Food Authority

Periodic review of the risk assessment: Dairy Food Safety Scheme

12 September 2023

Table of Contents

List of Tables

Glossary

ABS	Australian Bureau of Statistics
ACMSF	Advisory Committee on the Microbiological Safety of Food
ACT	Australian Capital Territory
AMR	antimicrobial resistance
ANZDAC	Australia New Zealand Dairy Authorities' Committee
APC	Aerobic Plate Counts
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose
ASTAG	Australian Strategic and Technical Advisory Group on AMR
ATDS	Australian Total Diet Study
AUSVETPLAN	Australian Veterinary Emergency Plan
BSE	bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention (United States)
CFIA	Canadian Food Inspection Agency
CFU	Colony Forming Unit
CPS	Coagulase positive staphylococci
CWD	chronic wasting disease
DAFF	Department of Agriculture, Fisheries and Forestry (Australia)
DFSV	Dairy Food Safety Victoria
DoH	Department of Health (Australia)
DPI	Department of Primary Industries (NSW)
D-R	dose-response
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EHEC	Enterohaemorrhagic *Escherichia coli*
ERIS	Emerging Risk Identification System (New Zealand)
ERL	extraneous residue limit
EU	European Union
FAO	Food and Agriculture Organization (United Nations)
FDA	Food and Drug Administration (United States)
FMD	foot-and-mouth disease
FSAI	Food Safety Authority of Ireland
FSANZ	Food Standards Australia New Zealand
FSP	Food Safety Program
GAP	Good Agricultural Practice

GBS	Guillain–Barré syndrome
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
HGA	hypoglycin A
HPP	High Pressure Processing
HUS	haemolytic uraemic syndrome
IBS	irritable bowel syndrome
IFIS	Imported Food Inspection Scheme (Australia)
IFSAC	Interagency Food Safety Analytics Collaboration (United States)
LSD	lumpy skin disease
ML	maximum level
MLVA	Multi Locus VNTR (Variable copy Numbers of Tandem Repeats) Analysis
MPI	Ministry for Primary Industries (New Zealand)
MPN	Most Probable Number
MRL	maximum residue limit
NORS	National Outbreak Reporting System (United States)
NSW	New South Wales
NZ	New Zealand
PCR	polymerase chain reaction
PDBM	producer-distributor bulk milk
QLD	Queensland
RASFF	Rapid Alert System for Food and Feed (EU)
RCS	Regulated Control Scheme (New Zealand)
RDM	raw drinking milk
RIS	Regulatory Impact Statement
RTE	ready-to-eat
SA	South Australia
SCC	Somatic Cell Count
SEA	Staphylococcal enterotoxin A
STEC	Shiga toxin-producing *Escherichia coli*
TAS	Tasmania
TBEV	tick-borne encephalitis virus
TDI	tolerable daily intake
UHT	ultra-high temperature
UK	United Kingdom
USA	United States of America
vCJD	variant Creutzfeldt–Jacob disease
VIC	Victoria

WA	Western Australia
WGS	Whole-genome sequencing
WHO	World Health Organization

Units of measurement

°C	degrees Celsius
b.w.	body weight
CFU	Colony Forming Unit
g	gram
kg	kilogram
L	litre
mg	milligram
ml	millilitre
MPN	Most Probable Number
ng	nanogram
s	second
µg	microgram

Executive summary

The previous risk assessment of the dairy food safety scheme was published in November 2014. The 2014 risk assessment was an update of the 2009 risk assessment. Reviews alternate between updates and full risk assessments and a full risk assessment is reported here, containing new or updated information identified in an environmental scan for issues related to dairy that have impacted dairy and dairy product food safety since 2014.

Information sources included:

- foodborne illness reports and recall data in Australia attributed to dairy and dairy products
- international issues arising from human illness or perceived hazards linked with dairy and dairy products
- border detections for dairy and dairy products
- risk assessments of dairy and dairy products
- emerging issues in the farm to consumer continuum for dairy and dairy products relevant to health risk
- research findings related to hazards in dairy and dairy product production and processing
- baseline surveys of microbiological and chemical hazards in dairy and dairy products
- other relevant sources if identified during the above activities

The hazard identification and main findings of the 2014 risk assessment remain essentially the same, in relation to the main microbiological hazards associated with dairy products. A scan of recent literature and foodborne illness reports did not reveal any material that would change the assessment of pasteurised dairy products. The frequency and severity of cases of foodborne illness in countries which allow the sale of raw milk and raw milk products, serves as a reminder that these commodities can harbor dangerous microorganisms that can pose serious health risks.

Milk and milk products are a significant component of the diet for the majority of the Australian population. Australian dairy consumption data was sourced from the 25th Australian Total Diet Study (ATDS) (FSANZ, 2019), Australian Bureau of Statistics (ABS) (ABS, 2022) and Dairy Australia (Dairy Australia, 2022). The comparison of consumption data from each of these sources is hampered by differences in the methodologies employed and in the categorisation of food groups and what has been reported. The ABS estimated that in 2019-2020, the apparent daily consumption per capita of milk, yoghurt, cheese and/or alternatives was 1.88 serves per person (equating to 275.1g).

The hazard characterisation included analysis of foodborne illness data in NSW from 2014 to 2020 due to dairy and dairy products. During this period, only one outbreak in NSW was identified in which the suspected or responsible vehicle involved a dairy product (Communicable Diseases Branch, 2015, 2016, 2017, 2018, 2019a, 2019b, 2022). In September 2014, an outbreak of *S*. Typhimurium MLVA 3-12-11-14-523 linked to chocolate milk occurred at a holiday resort and affected 20 people, resulting in five hospitalisations (Communicable Diseases Branch, 2014, 2015). However, milk was not believed to be the source of the contamination and cross contamination was suspected.

The literature search conducted as part of this risk assessment did not reveal any recent published data that enabled an update on the prevalence and levels of pathogens in raw milk in Australia.

Analysis of consumer level recalls and imported foods which failed inspection and testing requirements at Australia’s borders, provides some information on the foods and safety hazards that do or could enter the food supply from either domestic or imported food sources and pose a health risk.

National recalls and failures of imported food at border control:

- Reports between January 2014 to December 2020 revealed 171 imported dairy products that failed inspection and testing requirements, all of which were cheese products (Australian Government, 2022a; DAFF, 2022c). Half of all failed cheese products were imported from Italy (86/171; 50%). Microbial contamination of cheese was most frequently caused by *E. coli* (95/171; 56%), followed by *L. monocytogenes* (74/171; 43%). One cheese product was contaminated with both *E. coli* and *L. monocytogenes*. One cheese product failed due to visible mould contamination.
- Between the 6/7/2018 and 19/2/2022 there was a total of 32 consumer level recalls of milk and milk products due to microbial contaminants (69%, 22/32), foreign material contaminants (16%, 5/32), chemical contaminants (6%, 2/32), incorrect labelling (3%, 1/32), incorrect packaging (3%, 1/32) and a processing failure associated with pasteurisation (3%, 1/32) (FSANZ, 2021b). The 22 recalls due to microbial contamination were due to *E. coli* (73%, 16/22), *L. monocytogenes* (18%, 4/22), *Cronobacter* and *Salmonella* (1/22) and an unspecified microbial contaminant (1/22).

The risk characterisation largely aligns with the previous risk assessment and regulations are still applicable to manage risk. Regulation for the dairy industry has been in place for a long time and there is a high degree of compliance with Food Safety Program (FSP) requirements across the NSW dairy sector. The inherent food safety risks associated with raw milk mean that pasteurisation is the most reliable control measure and thereby the most effective means of protecting public health. The Food Standards Code (the Code) requires that milk is pasteurised (or equivalently processed) to eliminate disease-causing bacteria that may be present. In 2016, the NSW Food Authority approved the first application in Australia for the use of High-Pressure Processing (HPP) as an alternative to conventional thermal pasteurisation of dairy milk. HPP is a non-thermal technology that can achieve an equivalent level of inactivation of foodborne pathogens to heat pasteurisation, while meeting consumer demand for microbially safe and minimally processed dairy products.

The Code permits the production of raw milk cheeses that are produced in accordance with a FSP approved by the relevant state authority (for businesses in NSW, this would be the NSW Food Authority). Amongst those steps required to demonstrate compliance with food safety standards, the maturation of the cheese must meet certain time, temperature and water content requirements, a process which has a similar effect to pasteurisation in reducing pathogens. Raw goats' drinking milk is permitted for sale within NSW, if it has been produced in compliance with a FSP and if the milk bears the appropriate warning label. The volume of raw goats' milk products produced in NSW is low (< 20,000 litres per year) and there is no evidence of any foodborne illness attributed to this commodity. However, consumers of all raw milk products should be aware of the potential risks. This consumer advice is especially important for those at increased risk of severe disease; children younger than 5, pregnant women, adults 65 and older and people with weakened immune systems (NSW Food Authority, 2023d).

Aside from hazards which pose a current food safety risk, several hazards have been identified which may emerge and threaten Australia's livestock industries and export markets or represent a future food safety risk. This includes foot-and-mouth disease (FMD) and lumpy skin disease (LSD), which are viral diseases of animals and cannot be contracted by humans from consuming commercially produced milk or dairy products. Recent cases of FMD and LSD have been confirmed in Indonesia and in July 2022, FMD was also detected in Bali. An incursion of either FMD or LSD into Australia would require the rapid implementation of livestock disease control measures, that could have a devastating impact on the dairy sector. In addition, chlorates and perchlorates have been highlighted as emerging residues of concern by the European Food Safety Authority (EFSA). Aside from potential public health risks, the setting of new regulatory limits for the presence of these chemicals in food commodities in the EU may present a challenge to international trade. Lastly, an update is provided on prion diseases considering recent findings from various international surveillance programmes and studies. Prion diseases are a group of rare fatal neurodegenerative disorders that can affect both humans and animals. While there is a strong species barrier in most prion diseases, zoonotic transmission is a potential risk to humans as new and emerging prion agents arise. Active surveillance is critical for the control and prevention of human prion diseases, especially those diseases caused by animal-derived prion agents.

Introduction

NSW Food Regulation 2015

The Food Regulation 2015[a] underpins the NSW Food Authority's food regulatory work, which aims to reduce the incidence of foodborne illness linked to certain food sectors in NSW [for a review see (NSW Food Authority, 2020e)]. It is important to the food industry as it sets minimum food safety requirements for food industry sectors that have been identified as higher risk, including the dairy industry. These businesses are subject to Food Safety Schemes because of the priority classification.

In the *Dairy food safety scheme*, *milk* means the mammary secretions of a milking animal (other than colostrum) obtained from one or more milkings and intended for:

1. human consumption as a liquid, or
2. further processing.

In the *Dairy food safety scheme*, *dairy product* means:

1. colostrum,
2. milk,
3. any food that contains at least 50 per cent (measured by weight) of either or both of the following:
    a. milk,
    b. any substance produced from milk (but disregarding any weight of the substance not attributable to milk),
4. without limiting paragraph (c), any of the following that comply with the requirements of that paragraph:
    a. liquid milk products,
    b. cream and thickened cream,
    c. butter, butter concentrate, buttermilk, concentrated buttermilk, dairy blend, ghee and anhydrous milk fat (butter oil),
    d. casein, caseinate and cheese,
    e. whey, whey cream and concentrated whey cream,
    f. cultured milk and yoghurt,
    g. ice-cream and ice-cream mix,
    h. buttermilk powder, lactose powder, milk sugar, powdered milk, skim milk powder, whey powder, milk protein powder and other milk concentrates.

a The Food Regulation 2015 is scheduled for statutory repeal on the 1st of September 2023. This is a formal process which occurs every five years that requires the NSW Government to determine whether the Regulation should lapse and, in doing so, allow self-regulation, or be remade as is, or be remade with amendments. The NSW Food Authority intends to remake the Food Regulation by early 2024 to ensure the regulation remains contemporary and fit for purpose. Amendments are proposed for the new regulation, for example including businesses impacted by new Standards in the Food Standards Code. The draft regulation and Regulatory Impact Statement (RIS) will be available for public consultation for 4 weeks later in 2023. The NSW Food Authority will directly advise all stakeholder groups, Government agencies and industry sectors covered by the Regulation, including Local Government once the draft regulation and RIS are available for comment.

Under the *Dairy food safety scheme* there are licence categories that specify the types of activities each business is licensed to perform. Dairy food businesses need to meet food safety and labelling requirements which depend on each specific business type:

- dairy primary production
- dairy processing
- dairy collection and transportation
- dairy cold stores
- dairy food transport vehicles

The Food Regulation 2015 defines *dairy processing* as the packaging, treating, cutting or manufacturing of dairy products, and the packing and storing of those products on the premises where they are packaged, treated, cut or manufactured, but does not include dairy primary production. Dairy processing business means a food business that involves dairy processing. Licensed dairy processing businesses must comply with the sampling and analysis provisions of the *Dairy food safety scheme* of the Food Regulation 2015. The NSW Food Authority has prepared the NSW Food Safety Schemes Manual (the Manual) to specify certain requirements for the Food Safety Schemes under the Food Regulation 2015 (NSW Food Authority, 2019b). The requirements referred to in the Manual are mandatory. The Manual specifies the sampling and analysis requirements that licensed dairy processing businesses must comply with, in relation to water, chemical and microbiological testing.

The *Food Amendment (Raw Milk Products) Regulation 2018* has amended the NSW Dairy Food Safety Scheme in Food Regulation 2015 to require all raw milk activities to be licensed with the NSW Food Authority and creates an offence to supply raw milk products without one (NSW Food Authority, 2018a). *Raw milk product* means any product made from raw milk that is not intended for human consumption. For example, raw milk products include cosmetic products such as soaps and bath wash. Previously, only milk producers who supplied milk for human consumption were required to be licensed. It will also create an offence for any person to sell or supply raw milk products unless they have been treated, packaged, labelled and presented in a manner that deters human consumption and could not be reasonably mistaken for food. This offence can be applied to retailers.

The dairy sector in NSW

The NSW Food Authority licences approximately 1,700 businesses in the dairy sector (NSW Food Authority, 2023a). NSW has the second largest dairy industry in Australia in terms of farms and dairy production.

The NSW Food Authority licenses businesses across the supply chain in this sector (NSW Food Authority, 2021b). This includes:

- 534 dairy farms
- 205 dairy processing factories
- 145 farm milk collectors as well as cold food stores

Of the 7,629 food transport vehicles licensed with the NSW Food Authority approximately 4,440 are authorised to transport dairy products.

Legislation, Standards, and Industry Guidelines applicable to dairy businesses

Dairy products

The Australia and New Zealand food regulatory system involves the Australian Government, New Zealand and Australian states and territories. In this system food standards are developed under the Australia New Zealand Food Standards Code (the Code) (FSANZ, 2021c), which is administered by Food Standards Australia New Zealand (FSANZ) and enforced by state and territory governments. The standards in the Code are legislative instruments under the Legislation Act 2003. The NSW Food Authority enforces the Food Act 2003 (NSW) and associated regulations within NSW in respect of all food for sale. The type of dairy food business will determine the Standards which apply.

Equipment used for pasteurising dairy products at a dairy processing business must comply with the requirements of the *Guidelines for Food Safety: Validation and Verification of Heat Treatment Equipment and Processes* (ANZDAC, 2007). The guidelines have been developed to provide guidance on equipment and processing parameters that are to be reviewed and assessed as part of validation and verification of heat treatment.

Standard 4.2.4 – *Primary Production and Processing Standard for Dairy Products* mandates that for processing of milk and dairy products, milk must be pasteurised by –

1. heating to a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds; or
2. heating, using any other time and temperature combination of equivalent or greater lethal effect on any pathogenic micro-organisms in the milk; or
3. using any other process that provides an equivalent or greater lethal effect on any pathogenic microorganisms; unless an applicable law of a State or Territory otherwise expressly provides.

For paragraph (3), any other process used would need to be validated by the business and verified by the Authority.

No States or Territories have legislated to allow for raw cow milk to be sold. However, raw goat milk is permitted for sale in four States: Queensland, New South Wales, South Australia, and Western Australia. In NSW, unpasteurised goats' milk is only permitted subject to compliance with the *Dairy food safety scheme* and an advisory statement that the milk is unpasteurised must be included on the product (NSW Food Authority, 2018b).

Standard 4.2.4 of the Code permits the production of a raw milk cheese, but it must be produced in accordance with a Food Safety Program (FSP) approved by the relevant state authority. Divisions 1 to 4 of Standard 4.2.4 are generally applicable while Division 5 sets out additional requirements for primary production, transport, and processing of raw milk cheese. There are a number of steps and scientific trials that cheese makers wishing to manufacture raw milk cheese must go through in order to demonstrate compliance with food safety standards. The maturation of the cheese must meet certain time, temperature and water content requirements, a process which has a similar effect to pasteurisation in reducing pathogens. In NSW, businesses wanting to produce a raw milk cheese must complete a production process pro forma that will be used to assess compliance with Standard 4.2.4 (NSW Food Authority, 2023b). A pro forma is a written description of the steps used by a manufacturer to make a product. Critical information collected in this pro forma will be entered into the *Raw Milk Cheese Decision Support Tool* to determine if a raw milk cheese complies with Standard 4.2.4. The *Raw Milk Decision Support Tool* is based on published data and novel research funded by Australian and New Zealand regulatory agencies and developed by the University of Tasmania's Centre for Food Safety and Innovation within the Tasmanian Institute of Agriculture. A copy of this tool can be found on the NSW Food Authority's website (NSW Food Authority, 2023b).

The *Dairy pathogen manual* (DFSV, 2016) supports dairy processing businesses to meet the requirements of Standard 4.2.4 - *Primary production and processing standard for dairy products*, Standard 1.6.1 - *Microbiological limits in food* and Schedule 27 - *Microbiological limits for foods* of the Code. The *Dairy pathogen manual* references current microbiological limits, outlines actions to identify the cause of contamination and manage the problem, describes product clearance programs, discusses environmental monitoring and the importance of an organisation's food safety culture.

Special purpose foods

Infant formula is currently regulated under Standard 2.9.1 – *Infant Formula Products* and Schedule 29 – *Special Purpose Foods* of the Code. Through Proposal P1028, FSANZ aims to revise and clarify standards relating to infant formula (for use from birth to <12 months of age), comprising category definitions, composition, labelling and representation of products (FSANZ, 2023b). Although the standards for infant formula are, on the whole, functioning adequately, there is scope to improve the clarity of some standards and to consider the application of Ministerial policy guidance and alignment with international regulations (FSANZ, 2023b). The Second Call for Submissions is open until 7 July 2023.

Mandatory testing requirements that apply to producers of powdered infant formula are listed within Chapter 1 (dairy food safety scheme) of the NSW Food Safety Schemes Manual.

Consumer advice on the safe preparation, handling, storage and use of powdered and liquid infant formula in the home can be found on the FSANZ and NSW Food Authority websites (FSANZ, 2022; NSW Food Authority, 2023c).

Home-made infant formula and brew recipes are increasingly available online (FSANZ, 2015b; NSW Food Authority, 2023c) and provide no assurance of their safety, nutritional quality or appropriateness for babies. Many infant formula recipes specify the use of raw milk, as well as other potential high-risk ingredients. Further information on the risks associated with these recipes can be found on the NSW Food Authority website (NSW Food Authority, 2023c).

Updating the 2014 Risk Assessment

This Risk Assessment was produced following a literature review for issues related to dairy and dairy products that have impacted food safety since 2014. Information sources included:

- foodborne illness reports and recall data in Australia attributed to dairy and dairy products
- international issues arising from human illness or perceived hazards linked with dairy and dairy products
- border detections for dairy and dairy products
- risk assessments of dairy and dairy products
- emerging issues in the farm to consumer continuum for dairy and dairy products relevant to health risk
- research findings related to hazards in dairy and dairy product production and processing
- baseline surveys of microbiological and chemical hazards in dairy and dairy products
- other relevant sources if identified during the above activities

The current Risk Assessment includes discussion of dairy and dairy products identified from the literature review conducted as detailed above.

Risk Assessment

Hazard identification

The following section describes biological, chemical and physical hazards of concern in regard to dairy products intended for human consumption. In their Annual Report on Emerging and Ongoing Issues, FSANZ recognise antimicrobial resistance (AMR) as an ongoing food safety issue (FSANZ, 2021d). The hazard identification includes a section on antimicrobial resistant microorganisms.

Aside from work conducted domestically, a number of international risk assessments and reviews have recently been conducted to identify and assess hazards associated with the dairy supply chain. The hazard identification includes a summary of some of these risk assessments and reviews.

There is currently a heightened risk of both foot-and-mouth disease (FMD) and lumpy skin disease (LSD) entering Australia following outbreaks in nearby countries (DPI, 2023a, 2023b). Neither FMD nor LSD pose human health concerns (FSANZ, 2021a). However, an incursion of either FMD or LSD would require the rapid implementation of livestock disease control measures that could threaten Australia's livestock industries and export markets. A brief overview is provided of the Australian Veterinary Emergency Plan (AUSVETPLAN) response strategy policies to eradicate FMD (Animal Health Australia, 2022a) and LSD (Animal Health Australia, 2022b).

Prion diseases are discussed, in light of findings published recently in a number of international studies. However, there is no epidemiological evidence that currently indicates that prion diseases are an issue of public health concern.

Chlorates and perchlorates have been highlighted as emerging residues of concern by European Food Safety Authority (EFSA) (EFSA Panel on Contaminants in the Food Chain, 2014, 2015) and are also discussed.

Biological hazards

Milk can support a rich microbiota due to its high nutrient content, which includes proteins, fats, carbohydrates, vitamins, minerals and essential amino acids, all at a near neutral pH and at a high-water activity (Quigley et al., 2013). The diverse microbial flora of raw milk can include pathogens transmissible to humans (Quigley et al., 2013). The microbiological status of raw milk is influenced by animal health, exposure to faecal contamination, environmental contamination and temperature control. Microbiological contamination of raw milk can arise from direct excretion into the milk via the udder from animals with systemic infection as well as from localised infections, such as mastitis, or through external or environmental contamination (for example, equipment or from workers) during milk collection or during post-harvest handling and storage.

Raw milk and raw milk products may come from a number of milking animals including cow, goat, sheep, buffalo, horse and camel (NSW Food Authority, 2018b). The consumption of raw milk can present health risks from contamination by a variety of pathogenic microorganisms, including *Campylobacter*, *Salmonella*, *Listeria monocytogenes*, *Escherichia coli*, *Cryptosporidium* and *Staphylococcus aureus* (NSW Food Authority, 2018b). These pathogens can cause severe illness and death. In addition to acute illness, these infections can have long-term consequences, such as kidney failure resulting from haemolytic uraemic syndrome [HUS caused by Shiga toxin-producing *E. coli* (STEC)], Guillain–Barré syndrome (GBS caused by *Campylobacter*), reactive arthritis and functional gastrointestinal disorders such as irritable bowel syndrome (IBS) (Ajene, Fischer Walker, & Black, 2013; Majowicz et al., 2020; Porter et al., 2013). People who are immunocompromised, the very young and old, pregnant women and their unborn children are at greater risk for severe outcomes or death when infected with enteric pathogens.

In general, most information found in the scientific literature on food safety hazards is related to dairy cows and dairy products from cow milk (van Asselt, van der Fels-Klerx, Marvin, van Bokhorst-van de Veen, & Groot, 2017). Information on milk from other species is limited, which aligns with the fact that they represent only a fraction of the total volumes of dairy products produced (van Asselt et al., 2017).

In a microbiological risk assessment conducted by FSANZ (2009), the key pathogens associated with outbreaks implicating raw cow milk were *Campylobacter* spp., *L. monocytogenes*, Enterohaemorrhagic *E. coli* (EHEC)[a] and *Salmonella* spp. This is due to their likely occurrence in raw cow milk and their public health significance (FSANZ, 2009a). While other hazards associated with raw cow milk have been identified in the literature, epidemiological evidence of illness is either historical or limited to reports from outside of Australia. Australia is free from tuberculosis in all animal species (DAFF, 2012; More, Radunz, & Glanville, 2015). Bovine brucellosis (brucellosis in cattle) has been eradicated from all states of Australia, including NSW, since 1989 (NSW Health, 2019). Although *Brucella ovis* is present in many sheep flocks across NSW, it is not known to cause human disease (NSW Health, 2019). Caprine brucellosis (caused by *B. melitensis*) has never been reported in goats or sheep in Australia (QLD Health, 2022). There is no evidence that tick-borne encephalitis virus (TBEV) exists in Australia aside from those who have been infected overseas (Dehhaghi et al., 2019).

Raw goat milk has a mixed microflora which is not dissimilar to that found in raw cow milk (FSANZ, 2009b). Where pathogens have been detected in raw goat milk in Australia, they are similar to those reported internationally and reflect those generally found in raw cow milk (EFSA Panel on Biological Hazards, 2015; FSANZ, 2009b; Verraes et al., 2014). FSANZ (2009) conducted a risk assessment to identify the principal microbiological risks to public health and safety from the consumption of raw goat milk (FSANZ, 2009b). The assessment concluded that STEC poses a high risk to the total population (that is, general and susceptible populations). *Toxoplasma gondii* and *L. monocytogenes* were assessed to pose a high risk and *Salmonella* spp. pose a moderate risk to susceptible populations (FSANZ, 2009b).

There are established measures in place to ensure milk and milk products are safe from consumption of viable pathogenic bacteria. Pasteurisation of milk according to standard procedure (at least 72°C for minimally 15 s) reduces the probability of vegetative pathogens' survival by a factor of 10^6 (van Asselt et al., 2017). However, spores of pathogens, including those of *Clostridium botulinum* and *B. cereus*, are not eliminated by pasteurisation. To prevent outgrowth of surviving microorganisms or incidental recontamination, pasteurisation and temperature control (rapid cooling, chilled storage) are critical control points for foodborne pathogens associated with milk.

Organisms contaminating milk and milk products can die, survive or multiply depending on the varying compositional conditions they are exposed to. Awareness of pathogens and the particular niches they occupy in the dairy industry is essential if the risk they present is to be addressed. For example, powdered infant formula products[b] are not sterile, as during manufacture there is no processing step that can eliminate all microbiological hazards (FSANZ, 2015a). Powdered infant formulae are more likely to be at risk of contamination by organisms such as *Salmonella* or *Cronobacter*, both of which can readily survive in dry conditions (FAO/WHO, 2004, 2006). Powdered infant formula products include infant formula[c] and follow-on-formula[d]. Criteria for *Salmonella* were developed for all powdered infant formula products. Among infants, those at particular risk for *Cronobacter* infections are neonates (<28 days), particularly pre-term, low birthweight (<2500 g), and immunocompromised infants, and those less than 2 months of age. Therefore, a criterion for *Cronobacter* was developed for powdered infant formula only and not for follow-on formula.

Standard 1.6.1 of the Code specifies microbiological limits in dairy products and the NSW Food Authority has laid out mandatory testing requirements in the Food Safety Schemes Manual for dairy products (NSW Food Authority, 2019b). Depending on the dairy product to be tested, microbiological criteria have been set for organisms including *Campylobacter*, *L. monocytogenes*, *E. coli*, *Salmonella*, Coagulase Positive Staphylococci (CPS) and *Cronobacter*.

---

a Historically, EHEC was the term used to define STEC strains capable of causing haemorrhagic colitis (bloody diarrhoea), which sometimes develops into haemolytic uremic syndrome (HUS). However, not all EHEC contain the recognised accessory virulence markers associated with infection and it is often difficult to determine which STEC strains have the potential to cause disease. As a consequence, the term EHEC is becoming obsolete with the term STEC more frequently used instead (EFSA BIOHAZ Panel et al., 2020). Throughout this document, if a cited paper has used the term "EHEC", it has been replaced with the term "STEC".

b Standard 1.1.2 defines infant formula product as a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the sole or principal liquid source of nourishment for infants, depending on the age of the infant. Standard 1.1.2 defines an infant as a person under the age of 12 months.

c Standard 1.1.2 defines infant formula as an infant formula product that satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months.

d Standard 1.1.2 defines follow-on formula as an infant formula product that is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

Antimicrobial resistant organisms

The development of AMR and emergence of multidrug resistant pathogens are global concerns for both public health agencies and the agri-food industry. Antimicrobial resistant pathogens increase the risk of an infected individual suffering an adverse health effect, such as reduced treatment efficacy, increased disease severity, hospitalisation and mortality. FSANZ recognised AMR as an ongoing food safety issue which they will continue to monitor for developments domestically and globally (FSANZ, 2021d). FSANZ plays an active role in expert advisory groups [for example, as a member of the Australian Strategic and Technical Advisory Group on Antimicrobial Resistance (ASTAG) and Australian lead in the Codex AMR Taskforce] and contributes to the implementation of Australia's National Antimicrobial Resistance Strategy – 2020 and Beyond, through a new project on the surveillance of AMR in food (FSANZ, 2021d).

The Australian Pesticides and Veterinary Medicines Authority (APVMA) evaluates and registers antimicrobials for animal use in Australia. Australia's approach to the use of antimicrobials in livestock production is one of the most conservative in the world. Nearly all antimicrobials used for animal treatments are Schedule 4 medicines, which means that they must be prescribed by a veterinarian. The classification of different antimicrobials is an important approach to assist in managing antimicrobial resistance, ensuring that all antimicrobials, especially critically important antimicrobials, are used prudently in both human and veterinary medicine. In Australia, ASTAG has published guidance titled *Importance Ratings and Summary of Antibacterial Uses in Humans in Australia* (ASTAG, 2018). ASTAG uses the importance ratings of High, Medium and Low to categorise the severity of impact anticipated from the emergence of resistance to particular antimicrobials (ASTAG, 2018). In Australia, there are two antibiotics rated of high importance for human health that are registered for use in dairy cattle as a "last resort" (ASTAG, 2018). These antibiotics are a 3rd generation cephalosporin (ceftiofur) and streptogramin (virginiamycin) (ASTAG, 2018). Neither of these antibiotics are approved for use in humans, but they have the potential to select for cross resistance to antibacterials used in humans (ASTAG, 2018).

The Australian government published a review of published and grey literature[a] on AMR in food (DoH, 2018). The aim of this study was to review published and grey literature on the presence and extent of AMR in food in Australia and New Zealand for the period 1999 to early 2018. The report provided an overview of available evidence for AMR presence in the food production, processing and retail sectors of red meat, pork, poultry meat, dairy, egg, seafood and horticultural products. In regard to the Australian dairy industry, knowledge gaps were identified. As commercial production is mainly bovine, research on antibiotic resistant microorganisms in the dairy industry predominantly focuses on dairy cows. It was reported that information on AMR among bacteria derived from dairy products is limited to relatively small studies that investigated AMR in *L. monocytogenes* and enterococci. While information on AMR of foodborne pathogens such as *Salmonella* and pathogenic *E. coli* strains, and commensal bacteria derived from dairy farms, food processing environments and retail products is limited.

Outside of the 1999 to early 2018 period covered in the literature review of the report by the Department of Health (DoH, 2018), an Australian study was published on the AMR profiles of dairy isolates from the milk of dairy cows with and without clinical mastitis (Al-Harbi, Ranjbar, Moore, & Alawneh, 2021). While humans may be infected by some mastitis-causing bacteria, such as *S. uberis* and *T. pyogenes*, they are not important foodborne pathogens (DoH, 2018). Mastitis is the single most significant animal health problem affecting all Australian dairy farms (Coombe, 2021). Antibiotic therapy used to treat and control mastitis accounts for more than two thirds of all antibiotic courses supplied to dairy farmers by veterinarians (Coombe, 2021). The Australian dairy industry is committed to improving antibiotic stewardship and has implemented a number of recent initiatives, including the development of a machine learning underpinned clinical mastitis treatment decision tool that will reduce antibiotics used to treat clinical mastitis (Coombe, 2021; Dairy Australia, 2023a).

a Grey literature is research that has not been published commercially and is therefore not necessarily searchable via the standard databases and search engines. Examples of grey literature include, but are not limited to, government reports, conference proceedings, research reports and policy statements.

The NSW Government plays an established role in antimicrobial stewardship and resistance in accordance with the National Antimicrobial Resistance Strategy (Australian Government, 2022b). There is no current role for the NSW Food Authority beyond its existing role in promoting good hygienic practices to combat the foodborne transmission of bacteria with AMR.

Chemical hazards

Chemical hazards can be unintentionally introduced into milk and milk products, making them unsafe and unsuitable for consumption. Milk can be contaminated when the milking animals consume feed and/or water that contain chemicals. Other causes of contamination may be inadequate control of equipment, the environment and milk storage facilities.

Standard 4.2.4 sets out the requirement to control specific inputs, including any feed used in primary production. The control measures required may vary depending on whether the feed is purchased, pasture or silage. The importance of these controls is highlighted by recent international reports of the transfer of psychoactive cannabinoids into the milk of lactating dairy cows fed industrial hemp silage (Wagner et al., 2022) and the detection of hypoglycin A (HGA) toxin in the milk of cows grazing on pastures containing sycamore maple trees (Bochnia, Ziegler, Glatter, & Zeyner, 2021).

APVMA is the federal authority responsible for the evaluation and registration of agricultural and veterinary chemicals (agvet chemicals) for supply, sale and use in Australia. The APVMA assesses and approves agvet chemicals for use and sets a maximum residue limit (MRL) applying to both imported and domestic food. MRLs are listed in the Code following consideration by FSANZ.

The APVMA also sets extraneous residue limits (ERLs). ERLs are the maximum permitted limits of pesticide residues in food commodities arising from environmental sources.

A maximum level (ML) is the level of a specified contaminant or natural toxicant which is permitted to be present in a food and applies to chemicals such as heavy metals and mycotoxins.

The Code specifies that where no MRL or ERL has been established for a particular agvet chemical residue in a particular food, there must be no detectable level of that residue present. In contrast, where no ML has been set for a particular environmental contaminant in a food, residues are allowable at low levels.

The Australian Milk Residue Analysis survey is the national residue monitoring program for agvet chemicals and environmental contaminants in bovine milk (DAFF, 2022b). The survey is funded through the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF), who also approve the sampling plan. Dairy Food Safety Victoria (DFSV) co-ordinates the survey. Throughout each year around 1,000 samples of raw milk are collected from farms across all dairying regions of Australia. The number of samples collected from each dairying region is commensurate with its milk production volume. These samples are used to conduct around 13,000 analyses for nearly 70 different compounds covering antimicrobials, animal parasite control chemicals, feed contaminants and environmental contaminants. The chemicals selected for analysis reflect agvet chemical use patterns in Australian dairy production and those chemicals that may be of interest to Australia's trading partners. If a residue is detected in a sample at a level ≥ 50% of the Australian or European Union (EU) MRL/ERL (whichever is the most stringent) or at any level in the case where no MRL/ERL has been established, DFSV informs the relevant state regulatory authority and DAFF.

The results over the history of the survey have shown close to 100% compliance. During 2020–21, 1,030 milk samples were collected and a total of 14,500 analyses performed. Of the samples tested, no residues were detected at levels above the relevant Australian standard.

Physical hazards

Physical hazards may be introduced at any stage of the processing chain such as via raw materials, poorly maintained facilities and equipment, packaging materials and poor food safety practices. Physical hazards would normally be addressed by adherence to Good Manufacturing Practice (GMP), a Hazard Analysis and Critical Control Point (HACCP) system and requirements relating to safe and suitable food in Chapter 3 of the Code. Physical hazards are less likely than chemical or biological contaminants to affect large numbers of people and, are most likely to be reported by production or by consumer complaints. Between 6/7/2018 and 19/2/2022, there were five consumer level recalls in Australia of dairy products due to the presence of physical objects, including glass, metal, plastic and rubber. For further information, see the section on recalls and import border failures for dairy and dairy products.

International risk assessments and reviews to assess food safety hazards in the dairy supply chain

The sale of raw drinking milk (RDM) is permitted in a number of countries or states around the world. Many of the risk assessments that have been published on RDM and products made using raw milk, originate from these areas.

New Zealand

In New Zealand, the Ministry for Primary Industries (MPI) undertook an update to the assessment of the microbiological risks associated with the consumption of raw milk (MPI, 2019c). The report included review of available information covering the period from 2014 until 2018. The Raw Milk for Sale to Consumers Regulations 2015 have been fully operational in NZ since November 2016 and allow consumer choice to be exercised regarding raw milk, while using stringent controls, consumer education and monitoring to protect public health. From January 2014 to November 2018, raw milk was confirmed to be the source of 17 outbreaks. Of these 17 outbreaks, 11 outbreaks were due to *Campylobacter* spp., two outbreaks were due to STEC, one outbreak was due to *Cryptosporidium* and three outbreaks were caused by more than one pathogen (*Campylobacter* and STEC in one outbreak, *Campylobacter* and *Giardia* in two others). In outbreaks of STEC infection young children represent the highest number of cases. This trend was also confirmed in analysis of national data on sporadic cases of notifiable diseases associated with RDM. Of the 111 sporadic STEC infections in individuals who reported consumption of RDM between January 2014 to November 2018, the majority (60%, 66/111) were children under 16 years. A high proportion of these cases were hospitalised (29% of children and 17% of adults). Nine cases (eight children under eight years and one elderly person) developed HUS. The authors of the report concluded that *Campylobacter* and STEC are the main aetiological agents for which there is a demonstrable link between RDM and human illness in NZ (MPI, 2019c). While campylobacteriosis is the most common raw milk-borne illness, STEC infections are associated with the most severe sequelae. The assessment concluded that due to the inherent food safety risks associated with RDM, pasteurisation is the most reliable control measure and thereby the most effective means of protecting public health. Adherence to good hygienic practices during milking, packaging and storage can reduce, but not eliminate, the risk of contamination of RDM.

European Union

In the EU, the public health risks related to the consumption of RDM from the main milk-producing species were determined (EFSA Panel on Biological Hazards, 2015). The main milk-producing species in the EU are cows, sheep and goats, horses and donkeys and camels. The following were considered in order of priority in deciding whether a hazard qualified as a main hazard or not:

i) epidemiological evidence that the hazard has been associated with illness from the consumption of RDM in the EU. This included outbreak and other data, where available,

ii) the extent of occurrence of the hazard in different milk-producing species in the EU where available,

iii) the prevalence of the hazard in milk bulk tanks or retail RDM in the EU where available, and

iv) expert opinion.

The main bacterial hazards identified were STEC, *Salmonella* spp., *Campylobacter* spp., TBEV, *B. melitensis* and *M. bovis*. Of these, *Campylobacter* spp., *Salmonella* spp. and STEC were considered to be more widely distributed in the EU than the other hazards and *Campylobacter* spp. were the leading cause of outbreaks. TBEV and *B. melitensis* are restricted to certain parts of Europe, although in the case of TBEV it was reported that the range appears to be expanding. *B. melitensis* and *M. bovis* have been associated with outbreaks involving raw milk but these are much older and less frequent than for the other hazards. The authors of the report concluded that these pathogens are less common now than in the past and control programmes in Europe have generally been successful in reducing human disease from these organisms.

Another study undertaken in Europe by van Asselt et al. (2017), assessed the most relevant microbiological, chemical, and physical hazards that may be present in the dairy supply chain. While production chains can differ throughout Europe, it was assumed that the food safety hazards, and their points of entry are identical. The study focused on milk, cheese, butter and milk powder produced and imported into the EU derived from cows, goats, and sheep. Food safety hazards were evaluated from the farm to the final product and excluded the retail and the consumer stages. The study focused on dairy products and did not include possible hazards introduced from major additional ingredients. A literature review was combined with available data. Outbreak data on microbiological hazards were obtained from EFSA reports from 2010 to 2013. Additionally, EFSA reports on residues in animal products between 2012 and 2014 were analysed. Data on chemical hazards from the Dutch monitoring program on dairy products were retrieved from 2009 to 2013, which included over 2,000 samples for chemical compounds in butter, cheese, milk powder and milk. Most samples were taken from milk (around 70%), the majority of which were tested for the presence of veterinary drugs. The Rapid Alert System for Food and Feed (RASFF) portal was used to extract data for notifications of food safety hazards in milk and milk products within the EU during 2009 to 2014. All notifications were included, namely, border rejections, public information and alerts. In total, 243 notifications were retrieved from the RASFF database and microbiological contaminations were mainly reported (84%, 203/243). van Asselt et al. (2017) concluded that microbiological hazards are encountered more frequently in dairy products than chemical and physical hazards. *Listeria monocytogenes*, *S. aureus*, *Salmonella* and human pathogenic *E. coli* were identified as the most important microbiological hazards in dairy products. Soft and semisoft cheeses were reported to be most frequently associated with *L. monocytogenes* and *S. aureus* enterotoxins. Raw milk was most frequently associated with human pathogenic *E. coli* and *Campylobacter* spp. The microbiological hazards of most concern in powdered infant formula were reported to be *Cronobacter* spp., and *Salmonella* spp. Based on literature, monitoring and RASFF data, the most relevant chemical hazards in dairy products were concluded to be aflatoxin M1, dioxins, dioxin-like compounds and residues of veterinary drugs. The most relevant physical hazards were reported to be metal, glass and plastic particles introduced during processing.

Another study conducted in the EU, aimed to review safety and fraud issues within the dairy sector over a five-year period (2015–2019) (Montgomery, Haughey, & Elliott, 2020). Safety and adulteration/fraud data relating to milk and milk products collected from 2015 to 2019 was extracted from the online RASFF portal and HorizonScan. To support the data collected from the online databases, grey literature was also reviewed for news articles between 2015 and 2019. RASFF alerts from 2015 to 2019 were assigned to eight general dairy groups (cheese, milk, infant formula, milk powder, other dairy products, yoghurt, butter and cream). RASFF alerts were categorised under biological (n = 265), chemical (n = 29), physical (n = 43) contaminants and inadequate controls (n = 18). Of the 265 alerts related to biological contaminants, pathogenic microorganisms were responsible for 249 alerts and non-pathogenic microorganisms were responsible for 16 alerts. The study found that cheese products (which are often made from raw milk) had the highest number of biological notifications (83%, 220/265) and the majority involved *L. monocytogenes* originating from France. After *L. monocytogenes* (n = 117), the microorganisms responsible for the next greatest number of alerts in cheese were *E. coli* (n = 65) and *Salmonella* (n = 29). Cheese was also responsible for the highest total number of notifications for chemical, physical contaminants and inadequate controls (43/90; 48%). These notifications crossed over 9 different hazard groups including food additives, foreign bodies, labelling issues, legal veterinary products, mycotoxins, allergens, industrial contaminants, packaging defective and poor controls. In total there were 145 notifications within the HorizonScan database related to fraud issues in milk and milk commodities and included adulteration/substitution (fraudulent documentation), unapproved premises, produced without inspection and expiry date changes. Cheese commodities had the highest number of fraud notifications relating to fraudulent documentation (n = 73), followed by adulteration/substitution (n = 21), unapproved premises (n = 3), produced without inspection (n = 2) and expiry date changes (n = 2).

United Kingdom

In the UK, the Advisory Committee on the Microbiological Safety of Food (ACMSF) was asked to assess whether the risk associated with consumption of RDM (and certain unpasteurised products made using raw milk) made domestically had changed since this issue was last considered by the Board in July 2015 (ACMSF, 2018). The approach taken was to assess:

i) whether newly registered RDM producers in the UK present a greater likelihood of producing unsafe product than more established producers, and

ii) whether there has been a change in the profile of vulnerable groups becoming ill, and

iii) the aetiological agents involved.

The assessment focused on raw cows' drinking milk, although milk from other species (for example, sheep and goats) was also considered. Cream, smoothies, milkshakes and ice-cream made using raw milk were included following a request by risk managers, in particular as the latter three product types could potentially increase raw milk consumption among children. Other products made using raw milk such as butter and cheese were outside the scope of the assessment. The data represent England, Wales and Northern Ireland as the sale of RDM is not permitted in Scotland. Since July 2015, there has been a noticeable increase in the number of RDM producers and RDM-related outbreaks. The number of registered RDM producers (all species) in the UK increased from 108 in April 2014 (107 in England/Wales and 1 in Northern Ireland) to 168 in January 2018 (151 in England, 11 in Wales and 6 in Northern Ireland). There has been a five-fold increase in the volume of RDM production in the UK from around 610,000 litres in 2012 to 3.2 million litres in 2017. Consumer research indicated that the proportion of the population consuming RDM had increased from 3% of the population in 2012 to 10% of the population in 2018. Current RDM consumers also consumed RDM more frequently and in greater amounts in 2018 than in 2012. Provisional data indicated that in 2017 up to 14.8% of all foodborne infectious intestinal disease outbreaks in England and Wales were associated with RDM. In 2016, this figure was 4.5%.

This is significantly higher than in previous years, with 0.0 - 2.4% of all reported foodborne infectious intestinal disease outbreaks in England and Wales from 1992 to 2015 being associated with RDM and raw cream. From the beginning of 2015 to the end of December 2017, there were five reported outbreaks linked to consumption of RDM in the UK (4 in England and 1 in Wales). Four of the outbreaks were due to *C. jejuni* and one outbreak was due to STEC O157. In addition, in 2017 a single case involving *Salmonella* Dublin affected one child who consumed raw cows' drinking milk. This incident was not reported as an outbreak due to only one individual being affected. An indistinguishable strain of *S.* Dublin was detected in bulk milk and farm environmental samples. The ACMSF concluded that the aetiological agents involved had not changed since RDM was considered by the Board in July 2015. The main hazards involved in outbreaks since 2015 were *Campylobacter*, STEC O157 and non-typhoidal *Salmonella*. This is in line with the Scientific Opinion published by EFSA in 2015 (EFSA Panel on Biological Hazards, 2015), which identified these as among the main pathogens for which there is a clear link between RDM and human illness in the EU. It is also consistent with what has been seen in the UK historically (ACMSF, 2018).

In total, there were 103 affected cases, 4 reported hospitalisations and no deaths. Out of the 103 total cases reported to have been involved in outbreaks associated with consumption of RDM since July 2015 and the single salmonellosis case, 16 were children (of whom at least 3 were less than 5 years old). Children were involved in outbreaks associated with consumption of RDM both before and after this issue was considered by the Board in July 2015. Data on other vulnerable groups associated with outbreaks is not routinely collected. The authors of the report therefore stated that conclusions could not be drawn on whether the involvement of these groups in outbreaks associated with RDM has changed. All outbreaks were associated with RDM from cows.

The root causes of the outbreaks are not known. It was reported that there did not appear to be a correlation between the amount of trading time (that is, the period between the food business operator being registered to sell RDM and the date on which the outbreak was reported) and involvement in outbreaks. However, it was recognised that the number of outbreaks considered was too small to enable firm conclusions to be drawn (ACMSF, 2018).

Ireland

In Ireland, Tiwari et al. (2015) undertook a risk assessment of *L. monocytogenes* contamination in raw and pasteurised milk cheese (Tiwari et al., 2015). The objective of the study was to model and quantify the level of *L. monocytogenes* in raw milk cheese and pasteurised milk cheese from farm to fork. The modelling approach included a prediction of contamination arising from the farm environment as well from cross-contamination within the cheese-processing facility through storage and subsequent human exposure. Data was extracted from various scientific literature sources to inform model inputs, parameters and distributions used in the developed quantitative risk assessment. A possible direct route of transmission of *L. monocytogenes* into milk may be from animal contact (that is, raw milk contamination from animals with *L. monocytogenes* subclinical mastitis), but this was not considered for the model development as it is reported to be a rare occurrence. In addition, no growth was assumed to occur during transport of milk and therefore, it was not included in the model development. The model predicted a high concentration of *L. monocytogenes* in contaminated raw milk cheese (mean 2.19 $\log_{10}$ CFU/g) compared to pasteurised milk cheese (mean −1.73 $\log_{10}$ CFU/g). The mean probability of illness of adult Irish consumers following exposure to contaminated cheese was 7 x 10^{-8} (low-risk population) and 9 x 10^{-4} (high-risk population, for example the immunocompromised) for raw milk cheese and 7 x 10^{-10} (low-risk population) and 8 x 10^{-6} (high-risk population) for pasteurised milk cheese, respectively. In addition, the model was used to evaluate performance objectives at various stages, namely, the cheese making and ripening stages, and to set a food safety objective at the time of consumption. A scenario analysis predicted various probabilities of *L. monocytogenes* contamination along the cheese-processing chain for both raw milk cheese and pasteurised milk cheese. The sensitivity analysis showed the critical factors for both cheeses were the serving size of the cheese, storage time and, temperature at the distribution stage.

Italy

In Italy, several quantitative risk assessments have been conducted to describe the risk of foodborne illness due to raw milk consumption. These risk assessments report estimates of foodborne illness in susceptible and / or the general population, due to *Salmonella* and *L. monocytogenes* (Giacometti, Bonilauri, Albonetti, et al., 2015), *Campylobacter* (Giacometti, Bonilauri, Amatiste, et al., 2015), staphylococcal enterotoxin A (Crotta et al., 2016) and STEC (with a focus on HUS cases) (Giacometti et al., 2017). The sale of raw milk for human consumption in self-service vending machines has been allowed in Italy since 2004. Since December 2008, raw milk vending machines must display the notice "*milk must be consumed after boiling*". Reported estimates of the proportion of consumers who do not boil milk before consumption, ranges from 13.9 to 43% (Crotta et al., 2016; Giacometti, Bonilauri, Albonetti, et al., 2015). In each risk assessment discussed below, the probability of illness was considered negligible in all scenarios modelled if the raw milk was boiled prior to consumption.

Giacometti et al. (2015) undertook a quantitative risk assessment of human salmonellosis and listeriosis related to the consumption of raw milk in Italy (Giacometti, Bonilauri, Albonetti, et al., 2015). Two separate RA models were developed: one for the consumption of boiled milk and the other for the consumption of raw milk. The RA models predicted no human listeriosis cases per year either in the best or worst storage conditions and with or without boiling raw milk. Whereas the annual estimated cases of salmonellosis depend on the dose-response relationships used in the model, the milk storage conditions and consumer behaviour in relation to boiling raw milk or not. The estimated salmonellosis cases ranged from no expected cases, assuming that the entire population boiled milk before consumption, to a maximum of 980,128 cases, assuming that the entire population drank raw milk without boiling, in the worst milk storage conditions and with the lowest dose-response model. Giacometti et al. (2015) state that the predicted absence of listeriosis cases due to raw milk consumption is difficult to validate. However, the authors state that their results align with a previously published report estimating a low probability of listeriosis due to raw milk consumption (≤1 predicted case of listeriosis per billion of servings) in the case of direct selling from farmer to consumer (Latorre et al., 2011).

Giacometti et al. (2015) undertook a quantitative risk assessment to describe the risk of campylobacteriosis linked to consumption of raw milk sold in vending machines in Italy (Giacometti, Bonilauri, Amatiste, et al., 2015). Exposure assessment was based on microbiological records of raw milk samples from vending machines monitored by the regional Veterinary Authorities from 2008 to

2011, microbial growth during storage, destruction experiments, consumption frequency of raw milk, serving size, consumption preference and age of consumers. Two separate RA models were developed, one for the consumption of boiled milk and the other for the consumption of raw milk. Considering the higher risk reported for *Campylobacter* infection in children, two different dose-response (D-R) relationships were used to consider the higher susceptibility of some consumer populations. D-R I is the most frequently used D-R model for *Campylobacter* and is based on the data of a volunteer study, while D-R II includes consideration of data from two similar outbreaks among school children drinking raw milk at farms in the UK and the Netherlands. Giacometti et al. (2015) state that as the infection rate in children under five years is 1.7–2.6 times higher than the rates in other age groups, D-R II is best aligned with modelling the probability of infection in a “sensitive” population, while D-R I relationship is best suited for modelling infection in older populations. The RA model predicted no human campylobacteriosis cases per year if all consumers boil raw milk before consumption, for all of the simulated storage conditions of milk during its shelf life. Consequently, the authors concluded that the probability of illness could be considered negligible in this scenario. In case of consumption without boiling milk, the annual number of predicted campylobacteriosis cases varied widely depending by the D-R relationships used in the model, the storage conditions of milk during its shelf life and the age of consumers. The annual estimated cases for young consumers using D-R II for the sensitive population (≤5 years old) ranged between 1013.7/100,000 population and 8110.3/100,000 population and for adult consumers using D-R I between 79.4/100,000 population and 333.1/100,000 population.

Crotta et al. (2016) undertook a quantitative microbial risk assessment to investigate exposure to staphylococcal enterotoxin A in raw milk from vending machines in Lombardy, Italy (Crotta et al., 2016). The 0-to-2-year subpopulation was excluded, as it was assumed that consumption would be breast milk or reconstituted milk only. The model aimed to capture differences in pathogenicity between strains and consumer behaviour at the household level. The minimum dose of staphylococcal enterotoxin deemed sufficient to be harmful to humans was set at a conservative threshold of 20 ng per serving. Data from 301 questionnaires submitted to raw milk consumers were used to obtain uncertainty distributions around consumer behaviour. The key consumer variables considered for the model were the position of the milk in the refrigerator, storage time, litres purchased weekly, whether the milk was boiled before consumption or not, estimated transport time and utilisation of thermal bags. The level of contamination in purchased raw milk was estimated from the regional monitoring program for RDM between 2011 and 2014. The model included an estimate of the overall probability of finding *S. aureus* isolates with the staphylococcal enterotoxin A gene (*sea*) in Lombardy. In the model, the growth of *S. aureus* in milk was estimated as a function of temperature and SEA production was modelled as a function of the cell density of *S. aureus*. Crotta et al. (2016) reported that while raw milk is known to be an excellent medium for *S. aureus* growth, enterotoxin production sufficient to warrant a threshold of concern was linked only to very unlikely storage times. The very low predicted number of servings carrying a dose of ≥20 ng/ml, aligns with the fact that there is no evidence of *S. aureus* intoxication related to RDM consumption in Lombardy since the sale of RDM was allowed in 2004.

Giacometti et al. (2017) undertook a quantitative risk assessment to estimate HUS cases in the paediatric population associated with the consumption of RDM sold in Italy (Giacometti et al., 2017). The paediatric subpopulation (0–14 years old) is assumed to account for about 20% of total raw milk consumers. The exposure assessment of the risk assessment was based on the official STEC O157:H7 microbiological records of raw milk samples from vending machines monitored by the regional Veterinary Authorities from 2008 to 2014, microbial growth during storage, consumption frequency of raw milk, serving size, consumption preference and age of consumers. *E. coli* O157:H7 was detected in 0.15% of milk samples over the years 2007–2014. The differential risk considered milk handled under regulation conditions (4°C throughout all phases) and the worst time–temperature field handling conditions detected. In case of boiling milk before consumption, it was assumed that the risk of HUS is fixed at zero. The assessment revealed that milk storage scenario influences the risk but has less impact than consumer behaviour. The estimated number of HUS cases across all years (0 – 14 years) per year ranged from <1 case for worst- and best-case milk store scenarios if 99% of consumers boil their milk, to a maximum of 19.37 cases under worst case milk store scenarios in 2 year olds if only 80% of the consumers boil their milk.

South Africa

In South Africa, a quantitative risk assessment was conducted to estimate HUS cases associated with the consumption of bulk milk sold directly from producer to consumer (Ntuli, Njage, Bonilauri, Serraino, & Buys, 2018). Data were obtained from recently completed studies in South Africa, taking into account prior collected prevalence data of STEC in raw and pasteurised producer-distributor bulk milk and survey information from producer-distributor outlets and households. Producer-distributor bulk milk in South Africa is typically:

i) raw milk sold at producer-distributor outlets for human consumption,

ii) milk that has been pasteurised at producer-distributor outlets and sold directly to consumers, and

iii) pasteurised milk that has been pasteurised elsewhere at an approved facility and sold at producer-distributor outlets.

Producer-distributor bulk milk constitutes 2% of total milk produced and sold in South Africa. Inputs for the models were complemented with data from published and unpublished literature and a probabilistic exposure model was developed. Stages before the producer-distributor outlets were not included in this model (that is, from the farm to producer-distributor outlets). The model was developed from producer-distributor outlets to the household for producer-distributor bulk milk sold as either raw or pasteurised. The model considered the following steps:

i) producer-distributor storage,

ii) transport time and temperature from producer-distributor to home and consumer handling, and

iii) consumption habits at home and exposure to STEC per serving.

Hazard characterisation was based on an exponential D-R model to calculate the probability of illness from STEC infection in individuals 5 years and younger and individuals older than 5 years. The estimated mean STEC level was 0.12 CFU/mL for raw producer-distributor bulk milk and 0.08 CFU/mL for pasteurised producer-distributor bulk milk. Under ideal conditions, no STEC cells should survive pasteurisation. STEC contamination in pasteurised milk occurs from either inadequate pasteurisation or post-pasteurisation contamination, for example during consumer handling. Although inadequate pasteurisation may result in survival of STEC, subsequent dilution effects lower the probability of HUS risk associated with STEC to very low levels in packaged milk. A higher risk of HUS cases per year was recorded for raw than pasteurised producer-distributor bulk milk and, for individuals younger than 5 years of age. In simulations in which all consumers boiled milk before consumption, no risk was calculated for both raw and pasteurised producer-distributor bulk milk. For every 100,000 servings consumed, the expected median numbers of HUS cases per year from raw producer-distributor bulk milk were 52 for 5 years and younger and 3.2 for older than 5 years. For every 100,000 servings consumed, the median numbers of cases per year for pasteurised producer-distributor bulk milk were 47 for 5 years and younger and 2.9 for older than 5 years.

The higher number of HUS cases estimated by the model for children 5 years and younger, although they consume smaller milk volumes, was attributed to frequency of consumption (higher in this population) and infectious dose (lower in this population). The risk of infection and the subsequent development of HUS was most influenced by serving volumes and then by time needed to sell the milk at producer-distributor outlets. These factors were the most important for both age groups for both raw and pasteurised producer-distributor bulk milk. The authors state that one of the main sources of uncertainty of their study was the estimated level of STEC in both raw and pasteurised producer-distributor bulk milk. The estimated level of STEC exposure per serving in their study was very high for both raw and pasteurised producer-distributor bulk milk. The authors note that this could explain why serving volume was the most important parameter in determining the risk of infection and the subsequent development of HUS. The results differ considerably from those of other previously published reports cited in the paper and are stated to be the result of differences in the risk model and data (for example, temperature distributions, time distributions and pathogen prevalence) employed in each study. There were no official reports on HUS cases in South Africa to benchmark the author’s model outputs.

United States and Canada

A systematic review was conducted of disease outbreaks from 2007 up to October 2020 linked to pasteurised and unpasteurised dairy products in Canada and the United States (Sebastianski, Bridger, Featherstone, & Robinson, 2022). Sebastianski et al. (2022) searched MEDLINE, Embase, Cochrane Library, TRIP Database for guidelines and North American government agency websites. Outbreak reports were included where the pathogenic microbe was confirmed in both the patient and the dairy product through laboratory testing. Thirty-two outbreaks were linked to dairy consumption, with 62.5% (20/32) linked to unpasteurised dairy products. Twenty outbreaks involving unpasteurised products resulted in 449 confirmed cases of illness, 124 hospitalisations and five deaths. Of the twenty outbreaks that were reported, 14 outbreaks (70%) involved unpasteurised fluid milk (cow milk (n=11), goat milk (n=1), unknown animal (n=2)) and seven (35%) involved cheese made from unpasteurised milk (with one outbreak linked to both contaminated fluid milk and cheese made from the milk). One outbreak was caused by the parasite *Cryptosporidium parvum* while the others were caused by bacteria: *C. jejuni* (n=6; 30%), *Salmonella* (n=6; 30%), STEC (n=5; 25%) and *Listeria* spp. (n=2; 10%). Sebastianski et al. (2022) concluded that their findings aligned with previous reports of campylobacteriosis being more frequently associated with illness due to consumption of unpasteurised dairy products. Sebastianski et al. (2022) cite data reporting that campylobacteriosis was linked to unpasteurised milk in 69% of cases in Canada (Ontario) between 2005 and 2012 and 81% of outbreaks in the USA between 2007 and 2012. In regard to pasteurised products, twelve outbreaks resulted in 174 confirmed cases of illness, 134 hospitalisations, 17 deaths and seven foetal losses. The outbreak sources were soft cheese made from pasteurised milk (n=7; 58%), pasteurised fluid milk (n=3; 25%) (the milk was improperly pasteurised in at least one outbreak), liquid ice cream mix (n=1; 8%) and gas station nacho cheese sauce (n=1; 8%). *L. monocytogenes* accounted for 10 out of 12 outbreaks (83%) from pasteurised products between 2007 and 2020. Of the remaining outbreaks, *Yersinia enterocolitica* was responsible for one outbreak (8.3%) and one outbreak was due to *Clostridium botulinum* (8.3%). Sebastianski et al. (2022) concluded that *Listeria* outbreaks from pasteurised products may be an emerging problem and occur due to improper pasteurisation or from contamination post-pasteurisation.

Foot-and-mouth disease and lumpy skin disease

FMD and LSD are highly contagious viral diseases of animals (DPI, 2023a, 2023b). While neither of these diseases are present in Australia, there is currently a heightened risk of both FMD and LSD entering Australia following outbreaks in nearby countries (DPI, 2023a, 2023b). Neither FMD or LSD pose human health concerns (FSANZ, 2021a). Any measures that may be associated with one of these diseases undertaken in Australia are in no way related to human food safety risks (FSANZ, 2021a). Such measures would only be for the purposes of livestock disease control (FSANZ, 2021a). Humans cannot contract these diseases from consuming commercially produced products from meat, poultry, eggs, milk or dairy products (FSANZ, 2021a). If Australia ever had an outbreak of FMD or LSD, products from affected farms would not be commercially available as all animals must first pass an inspection to ensure they are healthy, and all products must meet strict food safety requirements (FSANZ, 2021a). Any meat, milk or dairy product from a livestock animal that has been vaccinated against any of the diseases (where vaccines are used) in accordance with an approved Australian use remain safe to eat (FSANZ, 2021a).

While not a food safety issue *per se*, an incursion of FMD or LSD would represent a substantial threat to Australia's livestock industries and export markets. The attitudes of trading partners toward an outbreak of either FMD or LSD will be contingent on a number of factors, including how widely it spreads and the measures that Australia would employ to contain and eradicate the diseases. The AUSVETPLAN contains the nationally agreed approach for the response to emergency animal disease incidents in Australia (Animal Health Australia, 2023). The AUSVETPLAN response strategy policies are to eradicate FMD (Animal Health Australia, 2022a) and LSD (Animal Health Australia, 2022b) in the shortest possible time, while minimising social, economic, animal welfare and environmental impacts. Stamping out will be the default policy initially, with or without vaccination, supported by a combination of other strategies (Animal Health Australia, 2022a, 2022b). There are several differences in the AUSVETPLAN response strategy policies to an incident of FMD or LSD in Australia, some of which reflect the varying transmission routes of these viruses.

Domestic and wild cloven-hoofed animals – cattle, pigs, sheep, goats, deer (red, fallow and roe) and water buffalo – are the natural hosts of FMD virus. A few species in other orders are also susceptible. Cattle, pigs, sheep, buffalo, deer, camelids and goats that are infected with FMD may initially show fever, drooling and reluctance to move (DAFF, 2022a). FMD also causes fluid filled blisters (vesicles) to form on the lips, tongue, palate, feet and teats of infected animals (DAFF, 2022a). Although few animals die from FMD, it can have significant effects on animal welfare and production (DAFF, 2022a).

FMD is one of the most contagious animal diseases and infected animals excrete large amounts of virus. Animals are infected via inhalation, ingestion and artificial or natural breeding. FMD spreads through close contact with infected animals and can be carried on animal products, equipment, vehicles, clothing, shoes, by the wind and feeding of contaminated swill. FMD virus can remain infective in the environment for several weeks and possibly longer in the presence of organic matter, such as soil, manure and dried animal secretions, or on chemically inert materials, such as straw, hair and leather. Movement of infected animals is widely recognised as one of the most important routes by which FMD spreads between herds and farms. Pigs are the main amplifying hosts and may excrete large volumes of virus in respiratory aerosols – susceptible species downwind from pig farms or a high density of feral pigs may be infected by windborne spread. Feral, wild and native animal species may become infected with FMD virus and serve as potential reservoirs of infection. No arthropod vector has been identified as being important in the spread of FMD virus. FMD virus is most likely to be introduced into Australia through contaminated, illegally imported animal products or through objects (for example, footwear) contaminated with the virus, that come in contact with susceptible animals.

The primary objectives of the AUSVETPLAN response strategy policy to an incident of FMD are to prevent:

i) contact between infected and susceptible animals,

ii) production of large volumes of virus by infected animals and,

iii) indirect spread of virus by people and fomites (Animal Health Australia, 2022a).

The diagnosis or strong suspicion of FMD in Australia, would result in an immediate national livestock standstill. This will enable epidemiological information to be gathered and collated, so that the potential extent and possible impacts of the outbreak can be assessed. Biosecurity (including quarantine) and movement controls will be placed over high-risk premises and declared areas. Infected animals and potentially contaminated animal products, by-products and wastes will be destroyed and disposed of in a biosecure manner. Disposal of milk will be a major challenge during an FMD outbreak involving a dairying area, because large volumes of milk may require disposal (depending on the time of year, and the location and size of the outbreak). This is because milk will be subject to biosecure disposal and will not be collected for commercial processing from infected premises or other high-risk premises. On-farm storage may be considered for suspect premises pending confirmation of their status if it is likely that the status will be resolved within food safety timelines and capacity is available.

LSD is an acute to chronic, highly infectious, generalised skin disease of cattle and buffalo characterised by widespread skin nodules, production losses and mortality. Some strains of LSD virus may replicate in sheep and goats, although there is no epidemiological evidence of small ruminants acting as a reservoir for the virus (Animal Health Australia, 2022b). Australian fauna are unlikely to be susceptible to LSD (Animal Health Australia, 2022b). LSD is a mechanically transmitted vector-borne disease, which can also be transmitted directly and through fomites. Mechanical transmission by biting insects is considered to be the main route of local transmission of LSD virus. Transmission of LSD virus is incompletely understood; however, transmission through direct contact between infected animals is believed to be inefficient and plays only a minor role in the epidemiology of the disease. Direct transmission between animals is likely to be more significant in animals managed under intensive scenarios (that is, feedlot and dairy), and non-bloodsucking insects may play a role in transmission via secretions between animals in these contexts. LSD virus may be spread from cows to their progeny.

Longer-distance spread (for example, by wind dispersal of vectors) has been implicated in the introduction of LSD into new countries. The most likely route for introduction of LSD into Australia is entry of vectors carrying the virus to northern Australia following establishment of the disease in neighbouring countries to the north. Responding to an incursion of LSD would be challenging in parts of Australia that have significant numbers of feral cattle and buffalo, and large areas that are only accessible with extreme difficulty (for example, northern Australia, especially during the wet season). Administering vaccine to feral buffalo poses significant logistical difficulties. There is also an incomplete understanding of the role of vector species in disease transmission under Australian conditions and any associated difficulties in managing vector control. Many different types of biting insects may be involved in transmission, but particularly mosquitoes and flies (Animal Health Australia, 2022b).

There is a risk that LSD could become endemic or be present in Australia for several years if the disease is not promptly controlled. The AUSVETPLAN response strategy policy to an incident of LSD, is the immediate quarantine of animals, animal products and fomites (facilities, equipment and other items) on infected premises and dangerous contact premises. Valuation and destruction will be undertaken of cattle and buffalo on infected premises and potentially on dangerous contact premises, as well as the decontamination and/or disposal of fomites. Tracing and surveillance activities will be undertaken to determine the source and extent of infection including, as necessary, in feral animals. Based on the epidemiological assessment, management of feral cattle and buffalo populations may be required. An assessment will also be undertaken of likely vector species, their distribution, ecology and methods of management to minimise transmission of the virus. If infected source animals can be destroyed and disposed of quickly, the risk of transmission to new vector populations will be reduced. Milk and milk products from cattle and buffalo, including from infected premises, can be processed for human consumption if appropriately treated (that is, pasteurised, or chemically treated by acidification).

Prion diseases

Prion diseases are fatal neurodegenerative diseases. A key feature of their pathogenesis is the accumulation of a misfolded form (PrP^{Sc}) of a normal host glycoprotein (PrP^{C}), which exists in all animal cells. Accumulation of PrP^{Sc} causes cell malfunction and death, resulting in the eventual death of the infected individual. Ruminant prion diseases include bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and goats and chronic wasting disease (CWD) in cervids (that is, a mammal of the deer family). Fortunately, there is a strong species barrier in most prion diseases, largely dependent on the degree of homology of PrP amino acid sequence between donor and recipient species (Nemani, Myskiw, Lamoureux, Booth, & Sim, 2020). The barrier is not absolute though; it can be influenced by PrP polymorphisms and different prion strains (Nemani et al., 2020). Zoonotic transmission is a theoretical concern for all prion diseases, but currently the only documented transmission to humans has been from BSE-infected cattle. In the late 1980s, the outbreak of BSE in cattle, and its transmission to humans through the food supply, resulted in a new form of prion disease, called variant Creutzfeldt–Jacob disease (vCJD), which led to 231 human deaths (Nemani et al., 2020). The appearance of vCJD following human exposure to BSE places the human species barrier to other animal prion diseases at the forefront of public health concerns.

Of recent concern, CWD has been spreading aggressively among cervids through North America, Canada, South Korea and Scandinavia (Benestad & Telling, 2018; Napper & Schatzl, 2023). CWD is the only currently recognised prion disorder of both farmed and wild animals, including free-ranging deer, elk and moose (Kurt & Sigurdson, 2016). Eradication of CWD from areas of endemicity is very unlikely and additional spread will occur. As the range and prevalence of CWD increase, so will the potential for human exposure to CWD prions. Within an individual infected animal, CWD prions are extraordinarily widespread and accumulate in neural and non-neural tissues and body fluids, including brain and spinal cord fat, pancreas, adrenal gland, heart, peripheral nerves, lymph nodes, saliva, blood, and skeletal muscle, many of which may be ingested by other animals (Kurt & Sigurdson, 2016). CWD is considered the most contagious prion disease and substantial shedding of CWD prion infectivity into the environment via urine, faeces and saliva significantly contributes to disease spread (Napper & Schatzl, 2023; Tranulis & Tryland, 2023). Disease management is also difficult due to the extraordinary physiochemical stability of CWD prions and long-term perseverance of their infectivity in environmental reservoirs, including soil, water and plants (Napper & Schatzl, 2023). Many animal species known to be susceptible to transmissible prions share habitats with cervids (for example, sheep, cows, rodents, swine, felines) and therefore are potential candidates for infection by CWD prions. Of particular importance is livestock that share pastures contaminated with CWD prions, creating a potential pathway for CWD prions to access the human food chain. With the increased exposure of wildlife and other species to CWD, there is concern that a new form of human prion disease may arise. If CWD was to infect humans, it is unclear how it would present clinically. Complicating matters is the fact that acquired prion diseases can have very long incubation periods (that is, the latency between the initial infection and the emergence of clinical signs). In humans, these range from 1 to 20 years or more in iatrogenic CJD[a] to over 50 years in kuru (Swire & Colchester, 2023).

Preliminary data indicate that the CWD strains identified in Europe and North America are different and also suggest the presence of strain diversity in European cervids (EFSA Panel on Biological Hazards et al., 2019). The emergence of different CWD strains is concerning, as different strains can have different abilities to cross species barriers. Current data do not allow any conclusion on the implications of strain diversity on transmissibility, pathogenesis, prevalence and the zoonotic potential of North American or European CWD isolates (EFSA Panel on Biological Hazards et al., 2019). However, experimental exposure to CWD prions by intracerebral or oral routes of inoculation have resulted in infection in a range of species (Kurt & Sigurdson, 2016). The existence of various CWD prion strains combined with the known PrP polymorphisms generates a dynamic, emerging and complex scenario for future CWD transmission risks (Napper & Schatzl, 2023).

Aside from the rapid emergence of CWD globally, there has also been the discovery of atypical forms of BSE and scrapie (EFSA, 2022) and the first detection of a prion disease in camels in 2018 (Horigan et al., 2020). Locally, cases of atypical scrapie have been confirmed in Australia (Cook et al., 2016). While there is no epidemiological evidence that these prions are associated with human prion disease, a global awareness of these prion diseases is required.

Prion transmission via colostrum and / or milk in small ruminants has been demonstrated, including transmission of classical scrapie via colostrum and milk in sheep (Konold et al., 2013), via goat milk to sheep (Konold et al., 2016) and via goat milk to lambs and goat kids (Madsen-Bouterse, Highland, Dassanayake, Zhuang, & Schneider, 2018). While classical scrapie is an animal disease and has not been found to affect humans, the risk of exposure for humans who consume milk and milk products from

a Iatrogenic transmission of the CJD agent have been linked to the use of contaminated human growth hormone, dura mater and corneal grafts, or neurosurgical equipment.

infected flocks of small ruminants cannot be excluded (EFSA, 2008). EFSA continue to report on the results of surveillance of prion diseases in cattle, sheep, goats, cervids and other species (EFSA, 2022).

In regard to food safety, it is important to note that prion agents are highly resistant to various physical and chemical treatments (Sakudo, 2020). Normal sterilization procedures are ineffective for the inactivation of prions. This resistance to inactivation is at least in part due to the absence of nucleic acid in prions. The heating procedures used to inactivate DNA-containing pathogens are not sufficient to eliminate prion proteins. Pasteurisation and ultra-high temperature (UHT) treatment (heating for 1–4 seconds to 135°C) have been reported to lead to only a partial reduction in the concentration of prion proteins (Franscini et al., 2006).

Chlorates and perchlorates

Chlorine-based (for example, calcium or sodium hypochlorite) sanitisers are commonly used on farms, in processing plants, and in municipal supplies for ensuring the safety of potable water, as well as in food or beverage processing plants to sanitise surfaces (EFSA Panel on Contaminants in the Food Chain, 2015). While chlorine plays a crucial role in helping to produce safe foods and beverages, the occurrence of chlorinated residues (chlorates and perchlorates) that have been generated as by-products of chlorine use has raised concerns with food regulatory bodies owing to their potential to inhibit iodine uptake or to cause acute methaemoglobin[a] (EFSA Panel on Contaminants in the Food Chain, 2015). These concerns have resulted in the EU mandating a reduction in the allowable maximum residue levels for chlorates and perchlorates in foods and beverages to such an extent that production practices throughout entire production chains are likely to be affected. Any efforts to reduce chlorinated residues in food need to account for any potential impact on microbiological food safety.

For chlorate, EFSA established a tolerable daily intake (TDI) of 3 µg/kg body weight per day and an acute reference dose (ARfD) of 36 µg/kg body weight (EFSA Panel on Contaminants in the Food Chain, 2015). Based on data collected in 2014, acute dietary exposure to chlorate did not exceed the ARfD (EFSA Panel on Contaminants in the Food Chain, 2015). The mean dietary exposures to chlorate in European countries exceeded the TDI in certain subgroups of the population such as infants and young children with mild to moderate iodine deficiency. In order to bring chlorate levels down and reduce exposure, coordinated efforts in several relevant and related sectors were directed towards actions in regard to drinking water, hygiene and the setting of temporary maximum residue levels for food and feed. Between 2014 and 2018, EFSA collected data to investigate the presence of residues of chlorate in food and drinking water (European Commission, 2020b). The data indicated that chlorate residues were present at levels that frequently exceed the default MRL under Regulation (EC) 396/2005 of 0.01 mg/kg and that the levels vary depending on the source and the product. A temporary solution was necessary since it was not possible to meet the default level of 0.01 mg/kg even with the best practices applicable at that time.

As a result, Commission Regulation 2020/749 established Maximum Residue Limits (MRLs) for chlorate in or on certain products, which came into force on June the 28th 2020 (European Commission, 2020b). The MRLs under Regulation 2020/749 are temporary and will be reviewed no later than June the 8th 2025. Data will be collected on chlorate residues to support an adjustment to the MRL. The current MRL for chlorate in milk under Regulation (EC) No. 2020/749 is 0.10 mg/kg (European Commission, 2020b). The MRL applies to raw milk and heat-treated milk, that is ready for use (marketed as such or reconstituted as instructed by the manufacturer) and intended for the manufacture of milk-based products and milk. As chlorinated drinking water is a standard in many countries, chlorate can be detected in many food products above the default MRL. No MLs for chlorate in drinking water have been set in the EU. The World Health Organisation (WHO) has established a guideline level for chlorate in drinking water of 0.7 mg/L (WHO, 2016, 2017).

In 2014, EFSA undertook an assessment of the risks to public health related to the presence of perchlorate in food (EFSA Panel on Contaminants in the Food Chain, 2014). At the time there were no MLs for perchlorate in food in the EU (EFSA Panel on Contaminants in the Food Chain, 2014). While perchlorate has a similar mode of action to chlorate, it is a more potent inhibitor. In *in vitro* studies

a Iodine is an essential element for human nutrition, as it is a necessary constituent of thyroid hormones. Methaemoglobin is a stable oxidized form of haemoglobin which is unable to release oxygen to the tissues.

comparing the inhibition of thyroid iodine transport by chlorate and perchlorate in rats, perchlorate is about 10 times more potent than chlorate (EFSA Panel on Contaminants in the Food Chain, 2015). EFSA established a TDI of 0.3 μg/kg b.w. per day for perchlorate (EFSA Panel on Contaminants in the Food Chain, 2014). No data was available on the acute toxic effects of perchlorate in humans. It was noted that a single-day acute exposure to perchlorate at levels found in food and drinking water would be unlikely to cause adverse effects on human health, including the more vulnerable groups of the population. Therefore, it was concluded that the establishment of an ARfD for perchlorate was not warranted. The estimated mean chronic dietary exposure levels for adolescents and the adult age groups did not indicate a health concern when compared with the TDI of 0.3 μg/kg b.w. per day. Overall, it was concluded that the chronic dietary exposure to perchlorate is of potential concern for the high consumers in the younger age groups of the population with mild to moderate iodine deficiency. Furthermore, it is possible that exposure to perchlorate is of concern for infants breast-fed by iodine-deficient mothers and in the short-term for young children with low iodine intake. Previously conducted exposure assessments had indicated that infant formula, and milk and dairy products are important contributors to the dietary exposure to perchlorate (for a review see (EFSA Panel on Contaminants in the Food Chain, 2014)). The EU commission imposed a ML under Regulation (EC) No. 2020/685 of 0.01 mg/kg for perchlorate in infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula (European Commission, 2020a). Young child formula are milk-based drinks and similar protein-based products intended for young children (European Commission, 2020a).

The entry points of chlorinated residues into dairy products can be at both farm and processor levels, including chlorinated water usage, sanitation practices and processing aids (McCarthy et al., 2022; McCarthy et al., 2018). Possible routes of entry of disinfectants in dairy processes include their application for teat and skin disinfection, cleaning of milk storage tanks and clean-in-place treatment of milking equipment. Contamination, with residues of detergents and sanitisers, can occur as a result of improper use of detergents and incorrectly conducting cleaning regimens at farm or dairy processor levels. There are currently no documented methods for removal of chlorinated residues from milk and no known practical and economical treatment methods to remove chlorinated residues once they are present in drinking water. However, recent research has been conducted into the application of nanofiltration for the removal of chlorate from skim milk (McCarthy et al., 2022). The industry is now faced with a difficult challenge of balancing the risk of chlorinated residues and microbiological risk while waiting for the outcome of on-going discussions within the EU to set MRLs which are set at realistic levels likely to arise from responsible use of disinfectants during food processing.

An alternative to the difficult task of policing proper use of chlorine-based detergents to achieve dairy product specifications, is to remove chlorine entirely as a cleaning agent from cleaning routines. In Ireland, Ornua is a dairy co-operative which markets and sells dairy products on behalf of Irish dairy processors and Irish dairy farmers (Ornua, 2022). Ornua is Ireland’s largest exporter of Irish dairy products, exporting to 110 countries worldwide (Ornua, 2022). The Board of Ornua passed a resolution to remove all chlorine-based detergents from both farms and processing plants in Ireland from January 2021 (Gleeson, Paludetti, O'Brien, & Beresford, 2022). Teagasc is the Agriculture and Food Development Authority of Ireland (Teagasc, 2023). Teagasc developed non-chlorine-based cleaning protocols and evaluated their performance on research farms (Teagasc, 2018). Guidelines on best practice plant cleaning (in the absence of chlorine) were compiled and distributed to 10,000 milk suppliers through the relevant milk processors (Gleeson, 2018; Teagasc, 2018).

Teagasc recommended five chlorine-free cleaning protocols for cleaning milking machines and three protocols for bulk tank cleaning (Teagasc, 2020). Gleeson et al. (2022) undertook the first study to investigate the implications of chlorine-free cleaning of milking equipment on commercial dairy farms and for an extended test period of eight months. Gleeson et al. (2022) reported on the impact of removing chlorine-based detergents (sodium hydroxide combined with sodium hypochlorite) and using alternative chlorine-free products (sodium hydroxide) on the microbiological quality and residue levels of bulk tank milk, in comparison to traditional chlorine-based protocols (Gleeson et al., 2022). Bulk tank milk was tested for the chlorine-related residues trichloromethane and chlorate. Microbiological analysis included total, psychrotrophic, thermoduric, thermophilic, presumptive *Bacillus cereus* group counts and enterococci enumeration. Gleeson et al. (2022) reported that total bacterial counts and residue levels were lower with chlorine-free than with chlorine-based protocols, demonstrating that the new chlorine-free cleaning protocols had a positive impact on milk quality when implemented on commercial farms. The adoption of chlorine-free cleaning protocols for cleaning milking equipment requires some changes in cleaning steps, including an increase in the number of hot washes per week, and an increased use of peracetic acid and acid descalers (phosphoric/nitric acid). Not all chlorine-free farms included in the study followed all the criteria specified in the guidelines developed by Teagasc. Gleeson et al. (2022) concluded that as not all the farms were following all steps of the chlorine-free cleaning guidelines, that there is the potential to achieve even better microbiological results when protocols are fully implemented.

In New Zealand, the Emerging Risk Identification System (ERIS) functions to identify key emerging food safety risks (NZFSSRC, 2023). In their Annual Report, new limits for chlorate in milk were identified as an emerging risk likely to be important to New Zealand and requiring further action (King, Thomas, & Watson, 2021). Aside from highlighting potential public health risks, the setting of new MRLs in the EU may present a challenge to international trade. As part of the 2022 – 2023 National Programme for the Monitoring of Chemical Residues and Contaminants in Milk, 60 random milk samples will be tested for chlorate and perchlorate to give insight into adherence to Good Agricultural Practice (GAP) at a farm level in New Zealand (MPI, 2022b). The Animal Products Notice came into force on the 16th of December 2022 and lists the action limit 0.1 mg/kg (no Maximum Limit listed) for chlorates for milks, including raw milk (MPI, 2022a). New maximum limits for chlorates apply from the 1st of July 2023, for infant formula (as powder) for infants 0 – 6 months (0.4 mg/kg) and follow-on formula (as powder) for infants 6 – 12 months (0.8 mg/kg) (MPI, 2022a).

The Code does not specify limits for the presence of chlorate or perchlorate in food. The literature review conducted during the course of writing this Risk Assessment, did not reveal any studies that have surveyed for the presence and level of chlorate and perchlorate residues in Australian food commodities. In the 24th ATDS, FSANZ screened perchlorate levels in eight tap water samples from across Australia and all results were below the limit of reporting (FSANZ, 2014a). For this reason, no risk assessment for perchlorates was conducted (FSANZ, 2014a). The Australian Drinking Water Guidelines cite the provisional guideline value for chlorate of 0.7 mg/L published by WHO (WHO, 2016, 2017), but conclude that further information on the occurrence and sources of chlorate in Australian waters is needed before a guideline value can be developed (NHMRC & NRMMC, 2011).

Trade implications could result if trading partners of Australia impose new limits on chlorates and perchlorates in dairy products. Australia is a significant exporter of dairy products, capturing 6% of the market share of world dairy trade (Dairy Australia, 2023c). Exports to Asia account for close to 85% of total Australian exports, dominated by the markets of Greater China, Japan and South-east Asia (Dairy Australia, 2023c). Overall, China is Australia's largest market for dairy. Liu et al. (2021) undertook the first report to assess the exposure of infant and young child formulas in China to perchlorate and chlorate (Liu, Mao, Jiang, Yang, & Yang, 2021). The level of perchlorate and chlorate were determined in a total of 278 samples of infant formulas marketed in China. The associated health risk via infant and young child formulas consumption for 0–36-month-old children in China was also assessed. The authors reported exceedances for infants (0-6 month) at the 95th percentile at the TDI of 3 µg/day for chlorate.

Exposure assessment

Consumption of dairy products

Australian dairy consumption data is summarised below and was sourced from the 25th Australian Total Diet Study (ATDS) (FSANZ, 2019), Australian Bureau of Statistics (ABS) (ABS, 2022) and Dairy Australia (Dairy Australia, 2022). Comparison of consumption data from each of these sources is hampered by differences in the methodologies employed and in the categorisation of food groups and what has been reported.

Dairy product consumption data for Australia was reported in the 25th ATDS (FSANZ, 2019) and is shown in Table 1. Mean food consumption is shown for either a nine-month-old, or for those two years and above. Cows' milk is not recommended as the main milk source for children aged less than 12 months of age and therefore, milk consumption for children within this age group is usually in the form of infant formula (FSANZ, 2019). As can be seen in Table 1, for those in the nine-month-old age range there was no reported consumption of milks and cream, while infant formula consumption was high. By the age of nine months, most infants will be consuming a mixed diet, in addition to human breast milk and/or infant formula (FSANZ, 2019). Within the dairy product group, consumption for a nine-month-old was highest in the yoghurt (except frozen), probiotic drinks and dairy desserts (except ice cream) category. For those two years and above, milk and cream consumption was highest, followed by consumption of yoghurt (except frozen), probiotic drinks and dairy desserts (except ice cream).

Data reported by the ABS show apparent consumption as measured by the amount of food purchased from sales data (ABS, 2020a, 2020b) (Table 2). The data reported does not measure actual consumption as it does not account for food purchases from fast food outlets, cafes and restaurants, home grown or produced foods, wild harvested foods, or foods not consumed due to waste or storage (ABS, 2020a, 2020b). The apparent mean daily per capita consumption of all milk, yoghurt, cheese and/or alternatives was higher during 2019-20 (274.7g), than during 2018-19 (273.9g). However, this increase in apparent consumption during 2019-20 needs to be interpreted with caution. Following the Australian outbreak of the coronavirus (COVID-19) in March 2020, restrictions were progressively implemented by the Australian government on citizens' activities, aiming to limit opportunities for the virus to spread through community transmission. A major behavioural response by Australian householders to the highly uncertain circumstances was an increase in purchasing of household supplies from supermarkets, resulting in a sales spike from early March which peaked in mid-March 2020 (ABS, 2020b). Apparent consumption data would also be distorted by the fact that households were preparing meals at home, instead of dining out (ABS, 2020b). ABS noted that it is likely that the significant change in consumer behaviour associated with COVID-19 would mean that the estimates from March 2020 to June 2020 would over represent consumption due to increases in home inventories and households substituting home prepared meals instead of dining out (ABS, 2020b). The ABS data shows that apparent consumption was highest for milk, followed by cheese and yoghurt.

Dairy Australia is the national services body for the Australian dairy industry and publishes consumption data from sources including dairy manufacturers (Table 3). Per capita consumption of major dairy products in Australia from 2013-14 to 2019-20 was highest for milk, followed by cheese, yoghurt and butter/blends. Per capita consumption of drinking milk during 2019 – 2020 in Australia was 97 litres, representing a small decline over recent years (Dairy Australia, 2022).

Table 1 Product consumption data for Australian consumers[a]

Food classification		Mean food consumption amount for respondents[b] (grams per person per day) 9 months	Mean food consumption amount for respondents[b] (grams per person per day) 2 years and above	Mean food consumption amount for consumers[c] (grams per consumer per day) 2 years and above
DAIRY PRODUCTS	Butter and animal fats	0.7	3.7	4.2
	Cheeses	5	17	25
	Frozen dairy based desserts	3	15	62
	Milks and cream	0	299	318
	Yoghurt (except frozen), probiotic drinks and dairy desserts (except ice cream)	15	29	84
INFANT PRODUCTS	Infant custards and yoghurts	0.2	<0.1[d]	68[e]
	Infant formulas	556	0.5[f]	389[g]

a Data reported in the 25th ATDS (FSANZ, 2019).

b Respondent – Any person included in a nutrition survey, irrespective of whether they are reported consuming a particular food of interest or not.

c Consumer – A respondent in a nutrition survey who reports consuming a particular food within the previous 24 hours.

d The mean consumption amount (grams per person per day) of infant custards and yoghurts for respondents 2 years and above included consumption values for those 2-5 years old (0.2g) and 6-12 years old (0.2g). No consumption was recorded for those 13 years old and above.

e The mean consumption amount (grams per person per day) of infant custards and yoghurts for consumers 2 years and above included consumption values for those 2-5 years old (137g) and 6-12 years old (55g). No consumption was recorded for those 13 years old and above.

f The mean consumption amount (grams per person per day) of infant formulas for respondents 2 years and above included consumption values for those 2-5 years old (9g) and 6-12 years old (0.9g). No consumption was recorded for those 13 years old and above.

g The mean consumption amount (grams per person per day) of infant formulas for consumers 2 years and above included consumption values for those 2-5 years old (353g) and 6-12 years old (893g). No consumption was recorded for those 13 years old and above.

Table 2 Apparent consumption of dairy products in Australia[a]

	Mean daily per capita consumption (grams)	
Food group	**2018 - 19**	**2019 - 20**
Milk total	227.2	227.9
Cheese total	24.3	24.7
Yoghurt total	22.3	22.1
Total milk, yoghurt, cheese and/or alternatives	273.9	274.7

Table 3 Per capita consumption of major dairy products in Australia (litres/kg)[a]

	Per capita consumption of major dairy products (litres/kg)			
Year	**Milk (litres)**	**Cheese (kg)**	**Butter/Blends (kg)**	**Yogurt (kg)** [b]
2013-14	105.7	13.5	4.0	7.4
2014-15	105.1	13.5	4.3	9.2
2015-16	104.9	13.6	4.9	9.2
2016-17	102.8	13.4	4.8	9.1
2017-18	100.7	13.6	4.7	9.0
2018-19	98.6	13.5	4.0	9.5
2019-20	97.0	13.6	4.1	9.4

Table 2

a Data reported by the ABS (ABS, 2020a, 2020b).

Table 3

a Data reported by Dairy Australia (Dairy Australia, 2022).

b From 2014/15, per capita consumption of yoghurt includes dairy snacks.

Hazard characterisation

Overview of foodborne illness and dairy products in NSW from 2014 to 2020

In NSW from 2014 to 2020, only one outbreak was identified in which the suspected or responsible vehicle involved a dairy product (Communicable Diseases Branch, 2015, 2016, 2017, 2018, 2019a, 2019b, 2022). In September 2014, an outbreak of *S*. Typhimurium MLVA 3-12-11-14-523 occurred at a holiday resort and affected 20 people, including five hospitalisations (Communicable Diseases Branch, 2014, 2015). The outbreak was linked to chocolate milk served during a breakfast buffet. The chocolate milk had been produced within the restaurant kitchen at the resort and cross contamination was suspected, as the commercial stick blender used to prepare the chocolate milk was also used for blending raw eggs and raw chicken products. The blender was swabbed on two occasions and then sent to the laboratory for further testing, however none of the swabs or tests resulted in a *Salmonella* spp. detection. The root cause of the contamination was not determined.

International outbreaks from 2014 to 2020

The following section contains an overview of foodborne disease and outbreak surveillance data compiled by various international agencies. It should be noted that the COVID-19 pandemic had a strong impact on notification rates of all communicable disease, including foodborne disease. The WHO declared the novel coronavirus (COVID-19) a worldwide pandemic on the 11th of March 2020. Many countries introduced public health and social measures to prevent the spread of COVID-19. An indirect consequence of the measures implemented to combat the spread of COVID-19, was a reduction in the exposure of people to contaminated food. In addition, a higher under-reporting of outbreaks likely occurred due to reduced access to medical care and laboratory testing priorities.

New Zealand

Annual reports of foodborne disease in New Zealand are available on the MPI website (MPI, 2021b). The annual reports contain information on reported cases of notifiable disease and reported outbreaks collected in New Zealand’s national notifiable disease surveillance database, EpiSurv. Notified cases of illness and reported outbreaks represent a subset of all the cases and outbreaks that occur in New Zealand each year.

From 2014 to 2020, there were 30 outbreaks in which a dairy product was identified as the single suspected food vehicle (MPI, 2015, 2016, 2017, 2019a, 2019b, 2020, 2021a). The 30 outbreaks were all associated with the consumption of raw milk and at least one outbreak occurred in each year in 2014 (n = 8), 2015 (n = 4), 2016 (n = 7), 2017 (n = 1), 2018 (n = 4), 2019 (n = 4) and 2020 (n = 2). *Campylobacter* was responsible for the majority (73%, 22/30) of outbreaks, as well as the largest number of total confirmed cases (n = 73). For one *Campylobacter* outbreak in 2020, STEC (one case) and *Yersinia* spp. (one case) were implicated as additional pathogens. STEC were involved in a total of four outbreaks involving raw milk, resulting in 19 confirmed cases. Norovirus was involved in a raw milk outbreak in 2014, resulting in a total of 2 confirmed cases. Foodborne transmission is rarely reported for *Cryptosporidium* outbreaks, however in 2015 strong evidence was found to implicate raw milk as the food vehicle in an outbreak with 7 confirmed cases. *Giardia* was involved in two outbreaks in 2016, resulting in a total of 12 confirmed cases.

United States

The Centers for Disease Control and Prevention (CDC) established the National Outbreak Reporting System (NORS) to capture data on foodborne, waterborne and enteric illness outbreaks in the United States (CDC, 2022). NORS is a web-based platform that relies on voluntary reporting by state, local, and territorial public health agencies to detect, investigate, and report outbreaks. Therefore, the NORS outbreak data likely represents a small proportion of actual cases of foodborne illness, with many outbreaks unrecognised and/or unreported.

Data was downloaded from the NORS dashboard for all foodborne outbreaks that occurred during 2014 to 2020 with the Interagency Food Safety Analytics Collaboration (IFSAC) Food Category of “dairy”, which includes solid/semisolid dairy products (that is, hard and soft cheese) and fluid milk (that is, whole milk and skim milk). No dairy based infant formula outbreaks were reported during this time. In total, there were 108 foodborne outbreaks associated with the consumption of dairy products between 2014 and 2020. Eleven of these outbreaks (10%, 11/108) were multistate outbreaks. In total, the 108 outbreaks resulted in 1,171 illnesses, including 208 hospitalisations and nine deaths.

It is assumed that the majority of these outbreaks involved bovine milk, with “*goat*” only specified in the “Food Vehicle” or “Food Contaminated Ingredient” in 6% (6/108) of all dairy outbreaks. Where specified, the word “*raw*” or “*unpasteurised*” was used to describe the “Food Vehicle” or “Food Contaminated Ingredient” in 73% (79/108) of all dairy outbreaks. Where specified, the word “*pasteurised*” was used to describe the “Food Vehicle” or “Food Contaminated Ingredient” in 8% (9/108) of all dairy outbreaks.

Of the 108 outbreaks, milk was the most common food vehicle (68%, 73/108). Of the 79 unpasteurised dairy products associated with outbreaks, the majority were due to milk (n = 65), followed by cheese (n = 8), goats’ milk (n = 5) and one outbreak due to milk and cheese products. Of the nine pasteurised dairy products, cheese (n = 7) was the most common food vehicle, followed by milk (n = 2). Of the twenty outbreaks due to dairy products for which there was no information specifying whether the product was pasteurised or unpasteurised, the most common food vehicle was cheese (n = 11), followed by yoghurt (n = 2), sour cream (n = 2) and one outbreak each attributed to milk (n = 1), goats’ cheese (n = 1), whey powder (n = 1), whipped cream (n = 1) and a "*dairy product*" (n = 1).

Where the etiologic agent was confirmed (74%, 80/108), the pathogen most associated with dairy outbreaks was *Campylobacter* (34%, 27/80), followed by *Salmonella* (23%, 18/80), *L. monocytogenes* (15%, 12/80), STEC (10%, 8/80), *Cryptosporidium* (9%, 7/80), *Bacillus cereus* (3%, 2/80), Norovirus (3%, 2/80), *Yersinia* (1%, 1/80) and *Brucella* (1%, 1/80). Multiple pathogens were associated with two outbreaks (one outbreak involved STEC O157:H7 and STEC O103, one outbreak involved *Campylobacter* and STEC O157:H7). In total, nine deaths occurred across eight outbreaks and *L. monocytogenes* was responsible for the majority (89%, 8/9), with the remaining death due to *Campylobacter* (11%, 1/9). *L. monocytogenes* was also responsible for the greatest number of hospitalisations, with 86% (50/58) of all illnesses across 12 outbreaks resulting in hospitalisation. The number of hospitalisations resulting from all illnesses was considerably lower for STEC (38%, 18/48), *Salmonella* (20%, 65/332) and *Campylobacter* (9%, 26/279).

The nine outbreaks involving “*pasteurised*” dairy products included seven pasteurised cheeses and two pasteurised milk products. Where the etiologic agent was confirmed for outbreaks involving pasteurised dairy products (67%, 6/9), *L. monocytogenes* (83%, 5/6) was the most common etiologic agent and was involved in five outbreaks associated with pasteurised cheese. The remaining outbreak was due to *Yersinia* in milk, which was responsible for the largest number of illnesses (n = 109) of any dairy outbreak between 2014 and 2020.

Of the six outbreaks involving dairy products made from goats’ milk, *Campylobacter* was the most frequently associated pathogen and responsible for four outbreaks (3 unpasteurised milk, 1 unpasteurised cheese). One outbreak each was also associated with and *Brucella* (cheese) and *Cryptosporidium* (unpasteurised milk).

Canada

The Canadian Food Inspection Agency (CFIA) reports on food safety incidents that have caused serious illnesses in Canada or have otherwise significant interest to the Canadian public (CFIA, 2020).

From 2014 to 2020, one outbreak investigation published on the CFIA website involved a dairy product (CFIA, 2016). This outbreak was caused by *L. monocytogenes* associated with pasteurised chocolate milk. The outbreak lasted for seven months, beginning in November 2015 and ending in June 2016 (Hanson et al., 2019). There were 34 confirmed listeriosis case-patients, with a reported median age of 73 years (range <1–90 years) (Hanson et al., 2019). Of the 34 case-patients, 32 (94%) were hospitalised and there were 4 deaths (12%) (Hanson et al., 2019).

Europe

The European monitoring system for foodborne diseases and zoonoses from animals, food, and feed relies on the annual collection of information from EU member states. The European Commission has directed EFSA and the European Centre for Disease Control and Prevention (ECDC) to collect and analyse data from EU member states. Annually, these data sets are jointly published in the One Health zoonoses report. It is important to note that monitoring and surveillance schemes for most zoonotic agents covered in the One Health zoonoses reports are not harmonised among European member states and the findings presented in the report must be interpreted with care.

The following section provides an overview of foodborne outbreaks associated with the consumption of dairy products and reported in the One Health zoonoses reports from 2014 to 2020 (EFSA and ECDC, 2015, 2016 2017, 2018a, 2019, 2021a, 2021b). Outbreaks are categorised as having 'strong evidence' or 'weak evidence' based on the strength of evidence implicating a suspected food vehicle. The evaluation of the strength of evidence implicating a suspected food vehicle is based on the assessment of all available types of evidence (that is, microbiological, epidemiological, descriptive environmental, trace-back of the investigated foodstuffs). The overview below focuses only on those outbreaks where the evidence implicating a particular food vehicle was strong, which represent a minority of all reported outbreaks.

Outbreaks categorised as having strong-evidence linking them to 'milk', 'cheese' and 'dairy products', were reported in 2020 (n = 16), 2019 (n = 17), 2018 (n = 38), 2017 (n = 49), 2016 (n = 45), 2015 (n = 55) and 2014 (n = 14). In most years, milk was responsible for the majority of outbreaks associated with dairy products. Outbreaks in which there was strong evidence that the food vehicle was milk, were reported in 2020 (56%; 9/16), 2019 (53%; 9/17), 2018 (37%; 14/38), 2017 (53%; 26/49), 2016 (29%; 13/45), 2015 (38%; 21/55) and 2014 (71%; 10/14). Outbreaks in which there was strong evidence that the food vehicle was cheese, were reported in 2020 (n = 4), 2019 (n = 4), 2018 (n = 20), 2017 (n = 14), 2016 (n = 25) and 2015 (n = 33)[a]. Outbreaks in which there was strong evidence that the food vehicle was a dairy product (other than cheese), were reported in 2020 (n = 3), 2019 (n = 4), 2018 (n = 4), 2017 (n = 9), 2016 (n = 7), 2015 (n = 1) and 2014 (n = 4). The causative agent involved in each of these outbreaks is not known, either due to this information being unknown or omitted from the annual reports. In addition, the data collected and method of reporting within the annual reports is not consistent across each year. It is therefore difficult to draw conclusions around trends in the causative agents responsible for outbreaks across food vehicle categories over time.

The annual reports provide further descriptive detail on a few dairy-related outbreaks.

In the 2020 annual report, details are provided on an outbreak reported by Switzerland associated with the consumption of cheese made from pasteurised milk and contaminated by *L. monocytogenes* serovar 4b (EFSA and ECDC, 2021b). The outbreak involved 34 laboratory-confirmed listeriosis cases, a high number of hospitalisations and ten deaths (Nüesch-Inderbinen et al., 2021). The investigation implicated a cheese dairy with sanitation shortcomings and persisting environmental contamination throughout the production site (Nüesch-Inderbinen et al., 2021). Also in the 2020 report, an outbreak in Italy was described involving *S*. Enteritidis linked to cheese. The outbreak included 86 cases, eight hospitalisations and one death.

In the 2018 annual report, a multi-country outbreak involving *S*. Agona was described (EFSA and ECDC, 2019). The outbreak was identified in France in 2017 and affected 39 infants (children <1 year of age), including 37 in France, one in Spain and one in Greece (EFSA and ECDC, 2018b). This contamination was traced back to a single processing company producing infant formula (powdered milk) for different brands (EFSA and ECDC, 2018b). The same manufacturing facility had previously been associated with an *S*. Agona outbreak affecting 141 confirmed cases in 2005, raising the possibility that the pathogen had persisted in the facility for 12 years (Jourdan-da Silva et al., 2018). The source of infection was traced back to the drying tower at the facility (Jourdan-da Silva et al., 2018).

a Data were reported in the EFSA and ECDC (2015) annual report on the total number of outbreaks in 2014 in which there was strong evidence that the food vehicle was cheese. However, the total number reported differs from the sum of strong evidence outbreaks attributed to cheese for each causative agent. Therefore, the 2014 data on cheese associated outbreaks has been omitted.

In the 2016 annual report, a multicounty outbreak of STEC O26 infection was described (EFSA and ECDC, 2017). The outbreak was linked to contaminated cheese and resulted in 25 cases, including many cases of HUS (n = 19), hospitalisations and deaths (n =3) among young children in Romania and Italy (EFSA and ECDC, 2016). Twelve cases had microbiological and/or serological evidence of STEC O26 infection; 13 additional cases met the probable case definition by developing HUS, testing positive for another STEC O serogroup (O157) or by testing positive by PCR for *stx1* and/or *stx2* and *eae* (EFSA and ECDC, 2016). The investigation led to the hypothesis that this was a multistrain outbreak. The investigation resulted in traceback to a milk processing establishment in Romania, which produced dairy products from cows' milk (EFSA and ECDC, 2016).

In the 2014 annual report, an outbreak in Finland caused by *Yersinia pseudotuberculosis* and associated with the consumption of unpasteurised milk was described (EFSA and ECDC, 2015). In total there were 55 cases from 48 households and illness was strongly associated with the consumption of raw milk from a single producer. The odds ratio of illness increased with the amount of raw milk consumed and previously healthy adults became infected after consuming raw milk.

National Surveys

NSW Food Authority dairy verification program

The food safety schemes verification program monitors ready-to-eat (RTE) food that is produced in NSW under one of the NSW Food Authority's Food Safety Schemes (NSW Food Authority, 2019b). Under the program, RTE foods that are manufactured or packaged under a Scheme are purchased from retail or directly from the manufacturer and tested against set requirements as prescribed by each Scheme. If samples are found to be non-compliant, when deemed necessary, the licensee is inspected by an authorised officer from the NSW Food Authority to investigate the reason for non-compliance and rectify the issue.

Table 4 displays the Food Safety Scheme Verification Program results from 2014 to 2021. In total, 492 dairy products were tested and of these 3% (13/492) were non-compliant. Most cases of non-compliance were due to elevated levels of *E. coli* in cheese (69%; 9/13), unpasteurised goats milk (15%; 2/13) or gelato (8%; 1/13). The remaining non-compliance was due to the presence of *L. monocytogenes* in Crème anglaise (8%; 1/13).

Table 4 NSW Food Authority dairy verification program results from 2014 to 2021[a]

Year	Number of samples tested	Number of non-compliant samples (%)	Description of non-compliant samples
2014-15	54	2 (3.7%)	- Two samples of unpasteurised goats milk contaminated with elevated levels of *E. coli*
2015-16	138	2 (1.4%)	- Crème anglaise contaminated with *L. monocytogenes* - Cheese contaminated with a high level of *E. coli*
2016-17	133	2 (1.5%)	- Two samples of hard cheese contained *E. coli* greater than the regulatory limit
2017-18	30	4 (13.3%)	- Four samples of soft cheese from four different manufacturers contaminated with *E. coli* greater than the regulatory limit of 10 CFU/g
2018-19	69	3 (4.3%)	Three products from three different manufacturers were found to be non-compliant due to the following reasons: - Two samples of soft cheese contained *E. coli* greater than the regulatory limit of 10 CFU/g - One sample of gelato contained *E. coli* greater than the regulatory limit of 10 CFU/g
2019-20	46	0 (0%)	-
2020-21	22	0 (0%)	-

a Data accessed from the NSW Food Authority Annual Food Testing Reports (NSW Food Authority, 2016, 2019a, 2020a, 2020b, 2020c, 2020d, 2021a).

Published domestic surveys of raw milk

A literature search did not reveal any recent published data on the prevalence and levels of pathogens in raw bovine milk in Australia. This is in keeping with previous reports of the limited availability of published data on the prevalence and levels of pathogens in raw milk produced domestically (FSANZ, 2009a). Milk processors screen incoming raw milk for a range of quality and shelf-life indicators but typically do not perform analyses for pathogens as the current practise of pasteurising milk destroys all pathogens (FSANZ, 2009a). Where industry does collect such data it is rarely made public or published (FSANZ, 2009a).

The most recent microbiological survey of raw goats' milk in Australia was conducted between January 2001 and December 2006 and involved the analysis of 269 milk samples collected from three of the six south-east QLD goat dairies producing unpasteurised goats' milk at the time (Eglezos et al., 2008). All samples were analysed for coliforms, 214 for aerobic bacteria, 74 for CPS and *E. coli*, 63 for *Campylobacter*, 55 for *Salmonella* and *Listeria*, and 34 for staphylococcal enterotoxin and *E. coli* O157:H7. No pathogens, toxins or faecal indicators (*E. coli*) were detected in any sample.

Published international microbiological surveys of raw milk and raw milk products

New Zealand

In New Zealand, data has been published on the presence and levels of pathogens and hygiene indicators in raw milk produced under the Regulated Control Scheme (RCS) (MPI, 2019c). Dairy farm operators registered to produce RCS raw milk for the purpose of sale routinely take samples of raw milk and send them for microbiological analysis. Bovine milk, produced by farmers following all RCS requirements, is considered acceptable for direct human consumption if results of microbiological tests satisfy certain criteria (MPI, 2019c). These criteria include limits for *Salmonella* spp. (absent in 5 x 25 ml), *L. monocytogenes* (absent in 5 x 25 ml), *Campylobacter* spp. (absent in 5 x 25 ml), CPS (<100 CFU/ml), *B. cereus* (<100 CFU/ml), *E. coli* (<3 CFU/ml), total coliforms (<100 CFU/ml), Aerobic Plate Counts (APC; <20,000 CFU/ml) and Somatic Cell Count (SCC; <160,000 cell/ml). MPI is notified of unsatisfactory results due to the presence of pathogens or elevated Aerobic Plate Counts (APC) and/or coliforms. Data from November 2016 to February 2019 on the presence and levels of pathogens and hygiene indicators in raw milk produced under the RCS revealed the presence of pathogens on 18 occasions (MPI, 2019c). There were ten detections of *Campylobacter*, six detections of *E. coli* and two detections of *L. monocytogenes*. On 12 occasions, hygiene and/or animal health indicators (total coliforms, APC and SCC) were detected in milk samples that were elevated to unacceptable levels.

Also in New Zealand, a survey published in 2016 reported on the prevalence of a variety of pathogens in bulk tank cow milk (Marshall, Soboleva, Jamieson, & French, 2016). Raw milk was collected from 80 randomly selected New Zealand dairy farms during 2011 and 2012 and tested five times for the presence of *Campylobacter*, *E. coli* O157, *L. monocytogenes* and *Salmonella*. *L. monocytogenes* had the highest prevalence (4.0%) in the study. The prevalences of *C. jejuni* (0.6%) and *E. coli* O157 (0.6%) were low. No *Salmonella* (0.0%) was found in the study. However, as stated by the authors, if a pathogen is not detected it does not guarantee its absence. The prevalences observed in the survey apply to milk after an extended period of refrigeration, with pathogen testing performed after the samples had been under refrigeration for up to 72 hours. Therefore, as stated by the authors, the growth characteristics of the pathogens at refrigeration temperature are an important consideration. There is little evidence that *C. jejuni*, *E. coli* O157 or *Salmonella* exhibit a propensity to grow under refrigeration temperatures, therefore it was expected that the tested prevalence would be no higher than the prevalence on the day of collection. In contrast, *L. monocytogenes* is a psychrotolerant bacterium that can grow in raw milk at 4°C.

United Kingdom

Willis et al. (2018) reviewed the microbiological results for RDM samples submitted to Public Health England laboratories between 2014 and 2016 (Willis et al., 2018). A total of 902 samples of RDM for direct human consumption in England were examined. The majority of samples were cows' milk (68.0%, 613/902), followed by goats' (28.8%, 260/902), sheep (1.0%, 9/902), buffalo (0.4%, 4/902) and camel milk (0.3%, 3/902). For the remainder of samples (1.4%, 13/902), the species was not specified at the time of submission to the laboratory. The majority of samples (85%, 770/902) were collected for the purposes of routine monitoring of microbiological quality. The remaining samples were taken to follow up previous poor results (13%, 114/902) or in response to a public health incident associated with consumption of RDM (2%, 18/902). For the 652 samples (72%) for which a place of sampling was specified, collection was from 116 different businesses. RDM samples were deemed to be unsatisfactory/potentially injurious to health based on criteria for the interpretation of microbiological results for *Campylobacter* (detected in 25 ml), CPS ($\geqslant 10^4$ per ml), STEC (detected in 25 ml), *L. monocytogenes* (>100 per ml) and *Salmonella* (detected in 25 ml). In total, 3% of samples (29/902) were categorised as unsatisfactory and potentially injurious to health due to the presence of pathogens. Whilst it is possible that the prevalence data may be somewhat skewed by the considerably larger number of cows' milk samples compared to other animal species, the majority of milk samples deemed unsatisfactory and potentially injurious to health were from cows' (n = 28). The remaining sample deemed unsatisfactory and potentially injurious to health was from goats' (n = 1), due to unacceptable levels of CPS. This equated to 4.6% (28/613) of all raw cow milk samples and 0.3% (1/260) of all raw goat milk samples, being deemed unsatisfactory and potentially injurious to health. The 29 samples were deemed unsatisfactory and potentially injurious to health due to the presence of STEC (n = 13), *Salmonella* (n = 8), CPS (n = 3), *Campylobacter* (n = 3) and *L. monocytogenes* (n = 2).

McLauchlin et al. (2020) undertook a study which included analysis of results from routine microbiological monitoring of RDM and other unpasteurised milk products (cream, ice-cream, butter, kefir and cheese) collected between 2013 and 2019 (McLauchlin et al., 2020). As the test results between 2014 and 2016 on raw bovine milk for drinking had been published previously (Willis et al., 2018), they were excluded from the analysis. Routine monitoring was either performed for the purpose of evaluating the hygiene of foods to support their routine food inspection process (in close collaboration with regulatory authorities) or directly for food manufacturers to support the validation of their food hygiene management systems. Microbiological results were deemed to be unsatisfactory/potentially injurious to health as described previously by Willis et al. (2018) and based on criteria for the interpretation of microbiological results for *Campylobacter* (detected in 25 g), CPS ($\geqslant 10^4$ per g), *E. coli* O157 or any STEC (detected in 25 g), *L. monocytogenes* (>100 per g) and *Salmonella* (detected in 25 g). Results from routine monitoring were satisfactory for 62% of milks, 82% of cream, 100% of ice-cream, 51% of butter, 63% of kefir and 79% of cheeses. In total, 5% of all samples were considered potentially hazardous (McLauchlin et al., 2020).

Microbiological results from routine monitoring of cows' drinking milk (2017–2019) from 126 dairies with between 1 and 39 samples tested per dairy, revealed that 4% (24/663) of samples were unsatisfactory (McLauchlin et al., 2020). The 24 cows' milk samples were unsatisfactory due to the presence of *Campylobacter* (n = 18, 1 sample also contained *Salmonella*), *Salmonella* (n = 3), STEC (n = 3) and *L. monocytogenes* (n = 1).

Microbiological results from routine monitoring of goat, sheep, buffalo and camel milk were also analysed (McLauchlin et al., 2020). Results from routine monitoring of goats' milk, revealed that 0.4% (2/534) of samples were unsatisfactory due to the presence of CPS. A total of 15 raw sheeps' milk samples were collected for testing from four dairies at the point of production. Twenty seven of the 28 buffalo milks collected for testing were from five dairies at production, one was from retail. The 7 camel milks were all collected at retail. None of the sheep (n = 15), buffalo (n = 28) or camel (n = 7) milk samples were deemed unsatisfactory.

Of the sampled dairy products made from unpasteurised milk, none of the samples of cream (n = 100; cows' milk: 98 described as double cream, one as crème fraiche, and one as cream), ice-cream (n = 2; goats' milk) or butter (n = 37; cows' milk) were deemed unsatisfactory (McLauchlin et al., 2020). Kefir samples were tested for routine monitoring purposes and were sampled at the point of production from eight different premises (16 were sampled from the same premises). Kefir prepared from goats' milk (18 samples) or cows' milk (six samples) was sampled and 7% (2/24; one cow and one goat) were unsatisfactory due to the presence of CPS. Cheese made from unpasteurised milk and sampled during routine monitoring included products made from cows' milk (n = 734), goats' milk (n = 134), sheeps' milk (n = 94) and milk from other species (n = 22; buffalo or cow and buffalo). Of these cheese samples, 3% (25/734) of cow, 10% (15/134) of goat, 3% (2/94) of sheep and 22% (5/22) of cheese made from the milk from other species, were deemed unsatisfactory. Of the 25 unsatisfactory cows' milk cheeses, 13 were unsatisfactory due to the presence of *L. monocytogenes*, nine were unsatisfactory due to the presence of CPS ($>10^4$ CFU/g), *S*. enterica serovar Newport ST45 was detected in one sample of a hard cheese collected at the point of production and STEC was isolated from two cheese samples. In total, fifteen goats' milk cheese samples were deemed unsatisfactory due to the presence of *L. monocytogenes* (n = 5, of which 2 samples also had unsatisfactory levels of CPS), CPS (n = 10), STEC O157:H7 (n = 1) and STEC (n = 1). Both sheep milk cheeses sampled were deemed unsatisfactory due to the presence of *L. monocytogenes*. Of the cheese prepared from milk of other species, *L. monocytogenes* was detected in five buffalo cheese samples collected at retail. All samples were identified as produced by the same manufacturer.

Ireland

The Food Safety Authority of Ireland (FSAI) coordinated a year-long study between June 2012 and June 2013 to establish the prevalence of pathogens in raw milk and raw milk filters from a random selection of cow, sheep and goat dairy farms (FSAI, 2015). Raw milk filters were taken aseptically from the milking lines directly after milking along with two raw milk samples from each farm's bulk storage tank. Samples were tested for a range of pathogens and indicator organisms including *Salmonella* spp., Shiga toxin producing STEC (isolates of O157 and O26 which had at least one Shiga toxin gene detected), *L. monocytogenes*, *Campylobacter* spp., CPS and *E. coli*. A total of 600 samples were collected nationally from 211 dairy farms, consisting of samples from dairy cow farms (94%, 199/211), goat dairy farms (5%, 10/211) and sheep dairy farms (1%, 2/211). These 600 samples comprised 32% (190/600) raw milk filter samples and 68% (410/600) raw milk samples. *L. monocytogenes* and *Campylobacter* spp. were the most commonly isolated pathogens from both raw milk filter and raw milk samples. Approximately 22% (42/190) and 20% (38/190) of raw milk filter samples were positive for *Campylobacter* spp. and *L. monocytogenes* respectively. While 7% (15/208) and 3% (6/200) of raw milk samples were positive for *L. monocytogenes* and *Campylobacter* spp. respectively. All positive *Campylobacter* spp. samples were taken from cow herds. All raw milk filters (n = 38) and the majority of raw milk (14/15) samples positive for *L. monocytogenes* came from cow herds. The remaining positive raw milk sample came from a goat herd. STEC (O157 and O26) was only tested in raw milk filters and was found to be present in 6% (12/190) of samples. The 12 isolates were all O26 and possessed *eaeA* and *hlyA*. *Salmonella* spp. was present in 1% (2/185) of raw milk filters and 0.5% (1/206) of raw milk samples. CPS were only tested in raw milk samples, none of which contained sufficient numbers of CPS against the threshold set by FSAI ($>10^5$ CFU/ml) required for enterotoxin formation. More than one pathogen type was detected in approximately 8% of raw milk filter samples and two of these raw milk filter samples had three pathogens detected (*L. monocytogenes*, STEC O26 and *Campylobacter* spp). Only one pathogen type was detected in the raw milk samples. In general, the isolation rates for all pathogens examined were higher on in-line raw milk filters than in the corresponding raw bulk tank milk samples. The presence of pathogens on in-line raw milk filters does not always correlate to the presence of pathogens in the bulk-tank raw milk. However, the presence of pathogens on the in-line raw milk filters does indicate the potential for contamination of bulk milk and is indicative of contamination of the milking parlour and/or the herd.

European Union

Amongst those zoonoses included in compulsory annual monitoring in food in the EU are *Salmonella*, *Campylobacter*, *L. monocytogenes* and STEC (EFSA and ECDC, 2015, 2016 2017, 2018a, 2019, 2021a, 2021b). However, the data reported is not harmonised across member states, because the sampling objectives, the place of sampling and the sampling frequency applied varies or are interpreted differently between member states.

EU Regulations 2073/2005, 1441/2007 and 1086/2011 prescribe sampling and testing requirements and set limits for the presence of *Salmonella* in specific food categories. According to microbiological criteria, *Salmonella* must be absent in these products when placed on the market, during their shelf-life. Absence is defined by testing five or, depending on the food category, 30 samples of 25 g per batch. The following section provides an overview of all *Salmonella* detections in dairy products prescribed for sampling and testing under these regulations between 2014 and 2020. Data was reported on *Salmonella* detections in cheese, butter and cream made from raw or low heat-treated milk in 2014 (0.12% of 1,658 total samples), 2015 (0.11% of 949 total samples), 2016 (0.12% of 842 total samples), 2017 (0% of 432 total samples), 2018 (0% of 2,442 total samples), 2019 (0.72% of 1,114 samples) and 2020 (0.64% of 1,574 total samples). There were no *Salmonella* detections in samples of ice cream in 2016 (1,747 total samples), 2017 (23 total samples) or 2020 (529 total samples). There were *Salmonella* detections in samples of ice cream in 2014 (0.01% of 7,478 total samples), 2015 (0.01% of 7,020 total samples), 2018 (0.18% of 556 total samples) and 2019 (0.01% of 755 samples). There were no *Salmonella* detections in samples of dried infant formulae, dried dietary foods for medical purposes and dried follow-on formulae, in 2014 (1,007 total samples), 2015 (1,094 total samples), 2016 (773 total samples), 2017 (172 total samples), 2018 (694 total samples) or 2020 (131 total samples). In 2019, ten retail samples of dried infant formula from Spain were positive for *Salmonella*. For milk powder and whey powder, there were no detections in 2014 (total samples = 204), 2015 (total samples = 135), 2016 (total samples = 170), 2017 (total samples = 31), 2018 (total samples = 135), 2019 (total samples = 227) or 2020 (total samples = 152).

Campylobacter was detected in milk samples in 2014 (0.93% of 2,262 total samples), 2015 (1.02% of 1,565 total samples), 2016 (1.07% of 1,494 total samples), 2017 (1.9% of 1,554 total samples), 2018 (0.58% of 1,882 total samples), 2019 (1.03% of 389 total samples) and 2020 (0.66% of 611 total samples). *Campylobacter* was detected in cheese samples tested in 2016 (1.04% of 288 total samples) and 2017 (0.5% of 522 total samples). *Campylobacter* was not detected in any cheese samples tested in 2014 (total samples = 251), 2015 (total samples = 423), 2018 (total samples = 620), 2019 (total samples = 615) and 2020 (total samples = 458).

Data from different member states reporting the proportion of STEC-positive samples, are not necessarily directly comparable. Reporting countries used analytical methods aimed at detecting any STEC (that is, regardless of the serotype) or methods designed to detect only STEC O157. The following section describes the data reported for the proportion of STEC-positive samples in various dairy commodities, regardless of the analytical method employed by the reporting state. The proportion of STEC-positive samples of raw cows' milk was reported in 2014 (3.6% of 871 samples), 2015 (1.8% of 617 samples), 2016 (1.9% of 863 samples), 2017 (1.2% of 498 samples), 2018 (5.9% of 944 samples), 2019 (3.9% of 1,195 samples) and 2020 (4.7% of 740 samples). No STEC-positive samples of raw milk from goats and sheep were reported in 2014, 2016, 2018 or 2019. STEC-positive samples of raw milk from goats and / or sheep were reported in 2015 (three member states provided information on 12 single units of raw milk from goats with STEC O103 detected in one sample), 2017 (four member states reported monitoring results of 38 sample units of raw goat milk and non-O157 STEC was isolated from one sample of raw goat milk) and 2020 (five member states reported monitoring results on 28 sample units of raw goats' milk and two member states reported on seven samples of raw sheep milk, with one positive sample recorded for each).

The reported results of *L. monocytogenes* testing in RTE food samples were evaluated in accordance with the *L. monocytogenes* criteria indicated in EU legislation applying certain assumptions, where appropriate. Regulation (EC) No 2073/2005 covers primarily RTE food products and requires:

i) in RTE products intended for infants and for special medical purposes *L. monocytogenes* must not be present in 25g of sample,

ii) *L. monocytogenes* must not be present in levels exceeding 100 CFU/g during the shelf-life of other RTE products and,

iii) in RTE foods that are able to support the growth of the bacterium, *L. monocytogenes* must not be present in 25g of sample at the time of leaving the production plant; however, if the producer can demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 CFU/g throughout its shelf-life, this criterion does not apply.

All samples of RTE food intended for infants and for medical purposes were compliant in 2014, 2015, 2016, 2017, 2018, 2019 and 2020. RTE milk samples collected at retail were found to be compliant in 2014, 2015, 2016, 2018, 2019 and 2020 and processing in 2017, 2018 and 2020. Non-compliance was observed for RTE milk samples collected at retail in 2017 (1.2%) and processing in 2014 (0.46%), 2015 (6.1%), 2016 (1.4%), 2019 (1.2%). Very low levels of non-compliance for hard cheeses and for soft and semi-soft cheeses were reported in 2014, 2015, 2016, 2018 and 2019. However, in 2017, soft and semi-soft cheeses' sampled at retail returned a non-satisfactory results range between 0.1% and 5%. This was due to one member state reporting positive samples from cheeses made from raw or low-treated sheep milk.

Canada

The CFIA undertook a targeted survey of raw milk cheeses from the 30th of November 2014 to the 31st of March 2018 (CFIA, 2018). In total, 2,009 samples were collected from retail locations in 11 cities across Canada. A variety of domestic, imported, conventional and organic raw milk cheeses were sampled. Of the samples tested, 19% (390/2,009) were domestic and 81% (1,619/2,009) were imported. An assessment criterion for raw milk cheese samples deemed unsatisfactory was set out for *Salmonella* spp (detected in 25g), *S. aureus* (>10^4 CFU/g), *E. coli* O157 (detected in 25g), *L. monocytogenes* (detected in 25g) and generic *E. coli* (>2x10^3 MPN/g or CFU/g).

All 2,009 samples were tested for *E. coli* O157. Of the 2,009 samples, 1,723 samples were tested for generic *E. coli* and the pathogens *Salmonella* spp, *S. aureus* and *L. monocytogenes*. *Salmonella* spp, *E. coli* O157 and generic *E. coli* (>500 MPN/g or CFU/g) were not found in any samples. *S. aureus* was detected at elevated levels ($10^3 < x \leq 10^4$ CFU/g) in 4/1,723 (0.2%) samples and at high levels (>10^4 CFU/g) in 2/1,723 (0.1%) samples. *L. monocytogenes* was detected in 2/1,723 (0.1%) samples which were Category 1 products. Category 1 RTE foods are those which support the growth of *L. monocytogenes* under reasonably foreseeable conditions of distribution, storage and use throughout the stated shelf-life.

United States

In 2014, the U.S. Food and Drug Administration (FDA) set out to collect and test raw milk cheese products (FDA, 2016). The FDA collected 1,606 raw milk cheese samples, of which 29% (n = 473) were domestic samples and 71% (n = 1,133) were of international origin. The 473 domestic samples of raw milk cheese were from 38 states and Puerto Rico and were collected from three types of establishments: manufacturers, distribution centres or warehouses and retail stores. International cheese samples were collected at import and originated from 22 countries, with the largest number sent from France (n = 531), followed by Spain (n = 145) and Italy (n = 137). The FDA also sampled raw milk cheese from Austria, Belgium, Bulgaria, Canada, Cyprus, Denmark, Germany, Greece, Hungary, Ireland, Lithuania, Mexico, the Netherlands, Nicaragua, Poland, Portugal, Switzerland, Turkey and the UK. The two biggest exporters of cheese to the United States are France and Italy. Product samples were included if they were made from the milk of cows, goats or sheep, or a combination thereof. However, the FDA did not require its field staff to document milk source. The FDA tested samples for the presence of the pathogens *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7 and STEC, as well as for generic *E. coli*.

Of the 1,606 samples tested, the overall contamination rate for each of the pathogens was less than 1% and the overall contamination rate for generic *E. coli* was 5.4% (87/1,606). Of the 1,606 samples tested, one sample contaminated with both violative levels of generic *E. coli* and a pathogen (*L. monocytogenes*).

The three samples that tested positive for *Salmonella* (0.19%, 3/1,606) were found in raw milk cheese made in France (2) and Italy (1).

The 10 samples that tested positive for *L. monocytogenes* (0.62%, 10/1,606) were found in raw milk cheese made in Italy (1), France (4), and the United States (5). Nine of the 10 samples that tested positive for *L. monocytogenes* were semi-soft cheeses. Of the five samples of domestically produced raw milk cheese containing *L. monocytogenes*, three of those five were collected from a single business.

The FDA did not detect *E. coli* O157:H7 in any of the 1,606 samples tested. The FDA detected STEC in 11 of the 1,606 samples tested, for a contamination rate of 0.68%. After further characterisation of the 11 samples, the agency determined one of them to be pathogenic (that is, potentially injurious to human health). The pathogenic sample, *E. coli* O111:H8 serotype, was found in a domestically produced hard, raw goat milk cheese.

With respect to common factors among the FDA's findings, the less than 1% contamination frequencies limited the agency's ability to detect differences in prevalence, such as based on the type of cheese or its origin. Thus, the agency concluded that it could not reliably make inferences with respect to possible common factors. The data collected by the FDA indicate that the prevalences of *Salmonella* and pathogenic STEC are relatively low and similar to the contamination rates in many other foods. *L. monocytogenes* prevalence, especially in semi-soft cheese, remains a concern.

Trmčić et al. (2016) undertook a study to evaluate cheese available on the market for the presence of coliforms and key pathogens (Trmčić et al., 2016). Cheese samples were collected from market sources throughout New York State during 2014 and 2015. A total of 273 cheese samples were selected to capture the diversity of cheese present on the market and to ensure representation of raw (n = 88) and pasteurised (n = 185) milk cheeses as well as representation of different cheese categories manufactured from cow (n = 125), sheep (n = 62), goat (n = 75) and mixed (n = 11) milks. Samples were selected to represent different cheese categories and rind types to ensure inclusion of cheeses representing a wide range and different combinations of pH and water activity. Cheese samples tested represented pH values from 3.5 to 7.7 and water activity values from 0.880 to 0.996. Cheeses sampled were manufactured in the United States (n = 137), as well as 13 other countries (n = 136), including Canada, New Zealand, Israel and EU countries. Among these samples, 213 represented natural cheese products that were sampled only once during the study. The remaining samples included instances in which the same cheese product was sampled more than once from a given processor representing either 2 (n = 21) or 3 (n = 6) different production dates. The cheese samples were tested for the presence of coliforms and for *Salmonella*, *S. aureus*, STEC, *L. monocytogenes* and other *Listeria* species. Among all tested cheese samples, 27% (75/273) tested positive for coliforms in concentrations >10 CFU/g. All cheese samples tested negative for *Salmonella*, *S. aureus* and STEC. *Listeria* spp. were found in 4% (12/273) of samples, including five samples positive for *L. monocytogenes*. Only 5 cheese samples positive for the presence of *Listeria* spp. were also positive for the presence of coliforms (>10 CFU/g); among them, only 1 cheese sample was positive for both *L. monocytogenes* and coliforms. No association was found between coliform and *Listeria* spp. detection. Trmčić et al. (2016) concluded that although the exact mechanism is still to be determined, their results suggest that washed rind cheese presents the highest risk of contamination with different *Listeria* species. Production of washed rind cheese is typically associated with frequent manual handling during ripening. In addition, the wash solutions used in the process can be very diverse and introduce different components that are associated with higher microbial contamination (that is, herbs and spices).

South Africa

A total of 258 raw and pasteurised producer-distributor bulk milk (PDBM) samples were collected from purchase points in 8 provinces in South Africa (Ntuli, Njage, & Buys, 2016). STEC were present in 7 and 3% (n = 258) of the raw and pasteurised PDBM samples, respectively. The prevalence of STEC O157:H7 in bulk milk samples was 2% (n = 258). All presumptive O157:H7 *E. coli* from PDBM that harboured *sxt1*, *stx2*, or both lacked the *eae* gene.

Recalls and import border failures for dairy and dairy products

Analysis of consumer level recalls and imported foods which failed inspection and testing requirements at Australia's borders, provides some information on the foods and safety hazards that do or could enter the food supply from either domestic or imported food sources and pose a health risk. Foods may be recalled due to issues associated with contamination (for example, microbial, biological toxins, chemical, foreign matter), non-compliant labelling, undeclared allergens, faulty packaging and for a variety of other reasons (for example, unsafe levels of additives) (FSANZ, 2018). Information on consumer level recalls of dairy products in Australian States and Territories can be accessed on the FSANZ website (FSANZ, 2023a). At the time of writing, records were accessible for consumer level recalls that occurred from 6/7/2018 onwards. Recalls due to the presence of allergens were excluded from the following discussion and from Table 5. There was a total of 32 consumer level recalls of milk and milk products between 6/7/2018 and 19/2/2022 (Table 5). The recalls were due to microbial contaminants (69%, 22/32), foreign material contaminants (16%, 5/32), chemical contaminants (6%, 2/32), incorrect labelling (3%, 1/32), incorrect packaging (3%, 1/32) and a processing failure associated with pasteurisation (3%, 1/32). The 22 recalls due to microbial contamination were due to *E. coli* (73%, 16/22), *L. monocytogenes* (18%, 4/22), *Cronobacter* and *Salmonella* (1/22) and an unspecified microbial contaminant (1/22). Five recalls were due to foreign material contamination involving glass, metal, plastic, rubber and a broken faulty seal. The two recalls due to chemical contamination involved a food grade dairy cleaning solution and an unspecified chemical contaminant.

Table 5 Consumer level recalls of dairy products in Australia from 6/7/2018 to 19/2/2022

Date	Location	Product	Outlet type	Reason
19/2/2022	National	EleCare, Similac and Alimentum infant formula products	Available nationally through prescription at pharmacies, hospitals and via direct mail order	Microbial contamination (*Cronobacter* and *Salmonella*)
14/2/2022	VIC, QLD and SA	Mortlake Organic Dairy L'Artisan Organic Marcel	Supermarkets and retailers	Microbial contamination (*E. coli*)
19/1/2022	National	Saputo Dairy Australia Pty Ltd Butter and Spreadable Butter Blend Products	Supermarkets and retailers	Microbial contamination (unspecified)
18/11/2021	NSW, ACT, QLD, VIC, SA and WA	Snackers Market Tasty Cheese and Mini Crackers and Pretzels	Supermarkets	Microbial contamination (*L. monocytogenes*)
3/6/2021	NSW, ACT, QLD, VIC and TAS	Community Co Cookies & Cream Ice Cream	Supermarkets and retailers	Foreign matter (rubber)
5/3/2021	QLD	Kenilworth Dairies Full Cream Milk	Kenilworth Dairies Café and Retailers	Microbial contamination (*E. coli*)
22/7/2020	TAS	Tasmanian Cheese Co Chilli Cheddar	Supermarkets and retailers	Microbial contamination (*L. monocytogenes*)
22/5/2020	National	Kmart Solid and Filled Egg and Filled Caramel Egg	Retailers	Foreign matter (plastic)
14/2/2020	NSW and ACT	Farmdale Full Cream Milk	Supermarkets	Microbial contamination (*E. coli*)
14/2/2020	NSW	Dairy Choice Full Cream Milk and Community Co 'The Good	Supermarkets and retailers	Microbial contamination (*E. coli*)

Date	Location	Product	Outlet type	Reason
		Drop' Full Cream Milk		
13/2/2020	NSW and ACT	7 Eleven Full Cream Milk	Retailers	Microbial contamination (*E. coli*)
13/2/2020	NSW	Dairy Farmers Full Cream Milk	Supermarkets and retailers	Microbial contamination (*E. coli*)
15/11/2019	NSW, QLD, VIC, WA, SA and TAS	Udder Delights White Mould Cheeses	Supermarkets and retailers	Microbial contamination (*E. coli*)
7/9/2019	WA	Coles Full Cream Milk	Supermarkets	Chemical contamination
26/7/2019	VIC	Gippsland Jersey Full Cream and Light Milk	Supermarkets and retailers	Processing failure associated with pasteurisation (milk that is not pasteurised according to the standard may be associated with food borne illness and decreased shelf life)
20/6/2019	NSW and VIC	Coles Fresh Full Cream Milk	Supermarkets	Microbial contamination (*E. coli*)
20/6/2019	NSW and VIC	Lactalis Australia Milks	Supermarkets and retailers	Microbial contamination (*E. coli*)
13/6/2019	NSW and VIC	Lactalis Australia Milks	Supermarkets and retailers	Chemical contamination (food grade dairy cleaning solution)
14/5/2019	QLD	Frolicking Goat Teddy Cheese	Supermarkets and retailers	Microbial contamination (*E. coli*)
18/4/2019	VIC	Timboon Brie	Timboon Cheesery	Microbial contamination (*E. coli*)

Date	Location	Product	Outlet type	Reason
15/4/2019	VIC	Organic Spring Pty Ltd imported French cheeses	Retailer	Microbial contamination (*L. monocytogenes*)
12/4/2019	NSW, QLD, VIC, SA and WA	Washed Rind Pty Ltd Washed Mould Cheeses	Retailers	Microbial contamination (*L. monocytogenes*)
29/3/2019	NSW, QLD, VIC, TAS, SA and WA	Chobani Flip Almond Coco Loco	Supermarkets and retailers	Incorrect packaging (Lemon Meringue Tang tub, with Almond Coco Loco foil and Almond Coco Loco ingredients)
6/2/2019	QLD	Maleny Herb and Garlic Feta	Supermarkets and retailers	Microbial contamination (*E. coli*)
31/1/2019	TAS	OMG Organic Milk	Supermarkets and retailers	Microbial contamination (*E. coli*)
30/1/2019	QLD	Mungalli Creek Kefir Milk	Retailers	Microbial contamination (*E. coli*)
18/12/2018	NSW, QLD and WA	True Organic Australian Organic Feta Marinated in Oil with Garlic and Herbs	Supermarkets and retailers	Incorrect labelling (best before date)
4/11/2018	ACT and NSW	Canberra Milk Full Cream	Retailers	Foreign matter (faulty seal which may result in broken parts of the cap being present in the milk)
16/8/2018	VIC	Mamma Lucia Greek Style Fetta	Mamma Lucia Cheese Shop Factory Outlet and retailers	Microbial contamination (*E. coli*)
3/8/2018	National	Home Ice Cream	Home Ice Cream outlets and retailers	Foreign matter (glass)

Date	Location	Product	Outlet type	Reason
2/8/2018	NSW and QLD	Woombye Cheese Company cheeses (Blackall Gold Washed Rind, Camembert, Truffle Triple Cream Brie & Triple Cream Brie)	Supermarkets and retailers	Microbial contamination (*E. coli*)
27/7/2018	Available online and in retailers within NSW, QLD, VIC, TAS, SA and WA	Lactose Free Whole Milk Powder	Online and retailers	Foreign matter (metal)

All food imported into Australia must comply with Australian Food Standards and requirements for safety. Imported food is inspected and tested under the Imported Food Inspection Scheme (IFIS) (DAFF, 2022e). The IFIS is operated based on food being classified as either risk food, surveillance food or compliance agreement food. The rate of sampling applied is set out in the Imported Food Control Regulations 2019. Imported dairy products (cheese, dried milk and raw milk cheese) and infant formula (powdered infant formula) are tested against a published list of potential hazards (DAFF, 2022d) and are briefly summarised below.

Cheese classified as either a risk food or a surveillance food is tested for *L. monocytogenes*. Cheese that supports the growth of *L. monocytogenes* is a risk food and referred for testing at the initial rate of 100% of consignments until compliance is demonstrated. Cheese that does not support the growth of *L. monocytogenes* is a surveillance food and referred for testing at the rate of 5% of consignments.

Dried milk includes milk and cream concentrated powders from milking animals. Dried milk is classified as a surveillance food and is tested for *Salmonella*.

Only raw milk cheese that is covered by a recognised foreign government certificate can be imported. Current certification arrangements include Roquefort cheese and Ossau Iraty from France, as well as 12 kinds of raw milk cheese from the United Kingdom (UK) (DAFF, 2022f). Consignments of raw milk cheese are sent for analytical testing at the rate of 5% and are tested for *Salmonella* and *L. monocytogenes.*

Infant formula includes powdered infant formula and powdered follow-on formula. This food is classified as a surveillance food. Powdered infant formula for infants 6 months and under, is tested for *Salmonella* and *Cronobacter*. Powdered follow-on formula for infants 6 months and over, is tested for *Salmonella*.

Reports of imported foods that fail inspection and testing requirements under the IFIS are publicly available (Australian Government, 2022a; DAFF, 2022c). Reports between January 2014 to December 2020 revealed 171 imported dairy products that failed inspection and testing requirements, all of which were cheese products (Table 6). Half of all failed cheese products were imported from Italy (86/171; 50%), followed by France (36/171; 21%), Spain (17/171; 10%), Greece (11/171; 6%), the UK (7/171; 4%), Portugal (4/171; 2%), Switzerland (3/171; 2%), Bulgaria (3/171; 2%), Germany (2/171; 1%), Denmark (1/171; 1%) and Macedonia (1/171; 1%). Microbial contamination of cheese was most frequently caused by *E. coli* (95/171; 56%), followed by *L. monocytogenes* (74/171; 43%). One cheese product was contaminated with both *E. coli* and *L. monocytogenes*. One cheese product failed due to visible mould contamination.

Table 6 Imported dairy products that failed inspection and testing requirements from January 2014 to December 2020

Date of fail	Product description	Country of Origin	Test failed
8/07/2020	Sheep milk cured cheese	Portugal	*L. monocytogenes*
22/06/2020	Compostelle cheese	France	*L. monocytogenes*
13/05/2020	Chalosse cheese	France	*L. monocytogenes*
13/05/2020	Compostelle cheese	France	*L. monocytogenes*
13/05/2020	Agour goat cheese	France	*L. monocytogenes*
9/04/2020	Ossau Iraty cheese (sheeps' milk cheese)	France	*L. monocytogenes*
21/01/2020	Gorgonzola dolce intero DOP cheese	Italy	*L. monocytogenes*
20/11/2019	Taleggio DOP cheese	Italy	*L. monocytogenes*
5/11/2019	Caprotto cheese	Italy	*L. monocytogenes*
31/10/2019	Dry mizithra cheese	Greece	*L. monocytogenes*
9/10/2019	Petit Agour cheese	France	*L. monocytogenes*
2/09/2019	Cheese	Italy	*L. monocytogenes*
6/08/2019	Diced mozzarella cheese	Italy	*L. monocytogenes*
25/07/2019	Gialloblu erborinato cheese	Italy	*L. monocytogenes*
4/07/2019	Pata de mulo cheese	Spain	*L. monocytogenes*
9/05/2019	Spicy caciocavallo cheese	Italy	*L. monocytogenes*
29/04/2019	Montasio cheese	Italy	*L. monocytogenes*
9/04/2019	Gorgonzola cheese	Italy	*L. monocytogenes*
24/01/2019	Peperoncino cheese	Italy	*L. monocytogenes*
17/12/2018	Gorgonzola cheese	Italy	*L. monocytogenes*
11/12/2018	Gialloblu cheese	Italy	*L. monocytogenes*
8/10/2018	Gorgonzola cheese	Italy	*L. monocytogenes*

Date of fail	Product description	Country of Origin	Test failed
4/10/2018	Gorgonzola cheese	Italy	*L. monocytogenes*
10/09/2018	Frozen pizza cheese	Italy	*L. monocytogenes*
23/04/2018	Cheese	Italy	*L. monocytogenes*
11/04/2018	Sheep cheese with truffle	Spain	*L. monocytogenes*
20/03/2018	Cheese	Italy	*L. monocytogenes*
24/01/2018	Gorgonzola cheese	Italy	*L. monocytogenes*
15/01/2018	Burrata cheese	Italy	*L. monocytogenes*
15/01/2018	Gorgonzola DOP tosi	Italy	*L. monocytogenes*
15/12/2017	Gorgonzola soft cheese	Italy	*L. monocytogenes*
23/11/2017	Asiago pressato DOP	Italy	*E. coli*
10/11/2017	Asiago DOP cheese	Italy	*E. coli*
11/09/2017	Cheese	France	*L. monocytogenes*
24/08/2017	Fontina DOP ¼ cheese	Italy	*L. monocytogenes*
9/08/2017	Taleggio DOP cheese	Italy	*L. monocytogenes*
9/08/2017	Asiago DOP cheese	Italy	*E. coli*
1/06/2017	Cheese	Switzerland	*L. monocytogenes*
26/05/2017	Cheese	Italy	*L. monocytogenes*
4/05/2017	Cheese	Italy	*L. monocytogenes*
3/04/2017	Burrata cheese	Italy	*L. monocytogenes*
31/03/2017	Blu di Caravaggio (cheese)	Italy	*L. monocytogenes*
31/03/2017	Gorgonzola e Marscarpone (cheese)	Italy	*L. monocytogenes*
10/02/2017	Montasio cheese	Spain	*L. monocytogenes*
3/02/2017	Blue cheese	Spain	*L. monocytogenes*
20/01/2017	Blue cheese	Italy	*L. monocytogenes*
16/01/2017	Cheese	Italy	*L. monocytogenes*

Date of fail	Product description	Country of Origin	Test failed
22/12/2016	Flamengo cheese	Portugal	*L. monocytogenes*
12/12/2016	Gorgonzola dolce	Italy	*L. monocytogenes*
6/12/2016	Blue cheese	Spain	*L. monocytogenes*
21/11/2016	Gorgonzola dolce	Italy	*L. monocytogenes*
21/11/2016	Gorgonzola piccante	Italy	*L. monocytogenes*
1/11/2016	Gorgonzola dolce	Italy	*L. monocytogenes*
14/10/2016	Dry mizithra cheese	Greece	*E. coli*
4/10/2016	Cheddar with truffle	UK	*L. monocytogenes*
13/09/2016	Blue cheese	UK	*L. monocytogenes*
11/08/2016	Gorgonzola	Italy	*L. monocytogenes*
11/08/2016	Fior d'aracio blue cheese	Italy	*L. monocytogenes*
18/08/2016	Pecora blue cheese	Italy	*L. monocytogenes*
11/08/2016	Semi hard cheese	Italy	*L. monocytogenes*
17/05/2016	Cheese	Italy	*E. coli*
29/04/2016	Havarty light	Spain	*L. monocytogenes*
1/03/2016	Mozzarella di bufala campana cheese	Italy	*E. coli*
17/02/2016	Pata de mulo curado cheese	Spain	*E. coli*
9/02/2016	Ricotta di Bufalo cheese	Italy	*E. coli*
7/02/2016	Graindorge livarot cheese	France	*E. coli*
7/02/2016	Graindorge livarot cheese	France	*E. coli*
14/01/2016	Kashkaval cheese	Bulgaria	*E. coli*
17/12/2015	Mizithra cheese	Greece	*E. coli*
17/12/2015	Mizithra cheese	Greece	*E. coli*
15/12/2015	Belometti cheese	Italy	*E. coli*

Date of fail	Product description	Country of Origin	Test failed
25/11/2015	Blue Stilton cheese	UK	*L. monocytogenes*
24/11/2015	Valdeon blue cheese	Spain	*E. coli*
3/11/2015	Cheese	Portugal	*E. coli*
30/10/2015	Blue cheese	Spain	*L. monocytogenes*
28/10/2015	Saracino cheese wheel	Italy	*E. coli*
22/10/2015	Casatica Di Bufala Cheese	Italy	*L. monocytogenes*
16/10/2015	Kefalotiri cheese in wheels	Greece	*E. coli*
14/10/2015	Graindorge livarot cheese	France	*E. coli*
14/10/2015	Mozzarella di bufala cheese	Italy	*E. coli*
13/10/2015	Sheep ricotta (smoked & salted)	Italy	*E. coli*
14/09/2015	Queso Arzua Ulloa Dop cheese	Spain	*E. coli*
7/08/2015	Brie Xavier David cheese	France	*E. coli*
3/08/2015	Gorgonzola Piccante DOP Rea Nero Cheese	Italy	*L. monocytogenes*
2/08/2015	Queso Arzua Ulloa DOP cheese	Spain	*E. coli*
29/07/2015	Cornish Blue Stilton cheese	UK	*L. monocytogenes*
27/07/2015	Puit Brebis de Pont Astier	France	*E. coli*
21/07/2015	Roucoulons cheese	France	*E. coli*
20/07/2015	Ricotta Salata vela Bianca cheese	Italy	*E. coli*
13/07/2015	Buche Prince soft cheese	France	*E. coli*
8/07/2015	Brillat Savarin Affine cheese	France	*E. coli*

Date of fail	Product description	Country of Origin	Test failed
7/07/2015	Reblochon cheese	Switzerland	*E. coli*
7/07/2015	St Germain cheese	France	*E. coli*
7/07/2015	Roucoulons cheese	France	*E. coli*
6/07/2015	Casatica di Bufala cheese	Italy	*L. monocytogenes*
1/07/2015	Tilsiter Grun cheese	Switzerland	*E. coli*
30/06/2015	Fontina cheese	Italy	*E. coli*
28/05/2015	Scamorza cheese	Italy	*E. coli*
26/05/2015	Camembert cheese	France	*E. coli*
21/05/2015	Gorgonzola Piccante DOP cheese	Italy	*L. monocytogenes*
18/05/2015	Gorgonzola DOP Dolce cheese	Italy	*E. coli*
1/05/2015	Taleggio cheese	Italy	*L. monocytogenes*
27/04/2015	Ricotta Salata Vela Bianca cheese	Italy	*E. coli*
27/04/2015	Queso Arzua Ulloa DOP cheese	Spain	*E. coli*
11/03/2015	Kefalotyri cheese	Greece	*E. coli*
27/02/2015	Gorgonzola cheese	Italy	*L. monocytogenes*
9/02/2015	Taleggio DOP cheese	Italy	*E. coli*
12/01/2015	Sweberg swiss cheese	Germany	*E. coli*
27/01/2015	Sheeps' cheese	Bulgaria	*E. coli*
19/01/2015	Ponte Nova cheese	Portugal	*E. coli*
22/12/2014	Fontina Valdostana DOP cheese	Italy	*E. coli*
22/12/2014	Fontina DOP cheese	Italy	*E. coli*
19/12/2014	Chevre du Poitou cheese	France	*E. coli*
13/12/2014	Meli Melo Chevre Brebis cheese	France	*E. coli*

Date of fail	Product description	Country of Origin	Test failed
9/12/2014	Fontina Valle D'Aosta cheese	Italy	*E. coli*
4/12/2014	Azul Valdeon cheese	Spain	*E. coli*
24/11/2014	Swiss cheese	Germany	*E. coli*
17/11/2014	Gorgonzola piccante DOP cheese	Italy	*L. monocytogenes*
17/11/2014	Kefalograviera cheese	Greece	*E. coli*
11/11/2014	Fontina DOP Alpeggio cheese	Italy	*E. coli*
11/11/2014	Fontina DOP Alpeggio cheese	Italy	*E. coli*
4/11/2014	Sola cheese and Moccagnetto cheese	Italy	*E. coli*
28/10/2014	Queso Traditional Garrotxa cheese	Spain	*E. coli*
27/10/2014	Roucoulons cheese	France	*E. coli*
22/10/2014	Feta cheese	Greece	*E. coli*
16/10/2014	Roucoulons cheese	France	*E. coli*
13/10/2014	Bleu de Brebis Cire cheese	France	*E. coli*
9/10/2014	Novella with hot pepper cheese	Italy	*E. coli*
29/09/2014	Gorgonzola Dolce cheese	Italy	*L. monocytogenes*
29/09/2014	Saint Germain cheese	France	*E. coli*
15/09/2014	Queso Traditional Garrotxa cheese	Spain	*E. coli*
22/09/2014	Fromaggio Asiago cheese	Italy	*E. coli* *L. monocytogenes*
12/09/2014	Soft cheese	France	*E. coli*
2/09/2014	Roucoulons cheese	France	*E. coli*
12/08/2014	Kefalograviera cheese	Greece	*E. coli*

Date of fail	Product description	Country of Origin	Test failed
11/08/2014	Greek feta cheese	Greece	*E. coli*
06/08/2014	Gorgonzola DOP cheese	Italy	*L. monocytogenes*
23/07/2014	Soft cheese	France	*E. coli*
22/07/2014	Occelli in foglie di castagno cheese	Italy	*E. coli*
11/07/2014	Soft cheese	France	*E. coli*
4/07/2014	Camembert cheese	France	*E. coli*
3/07/2014	Blue D'Auvergne cheese	France	*E. coli*
3/07/2014	Havarti cheese	Denmark	*L. monocytogenes*
27/06/2014	Piccolo Fiore di Bufala cheese	Italy	*E. coli*
26/06/2014	Brie mon sire cheese	France	*E. coli*
23/06/2014	Formaggio Asiago cheese	Italy	*E. coli*
11/06/2014	Piccolo Fiore di Bufala cheese	Italy	*E. coli*
5/06/2014	White cows' milk cheese	Macedonia	*E. coli*
5/06/2014	Gorgonzola DOP cheese	Italy	*L. monocytogenes*
13/05/2014	Gorgonzola DOP cheese	Italy	*L. monocytogenes*
5/05/2014	Gorgonzola Piccante DOP cheese	Italy	*E. coli*
2/05/2014	Formaggio Asiago cheese	Italy	*E. coli*
1/05/2014	Greek feta cheese	Greece	Visible mould contamination
1/05/2014	Brie Bons Mayennais cheese	France	*E. coli*
28/04/2014	Piccolo Fiore di Bufala cheese	Italy	*E. coli*

Date of fail	Product description	Country of Origin	Test failed
22/04/2014	Toma trifilera cheese	Italy	*E. coli*
17/04/2014	Piccolo Fiore di Bufala cheese	Italy	*E. coli*
10/04/2014	Valdeon blue cheese	Spain	*E. coli*
6/04/2014	Asiago cheese	Italy	*E. coli*
1/04/2014	Brie 'Mon Sire' cheese	France	*E. coli*
28/03/2014	La Perla cheese	Spain	*L. monocytogenes*
5/03/2014	Val. Traditional Bercbois cheese	France	*E. coli*
21/02/2014	Raclette cheese	France	*E. coli*
7/02/2014	Taleggio D.O.P cheese	Italy	*E. coli*
17/02/2014	Kashkaval cheese	Bulgaria	*E. coli*
21/01/2014	Traditional Bercbois cheese	France	*E. coli*
22/01/2014	Ricotta salata cheese	Italy	*L. monocytogenes*
6/01/2014	Organic Perl Las cheese	UK	*E. coli*
2/01/2014	Taleggio DOP cheese	Italy	*E. coli*
2/01/2014	Perl Las cheese	UK	*E. coli*
2/01/2014	Organic Perl Las cheese	UK	*E. coli*

Risk characterisation

Milk and milk products are a significant component of the diet for the majority of the Australian population. Daily consumption of milk, yoghurt, cheese and/or alternatives per capita in 2019-2020 was estimated to equate to 1.88 serves per person (ABS, 2022).

Contamination of dairy products can occur at the stage of production, processing, distribution or preparation. Raw milk can present health risks from contamination by a wide variety of pathogenic microorganisms. While there is limited published data on the prevalence and levels of foodborne pathogens in raw milk in Australia, numerous international surveys have recently been published. The results of these international surveys are not directly comparable, owing to differences in the sampling objectives and the testing methods employed. These microbiological surveys typically test for a subset of those foodborne pathogens commonly associated with dairy products. In two related studies focused on the results of routine microbiological monitoring of raw cow milk in the UK, contamination was reported for *Campylobacter* (0.5% - 2.7%), *Salmonella* (0.5% - 1.3%), STEC (0.5% - 2.1%), *L. monocytogenes*

(0.2% - 0.3%) and CPS (0.3%) (McLauchlin et al., 2020; Willis et al., 2018). While the survey results in general indicate a low level of contamination for each foodborne pathogen, their presence would have important consequences if the milk were consumed raw. In international reports of foodborne illness between 2014 and 2020, consumption of RDM was responsible for the majority of dairy associated outbreaks in New Zealand (100%) and the USA (60%). *Campylobacter* was the causative agent responsible for the majority of the RDM outbreaks in both New Zealand and the USA. Similarly, *Campylobacter* has also been assessed as the leading cause of outbreaks related to the consumption of RDM in the UK (ACMSF, 2018) and EU (EFSA Panel on Biological Hazards, 2015). Findings from a systematic review of disease outbreaks in Canada and the USA from 2007 to October 2020, also revealed that the majority of outbreaks linked to dairy consumption were due to unpasteurised dairy products and *Campylobacter*; the majority of which involved RDM (Sebastianski et al., 2022).

L. monocytogenes was responsible for the greatest number of failed inspections in cheese on import to Australia. The vast majority of these products originated from the EU. This aligns with the fact that *L. monocytogenes* was reported to be the foodborne pathogen responsible for the highest number of biological notifications of food safety hazards in cheese within the EU (Montgomery et al., 2020). Additionally, soft and semisoft cheeses in the EU were reported to be most frequently associated with *L. monocytogenes* and *S. aureus* enterotoxins (van Asselt et al., 2017). *L. monocytogenes* was also reported to be the most prevalent foodborne pathogen in microbiological surveys of pasteurised and / or raw milk cheeses in the UK (McLauchlin et al., 2020) and USA (FDA, 2016; Trmčić et al., 2016). In Canada, *S. aureus* and *L. monocytogenes* were the most prevalent pathogens in a targeted survey of raw milk cheeses (CFIA, 2018). A review of disease outbreaks in Canada and the USA from 2007 up to October 2020, also revealed that *L. monocytogenes* accounted for the most outbreaks involving pasteurised products and that most were due to soft cheeses (Sebastianski et al., 2022). Proper pasteurisation eliminates *L. monocytogenes* from milk, but cheesemaking involves several steps post-pasteurisation where the RTE product is exposed to the manufacturing environment and contamination can occur.

Regulation for the dairy industry has been in place for a long time in NSW and HACCP based food safety management programs are required along the supply chain. Standard 4.2.4 - *Primary Production and Processing Standard for Dairy Products*, sets out a number of food safety requirements including that dairy businesses implement a documented FSP to control the potential food safety hazards associated with their business. Management practices include controls for animal health, adherence to good milking practices, effective heat treatment (for example, pasteurisation or an equivalent process) and controls to prevent post-pasteurisation contamination in the dairy processing environment. Dairy primary producers, processors, cold stores, collection and transport businesses are routinely inspected by the NSW Food Authority for compliance with requirements. A high degree of compliance with FSP requirements across the NSW dairy sector has been demonstrated, with a 98% compliance rate for the 2020-21 financial period (NSW Food Authority, 2021b).

In NSW from 2014 to 2020, there were no outbreaks due to dairy products in which milk was identified as the initial source of contamination (Communicable Diseases Branch, 2015, 2016, 2017, 2018, 2019a, 2019b, 2022). Overall, the foodborne illness data and high degree of regulatory compliance across the NSW dairy sector, indicates that dairy products represent a low risk to public health when processed under existing standards.

Recent international foodborne outbreaks involving milk and dairy products highlight the importance of regulatory oversight and robust quality assurance processes, including routine sampling of the environment and finished products.

While pasteurisation is regarded as an effective method for eliminating foodborne pathogens and other bacteria from milk, pasteurised dairy products have caused recent outbreaks in the UK, USA and Canada due to pasteurisation failures or post-pasteurisation contamination (Gopfert et al., 2022; Gruber et al., 2021; Hanson et al., 2019; Jenkins et al., 2022; Rietberg et al., 2016). In the UK and USA, outbreaks linked to the consumption of pasteurised milk have mainly involved small-scale pasteurisers or on-site farm milk vending machines. Small-scale pasteurisation processes have been reported to be associated with a higher risk of microbiological contamination compared to commercial dairies (Gopfert et al., 2022; Opiyo, Wangoh, & Njage, 2013; Stobnicka-Kupiec, Gołofit-Szymczak, & Górny, 2019). For example, in a recent survey of 63 on-farm pasteurisers and 104 milk-vending machines in the South West of England, potential risks to public health identified included difficulties with effective cleaning of equipment, safe transportation of pasteurised milk on-farm, failure of pasteurisation processes, risk of post-pasteurisation contamination from the environment and a lack of guidance for food business operators and regulators on milk vending machines (Gopfert et al., 2022). An outbreak of STEC O157:H7 caused by a milk pasteurisation failure at a local dairy in South Yorkshire in November 2019, was the first recorded incident of this nature in England for over two decades (Jenkins et al., 2022). Inspection of the pasteuriser revealed a damaged seal, which resulted in pasteurised milk being contaminated by raw milk intermittently leaking through the broken seal. The outbreak involved 21 confirmed cases, including twelve (57%) patients who were treated in hospital and three cases who developed HUS. More recently in March 2021, an outbreak of *Cryptosporidium parvum* was linked to pasteurised milk from an on-farm vending machine in England (Gopfert et al., 2022). The outbreak involved two confirmed and one probable case. Post-pasteurisation contamination was identified as the source of outbreak, with specific concern noted regarding the cleaning of equipment and the vending machine churns. In the USA in June and July of 2019, 109 cases (48 confirmed and 61 probable) of *Y. enterocolitica* infections were associated with locally produced pasteurised milk from a small dairy in Pennsylvania (Gruber et al., 2021). Of the 109 cases, seven people were hospitalised. Pasteurisation records indicated proper temperatures were reached and no significant sanitary issues were identified at the dairy. It was hypothesised that contamination of the pasteurised milk most likely occurred in one of two ways. The pasteuriser was purchased second hand 10 years previously and the gasket sealing the bulk milk tank was worn and in need of replacement, which may have resulted in leaks and cross-contamination of milk during pasteurisation. It was also possible that pigs or wildlife near the dairy provided a potential source of *Y. enterocolitica*.

Outbreaks involving pasteurised dairy products are a major public health concern as, unlike unpasteurised milk, pasteurised milk is marketed as ‘safe to drink’ and may be sold to a larger, and more dispersed, population (Jenkins et al., 2022). In Canada, from November 2015 until June 2016, pasteurised chocolate milk was identified as the source of a listeriosis outbreak in Ontario which resulted in 34 cases, including 32 hospitalisations (94%, 32/34) and 4 deaths (12%, 4/34). Post-process contamination of the chocolate milk line was believed to be the root cause of the outbreak. Environmental sampling at the manufacturer confirmed the presence of the outbreak strain within a post-pasteurisation pump dedicated to chocolate milk and on non-food contact surfaces (CFIA, 2016). The deficiencies at the processing facility required corrections to be made to the HACCP plan, sanitation and maintenance practices, and monitoring procedures (CFIA, 2016).

In the USA, recent work conducted by the FDA has reinforced the importance of implementing comprehensive sanitation controls and environmental and product testing for *L. monocytogenes* with regulatory oversight for ice cream production. An outbreak of listeriosis was linked to a widely distributed brand of ice cream, with whole-genome sequencing (WGS) and product sampling helping to link cases which spanned 5 years (2010 - 2015) to 2 production facilities, indicating longstanding contamination (CDC, 2015; Conrad et al., 2023). Inspections of the production facilities conducted by the FDA revealed inadequate testing and cleaning procedures; facility design and construction that allowed for condensate and dripping; equipment storage locations and procedures that failed to protect food-contact surfaces from contamination; employee practices that provided opportunities for condensation and hose water spray to enter ice cream products; and use of wooden pallets and other equipment with mould-like stains (FDA, 2015a, 2015b, 2015c). Following this extended outbreak, the FDA conducted inspections and environmental sampling of 89 ice cream production facilities in 32 states (FDA, 2022a). At the time, the 89 ice cream production facilities accounted for ~16% of the domestic ice cream manufacturers in the FDA’s inventory. Investigators were instructed to collect two environmental samples at each establishment, one consisting of at least 50 subsamples to test for *L. monocytogenes* and the other consisting of at least 100 subsamples to test for *Salmonella*. Of the 89 ice cream production facilities, the FDA detected *L. monocytogenes* in 19 facilities (21%, 19/89) and *Salmonella* in one facility (1%, 1/89). Examining the findings by zone, *L. monocytogenes* was detected on food contact surfaces at one of the 19 establishments where *L. monocytogenes* had been found, whereas all the other detections of the pathogen involved non-food contact surfaces. The *Salmonella*-positive sample was collected from a non-food contact surface, the wheel of a forklift that transported ingredients from a storage area to a production area. WGS was undertaken on the subsamples that tested positive for a pathogen, to determine whether the isolates may be linked to human illness, finished products or other environmental samples. Bioinformatics analysis showed that three of the *L. monocytogenes*-positive samples were individually related to isolates obtained from four ill persons prior to 2016. However, at the time of the collection and testing, the FDA could not determine whether any of the bacteria found in the environment of the facilities were the likely cause of those four illnesses, due to the limited epidemiological data then available. In late summer 2018, additional information surfaced, strongly linking a Florida facility inspected under this assignment to a clinical listeriosis case. The *L. monocytogenes* isolate obtained from the clinical case was highly related to a positive environmental sample collected at the Florida facility in 2017. It was also confirmed that the patient had eaten ice cream made at the facility and a follow-up inspection by the FDA identified insanitary conditions that could lead to *L. monocytogenes* contamination in finished product. With respect to the assignment inspectional outcomes, the FDA classified 44 of the 89 inspections (49%) as requiring no further action. At 39 inspections (44%) objectionable conditions or practices were observed and documented requiring action from the business, without official action required by the FDA.

In total, there were six inspections (7%) where official action was required, as objectionable conditions or practices were observed and documented that were most likely to contribute to contamination in the food. The FDA detected *L. monocytogenes* in all six of the facilities where official action was required. In addition to the pathogen findings, agency investigators observed, for example, improper cleaning and sanitizing of utensils and production equipment food contact surfaces; employees' failure to thoroughly wash hands before starting work and after handling trash; a sink with holes that allowed waste water to drip onto the production room floor; and the use of a pressurized hose to spray waste product toward a floor drain while ingredients and food packaging were unprotected from the splash and mist. Since this time, another outbreak of *L. monocytogenes* linked to ice cream has occurred in the USA (FDA, 2022b). The outbreak occurred across 11 states and resulted in a total of 28 illnesses, including 27 hospitalisations, 1 death and 1 foetal loss. Environmental sampling conducted during the investigation, identified the outbreak strain in samples collected from the ice cream and the food production environment. In November 2022 the CDC declared the outbreak over, however the investigation is ongoing.

Sale of raw milk and raw milk products is legal in some countries and consumption of these products is a major cause of foodborne disease. While several countries have implemented strict controls for producers of RDM for human consumption, pathogen-free milk cannot be guaranteed. In an assessment of human illness associated with RDM (and certain raw milk products) in the UK, the ACMSF (2018) noted the poor predictive value of hygiene indicators and compliance ratings in identifying food safety concerns in RDM (ACMSF, 2018).

In the USA, Costard et al. (2017) demonstrated that consumption of unpasteurised dairy products compared with pasteurised dairy products leads to an increased incidence of outbreaks, illnesses and hospitalisations. Costard et al. (2017) conducted a review of outbreak data in NORS in the United States between 2009 - 2014 and developed a model to estimate the incidence rates of illness and hospitalisation for pasteurised and unpasteurised dairy products (Costard, Espejo, Groenendaal, & Zagmutt, 2017). The study included outbreaks in which the confirmed causative agents were any of the four pathogens of interest (*Campylobacter* spp., *Salmonella* spp., STEC and *L. monocytogenes*) and the implicated food vehicle or contaminated ingredient was cows' milk or cheese made from cows' milk (milk and cheese caused 99% of dairy-related outbreaks reported to NORS during the study period). The study reported that outbreaks associated with dairy consumption cause, on average, 760 illnesses/year and 22 hospitalisations/year, mostly from *Salmonella* spp. and *Campylobacter* spp. Unpasteurised milk, consumed by only 3.2% of the population, and cheese, consumed by only 1.6% of the population, caused 96% of illnesses caused by contaminated dairy products. Costard et al. (2017) estimated that unpasteurised dairy products cause 840 times more illnesses and 45 times more hospitalisations than pasteurised products.

In Australia, the treatment of milk and milk products to destroy pathogens is required by the Code with very few exceptions. There is no data publicly available on the level of consumption of raw milk in Australia. However, unpublished research suggests that consumption of raw milk is likely to be low among the general population, as sale of this product is illegal, and access is extremely limited (FSANZ, 2009a). Insight is only gained if information is obtained pertaining to the illegal sale of raw milk or if a foodborne outbreak occurs which is associated with the consumption of these products. Milk-borne outbreaks associated with RDM are typically smaller than those caused by pasteurisation failures and therefore, are more difficult to detect (Treacy et al., 2019). The NSW Food Authority investigates any reports of retailers illegally selling raw milk for human consumption. Evidence of illegal sale of raw milk in Australian jurisdictions occurred recently, with prosecutions of operators selling raw cow milk through 'herd share' schemes in NSW and SA (NSW Food Authority, 2017, 2019c). These 'herd share' arrangements have been used to attempt to circumvent Australian laws prohibiting the sale of unpasteurised milk. Under these arrangements, an individual purchases an ownership interest in a cow or herd, which remains under the care of the farmer, to gain access to a portion of the unpasteurised milk produced. In NSW in 2015, the NSW Food Authority conducted an investigation into a herd share arrangement in which samples of raw milk taken from one of the herd animals returned positive for the presence of *Listeria* (NSW Food Authority, 2017). Following this investigation, a fine was issued under section 104 of the Food Act 2003 for selling milk which was not pasteurised in contravention of Food Regulation 2010, and for conducting a food business without a licence as required by the Regulation. A further two charges were laid under section 21 of the Act for selling unpasteurised milk that exceeded acceptable microbiological limits for standard plate counts and *Listeria*. In SA in 2016, a couple were fined for selling unpasteurised cow milk contrary to the Food Act by setting up a share program on their dairy farm (NSW Food Authority, 2019c).

Research has supported the findings that perceived health benefits and taste are major drivers of raw milk consumption (Bigouette et al., 2018; FSA, 2018; Lando, Bazaco, Parker, & Ferguson, 2022). In a review of the scientific literature, the FDA examined 14 claims associated with drinking raw milk that ranged from raw milk as a cure to lactose intolerance to the nutritional superiority and safety of raw milk relative to pasteurised milk (FDA, 2011). The FDA concluded that there is no merit in the positive health and safety claims made for raw milk consumption. However, because of these perceived health benefits, raw milk is often marketed to and consumed by individuals who may have lowered immunity such as the very young, very old or immunocompromised or to people with specific dietary needs. Indeed, a number of studies have reported that a disproportionate number of young people are affected by foodborne illness associated with the consumption of raw milk. Davys et al. (2020) undertook a study to investigate the demographics of raw milk usage in New Zealand, by analysing notified cases of campylobacteriosis linked to raw and non-raw milk consumption in the MidCentral District Health Board area (Davys, Marshall, Fayaz, Weir, & Benschop, 2020). Daveys et al. (2020) reported that raw milk campylobacteriosis cases differed from non-raw milk cases on comparison of age. A proportionately larger percentage of raw milk cases were less than 10 years old (28.6%), in comparison to the percentage of non-raw milk cases less than 10 years old (16.9%). Citing a New Zealand national nutrition survey that reported that the proportion of people drinking milk seven or more times a week decreased significantly with age, the authors concluded that it was difficult to determine whether age-related differences in raw milk-associated campylobacteriosis rates were due to variations in susceptibility between groups or to differences in consumption rates between people of different ages. Koski et al. (2022) also found that a disproportionate number of younger people in the USA were affected by foodborne illness due to the consumption of raw milk (Koski et al., 2022). Between 1998 and 2018, there was a total of 675 illnesses linked to the consumption of raw milk and nearly half of all illnesses occurred in people aged 19 years and younger. Where information was available, approximately 14% (93/675) were young children aged <5 years and 34% (232/675) were aged 5–19 years. These outbreaks resulted in a reported 98 (15%) hospitalisations, including ten HUS cases and two GBS or Miller Fisher syndrome cases. Two deaths were reported. Dietary decisions for younger children, in particular, are often made by caregivers. It is important that parents are informed of the dangers of raw milk consumption and the higher frequency of severe symptoms of gastrointestinal disease observed in younger children (FSANZ, 2014b; NSW Food Authority, 2018b).

There are a number of novel technologies, which seem to be milder and if properly optimised may serve as suitable alternatives to pasteurisation (Alegbeleye, Guimarães, Cruz, & Sant'Ana, 2018). It is ideally hoped that consumers will find these alternatives more acceptable than pasteurisation and abandon the consumption of RDM (Alegbeleye et al., 2018). Of the available 'novel' technologies, High Pressure Processing (HPP) has been commercialised the most by the food industry (Alegbeleye et al., 2018). In Australia, any claims for equivalence made under the Code must be validated to demonstrate that any novel approach provides an equivalent or greater outcome than the accepted standard of pasteurisation.

In 2016, the NSW Food Authority approved the first application in Australia for the use of HPP as an alternative to conventional thermal pasteurisation of dairy milk. HPP is a non-thermal technology that can achieve an equivalent level of inactivation of foodborne pathogens to heat pasteurisation, while meeting consumer demand for microbially safe and minimally processed dairy products.

Unpasteurised goats' milk is permitted for sale in NSW, subject to compliance with the dairy Food Safety Scheme and an advisory statement that the milk is unpasteurised must be included on the product. While there are geographic variations, internationally it has been reported that goats' milk is most frequently used for cheese making and usually at farm level or in small dairies (Quigley et al., 2013). In NSW, there are currently nine dairy production and processing facilities which are licensed to produce goats' milk products. Eight of these facilities produce products for human consumption, including yoghurt and cheese and supplying milk to other cheese manufacturers. The production volume of these facilities ranges from 50 – 700 litres per week. One facility produces a range of goats' milk products for pets. Two of the eight facilities producing products for human consumption, manufacture unpasteurised dairy products. At the time of writing, the total production volume was 140 litres per week for one producer and 210 litres per week for the other producer. The total production volume reported per week, does not include a breakdown of the total amount of unpasteurised milk or dairy products produced. However, the two facilities would collectively produce less than 20,000 litres per year, or 0.02 million litres per year. For comparison, milk production in NSW across the financial year from 2022 – 2023 was reported to be 1,072.4 million litres (Dairy Australia, 2023b). The low volume of production / consumption and lack of evidence of any foodborne illness attributed to this commodity, indicates that the community risk attributable to consumption of raw goats' milk is seemingly low. This is in keeping with the conclusions of the previous risk assessment.

In NSW, the Food Safety Schemes Manual mandates that unpasteurised goats' milk intended for human consumption must be tested for *Campylobacter*, *E. coli*, *L. monocytogenes* and *Salmonella* at a frequency of one in 20 batches (NSW Food Authority, 2019b). Cheese made from raw milk must be tested for CPS, *E. coli*, *L. monocytogenes* and *Salmonella* (NSW Food Authority, 2019b). While finished product testing may be considered as a control measure at the end of the production process, the risk cannot be eliminated and consumers of all raw milk products should be aware of the potential risks, especially those at increased risk of severe illness (FSANZ, 2014b). STEC is a pathogen of particular concern owing to its very low infectious dose and its potential to cause serious disease, with children being at a higher risk of developing HUS. The prevalence and level of STEC in foods may be very low and unevenly distributed, making the probability of detection low from a sampling plan that would be commercially practical (MPI, 2018). Coliform detection in raw and pasteurised cheeses was previously reported to have no correlation with pathogen detection (Trmčić et al., 2016) and the utility of coliforms as indicators of unsanitary conditions for dairy products has been questioned (for a review see (Martin, Trmčić, Hsieh, Boor, & Wiedmann, 2016)).

Any NSW business producing raw milk cheese must complete a production process pro forma, which is a written description of the steps used to make a particular product. Cheeses can be categorised as soft, semi-soft, soft ripened or hard, depending on their moisture content and how they are made. In many cases the potential for pathogen growth in cheese can be assessed based on the physicochemical nature of the cheese which include pH, water activity, salt-in-moisture and the concentration of lactic acid. These parameters affect the cheeses' sensory attributes, as well as their ability to support growth of *L. monocytogenes*. The pro forma can demonstrate to the NSW Food Authority that the production process used is effective in reducing the numbers of *L. monocytogenes* to a safe level. Semi-hard to hard and blue vein cheeses are most likely to meet these requirements.

Internationally, there have been a number of recent outbreaks involving soft raw milk cheeses. In France, consumption of soft cheeses made from raw cows' milk from a single producer led to an outbreak of 20 paediatric cases of STEC O26:H11 HUS in spring 2019 (Minary et al., 2022). The patient ages ranged from 1 to 60 months, with a median age of 16 months. The HUS outbreak had an unusually severe clinical presentation, with a total of 13 patients requiring dialysis. In addition, 10 patients and four patients had central nervous system and cardiac involvement, respectively. No deaths occurred. In Scotland in 2016, an outbreak of *E. coli* O157:H7 affected 26 people who consumed soft raw cow milk cheese (MPI, 2018). Seventeen of the 26 cases were hospitalised. Five of the cases were linked to a childcare setting and a three-year-old child died. The patients' young age in both of these outbreaks reinforces the importance of raising caregiver awareness regarding consumption of at-risk foods by young children. Aside from the impacts of consumer behaviour, farm practices were in focus after an outbreak involving soft raw cows' milk cheeses led to one of the largest *S*. Dublin outbreaks in France in recent years (Ung et al., 2019). Between 17 November 2015 and 11 March 2016, 83 cases were identified with a median age of 70 years (range: 1–94). Ten (12%) deaths were reported with no information available on the cause of death. The investigation revealed several cheese producers from the same region as sources of the outbreak. For these producers, an increase in salmonellosis incidence at the end of summer 2015 was observed in cattle and likely explained the increase of contaminated cheese batches in autumn and winter 2015. Cattle infected with *S*. Dublin might carry chronic and possibly asymptomatic infections while still contributing to onwards transmission by excreting pathogens in faeces. To prevent future outbreaks, a reinforced control plan was implemented for processing plants of raw-milk cheeses in the production region (Ung et al., 2019). The action plan included systematic product testing for *Salmonella*, more regular farm visits by veterinarians and the detection and containment of infected cattle. Similarly, in another outbreak in France in 2018, a single infected animal was found to be the source of a domestically manufactured and internationally distributed raw goats' milk cheese that led to an outbreak of *Salmonella* Newport. The outbreak resulted in 153 cases and 13 hospitalisations (of 38 cases whose clinical history was known), including six cases in Scotland (Robinson et al., 2020). The source animal was removed from the herd and the facility underwent rigorous cleaning. After resumption of production, enhanced microbiological monitoring was implemented.

The frequency and severity of international outbreaks related to consumption of raw milk products, underscores the importance of compliance with food safety regulations by manufacturers of these products. Pasteurisation has a long history as a successful public health measure. As 'new pathogens' emerge, the effectiveness of the pasteurisation process in terms of food safety outcomes will need to be assessed.

Conclusions

A wide range of hazards may be associated with raw milk and dairy products. Australia has a long history of producing safe dairy products, due to the establishment of comprehensive management practices along the entire dairy supply chain and the routine pasteurisation of milk.

In NSW, the dairy sector has demonstrated a high degree of compliance with FSP requirements and there have been no cases of foodborne illness attributed to dairy products. Taken together, this indicates that dairy products present a low risk to public health when processed under existing standards.

In countries in which the sale of raw milk and raw milk products is legal, consumption of these commodities is a major cause of foodborne disease. Consumers are urged not to consume raw milk products (NSW Food Authority, 2018b). This consumer advice is especially important for those at increased risk of severe disease; children younger than 5, pregnant women, adults 65 and older and people with weakened immune systems (NSW Food Authority, 2023d).

References

ABS. (2020a). Apparent Consumption of Selected Foodstuffs, Australia, 2018-19 financial year. Retrieved from https://www.abs.gov.au/statistics/health/health-conditions-and-risks/apparent-consumption-selected-foodstuffs-australia/2018-19

ABS. (2020b). Apparent Consumption of Selected Foodstuffs, Australia, 2019-20 financial year. Retrieved from https://www.abs.gov.au/statistics/health/health-conditions-and-risks/apparent-consumption-selected-foodstuffs-australia/2019-20#key-statistics

ABS. (2022). Apparent Consumption of Selected Foodstuffs, Australia. Retrieved from https://www.abs.gov.au/statistics/health/health-conditions-and-risks/apparent-consumption-selected-foodstuffs-australia

ACMSF. (2018). *Assessment of whether the microbiological risk associated with consumption of raw drinking milk (and certain raw milk products) made in the UK has changed since 2015*. Retrieved from https://acmsf.food.gov.uk/sites/default/files/acm_1269_revised_final.pdf

Ajene, A. N., Fischer Walker, C. L., & Black, R. E. (2013). Enteric pathogens and reactive arthritis: a systematic review of *Campylobacter*, *Salmonella* and *Shigella*-associated reactive arthritis. *Journal of Health, Population and Nutrition*, *31*(3), 299-307. doi:10.3329/jhpn.v31i3.16515

Al-Harbi, H., Ranjbar, S., Moore, R. J., & Alawneh, J. I. (2021). Bacteria Isolated From Milk of Dairy Cows With and Without Clinical Mastitis in Different Regions of Australia and Their AMR Profiles. *Frontiers in veterinary science*, *8*, 743725-743725. doi:10.3389/fvets.2021.743725

Alegbeleye, O. O., Guimarães, J. T., Cruz, A. G., & Sant'Ana, A. S. (2018). Hazards of a 'healthy' trend? An appraisal of the risks of raw milk consumption and the potential of novel treatment technologies to serve as alternatives to pasteurization. *Trends in Food Science & Technology*, *82*, 148-166. doi:10.1016/j.tifs.2018.10.007

Animal Health Australia. (2022a). *Response strategy: foot-and-mouth disease (version 5.0) Australian Veterinary Emergency Plan (AUSVETPLAN)*, *edition 5*. Canberra, ACT. Retrieved from https://animalhealthaustralia.com.au//wp-content/uploads/dlm_uploads/2015/11/AUSVETPLAN-Manuals_Response_Foot-and-mouth-disease___.pdf

Animal Health Australia. (2022b). *Response strategy: Lumpy skin disease (version 5.0). Australian Veterinary Emergency Plan (AUSVETPLAN)*, *edition 5*. Canberra, ACT. Retrieved from https://animalhealthaustralia.com.au//wp-content/uploads/2023/05/AHAA1904-AUSVETPLAN-Manuals_Response_Lumpy-skin-disease_FA3_digital.pdf

Animal Health Australia. (2023). Informing EAD Responses – AUSVETPLAN. Retrieved from https://animalhealthaustralia.com.au/ausvetplan/

ANZDAC. (2007). *Guidelines for Food Safety: Validation and Verification of Heat Treatment Equipment and Processes*. Retrieved from www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/aqis/exporting/dairy/publications/anzdac-validation-heat-treatment.pdf

ASTAG. (2018). Importance Ratings and Summary of Antibacterial Uses in Human and Animal Health in Australia. Retrieved from https://www.amr.gov.au/resources/importance-ratings-and-summary-antibacterial-uses-human-and-animal-health-australia

Australian Government. (2022a). Imported Food Inspection Scheme - monthly failing food reports. Retrieved from https://data.gov.au/data/dataset/imported-food-inspection-scheme-monthly-failing-food-reports

Australian Government. (2022b). National AMR Strategy. Retrieved from https://www.amr.gov.au/australias-response/national-amr-strategy

Benestad, S. L., & Telling, G. C. (2018). Chronic wasting disease: an evolving prion disease of cervids. *Handbook of Clinical Neurology*, *153*, 135-151. doi:10.1016/b978-0-444-63945-5.00008-8

Bigouette, J. P., Bethel, J. W., Bovbjerg, M. L., Waite-Cusic, J. G., Häse, C. C., & Poulsen, K. P. (2018). Knowledge, Attitudes and Practices Regarding Raw Milk Consumption in the Pacific Northwest. *Food protection trends*, *38*(2), 104-110.

Bochnia, M., Ziegler, J., Glatter, M., & Zeyner, A. (2021). Hypoglycin A in Cow's Milk — A Pilot Study. *Toxins*, *13*(6), 381.

CDC. (2015). Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products (Final Update). Retrieved from https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html

CDC. (2022). National Outbreak Reporting System Dashboard. Retrieved from https://wwwn.cdc.gov/norsdashboard/

CFIA. (2016). *Listeria monocytogenes* Food Safety Investigation Saputo Inc. Georgetown, ON, Establishment 1590. Retrieved from https://inspection.canada.ca/about-cfia/transparency/regulatory-transparency-and-openness/food-safety-investigations/saputo-inc-/eng/1481319454061/1481319686139

CFIA. (2018). *Bacterial Pathogens in Raw Milk Cheese - November 30, 2014 to March 31, 2018*. Retrieved from https://inspection.canada.ca/DAM/DAM-food-aliments/STAGING/text-texte/bacterial_pathogens_raw_milk_cheese_nov_2014_mar_2018_full_pdf_1582740211933_eng.pdf

CFIA. (2020). Food safety investigations. Retrieved from https://inspection.canada.ca/about-cfia/transparency/regulatory-transparency-and-openness/food-safety-investigations/eng/1332299626115/1332299812611

Communicable Diseases Branch. (2014). *NSW OzFoodNet Quarterly Report: Third Quarter Summary, 2014*. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-3rd-quarterly-report-2014.pdf

Communicable Diseases Branch. (2015). *NSW OzFoodNet Annual Surveillance Report: 2014*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ofn-annual-report-2014.pdf

Communicable Diseases Branch. (2016). *NSW OzFoodNet Annual Surveillance Report: 2015*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ofn-annual-report-2015.pdf

Communicable Diseases Branch. (2017). *NSW OzFoodNet Annual Surveillance Report: 2016*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ofn-annual-report-2016.pdf

Communicable Diseases Branch. (2018). *NSW OzFoodNet Annual Surveillance Report: 2017*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ofn-annual-report-2017.pdf

Communicable Diseases Branch. (2019a). *NSW OzFoodNet Annual Surveillance Report: 2018*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ofn-annual-report-2018.pdf

Communicable Diseases Branch. (2019b). *NSW OzFoodNet Annual Surveillance Report: 2019*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ozfoodnet-annual-report-2019.pdf

Communicable Diseases Branch. (2022). *NSW OzFoodNet Annual Surveillance Report: 2020*. Sydney: Health Protection NSW. Retrieved from https://www.health.nsw.gov.au/Infectious/foodborne/Publications/nsw-ozfoodnet-annual-report-2020.pdf

Conrad, A. R., Tubach, S., Cantu, V., Webb, L. M., Stroika, S., Moris, S., . . . Jackson, B. R. (2023). *Listeria monocytogenes* Illness and Deaths Associated With Ongoing Contamination of a Multiregional Brand of Ice Cream Products, United States, 2010–2015. *Clinical Infectious Diseases*, *76*(1), 89-95. doi:10.1093/cid/ciac550

Cook, R., Bingham, J., Besier, A., Bayley, C., Hawes, M., Shearer, P., . . . Middleton, D. (2016). Atypical scrapie in Australia. *Australian Veterinary Journal*, *94*(12), 452-455. doi:10.1111/avj.12529

Coombe, J. (2021). *Antimicrobial Stewardship in Australian Livestock Industries 2nd Edition*. Retrieved from https://animalhealthaustralia.com.au//wp-content/uploads/dlm_uploads/2018/11/Antimicrobial-stewardship-in-Livestock-Report-2021-.pdf

Costard, S., Espejo, L., Groenendaal, H., & Zagmutt, F. (2017). Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009–2014. *Emerging Infectious Disease journal*, *23*(6), 957. doi:10.3201/eid2306.151603

Crotta, M., Rizzi, R., Varisco, G., Daminelli, P., Cunico, E. C., Luini, M., . . . Guitian, J. (2016). Multiple-Strain Approach and Probabilistic Modeling of Consumer Habits in Quantitative Microbial Risk Assessment: A Quantitative Assessment of Exposure to Staphylococcal Enterotoxin A in Raw Milk. *Journal of Food Protection*, *79*(3), 432-441. doi:10.4315/0362-028x.Jfp-15-235

DAFF. (2012). *Australia's Freedom from Bovine Tuberculosis (TB)*. Retrieved from https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/animal-plant/animal-health/pet-food-safety/tb-28feb12.pdf

DAFF. (2022a). About FMD and the risk. Retrieved from https://www.agriculture.gov.au/biosecurity-trade/pests-diseases-weeds/animal/fmd/aboutfmd#how-it-affects-animals

DAFF. (2022b). Australian milk residue analysis survey. Retrieved from https://www.agriculture.gov.au/biosecurity-trade/export/controlled-goods/dairy/links/australian-milk-residue-survey

DAFF. (2022c). Failing food reports. Retrieved from https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/failing-food-reports

DAFF. (2022d). Import requirements by food type. Retrieved from https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/type#infant-formula

DAFF. (2022e). Imported Food Inspection Scheme. Retrieved from https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing/ifis

DAFF. (2022f). Raw milk cheese. Retrieved from https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/type/raw-milk-cheese

Dairy Australia. (2022). Dairy Consumption in Australia. Retrieved from https://www.dairyaustralia.com.au/industry-statistics/dairy-consumption-in-australia#.YzPXjXZByUm

Dairy Australia. (2023a). Australian Dairy Sustainability Framework. Retrieved from https://www.dairy.com.au/sustainability/australian-dairy-sustainability-framework

Dairy Australia. (2023b). *NSW Milk Production Report November 2022*. Retrieved from https://cdn-prod.dairyaustralia.com.au/-/media/project/dairy-australia-sites/national-home/pages/milk-production-reports/nsw-milk-production-report-november-2022.pdf?rev=91fb08afe7e442a58c6ba897242733b0

Dairy Australia. (2023c). Situation Analysis. Retrieved from https://www.dairyaustralia.com.au/strategic-plan-2020-25/situation-analysis#.ZGGh2nZByUk

Davys, G., Marshall, J. C., Fayaz, A., Weir, R. P., & Benschop, J. (2020). Campylobacteriosis associated with the consumption of unpasteurised milk: findings from a sentinel surveillance site. *Epidemiology & Infection*, *148*, e16. doi:10.1017/S0950268819002292

Dehhaghi, M., Kazemi Shariat Panahi, H., Holmes, E. C., Hudson, B. J., Schloeffel, R., & Guillemin, G. J. (2019). Human Tick-Borne Diseases in Australia. *Frontiers in Cellular and Infection Microbiology*, *9*. doi:10.3389/fcimb.2019.00003

DFSV. (2016). Dairy pathogen manual. Retrieved from www.dairysafe.vic.gov.au/publications-media/regulations-and-resources/guidelines/417-pathogen-manual/file?force_download=1

DoH. (2018). Review of published and grey literature on the presence of antimicrobial resistance in food in Australia and New Zealand. Retrieved from https://www.amr.gov.au/resources/review-published-and-grey-literature-presence-antimicrobial-resistance-food-australia-and

DPI. (2023a). Foot and mouth disease. Retrieved from https://www.dpi.nsw.gov.au/animals-and-livestock/beef-cattle/health-and-disease/viral-diseases/fmd

DPI. (2023b). Lumpy skin disease. Retrieved from https://www.dpi.nsw.gov.au/biosecurity/animal/info-vets/lumpy-skin-disease

EFSA. (2008). Human and animal exposure risk related to Transmissible Spongiform Encephalopathies (TSEs) from milk and milk products derived from small ruminants. Scientific opinion of the Panel on Biological Hazards. *EFSA Journal*, *6*(11), 849. doi:10.2903/j.efsa.2008.849

EFSA. (2022). The European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2021. *EFSA Journal*, *20*(11), e07655. doi:10.2903/j.efsa.2022.7655

EFSA and ECDC. (2015). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2014. *EFSA Journal*, *13*(12), 4329. doi:10.2903/j.efsa.2015.4329

EFSA and ECDC. (2016). Multi-country outbreak of Shiga toxin-producing *Escherichia coli* infection associated with haemolytic uraemic syndrome. *EFSA Supporting Publications*, *13*(4), 1017E. doi:10.2903/sp.efsa.2016.EN-1017

EFSA and ECDC. (2016). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2015. *EFSA Journal*, *14*(12), 231. doi:10.2903/j.efsa.2016.4634

EFSA and ECDC. (2017). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016. *EFSA Journal*, *15*(12), e05077. doi:10.2903/j.efsa.2017.5077

EFSA and ECDC. (2018a). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017. *EFSA Journal*, *16*(12), e05500. doi:10.2903/j.efsa.2018.5500

EFSA and ECDC. (2018b). Multi-country outbreak of *Salmonella* Agona infections linked to infant formula. *EFSA Supporting Publications*, *15*(1), 1365E. doi:10.2903/sp.efsa.2018.EN-1365

EFSA and ECDC. (2019). The European Union One Health 2018 Zoonoses Report. *EFSA Journal*, *17*(12), e05926. doi:10.2903/j.efsa.2019.5926

EFSA and ECDC. (2021a). The European Union One Health 2019 Zoonoses Report. *EFSA Journal*, *19*(2), e06406. doi:10.2903/j.efsa.2021.6406

EFSA and ECDC. (2021b). The European Union One Health 2020 Zoonoses Report. *EFSA Journal*, *19*(12), e06971. doi:10.2903/j.efsa.2021.6971

EFSA BIOHAZ Panel, Koutsoumanis, K., Allende, A., Alvarez-Ordóñez, A., Bover-Cid, S., Chemaly, M., . . . Bolton, D. (2020). Pathogenicity assessment of Shiga toxin-producing *Escherichia coli* (STEC) and the public health risk posed by contamination of food with STEC. *EFSA Journal*, *18*(1), e05967. doi:10.2903/j.efsa.2020.5967

EFSA Panel on Biological Hazards. (2015). Scientific Opinion on the public health risks related to the consumption of raw drinking milk. *EFSA Journal*, *13*(1), 95. doi:10.2903/j.efsa.2015.3940

EFSA Panel on Contaminants in the Food Chain. (2014). Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables. *EFSA Journal*, *12*(10), 3869. doi:10.2903/j.efsa.2014.3869

EFSA Panel on Contaminants in the Food Chain. (2015). Risks for public health related to the presence of chlorate in food. *EFSA Journal*, *13*(6), 4135. doi:10.2903/j.efsa.2015.4135

EFSA Panel on Biological Hazards, Koutsoumanis, K., Allende, A., Alvarez-Ordoňez, A., Bolton, D., Bover-Cid, S., . . . Simmons, M. M. (2019). Update on chronic wasting disease (CWD) III. *EFSA Journal*, *17*(11), e05863. doi:10.2903/j.efsa.2019.5863

Eglezos, S., Huang, B., Dykes, G. A., Fegan, N., Bell, K., & Stuttard, E. (2008). A survey of the microbiological quality of frozen unpasteurised goats' milk in Queensland, Australia. *The Australian Journal of Dairy Technology*, *63*(3), 79-81.

European Commission. (2020a). Commission Regulation (EU) 2020/685 of 20 May 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of perchlorate in certain foods (Text with EEA relevance). *Official Journal of the European Union*, *L 160/3*.

European Commission. (2020b). Commission Regulation (EU) No 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products (Text with EEA relevance). *Official Journal of the European Union*, *L178/7*.

FAO/WHO. (2004). *Enterobacter sakazakii* and other microorganisms in powdered infant formula: meeting report. *Microbiological Risk Assessment series 6*. Retrieved from https://www.who.int/publications/i/item/9789241562775

FAO/WHO. (2006). *Enterobacter sakazakii* and *Salmonella* in powdered infant formula: meeting report. *Microbiological Risk Assessment series 10*. Retrieved from https://www.who.int/publications/i/item/9241563311

FDA. (2011). Raw Milk Misconceptions and the Danger of Raw Milk Consumption. Retrieved from https://www.fda.gov/food/buy-store-serve-safe-food/raw-milk-misconceptions-and-danger-raw-milk-consumption

FDA. (2015a). Blue Bell Creameries, LP, Brenham, TX 77833-441 3 Issued 05/01/2015. Retrieved from https://www.fda.gov/media/92059/download

FDA. (2015b). Blue Bell Creameries, LP, Broken Arrow, OK 74014-2900 Issued 04/23/2015. Retrieved from https://www.fda.gov/media/91871/download

FDA. (2015c). Blue Bell Creameries, LP, Sylacauga, AL, 35150-2009 Issued 04/30/2015. Retrieved from https://www.fda.gov/media/91865/download

FDA. (2016). *FY 2014 – 2016 Microbiological Sampling Assignment, Summary Report: Raw Milk Cheese Aged 60 Days*. Retrieved from https://www.fda.gov/media/99340/download

FDA. (2022a). Inspection and Environmental Sampling of Ice Cream Production Facilities for *Listeria monocytogenes* and *Salmonella* FY 2016-17. Retrieved from https://www.fda.gov/food/sampling-protect-food-supply/inspection-and-environmental-sampling-ice-cream-production-facilities-listeria-monocytogenes-and

FDA. (2022b). Outbreak Investigation of *Listeria monocytogenes*: Ice Cream (July 2022). Retrieved from https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-listeria-monocytogenes-ice-cream-july-2022

Franscini, N., Gedaily, A. E., Matthey, U., Franitza, S., Sy, M.-S., Bürkle, A., . . . Zahn, R. (2006). Prion Protein in Milk. *PLOS ONE*, *1*(1), e71. doi:10.1371/journal.pone.0000071

FSA. (2018). *Raw Drinking Milk Consumer Research*. Retrieved from https://www.food.gov.uk/sites/default/files/media/document/Raw%20Drinking%20Milk%20Consumer%20Insight%20Report%202018.pdf

FSAI. (2015). *Raw Milk and Raw Milk Filter Microbiological Surveillance Programme (12NS2)*. Retrieved from https://www.fsai.ie/publications_survey_raw_milk/

FSANZ. (2009a). *Microbiological Risk Assessment of Raw Cow Milk*. Retrieved from https://www.foodstandards.gov.au/code/proposals/documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD1%20Cow%20milk%20Risk%20Assessment.pdf

FSANZ. (2009b). *Microbiological Risk Assessment of Raw Goat Milk*. Retrieved from www.foodstandards.gov.au/code/proposals/documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD2%20Goat%20milk%20Risk%20Assessment.pdf

FSANZ. (2014a). *24th Australian Total Diet Study*. Retrieved from www.foodstandards.gov.au/publications/Documents/1778-FSANZ_AustDietStudy-web.pdf

FSANZ. (2014b). Raw drinking milk. Retrieved from https://www.foodstandards.gov.au/consumer/safety/Pages/Raw-drinking-milk.aspx

FSANZ. (2015a). *Call for submissions – Proposal P1039, Microbiological Criteria for Infant Formula*. Retrieved from https://www.foodstandards.gov.au/code/proposals/Documents/P1039%20Micro%20criteria%20for%20infant%20formula%20CFS.pdf

FSANZ. (2015b). Infant formula products. Retrieved from https://www.foodstandards.gov.au/consumer/generalissues/Pages/Infant-formula-products.aspx#:~:text=The%20Australian%20National%20Health%20and%20Medical%20Research%20Council%E2%80%99s,to%20breast%20milk%20until%2012%20months%20of%20age

FSANZ. (2018). Food recalls. Retrieved from https://www.foodstandards.gov.au/industry/foodrecalls/Pages/default.aspx

FSANZ. (2019). *25th Australian Total Diet Study: Appendices*. Retrieved from https://www.foodstandards.gov.au/publications/Documents/25th%20Australian%20Total%20Diet%20Study%20appendices.pdf

FSANZ. (2021a). Animal diseases, human health and food safety. Retrieved from https://www.foodstandards.gov.au/consumer/safety/Pages/Animal-diseases,-human-health-and-food-safety.aspx

FSANZ. (2021b). Current food recalls. Retrieved from https://www.foodstandards.gov.au/industry/foodrecalls/recalls/Pages/default.aspx

FSANZ. (2021c). Food Standards Code. Retrieved from https://www.foodstandards.gov.au/code/Pages/default.aspx

FSANZ. (2021d). Report on Emerging and Ongoing Issues - Annual Report-2020. Retrieved from https://www.foodstandards.gov.au/publications/Pages/Report-on-Emerging-and-Ongoing-Issues%20-%20Annual-Report-2020.aspx

FSANZ. (2022). Attachment 1 – Microbiological safety of powdered infant formula: Effect of water temperature on risk. *Supporting document 1, Safety and food technology, Proposal P1028 – Infant formula*. Retrieved from www.foodstandards.gov.au/code/proposals/Documents/Attachment%20to%20SD1%20-%20Microbiological%20safety%20of%20PIF.pdf

FSANZ. (2023a). Current food recalls. Retrieved from https://www.foodstandards.gov.au/industry/foodrecalls/recalls/Pages/default.aspx

FSANZ. (2023b). P1028 – Infant Formula. Retrieved from https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

Giacometti, F., Bonilauri, P., Albonetti, S., Amatiste, S., Arrigoni, N., Bianchi, M., . . . Serraino, A. (2015). Quantitative risk assessment of human salmonellosis and listeriosis related to the consumption of raw milk in Italy. *Journal of Food Protection*, *78*(1), 13-21. doi:10.4315/0362-028x.Jfp-14-171

Giacometti, F., Bonilauri, P., Amatiste, S., Arrigoni, N., Bianchi, M., Losio, M. N., . . . Serraino, A. (2015). Human campylobacteriosis related to the consumption of raw milk sold by vending machines in Italy: Quantitative risk assessment based on official controls over four years. *Preventive Veterinary Medicine*, *121*(1-2), 151-158. doi:10.1016/j.prevetmed.2015.06.009

Giacometti, F., Bonilauri, P., Piva, S., Scavia, G., Amatiste, S., Bianchi, D. M., . . . Serraino, A. (2017). Paediatric HUS Cases Related to the Consumption of Raw Milk Sold by Vending Machines in Italy: Quantitative Risk Assessment Based on *Escherichia coli* O157 Official Controls over 7 years. *Zoonoses Public Health*, *64*(7), 505-516. doi:10.1111/zph.12331

Gleeson, D. (2018). Moorepark Dairy Levy Research Update, Non-chlorine cleaning protocols for milking equipment and bulk milk tanks, Series 37.

Gleeson, D., Paludetti, L., O'Brien, B., & Beresford, T. (2022). Effect of 'chlorine-free' cleaning of milking equipment on the microbiological quality and chlorine-related residues in bulk tank milk. *International Journal of Dairy Technology*, *75*(2), 262-269. doi:10.1111/1471-0307.12853

Gopfert, A., Chalmers, R. M., Whittingham, S., Wilson, L., van Hove, M., Ferraro, C. F., . . . Nozad, B. (2022). An outbreak of *Cryptosporidium parvum* linked to pasteurised milk from a vending machine in England: a descriptive study, March 2021. *Epidemiology and Infection*, *150*, e185. doi:10.1017/S0950268822001613

Gruber, J. F., Morris, S., Warren, K. A., Kline, K. E., Schroeder, B., Dettinger, L., . . . Longenberger, A. H. (2021). *Yersinia enterocolitica* Outbreak Associated with Pasteurized Milk. *Foodborne Pathogens and Disease*, *18*(7), 448-454. doi:10.1089/fpd.2020.2924

Hanson, H., Whitfield, Y., Lee, C., Badiani, T., Minielly, C., Fenik, J., . . . Warshawsky, B. (2019). *Listeria monocytogenes* Associated with Pasteurized Chocolate Milk, Ontario, Canada. *Emerging Infectious Disease journal*, *25*(3), 581. doi:10.3201/eid2503.180742

Horigan, V., Gale, P., Adkin, A., Konold, T., Cassar, C., Spiropoulos, J., & Kelly, L. (2020). Assessing the aggregated probability of entry of a novel prion disease agent into the United Kingdom. *Microbial Risk Analysis*, *16*, 100134. doi:10.1016/j.mran.2020.100134

Jenkins, C., Bird, P. K., Wensley, A., Wilkinson, J., Aird, H., Mackintosh, A., . . . Hughes, G. J. (2022). Outbreak of STEC O157:H7 linked to a milk pasteurisation failure at a dairy farm in England, 2019. *Epidemiology and Infection*, *150*, e114. doi:10.1017/s0950268822000929

Jourdan-da Silva, N., Fabre, L., Robinson, E., Fournet, N., Nisavanh, A., Bruyand, M., . . . Le Hello, S. (2018). Ongoing nationwide outbreak of *Salmonella* Agona associated with internationally distributed infant milk products, France, December 2017. *Eurosurveillance*, *23*(2), 17-00852. doi:10.2807/1560-7917.ES.2018.23.2.17-00852

King, N., Thomas, K., & Watson, S. (2021). *Emerging Risk Identification System (ERIS), Annual Report, Year One (March 2021–February 2022)*. Prepared for the New Zealand Food Safety Science & Research Centre by the Institute of Environmental Science and Research (ESR) Ltd. ESR report number CSC22003.

Konold, T., Moore, S. J., Bellworthy, S. J., Terry, L. A., Thorne, L., Ramsay, A., . . . Simmons, H. A. (2013). Evidence of effective scrapie transmission via colostrum and milk in sheep. *BMC Veterinary Research*, *9*(1), 99. doi:10.1186/1746-6148-9-99

Konold, T., Thorne, L., Simmons, H. A., Hawkins, S. A. C., Simmons, M. M., & González, L. (2016). Evidence of scrapie transmission to sheep via goat milk. *BMC Veterinary Research*, *12*(1), 208. doi:10.1186/s12917-016-0807-4

Koski, L., Kisselburgh, H., Landsman, L., Hulkower, R., Howard-Williams, M., Salah, Z., . . . Nichols, M. (2022). Foodborne illness outbreaks linked to unpasteurised milk and relationship to changes in state laws – United States, 1998–2018. *Epidemiology and Infection*, *150*, e183. doi:10.1017/S0950268822001649

Kurt, T. D., & Sigurdson, C. J. (2016). Cross-species transmission of CWD prions. *Prion*, *10*(1), 83-91. doi:10.1080/19336896.2015.1118603

Lando, A. M., Bazaco, M. C., Parker, C. C., & Ferguson, M. (2022). Characteristics of U.S. Consumers Reporting Past Year Intake of Raw (Unpasteurized) Milk: Results from the 2016 Food Safety Survey and 2019 Food Safety and Nutrition Survey. *Journal of Food Protection*, *85*(7), 1036-1043. doi:10.4315/jfp-21-407

Latorre, A. A., Pradhan, A. K., Van Kessel, J. A., Karns, J. S., Boor, K. J., Rice, D. H., . . . Schukken, Y. H. (2011). Quantitative risk assessment of listeriosis due to consumption of raw milk. *Journal of Food Protection*, *74*(8), 1268-1281. doi:10.4315/0362-028x.Jfp-10-554

Liu, Q., Mao, W., Jiang, D., Yang, X., & Yang, D. (2021). The contamination and estimation of dietary intake for perchlorate and chlorate in infant formulas in China. *Food Additives & Contaminants: Part A*, *38*(12), 2045-2054. doi:10.1080/19440049.2021.1973112

Madsen-Bouterse, S. A., Highland, M. A., Dassanayake, R. P., Zhuang, D., & Schneider, D. A. (2018). Low-volume goat milk transmission of classical scrapie to lambs and goat kids. *PLOS ONE*, *13*(9), e0204281. doi:10.1371/journal.pone.0204281

Majowicz, S. E., Panagiotoglou, D., Taylor, M., Gohari, M. R., Kaplan, G. G., Chaurasia, A., . . . Galanis, E. (2020). Determining the long-term health burden and risk of sequelae for 14 foodborne infections in British Columbia, Canada: protocol for a retrospective population-based cohort study. *BMJ Open*, *10*(8), e036560. doi:10.1136/bmjopen-2019-036560

Marshall, J. C., Soboleva, T. K., Jamieson, P., & French, N. P. (2016). Estimating Bacterial Pathogen Levels in New Zealand Bulk Tank Milk. *Journal of Food Protection*, *79*(5), 771-780. doi:10.4315/0362-028x.Jfp-15-230

Martin, N. H., Trmčić, A., Hsieh, T.-H., Boor, K. J., & Wiedmann, M. (2016). The Evolving Role of Coliforms As Indicators of Unhygienic Processing Conditions in Dairy Foods. *Frontiers in Microbiology*, *7*. doi:10.3389/fmicb.2016.01549

McCarthy, W. P., Blais, H. N., O'Callaghan, T. F., Hossain, M., Moloney, M., Danaher, M., . . . Tobin, J. T. (2022). Application of nanofiltration for the removal of chlorate from skim milk. *International Dairy Journal*, *128*, 105321. doi:10.1016/j.idairyj.2022.105321

McCarthy, W. P., O'Callaghan, T. F., Danahar, M., Gleeson, D., O'Connor, C., Fenelon, M. A., & Tobin, J. T. (2018). Chlorate and Other Oxychlorine Contaminants Within the Dairy Supply Chain. *Comprehensive Reviews in Food Science and Food Safety*, *17*(6), 1561-1575. doi:10.1111/1541-4337.12393

McLauchlin, J., Aird, H., Elliott, A., Forester, E., Jørgensen, F., & Willis, C. (2020). Microbiological quality of raw drinking milk and unpasteurised dairy products: results from England 2013–2019. *Epidemiology and Infection*, *148*, e135. doi:10.1017/S0950268820001016

Minary, K., Tanne, C., Kwon, T., Faudeux, C., Clave, S., Langevin, L., . . . Fila, M. (2022). Outbreak of hemolytic uremic syndrome with unusually severe clinical presentation caused by Shiga toxin-producing *Escherichia coli* O26:H11 in France. *Archives de Pédiatrie*, *29*(6), 448-452. doi:10.1016/j.arcped.2022.05.011

Montgomery, H., Haughey, S. A., & Elliott, C. T. (2020). Recent food safety and fraud issues within the dairy supply chain (2015-2019). *Global Food Security*, *26*, 100447. doi:10.1016/j.gfs.2020.100447

More, S. J., Radunz, B., & Glanville, R. J. (2015). Lessons learned during the successful eradication of bovine tuberculosis from Australia. *Veterinary Record*, *177*(9), 224-232. doi:10.1136/vr.103163

MPI. (2015). *ANNUAL REPORT FOODBORNE DISEASE IN NEW ZEALAND 2014*. (MPI Technical Paper No: 2015/35). Retrieved from https://www.mpi.govt.nz/dmsdocument/10370-Annual-report-concerning-foodborne-disease-in-New-Zealand-2014

MPI. (2016). *Foodborne Disease in New Zealand 2015*. Retrieved from https://www.mpi.govt.nz/dmsdocument/13696-Annual-report-concerning-foodborne-disease-in-New-Zealand-2015

MPI. (2017). *Foodborne Disease in New Zealand 2016*. Retrieved from https://www.mpi.govt.nz/dmsdocument/19700-Annual-report-concerning-foodborne-disease-in-New-Zealand-2016

MPI. (2018). Review of Risk Management Actions by Food Standards Scotland Relating to the *Escherichia coli* O157 PT 21/28 Raw Cow's Milk Cheese Recall in 2016. *MPI Report No: 2018/06*. Retrieved from https://www.foodstandards.gov.scot/downloads/MPI_FSS_STEC_in_Raw_Cheese_Review_10082018.pdf

MPI. (2019a). *ANNUAL REPORT CONCERNING FOODBORNE DISEASE IN NEW ZEALAND 2017*. Retrieved from https://www.mpi.govt.nz/dmsdocument/35670-Annual-report-concerning-foodborne-disease-in-New-Zealand-2017

MPI. (2019b). *ANNUAL REPORT CONCERNING FOODBORNE DISEASE IN NEW ZEALAND 2018*. Retrieved from https://www.mpi.govt.nz/dmsdocument/36771-Annual-report-concerning-foodborne-disease-in-New-Zealand-2018

MPI. (2019c). *Update to the assessment of the microbiological risks associated with the consumption of raw milk*. Retrieved from https://www.mpi.govt.nz/dmsdocument/37970-Update-to-the-assessment-of-the-microbiological-risks-associated-with-the-consumption-of-raw-milk-Technical-Paper

MPI. (2020). *Annual report concerning Foodborne Diseases in New Zealand 2019*. Retrieved from https://www.mpi.govt.nz/dmsdocument/42874-Annual-report-concerning-foodborne-disease-in-New-Zealand-2019

MPI. (2021a). *Annual report concerning Foodborne Diseases in New Zealand 2020*. Retrieved from https://www.mpi.govt.nz/dmsdocument/47986-Annual-report-concerning-Foodborne-Diseases-in-New-Zealand-2020

MPI. (2021b). Foodborne disease annual reports. Retrieved from https://www.mpi.govt.nz/science/food-safety-and-suitability-research/human-health-surveillance-and-attribution-programme/foodborne-disease-annual-reports/

MPI. (2022a). Animal Products Notice: Production, Supply and Processing. Retrieved from www.mpi.govt.nz/dmsdocument/50182-Animal-Products-Notice-Production-Supply-and-Processing

MPI. (2022b). National Programme for the Monitoring of Chemical Residues and Contaminants in Milk Plan for 1 July 2022 to 30 June 2023. *New Zealand Food Safety Technical Paper No: 2022/25*. Retrieved from https://www.mpi.govt.nz/dmsdocument/53827-National-Programme-for-the-Monitoring-of-Chemical-Residues-and-Contaminants-in-Milk-Plan-for-1-July-2022-to-30-June-2023

Napper, S., & Schatzl, H. M. (2023). Vaccines for prion diseases: a realistic goal? *Cell and Tissue Research*, *392*(1), 367-392. doi:10.1007/s00441-023-03749-7

Nemani, S. K., Myskiw, J. L., Lamoureux, L., Booth, S. A., & Sim, V. L. (2020). Exposure Risk of Chronic Wasting Disease in Humans. *Viruses*, *12*(12), 1454.

NHMRC, & NRMMC. (2011). *Australian Drinking Water Guidelines Paper 6 National Water Quality Management Strategy*. Commonwealth of Australia, Canberra.

NSW Food Authority. (2016). *ANNUAL FOOD TESTING REPORT 2014 - 2015*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/_Documents/scienceandtechnical/annual_food_testing_report_2014_2015.pdf

NSW Food Authority. (2017). Raw milk conviction sweet success for food safety. Retrieved from https://www.foodauthority.nsw.gov.au/news/departmental-media-releases/raw-milk-conviction

NSW Food Authority. (2018a). *CHANGES TO THE RETAIL SALE OF ALL RAW MILK PRODUCTS IN NSW FOR RETAILERS*. Retrieved from www.foodauthority.nsw.gov.au/sites/default/files/_Documents/retail/changes_to_retail_sales_raw_milk_products_in_nsw.pdf

NSW Food Authority. (2018b). *RAW MILK ADVICE TO CONSUMERS*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/_Documents/foodsafetyandyou/raw-milk-advice.pdf

NSW Food Authority. (2019a). *ANNUAL FOOD TESTING REPORT 2017-2018*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/_Documents/scienceandtechnical/annual_food_testing_report_2017_2018.pdf

NSW Food Authority. (2019b). *Food Safety Schemes Manual*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2020-01/food_safety_schemes_manual.pdf

NSW Food Authority. (2019c). *Summary of meeting outcomes, NSW Dairy Industry Consultative Committee, 10 September 2019*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2020-04/summary_of_outcomes_-_nsw_dairy_industry_consultative_committee_10_september_2019.pdf

NSW Food Authority. (2020a). *ANNUAL FOOD TESTING REPORT 2015 - 2016*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2020-08/annual_food_testing_report_2015_2016_0.pdf

NSW Food Authority. (2020b). *ANNUAL FOOD TESTING REPORT 2016 - 2017*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2020-08/annual_food_testing_report_2016_2017_0.pdf

NSW Food Authority. (2020c). *ANNUAL FOOD TESTING REPORT 2018-2019*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2020-08/annual_food_testing_report_2018_2019_1.pdf

NSW Food Authority. (2020d). *ANNUAL FOOD TESTING REPORT 2019-2020*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2020-12/Annual%20Food%20testing%20report%202019%20-%20EM151220_4.20pm.pdf

NSW Food Authority. (2020e). Legislation. Retrieved from https://www.foodauthority.nsw.gov.au/about-us/legislation

NSW Food Authority. (2021a). *ANNUAL FOOD TESTING REPORT 2020-2021*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2021-11/FI3782111AnnualFoodTestingReport2020-2021.pdf

NSW Food Authority. (2021b). *ANNUAL REPORT 2020–21*. Retrieved from https://www.foodauthority.nsw.gov.au/sites/default/files/2021-11/2020-21-Annual-Report-of-the-NSW-Food-Authority.pdf

NSW Food Authority. (2023a). Dairy. Retrieved from https://www.foodauthority.nsw.gov.au/industry/dairy

NSW Food Authority. (2023b). Dairy processing. Retrieved from https://www.foodauthority.nsw.gov.au/industry/dairy/dairy-processing

NSW Food Authority. (2023c). Infants. Retrieved from https://www.foodauthority.nsw.gov.au/consumer/life-events-and-food/infants

NSW Food Authority. (2023d). Low immunity. Retrieved from https://www.foodauthority.nsw.gov.au/consumer/life-events-and-food/low-immunity

NSW Health. (2019). *Brucellosis fact sheet*. Retrieved from https://www.health.nsw.gov.au/infectious/factsheets/pages/brucellosis.aspx#:~:text=Brucellosis%20is%20an%20infection%20that%20can%20be%20transmitted,from%20consuming%20unpasteurized%20dairy%20products%20while%20overseas.%20%E2%80%8B%E2%80%8B

Ntuli, V., Njage, P. M. K., Bonilauri, P., Serraino, A., & Buys, E. M. (2018). Quantitative Risk Assessment of Hemolytic Uremic Syndrome Associated with Consumption of Bulk Milk Sold Directly from Producer to Consumer in South Africa. *Journal of Food Protection*, 472-481. doi:10.4315/0362-028x.Jfp-17-199

Ntuli, V., Njage, P. M. K., & Buys, E. M. (2016). Characterization of *Escherichia coli* and other Enterobacteriaceae in producer-distributor bulk milk. *Journal of Dairy Science*, *99*(12), 9534-9549. doi:10.3168/jds.2016-11403

Nüesch-Inderbinen, M., Bloemberg, G. V., Müller, A., Stevens, M. J. A., Cernela, N., Kollöffel, B., & Stephan, R. (2021). Listeriosis Caused by Persistence of *Listeria monocytogenes* Serotype 4b Sequence Type 6 in Cheese Production Environment. *Emerging Infectious Diseases*, *27*(1), 284-288. doi:10.3201/eid2701.203266

NZFSSRC. (2023). ERIS. Retrieved from https://www.nzfssrc.org.nz/resources/eris/#/

Opiyo, B. A., Wangoh, J., & Njage, P. M. K. (2013). Microbiological Performance of Dairy Processing Plants Is Influenced by Scale of Production and the Implemented Food Safety Management System: A Case Study. *Journal of Food Protection*, *76*(6), 975-975. doi:10.4315/0362-028x.Jfp-12-450

Ornua. (2022). Our Co-Operative. Retrieved from https://www.ornua.com/our-co-operative/

Porter, C. K., Choi, D., Cash, B., Pimentel, M., Murray, J., May, L., & Riddle, M. S. (2013). Pathogen-specific risk of chronic gastrointestinal disorders following bacterial causes of foodborne illness. *BMC Gastroenterology*, *13*(1), 46. doi:10.1186/1471-230X-13-46

QLD Health. (2022). Brucellosis. Retrieved from https://www.health.qld.gov.au/cdcg/index/brucell

Quigley, L., O'Sullivan, O., Stanton, C., Beresford, T. P., Ross, R. P., Fitzgerald, G. F., & Cotter, P. D. (2013). The complex microbiota of raw milk. *FEMS Microbiology Reviews*, *37*(5), 664-698. doi:10.1111/1574-6976.12030

Rietberg, K., Lloyd, J., Melius, B., Wyman, P., Treadwell, R., Olson, G., . . . Duchin, J. S. (2016). Outbreak of *Listeria monocytogenes* infections linked to a pasteurized ice cream product served to hospitalized patients. *Epidemiology and Infection*, *144*(13), 2728-2731. doi:10.1017/s0950268815003039

Robinson, E., Travanut, M., Fabre, L., Larréché, S., Ramelli, L., Pascal, L., . . . Jourdan-Da Silva, N. (2020). Outbreak of *Salmonella* Newport associated with internationally distributed raw goats' milk cheese, France, 2018. *Epidemiology and Infection*, *148*, e180. doi:10.1017/S0950268820000904

Sakudo, A. (2020). Inactivation Methods for Prions. *Current Issues in Molecular Biology*, *36*, 23-32. doi:10.21775/cimb.036.023

Sebastianski, M., Bridger, N. A., Featherstone, R. M., & Robinson, J. L. (2022). Disease outbreaks linked to pasteurized and unpasteurized dairy products in Canada and the United States: a systematic review. *Canadian Journal of Public Health*, *113*(4), 569-578. doi:10.17269/s41997-022-00614-y

Stobnicka-Kupiec, A., Gołofit-Szymczak, M., & Górny, R. (2019). Microbial contamination level and microbial diversity of occupational environment in commercial and traditional dairy plants. *Annals of Agricultural and Environmental Medicine*, *26*(4), 555-565. doi:10.26444/aaem/112381

Swire, E., & Colchester, A. (2023). Out of sight, out of mind? BSE 30 years on: continuing environmental risks to human health. *Land Use Policy*, *126*, 106521. doi:10.1016/j.landusepol.2022.106521

Teagasc. (2018). Chlorine-free cleaning. Retrieved from https://www.teagasc.ie/about/research--innovation/research-impact-highlights/2018-research-impact-highlights-/chlorine-free-cleaning/

Teagasc. (2020). *Chlorine-free cleaning - What is required*. Retrieved from www.teagasc.ie/media/website/animals/dairy/research-farms/Chlorine-free-wash-routines_2020.pdf

Teagasc. (2023). About. Retrieved from https://www.teagasc.ie/about/

Tiwari, U., Cummins, E., Valero, A., Walsh, D., Dalmasso, M., Jordan, K., & Duffy, G. (2015). Farm to Fork Quantitative Risk Assessment of *Listeria monocytogenes* Contamination in Raw and Pasteurized Milk Cheese in Ireland. *Risk Analysis*, *35*(6), 1140-1153. doi:10.1111/risa.12332

Tranulis, M. A., & Tryland, M. (2023). The Zoonotic Potential of Chronic Wasting Disease - A Review. *Foods*, *12*(4), 824.

Treacy, J., Jenkins, C., Paranthaman, K., Jorgensen, F., Mueller-Doblies, D., Anjum, M., . . . Kar-Purkayastha, I. (2019). Outbreak of Shiga toxin-producing *Escherichia coli* O157:H7 linked to raw drinking milk resolved by rapid application of advanced pathogen characterisation methods, England, August to October 2017. *Eurosurveillance*, *24*(16). doi:10.2807/1560-7917.ES.2019.24.16.1800191

Trmčić, A., Chauhan, K., Kent, D. J., Ralyea, R. D., Martin, N. H., Boor, K. J., & Wiedmann, M. (2016). Coliform detection in cheese is associated with specific cheese characteristics, but no association was found with pathogen detection. *Journal of Dairy Science*, *99*(8), 6105-6120. doi:10.3168/jds.2016-11112

Ung, A., Baidjoe, A. Y., Van Cauteren, D., Fawal, N., Fabre, L., Guerrisi, C., . . . Le Hello, S. (2019). Disentangling a complex nationwide *Salmonella* Dublin outbreak associated with raw-milk cheese consumption, France, 2015 to 2016. *Eurosurveillance*, 24(3). doi:10.2807/1560-7917.Es.2019.24.3.1700703

van Asselt, E. D., van der Fels-Klerx, H. J., Marvin, H. J. P., van Bokhorst-van de Veen, H., & Groot, M. N. (2017). Overview of Food Safety Hazards in the European Dairy Supply Chain. *Comprehensive Reviews in Food Science and Food Safety*, *16*(1), 59-75. doi:10.1111/1541-4337.12245

Verraes, C., Claeys, W., Cardoen, S., Daube, G., De Zutter, L., Imberechts, H., . . . Herman, L. (2014). A review of the microbiological hazards of raw milk from animal species other than cows. *International Dairy Journal*, *39*(1), 121-130. doi:10.1016/j.idairyj.2014.05.010

Wagner, B., Gerletti, P., Fürst, P., Keuth, O., Bernsmann, T., Martin, A., . . . Pieper, R. (2022). Transfer of cannabinoids into the milk of dairy cows fed with industrial hemp could lead to Δ9-THC exposure that exceeds acute reference dose. *Nature Food*, *3*(11), 921-932. doi:10.1038/s43016-022-00623-7

WHO. (2016). Chlorine Dioxide, Chlorite and Chlorate in Drinking-water, Background document for development of WHO. *Guidelines for Drinking-water Quality WHO/FWC/WSH/16.49*. Retrieved from www.who.int/docs/default-source/wash-documents/wash-chemicals/chlorine-dioxide-chlorite-chlorate-background-document.pdf

WHO. (2017). Guidelines for drinking-water quality, 4th edition, incorporating the 1st addendum. Retrieved from https://www.who.int/publications/i/item/9789241549950

Willis, C., Jørgensen, F., Aird, H., Elviss, N., Fox, A., Jenkins, C., . . . McLauchlin, J. (2018). An assessment of the microbiological quality and safety of raw drinking milk on retail sale in England. *Journal of Applied Microbiology*, *124*(2), 535-546. doi:10.1111/jam.13660

More information

Visit the Food Authority's website at www.foodauthority.nsw.gov.au

Email the Helpline at food.contact@dpi.nsw.gov.au

Phone the Helpline on 1300 552 406.