

### 31 March 2025 335-25

## Call for submissions - Proposal P1060

## Egg food safety and primary production requirements

Food Standards Australia New Zealand (FSANZ) has assessed a proposal to review egg food safety and primary production requirements in the Australia New Zealand Food Standards Code and has prepared a draft variation of food regulatory measures. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this proposal need to be made through the <u>Consultation Hub</u> (<u>https://consultations.foodstandards.gov.au/</u>).

All submissions on proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at <a href="Making a submission">Making a submission</a>.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the Consultation Hub.

#### DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 12 May 2025

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. For information about making a submission, visit the FSANZ website at <a href="mailto:current calls for public comment">current calls for public comment</a> and how to make a submission. Questions about making a submission or application and proposal processes can be sent to <a href="mailto:standards.management@foodstandards.gov.au">standards.management@foodstandards.gov.au</a>.

Submissions in hard copy may be sent to the following addresses:

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## **Supporting documents**

The following documents which informed the assessment of this Proposal are available on the FSANZ website:

SD1	Microbiological risk assessment of Salmonella in eggs
SD2	Quantitative risk model: development of a base model for Salmonella Enteritidis
	in eggs
SD3	Current food safety measures for eggs and egg product
SD4	Consideration of costs and benefits
SD5	Overview of the egg industry in Australia
SD6	Consumer literature review
SD7	Guidance plan for compliance with Standard 4.2.5

## **Executive summary**

For many Australians, eggs are an important part of a healthy diet. Each year, the Australian egg industry produces nearly 7 billion eggs, worth about \$1.4 billion. Food safety is an integral part of egg production systems. Addressing hazards through chain is essential for food safety and preventing foodborne illness.

Salmonella Enteritidis (SE) was previously assessed as absent in Australia but has now been linked to egg-related foodborne illness outbreaks in Australia. Salmonella outbreaks including those from SE have significant public health and economic consequences, with salmonellosis costing the Australian healthcare system about \$140 million each year. Between 2015 and 2019, eggs were the suspected source in approximately 40% of foodborne Salmonella outbreaks.

Food Standards Australia New Zealand (FSANZ) prepared Proposal P1060 following a large SE outbreak linked to eggs in 2018-19 that resulted in 245 illnesses. The proposal considers ways to strengthen food safety management in the primary production and processing of eggs and egg product. It assesses microbiological risk, particularly for SE, considers domestic and international best practice, cost-benefit and stakeholder input and proposes amendments to the Australia New Zealand Food Standards Code (the Code).

#### The analyses

The microbiological risk assessment focused on SE and other *Salmonella* spp., considering contamination sources, risk factors and control measures during egg primary production. The risk assessment developed a quantitative model. This model simulates the journey of individual eggs laid on either a small (1,000 laying hens) or medium-size (20,000 laying hens) farm that becomes SE-positive during a production cycle. The model has been used to answer the risk assessment questions relating to through-chain temperature control and testing for SE in layer environments. The model predicts the number of actual and notified illnesses for different scenarios to inform the cost benefit analysis. Two mitigations are considered: environmental testing regimes (once or regular 13 week tests (91 days) per production cycle) and temperature control (refrigeration or ambient storage after egg grading).

The risk assessment concluded *Salmonella* is managed through effective biosecurity and food safety measures applied across the supply chain. Illness can be avoided by environmental monitoring and strong traceability to enable rapid response. Refrigeration is a critical safety measure if an egg is internally contaminated with *Salmonella*, because it prevents bacterial growth within the egg.

The costs and benefits of three regulatory options including the status quo were considered. FSANZ recommends strengthening food safety through a multi-pronged approach that balances costs for industry and government (Option 2). The main proposed changes are:

- introducing environmental monitoring of poultry houses for presence of SE
- strengthening egg traceability requirements
- temperature control during egg storage and transport.

Benefits of this option include preventing illness through detecting SE early, minimising spread of SE to nearby properties, enabling rapid traceback to an infected farm and proactively implementing measures across the egg supply chain before SE establishes in the Australian laying flock. Costs include expenses for businesses that have not yet put these measures in place.

Due to likely costs for refrigeration (i.e. storage and transport at or below 7°C) of eggs throughout the supply chain to point of retail sale, and continued sporadic nature of flock infection with SE, mandating refrigeration of eggs following grading was not the preferred approach at this time. If the SE situation in Australia were to change, this inclusion of through chain refrigeration would need further analysis.

For the reasons detailed in this report, FSANZ decided to prepare a draft variation to Standard 4.2.5 – Primary production and processing standard for eggs and egg product and Standard 2.2.2 – Eggs and egg products. If approved, the draft variation would strengthen requirements to enhance food safety outcomes for eggs and egg product. The changes would help minimise public health risks, improve industry's ability to respond to potential outbreaks and support nationally consistent regulation.

If approved, the draft variation will commence in 12-months from the date of gazettal. FSANZ is seeking submissions on the draft variation.

**Summary of proposed changes** 

Requirement	No change	Amended	New			
Primary production of eggs						
General food safety management requirements		$\sqrt{}$				
Inputs – water, feed, chemicals, litter and other	√					
Waste disposal	V					
Health and hygiene	V					
Animals and pests			V			
Skills and knowledge						
Design, construction and maintenance of premises,						
equipment and transportation vehicles						
Range area			V			
Bird health						
Environmental sampling to monitor bird health			$\sqrt{}$			
Storage and transport of collected eggs and egg			$\sqrt{}$			
product						
Traceability		$\sqrt{}$				
Sale or supply		$\sqrt{}$				
Egg processing						
Application of food safety standards						
General food safety management		$\sqrt{}$				
Receiving unacceptable eggs						
Inputs – water, ingredients, packaging, chemicals, other		$\sqrt{}$				
Cleaning of eggs			$\sqrt{}$			
Waste disposal	$\sqrt{}$					
Skills and knowledge	$\sqrt{}$					
Health and hygiene						
Animals and pests			$\sqrt{}$			
Design, construction and maintenance of premises,						
equipment and transportation vehicles						
Traceability		$\sqrt{}$				
Processing egg product						
Storage or transport of eggs			$\sqrt{}$			
Storage and transport of egg product		$\sqrt{}$				
Sale or supply						

## 1 Introduction

### 1.1 The Proposal

FSANZ prepared this proposal P1060 to consider amendments to the Code to address two issues:

- a. Increasing and persistently high rates of foodborne illness due to *Salmonella* spp, with a significant proportion linked to consumption of eggs and egg product; and
- b. Significant changes to the Australian food safety risk environment with the emergence of *Salmonella* Enteritidis (SE) and new evidence *Salmonella* Typhimurium (ST) has been found on <u>and</u> within eggs at point of lay. These new risks had not been factored into current egg food safety risk management measures in the Australia New Zealand Food Standards Code (the Code).

As part of this proposal, FSANZ also reviewed the requirement for each individual egg to be marked with the producer's unique identification—commonly referred to as 'egg stamping'.

#### 1.2 The current standard

Australian state and territory food laws require food for sale, food businesses and primary food production to comply with relevant requirements in the Code.

Relevant Code requirements include the requirements set by Standard 4.2.5 for egg producers and for egg processors and by Standard 2.2.2 for food businesses that sell eggs in a retail sale or to a caterer.

Standard 2.2.2 Eggs and egg products contains requirements for the sale or supply of unacceptable eggs and for traceability of eggs for retail sale or for sale to a caterer. Eggs must be marked with the producer's or processor's unique identification.

Refer to SD3 for further information on current food safety requirements.

This proposal is separate to the Code Revision work that is revising the Code format, structure and text to improve legal efficacy and for related purposes. Proposal P1025 – Code Revision, revised Chapters 1 and 2 of the Code. Chapters 3 and 4 are to be revised in a separate proposal and is out of scope for this proposal. The draft variation for proposal P1060 uses the existing format and structure for Standard 4.2.5.

## 1.3 Reasons for preparing the Proposal

FSANZ prepared proposal P1060 in response to findings of the review of Standard 4.2.5 (W1138). That review concluded the current requirements in the Code do not adequately manage food safety risks associated with SE in Australian layer flocks.

Proposal P1060 was prepared to consider the need for new and/or amended standards for food safety and primary production requirements for eggs and egg product to address these SE risks, including:

- strengthened bird health requirements (such as controls on source of pullets; flock vaccination for *Salmonella*; mandatory SE testing);
- greater controls on spent hens;
- refrigeration and through chain temperature controls particularly aimed at reducing the risk from internalised SE or ST;
- strengthened traceability (including egg marking) requirements.

In 2017, the Australia and New Zealand Ministerial Forum on Food Regulation (now Food Ministers Meeting – FMM) established Priority 1 of the food regulation system, aimed at reducing foodborne illness, particularly focused on *Campylobacter* and *Salmonella*. Australia's *Foodborne Illness Reduction Strategy 2018–2021*+ (the strategy) was established. A review of Standard 4.2.5 was an action item in the strategy, to reduce salmonellosis.

In Australia, foodborne illness caused by *Salmonella* has increased over the past 20 years. Compared to similar countries, Australia has one of the highest rates of salmonellosis (Glass et al. 2022) — circa 2019 annual estimates: 61,600 cases of foodborne salmonellosis (3,740 hospitalisations and 11 deaths); and following salmonellosis, a further 5,750 cases and 172 hospitalisations due to reactive arthritis; and 5,400 cases and 460 hospitalisations due to irritable bowel syndrome. The total cost of salmonellosis and its sequelae was estimated at AUD 140 million per year (Glass et al. 2022, Table 13).

The dominant serovar in Australia responsible for illness associated with eggs is ST, whereas in other countries SE is also a major concern. The significant food safety concern with SE is its ability to colonise reproductive tissue of infected birds, enabling direct internal contamination of eggs with *Salmonella* (vertical transmission).

During February 2020, the Food Regulation Standing Committee (FRSC) requested Food Standards Australia New Zealand (FSANZ) review Standard 4.2.5 to address the risk of SE to human health. FRSC also requested FSANZ address the egg stamping issue raised by the 2016 Productivity Commission<sup>1</sup> inquiry into the regulation of Australian agriculture.

In response to FRSC, FSANZ reviewed existing risk management measures in the Code on egg food safety in Australia (project W1138). Public consultation occurred on an <u>information paper</u> in September 2021. Seven submissions received by FSANZ assisted in completing the initial review. It concluded current regulatory and non-regulatory measures are not adequate to protect public health and safety from the risk of salmonellosis from consuming eggs and egg product in Australia.

Standard 4.2.5 Primary production and processing standard for eggs and egg product (the egg PPP standard) was developed under Proposal P301 and took effect in 2012. The 2012 risk assessment considered all risks associated with *Salmonella* spp. including vertical transmission. As SE strains capable of vertical transmission in poultry were not known in Australia at that time, the standard did not include measures to address unique SE risks.

Australian egg production has also changed since 2012 with production systems shifting from primarily caged systems to more barn laid and free range egg production. A key driver for the shift to free range egg production is responding to consumer demand and commercial requirements (Jeswanth 2022). This trend is expected to continue.

SE has caused outbreaks linked to egg production in New South Wales, Queensland and Victoria. The 2018–19 outbreak of locally acquired SE linked to eggs changed the risk profile

<sup>&</sup>lt;sup>1</sup> https://www.pc.gov.au/inquiries/completed/agriculture/report (see pp 431–436).

for Australian eggs, triggering a review of through-chain food safety controls. It also highlighted complex supply chains that exacerbated finding the source farm/s. The outbreak caused 245 cases of illness; culling of a large number of birds; and several consumer and/or trade level recalls of eggs across the country. Subsequent sporadic cases of SE in Victoria, New South Wales and Queensland between 2020 and 2024 have occurred and been associated with commercial and backyard flocks.

These events show the current Standard 4.2.5 did not and does not manage risk factors associated with SE's ability to be transmitted from the hen into the egg during formation.

#### 1.4 Procedure for assessment

P1060 is being assessed under the general procedure in the *Food Standards Australia New Zealand Act 1991* (Cth) (the FSANZ Act), with one round of public consultation.

## 2 Summary of the assessment

#### 2.1 Risk assessment

FSANZ assessed the proposal in accordance with the *Food Standards Australia New Zealand Act 1991* (Cth). To identify risk and management options for the primary production and processing of eggs and egg products in Australia, FSANZ has completed a:

- microbiological risk assessment to identify risk factors and mitigation measures
- gap analysis of existing measures to identify current regulatory and non-regulatory measures, and has modelled the proposed measures based on existing measures, and
- cost-benefit analysis to inform the most appropriate risk management measures.

#### 2.1.1 Nature of egg production in Australia

What started as family based egg production is now a major commercial enterprise within Australia. Over time, flock sizes have grown to meet demand from increasing urbanisation (Scott, et al 2009). The sector now produces 6.98 billion eggs with a gross production value of approximately \$1.37 billion in the 2023-24 financial year (Australian Eggs, 2024).

The three main egg production systems in Australia are caged, barn-laid and free range. Free range may be further divided into other types, such as pasture raised and/or organic. Based on retail data from major supermarkets, free range eggs make up the largest number of sales by volume, followed by caged eggs and barn-laid eggs.

Supply chains for eggs vary considerably, from short simple pathways where eggs are sold to consumers within a week of being laid, to complex networks where eggs are transported significant distances to meet demand in locations facing short supply.

Commercial egg production occurs in all states and territories except for the Northern Territory. The majority of egg production is in the eastern states, with New South Wales, Queensland and Victoria making up approximately 85% of the national layer flock.

Refer to SD5 for further information on egg production in Australia.

SD5 (Table 1) provides estimated numbers of egg producers by layer farm size. The medium to large egg producers represent about 18.8% of the total number of layer farms.

#### 2.1.2 Current domestic and international food safety measures

Supporting Document 3 (SD3) provides a summary of current food safety measures (both regulatory and non-regulatory) for eggs and egg product in Australia. We examined current regulatory arrangements and compared them with five international markets that have legislation to manage SE. This review and comparison helped to:

- document existing measures
- create a baseline for this review of Standard 4.2.5
- · examine differences between Australian states and territories
- compare existing measures to international standards (Codex), and to other countries
- determine whether the existing measures adequately support food safety in Australia
- create a gap analysis between existing measures and the P1060 proposal
- align proposed measures to existing practices, reducing impact on industry and government food regulators.

Since 2011, the egg industry introduced and updated guidance materials and procedures to manage the risks associated with *Salmonella* spp. on layer farms. These include:

- a range of research, development and extension programs to improve Salmonella spp. risk management and provision of technical expertise for development of biosecurity manuals and response plans
- development of Salmonella monitoring programs
- use of feed from accredited feed suppliers and feed mills
- · development of SE response plans
- development of traceability resources including the tool, EggTrace, and
- Egg Standards of Australia (ESA) accreditation systems for pullets, layers and grading floors.

In addition to ESA accreditation, there is the Safe Quality Food Institute (SQFI) Food Safety Code that has been benchmarked to the Global Food Safety Initiative, with two components covering egg production.

The ESA and SQFI schemes include control measures that cover the microbiological risk factors FSANZ identifies in this proposal. Compliance with these schemes is assessed through a third-party audit. While the schemes are voluntary, most large retailers require them; this captures all large and many medium sized egg producers, estimated to be 18% of producers (Egg Farmers, personal communication). This means the majority of eggs (estimated at 82%, Australian Eggs, 2024b) are produced under these schemes (i.e. those produced by the accredited large and medium size layer farms and processing facilities to meet commercial arrangements).

However, a large number of egg producers have not adopted voluntary materials and are not accredited to ESA or SQFI, including the majority of small egg producers.

#### 2.1.3 Potential SE situation for Australia

For this assessment, FSANZ considered three potential situations for SE spread in the Australian national flock and considered the likelihood of each situation occurring. The risk assessment then focussed on the most likely situation. The three situations were:

- Situation 1: SE is eradicated with no further infection of flocks.
- Situation 2: SE infecting a flock continues to be sporadic, with egg-associated SE human illness occurring.

• Situation 3: SE becomes endemic in the national flock, infecting multiple farms with a potential SE prevalence at 2% of flocks<sup>2</sup>.

SD1 contains further detail on the above situations and their likelihood.

FSANZ determined it would proceed with assessment under Situation 2, where SE infecting a flock continues to be sporadic, with egg-associated SE human illness occurring.

#### 2.1.4 Microbiological Risk Assessment

The microbiological risk assessment (SD1) assessed the best available data to address public health risks associated with consuming eggs and egg product in Australia. FSANZ assessed data to identify key risk factors for the hazard *Salmonella* spp. and where in the primary production and processing supply chain it may be introduced, increased, reduced or eliminated. More detail on the risk factors covered by the quantitative risk model is in SD1 and SD2.

#### Salmonellosis

Salmonella is a leading cause of bacterial diarrhoeal disease globally, causing gastroenteritis. The severity varies with host factors and serotype. Egg and egg-containing foods are the most common cause of Salmonella outbreaks in Australia (when the food vehicle was identifiable). Eggs continue to be a source of Salmonella outbreaks in Australia. From 2010–2017 eggs caused almost 50% of Salmonella outbreaks. Since 2017, available data from NSW and WA show that 43% of Salmonella outbreaks are egg-associated. The significant 2018–2019 NSW SE outbreak shows that when SE enters laying flocks in Australia, it can have a major human health impact. It resulted in widespread illness, recalls and biosecurity responses, highlighting the need to improve food safety risk management.

#### Salmonella on farm

Like many countries, Australia has different egg farming systems and sizes which means onfarm practices to manage SE contamination vary. *Salmonella* can be transmitted vertically and horizontally within poultry flocks. *Salmonella* infections in poultry can vary, with SE demonstrating higher frequencies of vertical transmission and internal egg contamination than other strains. SE-infected flocks are often asymptomatic, complicating detection and control.

Notifiable animal disease investigations for SE have continued to occur on commercial farms post the 2018-2019 SE incident. While SE is not considered to be endemic in Australian laying flocks, the frequency of *Salmonella* outbreaks linked to consuming SE-contaminated eggs suggests there is undetected SE in Australia; occurring sporadically within Australian commercial laying flocks, the environment and/or wild birds. SE remains a challenge to Australian egg-producers and the current sporadic nature of outbreaks adds to the difficulty in predicting its transmission routes and cost-effective management.

<sup>&</sup>lt;sup>2</sup> This is an arbitrary figure; if 2% of flocks are positive for SE, this represents a significant increase in prevalence in layer flocks. This percentage is consistent with other countries; the EU's target is to reduce *Salmonella* from 2% of flocks (and their target serovars are SE and ST). <u>Salmonella control in poultry flocks and its public health impact - 2019 - EFSA Journal - Wiley Online Library</u>

#### Complex supply chains

Egg supply chains vary widely; from simple ones where eggs are sold to a consumer within a few days of being laid to complex distribution networks, where eggs reach point of retail sale weeks after being laid. The time and temperature at which eggs spend in the distribution chain contribute to the risk factors. Storage conditions vary widely, with some eggs refrigerated shortly after lay and maintained at that temperature, whereas others are held eggs initially at 15°C and then at ambient temperatures during transport and sale.

Eggs exposed to elevated temperatures go through internal changes more quickly, with the yolk membrane breaking down and allowing growth of microorganisms present in the egg. Exposure to lower temperatures prolongs the time it takes before conditions inside the egg support microbial growth. Reducing the temperatures down to refrigeration temperatures will prevent growth of *Salmonella*, even if the internal conditions would otherwise support growth.

#### Control measures

Commercial egg production facilities are complex environments. The introduction and spread of *Salmonella* in laying flocks both largely depend on environmental conditions in egg production facilities. Once introduced into laying houses, *Salmonella* can spread rapidly and extensively throughout flocks by direct contact between hens, ingestion of contaminated feed or faeces, movement of personnel and equipment and airborne circulation of contaminated dust and aerosols.

Effective biosecurity practices reduce the risk of *Salmonella* contamination, such as controlling access to premises, boot washing, handwashing, rodent and insect control, and maintaining feed and water quality. There are reports of low adoption of biosecurity practices in different egg production systems in Australia (Scott et al., 2018; NSW Food Authority, 2022). Practices including equipment sharing between sheds and limited disinfection of shared equipment were a leading factor in the spread of SE between facilities during the 2018-2019 incident.

Effective sampling programs are crucial for detecting *Salmonella* in poultry flocks, given birds can be asymptomatic. Environmental sampling, including faecal and dust samples, is key to identifying SE in laying houses. Traditional culturing methods are used for *Salmonella* detection, with whole genome sequencing (WGS) recommended to identify a specific strain and/or source of infection.

Salmonella infection of flocks and contamination of eggs is commonly mitigated through chain via several measures including vaccination, washing, and refrigeration. Further, effective egg traceability reduces the time unsafe eggs are in supply and enables faster farm identification to prevent further spread.

Storing eggs at refrigeration temperatures is an effective way of reducing the liquefaction of egg white, the loss of integrity of the vitelline membrane and consequently, bacterial penetration and growth. Refrigeration of eggs post-lay and through chain minimises microbial growth including *Salmonella*.

FSANZ notes the 2012 risk assessment underpinning the current Standard 4.2.5 focused on risks associated with horizontal transmission of *Salmonella* spp. on egg shells that then moved into the egg and egg contents. That assessment was based on eggs becoming a food safety risk due to hazards from cross contamination, during production or processing. While it considered the potential for internal contamination of eggs at point of lay and significant growth, or inactivation of the pathogen with time and temperature, measures were not

included as SE was not in Australia at that time.

#### Conclusion

The 2018-19 outbreaks and subsequent sporadic occurrences of SE reinforce that current Code requirements do not manage SE risks or effectively protect public health and safety. FSANZ reconfirms our conclusion under the initial discussion paper that the current standard did not address vertical transmission of SE during egg formation.

A combination of multiple strategies can be used to control SE risks, including biosecurity measures, vaccination, animal and pest control, farm hygiene, environmental monitoring and egg refrigeration. Of particular note are on-farm monitoring for SE, temperature control of eggs and enhanced on-farm hygiene and biosecurity.

#### 2.1.5 Quantitative Risk Model

FSANZ developed a model to simulate the various stages of egg production, distribution, and consumption, estimating the probability of contamination and subsequent illness under different scenarios (size of farm, on-farm monitoring, supply-chain time and temperature). Refer to SD2 for information on the model, its design, assumptions and inputted variables.

As the model reflects unique characteristics of the Australian egg production and supply chain, it allows for a more granular assessment of SE risks, accounting for factors such as farm-level contamination, storage conditions (temperature and time) and the impact of regulatory interventions.

The model outputs several metrics, including the number of SE-positive eggs, actual illnesses, notified illnesses, outbreak events, and effectiveness of interventions (i.e. illnesses avoided).

#### Output and conclusions from the model

#### Environmental monitoring

- Introducing on-farm environmental monitoring significantly reduces the number of illnesses associated with SE-positive egg layer farms (both small and medium).
- While a single test at peak production shows a decrease in SE illness, the most effective testing schedule considered is at regular 13-week periods.
- Regular testing is more likely to detect SE on-farm *prior* to illnesses occurring.
- Broadly, applying a single test during a flock's production cycle achieves similar reduction in illnesses as relying on Passive Human Surveillance (PHS) (i.e. illnesses avoided is similar for both one test and PHS, and not as effective as 13 weekly testing at protecting public health).
- Without environmental monitoring, the majority of small (1,000 hens) farms go undetected (and for longer) because the number of notified illnesses are not high enough to trigger epidemiological traceback investigations.
- Within an ambient supply chain, monitoring with 13-week testing shows variability in reducing illness, but overall is more likely to reduce the likelihood of illness and is a valuable tool within the management system.
- On-farm environmental monitoring is a proactive public health and safety measure and does not rely on human illness for a farm to be identified as SE-positive.

 Regular testing reduces the number of days a farm is SE-positive before it is identified, regardless of supply chain temperature; i.e. testing allows for early detection of a SEpositive farm. The more regular the testing, the faster a positive farm is detected.

#### Through chain refrigeration

- For both small and medium size farms, there is a significant decrease in SE illness when through-chain refrigeration is applied.
- Refrigeration alone (i.e. without environmental monitoring) significantly reduces the number of illnesses associated with SE, reducing the burden on the public health system.
- Refrigeration prevents growth of many microorganisms including SE if present in egg contents.
- All businesses in the supply chain (producer, processor and/or retailer) can be more confident in preventing foodborne illnesses when through-chain refrigeration is in place.
- It is noted when fewer illnesses occur, it can take longer to trigger the epidemiological traceback investigation to find SE-positive farms.

#### Other findings

- When implemented in tandem, environmental monitoring and refrigeration show the greatest decrease in SE illness.
- The total number of illnesses is lower for a small farm than a medium size farm: this relates to scale (fewer eggs produced) and also that its supply chain is generally shorter, decreasing the time available for SE growth.
- Longer supply chains provide greater opportunity for SE growth inside the egg, if
  present. This explains the marked impact of refrigeration on reducing illnesses in a
  medium size farm; refrigerating the supply chain for a medium-sized farm has greater
  impact than for a small farm because its typically longer supply chain provides more time
  for SE growth to occur.

#### 2.1.6 Consumer literature review

FSANZ did a rapid systematic literature review to inform P1060 by investigating the following research questions:

- What are consumers' perceptions of risk in relation to eggs?
- How often do consumers eat eggs? In what setting? And how are they cooked, if at all?
- Where do consumers store eggs and/or leftovers of eggs, and for how long?
- What are consumers' egg handling behaviours? Do egg handling behaviours differ between types of households?
- Are behaviour change techniques effective for improving safe egg handling behaviours among consumers? If so, what techniques are most effective?

The review included six studies, all done within Australia. Only reviewing studies completed within Australia is appropriate due to the unique microbiological risk environment beyond Australia: while SE has only recently emerged within Australia, it is endemic in many other countries. While New Zealand may have a comparable microbiological environment, no studies of New Zealand consumers were found.

#### 2.1.6.1 Key messages

Research Question 1: What are consumers' perceptions of risk in relation to eggs?

Most Australians perceive eating eggs that have runny yolks and/or whites to be low risk. Consumers lack awareness of risks posed by dirty eggs with a very low percentage believing dirty eggs should be discarded. Most consumers believe dirty eggs can be safe to eat if cleaned. Most consumers don't know eggs shouldn't be washed or that washing eggs (poorly) can result in unsafe eggs. Typically, eggs are considered to have a lower food safety risk than raw meat and a large proportion did not wash their hands after handling eggs.

Research Question 2: How often do consumers eat eggs? In what setting? And how are they cooked, if at all?

Though evidence on egg consumption is limited, most eggs are eaten at home. Most consumers report eating eggs or a meal containing eggs at least weekly. Most consumers consume eggs with a runny yolk, though the white tends to be cooked until firm.

Research Question 3: Where do consumers store eggs and/or leftover of eggs, and for how long?

The vast majority of consumers store eggs in the refrigerator but it is unknown for how long eggs are stored.

Research Question 4: What are consumers' egg handling behaviours? Do egg handling behaviours differ between types of households?

A large proportion of consumers handle eggs in an unsafe manner, for multiple reasons, such as not washing hands after handling eggs (43-61%), washing eggs (47%), consuming cracked eggs after checking them (up to 40%), reusing egg cartons (31%), using a carton that had a cracked egg in it (31%) and using the 'float in water' or 'sniff' test to check if eggs are acceptable to eat.

Research Question 5: Are behaviour change techniques effective for improving safe egg handling behaviours among consumers? If so, what techniques are most effective?

Attempts to influence consumers egg handling behaviour have had mixed impact.

#### 2.1.6.2 Conclusion

Overall, the review found consumers generally have perceptions of low risk in relation to eggs, a large proportion engage in at least one unsafe egg-handling or cooking behaviour, and are resistant to attempts to change these behaviours. Knowledge of safe egg-handling practices does not always translate into actual practice (e.g. despite almost three-quarters of consumers believing cracked eggs should be discarded, a substantial minority [40%] report using them if they can check them first), and increases in safe egg-handling knowledge have not been found to result in changes to actual behaviour.

On the more positive side, the vast majority of consumers report storing eggs and meals containing eggs in a safe manner (i.e. refrigeration).

It is important to note consumers' risk perceptions and behaviours as reported in this review have been formed in the Australian microbiological risk environment, where SE is not endemic. These findings are therefore specific to these conditions. It is possible consumer

risk perceptions and behaviour could change, potentially quite rapidly, if there was a perceived shift in this risk environment (i.e. eggs have become a higher risk due to SE). The report is included as SD6.

### 2.3 Risk management

#### 2.3.1 Risk management measures

FSANZ assessed three risk management options.

- Option 1 Retaining the status quo
- Option 2 Introducing a combination of regulatory and non-regulatory measures
- Option 3 Introducing a combination of regulatory and non-regulatory measures, plus mandatory refrigeration requirements for eggs

Each option was assessed against the objectives and criteria set out in sections 18 and 59 of the FSANZ Act.

SE is a nationally notifiable animal disease<sup>3</sup>. Australia's domestic biosecurity response to detecting SE on farm is to apply movement restrictions to prevent the spread of SE, depopulating that farm and then extensive decontamination to eradicate the presence of SE. FSANZ's assessment took account of these biosecurity requirements that prevent eggs (and other materials) from leaving a SE positive farm unless expressly permitted by the relevant authorities.

The risk assessment found the current regulatory measures - including Standard 4.2.5 - do not adequately address the risks of vertical (internal) transmission of *Salmonella*. Measures do not account for flocks infected with SE being asymptomatic, that SE can be present inside the egg at time of lay and typically only a small percentage of eggs will be positive. This means SE detection on farm can only occur through either effective SE monitoring of the flock or effective investigation of a foodborne illness (with successful traceback to farm). FSANZ notes relying on human illness as a means of monitoring for SE on farm does not protect public health and safety

The food safety risk assessment confirms previous conclusions:

- there is no single measure that manages risks with Salmonella spp. including SE in eggs and a combination of multiple intervention strategies is required; and
- there are gaps in current regulatory and non-regulatory measures that increase the risk of foodborne illness due to SE infection of flocks.

FSANZ concluded amendments to the Code are required to address these issues, protecting public health and safety.

#### 2.3.2 Preferred regulatory approach

FSANZ concluded changes are required to Standards 4.2.5 and 2.2.2 to manage potential presence of *Salmonella* within the egg.

The preferred approach is Option 2, where the Code is amended and guidance material is developed to support understanding of requirements. Amendments to the Code will protect public health and safety, are cost effective, risk proportionate measures that support national

<sup>&</sup>lt;sup>3</sup> National list of notifiable animal diseases - DAFF

consistency and are based on the best available scientific evidence.

The proposed amendments to the Code are set out in the draft variation at Attachment A and an associated draft explanatory statement is at Attachment B.

#### Option 1

Retaining the status quo is not the preferred option for protecting public health and safety, is not a risk proportionate response and does not support national consistency given only some jurisdictions have implemented requirements to address the food safety risk posed by SE.

Consideration of non-regulatory measures (such as guidance) alone to improve public health and safety was considered by FSANZ as part of project W1138 – *Review of the egg primary production and processing standard.* It concluded the current regulatory and non-regulatory measures are not adequate to safeguard public health and safety from the risk of salmonellosis due to consumption of eggs. The project recommended FSANZ prepare a proposal to amend the Code.

#### Option 3

Refrigeration is known to be a major cost to businesses. To fully understand costs implications with refrigeration, further consideration of the following aspects is required: upfront capital of new refrigeration units (along the supply chain), ongoing running costs at refrigeration temperatures and impact on businesses that do not currently store eggs under refrigeration (eg transportation, storage and distribution centres, smaller retail stores). Costs associated with refrigeration through chain would likely be passed onto consumers, increasing the price of eggs.

Due to likely costs for refrigeration (i.e. storage and transport at or below 7°C) of eggs throughout the supply chain to point of retail sale, and sporadic nature of flock infection with SE, option 3 was not the preferred approach at this time. If the SE situation in Australia were to change, this option would need further analysis.

#### 2.3.3 Regulatory measures for Option 2

Based on the risk assessment and after consideration of existing regulatory and non-regulatory measures (including the biosecurity response to SE detection and outbreaks), FSANZ identified measures to strengthen protection of public health and safety. Requirements to be included in the Code are:

- environmental monitoring for SE
- improved traceability
- · rodent, insect and wild bird control
- safe cleaning of eggs
- range area management
- temperature control during storage and transport of eggs and egg product

No single measure alone would sufficiently manage risks of foodborne illness identified in the risk assessment. However, for the reasons explained below and in the SDs, FSANZ's assessment is that together these would act to minimise introduction and spread of SE to the flock; verify prevention measures are working and detect infection early; reduce likelihood of foodborne illness (FBI) from internalised *Salmonella*; and minimise FBI during an incident through rapid withdrawal.

#### Environmental monitoring for SE

Quantitative modelling (refer section 2.1.2 and SD1) demonstrated implementing on-farm environmental testing reduces the number of illnesses associated with SE-positive egg layer farms, on both small (1,000 hens) and medium (20,000 hens) sized farms, with more impact for medium sized farms. Currently existing regulatory requirements for on-farm environmental testing vary, with only two jurisdictions requiring on-farm environmental testing but at different frequencies and under different legislation. One of these jurisdictions regulates under biosecurity legislation, the other under primary production food safety legislation. The remaining jurisdictions do not require testing on-farm. Similarly, there is inconsistent adoption of non-regulatory on-farm monitoring measures as they are voluntary; a relatively small percentage of egg producers (18% representing all of the large and most of the medium sized egg producers) adopt practices such as the National SE Monitoring Accreditation Program which require environmental testing. This means there are gaps in application of on-farm testing for SE, with many flocks (mostly the small egg producers) not subject to any sampling and monitoring for presence of SE.

FSANZ proposes to amend Standard 4.2.5 to require egg producers to sample and test the layer flock environment for presence of SE. A positive detection would trigger response activity to determine whether the flock is infected or not. When a SE positive flock is detected, each jurisdiction has biosecurity legislation that gives effect to domestic biosecurity controls. These controls are implemented to prevent the spread of SE which includes ceasing supply of eggs from the farm. Standard 4.2.5 therefore does not need to prescribe requirements for a layer flock infected with SE.

FSANZ has proposed a new requirement for environmental sampling and testing for presence of SE, but has not prescribed the frequency of sampling and testing in the proposed draft variations to the Code at Attachment A.

The frequency of sampling and testing needs to be adequate to manage the risk of SE positive eggs entering the food supply and causing illness. Modelling shows the impact of testing frequency on minimising the potential for SE positive eggs to enter supply. More regular monitoring (i.e. every 13 weeks) provides the most effective means of detecting the presence of SE on farm. FSANZ notes the current low SE prevalence in Australian flocks, and that the suite of management measures used on-farm needs to be considered in its entirety. FSANZ concluded that under the current SE situation in Australia (ie sporadic – refer to section 2.1.2), frequency of sampling and testing should be risk based taking into account localised conditions, other risk mitigations used and other regulatory requirements. This approach enables sampling and testing to be altered based on a changing SE situation.

#### Effective traceability system

The microbiological risk assessment (SD1) demonstrated rapid traceback of eggs following illness enables quickly identifying the egg producer and subsequent removal of unsafe eggs from the market place, thereby reducing foodborne illnesses. Where unsafe eggs cannot be identified, they continue to be supplied and remain in the market place, causing more illness.

Current egg marking requirements have shown traceback to the egg producer to be a fraught, time consuming and often unsuccessful activity until more foodborne illnesses have occurred.

To address these traceability problems, FSANZ proposes to amend Standard 4.2.5 to require each egg to identify the relevant egg producer by the use of a unique mark applied to the egg

before the egg can be sold.

Enhancing traceability requirements to identify the producer from an egg mark will enable faster traceback to a source farm, ceasing supply of potentially SE-positive eggs in the human food supply and where required, recalling potentially unsafe eggs.

In addition, FSANZ proposes to require egg producers and egg processors to keep and maintain specific records to enable eggs and egg pulp to be traced more effectively. These amendments will support faster identification of the egg producer and recall of potentially unsafe eggs.

#### Transport and storage requirements

The microbiological risk assessment and modelling (SD1) demonstrated decreases in SE illness when through-chain refrigeration was applied after grading of eggs. Temperature control is a known and effective risk management measure to control microbiological growth including SE in eggs.

Existing regulatory measures do not address the problem of *Salmonella* presence and growth inside the egg and resulting increased risk of FBI, except for New South Wales where temperature control is required under biosecurity legislation. Non-regulatory measures under voluntary schemes require eggs to be placed under temperature control between 12 - 15°C (Egg Standards of Australia). As a result there are gaps in application of transport and storage temperature control requirements, with many egg producers not required to control temperatures to which eggs are exposed, with increased risk of FBI.

To address this issue, FSANZ proposes to amend Standard 4.2.5 to require egg producers and egg processors to ensure time and temperature conditions under which eggs are stored and transported do not make eggs unsafe or unsuitable. In addition, an egg processor must also ensure time and temperature conditions under which egg product is stored and transported will control the growth of pathogenic micro-organisms in the egg product and not make egg product unsafe or unsuitable.

The effect of these amendments will be to prevent eggs being exposed to temperatures for periods of time that would result in more rapid changes inside the egg e.g. loss of integrity of the vitelline membrane, supporting growth of *Salmonella*, when present. The amendments also support flexibility for temperature control through supply chains, given the multiple pathways some eggs progress through prior to consumption.

Currently, infection of Australian flocks with SE is a sporadic occurrence. Mandating refrigeration while SE infrequently occurs on farm is not supported by the cost benefit analysis.

This outcomes-based approach provides flexibility to adjust time and temperature conditions when and where required, such as in response to more wide-spread emergence of SE in layer farms. Where there is increased risk of flock infection with SE and thus likelihood of SE presence inside eggs, reduced storage and transport temperatures (such as refrigeration) would prevent SE growth and minimise risk of illness.

#### Contamination from presence of animals and pests

The risk assessment concluded rodents, insects and wild birds are known carriers of SE and their presence may introduce SE into the environment. On a layer farm this may lead to infection of layer hens and at a processing facility it may lead to cross-contamination of

equipment, packaging, staff or vehicles and spread back to layer farms that supply eggs to the processor.

The presence of these animals should be minimised through preventing or restricting their access.

There are no regulatory measures in Standard 4.2.5 to address this risk factor (flock infection with SE or spread of SE in the environment). Regulatory measures exist in biosecurity legislation in each jurisdiction, with some variation between jurisdictions in application. There are non-regulatory measures that also address animal and pest control, but these are voluntary and not adopted by all.

To address the inconsistency in application of this pest control requirement and gaps in industry adoption of the non-regulatory activities to control the presence of animals and pests, FSANZ proposes to amend Standard 4.2.5 to require an egg producer and egg processor to ensure the presence of animals, pests and vermin in premises, grading floors, equipment, range areas, sheds and transportation vehicles do not make eggs unsafe or unsuitable.

#### Contamination of eggs due to cleaning of eggs

The risk assessment identified cleaning of eggs, if done incorrectly, may contaminate internal egg contents and cause an egg to become unsafe or unsuitable.

There are no regulatory measures addressing this risk factor. There are non-regulatory measures such as ESA and guidance material that address it, but these are voluntary and not all adopt it. Information collected for this proposal indicates many businesses wash their eggs; there was evidence best practice washing guidance was not always followed.

To address this problem where eggs may be contaminated through incorrect cleaning, FSANZ proposes to amend Standard 4.2.5 to require egg producers and egg processors which clean eggs, to ensure the cleaning does not make the eggs unsafe or unsuitable.

#### Contamination from range areas

Range areas are the open area that free range hens have access to, external to the poultry house. The risk assessment identified several risk factors associated with the environment including the range area, that if not controlled, may result in layer hens becoming infected and eggs being contaminated. These risk factors include wild bird, pest and rodent access to free range areas, proximity of water bodies to and previous use of, the range area (e.g. grazing herd or crop).

The existing Standard 4.2.5 does not explicitly require the range area to be managed. Existing biosecurity regulatory measures may address it in part but the risk assessment noted evidence of poor biosecurity practices by egg producers. There are non-regulatory measures available, but these are voluntary and not uniformly adopted by the industry.

To address these risk factors, FSANZ proposes to amend Standard 4.2.5 to require an egg producer to ensure a range area does not make eggs unsafe or unsuitable.

Preventing sale of eggs that are broken and leaking at time of collection from flock

The risk assessment identified when a foodborne pathogen is inside an egg, an egg is hazardous.

An egg that is broken and leaking at the time of collection has exposed the egg pulp to direct contamination from the poultry house environment. If contaminated with micro-organisms, the lack of temperature control and time until collection provide opportunity for pathogen growth.

There is regulatory uncertainty on requirements for broken and leaking eggs at the time of collection in Standard 4.2.5.

The current requirements in Standard 4.2.5 that could apply to a broken and leaking egg at the time of collection are requirements for a cracked egg. These are:

- a cracked egg must not be sold and must either be disposed of or sent to an egg processor for heat treatment; and
- require processed egg product to be stored or transported under time and temperature conditions that control the growth of pathogenic micro-organisms.

These current requirements in Standard 4.2.5 mean a broken and leaking egg may be considered a 'cracked egg' and go for processing prior to sale for human consumption.

Regulatory measures that could be applied to broken and leaking eggs exist under food Acts where the jurisdiction could decide eggs that are broken and leaking at the time of collection are unsafe and unsuitable. Food Acts have a prohibition on the sale of unsafe and unsuitable food.

There are voluntary non-regulatory measures available such as compliance with Codex Code of Hygienic Practice for Eggs and Egg Products (CXC 15-1976), where broken eggs should not be used for human consumption and be disposed of in a safe manner. CXC 15-1976 further advises broken/leaker eggs are considered unsafe and unsuitable, and should not be used for egg products.

Current industry practice is to divert to waste eggs that were broken and leaking at the time of collection. However, some concerns were raised with FSANZ by industry representatives that some egg producers do not discard these eggs.

To improve clarity a broken and leaking egg at the time of collection is unsafe and unsuitable, FSANZ proposes to amend Standard 4.2.5 to:

- include a definition for a broken egg; and
- prohibit the sale or supply of broken eggs.

Improve alignment in Chapter 4 of the Code

The draft variation prepared by FSANZ would make a number of proposed amendments to Standard 4.2.5 to improve that Standard's alignment with other standards in Chapter 4 of the Code, and update references to the general food safety management requirements.

These proposed amendments are new references to general food safety management requirements and the amendment to the title for health and hygiene requirements clauses.

Amendments as part of the Code revision

Some clauses within Standard 4.2.5 include references to 'taking all reasonable measures'.

State and Territory Food Acts apply and give effect to the Code, including Standard 4.2.5.

The Food Acts generally provide that non-compliance with a requirement imposed on a person by a provision of the Code is an offence. However, the Food Act also provide it shall not be an offence if the person took all reasonable precautions and exercised all due diligence to prevent non-compliance with the relevant Code requirement. See, for example, section 26 of the *Food Act 2003* (NSW). These Food Act provisions mean that the 'take all reasonable measures' proviso used by some clauses within Standard 4.2.5 is duplicative and not required in the Code.

The draft variation prepared by FSANZ will remove these references. For example:

Current clause 4 – Inputs: An egg producer must take all reasonable measures to ensure inputs do not make the eggs unsafe or unsuitable.

Revised draft clause 4 – Inputs: An egg producer must ensure inputs do not make the eggs unsafe or unsuitable.

Non-regulatory measures – guidance materials

Draft guidance materials have been developed by the Egg Implementation Working Group (EIWG) and provided in SD8 to assist industry in complying with the proposed amendments to the Code. More materials will be developed by the EIWG and provided for reference by industry.

#### 2.4 Risk communication

#### 2.4.1 Stakeholder consultation

Stakeholder consultation is a key part of FSANZ's proposal assessment process.

Initial consultation occurred on an <u>Information Paper</u> on the egg standard review in September 2021. Submissions were received from three state governments, two egg farmer representative groups, the egg industry marketing and research and development services body and the industry peak body for producers and suppliers of veterinary products for livestock and companion animals.

Submissions from state governments were generally supportive of FSANZ amending the Food Standards Code to address inadequacies in the management of egg-related food safety risks, where supported by the risk assessment and cost-benefit analyses.

Submissions from egg production and primary processing stakeholders were also supportive of the need to reconsider the efficacy of food safety risk management for eggs. They support improved egg traceability and raised concerns about gaps in regulatory oversight due to inconsistent jurisdictional exemptions applying to small-scale and backyard egg producers. While there were reservations about a requirement for refrigeration of eggs on-farm, there was tentative support for temperature control if informed by a risk assessment and cost-benefit analysis.

In progressing this proposal, FSANZ convened the following consultation for with industry, government and technical experts.

Scientific Advisory Group for Eggs

FSANZ convened this group to assist in its work on the microbiological risk assessment

which involved modelling for quantitative risk assessment. The SAGE provided expert advice, opinion and information to FSANZ relating to the microbiological risk assessment for this proposal.

#### Egg Standards Development Advisory Group

FSANZ convened this group, comprising of government and industry representatives, to provide input on development of risk management measures and conduct of economic and social analyses of proposed amendments to the Code. Proposed amendments were to improve management of the new food safety risk environment for eggs and address the request from the Food Regulation Standing Committee Chair.

#### Industry visits

Representatives of FSANZ completed several industry site visits to improve understanding of current industry practices. These visits also provided further opportunities to engage directly with a range of businesses and staff employed within the egg sector.

Visits assisted with understanding how the current Code requirements are interpreted and applied. It also provided an opportunity to receive feedback on issues with the standards and to improve understanding of potential impacts from any proposed changes.

Industry visits occurred during late 2022 through to December 2023, across Victoria, New South Wales, Australian Capital Territory, South Australia and Queensland. Layer farms visited varied from small operations of approximately 3000 hens up to large operations with over 500 000 hens. Several processors were also visited which included pulping-pasteurising facilities and food manufacturers.

#### 2.4.2 Communicating how the proposed amendments will work

Implementation of Standards 2.2.2 and 4.2.5 as amended by the draft variation will be responsibility of the states and territories. ISFR facilitates the consistent national implementation of standards by developing agreed approaches and compliance materials. The EIWG was established by ISFR for this purpose. This proposal progressed using the <a href="Integrated Model for Standards Development and Consistent Implementation of Primary Production and Processing Standards">Implementation of Primary Production and Processing Standards</a>.

FSANZ has been working with states and territories to ensure the proposed amendments, if approved, could be adopted by industry and implemented in each jurisdiction. As part of this work, the EIWG has developed a range of tools to help businesses and regulators understand how the amendments set out in the draft variation, if approved, would be implemented. These tools include a proposed guidance plan. A copy of the proposed guidance plan is provided for information and comment in SD8.

#### 2.4.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There is already a standard within the Food Standards Code for primary production and processing of eggs and egg product and there are relevant international standards.

Amending the Code to improve regulatory measures to adequately safeguard public health and safety is unlikely to have a significant effect on international trade given there is an existing standard in Australia and these new measures are consistent with relevant existing international standards for managing vertically transmitted pathogens.

Relevant international standards are those of the Codex Alimentarius Commission:

- General principles of food hygiene CXC 1-1969; and
- Code of hygienic practice for eggs and egg products (CAC/RCP 15 1976)

## 2.5 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

#### 2.5.1 Section 59

#### 2.5.1.1 Consideration of costs and benefits

The FSANZ Act requires FSANZ to have regard to whether costs arising from proposed measures outweigh direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59(2)(a)).

FSANZ has had regard to the possible costs and benefits of introducing and amending egg food safety requirements in the Code under option 2 and 3. See Supporting Document 5 (SD 4).

FSANZ's initial assessment concludes the quantified and unquantified benefits that would arise from the measures proposed in option 2 are expected to outweigh the costs and return a greater net benefit than option 3. However, information received from this CFS may result in FSANZ arriving at a different conclusion.

The Office of Impact Analysis (OIA) agreed to exempt FSANZ from formal consultation RIS requirements for Proposal P1060, recognising consultation undertaken to date and FSANZ's statutory consultation processes meet exemption criteria given in the Guide (reference number: OIA24-08429).

FSANZ will review its assessment of costs and benefits in light of feedback received in response to this CFS and then prepare a Decision Regulation Impact Statement (DRIS). The DRIS will inform a final decision on whether to approve, amend or reject the draft variations proposed in this CFS. Before that final decision is made, the DRIS will be submitted to the OIA to confirm quality and adequacy of the DRIS's analysis, and to review the DRIS for compliance under the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies (the Guide; OIA, 2024).

**Consultation question 1:** Have all the major impacts to industry, consumers and government from the proposed options been identified in Table 1 of SD 4? Please provide evidence (where possible) to support the inclusion and magnitude of other impacts.

**Consultation question 2:** Do you have information to provide to assist FSANZ in quantifying the costs and benefits currently identified as unquantified in Table 2 of SD 4? Please provide data and evidence to support the inclusion of such information.

Consultation question 3: Do you agree with the estimated cost of the proposed

interventions as outlined in section 5 and Appendix A of SD 4? Please provide data or evidence to support the inclusion of alternative estimates.

**Consultation question 4:** Do you have any information to assist with estimating the proportion of egg producers already undertaking the proposed interventions discussed in section 5 of SD 4? Please provide data or evidence to support the inclusion of alternative estimates.

#### 2.5.1.2 Other measures

Paragraph 59(2)(b) requires FSANZ to have regard to whether other measures (available to FSANZ or not) would be more cost-effective. We reviewed existing measures as part of option 1 (status quo) and consider the incomplete uptake of existing industry schemes and inconsistent jurisdictional regulatory approaches have created gaps in egg food safety management and national inconsistency in application of requirements in the egg industry. Existing measures do not adequately address the food safety issues.

FSANZ's preliminary assessment is there are no other more cost-effective measures than the amendment proposed by the draft variation, noting the findings of the risk assessment that existing regulatory and non-regulatory measures do not adequately protect consumers of eggs and egg product and public health and safety.

#### 2.5.1.3 Any relevant New Zealand standards

Chapter 4 Primary Production and Processing Standards do not apply in New Zealand. No other standards have been identified.

#### 2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

#### 2.5.2 **Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### 2.5.2.1 Protection of public health and safety

FSANZ has assessed the available evidence and information on food safety risks, and risk management measures currently applying to eggs and egg product. A major foodborne illness outbreak associated with SE and eggs occurred between 2018 and 2019, which resulted in over 245 cases of illness. This SE was capable of vertical transmission and had not been considered in the 2011 development of Standard 4.2.5, as SE capable of vertical transmission was not considered to be present in Australia at that time.

The risk profile for eggs and egg product has now changed and FSANZ has assessed that current egg food safety risk management measures in the Code do not take this into account. Changes to the risk environment for eggs and egg product are:

- Vertically-transmitted SE has caused foodborne illness in Australia. SE is of high concern as it can colonise the ovaries of layer hens and contaminate internal parts of eggs during development.
- ST has been found in the internal contents of intact eggs at retail at much higher prevalence than was previously known.

As a result, the Code and in particular Standard 4.2.5 does not manage the transmission of SE from the hen into the egg during formation. A new risk assessment of eggs and egg product was required, which informed consideration of changes to current egg food safety risk management measures to adequately protect public health and safety. Amendments are proposed to protect public health and safety as current requirements are not adequate to manage SE risks in eggs.

## 2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

FSANZ has not identified any issues relevant to this objective.

#### 2.5.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any issues relevant to this objective.

#### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

 the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ used the best available scientific information to assess this proposal, including for the microbiological risk assessment to consider risk factors at different stages of egg production, processing and sale. The consideration of costs and benefits provided additional analysis and guided the selection of risk management measures for inclusion in the proposed draft variation. These documents and the other SDs formed the primary basis for risk identification and management for this proposal.

the promotion of consistency between domestic and international food standards

Internationally, there is considerable variation in legislation applicable to production and processing of eggs. We have considered international and domestic standards, including requirements for import and export of eggs in our assessment. Refer to SD3 Current food safety measures for eggs.

the desirability of an efficient and internationally competitive food industry

FSANZ has had regard to public health and safety risks associated with eggs and impacts these can have on the domestic and international food industry.

FSANZ does not anticipate any significant impact on efficiency and international competition from introduction of any proposed regulatory measure.

• the promotion of fair trading in food

Introduction of nationally consistent food safety requirements can encourage a more level playing field for all egg producers in the market place.

• any written policy guidelines formulated by the Forum on Food Regulation

The Ministerial Council Overarching Policy Guideline on Primary Production and Processing Standards.<sup>4</sup> contains high-order principles that must be considered when such a standard is reviewed and/or developed. These principles state that standards will be outcomes based and address food safety across the entire food chain where appropriate. Standards will also ensure the cost of the overall system is proportionate with the assessed level of risk. They will provide a regulatory framework that only applies to the extent justified by market failure. We have considered these guidelines in our assessment.

## 3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect 12 months from date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

## 4 References

Australian Eggs, (2024a), Australian egg industry overview, accessed 3 December 2024

Australian Eggs, (2024b), Annual Report 2024

Jeswanth DK, *Egg farming in Australia*, IBIS World Industry report A0172 March 2022: 7, 9, 11-12.

Glass K, McLure A, Bourke S, Cribb D, Kirk MA, Lancsar E, *The annual cost of foodborne illness in Australia. Final report to Food Standards Australia New Zealand* 2022.

Codex Alimentarius Commission (1976), Code of hygienic practice for eggs and egg products, CAC/RCP 15.

NSW FA (New South Wales Food Authority) (2022) *Egg food safety scheme: Periodic review of the risk assessment.* NSW Food Authority. Accessed November 5, 2024 from <a href="https://www.foodauthority.nsw.gov.au/sites/default/files/">https://www.foodauthority.nsw.gov.au/sites/default/files/</a> Documents/scienceandtechnical/egg food safety scheme.pdf

Scott AB, Singh M, Groves P, Hernandez-Jover M, Barnes B, Glass K, Moloney B, Black A, Toribio JA (2018) Biosecurity practices on Australian commercial layer and meat chicken farms: Performance and perceptions of farmers. PLoS One. 13(4):e0195582. doi: 10.1371/journal.pone.0195582. PMID: 29668707.

Scott P, Turner A, Bibby S, Chamings A (2009) *Structure and dynamics of Australia's commercial poultry and ratite industries*, Report prepared for the Department of Agriculture, Fisheries and Forestry, published June 2005, updated December 2009

#### **Attachments**

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

<sup>&</sup>lt;sup>4</sup> Available at https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies

# Attachment A – Draft variation to the Australia New Zealand Food Standards Code



## Food Standards (Proposal P1060 – Egg food safety and primary production requirements) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

#### Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

#### 1 Name

This instrument is the Food Standards (Proposal P1060 – Egg food safety and primary production requirements) Variation.

#### 2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies Standards in the Australia New Zealand Food Standards Code.

#### 3 Commencement

The variation commences on the date that is 12 months after the date of gazettal.

#### **Schedule**

#### Standard 4.2.5—Primary production and processing standard for eggs and egg product

#### [1] Table of Provisions

Repeal the Table, substitute:

#### **Table of Provisions**

Division 1 – Preliminary 1 Application 2 Interpretation

#### Division 2 – Primary production of eggs

- 3 General food safety management
- 4 Inputs
- 5 Waste disposal
- 6 Health and hygiene of personnel and visitors
- 6A Animals and pests
- 7 Skills and knowledge
- 8 Design, construction and maintenance of premises, equipment and transportation vehicles
- 8A Range area
- 9 Bird health
- 9A Environmental sampling to monitor bird health
- 9B Storage and transport of collected eggs and egg product
- 10 Traceability
- 11 Sale or supply

#### Division 3 – Processing of eggs and egg pulp

- 12 Application
- 13 General food safety management
- 14 Receiving unacceptable eggs
- 15 Inputs
- 15A Cleaning of eggs
- 16 Waste disposal
- 17 Skills and knowledge
- Health and hygiene of personnel and visitors
- 18A Animals and pests
- 19 Design, construction and maintenance of premises, equipment and transportation vehicles
- 20 Traceability
- 21 Processing egg product
- 22 Storing and transport of eggs
- 22A Storage and transport of egg product
- 23 Sale or supply

#### [2] Clause 1

Repeal the clause, substitute:

#### 1 Application

This Standard does not apply to any of the following -

- (a) the retail sale of eggs other than the direct sale of eggs by an egg producer to the public:
- (b) catering activities other than the direct sale of eggs by an egg producer to a caterer.

#### [3] Subclause 2(2)

Insert in alphabetical order:

broken egg means an egg that has both --

- (a) a shell with one or more cracks; and
- (b) contents that are leaking at the time of collection.

**flock** means all the birds that share a contained area (such as a range area or a poultry house).

poultry house means any of the following -

- (a) the fixed or mobile housing where birds roost;
- (b) the ground that is directly beneath fixed or mobile housing where birds roost and where bird faeces accumulate.

range area means an outside area that a flock has access to for roaming and foraging.

#### [4] Subclause 2(2) (definition of *cracked egg*)

Repeal the definition, substitute:

cracked egg means an egg that has -

- (a) a shell with one or more cracks that are:
  - (i) visible; or
  - (ii) visible by candling or another equivalent method; and
- (b) an intact membrane at the time of collection.

#### [5] Subclause 2(2) (definition of egg processor)

Repeal the definition, substitute:

**egg processor** means a business, enterprise or activity that includes any of the following activities in relation to eggs –

- (a) assessing for cracks;
- (b) candling;
- (c) cleaning;
- (d) grading;
- (e) oiling;
- (f) packing;
- (g) processing in accordance with clause 21 of this Standard;
- (h) pulping;
- (i) separating;

- (j) storing un-marked eggs;
- (k) transporting un-marked eggs.

#### [6] Subclause 2(2) (definition of food safety management statement)

Repeal the definition.

## [7] Subclause 2(2) (Editorial note to the definition of food safety management statement)

Repeal the Editorial note.

#### [8] Clause 3

Repeal the clause, substitute:

#### 3 General food safety management

An egg producer must comply with the general food safety management requirements.

Note: The general food safety management requirements are set out in Division 2 of Standard 4.1.1.

#### [9] Clause 4

Omit the words 'take all reasonable measures to'.

#### [10] Clause 4 (Editorial note)

Repeal the Editorial note, substitute:

**Note 1** Clause 2(1) provides that the definitions in Chapter 3 apply to this Standard, and the terms 'unsafe' and 'unsuitable' are defined in Standard 3.1.1.

**Note 2** The term 'inputs' is defined in Standard 4.1.1 to include 'any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity' (which, in this case, is egg production).

#### [11] Clause 6 (title)

Omit 'requirements', substitute 'of personnel and visitors'.

#### [12] Subclause 6(2)

Omit the words 'take all reasonable measures to'.

#### [13] After clause 6

Insert:

#### 6A Animals and pests

- (1) An egg producer must ensure the presence of any animals, vermin and pests in any of the following does not make eggs unsafe or unsuitable
  - (a) equipment;
  - (b) grading floors;
  - (c) premises;
  - (d) range areas;
  - (e) sheds;
  - (f) transportation vehicles.
- (2) An egg producer must ensure that any animal used to guard or protect a flock does not make eggs unsafe or unsuitable.

#### [14] After clause 8

Insert:

#### 8A Range area

An egg producer must ensure that a range area does not make eggs unsafe or unsuitable.

#### [15] Clause 9

Omit "the bird is', substitute 'the birds are'.

#### [16] After clause 9

Insert:

#### 9A Environmental sampling to monitor bird health

An egg producer must -

- (a) take samples from each poultry house used by a flock; and
- (b) test those samples for presence of Salmonella Enteritidis.

#### 9B Storage and transport of collected eggs and egg product

An egg producer who transports or stores eggs must ensure that the time and temperature conditions under which those activities are undertaken do not make eggs unsafe or unsuitable.

#### [17] Subclause 10(1)

Repeal the subclause, substitute:

(1) An egg producer must not sell eggs unless each individual egg is uniquely marked to identify the egg producer.

#### [18] Subclause 10(4)

Repeal the subclause, substitute:

- (4) In addition to subclauses (1) and (2), an egg producer must keep and maintain a record of each of the following
  - (a) the number of eggs collected on each date of collection;
  - (b) the flock from which the eggs were collected;
  - (c) the number or amount of collected eggs diverted to waste or to egg product;
  - (d) the name and contact details of each person to whom eggs or egg pulp are sold or supplied (other than by direct sale of eggs to the public);
  - (e) the date of each sale or supply referred to in paragraph (d);
  - (f) the number of eggs sold or supplied to each person referred to in paragraph (d) on each date referred to in paragraph (e).

#### [19] Clause 11

Repeal the clause (including the Editorial note), substitute:

#### 11 Sale or supply

- (1) An egg producer must not sell or supply broken eggs for human consumption.
- (2) An egg producer must not sell or supply eggs or egg pulp for human consumption that the producer knows, ought to reasonably know or to reasonably suspect, are unacceptable.
- (3) Subclause (2) does not apply to an egg producer that sells or supplies unacceptable eggs to an egg processor for processing in accordance with clause 21.

Note 'Supply' is defined in Standard 4.1.1 as including intra company transfers of product.

#### [20] Clause 12

Omit 'clause 22', substitute 'clauses 22 and 22A'.

#### [21] Clause 13

Repeal the clause, substitute:

#### 13 General food safety management

An egg processor must comply with the general food safety management requirements.

Note The general food safety management requirements are set out in Division 2 of Standard 4.1.1

#### [22] Clause 15

Repeal the clause (including the Editorial note), substitute:

#### 15 Inputs

- (1) An egg processor must ensure inputs do not make eggs or egg product unsafe or unsuitable.
- (2) For the purposes of subclause (1), *inputs* includes any of the following
  - (a) chemicals;
  - (b) packaging;
  - (c) salt;
  - (d) sugar;
  - (e) water (including recycled water);
  - (f) other inputs used in, or in connection with egg processing.

**Note** The term 'inputs' is defined in Standard 4.1.1 to also include 'any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity'.

#### 15A Cleaning of eggs

An egg processor who cleans eggs must ensure that the cleaning does not make the eggs unsafe or unsuitable.

#### [23] Clause 18 (title)

Omit 'requirements', substitute 'of personnel and visitors'.

#### [24] Subclause 18(2)

Omit the words 'take all reasonable measures to'.

#### [25] After clause 18

Insert:

#### 18A Animals and pests

An egg processor must ensure that the presence of any animals, vermin and pests in premises, equipment and transportation vehicles, does not make eggs unsafe or unsuitable.

#### [26] Clause 20

Repeal the clause, substitute:

#### 20 Traceability

- (1) An egg processor must not sell eggs unless each individual egg is uniquely marked to identify the egg producer who produced that egg.
- (2) An egg processor must not sell or supply egg product unless each package or container containing the egg product is marked with both of the following
  - (a) the date on which it was made; and
  - (b) the unique identification of the egg processor.
- (3) In addition to subclauses (1) and (2), an egg processor must keep and maintain a record of each of the following
  - (a) the name and contact details of each person from whom the egg processor received eggs for processing;
  - (b) the name and contact details of each person from whom the egg processor received egg pulp for processing;
  - (c) the number of eggs received from each person referred to in paragraph (a) and the date on which those eggs were received;
  - (d) the amount of egg pulp received from each person referred to in paragraph (b) and the date on which the egg pulp were received;
  - (e) the name and contact details of each person to whom the egg processor sold or supplied eggs or egg pulp (other than by direct sale to the public);
  - (f) the date of each sale or supply referred to in paragraph (e);
  - (g) the number of eggs and amount of egg pulp sold or supplied to each person referred to in paragraph (e) on each date referred to in paragraph (f).

#### [27] Clause 22

Repeal the clause, substitute:

#### 22 Storage and transport of eggs

An egg processor must ensure that eggs are stored and transported under time and temperature conditions that will not make the eggs unsafe or unsuitable.

#### 22A Storage and transport of egg product

- (1) An egg processor must ensure that egg product is stored and transported under time and temperature conditions that will
  - (a) not make the egg product unsafe or unsuitable; and
  - (b) control the growth of pathogenic micro-organisms.
- (2) For the purposes of subclause (1), **egg product** includes egg product that is unprocessed and egg product that has been processed under clause 21.

#### Standard 2.2.2—Eggs and egg products

#### [28] Section 2.2.2—4

Repeal the section, substitute:

#### 2.2.2—4 Traceability

Eggs for retail sale or for sale to a \*caterer must be individually marked to identify the egg producer who produced the egg.

### **Attachment B – Draft explanatory statement**

#### DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

## Food Standards (Proposal P1060 – Egg food safety and primary production requirements) Variation

#### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1060 to consider amendments to the Code to further strengthen food safety management of eggs and egg product during primary production and processing. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared a draft variation – the Food Standards (Proposal P1060 – Egg food safety and primary production requirements) Variation (the draft variation).

#### 2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers' Meeting (FMM). The FMM is established under the Food Regulation

Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied, and enforced by these jurisdictions' regulators as part of those food laws.

#### 3. Purpose

The Authority prepared the draft variation to amend the Code to clarify and improve the requirements relating to food safety management of eggs and egg product during primary production and processing, and when sold by retail sale or to caterers and, thereby, better protect public health and safety.

#### 4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

#### 5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1060 will include one round of public consultation following an assessment, targeted communication with key stakeholders, and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

A Standards Development Advisory Group (SDAG) was established with representatives from the industry sector, and the relevant State, Territory and federal government agencies, to provide ongoing advice to the Authority throughout the standard amendment process. The SDAG contributed a broad spectrum of knowledge and expertise covering industry, government and research.

An Egg Implementation Working Group comprised of State, Territory and federal government regulators was established by the Implementation Sub-committee for Food Regulation to work with the Authority to ensure a nationally consistent approach to implementation of the proposed amendments to the Code.

The Office of Impact Analysis agreed to exempt FSANZ from formal consultation Regulation Impact Statement requirements for Proposal P1060, recognising consultation undertaken to date and FSANZ's statutory consultation processes meet exemption criteria given in the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies (reference number: OIA24-08429).

#### 6. Statement of compatibility with human rights

If approved, the draft variation would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

#### 7. Variation

References to 'the variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards* 

(Proposal P1060 – Egg food safety and primary production requirements) Variation.

**Clause 2** of the variation provides that the Code is amended by the Schedule to the variation.

**Clause 3** of the variation provides that the variation commences on the date that is 12 months after the date of gazettal. This means food businesses would have 12 months to make the necessary changes to their business operations to be in a position to comply with the proposed new requirements in the draft variation.

#### Schedule to the variation

Standard 4.2.5 Primary production and processing standard for eggs and egg product

Items [1] – [27] of the Schedule to the variation would amend Standard 4.2.5.

Standard 4.2.5 sets food safety requirements for the primary production and processing of eggs, egg pulp and other egg product for human consumption. Standard 4.2.5 applies in Australia only.

**Item [1]** of the Schedule would repeal the Table of Provisions in Standard 4.2.5 and substitute it with an amended Table of Provisions.

The amended Table includes amended and new headings in Standard 4.2.5 as a consequence of other amendments proposed to the Standard (see items below). **Item [2]** of the Schedule would repeal clause 1 of Standard 4.2.5 and substitute it with an amended clause 1.

Existing clause 1 provides that Standard 4.2.5 does not apply to retail sale or catering activities other than the direct sale of eggs to the public by an egg producer.

Amended clause 1 would provide that Standard 4.2.5 does not apply to any of the following:

- the retail sale of eggs other than the direct sale of eggs by an egg producer to the public;
- catering activities other than the direct sale of eggs by an egg producer to a caterer.

The intent of this amendment to clarify the operation of clause 1 and that Standard 4.2.5 applies to the direct sale of eggs by an egg producer to a caterer.

**Item [3]** of the Schedule would insert the definitions for each of the following terms into subclause 2(2) of Standard 4.2.5:

- 'broken egg',
- 'flock',
- 'poultry house',
- 'range area'.

Subclause 2(2) provides definitions of certain terms for the purposes of Standard 4.2.5.

This amendment will mean that, for the purposes of Standard 4.2.5:

- A 'broken egg' is an egg that meets both of the following criteria: it has a shell with one or more cracks; and its contents of the egg are or were leaking at the time of its

collection. The intent of this amendment and new definition is to make clear that the requirements imposed by Standard 4.2.5 in relation to a 'broken egg' apply only to eggs meeting both of these two criteria. These requirements do not apply, for example, to a cracked egg that has been collected and then handled, and at some point during the handling and grading, the egg membrane ruptures and the egg contents then leak.

- A 'flock' means all the birds that share a contained area (such as a range area or a poultry house). The intent of this amendment and new definition is to clarify that a flock consists of all the layer hens that inter-mingle and have direct contact with one another, whether that is due to the sharing of the same range area or where they roost overnight. This is important for requirements imposed by Standard 4.2.5 in relation to environmental sampling and the monitoring of bird health as these birds can become infected and spread disease through direct contact with each other.
- A 'poultry house' means any of the following: the fixed or mobile housing where birds roost; and/or the ground directly beneath poultry houses where birds roost and where the bird faeces fall and accumulate. Standard 4.2.5 will impose a requirement to undertake environmental sampling in each area that is a 'poultry house'. The amendment and new definition make clear such sampling must also include the ground beneath the housing where birds roost and where the bird faeces fall and accumulate on the ground.
- A 'range area' means an outside area that a flock can access for roaming and foraging. Standard 4.2.5 will impose a requirement that egg producers ensure that range areas do not make eggs unsafe or unsuitable (as defined in Standard 3.1.1). That is, by managing range areas to prevent hazards that could infect or contaminate the birds and eggs they produce.

**Item [4]** of the Schedule would repeal the existing definition for a 'cracked egg' in subclause 2(2) and substituting it with an amended definition for 'cracked egg'.

The existing definition of 'cracked egg' states that the term means an egg which has a cracked shell which is visible, or visible by candling or other equivalent methods, and includes a broken egg.

The amended definition of 'cracked egg' provides that the term means an egg that has:

- a shell with one or more cracks that are:
  - visible; or
  - visible by candling or another equivalent method; and
- an intact membrane at the time of collection.

The purpose of this amendment is to clarify that a cracked egg is not a broken egg for the purposes of Standard 4.2.5. This is important as cracked eggs are 'unacceptable eggs' for the purposes of the Standard. The Standard permits 'unacceptable eggs' that have been processed in accordance with clause 21 to be sold as food (see subclause 23(2)). In contrast, 'broken eggs' must not be sold for food and must be diverted away from the human food supply chain.

**Item [5]** of the Schedule would repeal the definition for 'egg processor' in subclause 2(2) and substitute it with an amended definition for 'egg processor'.

The existing definition of 'egg processor' provides that the term means a business, enterprise

or activity that involves:

- pulping, separating, grading, packing, washing, candling, assessing for cracks or oiling eggs received from an egg producer; or
- storing or transporting eggs in association with any of the activities listed in the first bullet point; or
- processing egg product under clause 21 of Standard 4.2.5.

The amended definition of 'egg processor' provides that the term means a business, enterprise or activity that includes any of the following activities in relation to eggs:

- assessing for cracks;
- candling;
- cleaning;
- grading;
- oiling;
- packing;
- processing in accordance with clause 21 of Standard 4.2.5;
- pulping;
- separating;
- storing un-marked eggs;
- transporting un-marked eggs.

The amended definition is not intended to capture a business that only receives graded, marked, retail-ready eggs, as this is a 'food business' for the purposes of Chapter 3 *not Chapter 4* of the Code.

**Item [6]** of the Schedule would repeal the definition of 'food safety management statement' in subclause 2(2).

This definition would no longer be required as a consequence of the amendment to clause 3 proposed in **item [8]** below.

**Item [7]** of the Schedule to the variation would repeal the Editorial note to the definition of 'food safety management statement' in subclause 2(2).

This Editorial Note would no longer be required as a consequence of the amendment proposed in **item [6]** above, which would repeal definition of 'food safety management statement'.

**Item [8]** of the Schedule would repeal clause 3 and substitute it with an amended clause 3 and an accompanying Note.

Existing clause 3 sets out the following general food safety management requirements, with which egg producers must comply, i.e., an egg producer must:

- systematically examine all of its production operations to identify potential hazards and implement control measures to address those hazards,
- have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented, and
- operate according to a food safety management statement that sets out how the requirements of this Division are to be or are being complied with.

Amended clause 3 requires that an egg producer must comply with the general food safety management requirements.

The Note to amended clause 3 explains to the reader that the general food safety management requirements are set out in Division 2 of Standard 4.1.1. Division 2 of that Standard applies where Standards in Chapter 4 of the Code provide that a person or business must comply with the general food safety management requirements (subclause 4(1) of Standard 4.1.1).

**Item [9]** of the Schedule would omit the words 'take all reasonable measures to' from clause 4

The amended clause 4 would impose a requirement that an egg producer must ensure that inputs do not make the eggs unsafe or unsuitable.

The purpose of the amendment is to take account of the provisions of the State and Territory Food Acts which apply and give effect to the Code, including Standard 4.2.5. The Food Acts generally provide that non-compliance with a requirement imposed on a person by a provision of the Code is an offence. However, the Food Act also provide it shall not be an offence if the person took all reasonable precautions and exercised all due diligence to prevent non-compliance with the relevant Code requirement. See, for example, section 26 of the *Food Act 2003* (NSW). These Food Act provisions mean that the 'take all reasonable measures' proviso in clause 4 is not required.

**Item [10]** of the Schedule would repeal the Editorial note to clause 4 and substitute that note with two new Notes.

New Note 1 explains to the reader that subclause 2(1) of Standard 4.2.5 provides that the definitions in Chapter 3 apply to this Standard, and the terms 'unsafe' and 'unsuitable' are defined in Standard 3.1.1 of the Code.

New Note 2 explains to the reader that the term 'inputs' is defined in Standard 4.1.1 of the Code to include 'any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity' (which, in this case, is egg production). Definitions in Standard 4.1.1 apply to all Standards in Chapter 4 of the Code – unless a contrary intention is expressed (see clause 1 of Standard 4.1.1).

**Item [11]** of the Schedule would omit the word 'requirements' from the title to clause 6 and substitute that word with the words 'of personnel and visitors'.

If approved, the effect of this proposed amendment would be that the title to clause 6 would be 'Health and hygiene of personnel and visitors'.

The amended title would be consistent with titles of clauses dealing with the same requirement in other Standards in Chapter 4 of the Code.

**Item [12]** of the Schedule would omit the words 'take all reasonable measures to' from subclause 6(2).

The amended subclause would impose a requirement on an egg producer to ensure that personnel and visitors exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.

The purpose of the amendment is to take account of the provisions of the State and Territory Food Acts which apply and give effect to the Code, including Standard 4.2.5. The Food Acts generally provide that non-compliance with a requirement imposed on a person by a provision of the Code is an offence. However, the Food Act also provide it shall not be an offence if the person took all reasonable precautions and exercised all due diligence to prevent non-compliance with the relevant Code requirement. See, for example, section 26 of the *Food Act 2003* (NSW). These Food Act provisions mean that the 'take all reasonable measures' proviso in subclause 6(2) is not required.

**Item [13]** of the Schedule would insert new clause 6A into Standard 4.2.5.

The proposed new clause would be inserted after clause 6.

Proposed new clause 6A would require an egg producer to ensure the following:

- the presence of any animals, vermin and pests in any of the following does not make eggs unsafe or unsuitable:
  - equipment;
  - grading floors;
  - premises;
  - range areas;
  - sheds;
  - transportation vehicles; and
- any animal used to guard or protect a flock does not make eggs unsafe or unsuitable.

For the definitions of 'flock' and 'range area' – see item [3] above.

Clause 2 of Standard 4.2.5 defines the term 'premises' to mean egg production premises or processing premises.

As stated in **item [10]** above, clause 2(1) of Standard 4.2.5 provides that the definitions in Chapter 3 apply to this Standard (unless a contrary intention appears and subject to Standard 4.1.1). Consequently, the definitions in Standard 3.1.1 for 'equipment' and 'pests' would apply to proposed new section 6A.

Animals, vermin and pests are known vectors of *Salmonella* spp and their presence may contaminate eggs. New clause 6A will in effect require egg producers to have controls in place to manage their presence and the risk of contamination.

The clause recognises that egg producers may rely on guard animals to protect their flock. In this case, the egg producer must ensure that use of the animal does not make eggs unsafe or unsuitable.

**Item [14]** of the Schedule would insert new clause 8A into Standard 4.2.5.

The proposed new clause would be inserted after clause 8.

Proposed new clause 8A would require egg producers to ensure that a range area does not make eggs unsafe or unsuitable.

New clause 8A does not prescribe how the egg producer must ensure the above and meet

this requirement. This lack of prescription provides egg producers with flexibility in how they manage food safety risks associated with the range areas and when required to respond to issues that may arise such as local flock infections with *Salmonella* Enteritidis. The requirement will in effect require egg producers to consider risk factors such as location (and adjacent land activities), design (such as drainage, restriction of access), maintenance (for example, removal or control of vermin attractants such as spilt feed) and operation (such as when layer hens can access the area following adverse weather).

For the definition of 'range area' – see item [3] above.

As stated in **item [10]** above, clause 2(1) of Standard 4.2.5 provides that the definitions in Chapter 3 apply to this Standard (unless a contrary intention appears and subject to Standard 4.1.1) - the terms 'unsafe' and 'unsuitable' are defined in Standard 3.1.1 of the Code.

**Item [15]** of the Schedule to the variation would omit the words 'the bird is' from clause 9 and substitute these with the words 'the birds are'.

The amended clause 9 would provide that an egg producer must not obtain eggs for human consumption from birds if the proprietor, supervisor or employee of the egg producer knows, ought to reasonably know or to reasonably suspect, the birds are affected by disease or a condition that makes the eggs unsafe or unsuitable.

The ordinary meaning of 'condition' would apply, which includes 'a state of health'.

The aim of this proposed amendment is to correct the grammar of the clause.

Item [16] of the Schedule would insert new clauses 9A and 9B into Standard 4.2.5.

The new clauses will be inserted after existing clause 9.

New clause 9A imposes requirements on egg producers to undertake environmental sampling to monitor bird health. In particular, new clause 9A requires an egg producer to:

- take samples from each poultry house used by a flock; and
- test those samples for presence of Salmonella Enteritidis.

The proposed requirement focussed on *Salmonella* Enteritidis given its ability to infect the internal organs of birds and be deposited within an egg as the egg is formed.

New clause 9B would require egg producers who transport or store collected eggs to ensure the time and temperature conditions under which transport and storage are undertaken do not make eggs unsafe or unsuitable.

New clause 9B does not prescribe how the egg producer must ensure the above and meet this requirement. Nor does it prescribe a temperature or a time for storage and transport. The requirement will in effect require egg producers to be aware of and monitor the temperatures that eggs they transport and store are exposed to and the amount of time that the eggs spend in storage or being transported at such temperatures. This lack of prescription provides egg producers with flexibility in how they manage food safety risks associated with the transport and storage of eggs. It allows, when required, for response to issues that may arise such as local flock infections with *Salmonella* Enteritidis or periods of high temperatures requiring a different management approach.

Item [17] of the Schedule to the variation would repeal subclause 10(1) in Standard 4.2.5

and substitute it with an amended subclause 10(1).

Clause 10 sets out traceability requirements with which egg producers must comply.

Existing subclause 10(1) provides that an egg producer must not sell eggs unless each individual egg is marked with the producer's unique identification.

Amended subclause 10(1) provides that an egg producer must not sell eggs unless each individual egg is uniquely marked to identify the egg producer.

The intent of this proposed amendment is to clarify the requirement imposed by subclause 10(1), align the wording with that used in amended clause 20 (1), strengthen traceability of eggs and facilitate rapid traceback to the egg producer where foodborne illness has been linked to an egg.

**Item [18]** of the Schedule to the variation would repeal subclause 10(4) in Standard 4.2.5 and substitute it with an amended subclause 10(4).

As explained above, clause 10 sets out traceability requirements with which egg producers must comply. Existing subclause 10(4) requires an egg producer to have a system to identify to whom eggs or egg pulp is sold or supplied.

Amended subclause 10(4) provides that an egg producer must keep and maintain a record of each of the following:

- (a) the number of eggs collected on each date of collection;
- (b) the flock from which the eggs were collected;
- (c) the number or amount of collected eggs diverted to waste or to egg product;
- (d) the name and contact details of each person to whom eggs or egg pulp are sold or supplied (other than by direct sale of eggs to the public);
- (e) the date of each sale or supply referred to in paragraph (d);
- (f) the number of eggs sold or supplied to each person referred to in paragraph (d) on each date referred to in paragraph (e).

The purpose of this proposed amendment is to ensure the egg producer's traceability system contains records for each of these points to enable the system to trace forward and trace back effectively and quickly during an incident.

**Item [19]** of the Schedule would repeal clause 11 of Standard 4.2.5 (including the Editorial note) and substitute it with an amended clause 11 (including a new Note).

Existing clause 11 provides that an egg producer must not sell or supply eggs or egg pulp for human consumption if the egg producer knows, ought to reasonably know or to reasonably suspect, that the eggs are unacceptable. However, this requirement does not apply where the egg producer sells or supplies unacceptable eggs to an egg processor for processing in accordance with clause 21. Clause 2 of Standard 4.2.5 defines what constitutes an 'unacceptable egg' for the purposes of clause 11.

The Editorial note for clause 11 explains that 'supply' is defined in Standard 4.1.1 of the Code as including intra company transfers of product.

Amended clause 11 maintains the existing requirement for unacceptable eggs and egg pulp, but introduces a new requirement for broken eggs. Amended subclauses 11(1) and (2) provide that an egg producer must not sell or supply each of the following respectively:

- broken eggs for human consumption;
- eggs or egg pulp for human consumption that the producer knows, ought to reasonably know or to reasonably suspect, are unacceptable.

As with existing subclause 11(2), amended subclause 11(3) provides that subclause (2) does not apply to an egg producer that sells or supplies unacceptable eggs to an egg processor for processing in accordance with clause 21.

The Note to amended clause 11 also explains to the reader that 'supply' is defined in Standard 4.1.1 as including intra company transfers of product.

For the definition of 'broken egg' - see item [3] above.

The intent of this proposed amendment is to prohibit the sale or supply of broken eggs for human consumption.

**Item [20]** of the Schedule would omit the reference to 'clause 22' in clause 12 of Standard 4.2.5 and substitute that reference with a reference to 'clauses 22 and 22A'.

Existing clause 22 sets out a requirement for the storage or transport of processed egg product with which egg processors must comply.

Clause 22 would be amended by item [27] of the Schedule to the variation below.

New clause 22A would also be inserted by item [27].

The intent of the proposed amendment in **item [20]** is that the requirements contained within Standards 3.2.2 and 3.2.3 would apply to the storage and transport requirements in both clause 22 (as amended) and new clause 22A – as a consequence of the amendments proposed in **item [27]** (see below).

**Item [21]** of the Schedule would repeal clause 13 of Standard 4.2.5 and substitute it with an amended clause 13.

Existing clause 13 sets out general food safety management requirements for egg processors - it provides that an egg processor must:

- systematically examine all of its processing operations to identify potential hazards and implement control measures to address those hazards;
- have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented; and
- operate according to a food safety management statement that sets out how the requirements of Division 3 of the Standard are to be or are being complied with.

Amended clause 13 simply provides that an egg processor must comply with the general food safety management requirements.

The Note to this clause explains to the reader that the general food safety management requirements are set out in Division 2 of Standard 4.1.1.

**Item [22]** of the Schedule would repeal clause 15 of Standard 4.2.5 (including the Editorial note) and substitute it with an amended clause 15 (with a new Note) and a new clause 15A.

Existing clause 15 requires an egg producer to take all reasonable measures to ensure inputs do not make the eggs or egg product unsafe or unsuitable. The requirement in effect requires egg producers to consider risk factors associated with assessment, selection, storage, handling and use of inputs.

The Editorial note to this clause refers the reader to Standard 4.1.1 for the definition of 'inputs'.

Amended clause 15 contains two subclauses.

Subclause 15(1) requires an egg producer to ensure that inputs do not make eggs or egg product unsafe or unsuitable. There is no longer a reference to 'take all reasonable measures'.

The purpose of the amendment is to take account of the provisions of the State and Territory Food Acts which apply and give effect to the Code, including Standard 4.2.5. The Food Acts generally provide that non-compliance with a requirement imposed on a person by a provision of the Code is an offence. However, the Food Act also provide it shall not be an offence if the person took all reasonable precautions and exercised all due diligence to prevent non-compliance with the relevant Code requirement. See, for example, section 26 of the *Food Act 2003* (NSW). These Food Act provisions mean the 'take all reasonable measures' proviso in subclause 15(1) is not required.

Subclause 15(2) provides that for the purposes of subclause (1), 'inputs' includes any of the following:

- chemicals:
- packaging;
- salt;
- sugar;
- water (including recycled water);
- other inputs used in, or in connection with egg processing.

The Note to amended clause 15 explains that the term 'inputs' is defined in Standard 4.1.1 of the Code to also include 'any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity'.

These definitions of 'input' are inclusive.

The purpose of the amendment is to clarify what constitutes 'an input' for the purposes of the requirement to ensure that inputs do not make eggs or egg product unsafe or unsuitable.

New clause 15A sets out a requirement for the cleaning of eggs with which egg processors cleaning eggs must comply. In particular, new clause 15A provides that an egg processor who cleans eggs must ensure that the cleaning does not make the eggs unsafe or unsuitable. The new clause does not prescribe how the egg processor must ensure the latter and meet this requirement. This lack of prescription provides egg processors with flexibility in how they manage the food safety risks associated with cleaning eggs.

**Item [23]** of the Schedule would omit the word 'requirements' from the title of clause 18 of Standard 4.2.5 and substitute that word with the words 'of personnel and visitors'.

The amended title of clause 18 would be 'Health and hygiene of personnel and visitors'.

The intent of this proposed amendment is to align the title for this clause with other similar clauses in recent Standards in Chapter 4 of the Code.

**Item [24]** of the Schedule would omit the words 'take all reasonable measures to' from clause 18 of Standard 4.2.5.

The amended clause would require an egg processor to ensure that personnel and visitors exercise personal hygiene and health practices that do not make the eggs or egg product unsafe or unsuitable.

The purpose of the amendment is to take account of the provisions of the State and Territory Food Acts which apply and give effect to the Code, including Standard 4.2.5. The Food Acts generally provide that non-compliance with a requirement imposed on a person by a provision of the Code is an offence. However, the Food Act also provide it shall not be an offence if the person took all reasonable precautions and exercised all due diligence to prevent non-compliance with the relevant Code requirement. See, for example, section 26 of the *Food Act 2003* (NSW). These Food Act provisions mean that the 'take all reasonable measures' proviso in clause 18 is not required.

Item [25] of the Schedule would insert a new clause 18A into Standard 4.2.5

The new clause would be inserted after existing clause 18.

New clause 18A would provide that an egg processor must ensure that the presence of any animals, vermin and pests in premises, equipment and transportation vehicles, does not make eggs unsafe or unsuitable.

Animals, vermin and pests are known vectors of *Salmonella* spp and their presence may contaminate eggs. New clause 18A will in effect require egg processors to have controls in place to manage their presence and the risk of contamination.

**Item [26]** of the Schedule would repeal clause 20 of Standard 4.2.5 and substitute it with an amended clause 20.

Existing clause 20 sets out traceability requirements with which egg processors must comply i.e., egg processors must:

- not sell eggs unless each individual egg is marked with the processor's or producer's unique identification; and
- not sell or supply egg product unless each package or container containing the egg product is marked with the processor's or the producer's unique identification; and
- have a system to identify:
  - from whom eggs were or egg pulp was received; and
  - to whom eggs or egg product was supplied.

Amended clause 20 would provide that egg processors must:

- not sell eggs unless each individual egg is uniquely marked to identify the egg producer who produced that egg (see also the amendment proposed to subclause 10(1) in **item [17]** above) (amended subclause 20(1)); and
- must not sell or supply egg product unless each package or container containing the egg product is marked with both of the following:

- the date on which it was made; and
- the unique identification of the egg processor (amended subclause 20(2)); and
- keep and maintain a record of each of the following:
  - (a) the name and contact details of each person from whom the egg processor received eggs for processing;
  - (b) the name and contact details of each person from whom the egg processor received egg pulp for processing;
  - (c) the number of eggs received from each person referred to in paragraph (a) and the date on which those eggs were received;
  - (d) the amount of egg pulp received from each person referred to in paragraph (b) and the date on which the egg pulp were received;
  - (e) the name and contact details of each person to whom the egg processor sold or supplied eggs or egg pulp (other than by direct sale to the public);
  - (f) the date of each sale or supply referred to in paragraph (e);
  - (g) the number of eggs and amount of egg pulp sold or supplied to each person referred to in paragraph (e) on each date referred to in paragraph (f) (amended subclause 20(3)).

The purpose of this proposed amendment is to ensure that the egg processor's traceability system contains records for each of the above in order to enable the system to trace forward and trace back effectively and quickly during an incident.

**Item [27]** of the Schedule would repeal clause 22 of Standard 4.2.5 and substitute it with an amended clause 22 and a new clause 22A.

Existing clause 22 provides that an egg processor must ensure that egg product processed under clause 21 is stored or transported under time and temperature conditions that control the growth of pathogenic micro-organisms. Clause 21 sets out requirements for processing egg product.

Amended clause 22 would be entitled 'Storage and transport of eggs' and provide that an egg processor must ensure that eggs are stored and transported under time and temperature conditions that will not make the eggs unsafe or unsuitable.

New clause 22A would be entitled 'Storage and transport of egg product' and contain two subclauses.

Subclause 22A(1) provides that an egg processor must ensure that egg product is stored and transported under time and temperature conditions that will:

- not make the egg product unsafe or unsuitable; and
- control the growth of pathogenic micro-organisms.

Subclause 22A(2) defines 'egg product' for the purposes of subclause 22A(1) i.e., 'egg product' includes egg product that is unprocessed and egg product that has been processed under clause 21.

This effectively means the egg processor would have to understand these products require temperature control to prevent the growth of pathogenic micro-organisms.

Amended clause 22 and new clause 22A do not prescribe how an egg processor must ensure the above and meet the requirements each imposes. Nor does each prescribe a temperature or a time for storage and transport. The requirement will in effect require egg processors to be aware of and monitor the temperatures that eggs or egg product are

exposed to during storage and transport and the amount of time that the eggs and egg product spend in storage or being transported at such temperatures. This lack of prescription provides egg processors with flexibility in how they manage food safety risks associated with the transport and storage of eggs and egg product. It provides flexibility to respond to issues that may arise such as periods of high temperatures, local flock infections with *Salmonella* Enteritidis, and the risk posed by growth of pathogenic micro-organisms during storage or transport of egg product.

Standard 2.2.2 – Eggs and egg products

**Item [28]** of the Schedule would amend Standard 2.2.2. Standard 2.2.2 applies in Australia only and imposes requirements for sale of eggs and egg product at retail sale and to caterers.

Item [28] would repeal section 2.2.2—4 and substitute it with an amended section 2.2.2—4.

Existing section 2.2.2—4 provides that eggs for retail sale or for sale to a caterer must be individually marked with the producer's or processor's unique identification.

Amended section 2.2.2—4 provides that eggs for retail sale or for sale to a caterer must be individually marked to identify the egg producer who produced the egg.

The term 'caterer' is defined in section 1.1.2—2 of the Code.

The intent of this proposed amendment is to align this requirement applying at retail sale and sale to caterers with the amended traceability requirements in clauses 10 and 20 in Standard 4.2.5 applying during egg production and processing (see **items [17]** and **[26]** above).