducted in Australia by other government and non-government organisations. These include:   
•

Sumner, J. (2002). Food safety risk profile for primary industries in South Australia. Department of Primary Industries and Resources SA, Adelaide

•

FSANZ [Food Standards Australia New Zealand] (2002). Final assessment report proposal P263. Safety assessment of raw milk very hard cooked-curd cheeses. Food Standards Australia New Zealand Report

•

FSANZ (2006). A risk profile of dairy products in Australia. Food Standards Australia New Zealand Report

•

MLA [Meat & Livestock Australia] (2003). Through chain risk profile for the Australian red meat industry Part 1: Risk Profile

•

FSANZ (2005). Scientific assessment of the public health and safety of poultry meat in Australia

•

FSANZ (2006). Public health and safety of poultry meat in Australia – Explanatory summary of the scientific assessment, Canberra

•

MLA (2006) Listeria monocytogenes in smallgoods: Risks and controls

•

Ross, T. Walsh, P. and Lewis, T. (2002). Risk assessment of fish cold smoking and marination processes used by Australian businesses. Biodevelopment Consulting Pty. Ltd for SafeFood Production NSW

•

FSANZ (2005). Final assessment report, P265, primary production and processing standard for seafood (Attachment 10)

•

Daughtry, B., Sumner, J. Hooper, G., Thomas, C. Grime, T., Horn, R., Moses, A. & Pointon, A. (2005). National food safety risk profile of egg and egg products. A report for the Australian Egg Corporation Limited (AECL) Publication No 05/06 Project SAR-47

•

Thomas, C., Daughtry, B., Padula, D., Jordan, D., Arzey, G., Davey, K., Holds, G., Slade, J., & Pointon, A. (2006). An egg: Salmonella quantitative risk assessment model. AECL publication

Current approach   
As there has been a considerable amount of risk assessment work already undertaken on industries covered by the food safety schemes, the approach taken in this document was to provide a review of previous work conducted. This information has been supplemented with other more recently published information where necessary (CAC, 2007). To minimise repetition, information   
common to the different food safety schemes has been placed in the appendices to the document: •

Appendix 1 – Common microbiological and chemical food safety hazards

•

Appendix 2 – Food recalls in Australia

•

Appendix 3 – Foodborne illness outbreaks in Australia

A number of methods have been used to estimate the level of exposure to hazards. The approaches used include production data, consumption data, imported foods testing failures, recalls, epidemiological data and results of food surveys. When considering exposure the fate of the hazard during processing and preparation must be taken into account.

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Dairy food safety scheme   
Hazard identification   
The safety of milk and milk products has been extensively reviewed by regulatory agencies in Australia and internationally. A large number of risk assessments and risk profiles have been undertaken, examining the risks across the entire dairy supply chain and conducting in-depth evaluations of specific pathogen-product combinations. This risk assessment will summarise the major body of relevant work undertaken to date.

In 1999, the former NSW Dairy Corporation commissioned Food Science Australia to review the food safety systems that had been implemented in the NSW dairy industry (Jansson et al, 1999). The report included a brief risk assessment and endorsed the preventative approach to food safety through the implementation of HACCP-based food safety programs throughout the dairy supply chain. This was later updated in 2004, when the NSW Food Authority completed a qualitative risk assessment of the NSW dairy industry which examined the microbiological and chemical hazards along the dairy supply chain (Miles, 2004). This was developed as an internal document to provide scientific rigour to the updated dairy food safety scheme and provide a basis for determining the priority classification for segments of the industry. In 2002, Primary Industries and Resources South Australia (PIRSA) commissioned a food safety risk profile on primary production, including milk and dairy products (Sumner, 2002). This report highlighted consumption of raw (unpasteurised) milk as a high risk activity.

In 2006, Food Standards Australia New Zealand (FSANZ) undertook a comprehensive risk profile of dairy products in Australia to inform the development of the Primary Production and Processing Standard for dairy   
products (FSANZ, 2006). The FSANZ risk profile examined both microbiological and chemical hazards. The findings of the FSANZ risk profile are reported here.

Microbiological hazards   
A wide range of microbiological hazards may be introduced into milk during primary production and processing. Raw milk may have a diverse range of bacteria present in it, either shed directly into the milk from the udder as a result of illness or disease, or through contamination from the external surface of the cow and the milking environment. FSANZ (2006) highlighted the on-farm factors that most significantly impact on the microbiological quality of raw milk as:

•

animal-related factors (eg animal health, herd size, age and production status)

•

environmental factors (eg housing, faeces, feed, soil, and water)

•

method of milking, operation of milking and storage equipment (eg cleanliness of equipment and lines, appropriate storage temperature to limit pathogen growth)

The initial levels of bacteria in raw milk can vary considerably, dependent on the level of control over these factors. Boor (1997) reviewed the different types of pathogenic microorganisms that have been detected in raw milk (Table 1).

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Table 1 – Pathogenic microorganisms detected in raw milk   
Microorganism   
Enterobacteriaceae   
pathogenic Escherichia coli (eg EHEC, STEC)

Disease

Salmonella   
Shigella   
Yersinia enterocolitica   
Cronobacter sakazakii

Gastroenteritis, other complications   
involve Haemolytic uraemic   
syndrome (HUS) and Thrombotic   
thrombocytopenic purpura (TTP)   
Gastroenteritis, typhoid fever   
Dysentery   
Gastroenteritis   
Meningitis in premature infants

Campylobacter jejuni   
Aeromonas hydrophila

Gastroenteritis   
Gastroenteritis

Pseudomonas aeruginosa   
Brucella spp.

Gastroenteritis   
Brucellosis (Bang’s Disease)

Bacillus cereus   
Bacillus anthracis   
Clostridium perfringens   
Clostridium botulinum

Gastroenteritis   
Anthrax   
Gastroenteritis   
Botulism

Staphylococcus aureus   
Streptococcus agalactiae   
Streptococcus pyogenes   
Streptococcus zooepidemicus

Emetic intoxication   
Sore throat   
Scarlet fever/sore throat   
Pharyngitis, nephritic sequelae

Listeria monocytogenes   
Corynebacterium spp.   
Mycobacterium bovis   
Mycobacterium tuberculosis   
Mycobacterium paratuberculosis

Listeriosis (various manifestations)   
Diphtheria   
Tuberculosis   
Tuberculosis   
Johne’s disease (ruminants)   
Crohn’s disease (unproven in   
humans)

Vibrionaceae and Campylobacter

Other Gram-negatives

Gram-positive sporeformers

Gram-positive cocci

Miscellaneous Gram-positives

Rickettsia

Coxiella burnetii

Viral   
Enteroviruses, including polioviruses and Coxsackie   
virus, Rotaviruses   
Foot and mouth disease virus   
Hepatitis virus   
Fungi   
Mould (and associated aflatoxins)   
Protozoan parasites

Cryptosporidium parvum   
Entamoeba histolytica   
Giardia lamblia   
Toxoplasma gondii

Q fever   
Enteric infection   
Foot-and-mouth disease   
(not a human disease)   
Infectious hepatitis   
Mycotoxicoses   
Cryptosporidiosis   
Amoebiasis

Giardiasis   
Toxoplasmosis

adapted from Boor (1997)

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In the past, prior to the introduction of mandatory pasteurisation for milk in Australia, the most important human diseases disseminated by the consumption of raw milk were tuberculosis and brucellosis. These diseases have now been eradicated in Australian dairy cow herds. As a result, the FSANZ risk profile (FSANZ, 2006) went on to identify the most significant pathogenic microorganisms to public health and safety for the Australian dairy industry (Table 2). Further details on these microbiological hazards are available in Appendix 1.

Table 2 – Microbiological hazards in dairy products   
Pathogens   
pathogenic Escherichia coli

Significance in dairy products   
Pathogenic strains of E. coli can be found in cattle and may enter milk through faecal contamination. Is destroyed by pasteurisation

Salmonella

Salmonella is occasionally present in raw milk but is destroyed by

Yersinia enterocolitica

Campylobacter spp.   
Bacillus cereus

Clostridium botulinum   
Staphylococcus aureus   
Listeria monocytogenes   
Cronobacter sakazakii   
(formerly Enterobacter   
sakazakii)

pasteurisation. Can contaminate products after pasteurisation, with nondairy ingredients a source of contamination. Frequently isolated in milk powder   
Y. enterocolitica is destroyed by pasteurisation and its presence in heat treated milk products is due to environmental contamination after heat treatment. Y. enterocolitica is able to grow in dairy products held at refrigeration temperatures and therefore may be considered as a hazard in prolonged shelf life products

Campylobacter spp. is destroyed by pasteurisation and its presence in milk products is due to environmental contamination after heat treatment. Not normally able to grow in foods   
Vegetative cells of B. cereus do not survive pasteurisation, however spores will survive. B. cereus is rapidly outgrown by psychrotrophic bacteria at refrigeration temperatures. However, in the absence of a competitive microflora, growth to levels of concern is possible Vegetative cells of C. botulinum do not survive pasteurisation, however spores will survive. Will only grow under anaerobic conditions May enter raw milk through udder infection. S. aureus is destroyed by pasteurisation, however toxins are heat stable. S. aureus does not grow well at refrigeration temperatures or compete with starter cultures L. monocytogenes is destroyed by pasteurisation. Its presence in dairy products is due to post-pasteurisation contamination. Can grow in milk products at refrigeration temperatures

C. sakazakii will not survive pasteurisation. Recontamination of powdered infant formula during manufacture is a risk. C. sakazakii cannot grow in a dry substrate, but it can survive for long periods of time and is a potential hazard when the powder is reconstituted and held at favourable temperatures. Contamination and subsequent growth may occur during   
reconstitution and preparation

adapted from FSANZ (2006)

These hazards were considered significant due to either:   
•

association with reported incidents of foodborne illness (including overseas outbreaks), or

•

the potential to contaminate dairy products after pasteurisation.

This conclusion is supported by other work, such as that by Todd & Harwig (1996) in a risk analysis of Canadian food, who stated that although 21 microbial hazards have been reported to occur in Canadian milk, only eight of those presented a significant risk to the human population, with Campylobacter jejuni, Salmonella serovars and E. coli O157: H7 identified as the most important hazards. Johnson et al (1990) identified Salmonella, Listeria monocytogenes and pathogenic E. coli as the three Food Safety Scheme Risk Assessment

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high risk organisms to the cheese industry in the USA. While, more recently, the presence of Cronobacter sakazakii in infant formula has presented a significant risk to premature infants (Lai, 2001; FDA, 2002; Himelright et al, 2002). Chemical hazards

Chemicals are used by the dairy industry for a number of purposes, including pest and weed control on farm, animal health and sanitising equipment. As a result, milk may be susceptible to chemical contamination if proper controls are not in place. The FSANZ risk profile evaluated the following potential chemical hazards (FSANZ, 2006): •

agricultural and veterinary chemical used in dairy primary production

•

environmental contaminants, including heavy metals, organic contaminants and micro nutrients

•

naturally-occurring chemicals found in plants or in fungi or bacteria associated with plants which may be ingested by grazing cattle

•

food processing by-products

•

food additives, processing aids, and those chemicals that may migrate from packaging into dairy products

Dairy products must comply with Standard 1. 4. 1 – Contaminants and Natural Toxicants and Standard 1. 4. 2 – Maximum Residue Limits of the Food Standards Code. These Standards sets out the Maximum Levels (MLs) of specified metal, nonmetal contaminants and natural toxicants and the Maximum Residue Limits (MRLs) for agricultural and veterinary chemical residues present in food respectively.

Agricultural and veterinary chemical hazards   
Without appropriate controls and the observance of appropriate withholding periods for treated dairy cattle, it is possible for residues of these chemicals to occur in raw milk. In Australia, the Australian Pesticide and Veterinary Medicines Authority (APVMA) is responsible for registering agricultural and veterinary chemical products, granting permits for use of   
chemical products and regulating the sale of agricultural and veterinary chemical products. Veterinary chemicals administered to dairy cattle are mainly antimicrobials and endo- and ectoparasiticides. Other veterinary chemical uses include reproductive therapy and use of anti-inflammatory drugs or anaesthetics. If the cow is lactating, then the product must specifically state that it can be used in lactating dairy cows, and a milk withholding period may be specified. The use of environmentally persistent pesticides, such as organochlorines, still poses a potential problem for grazing animals. Potential hazards include excessive levels of herbicides, pesticides or fungicides. Cereals and treated seeds used as animal feed supplement are the most likely source of these contaminants, with the most significant hazard to human health being those chemicals that can accumulate in animal tissues or are excreted in the milk.

Aflatoxins   
Grain crops can become contaminated with biological toxins, such as aflatoxins, a group of extremely toxic metabolites produced by the fungi Aspergillus flavus and Aspergillus parasiticus. When these moulds are allowed to germinate and grow on harvested seed crops, the aflatoxins can be formed and ingested by dairy cattle during feeding, eventually contaminating the milk. Aflatoxin contamination of milk is more common in Europe where intensive supplementary feeding of dairy herds is

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conducted. In Australia, where herds predominantly graze on pasture, aflatoxin contamination has not been reported (ANZFA, 2001).

Cleaning chemicals   
Milking premises and equipment must be cleaned and sanitised to prevent the risk of contaminating the milk with microbiological pathogens. However, overuse of these chemicals can in itself create a hazard with the risk of chemical residues being left on equipment. All chemicals used in detergents   
and sanitisers have the potential to leave a residue on the dairy equipment surface if not used in the correct manner. Physical hazards

The probability of introduction on farm of physical hazards which end up in the final product is thought to be minimal. Any physical hazard contamination that may be introduced on farm should be removed at the farm level. Most dairy farms include a filter ‘ sock’ through which the milk passes prior to entering into the farm vat. This filter will remove most gross physical contaminants.

The introduction of physical hazards at the processing level has occasionally happened in the past, with pieces of equipment ending up in a dairy product. The instances of this occurring are very rare, and the preventative maintenance of equipment means the risk is very low. Good manufacturing practices and staff training should also ensure that the risk of physical contaminants through the wearing of personal effects such as jewellery are minimal.

Exposure assessment   
Consumption of pasteurised milk and dairy products   
Consumption of milk and milk products forms a significant part of the average Australian’s diet. Standard 4. 2. 4 – Primary Production and Processing Standard for Dairy Products of the Food Standards Code requires all milk for human consumption (including milk used to make dairy products) to be pasteurised at a minimum of 72°C for 15 seconds (or equivalent), unless an applicable law of a State or Territory provides an exemption 1. There is no such exemption for cows milk in NSW, therefore all dairy products for human consumption commercially sold in NSW are made from pasteurised milk. In 2006/07, 684 million litres of milk were sold in NSW/ACT, including modified and flavoured milk. Data from Dairy Australia shows the average consumption of dairy products in Australia each year is 103. 6 L milk, 11. 9 kg cheese, 6. 8 kg yoghurt and 3. 9 kg butter/blends per person (Dairy Australia, 2007). A closer analysis of consumption trends is shown in the Australian National Nutrition Survey (ABS, 1995), which showed that 84% of people surveyed consumed dairy products at a median amount of 347 g/day with the quantity   
ranging from 209–471 g/day (Table 3). Consumption of dairy products varies with age, declining from 98% for children aged 2–3 years to 90% for adults aged 19–24 years and then increasing again to 95% for persons aged 65 years and over.

1

Standard 4. 2. 4A – Primary Production and Processing Standard for Specific Cheeses of the Food Standards Code does allow imported Gruyere, Sbrinz, Emmental and Roquefort to be made from raw milk.

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Table 3 – Consumption of dairy products   
Sex

Age

Male   
Male   
Male   
Male   
Male   
Male   
Male   
Male   
Male   
Female   
Female   
Female   
Female   
Female   
Female

Female   
Female   
Female

Proportion of persons   
consuming milk products   
and dishes 2   
(%)

2–3   
4–7   
8 – 11   
12 – 15   
16 – 18   
19 – 24   
25 – 44   
45 – 64   
65+   
2–3   
4–7   
8 – 11   
12 – 15   
16 – 18   
19 – 24   
25 – 44   
45 – 64   
65+

98. 2   
95. 5   
90. 9   
92. 8   
94. 2   
89. 1   
93. 7

91. 3   
94. 5   
98. 1   
96. 0   
93. 3   
90. 8   
87. 3   
90. 1   
94. 3   
94. 7   
95. 6

Median daily intake per   
consumer of milk products and   
dishes   
(g/day)   
471. 8   
365. 0   
401. 4   
424. 0   
392. 2   
323. 0   
263. 2   
258. 0   
255. 0   
394. 3   
280. 5   
312. 0   
297. 7   
258. 0   
251. 3   
209. 3   
216. 6   
225. 8

adapted from National Nutrition Survey (ABS, 1995)

Liquid milk accounts for approximately 70% of the mean daily intake of dairy products for persons of all ages. However, the trend of milk consumption within Australia has been changing to more specialty types. Whole milk accounts for around 56% of milk sales, with lower fat lines increasing to 26%, long life or ultra high temperature (UHT) treated milk 8. 5%, and the remainder as flavoured and specialty milks (Dairy Australia, 2007). Cheese consumption in Australia has jumped more than 20% in the past decade. The recent consumer trend has been away from cheddar cheeses to non-cheddar cheese types, and this is also being reflected in Australia’s cheese exports, where the non-cheddar share of total export sales has increased from 45% to 57% over the past seven years.

Consumption of raw milk   
The current Dairy food safety scheme in the Food Regulation 2004 does not provide an exemption from the requirement to pasteurise cows milk sold for human consumption. However, no such limit exists on the private consumption of raw cows milk. This is believed to be limited to small communities in NSW, such as farm families. The amount of raw milk consumed on farm within NSW is difficult to estimate, but is considered to be extremely small when compared to the volume of pasteurised milk. The US Food and Drug Administration (FDA) and US Department of 2

Milk products and dishes are defined in the National Nutrition Survey (ABS, 1995) as including the following: – Dairy milk   
– Yoghurt   
– Cream   
– Cheese   
– Frozen milk products (eg ice -cream)   
– Other dishes where milk or a milk product is the major component – Milk substitutes (eg soy-based milk)   
– Flavoured milks

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Agriculture (USDA) in its quantitative risk assessment on listeriosis estimated raw milk consumption to be less than 0. 5% of total milk consumption in the USA (FDA/USDA, 2003). Todd & Harwig (1996) made the assumption that ‘ farm families’ were the people most likely to consume unpasteurised dairy products and consequently be exposed to the microbiological hazards that may contaminate raw milk.

The dairy food safety scheme does provide an exemption to allow the sale of unpasteurised goats milk in NSW. This was initially a continuation of the permit system implemented by NSW Health. The former SafeFood NSW commissioned a risk assessment (AgriQuality New Zealand, 2002), but the authors could not fully determine the risk from unpasteurised goats milk due to a lack of data. Recommendations from the risk assessment report included the implementation of HACCP-based food safety programs and a microbiological survey of unpasteurised goats milk to generate data to provide the basis for a risk assessment. The National Nutrition Survey (ABS, 1995) estimated that less than 1% of respondents consumed goats milk and there is no evidence to suggest this has increased in recent years. In fact the number of licensed goat milk producers in NSW has declined. Recently ‘ cosmetic’ and ‘ bathing’ raw milk products have become available for sale in NSW and other states. Although marketed for non-food use, it is believed these labelling terms are being used to bypass the Food Standards Code, and that these products are being consumed. While the volume consumed is considered to be very small, the products are potentially unsafe. As such, the NSW Food Authority has taken enforcement action when these products have been identified in the marketplace, as they do not comply with the Food Standards Code requirem