

23 September 2009 [16-09]

# DRAFT ASSESSMENT REPORT

# **PROPOSAL P301**

# PRIMARY PRODUCTION & PROCESSING STANDARD FOR EGGS & EGG PRODUCTS

# DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 November 2009 SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <a href="http://www.foodstandards.gov.au/standardsdevelopment/">http://www.foodstandards.gov.au/standardsdevelopment/</a>

# **Executive Summary**

#### **Purpose**

FSANZ has prepared this Draft Assessment Report<sup>1</sup> on Proposal P301 which includes a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

This Report is prepared in accordance with the principles of best practice regulation recommended by the Council of Australian Governments: identifying the problem that has prompted government action; the objectives of such action and possible options for achieving the objectives. A summary of the scientific Risk Assessment and an impact analysis of risk management options are included.

FSANZ invites public comment on this Draft Assessment Report and supporting documents. The Draft Assessment Report includes FSANZ's preferred option to vary the Code by introducing a primary production and processing Standard for Eggs and Egg Products and making consequential amendments to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Provisions; Standard 1.6.1 – Microbiological Limits for Foods; Standard 1.6.2 –Processing Requirements and Standard 2.2.2 – Eggs and Egg Products.

Proposal P301 is a pilot to trial a model for aligning implementation arrangements for food standards with the FSANZ food standards development processes. Therefore, public comment is also sought on the draft Compliance Plans for the implementation of the proposed draft variation to the Code attached to this Report.

#### Introduction

This Draft Assessment Report is the next assessment stage to improve the safety of shell eggs and egg products for sale in Australia, following outbreaks of illness attributed to these products. The work has progressed with the advice and guidance of a Standard Development Committee (SDC) comprising representatives from the egg industry, government regulators and consumers.

#### The Problem

The social and economic costs attributable to food-borne illness caused by eggs and egg products, is estimated to be \$AUD120.96m annually. This is not sufficiently addressed by current regulatory and self-regulatory measures.

In order to understand the significance of the problem, FSANZ undertook a scientific evaluation (Risk Assessment) of the public health and safety risks posed by microbiological and chemical hazards associated with the consumption of eggs and eggs products in Australia. It was concluded that although clean, whole shell eggs are rarely associated with food-borne illness in Australia, *Salmonella* in cracked and dirty eggs, and unpasteurised pulp, is the key hazard associated with public health risk.

<sup>1</sup> This Report has been prepared according to the FSANZ standard development process as was in force prior to 1 July 2007.

An analysis of the current regulatory and self-regulatory measures concluded that:

- There is currently no national regulatory framework to address this problem. Two States have introduced legislation and other States have recognised the problem and are preparing legislation.
- Chapter 3 has provisions addressing food handling, but there is a need to reduce the likelihood of cracked and dirty eggs reaching the public and food businesses. Cracked and dirty eggs are more likely to be contaminated with *Salmonella*.
- Industry measures focus on production and processing parameters and do not emphasise that cracked and dirty eggs must not be sold to the public.
- The uptake of self-regulatory measures (i.e. quality assurance programs, Codes of Practice) is voluntary and whilst larger producers and processors are accredited and comply, consultation with industry and the SDC has indicated that there are egg businesses who do not comply.
- The current requirements in the Code regarding availability of eggs and egg products, are inadequate as cracked and dirty eggs are reaching the market place and are being used in making manufactured products. This practice has been responsible for outbreaks of food-borne illness.
- In terms of egg processing, the Code is unclear how, and if, dirty eggs can be sold or processed into egg products. This also is not addressed explicitly in the industry guidance. The processing requirements in the Code adequately control the presence of Salmonella in egg products but the requirements are unclear.
- Finally, there is no mechanism for product traceability within either the regulatory or self-regulatory framework. Clear identification of the source of each egg is needed to ensure that unsafe eggs are not on the market.

Nationally consistent and enforceable regulatory action is required to control hazards through the eggs supply chain as the current regulatory and self-regulatory framework is inadequate.

An impact analysis evaluated different risk management options by examining the advantages and disadvantages of each option and assessing the costs and benefits for industry, Government and consumers.

#### **Objective**

The objective of this Proposal is to reduce the incidence of food-borne illness from *Salmonella* by minimising the prevalence of *Salmonella* in eggs and egg products. As there is an increased likelihood of cracked and dirty eggs containing *Salmonella*, the objective includes ensuring that cracked and dirty eggs are not sold as shell eggs and that all liquid egg (egg pulp) is treated to control *Salmonella*.

#### **Options**

In order to decide the most effective and efficient approach for achieving the objective, FSANZ is proposing risk management options. These options include the *status quo* as a comparative measure against which appropriate non-government (industry) and regulatory (government) approaches can be assessed.

The options are:

#### Option 1 Abandon the Proposal, thus maintaining the status quo

• No change is made to the existing regulatory regime

#### **Option 2** Self-regulation

 Voluntary uptake of requirements for production and processing by industry, based on industry formulating recommendations and guidance. Possible combination with an education campaign.

#### **Option 3** Regulation

• Requirements for production and processing by an amendment to the Code.

#### **Impact analysis**

All Australian Government departments and agencies need to demonstrate that their proposals deliver net benefits to the community. This includes an analysis of the impact of each proposed risk management option on different affected parties. The parties likely to be affected by the proposed solutions are consumers of egg and egg products; businesses involved in the production, distribution and sale of eggs and egg products; and State and Territory agencies.

#### **Preferred Approach**

FSANZ recommends that the Code be amended to include Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products into Chapter 4 and other consequential amendments.

#### **Reasons for Preferred Approach**

At Draft Assessment, FSANZ recommends that the Code be amended to include Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products (see Attachment 1<sup>2</sup>) into Chapter 4 for the following reasons. The proposed amendments:

- address public health and safety concerns raised in the Risk Assessment
- are consistent with the section 18 objectives of the FSANZ Act to protect public health and safety
- provide a nationally consistent legislative framework for a whole-of-chain approach to egg and egg product safety

<sup>&</sup>lt;sup>2</sup> Draft Standard 4.2.5 refers to definitions described in Draft Standard 4.1.1 – Primary Production and Processing Standards Preliminary Provisions. Standard 4.1.1 is consequential drafting arising from Proposal P282 – Primary Production & Processing Standard for Poultry Meat.

- take into account existing State-based requirements, providing a consolidated set of requirements based on scientific assessment
- provide measures that are outcome based and would not impose any unwarranted overall additional costs to industry over existing requirements.

#### Conclusion

Option 3, the introduction of a primary production and processing Standard for Eggs and Egg Products, has the potential to deliver maximum net benefits to the community.

It is estimated that adopting a mandatory egg standard will lead to a 35-50% reduction in the burden of disease. This would translate into net benefits exceeding \$AUD150 m over a 5 year period.

At Draft Assessment, FSANZ recommends that the Code be amended to include Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products into Chapter 4, and to include subsequent amendments to the Code. The proposed Standard addresses food safety concerns raised in the Risk Assessment; meets FSANZ's statutory considerations; provides a nationally consistent legislative framework for a whole-of-chain approach to egg and egg product safety and provides measures that are outcome based and would not impose any unwarranted overall additional costs to industry over existing requirements.

#### **Implementation**

The Implementation Sub-Committee<sup>3</sup> (ISC) is trialling an implementation plan using the egg and egg products Proposal as a pilot. A working group has developed draft Compliance Plans for the draft proposed eggs and egg products Standard. The public are invited to

provide comments on the draft Compliance Plans.

<sup>&</sup>lt;sup>3</sup> ISC is a sub-committee of the Food Regulation Standing Committee. Its role is to develop and oversee a consistent approach across jurisdictions to implementation and enforcement of food regulations and standards, regardless of whether food is sourced from domestic producers, export-registered establishments or from imports.

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# **SUPPORTING DOCUMENTS**

The following materials, which were used in the preparation of this Draft Assessment Report, are available on the FSANZ website at:

 $\underline{http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp301primaryp3426.cfm}$ 

- SD1 Risk Assessment of Eggs and Egg Products
- SD2 Quantitative survey of consumer behaviour and egg consumption
- SD3 Overview of the egg and egg product industries in Australia
- SD4 Current food safety management for the Australian egg and egg products industry
- SD5 Potential hazards in the primary production and processing of eggs: Government and industry control measures and perceived gaps
- SD6 Cost-benefit analysis
- SD7 Draft Standard 4.1.1 Primary Production and Processing Standards Preliminary Provisions
- SD8 Egg and Egg products Standard Development Committee membership

#### **INVITATION FOR PUBLIC SUBMISSIONS**

FSANZ invites public comment on this Report based on the principles of best practice regulation for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

This Report has two components:

- Components prepared by FSANZ: the Draft Assessment Report, Attachments 1, 2 and 3, and Supporting Documents
- Components prepared by the Egg Implementation Model Working Group<sup>4</sup> (EIMWG): Draft Compliance Plans (Attachment 4)

Public submissions are invited on the components prepared by FSANZ and on the draft Compliance Plans. Please provide all comments to FSANZ (see details below). FSANZ will address the components prepared by FSANZ. Comments on the Draft Compliance Plans will be forwarded to the EIMWG by FSANZ. Please identify which components your comments relate to. Comments on both components will be reported upon in the FAR.

#### If commenting on both components above, please separate submissions on each component.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. <u>If you wish any information contained in a submission to remain confidential to FSANZ or to the EIMWG, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.</u>

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the <u>Standards Development</u> tab and then through <u>Documents for Public Comment</u>. Alternatively, you may email your submission directly to the Standards Management Officer at <u>submissions@foodstandards.gov.au</u>. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

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<sup>&</sup>lt;sup>4</sup> A working group of the Implementation Sub-Committee (a sub-committee of the Food Regulation Standing Committee).

#### **DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 November 2009**

#### SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand PO Box 7186 Canberra BC ACT 2610 AUSTRALIA Tel (02) 6271 2222 www.foodstandards.gov.au Food Standards Australia New Zealand PO Box 10559 The Terrace WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 www.foodstandards.govt.nz

## INTRODUCTION

#### 1. Introduction

Since June 2002, Food Standards Australia New Zealand (FSANZ) has had responsibility for developing national food safety requirements that cover all parts of the food supply chain – an integrated farm-to-fork approach. The Australian Government requires that any mandatory requirements are justified on the basis that the benefits in protecting public health outweigh any costs to industry, governments and consumers.

This Draft Assessment Report describes the second stage of the assessment of this Proposal, begun in 2006, to improve the safety of shell eggs and egg products for sale in Australia. This work was prompted by outbreaks of illness attributed to eggs or egg products. FSANZ established an Egg and Egg Products Standard Development Committee (SDC) specifically to assist with this Proposal. The SDC consists of representatives from the egg industry, government regulators and consumers. An Initial Assessment Report was published in December 2006, for the first round of public consultation.

During the progress of the Proposal, the State and Territory Governments that are responsible for enforcing the *Australia New Zealand Food Standards Code* (the Code), have been developing a national model for implementing any new requirements for eggs and egg products in the Code. Information on the model is included in this report. Comment on the model may be included in submissions to FSANZ and will be provided to the jurisdictional working group<sup>5</sup> responsible for considering these comments.

# 2. Background

## 2.1 Background to the Proposal

FSANZ has developed primary production and processing Standards for seafood and processed dairy products and is currently developing standards for poultry meat, other meat (beef, pork, sheepmeat and goat meat), raw milk products and seed sprouts<sup>6</sup>.

Following the release of the Initial Assessment Report for this Proposal, twenty five submissions were received from the egg industry, State and Territory enforcement agencies, egg-related industry associations and individuals. Submissions generally supported the Proposal and the comments have informed the second stage of the work. A discussion of key issues raised and a summary of issues is given in Attachment 3.

The second stage of the work has involved assessing the hazards and risks associated with eggs and egg products in Australia and developing options to manage these risks. In considering risk management options for improving food safety, FSANZ uses an internationally agreed risk analysis approach embodied in the FSANZ Act<sup>7</sup>.

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<sup>&</sup>lt;sup>5</sup> A working group of the Implementation Sub-Committee (ISC - a sub-committee of the Food Regulation Standing Committee), is developing a national model. For further information see 'Implementation and Review'.

<sup>&</sup>lt;sup>6</sup> Further information on these Proposals is available on the FSANZ website.

<sup>&</sup>lt;sup>7</sup> Food Standards Australia New Zealand Act 1991.

The food safety risks associated with eggs and egg products have been identified and described in the report; *Risk Assessment of Eggs and Egg Products February 2008* (SD1). An Egg Scientific Advisory Panel was established to advise specifically on the Risk Assessment<sup>8</sup>. Discussions with the egg and egg products industry and site visits have also assisted. The SDC has assisted with the development of options to manage the risks described in the Risk Assessment report.

FSANZ also commissioned a quantitative consumer survey on egg consumption in Australia to gain information on handling and storing eggs, and the frequency of consumption of raw or lightly cooked eggs (SD2). The results have been used to validate some of the assumptions made in the scientific assessment and to provide an insight into how consumer behaviour could be contributing to the problem of food-borne illness (see 'Other information' Section 5.2.1).

## 2.2 Primary Production and Processing standards

A primary production and processing standard is a set of obligations on primary producers and processors of food commodities. They include measures to control food safety hazards that could occur during the production and processing of agricultural produce. Primary production and processing standards are incorporated into Chapter 4 of the Code and apply in Australia only. With other standards in the Code, they provide an approach to managing food safety and suitability in Australia that extends from production on the farm through to sale to the consumer.

The process for developing such standards takes into account existing food safety requirements implemented by the sector, including any existing regulations (e.g. State legislation), industry codes of practice or guidelines and accredited food safety systems.

Implementation of primary production and processing standards is the responsibility of the State and Territory Governments. In order to harmonise the process of standard development and implementation, the Implementation Sub-Committee (ISC) has established an implementation plan to run parallel with the standard development process. The implementation plan includes a 'compliance plan' which outlines what a business has to do to comply with the standard and how the jurisdictions will monitor compliance.

An approved draft primary production and processing standard will be notified to the Australia and New Zealand Food Regulation Ministerial Council for consideration along with the associated implementation arrangements (including the compliance plan) and regulatory impact statement <sup>10</sup>. Ministers are then able to consider the standard in light of its impact on industry and governments.

The implementation plan is being trialled using the eggs and egg products Proposal as a pilot, and is being conducted by the Egg Implementation Model Working Group (EIMWG), a working group of ISC. The working group has developed Draft Compliance Plans for the draft eggs and egg products primary production and processing standard. The Draft Compliance Plans are provided in Attachment 3.

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<sup>&</sup>lt;sup>8</sup> For further information on the Panel see SD1.

<sup>&</sup>lt;sup>9</sup> The term 'unsafe and unsuitable' covers hazards that could affect the health of consumers as well as levels of contaminants and residues which, while not unsafe, are in excess of the limits in the Code.

<sup>&</sup>lt;sup>10</sup> A regulatory impact statement of identified risk management options aimed at addressing a specified problem.

# 3. Scope of the Proposal

At Initial Assessment, the majority of submission from industry and the jurisdictions stated that the scope of the Proposal was acceptable.

The Proposal considers eggs from avian species such as chickens, ducks, geese, turkeys, quail, pheasants and pigeons, available for sale for human consumption and irrespective of the type of production system (cage, barn or free-range). Eggs from ratites, i.e. emus and ostrich, are not included in the scope as they are rarely available for sale in Australia and require considerably different production systems to those of avian species. They will be considered later under a separate Proposal.

The Proposal included two types of businesses which FSANZ has subsequently decided not to include in the scope of the risk management options. These are:

- producers of speciality egg products such as Salted, Century and Balut eggs and embryonic quail eggs
- businesses keeping breeding stock that produce eggs hatched into laying hens<sup>11</sup>.

Following further consultation with the SDC, FSANZ considers that the production of specialty eggs is adequately covered by the provisions within Standard 3.2.2 – Food Safety Practices and General Requirements and Standard 3.2.3 – Food Premises and Equipment. Therefore, the activity of manufacturing specialty eggs is covered within Standards 3.2.2. and 3.2.3. The production of eggs that will be used for specialty eggs is considered in the risk management options.

If a business keeps layers, or ducks and quails, for the production of specialty eggs they are egg producers and if they carry out other activities (prior to manufacturing the specialty eggs) they would be egg processors<sup>12</sup>.

Businesses that keep breeding stock are not within the scope of food legislation because they do not produce food.

# 4. The egg and egg products production chain

The general flow of activities related to egg production and processing is illustrated in Figure 1. An overview of the industry is provided in SD3.

Egg industry activities include the production (laying and collection) of eggs, initial sorting of shell eggs on the farm to remove eggs that have no commercial value for example, eggs that are crushed or too dirty to clean, grading (including further sorting, cleaning, crack detection) followed by packing, labelling, storage and distribution of eggs.

<sup>&</sup>lt;sup>11</sup> However, if the breeder eggs do enter the human food chain for processing into egg pulp, for example, then they are considered to be within the scope of the Proposal.

<sup>&</sup>lt;sup>12</sup> As noted in Section 10.3, under the preferred option, manufacturers of speciality eggs will only be able to obtain whole, clean eggs.

Eggs may be transported long distances for grading, with some farms up to 500 kilometres from grading facilities<sup>13</sup>.

The activities of individual producers varies for example, eggs may be produced on one farm, graded and packed at another business' premises and then sold to wholesalers or at retail. Conversely, eggs may be produced, graded, and packed all at the same premises. Eggs are also sold at the farm gate, at famers markets or at local shops. Very small producers i.e. those with a few hens kept in the 'backyard' often sell locally to neighbours.

There are significant variations in the size of the egg layer industry in Australia<sup>14</sup>, ranging from small producers with less than 100 birds to large enterprises with more than 300,000 birds.

Egg production in Australia is predominantly from cage-based systems (74.9%) with the freerange market share increasing over the past few years (20%) and barn-laid market share decreasing slightly  $(5.1\%)^{15}$ .

Eggs are pulped as whole liquid egg or separated into yolks and egg whites to produce liquid egg white and liquid egg yolk. Ingredients such as salt or sugar may be added (depending on the intended use of the liquid egg) and the liquid egg is heat-treated and either dried, chilled or frozen, prior to storage and distribution.

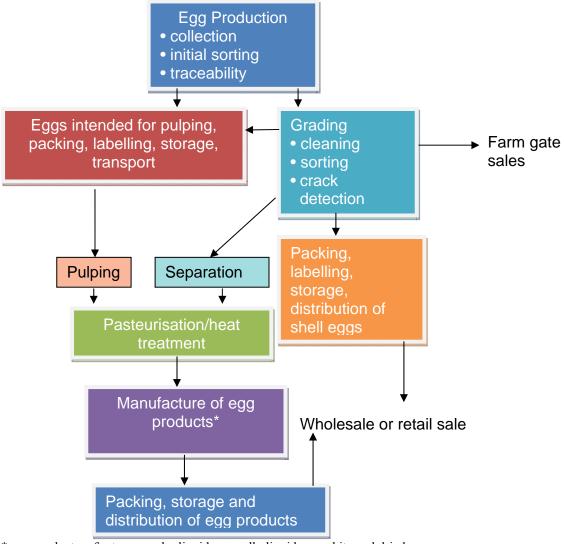
Some businesses make pulp at the egg laying establishment and send it, chilled or frozen, to a processor for heat treatment.

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<sup>&</sup>lt;sup>13</sup> Scott, P., Turner, A., Bibby, S and Chamings, A. (2005) Structure and dynamics of Australia's commercial poultry and ratite industries. Department of Agriculture, Fisheries and Forestry. <a href="http://www.daff.gov.au/animal-plant-health/animal/livestock">http://www.daff.gov.au/animal-plant-health/animal/livestock</a> movement in australia and emergency disease preparedness

<sup>&</sup>lt;sup>14</sup> East, I.J. and Hamilton, S.S. (2009) Restructuring of the Australian chicken industry: identification of risk factors for the closure of farms. Animal Production Science 49: 711 – 716.

<sup>&</sup>lt;sup>15</sup> AECL Annual Report 2008 http://www.aecl.org/images/File/AECL%20Annual%20Report%20web.pdf



st egg products refer to egg pulp, liquid egg yolk, liquid egg white and dried egg.

Figure 1: Production chain for eggs and egg products

# THE PROBLEM

The social and economic costs attributable to food-borne illness caused by eggs and egg products, is estimated to be \$AUD120.96m annually. This is not sufficiently addressed by current regulatory and self-regulatory measures.

# 5. Significance of the problem

#### 5.1 Cost of food-borne illness attributable to eggs

Based on information from previous egg-associated outbreaks, the impact analysis (Section 8) estimates that the egg and egg products industry in Australia could be incurring costs amounting to \$AUD6.75m annually as a consequence of reputation damage, inefficiencies and product recall. Government annual costs due to recalls, compliance and investigation costs due to outbreaks of egg-related food-borne illness are estimated to be \$AUD1.75m annually.

The total costs to consumers and the community attributed to food-borne salmonellosis, is about \$AUD112.5m annually. This includes health related costs, loss of income and/or leisure, in addition to a monetary value attributed to pain and suffering. The total cost of food-borne illness attributable to eggs is therefore estimated to be in the order of \$AUD120m annually.

#### 5.2 Public health risk

The Risk Assessment (Risk Assessment of Eggs and Egg Products, SD1) found that the main microbiological hazard associated with eggs and egg products is *Salmonella*. The reported outbreaks associated with eggs in Australia were attributed to the consumption of uncooked or lightly-cooked foods containing contaminated raw egg, for example, sauces and desserts<sup>16</sup>. A common risk factor identified in outbreaks was the use of eggs with visible surface faecal contamination (dirty eggs), cracked eggs or unpasteurised pulp.

Salmonella are bacteria that can infect poultry and are pathogenic to humans, causing gastroenteritis. Most symptoms of salmonellosis are mild but in a small number of cases, Salmonella infection can lead to more severe invasive diseases characterised by septicaemia and, sometimes, death. In Australia between the years 2001-2005, three deaths were associated with outbreaks attributed to consumption of eggs contaminated with Salmonella.

Salmonellosis is the second most commonly reported food-borne disease in Australia. In 2007, there were 9484 notifications, a rate of 45 cases per 100,000 population<sup>17</sup>. It is not possible to estimate what proportion of the notified cases of salmonellosis were caused from consuming contaminated eggs, as the cause of notified food-borne diseases is often unknown. Additionally, many cases of food-borne disease are not reported. However, where the food vehicle can be identified in a food-borne disease outbreak, eggs are the most commonly identified food vehicle.

In 2007, of the 149 food-borne outbreaks reported, 24 (16%) were associated with eggs<sup>18</sup>. These outbreaks were due to a variety of dishes and food items containing raw or undercooked eggs. Cracked eggs are more likely to be contaminated (by *Salmonella*) as the *Salmonella* can infect the egg content through the cracks.

At Initial Assessment, submissions from industry and the jurisdictions supported the finding of the Risk Assessment, expressing concern over the sale and use of cracked and dirty eggs and unpasteurised pulp.

Chemical residues in eggs and eggs products were found to be either absent or low and of little public health and safety risk.

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<sup>&</sup>lt;sup>16</sup> Reported outbreaks are those where two or more people are known to be affected by a source of contamination. They do not necessarily indicate the incidence and causes of sporadic egg-associated cases of salmonellosis.

<sup>&</sup>lt;sup>17</sup> The OzFoodNet Working Group, 2008

<sup>&</sup>lt;sup>18</sup> Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual report of the OzFoodNet Network, 2007<a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\$FILE/cdi3204.pdf">http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\$FILE/cdi3204.pdf</a> (accessed July 2009)

In summary, the *Risk Assessment* concluded that cracked and dirty eggs, and unpasteurised pulp, are key hazards associated with public health risk. In Australia, clean, whole shell eggs are rarely associated with food-borne illness.

#### 5.2.1 How eggs and egg products become contaminated

## 5.2.1.1 Primary production

The contents of eggs can become contaminated with *Salmonella* via two routes, from the oviduct of the hen as the egg is formed (trans-ovarian or vertical transmission) or through the shell after it is laid (trans-shell or horizontal transmission). In Australia, eggs primarily become contaminated trans-shell as the *Salmonella* serovar that is responsible overseas for trans-ovarian contamination, *Salmonella* Enteritidis, is not endemic in Australian flocks.

In Australia, the two main pathways by which eggs become contaminated with *Salmonella* trans-shell are:

- (1) faecal contamination of the egg as it exits the bird the vent of the bird is the common opening for waste material and eggs, and as a result, contamination of the egg surface with faeces can take place as it is laid and before the shell is fully dried.
- (2) contamination of the egg from the environment the egg surface can also become contaminated by contact with faeces or faecally contaminated material found in the immediate environment where the egg is laid. Birds infected with *Salmonella* can shed large numbers of this bacterium in their faeces, and these organisms may persist in the environment.

The shell is porous and therefore presents a route for microorganisms to gain entry. If *Salmonella* penetrates the shell and the egg white, the egg yolk provides an ideal growth medium if stored at temperatures that allow its growth i.e. above 7°C. This is more likely to occur where the egg is contaminated on the outside with faecal contamination and/or is cracked.

Numerous factors during primary production have the potential to introduce *Salmonella* into a laying flock including feed, water, pests e.g. rodents and insects, the environment, personnel, new laying stock and equipment.

#### 5.2.1.2 Primary processing

Following collection, shell eggs are generally sorted, washed, candled (crack detection), graded and packaged. This can occur either on the farm where the eggs are produced or at a centralised grading facility. The main reason for carrying out these procedures is to maintain consistent quality and size of eggs. A second, but equally important reason is to minimise cracked and/or dirty eggs being packaged and made available for retail sale.

Eggs may be washed to remove extraneous material, which may include faeces, from the egg surface. If performed correctly, commercial egg washing results in a reduction in the level of microorganisms on the egg surface. Factors that are critical to the effectiveness of egg washing include the correct use of detergents and sanitising agents and use of appropriate wash water temperatures.

Alternatively, if performed incorrectly, washing can increase the potential for transmission of *Salmonella* from the shell surface into the egg contents. For example, if the temperature of the wash water is lower than that of the egg, a pressure differential can be created allowing microorganisms that may be present on the shell surface to be drawn into the egg contents.

## 5.2.1.3 Production of egg products

Contents of an egg are collected whole, or separated into their component parts of albumen and yolk. Whole liquid egg can be collected by crushing the egg and removing the shell particles by centrifugation and/or filtration. In this process, the egg contents have contact with the external surface of the shell, increasing the potential for cross-contamination – especially if the shell is contaminated with faeces. There are also opportunities for contamination of egg contents when eggs are separated as there is still some contact with the shell and small pieces of shell can mix with the yolk or the white.

Due to the possible presence of *Salmonella* in raw liquid egg<sup>19</sup>, these products are heat treated (pasteurised) prior to being packaged and stored at temperatures that prevent the growth of *Salmonella*. Discussions with the SDC and submissions to the Initial Assessment Report indicate that there is concern that food businesses purchase unpasteurised pulp and potentially manufacture unsafe products.

Product could also be contaminated after being treated if not protected, and *Salmonella* (and any other potential contaminants) would have the opportunity to grow if temperatures are above 7°C.

#### 5.2.1.4 Handling and preparation (food service or by the consumer)

Although the frequency of eggs contaminated with *Salmonella* is very low, there remains a risk of food-borne illness if cracked or dirty eggs, which have a higher likelihood of being contaminated with *Salmonella*, are consumed raw or lightly cooked (e.g. runny eggs) – this would be the same when uncooked foods containing raw egg (e.g. eggnog, home-made ice cream, mayonnaise) are consumed.

Similarly, sauces, desserts and other foods prepared and consumed outside of the home (e.g. restaurants) may contain egg or egg products which are raw or which have not received sufficient heat treatment to inactivate *Salmonella* if it was present. There have been several incidences of contaminated eggs being the causal agent of food-borne illness outbreaks, for example, in aged care facilities. In a recent case, a raw-egg dessert was epidemiologically implicated as the likely source of *Salmonella*<sup>20</sup> in an aged care facility.

Unhygienic practices during preparation of food containing egg have also been reported as contributing factors to the risk of food-borne illness.

<sup>&</sup>lt;sup>19</sup> Submissions to the Initial Assessment Report, from both industry and the jurisdictions, identified that there is a need to control the sale and use of unpasteurised pulp (for example, by manufacturers).

<sup>&</sup>lt;sup>20</sup> Egg-Associated *Salmonella* outbreak in an aged care facility, New South Wales, 2008. Commun. Dis. Intell 2009; 33: 50 – 53. <a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3301k.htm">http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3301k.htm</a> (accessed July 2009)

#### 5.2.1.5 Other information

Other sources, in addition to the Risk Assessment, have contributed to information on the reasons eggs and egg products become contaminated and contribute to food-borne illness.

In 2008, collaborative work between the Department of Primary Industries and Water (Tasmania) and FSANZ<sup>21</sup> corroborated information from the Risk Assessment regarding the prevalence of *Salmonella* on egg shells prior to washing and grading (i.e. 0.049%, which is within the previously estimated range of 0.016-0.12%). This survey also indicated that *Salmonella* may be present in the farm environment in manure, feed, egg belts, walkways and subsequently on egg shells.

In 2007, FSANZ repeated a survey of food handling practices in food business previously carried out in 2001<sup>22</sup>. Food handling in bakeries and their use of eggs was specifically included in the survey because of a number of food-borne illness outbreaks associated with food from bakeries. Of the 120 bakeries included in the survey, 80 used shell eggs and 19% of these bakeries had eggs with cracked shells.

The survey showed that 17% of bakeries that used eggs or egg products sourced them directly from farms. Eggs supplied at the farm gate may not have had adequate crack detection, undergoing only visual crack inspection, rather than the more sensitive detection used at large grading floors. Therefore, the shells may be more likely to have small (hairline) cracks. It is therefore possible that bakeries may be obtaining eggs with hairline cracks from farms.

The sale of cracked and dirty eggs does occur and was the cause of a consumer level recall of eggs in Queensland in March  $2007^{23}$ .

In 2008, FSANZ commissioned a consumer study<sup>24</sup> to collect data on:

- the proportion of eggs which are consumed raw and lightly cooked in Australia
- consumers' storage and food safety behaviours with regards to eggs.

A total of 1,673 households in Australia completed an online diary on egg consumption and storage and handling behaviours. The survey found:

- of the exposure to eggs (including dishes containing eggs) during the survey, 5% were raw, 56% were lightly cooked and 39% were well-cooked
- 12% of households would use a cracked egg, 40% would check the egg before using it (by cracking it into a separate bowl) and 39% would not use the egg
- 17% households would use a dirty egg as is, 86% would wash or wipe it before using and 3% would not use it<sup>25</sup>
- 54% of households always or almost always sample raw batter when making cakes.

<sup>22</sup> 2007 National Food Handling Survey Final Report, Evaluation Report Series No. 19 FSANZ November 2008
 <sup>23</sup> FSANZ archived recall information

<sup>&</sup>lt;sup>21</sup> DPIW (2008) Tasmanian Egg Shell Survey, unpublished.

<sup>&</sup>lt;sup>24</sup> The FSANZ draft study a 'Quantitative survey of consumer behaviour and egg consumption', is provided in SD2. The study is currently subject to peer review.

<sup>&</sup>lt;sup>25</sup> Multiple responses were permitted and therefore the overall percentage is more than 100 per cent.

This indicates that if eggs are contaminated, they are being consumed raw in 5% of cases. Twelve percent of households will use cracked eggs and 17% dirty eggs. While 40% of households will check a cracked egg (by cracking it into a separate bowl) for quality before using it, this will not enable detection of any *Salmonella* bacteria that may be present. Just over half of households are also consuming raw egg when sampling raw batter.

The Department of Human Services Victoria<sup>26</sup> and the New South Wales Food Authority (in 2009) also carried out consumer research on egg safety awareness and egg handling. These studies corroborated the findings of the consumer survey with regard to egg storage and food safety behaviours<sup>27</sup>.

A recent survey of the incidence of *Salmonella* contamination in egg mixes in restaurants and takeaways in the United Kingdom showed poor egg handling hygiene <sup>28</sup>. For example, 14% of takeaways were not aware of key food safety practices for the use of egg mixes, 43% of staff did not wash and dry hands after handling eggs and egg mixes and that 41% did not refrigerate egg mixes properly.

Following the Initial Assessment Report, submissions from industry and the jurisdictions clearly indicated that cracked and dirty eggs, and unpasteurised pulp, were the major concern due to the potential for *Salmonella* contamination and for cross contamination in food businesses. The current requirements in the Code on prohibiting the sale of cracked and dirty eggs and allowing egg pulp to be further processed by an equivalent method were seen as being inadequate and ambiguous.

#### 5.2.1.6 Summary of where hazards may be introduced

After laying, the factors that impact on the safety of eggs occur during egg collection, grading, packing, storage, distribution and use of eggs. These factors include:

- handling practices that result in cracked shells
- contamination of eggs and egg products from handlers, processes, such as washing, premises and equipment and the environment
- temperature differences between shell eggs and their environment and the environmental humidity
- cross-contamination and temperature abuse of egg contents and the degree to which the eggs are cooked or used in cooked products.

#### 5.2.2 Control measures that will prevent, eliminate or reduce the hazards

FSANZ referred to several sources, including the Codex<sup>29</sup>Code of Hygienic Practice for Eggs and Egg Products<sup>30</sup> and industry Codes of Practice<sup>31</sup>, for information on control measures that will prevent, eliminate or reduce microbiological hazards in eggs and egg products.

<sup>&</sup>lt;sup>26</sup> Auspoll Pty Ltd., 2008

A further comparison between the findings of the FSANZ study and these two studies is given in SD2.

Microbiological Study on Salmonella Contamination of Pooled Raw Shelled Egg Mix and Environmental Samples from Catering Establishments <a href="http://www.hpa.org.uk/web/HPAwebFile/HPAweb\_C/1245309914251">http://www.hpa.org.uk/web/HPAwebFile/HPAweb\_C/1245309914251</a>
The Codex Alimentarius is the international body whose purpose is protecting the health of consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. The Codex Alimentarius commission develops food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food

The key control measures in managing the hazards at egg production and processing are:

- Managing on-farm factors such as bird health, inputs (feed, water) that could introduce hazards, cleaning and sanitising premises and equipment, control of pests and vermin and disposal of waste including used litter, manure and dead birds
- Managing egg collection, initial sorting, storage and transport conditions and separating of dirty and cracked eggs for cleaning and/or processing
- Carrying out processing, such as washing eggs, separating yolks from whites and centrifuging to remove shell, in a way that avoids contamination
- Heat treating (or equivalent) liquid eggs to destroy *Salmonella* and ensure egg products are protected from post-processing contamination and stored under temperature control
- Ensuring that cracked or dirty eggs are not available for sale to users who potentially could use them in raw or lightly cooked foods.

'Tools' or supporting measures enable businesses to control hazards more effectively. These measures include the business:

- ensuring that personnel involved in food production have skills and knowledge in food safety to carry out the work they do
- being able to identify its products to ensure rapid and effective recall and investigate the cause of any food safety problem
- being responsible for ensuring that hazards specific to its business (each business operates slightly differently) are identified and controlled
- demonstrating control to others either as part of an industry certification system or to provide assurance to government.

The last two points reflect a proactive approach to managing safety. It is based on the principle that the business, by acknowledging that food safety is an essential part of food production and examining its activities to establish where hazards could arise, will take more active steps to manage hazards. Without such an approach, a business could take a reactive approach and wait for hazards to occur before deciding how to control them. By this time, the food may have caused illness.

#### 5.2.3 Factors which impact on safety

The Risk Assessment examined which production and processing factors have the most significant impact on public health and safety.

Standards Programme. The scope is the hygienic production and processing of eggs and egg products of domesticated birds, intended for human consumption. The Codex Code of Hygienic Practice is a set of internationally agreed guidelines for the safe production of eggs and egg products and provides a valuable source of guidance on control measures for the safety and suitability of eggs and egg products.

<sup>&</sup>lt;sup>30</sup> The Codex Code is available on the Codex Alimentarius website <u>www.codexalimentarius.net</u>

<sup>&</sup>lt;sup>31</sup> The existing industry schemes, Egg Corp Assured and Hen Care, Codes of Practice and guidance material developed by the States and Territories to support their regulation of the egg industry were also used as sources of information on control measures (see SD4).

#### 5.2.3.1 Egg production and processing

The Risk Assessment considered the relative importance of the various controls measures and the effect they could have on contamination by *Salmonella*. It concluded that due to the multi-factorial nature of transmission of *Salmonella* into laying flocks, and a lack of quantitative data, it was not possible to determine which factors have greater impacts on flock contamination than others. Despite this, limiting the opportunity for flocks to become infected with *Salmonella* from on-farm sources (mentioned above) will have an impact on the potential for egg contamination. The quantitative Risk Assessment model indicates that a 50% reduction in the prevalence of contaminated eggs will result in a 50% reduction in the risk of illness from eggs that are consumed raw if those eggs have been stored under time and temperature conditions that have allowed *Salmonella* to grow in the yolk.

The Risk Assessment concluded that sorting, washing and grading of eggs has the potential to impact on exposure to *Salmonella*-contaminated eggs. Sorting removes grossly contaminated eggs and diverts eggs that are able to be cleaned to cleaning processes. Washing, if carried out under the appropriate conditions, results in a reduction in the microbial load on the egg surface. However, if carried out incorrectly for example, incorrect wash water temperature, it may actually increase the potential for egg contamination by cross contamination and transmission of *Salmonella* through the shell.

Crack detection is also important as it identifies eggs that are more likely to break during packing and distribution and removes eggs from the shell egg market that are more likely to be contaminated

Clean, whole shell eggs are very unlikely to be contaminated provided they are protected from contamination (from other foods and handlers) during storage, distribution and sale.

The Risk Assessment considered temperature storage of shell eggs. Temperature control at storage, distribution and sale is a function of the temperature and the time the eggs are at a particular temperature. For eggs that are *not* contaminated, low temperatures serve to prolong shelf life i.e. prolong the eating quality of the egg or use as an ingredient. In the *low* likelihood that an egg *is* contaminated, *and* the egg is used in a dish that is eaten raw or lightly cooked, there is a potential for causing illness. However, the contaminated egg would have to be stored for a period (dependant on the temperature) such that the bacteria penetrate the shell, pass through the egg white and grow in the yolk to a level sufficient to cause illness. That level is dependent on the susceptibility of the consumer; the young, elderly and immunocompromised are generally more susceptible than the general population.

Based on the following, FSANZ concluded that temperature, and time at that temperature, of shell eggs is important to ensure quality but is not a key factor in ensuring safety:

- information in the Risk Assessment that there is very little epidemiological data to implicate clean, intact eggs as the source of egg-associated illness
- information in the Risk Assessment that the prevalence of Salmonella contaminated eggs in Australia is very low (imported raw shell eggs for food are not permitted)
- the limitations on shelf life for quality reasons
- current industry practices of recommending that producers store eggs at lower than ambient temperatures and advice on cartons to consumers to refrigerate shell eggs after purchase (to achieve the shelf life).

Differences in temperature between the egg and the environment and high humidity can result in water droplets condensing on the shell surface. This moisture increases the ability of *Salmonella* on contaminated shells to migrate into the egg contents. The Risk Assessment concluded that temperature differences and humidity are likely to affect trans-shell contamination but there is a lack of data relevant to Australian egg production to indicate the significance of these factors in controlling contamination of the egg contents.

The Risk Assessment noted that there is evidence of fungal growth on eggs, particularly in areas with high temperatures and relative humidity. Although toxin production (as a result of fungal growth) could be an issue, there is no evidence of illness associated with exposure to toxigenic fungi from the consumption of eggs and egg products.

The Risk Assessment found that raw whole egg pulp has been identified as often being contaminated with *Salmonella* and that *Salmonella* will grow in the pulp at temperatures above 7°C. Pasteurisation treatments specified in the Code for liquid whole egg were assessed as being more than sufficient to inactivate any *Salmonella* likely to be present. Pasteurisation requirements for liquid yolk and albumen were predicted to provide lower inactivation. The Code has limits for levels of *Salmonella* in 'pasteurised egg products' (see Section 5.3.1). However, the Risk Assessment estimated the predicted probability of liquid yolk and albumen failing to meet the *Salmonella* limit in the Code is low. Pulp produced from cracked or dirty eggs that have been subject to poor management practices (such as storage in a warm environment for more than a few hours), could fail microbiological testing.

#### 5.2.3.2 Use of eggs in food service and by consumers

A major risk factor identified in outbreaks associated with the consumption of uncooked/ undercooked foods containing raw eggs was the use of eggs that are more likely to be contaminated i.e. eggs that are cracked and/or with visible surface faecal contamination. Contributing factors in these outbreaks included cross-contamination during food preparation and temperature abuse of the food containing the raw egg. Therefore, ensuring food handlers in food businesses comply with requirements for preparing food safely and limiting the availability of dirty and cracked eggs for use in preparing foods by the food service industry and by consumers are effective control measures.

#### 5.3 Gaps and inadequacies in existing regulatory and self-regulatory requirements

Following the above analysis of hazards and control measures associated with the production and processing of eggs and egg products, gaps and inadequacies in both the current regulatory and self-regulatory framework have been identified.

A summary of potential hazards and perceived gaps in regulatory (and self-regulatory) requirements is given in Table 1, and in greater detail in SD5.

# 5.3.1 Background

#### 5.3.1.1 Chapter 1 – General food standards

The food standards in Chapter 1 apply to all food sold or traded at retail and wholesale level in Australia and New Zealand. The exceptions are Standard 1.6.2 – Processing Requirements and Standard 1.4.2 – Maximum Residue Limits which apply in Australia only.

These standards include labelling requirements, the maximum permitted levels for additives, processing aids, contaminants and natural toxicants, maximum residue levels for agricultural and veterinary chemicals in food, requirements for materials in contact with food, processing requirements and microbiological limits for food.

A microbiological limit has been set specifically for 'pasteurised egg products' in Standard 1.6.1 – Microbiological Limits for Food, where *Salmonella* must not be detected in 25 g.

Processing requirements specifically for egg products are included in Standard 1.6.2. Liquid whole egg, liquid egg yolk and liquid egg white must not be sold or used in the manufacture of food unless they have been pasteurised in accordance with the times and at the temperatures specified. The requirement for liquid egg white is subject to requirements in Standard 2.2.2 – Egg and Egg Products (see below).

## 5.3.1.2 Chapter 2 – Food Product Standards

Chapter 2 contains requirements for specified classes of foods. Standard 2.2.2 is a joint standard with New Zealand. It contains definitions of 'eggs', 'egg products' and 'visible cracks', contains requirements for the processing of egg products and restrictions on the sale of cracked eggs.

The definition of an 'egg' is drafted so that an 'egg' is only an 'egg' if the shell is free of visible cracks, faecal matter, soil or other foreign matter.

Standard 2.2.2 states that egg products must be pasteurised or undergo an equivalent treatment so that the egg product meets the microbiological limit for *Salmonella* in Standard 1.6.1. The Standard states that this requirement does not apply to the non-retail sale of egg products used in a food which is pasteurised or undergoes equivalent treatment so that the food meets the microbiological limit. Standard 1.6.2 states that the liquid egg white pasteurisation requirement (in Standard 1.6.2) is also 'subject to this exemption'.

Standard 2.2.2 also prohibits the availability of cracked eggs for retail sale or for catering purposes and requires egg products made from cracked eggs to be pasteurised or undergo equivalent treatment so that the egg products meets the microbiological limit in Standard 1.6.1.

#### 5.3.1.3 Chapter 3 – Food Safety Standards

Chapter 3, Standards 3.2.2 – Food Safety Practices and General Requirements and 3.2.3 – Food Premises and Equipment set out specific requirements for food businesses, food handlers and the food premises and equipment with which they operate to ensure the safe production of food. The Chapter 3 Food Safety Standards apply in Australia only and apply to all food businesses, other than primary production businesses<sup>32</sup>, involved in the handling of food intended for sale.

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<sup>&</sup>lt;sup>32</sup> Primary food production means the growing, cultivation, picking, harvesting, collection or catching of food and includes transportation or delivery, and the packing, treating (such as washing) or storing of food on the premises on which it was grown, cultivated, picked etc.

Standard 3.2.2 applies to retail and wholesale sectors, distribution, the food service sector: restaurants, cafes, catering and similar activities and to the manufacturing sector such as bakeries. The Standard requires food to be protected from contamination, to be stored under appropriate temperatures and other environmental conditions (to ensure safety and suitability), to use safe ingredients and to be processed so that the food is safe to eat. There are also requirements for health and hygiene of personnel and for cleaning and sanitation. Standard 3.2.3 has requirements for premises and equipment that facilitates compliance with Standard 3.2.2<sup>33</sup>.

Where food safety requirements are required for primary production activities they are developed as primary production and processing standards in Chapter 4.

Egg producers are primary producers under the current definition in the Code. Therefore the requirements in Standards 3.2.2 and 3.2.3 do not apply. Although their primary activity is the keeping of layers and egg collection, their operations may involve a number of the food handling activities that are also undertaken by food businesses such as cleaning, storing, packaging, grading and selling their eggs direct from the farm (farm gate sales) or at local markets. Where these activities take place on the premises where the eggs are produced and involve only their own eggs, they remain part of the primary production activity and Chapter 3 does not apply.

Egg processing businesses producing liquid egg products are food businesses and therefore Standards 3.2.2 and 3.2.3 apply.

Standard 3.2.2 contains requirements for temperature control of potentially hazardous foods. The guide to Standard 3.2.2 explains that whole uncracked hens' eggs are not considered potentially hazardous because they are unlikely to be infected internally with *Salmonella* in Australia and therefore there is no need to refrigerate them to prevent bacterial growth.

This summarises the current regulatory situation, for what is being proposed, refer to Section 9.3.

#### 5.3.2 Gaps and inadequacies in the Code

#### 5.3.2.1 Primary production

Chapters 1 and 2 apply to eggs and egg products once they enter the food chain. Although there are requirements limiting the sale of cracked and dirty eggs in Chapter 2, the

interpretation of these and their application to egg producers are unclear.

Advice from industry, jurisdictions and the SDC is that these requirements are difficult to interpret because the standards cross reference each other and the wording is not straightforward. Specifically, they are not clear as to whether untreated liquid egg can be sold to manufacturers such as bakeries and also, that they may still permit cracked and dirty eggs to be sold. In addition, these requirements address the hazards only once the eggs have left the farm whereas the problem may occur on-farm.

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<sup>&</sup>lt;sup>33</sup> Detailed inclusions in these Standards can be found on the FSANZ website: <a href="http://www.foodstandards.gov.au/thecode/primaryproductionprocessingstandards/index.cfm">http://www.foodstandards.gov.au/thecode/primaryproductionprocessingstandards/index.cfm</a> (accessed July 2009).

In managing hazards that occur on the egg farm, there is currently no primary production and processing standard for eggs and egg products in Chapter 4 and Chapter 3 standards do not apply to egg production activities on the egg farm<sup>34</sup>. This is a particularly significant gap in light of evidence from the FSANZ Food Handling Survey (Section 5.2.1), that a significant number of bakeries are sourcing ungraded eggs directly from the farm gate. Epidemiological evidence<sup>35</sup> indicates that egg associated food-borne illness outbreaks have often been traced back to bakeries and the food service industry.

There are no requirements in the Code for egg producers to have programs in place to manage hazards or to demonstrate that they manage the hazards they have identified in their business.

Therefore, there are no requirements in the Code, for incorporation into State and Territory legislation, for:

- layer management and collection of eggs
- sorting, cleaning, grading, packing, storing, and transporting eggs on or from the premises where the eggs were laid
- hygienic handling of eggs by personnel on the farm
- skills and knowledge in egg safety of personnel on the farm
- identification, recall by egg producers or traceability of eggs
- diverting cracked eggs and dirty eggs to processing
- a means to demonstrate compliance.

There are no evident gaps in the Code in regard to egg processing activities. However, there is an inconsistency in approach in that the control measures were not designed to apply where processing activities take place on the egg farm.

Chapter 3 applies to retail sale activities from the egg farm and to pulp production on the farm whether or not the pulp is made from eggs on the farm or from other egg farms. Again, there is inconsistency in the approach (in the Code) to controlling hazards from these activities.

Chapter 3 applies to the processing of all foods and therefore applies to processing of eggs into egg products such as liquid, frozen and dried egg. Chapter 3 also applies to food businesses likely to use eggs and egg products such as restaurants and bakeries. If complied with, these standards are adequate to require food to be produced safely.

A requirement in Chapter 2 prohibits the availability of cracked eggs for retail and catering purposes and requires egg products made from these eggs to be pasteurised. The intent is satisfactory, but the requirements as drafted are unclear as to their interpretation and application to food service other than 'catering'.

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<sup>&</sup>lt;sup>34</sup> Except for pulp making and retail sale activities (covered later)

<sup>&</sup>lt;sup>35</sup> Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual report of the OzFoodNet Network, 2007<a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf">http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf</a>-cnt.htm/\$FILE/cdi3204.pdf (accessed July 2009)

Through discussion at the SDC and submissions at initial assessment, industry expressed concerns with the lack of clarity around Standard 2.2.2. resulting in the potential for inadequate processing of cracked eggs and unpasteurised pulp. It was suggested that only egg processors should be permitted to process cracked eggs and unpasteurised pulp,

The Chapter does not contain an explicit prohibition on the use of dirty eggs as shell eggs and is silent on whether they can be cleaned or used to make egg products. This is not addressed specifically in Chapter 3 although Chapter 3 does require businesses to ensure that foods used in processing are safe and suitable for their intended use.

The microbiological criterion in Chapter 1 (Standard 1.6.1) applies to 'pasteurised egg products'. This would only require amendment as a consequence to any changes to the definitions as a result of this Proposal.

The processing requirements in Chapters 1 and 2 adequately control the presence of *Salmonella* in egg products but these are open to different interpretations and therefore potentially pose a problem for enforcement and compliance. Submissions support this.

Chapter 3 is inadequate in terms of product tracing and previous Proposals for primary products have addressed this by including requirements in Chapter 4. Currently, egg processors do not have to be able to identify their eggs other than the identification on the carton<sup>36</sup>. Generally eggs for retail sale are in unsealed cartons.

Once the eggs are removed (either at the store when cartons are opened and eggs swapped or at home), they are not identifiable<sup>37</sup>. Industry and governments have raised that this presents a gap in the tools to enable food safety problems to be investigated and to ensure unsafe eggs are not on the market.

There are no requirements in the Code for egg processors to have programs in place to manage the hazards or to demonstrate compliance.

# **5.4** Gaps and inadequacies in State and Territory legislation<sup>38</sup>:

# 5.4.1 Background

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As egg production is primary production under State and Territory legislation, any regulatory measures applying to them would have to be developed under State and Territory primary production legislation in lieu of any requirements in Chapter 4. Whereas Chapter 4 standards would be adopted nationally, in the absence of any national standard, the States and Territories will develop their own requirements independently. This could lead to inconsistent requirements between States and ultimately confound the business-related problem (i.e. costs) due to the high volume of inter-state sales of eggs and egg products.

<sup>&</sup>lt;sup>36</sup> Except in Queensland.

<sup>&</sup>lt;sup>37</sup> Sealed cartons for eggs are not currently a viable solution. Industry advice is that consumers prefer cartons that can be opened to check for cracked eggs. It is preferable for industry and consumers that the check is available at the point of sale rather than once the consumer leaves the store.

<sup>&</sup>lt;sup>38</sup> A summary of current State and Territory egg food safety management is given in SD4.

Queensland and Tasmania, have already introduced legislation specific to egg producers. New South Wales and South Australia are currently developing legislation. (State and Territory legislation is detailed in SD4).

#### 5.4.1.1 Primary production

The legislation in Queensland includes the control measures identified previously. It also requires the business to identify its eggs and to have a documented program in place to manage hazards. The Tasmanian legislation is similar in its intent but is expressed differently and limits its application based on the number of birds kept by the business and to eggs from hens (but not other birds such as ducks). However, businesses that produce eggs must have a documented program in place that manages egg safety. There are no similar provisions in force in other jurisdictions.

South Australia and New South Wales are proposing regulations to control egg production and are likely to proceed in the absence of national requirements.<sup>39</sup>

Animal welfare and biosecurity were considered outside the scope of this Proposal other than where they may impact on food safety. Model Codes of Practice for the welfare of animals and biosecurity have been developed by government in consultation with industry and endorsed by Primary Industries Ministerial Council (or predecessor).

States and Territories have legislation that enable Codes of Practice to be adopted by reference or included in regulations. However, adoption is not uniform. Details of the Codes of Practice for welfare and biosecurity are given in SD4.

#### 5.4.1.2 Processing

The Queensland food safety scheme extends to production of liquid egg products and their treatment. In Victoria, egg processing businesses must develop and implement a food safety program and have the program audited in compliance with Victorian food legislation. There are no requirements in addition to those in Chapters 1, 2 and 3 of the Code in all other States and Territories.

#### 5.5 Gaps and inadequacies in industry schemes

#### 5.5.1 Background to industry schemes

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Egg Corp Assured is a national egg quality assurance program developed by the Australian Egg Corporation Limited (AECL) which includes food safety elements. It is designed to help commercial egg producers develop a quality assurance program for their business and be recognised for doing so, through promotion by AECL and use of the Egg Corp Assured trademark. The program must be audited by an accredited Egg Corp Assured auditor. The scope of the program is egg production and also pullet rearing, egg grading and packaging where these activities are conducted on the egg production site. Victoria has also developed 'Hen Care' a quality assurance system that includes a guide to through-chain food safety practices.

<sup>&</sup>lt;sup>39</sup> Health Bulletin and Health Directive (Minimum Requirements for Food Safety for Egg Production). For information on the proposed SA regulation see Consultation Paper 12 January 2009 available from PIRSA on request. For information on the proposed NSW food safety scheme see <a href="http://www.foodauthority.nsw.gov.au/">http://www.foodauthority.nsw.gov.au/</a>

There are two Codes of Practice developed by the egg industry which serve as guidance material for the Egg Corp Assured program: the *Code of Practice for Shell Egg, Production, Grading, Packing and Distribution* and the *Code of Practice for Manufacture of Egg Products* 40. (Further details on industry schemes and Codes of Practice are given in SD4).

## 5.5.1.1 Self-regulatory measures (government advice to industry)

In response to food-borne illness outbreaks in Australia attributable to eggs, the South Australian Government issued advice to South Australian food businesses in 2007 on safe handling and use of eggs and recommendations on the minimum requirements for food safety to all South Australian commercial egg producers<sup>41</sup>. NSW and other States also provide similar advice. Despite these recommendations, there are sustained levels of food-borne illness associated with eggs and egg products<sup>42</sup>.

## 5.5.1.2 Self-regulatory measures (government advice to consumers)

The FSANZ consumer study indicated that although the majority of households sourced their eggs from supermarkets (81%) and other retail stores (18%) other sources were farmers and growers markets (11%), backyard producers or from their own chickens (5%). Some respondents (22%) obtain their eggs from multiple sources.

As mentioned in Section 5.2.1, eggs sold directly from farms are potentially more likely to be sold with cracks as they may not have undergone adequate crack detection. Potentially, they may also have feathers, detritus and dirt attached because to some consumers this indicates the eggs have not been 'processed' and are fresh. As suggested by the consumer study, some consumers do use cracked and/or dirty eggs.

State and Territory governments and industry provide advice to consumers in the form of fact sheets on handling and storage of eggs, and to avoid purchasing cracked and dirty eggs. There is no nationally-agreed set of egg safety messages for consumers. The advice in the fact sheets reflects generally accepted advice on ensuring safe egg use and is reasonably consistent for example, in terms of avoiding cracked and dirty eggs. However, several of the messages differ for example, NSW recommends that children under 2 years old<sup>44</sup> are not fed raw eggs while Victoria applies the same advice for children younger than 5. From the FSANZ egg consumer survey, a comparison was made of the consumption of raw eggs between ages; approximately 11% of children aged 4 years and under consumed raw eggs during the survey period, compared with 24% of 25-34 year olds. This indicates that a proportion of young children are exposed to raw eggs.

It is difficult to judge to what extent consumers follow the advice.

<sup>&</sup>lt;sup>40</sup> AECL (2005) <a href="http://www.aecl.org/index.asp?pageid=486">http://www.aecl.org/index.asp?pageid=486</a> (accessed July 2009). These documents are Codes originally developed in Victoria and adopted nationally through the Australian Egg Industry Association (AEIA). They are included in the NEOAP program.

<sup>(</sup>AEIA). They are included in the NEQAP program.

41 Health Bulletin on safe handling of eggs and Health Directive on minimum requirements for food safety for egg production.

<sup>&</sup>lt;sup>42</sup> Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual report of the OzFoodNet Network, 2007<a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\$FILE/cdi3204.pdf">http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\$FILE/cdi3204.pdf</a> (accessed July 2009).

<sup>&</sup>lt;sup>43</sup> Backyard producers are small local producers or neighbours that keep hens in the backyard.

<sup>44 &#</sup>x27;Enjoy eggs safely' NSW Food Authority website 3 July 2006.

There are indications that some do not. For example, Victoria's Better Health website advises<sup>45</sup> that dirty eggs should not be washed because it increases the likelihood of bacterial penetration. However, the consumer study found that 47% of households would wash a dirty egg and 37% wipe the egg. The consumer study also indicates that there were areas where behaviour could be improved for example, washing hands after handling eggs and using cracked and dirty eggs.

The national egg industry scheme, Egg Corp Assured (ECA), controls the hazards and requires a business to implement a food safety program. Certification is based on satisfactory audits of the program by an AECL registered third party auditor. The AECL actively promotes its program but it is voluntary and there are no restrictions on egg producers in marketing their eggs as a consequence of not being accredited under the scheme. Currently there are approximately 30% of egg businesses registered in the program capturing 93% of the national layer flock and 80% of eggs sold<sup>46</sup>.

Similarly, the Victorian Egg Producers Quality Assurance Program, Hen Care, is voluntary and only 10% of producers are accredited. Other Victorian producers may be accredited with the national ECA program or a scheme that is required by their customers (such as the major retailers which have their own quality assurance schemes).

The AECL Code of Practice for Shell Egg, Production, Grading, Packing and Distribution provides guidance to egg producers but compliance with the requirements is voluntary. The document requires updating particularly its references to the Code and this may impact on its usefulness. There is no information available as to the number of producers that meet the requirements in those States where there is no legislation requiring similar measures to be introduced.

The South Australian government carried out a survey in 2007<sup>47</sup> to establish whether commercial egg producers and food businesses were complying with recommended egg control measures it issued earlier that year. It found that 97% of egg production (measured by bird numbers) substantially complied and non-conformance was identified in 11 smaller producers.

The ECA program also incorporates requirements for egg producers to abide by poultry welfare and biosecurity Codes of Practice. These Codes of Practice include requirements aimed at ensuring the health of poultry. Therefore those businesses that comply with ECA would comply with the welfare and biosecurity Codes of Practice. However, there may be businesses that do not comply.

Advice from the SDC and public submissions indicates that not all Australian egg producers comply with the egg quality assurance programs. In particular, small businesses i.e. those keeping a small number of hens are not accredited. Larger businesses, in terms of layer numbers/eggs produced, are more likely to comply with voluntary measures.

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<sup>45</sup> www.betterhealth.vic.gov.au

<sup>(</sup>http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Food\_safety\_storing\_eggs?open) (accessed July 2009.

<sup>&</sup>lt;sup>46</sup> AECL personal communication.

<sup>&</sup>lt;sup>47</sup> South Australian government (Department of Primary Industries and Resources South Australia) consultation paper on the production of eggs through the development of an Egg Food Safety Scheme.

The scope of ECA focuses on production of shell eggs and does not extend beyond the grading floor. There is no egg industry scheme supporting an industry association by registration or certification for the production of egg products such as liquid, frozen or dried egg.

The Code of Practice for Manufacture of Egg Products is a voluntary Code. There is no information available on the extent to which industry uses it. However, the references in it to requirements in the Code are several years out of date.

#### 5.6 Conclusion

From the above evidence we can conclude that:

- Eggs become contaminated during lay and at subsequent steps in primary production i.e. at the laying farms.
- Subsequent activities, such as washing and grading may contribute to contamination.
- Cracked and dirty eggs, and unpasteurised pulp are more likely to be contaminated with Salmonella. Therefore, there is a need to limit their availability.
- There is currently no national regulatory framework to address this problem. Two States have introduced legislation and other States have recognised the problem and are preparing legislation.
- Poor handling practices of cracked or dirty eggs can cause cross-contamination. Chapter 3 has provisions addressing food handling, however there is a need to reduce the likelihood of cracked and dirty eggs reaching the public and food businesses.
- Industry measures focus on production and processing parameters and the dangers of using cracked and dirty eggs is not emphasised.
- The uptake of self-regulatory measures (i.e. quality assurance programs, Codes of Practice) is voluntary and whilst larger producers and processors are accredited and comply, consultation with industry and the SDC has indicated that there are egg businesses who do not comply.
- The current requirements in the Code regarding availability of eggs and egg products, are inadequate as cracked and dirty eggs are reaching the market place and are being used in making manufactured products. This practice has been responsible for outbreaks of food-borne illness.
- In terms of egg processing, the Code is unclear how, and if, dirty eggs can be sold or processed into egg products. This also is not addressed explicitly in the industry guidance. The processing requirements in the Code adequately control the presence of Salmonella in egg products but the requirements are unclear.
- Finally, there is no mechanism for full product traceability within either the regulatory or self-regulatory framework. Clear identification of the source of each egg is needed to ensure that unsafe eggs are not on the market.

Furthermore, the impact analysis estimated that the total cost of food-borne illness attributable to eggs is approximately \$AUD120m annually. Therefore, nationally-consistent and enforceable regulatory action is required to control hazards through the eggs supply chain as the current regulatory and self-regulatory framework is inadequate.

Discussions with the SDC support this conclusion and that it is highly desirable for the Government to act to ensure the safety of **all** eggs and egg products sold. SDC members, particularly from industry, have shown full support for a nationally consistent regulatory framework.

Table 1: Summary of potential hazards and perceived gaps in current regulatory and self-regulatory requirements.

Step	Hazard	Perceived gaps/comments
Bird Management	Microbiological contamination of eggs due to diseased birds .	The hazards are adequately addressed by Qld and Tas legislation and industry schemes where implemented. The regulatory gap is in the remaining states where businesses (mainly small businesses) have not implemented the industry programs.
	Microbiological and chemical contamination of hens from litter, feed, water and veterinary treatments which could adversely affect eggs.	
	Contamination is spread by vermin and domestic animals Microbiological contamination of housing, nest boxes and equipment which could adversely affect hens and contaminate eggs.	
	Microbiological contamination of production area due to waste products (including litter, manure and dead birds)	
Collection and initial sorting	Microbiological contamination due to:  age/damage/soiling of eggs if not collected  dirty equipment  handling (personnel)  cross-contamination from broken, dirty or cracked eggs  temperature and humidity fluctuations increasing likelihood of trans-shell penetration of bacteria Microbial growth if eggs contaminated and time/temperature conditions.	The Code has no requirements for collecting or sorting eggs, although cracked and dirty eggs are not allowed to be sold at retail. These requirements are unclear though due to the current definition of an 'egg'.  The hazards are adequately addressed by Qld and Tas legislation and industry schemes where implemented. The regulatory gap is in the remaining states and where businesses (mainly small businesses) have not implemented the industry programs.
Cleaning /washing and drying of intact shell eggs	Microbiological contamination of eggs due to penetration of bacteria from wash water, equipment etc with increased risk if eggs are cracked or broken during handling.  Microbial contamination of the egg surface from:  • dirty equipment  • poor hygiene practices of personnel  • wash/rinse water and/or build up of faecal matter in wash water	There is a gap in the Code: requirements of Standard 3.2.2 and 3.2.3 apply if the premises are off- site from egg production, but do not apply if these activities take place at the egg production facility.
	Chemical residues on the egg surface from oiling, sanitisers, surface sanitising treatments or disinfection by-products	

Step	Hazard	Perceived gaps/comments
Packing, storage and transport of	Microbiological contamination of shells from premises, equipment and	There is a regulatory gap in that Standard 3.2.2 and 3.2.3 apply if
cracked eggs	personnel	the premises are off- site from egg production, but do not apply if
	Microbial growth in the egg contents	these activities take place at the egg production facility.
	Wicrobial growth in the egg contents	
	Chemical contamination from packaging material (migrations of chemical)	
Package, storage and transport of	Microbiological contamination of shells from premises, equipment and	No gap
clean, intact eggs <sup>48</sup>	personnel	
	Chemical contamination from packaging material (migrations of chemical)	
Packing, storage and transport of	Microbiological contamination of egg pulp due to :	There is a regulatory gap in that Standard 3.2.2 and 3.2.3 apply if
raw egg pulp produced on	-contamination from storage environment (premises, equipment, personnel)	the premises are off- site from egg production, but do not apply if
premises where eggs produced (	-pooling of multiple batches of pulp and cross-contamination from dirty egg	these activities take place at the egg production facility.
from broken or cracked eggs –	product	
shell usually separated out- may or may not be from cleaned eggs)	Chemical contamination from packaging material (migrations of chemical)	
of may not be from cleaned eggs)	Chemical contamination from packaging material (migrations of chemical)	
	Microbial growth during packing, storage and transport	
Pulping (Commercial off-farm)	Microbiological contamination of the pulp from:	There is a gap in self-regulation in that Egg Corp Assured does
	<ul> <li>dirty egg shell in contact with pulp</li> </ul>	not apply to processing of egg products.
	<ul> <li>premises, equipment and personnel</li> </ul>	
	Microbial growth in pulp	
Pasteurisation	Survival of pathogens if processing inadequate.	The Code has requirements for pasteurisation. However, the
		definitions of different egg products require clarification and
	Product re-contaminated post processing	there is a need to consider process other than pasteurisation for
Gr. 1.11 cl. 10		the control of pathogens.
Storage and distribution of	Post processing contamination	There is a regulatory gap in that processed egg products need to
treated (pasteurised products)	Microbial growth	be stored or transported under time/temperature control.
Use of eggs and egg products by	Use of cracked and or dirty eggs	The regulatory requirements are unclear: the current requirements
manufacturing	coo of fraction and of unity oppo	in the Code are not clear as to whether unpasteurised pulp can be
businesses/caterers and other	Contamination by physical. chemical and microbiological contaminants.	sold for use in other foods. It is also unclear whether businesses
types of food businesses		can use cracked eggs in products that are subsequently heat
	Microbial growth	treated.

<sup>&</sup>lt;sup>48</sup> The Risk Assessment found that whole clean eggs have a very low likelihood of presenting a risk to public health and therefore the contamination of contents is not considered here.

Step	Hazard	Perceived gaps/comments
Retail sale of shell eggs and egg	Sale of cracked or dirty eggs and untreated pulp	The regulatory requirements are unclear as to whether
products		unpasteurised pulp can be sold for use in other foods and which
		businesses can use cracked eggs in products that are subsequently
		heat treated.
Traceability	Inadequate traceability due to unknown source and/or destination of eggs and/or egg products with consequent difficulty in determining the cause of food-borne outbreaks and recalling only affected product.	There are traceability requirements in two States only.
Skills and knowledge of food	Use (and storage) by producers, caterers/retailers and processors of :	There is a gap in the need for skills and knowledge for egg
handlers	<ul> <li>cracked and dirty eggs</li> </ul>	producers who may handle cracked and dirty eggs or raw egg
	<ul> <li>raw egg pulp</li> </ul>	pulp.
	foods containing raw egg	

# **OBJECTIVE**

# 6. Objective of the Proposal

The objective of this Proposal is to reduce the incidence of food-borne illness from *Salmonella* by minimising the prevalence of *Salmonella* in eggs and egg products. As there is an increased likelihood of cracked and dirty eggs containing *Salmonella*, the objective includes ensuring that cracked and dirty eggs are not sold as shell eggs and that all liquid egg (egg pulp) is treated to control *Salmonella*.

#### **6.1** Statutory considerations

#### 6.1.1 FSANZ Act

As one of the risk management options to address the safe production and processing of eggs, FSANZ may develop or vary existing standards in the Code. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

# 6.1.2 Policy guidelines

FSANZ received guidance in 2002 from the Australia and New Zealand Food Regulation Ministerial Council in the form of the *Overarching Policy Guideline on Primary Production and Processing Standards* (Ministerial Policy Guideline<sup>49</sup>) to develop standards for primary production sectors, including eggs. The Ministerial Policy Guideline states that FSANZ should take into account the following objectives of the Food Regulation Agreement 2000:

- providing safe food controls for the purpose of protecting public health and safety;
- reducing the regulatory burden on the food sector;
- facilitating the harmonisation of Australia's domestic and export food standards and their harmonisation with international standards:

<sup>&</sup>lt;sup>49</sup> Overarching Policy Guideline on Primary Production and Processing Standards <a href="http://www.health.gov.au/internet/main/Publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/\$File/anzfrmc\_standards.pdf">http://www.health.gov.au/internet/main/Publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/\$File/anzfrmc\_standards.pdf</a> (accessed July 2009)

- providing cost effective compliance and enforcement arrangements for industry, governments and consumers;
- providing a consistent regulatory approach across Australia through nationally agreed policy, standards, compliance and enforcement procedures;
- recognising the responsibility for food safety encompasses all levels of government and a variety of portfolios; and
- supporting the joint Australia and New Zealand efforts to harmonise food standards.

# 6.2 Achieving the objective

The objective is achieved through addressing FSANZ's statutory considerations and identifying feasible effective options to address current gaps in the regulatory and non-regulatory framework. The overall benefits to consumers, industry and Government are compared to the costs of each option through an impact analysis. The preferred option for public consultation is then decided on the basis of this impact analysis.

# **OPTIONS**

# 7. Risk management options

In order to achieve the objective stated in Section 6, FSANZ, in consultation with the SDC and with regard to submissions, developed risk management options. These options include the *status quo* as a comparative measure against which the non-government (industry) and regulatory (government) approaches have been assessed.

The options are:

#### 7.1 Abandon the Proposal, thus maintaining the status quo

No change is made to the existing regulatory system. This option reflects the current situation whereby there is a combination of State-based regulation, self-regulation and some national requirements in the Code. Egg producers that sell eggs direct from the farm gate or at farmers' markets are currently expected to comply with the requirements in Standards 3.2.2 and 3.2.3 that apply to their retail sale activities. Individual States and Territories could continue to introduce legislation that applied to these businesses as is the case in Queensland and Tasmania.

Egg processors would continue to comply with requirements in the Code which would remain unchanged as a result of this Proposal.

Industry could continue to promote compliance with voluntary requirements, such as the Egg Corp Assured program.

#### 7.2 Option 2 – Self-regulation

Under this option industry would review current practices, in light of the outcomes of the risk assessment, and adopt measures to ensure contaminated eggs and egg products do not enter the market place, and eggs and egg products are traceable.

This option would need to include any additional (compared to the status quo) measures, practices and protocols to achieve the food safety objectives.

Under this option, industry would be solely responsible for implementation. Industry compliance with control measures could be supplemented by an industry-promoted education campaign directed at industry. There could also be the inclusion of education campaigns targeted at consumers to promote safe practices in regard to eggs.

This option would require strong, industry-wide commitment for example, the ability for industry to apply sanctions or incentives (such as a logo or identification mark which indicates the eggs were produced in compliance with safe practices) and there would have to be consequences on businesses that opted not to participate. There also would need to be evidence that voluntary participation is working through for example, a review of compliance by industry and/or government.

# 7.3 Option 3 – Regulatory – Amendment to the Code

FSANZ would include a Primary Production and Processing Standard for Eggs and Egg Products in Chapter 4 to apply to egg producers and egg processors. This would supplement requirements in Chapter 3 and ensure through-chain control of food safety hazards related to eggs and egg products.

The current requirements for processing would be transferred to the new standard in Chapter 4 to ensure that the requirements on egg processors are located in one place in the Code. Amendments to other standards as a consequence of these changes would be made, with due regard to New Zealand requirements where the standards are joint standards with New Zealand.

States and Territories would be expected to include the amendments to the Code in their legislation.

The impact of each option is analysed in the following section.

# **IMPACT ANALYSIS**

# 8. Impact Analysis

The Government is now placing greater emphasis on improving the effectiveness and efficiency of regulation through the Office of Best Practice Regulation (OBPR). Hence Australian Government departments and agencies are expected to demonstrate that their proposals deliver net benefits to the community. This includes an analysis of the impact of each proposed risk management option.

# 8.1 Affected parties

The parties mainly affected by outbreaks of food-borne illness and also most likely to be affected by the proposed solutions are:

consumers of egg and egg products

- businesses involved in the production, distribution and sale of eggs and egg products
- State and Territory agencies that investigate such outbreaks, and enforce provisions of legislation.

Consultation with these parties has occurred through the SDC, during industry visits and through public consultation at Initial Assessment. Information on consultation and communication is detailed in Sections 10 and 11 respectively. The views and comments of all stakeholders have been taken into account (Attachment 3) in developing and analysing risk management options. This Draft Assessment Report provides a further opportunity for feedback.

#### 8.2 **Analysis of the options and Benefit Cost Analyses**

In order to carry out an impact analysis, FSANZ considers the costs and benefits of the risk management options on the affected parties identified above.

# 8.2.1 Key assumptions and limitations underpinning the Impact Analysis:

- The conclusion of the Benefit Cost Analyses must be regarded as indicative, rather than as definitive, as they are based on data from a number of businesses, jurisdictions and other sources.
- The status quo or 'do nothing 'option is the base case against which other options are compared. It represents the prevailing situation and does not imply any changes.
- The impact analysis for options 2 and 3 is the additional or incremental costs and benefits when compared to the status quo.
- Wherever possible, impacts have been quantified. In absence of specific information, FSANZ has drawn on the best available evidence, such as secondary studies and other general information.
- Due to lack of Australian data, FSANZ has made use of international data on adverse health outcomes pertaining to countries with comparable levels of health care and disease incidence. However the computation of costs for such health incidents are based on recommended Quality Adjusted Life Years (QALY) values / health care costs in Australia (AUD).
- Efficacy of an option means effectiveness in reducing the burden of food-borne disease.
- Government and Business Compliance Costs for the Regulatory Option are based on detailed information provided by State Governments<sup>50</sup>.
- Impacts on small business have been separately identified and reported where possible, and largely rely on data obtained from Victoria.

<sup>&</sup>lt;sup>50</sup> FSANZ requested information on upfront and on-going costs through the Egg Implementation Model Working Group. Detailed information was received from three States (NSW, Queensland, Tasmania and Victoria, which together constitute more than 90% of the national flock). This data was most useful and was used to provide indicative ranges of costs which were then extrapolated to estimate overall national costs.

- An annual discount rate of 7% applies to both costs and benefits in FSANZ's calculations.
- Sensitivity analyses are undertaken to indicate a range of outcomes from the Standard (See SD6 for details).
- The regulatory option is estimated to deliver a 20% to 50% efficacy rate (See analysis under Option 3).

Details of the Benefit Cost Analyses are provided in SD6 and are summarised in Table 2.

#### 8.3 Option 1: Status quo - No change is made to the existing regulatory system

The major *advantage* of this approach is that there are no new costs<sup>51</sup>. However the *disadvantages* are that the outbreaks of egg related illness and the associated burden on those falling ill and their families, their employers and medical services remain the same. The costs to government and industry remain unchanged. The inconsistencies in requirements in the different States remain and there is the potential for those States without legislation to introduce their own egg safety schemes.

It is unlikely that the situation regarding food-borne illness will improve on its own account. If there are opportunities for businesses and consumers to buy cheaper eggs because they are cracked or dirty, if advice to the contrary is not entirely effective and, furthermore, the legislation currently managing hazards is unclear, then the possibility of illness remains unchanged. Advice from industry and governments<sup>52</sup> emphasises that the current problems associated with the sale and use of cracked and dirty eggs, and unpasteurised pulp, supports the need for an improvement of the *status quo*.

#### 8.3.1 *Costs*

8.3.1.1 Costs to industry

There are costs to industry arising from the outbreak of food-borne illnesses as a consequence of consuming unsafe eggs and egg products. These costs are associated with the loss of reputation, fines and compensation payments. Studies indicate that businesses with an annual turnover of \$AUD1.3-13m have either lost sales or have been shut down as a result of causing food-borne illnesses<sup>53</sup>.

For example, oyster farmers and the local fishing industry of Wallis Lake lost \$AUD700,000 annually after their produce was identified as the cause of around 444 cases of Hepatitis A across Australia<sup>54</sup>.

<sup>53</sup> A case of food-borne illness is interpreted in the impact analysis as the number of people affected, regardless of whether each case has been reported.

<sup>&</sup>lt;sup>51</sup> This refers to the situation at the present time. The Status Quo option does not take into account any future changes such as other States introducing their own requirements in the absence of national requirements (which could potentially mean additional costs to industry if implemented at the State level).

<sup>&</sup>lt;sup>52</sup> Through public submissions, the SDC and broader industry fora.

<sup>&</sup>lt;sup>54</sup> Abelson P., Forbes, M.P. and Hall, G. (2006) Cost of Food-borne illness in Australia and Willingness-to pay principles. <a href="http://www.ozfoodnet.org.au/internet/ozfoodnet/publishing.nsf/Content/7F6D9DE21AB6F102CA257">http://www.ozfoodnet.org.au/internet/ozfoodnet/publishing.nsf/Content/7F6D9DE21AB6F102CA257</a> 1650027861F/\$File/cost-food-borne.pdf (accessed July 2009).

The proposed New South Wales Food Authority Egg Food Safety Scheme<sup>55</sup> (2005) indicates that if egg safety and flock management programs were even 50% effective in reducing foodborne illness, there would be an estimated decrease in the damage to the reputation of the egg industry amounting to \$AUD270,000 per annum. In addition, there would be an estimated reduction in wastage and spoilage which costs the industry around \$AUD405,000 per annum. If current programs were fully (100%) effective, then a saving of about \$AUD1.35m per annum would accrue.

Given that NSW accounts for 35% of the national value of egg production, the cost of reputation, damage and wastage to industry Australia-wide in 2005 is estimated to have been \$AUD3.85m. Applying the Australian Taxation Office (ATO) CPI inflation rate<sup>57</sup> of 12.7% for the period 2005-09, the cost of reputation damage and wastage currently affecting the industry is projected at \$AUD4.34m per annum for Australia.

In addition, there are costs associated with product recall, which average \$AUD13.75m per annum in 2006 for food products in general<sup>58</sup>.

OzFoodNet states that 16%<sup>59</sup> of the reported food-borne illness outbreaks in 2007 were related to the consumption of eggs. At current prices this amounts to \$AUD2.41m (a total of \$AUD2.2m in 2006 adjusted by the ATO's CPI index of 9.4 % for 2006-09).

It is therefore estimated that under the status quo, the egg and egg products industry in Australia could be incurring costs as a consequence of reputation damage, inefficiencies and product recall<sup>60</sup>, amounting to \$AUD6.75m annually.

# 8.3.1.2 Costs to consumers and the community

The cost of food-borne illness impacts on consumers in the form of medical expenses and lost productivity. Costs also accrue due to loss of overall health and welfare.

The cost of a general food-borne salmonellosis illness case was calculated to be approximately \$AUD8786 (See SD6). While the cost per case is based on recommended OALY values for Australia, there is a lack of domestic evidence regarding the incidence and weightings of the adverse health outcomes, therefore these have been derived from international studies<sup>61</sup>. From a risk analysis perspective, the health outcomes from a foodborne salmonellosis illness would be quite similar, irrespective of the physical location and the food vehicle (e.g. eggs, meat, milk or other primary produce).

<sup>55</sup> The proposed NSW Food Authority egg scheme is awaiting approval. Estimates of costs associated with implementing the scheme were included in the Risk Impact Statement developed in 2005.

<sup>&</sup>lt;sup>56</sup> Based on ABS data cited in the proposed New South Wales Food Authority Egg Food Safety Scheme RIS  $\begin{array}{c} (2005) \\ ^{57} \text{ http://www.ato.gov.au/taxprofessionals/content.asp?doc=/content/1566.htm} \end{array}$ 

<sup>&</sup>lt;sup>58</sup> Abelson, P. et al. (2006) The annual cost of food-borne illness in Australia.

<sup>&</sup>lt;sup>59</sup> OzFoodNet Network, (2007) <a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-">http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-</a> pdf-cnt.htm/\$FILE/cdi3204.pdf. While 16% refers to the number of outbreaks, actual numbers of affected people (cases) could be higher; numbers of cases also vary from year to year. FSANZ has therefore conservatively used 16% as the basis for calculations.

<sup>&</sup>lt;sup>60</sup> A recent recall on cracked and dirty eggs accrued a cost of \$55,000 (see 'Costs to Government')

<sup>&</sup>lt;sup>61</sup> The USFDA Egg Safety Final Rule, published July 7, 2009 http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170615.htm

Studies indicate that taking into account underreporting there may be about 23,000-138,000 number of food-borne salmonellosis cases in Australia in a typical year<sup>62</sup>. If there are an average 80,000 cases in the community and eggs are estimated to account for approximately 16 % of food-borne illness, then there could potentially be about 12,800 cases of egg-related salmonellosis per year. Having computed that each salmonellosis case results in a cost of \$AUD8,786, then the total costs currently being borne by consumers and the community due to egg-related food-borne illness is approximately \$AUD112.46m per annum. This includes health related costs, loss of income and/or leisure as well as a monetary value attributed to pain and suffering.

#### 8.3.1.3 Costs to Government

Government costs due to the outbreak of food-borne illness cover recalls, compliance and investigation costs. For example a recent recall incident in relation to eggs in Queensland would have amounted to at least \$AUD55,000 for the government<sup>63</sup>.

The annual costs of surveillance, investigation and maintaining current food safety systems were estimated at \$AUD10m annually<sup>64</sup>. Apportioning an estimated 16% of these costs to egg-related operations equates to a cost of \$AUD1.75m per year at current prices (adjusting the 2006 estimate of \$AUD1.6m by the 2006-09 ATO index of 9.4 %).

Therefore total costs per year of the status quo option is estimated at \$AUD6.75m for industry, \$AUD112.46m for the community and \$AUD1.75 m for the government or about \$AUD120m annually.

#### 8.3.2 Benefits

The benefit that could arise from remaining with the *status quo* option is the absence of any new financial burden, which could occur if there were any changes to the current mode of activity. This applies equally to industry, consumers and jurisdictions.

# 8.4 Option 2: Self-regulation - Voluntary uptake of requirements for production and processing by industry.

The major *advantage* of this option is that industry already has significant responsibility for egg safety, through current industry schemes and it could potentially have a stronger, industry-wide commitment to ensuring egg safety.

The major *disadvantage* is that not all industry could choose to comply with such a scheme and without a government role consumer confidence in egg safety could be compromised.

Education campaigns are tools which can be used to reinforce food safety messages. For education campaigns to be effective, programs based on nationally consistent egg safety messages are best developed and implemented by the jurisdictions.

<sup>62</sup>Hall, G., Kirk, M.D., Becker, N., Gregory, J.E., Unicomb, L., Millard, G., Stafford, R. And Lalor, K. (2005). Estimating food-borne gastroenteritis, Australia. *Emerg Infect Dis.* **11** (8): 1257 - 1264.

<sup>64</sup> Abelson et al. 2006. The annual cost of food-borne illness in Australia

<sup>&</sup>lt;sup>63</sup> SFPQ personal communication indicated about 1200 hours involvement from several agencies. Based on FSANZ's previous experience in collecting enforcement costs a base officer rate of \$ 45 per hour has been applied. In practice the costs will be much higher due to some involvement of legal and senior staff.

Nationally this could be achieved through ISC and in partnership with the egg industry. Some jurisdictions have shown support for education initiatives for the farming sector, food handlers and the public.

The effectiveness of education campaigns and current egg food safety messages (for example, website information, fact sheets and flyers) is questionable as shown in FSANZ's consumer survey (SD2). The data *suggest* that some consumers are unaware of current egg safety messages, that the messages are not effective, or that there are no consistent messages regarding egg handling.

There are also education messages aimed at egg handling in the food service industry. The effectiveness of such campaigns could be questioned as food-borne illness outbreaks associated with eggs at restaurant and catering facilities continue to occur<sup>65</sup>.

A self-regulatory option, with additional education programs, is dependent on industry-wide voluntary adoption. It would be less effective than a regulatory approach to address the public health and food safety problem. Furthermore, advice from the SDC and through broader consultation is that self-regulation is not supported by State or Territory Governments or by the egg industry. However, in exploring this option, FSANZ has undertaken an analysis of the costs and benefits to all stakeholders.

#### 8.4.1 *Costs*

#### 8.4.1.1 Costs to industry

Under the self—regulation option, depending on the number of businesses and the extent to which the industry voluntarily adopts best practice, a wide range of costs may be incurred. Additional costs of establishing and maintaining the necessary protocols may range broadly from no additional cost to on-going costs of \$AUD3.89m annually<sup>66</sup>.

There could be additional costs involved with the introduction of registering, accreditation or licensing requirements.

Also, there may be disproportionate costs to those who adhere to industry self regulation initiatives, compared to those who do not.

#### 8.4.1.1.1 Education initiatives

An education campaign may be undertaken by industry (possibly in conjunction with government) to inform producers and consumers about food safety practices in order to minimise adverse health outcomes and the disease burden arising from the consumption of contaminated eggs and egg products.

<sup>&</sup>lt;sup>65</sup> Stephens, N., Coleman D. And Shaw K. (2008) Recurring outbreaks of *Salmonella typhimurium* phage type 135 associated with the consumption of products containing raw egg in Tasmania (<a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\$FILE/cdi3204.pdf">http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\$FILE/cdi3204.pdf</a>
<sup>66</sup> The Australian Egg Corporation Limited's (AECL) Annual Report for 2008 indicates that they received approximately \$ 3.89 m in promotion, research and development levies from industry. While these costs had been incurred to promote and increase sales for the industry, because AECL is a producer owned company operating for the benefit of its members the same amount has been used as an estimate to cost a self-regulation approach by the industry.

Irrespective of whichever sector (industry or Government) undertakes the education program, it will add to the costs. The cost of egg related education initiatives (including education campaigns) may range from a few thousand dollars, for example, for distributing pamphlets and fact sheets, to more significant measures such as preparing advertising on the radio or television.

For example, The Australian Egg Corporation Limited (AECL)<sup>67</sup> states that approximately \$AUD2.77m was spent in 2008 on market awareness, education and public affairs activities.

Therefore the total cost of the self-regulation option for industry is estimated to be in the range of no extra costs up to \$AUD6.6m annually (i.e. ranging from no further action, to the establishment of significant measures and education initiatives).

#### 8.4.1.2 Cost to consumers

It is anticipated that industry will pass on to consumers some part of the cost burden of self-regulation. This figure is already present in the cost that FSANZ has computed for industry.

Besides the financial burden, self-regulation may also have the effect of limiting the choice of eggs and egg products in the market if industry phase out, or discard, products that have not been produced in accordance with industry schemes.

# 8.4.1.3 Costs to Government

Under a self- regulatory regime, Governments may incur costs arising out of supporting and maintaining industry's self regulation systems. In 2008, the Government contributed to AECL (through grants) a sum of \$AUD1m<sup>68</sup>. The Government may also choose to provide funding to other egg industry bodies or organisations.

In estimating the probable costs of a Government-assisted self-regulation program (\$AUD3.89m per annum), FSANZ has been guided by the existing industry-wide program run by AECL. Thus a comparable Government program for the egg industry, aimed at promoting, implementation and maintaining an industry-wide self-regulation scheme could also cost up to \$AUD3.89m.

In addition the Government may complement industry's education initiatives and could incur up to \$AUD2.77m annually (through an equal contribution to industry's cost of education initiatives). Thus the total cost to Government for a self-regulation program is also estimated at \$AUD6.6m annually.

#### 8.4.2 Benefits

8.4.2.1 Benefits to industry

The benefits of a self-regulation program for industry include monetary as well as less-tangible benefits such as improved goodwill and less spoilage/ wastage.

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<sup>&</sup>lt;sup>67</sup> AECL *Annual Report 2008* <a href="http://www.aecl.org/images/File/AECL%20Annual%20Report%20web.pdf">http://www.aecl.org/images/File/AECL%20Annual%20Report%20web.pdf</a> (accessed July 2009)

<sup>&</sup>lt;sup>68</sup> AECL Annual Report 2008.

#### 8.4.2.2 Benefits to the community

If there was complete industry uptake of a self-regulatory option, the benefits to consumers from an industry wide self-regulation program would be an increase in the level of food safety and a consequent reduction in food-borne illness linked to the consumption of eggs and egg products. However the extent or magnitude of benefits to the consumers and community from an industry self regulation approach is uncertain.

#### 8.4.2.3 Benefits to Government

From the self-regulation option, Government would benefit from a reduction in public health and medical costs when there is a reduction in food-borne illnesses and improved levels of food safety.

# 8.5 Option 3: Regulatory option –including a Primary Production and Processing Standard in the Code

The major *advantage* of this approach, if businesses comply with the requirements, is that it addresses the identified problem of public health and safety concerns and will achieve the objective of reducing the prevalence of *Salmonella* in eggs and the availability of cracked and dirty eggs for sale.

Several submissions at Initial Assessment raised concerns that food safety practices could differ with the size of the production facility. Small or backyard producers may not clean, grade or assess their eggs and therefore compromise the safety of their produce. The regulatory option will apply to all businesses involved in the production and processing of eggs and egg products, irrespective of the number of eggs produced or layers kept.

The proposed standard is applicable nationally and will manage the hazards at the points in the chain where they are most likely to occur. The development of outcome based standards ensures that requirements are flexible enough to allow businesses to decide on the specific measures needed in their business to manage the hazards. Jurisdictions and industry have shown overall support for through-chain traceability requirements to enable easy identification of eggs and investigations of food-borne illness.

The major *disadvantage* of this approach is that there are likely to be new costs for industry and government and, potentially, consumers. As a result of this there may be potential unintended consequences such as an increase in the market for un-regulated eggs. Potentially there may be an increase in farm-gate sales. However, these are within the scope of the standard.

#### 8.5.1 *Costs*

#### 8.5.1.1 Costs to industry

#### 8.5.1.1.1 Summary of Potential Costs (\$AUD)

Additional Upfront / Initial Costs	Large – Medium	Small scale farms	Total costs
	scale farms		
Building / Infrastructure			\$371,000
Inputs	\$120,000	\$ 427,000	\$547,000
Training, skills, and development	\$ 47,000	\$ 353,000	\$400,000
Traceability/ Stamping	\$ 2,800,000	\$ 1,500,000	\$4,300,000
Implementation or Compliance	\$ 43,000	-	\$43,000
Total initial cost	\$ 3,010,000	\$ 2,280,000	\$ 5,661,000
Additional Ongoing / Annual Costs			
Health, Hygiene and Food Safety management	\$ 875,000	\$ 278,000	\$ 1,153,000
Compliance or Implementation	\$ 514,000	\$ 350,000	\$864,000
Traceability/ Stamping	\$ 800,000	\$ 660,000	\$ 1,460,000
<b>Total Ongoing Costs</b>	\$ 2,189,000	\$ 1,288,000	\$ 3,477,000

# **Initial / Upfront Costs**

# Medium – Large size businesses (> 500 birds per farm or producing > 60,000 dozen eggs per annum)

One-off building/infrastructure Costs

Improvements to infrastructure/buildings are estimated to cost \$AUD371,000.

This is based on data provided by NSW Food Authority Egg Food Safety Scheme Regulatory Impact Statement (2005) which indicates a one-off estimated cost, state-wide, of \$AUD115,000. When adjusted for inflation this equates to \$AUD130,000 in current terms (applying an ATO inflation index of 12.7% over 2005-09). NSW accounts for about 35% of the total production in terms of value<sup>69</sup>. Extrapolating, it is estimated that nationally the cost relating to buildings is approximately \$AUD371,000.

The building and infrastructure costs represented here covers all types of farms (break down of costs for small business is not available). Infrastructure is not listed in the small business section to avoid double counting.

Input costs, covering the infrastructure for the provision of water, feed and chemicals are

#### One-off input costs

\$AUD120,000. This is based on data for Victoria (approximately \$AUD36,000, which is then extrapolated to arrive at a national estimate).

<sup>&</sup>lt;sup>69</sup> NSW Food Authority Risk Impact Analysis (2005) for proposed Egg Food Safety Scheme.

One-off skills, training and development costs

The cost of upgrading skills will be \$AUD47,000. This is based on the start-up costs of a training and skills program for Victorian producers who account for 30% of the national flock. The training was estimated to cost \$AUD200 per farm, or about \$AUD14,000 statewide.

One-off costs for stamping

Stamping (for traceability purposes) could cost up to \$AUD2.8m across Australia. This is based on the higher of the two estimates made below:

- (1) In Victoria, the cost of printing equipment<sup>70</sup> was estimated at \$AUD4000-30,000 for each producer. For all medium and large producers and processors (more than 500 birds on farm) the cost is approximately \$AUD450,000 for stamping equipment (in Victoria). Taking base case estimates of \$AUD450,000 (in Victoria), the upfront costs of stamping nationally for medium and large scale producers would be \$AUD1.5m. However, Queensland egg producers are excluded from this computation as they are already required to stamp their eggs under the *Egg Food Safety Scheme*. Therefore, the incremental costs are estimated for all states other than Queensland. As Queensland constituted about 30%<sup>71</sup> of the national production, \$AUD1.5M is proportionately scaled down to about \$AUD1m to reflect total up-front stamping costs for medium and large producers across Australia.
- (2) Data from Queensland<sup>72</sup> indicate that the cost of stamping in the first year of production is estimated at about 0.10c per egg to 0.75c per egg, depending on whether they are large or medium scale businesses. Excluding Queensland, there are about 150 million dozen eggs produced annually that could potentially require stamping. Based on the size distribution of producers in Queensland, about 87% of the total output is from the largest farms. These producers would incur a cost of 0.104c per egg or \$AUD1.63m and another 8.7% of the total eggs produced could be stamped at 0.75c per egg or \$AUD1.17m. Small farms, which account for 4% of the output, are dealt in the small business section below.

Total upfront costs of stamping for medium and large scale producers is about \$AUD2.8m.

One-off costs for compliance or implementation

Nationally, it is estimated that there could also be a one –off implementation cost for businesses amounting to \$AUD43,000. NSW, which accounts for 35% of national production, anticipate a license fee (applying to 300 businesses), which totals \$AUD15,000<sup>73</sup>. Since no other start-up implementation costs have been reported, these data have been used to estimate a national figure.

http://www.aecl.org/images/File/AECL%20Annual%20Report%20web.pdf (accessed July 2009)

<sup>&</sup>lt;sup>70</sup> Data provided by the Victorian Department of Primary Industries, August 2009

<sup>&</sup>lt;sup>71</sup> AECL 2008 Annual Report

<sup>72</sup> Data provided by Safe Food Production Queensland, August 2009

<sup>&</sup>lt;sup>73</sup> data provided by NSW Food Authority

Total initial costs to medium and large businesses

Total upfront cost to large and medium scale producers and processors is estimated at about \$AUD3.01m.

# Initial costs to small business and/or duck and quail farms (<500 birds per farm / producing< 60,000 dozen eggs per annum)

In regard to smaller businesses the following estimates have been made<sup>74</sup>.

One-off Costs for Inputs, Skills and Training

Duck and quail farmers<sup>75</sup> generally supply eggs to a niche market (for example, for the production of speciality eggs). As they are small egg businesses it is relevant to include them in this Impact Analysis.

It is estimated that about 500 small chicken egg producers in Victoria could incur \$AUD250 per farm or a total of \$AUD125,000 for inputs. Duck and quail farm input costs sum up to \$AUD3000. The total input cost of \$AUD128,000 for small chicken egg producers and duck and quail farms is extrapolated to about \$AUD427,000 to arrive at a national figure.

For skills and knowledge costs, these 500 small chicken egg farms may incur \$AUD200 per farm or a total of \$AUD100,000. For the duck and quail farms, costs were estimated to total \$AUD6000 for skills and knowledge. As no other small business information was available (and Victoria accounts for 30% of the national flock), total state skills and training costs of \$AUD106,000 were extrapolated to \$AUD353,000 nationally.

#### One-off stamping costs

For small businesses, stamping and printing equipment may cost up to \$AUD1.5m. This is based on the higher of the two estimates that follow:

- \$\text{\$AUD4000}\$ each for about 160 small chicken egg producers\$^{76}\$ in Victoria; in addition \$\text{\$AUD3000}\$ was reported as upfront stamping costs for duck and quail farms. Therefore, total stamping costs are estimated at \$\text{\$AUD643,000}\$ for Victoria. Nationally, the additional stamping and printing costs for small producers would be approximately \$\text{\$AUD2.14m}\$. As Queensland producers are already stamping their eggs and account for about 30% of the production, total upfront stamping costs for small businesses is scaled down to about \$\text{\$AUD1.5m}\$.
- Queensland<sup>77</sup> indicated that the cost of stamping in the first year of production for about 4.3 % of the remaining national output (150 million dozen eggs, excluding Queensland) from small farms using hand stamping, could be .11 c per egg or \$AUD85,000.

<sup>77</sup> Data provided by Safe Food Production Queensland

<sup>&</sup>lt;sup>74</sup> data provided by the Victorian Department of Primary Industries

<sup>&</sup>lt;sup>75</sup> There are approximately 10 duck farms (50 – 60,000 ducks in total) and 5 quail farms (20,000 quail in total) in Victoria (Victorian Department of Primary Industries, personal communication).

<sup>&</sup>lt;sup>76</sup> data provided by the Victorian Department of Primary Industries

Total initial costs to small businesses

Total upfront cost to small scale producers and processors is estimated at about \$AUD2.28m.

*Industry wide initial costs* 

In summary, the total initial or upfront costs for industry under Option 3, is therefore approximately \$AUD5.66m, taking into consideration the costs of plant, premises and equipment installation or upgrades, training and stamping and some implementation costs.

#### **Ongoing or Annual Costs**

# Medium - Large size businesses (> 500 birds per farm or producing> 60,000 dozen eggs per annum)

Ongoing costs for health, hygiene and food safety management

Ongoing costs to producers and processors relate to general food safety management and traceability. This includes health and hygiene of personnel, visitors and flock at production and processing units.

In Victoria, medium to large producers and processors would incur additional costs of up to \$AUD65,000 per annum in order to comply with health and hygiene requirements. Costs provided by NSW indicated additional food safety management costs per year are approximately total \$AUD504,000 per annum for the NSW industry. Given that these two states contribute about 65 % of the national production of eggs, the total costs of \$AUD569,000 annually (for health, hygiene and food safety management) have been extrapolated Australia-wide to \$AUD875,000 per annum.

Ongoing compliance or implementation costs

In addition, there may be other costs such as record keeping, auditing and accreditation costs in demonstrating compliance. Costs for larger producers and/or processors in Victoria are estimated at \$AUD45,000 per annum for a range of activities, including cleaning and sanitation programs, testing and vaccination. Similarly, NSW reported approximately \$AUD289,000 per year for implementation costs. Therefore total implementation or compliance costs of Victoria and NSW combined i.e. \$AUD334,000 would be scaled up to about \$AUD514,000 per annum for the industry Australia-wide.

Ongoing traceability and identification costs

The ongoing cost of traceability and identification requirements to medium-large scale producers and processors is estimated up to \$AUD800,000 per year.

<sup>78</sup> The NSW Food Authority licenses food businesses which must implement and maintain a food safety program based on Codex' HACCP, or *Standard 3.2.1* of the Food Standards Code.

<sup>&</sup>lt;sup>79</sup> NSW Food Authority Egg Food Safety Scheme (2005) reported that NSW contributed about 35% of the total value of national production; Victoria makes up approximately 30% of the national flock (AECL 2008 Annual Report).

This figure is the higher of the following two estimates:

- (1) Base costs of traceability and identification requirements for medium-large scale businesses in Victoria is reported at \$AUD246,000 per annum and is extrapolated nationally to about \$AUD820,000 annually. However, this amount is adjusted and scaled down to approximately \$AUD570,000 to discount costs of Queensland producers who are already stamping their eggs.
- (2) Data from Queensland<sup>80</sup> indicate that the cost of stamping in the second year of production is estimated as being between 0.031c-0.2 c per egg, depending on scale (large –medium) business. Excluding Queensland, there are about 150 million dozen eggs produced annually that could potentially require stamping. Based on the break up for Queensland, about 87% of the total output is from the largest farms that would incur a cost of 0.0312 c per egg or \$AUD490,000 and another 8.7 % of the total eggs produced from medium scale firms could be stamped at 0.2c per egg or \$AUD315,000 (details of the remaining 4% of the small farms stamping costs appear in the small business section below). Total ongoing costs of stamping for medium and large scale producers is about \$AUD800,000 annually.

Total Ongoing Costs to medium and large businesses

Total ongoing cost to large and medium scale producers and processors is estimated at about \$AUD2.19m per year.

# Ongoing or annual costs to small business and/or duck and quail farms (<500 birds per farm / producing< 60,000 dozen eggs per annum)

Ongoing Costs for health, hygiene and food safety

The ongoing costs for small producers and processors for health, hygiene and food safety is estimated at \$AUD278,000 per year . This figure is derived from 350 small farms<sup>81</sup> at a cost of \$AUD200 per farm for health, hygiene requirements; and a total of \$AUD13,500 for duck and quail farms i.e. in Victoria total \$AUD83,500 per year. This figure is scaled up to \$AUD278,000 per year nationally.

Ongoing Implementation or Compliance Costs

In regard to ongoing implementation costs, Victoria reported \$AUD105,000 per year (300 farms at the cost of \$300 per farm and another \$ AUD15,000 per year for all duck and quail farms). This cost has been scaled up to \$AUD350,000 nationally.

Ongoing Stamping Costs

Total ongoing stamping costs for small scale producers, processors and duck quail farms have been estimated up to \$AUD660,000 per year . This is based on the higher of the following two estimates:

<sup>80</sup> Data provided by Safe Food Production Queensland, August 2009

<sup>&</sup>lt;sup>81</sup> Estimated on-going 'health and hygiene' costs for 350 egg producers with <500 birds (Victorian Department of Primary Industries)

(1) Traceability requirement costs in Victoria were identified to be about \$AUD280,000 per annum for the smaller chicken egg producers and processors.

This was based on 160 producers incurring a cost of \$AUD1000 per farm and 300 processors incurring a cost of \$AUD400 per farm.

The costs of traceability requirements for duck and quail egg producers were estimated to total \$AUD4000 per year in Victoria. Therefore the total additional costs of traceability requirements for smaller producers and processors and duck and quail farms (in Victoria) are \$AUD284,000. This cost, when extrapolated to the remaining states, results in total incremental costs of about \$AUD946,000 per annum. As Queensland producers are already stamping, the national total of \$AUD946,000 has been discounted to about \$AUD660,000 per year to arrive at the cost of stamping for small scale producers, processors and duck and quail farms Australia-wide.

(2) In Queensland<sup>82</sup> the cost of stamping in the second year of production for about 4.3 % of the remaining national output (150 million dozen eggs produced annually, excluding Queensland) from small scale farms using hand stamping could be .083c per egg or approximately \$AUD65,000.

Total Ongoing Costs to small businesses

Therefore, total ongoing costs to the smaller producers and processors are approximately \$AUD1.29 m per annum.

Industry-wide ongoing costs

In summary total ongoing costs for industry are approximately \$AUD3.48m per annum

#### 8.5.1.2 Costs to the community/ consumers

The cost to consumers could be an increased cost of eggs and egg products on the market, to the extent that industry passes on the additional costs to the consumers. These costs have already been incorporated in the computations FSANZ has made for industry.

In addition, as some smaller businesses may not be able to meet the requirements of the new standard they may be forced to close down and the sale of ungraded backyard eggs will cease (produce that does not comply cannot be sold). Some consumers may then feel disadvantaged due to a reduction in the choice of eggs and egg products.

#### 8.5.1.3 Costs to Government

There would be enforcement costs incurred by jurisdictions in implementing the standard. NSW Food Authority reported a once off setup cost of \$AUD50,000. In addition, Safe Food Production Queensland reported an additional upfront (set up cost) of approximately \$AUD8400, and of \$AUD17,300 in ongoing annual costs. Depending on the cost recovery practices employed by the jurisdictions, industry may contribute towards these enforcement costs. These factors have already been computed under implementation costs and/or damage and risk to industry.

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<sup>&</sup>lt;sup>82</sup> Data provided by Safe Food Production Queensland

Therefore, the total reported costs to Government are approximately \$AUD58,000 upfront and \$AUD17,000 ongoing for NSW and Queensland.

Based on these data, it is estimated that set-up costs for all jurisdictions will be approximately \$AUD97,000, and \$AUD57,000 for ongoing costs. This information is scaled up from NSW and QLD costs which combined account for about 60% of national flock.

#### 8.5.2 Benefits

# 8.5.2.1 Benefits to industry

Under the regulatory option, there would be a range of benefits for industry, from making egg and egg products safe and current requirements simpler, to improved goodwill and consumer confidence in their products to increased sales revenue.

The following evidence reflects the magnitude of efficacy and expected outcomes from food safety control measures.

The Preliminary Regulatory Impact Analyses of the United States Food and Drug Administration (USFDA) on Prevention of Salmonella Enteritidis in Shell Eggs during Production forecast a 35% reduction (33,452 illnesses averted out of base of 94,620 foodborne egg related Salmonellosis cases). The final report indicates a prevention of about 79,000 cases of egg-related food-borne salmonellosis illnesses out of a base line estimate of about 140,000 cases or more than 50% efficacy<sup>83</sup>.

The proposed NSW Food Authority's Egg Food Safety Scheme Risk Impact Statement (2005) and Food Amendment Regulation (2008) in regard to child and day care centres predict a 50% reduction in the risk of food-borne illness through food safety control measures (if there is complete industry uptake of measures). However, the National Risk Validation project<sup>84</sup> claims that a robust food safety program could achieve up to a 70% success rate in reducing food-borne illnesses.

Having considered the foregoing, if the whole of industry complies with primary production and processing control measures that are not optional and enforceable, a reduction in the risk of food-borne illness of up to 50% is estimated.

There will be potential benefits for industry due to the introduction of mandatory standards. As detailed above, adherence to regulatory control measures may reduce the incidence of disease by 35-70%. Erosion of business reputation, litigation, recall as well as fines and penalties as a consequence of egg related illness were already considered under the status quo option. Conforming to a standard would mitigate such commercial adversity and nationally the egg industry would have a benefit assessed at \$AUD6.75m annually.

SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170615.htm

http://www.federalregister.gov/OFRUpload/OFRData/2009-16119 PI.pdf: 90.

<sup>83</sup> The USFDA Egg Safety Final Rule, published July 7, 2009 http://www.fda.gov/Food/FoodSafety/Product-

<sup>84</sup> National Risk Validation project - NSW Department of Health and Commonwealth Department of Health and Ageing (2002)

Making a conservative assumption, it has been estimated that there could be a reduction of egg-related disease of 20-50%. In monetary terms this translates to a national benefit averaging around \$AUD2.36m per annum.

#### 8.5.2.2 Benefits to community & consumers

Consumers and the community would benefit from the reduced risk of food-borne illness as a consequence of the adoption of a national standard. This would lead to improved health, welfare and productivity.

Under the *status quo* option, it was estimated that the loss to the community, in terms of health, welfare and productivity, from an individual *Salmonella* food-borne illness was \$AUD8786 per case.

With the implementation of a standard the reduced disease burden will be in the range of 35-70%. Again taking a conservative estimate of a reduction of egg-related disease of 20-50%, that is 2560-6400 less cases of illness, the benefit to the community will be \$AUD39.36m annually.

### 8.5.2.3 Benefits to Government

Governments would also benefit from improved food safety and reduced food-borne illness due to the introduction and enforcement of a national egg standard. The current burden of food-borne illness related investigation, surveillance and recall costs was estimated under the *status quo* option at \$AUD1.75m annually. In light of the costs of non-compliance and response in relation to egg-associated food-borne illness, the jurisdictions have indicated support for and a need to address the food safety risks posed by cracked and dirty eggs and inadequate traceability requirements through a national primary production and processing standard for eggs<sup>85</sup>.

Applying a conservative 20-50% reduction in disease, there will be a savings average of about \$AUD610,000 for Government in the area of recall, investigation and surveillance. Benefits arising from reduced medical and hospital costs have already been included under community and consumer benefits. The primary production and processing Standard will make the current requirements more straightforward to enforce. Therefore the government should also benefit from consistent implementation across the states.

There will also be indirect qualitative benefits in the areas of consumer and industry well-being, potential savings in litigation costs and increased goodwill.

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<sup>&</sup>lt;sup>85</sup> Slinko, V., McCall, B., Stafford, R., Bell, R., Hiley L., Sandberg, S., White, S. And Bell, K. (2009) Outbreaks of Salmonella Typhimurium type 197 of multiple genotypes linked to an egg producer (in publication).

**Table 2: Summary of costs and benefits (Australian dollars)** 

Option	Impacts, costs and benefits			Overall impacts	
(self-regulatory and regulatory)	Business	Government	Other Stakeholder groups		
	(small, medium and large) and Industry	(Australian Govt, state/territory, local government)	(e.g. consumers)	(Net Benefits/Cost)	
Option 1 – Status	Costs	Costs	Costs	Costs	
quo	\$AUD6.75 Million p.a.	\$AUD1.75 Million p.a.	\$AUD112.46 Million p.a.	\$AUD120.96 Million p.a.	
	Risk of Damage and reputation to industry	Recall costs, investigation and surveillance	Food-borne illness to the community		
No additional benefit counting.	s of <i>status quo</i> . Benefits such as no o	cost of regulatory / non regulatory a	ction considered in increased cost	s of other options to avoid double	
Option 2 – Self Regulation	Costs	Costs	Costs	Costs	
	up to \$AUD6.6 Million p.a.	up to \$AUD6.6 Million p.a.	Industry could pass on increase costs to consumers	up to \$AUD13.2 Million p.a.	
	up to \$AUD6.6 Million p.a.  Cost of voluntary program & Education campaign	up to \$AUD6.6 Million p.a.  Equal contribution towards a self regulation program,	Industry could pass on increase costs to consumers	up to \$AUD13.2 Million p.a.	
	Cost of voluntary program	Equal contribution towards a	, i	up to \$AUD13.2 Million p.a.  Benefits	

Self Regulation is not supported by the SDC and it is not considered a viable option as the likelihood of small producers not complying is high. The efficacy of this option is unknown.

Option	Impacts, costs and benefits			Overall impacts
	Business	Government	Other Stakeholder groups	(Net Benefits/Cost)
	(small, medium and large) and Industry	(Australian Govt, state/territory, local government	(e.g. consumers)	(1.00 20111111111111111111111111111111111
Option 3 – regulatory (mandatory minimum standard)	Costs  \$AUD3.18 Million upfront \$AUD2.9 Million ongoing  Benefits  \$AUD2.36 Million p.a. Improved reputation /reduced risk & damage etc	Costs  \$AUD97,000 upfront  \$AUD57,000 ongoing  Enforcement costs  Benefits  \$AUD610,000 p.a.  Savings in surveillance, recall & investigation	Costs  Industry could pass on increased costs to consumers  Benefits  \$AUD22.49-56.23 Million p.a. Health, Welfare and productivity	Benefits  Net Benefits in present value ranges from \$AUD 95 Million - over \$AUD200 Million over 5 years (See SD 6)  Depending on 20-50% efficiency of standard  Discount rate 7%

A detailed comparison of the costs and benefits of the options considered above is provided in SD6.

# 9. Conclusion and Preferred Approach

#### 9. 1 Conclusion

The impact analysis concluded that the costs for maintaining the *status quo* (i.e. choosing Option 1) outweigh the benefits. This option is not supported by FSANZ as it does not achieve the public health and safety objectives.

Self-regulation (Option 2) with regard to producers is not a viable option because evidence and advice from the SDC indicates that the likelihood of small producers participating is low and the public health and safety objectives will not be achieved.

With regard to processors, for public health reasons industry has throughout supported retaining the requirement that liquid eggs are treated to destroy pathogens, and that cracked and dirty eggs are not made available to the public or to businesses (such as bakeries and food service) for use in other products. Jurisdictions, for the same reason, have also continued to support the inclusion of regulatory requirements in the Code. Also some States have introduced (or will introduce) their own legislation, which indicates that they do not consider the self-regulation option is viable.

Therefore, on the basis of the impact analysis and viability of each option in achieving the stated objectives, it is concluded that Option 3: the introduction of a primary production and processing Standard for Eggs and Egg Products has the potential to deliver maximum net benefits to the community. Even at a conservative level of 20% efficacy, the benefits outweigh the costs. As set out in Table 2, the total cost over 5 years is \$AUD17.22m compared with benefits estimated at over \$AUD100m, taking into account health, welfare and productivity. Although the outcome is based on national averages and estimates, even if the costs are doubled and benefits are halved, the Standard has the potential to generate significant net benefits to the community

In practice, the net benefits from the standard are expected to be much higher since FSANZ has used conservative estimates. In reality, there may be more preventable cases of food-borne salmonellosis due to eggs in the community and compliance with a primary production and processing standard could lead to a greater reduction in the burden of disease i.e. 35-50%.

#### **Preferred Approach**

FSANZ recommends that the Code be amended to include Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products into Chapter 4 and other consequential amendments.

# 9.2 Reasons for Preferred Approach

At Draft Assessment, FSANZ recommends that the Code be amended to include Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products (see Attachment 1<sup>86</sup>) into Chapter 4 for the following reasons. The proposed amendments:

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<sup>&</sup>lt;sup>86</sup> Draft Standard 4.2.5 refers to definitions described in Draft Standard 4.1.1 – Primary Production and Processing Standards Preliminary Provisions. Standard 4.1.1 is consequential drafting arising from P282 Poultry Meat.

- address public health and safety concerns raised in the Risk Assessment
- are consistent with the section 18 objectives of the FSANZ Act to protect public health and safety
- provide a nationally consistent legislative framework for a whole-of-chain approach to egg and egg product safety
- take into account existing State-based requirements, providing a consolidated set of requirements based on scientific assessment
- provide measures that are outcome based and would not impose any unwarranted overall additional costs to industry over existing requirements.

# 9.3 Description of the draft Standard

Standard 4.2.5 is a Standard with requirements on egg producers and egg processors for the production and processing of eggs and egg products. The activities encompassed in the standard are outlined in Figure 1 (Section 4). Egg producers and processors will be required to demonstrate that they control potential food safety hazards associated with their business.

Both producers and processors will be required to produce safe and suitable eggs or egg products through ensuring that layers are healthy and inputs, waste disposal, premises, equipment, vehicles and health and hygiene requirements minimise contamination. They will also be required to have skills and knowledge in food hygiene.

Dirty and cracked eggs and egg pulp that has not been processed in accordance with the proposed standard are defined as unacceptable eggs. Dirty eggs can either be sent for cleaning and subsequent sale as shell eggs or for processing, whereas cracked eggs and egg pulp may only be sent for processing into egg products (i.e. processed egg pulp, liquid egg yolk, liquid egg white and dried egg). These egg products can be processed in a number of ways which will eliminate pathogens, for example by pasteurisation<sup>87</sup>. Following processing, egg products must be stored or transported under time/temperature control. A processor cannot sell product that is unacceptable.

All eggs must be marked with the producer's or processor's unique identifier. Egg pulp and egg products also need to be similarly identified.

These requirements aim to minimise the contamination of eggs on farm, prevent the sale of cracked and dirty eggs to the shell egg market, and allow the sale of cracked eggs and egg pulp solely to egg processors making egg products.

Within draft Standard 4.2.5, the Chapter 3 – Food Safety Standards do not apply to **any** activities other than the pasteurisation of egg products and post-pasteurisation storage and transport. This approach ultimately results in removing current regulation on egg processors in Chapter 3 and targets regulation to the critical points in the production and processing chain.

<sup>&</sup>lt;sup>87</sup> The current processing requirements will be moved from Standard 1.6.2 into Standard 4.2.5 (see Section 10.4)

# 9.4 Draft consequential amendments to the Code<sup>88</sup>

As a result of the development of draft Standard 4.2.5, there will be some consequential changes required to the Code which will add clarification or remove duplication of requirements. These changes have been considered as part of the whole package during the impact analysis. Consequential amendments will be made to:

- Standard 1.1.1 Preliminary Provisions Application, Interpretation and General Provisions a general definition of 'egg product' will be introduced.
- Standard 1.6.1 Microbiological Limits for Foods the requirement for 'pasteurised egg products' will be changed to 'processed egg products'. A definition of processed pertaining to egg products will also be included for clarification.
- Standard 1.6.2 Processing Requirements the requirements in this Standard will be clarified and moved into Standard 4.2.5.
- Standard 2.2.2 Eggs and Egg Products through the standard development process it was considered that Standard 2.2.2 Eggs and Egg Products should be replaced with a simplified Standard 2.2.2 which would include retail sale and catering provisions (which have been clarified) and traceability provisions for retail sale and catering purposes. This would be an Australia only Standard.

# CONSULTATION AND COMMUNICATION

# 10. Consultation

#### 10.1 Standard Development Committee

FSANZ established an SDC at the commencement of this Proposal in July 2006. The SDC has representatives from major stakeholder groups (industry, government, research, veterinary practice and consumers). Its role is to provide scientific, technical, policy, regulatory/enforcement, cost benefit or any other input that may be relevant to the Proposal and provide a communication link with members' respective groups.

Membership of the SDC is provided in SD8.

#### 10.2 Scientific Advisory Panel

FSANZ established an Egg Scientific Advisory Panel to assist the Risk Assessment team in the preparation of the scientific assessment. Panel members were selected for their expertise and experience in the following areas: food processing/manufacturing; egg production; animal health; Risk Assessment; microbiology; toxicology/chemistry and public health (epidemiology). The Panel's role was to advise on the egg and egg products scientific assessment, provide guidance in identifying additional sources of data and assist in addressing uncertainty or variability in the information underpinning the scientific assessments.

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<sup>88</sup> These amendments are for noting only.

Membership of the Egg Scientific Advisory Panel is provided in SD1.

# 10.3 Industry visits

In the initial stages of the Proposal, FSANZ undertook a series of industry visits to develop an understanding of the egg and egg product production process and to establish relationships with egg producers and processors as well as the State/Territory enforcement agencies. FSANZ members visited several egg farms (cage, barn and free-range for both hens and ducks), egg product processing facilities and specialty egg producers in five States and Territories. The visits were arranged in consultation with industry and enforcement agencies and provided FSANZ with the opportunity to gain a greater understanding of the regulatory framework of those jurisdictions.

#### 10.4 Public consultation

FSANZ undertook the first round of public consultation on this Proposal in December 2006. The Initial Assessment Report was released for an eight week consultation period from 13 December 2006 until 21 February 2007. Twenty-five submissions were received. A list of submitters, their comments and a response by FSANZ to the comments, are provided in Attachment 3. The comments have been considered in determining the risk management options, the impact analysis and the preferred option.

The Draft Assessment Report presents the findings of further work on this Proposal for public consultation. The conclusions and preferred approach are described in Attachment 3.

#### 10.5 Consultation with New Zealand

New Zealand is represented on the SDC and has therefore been involved in the Proposal since its inception because changes to the Code may impact on requirements in New Zealand and trade between the two countries. Two Standards that currently apply to eggs and egg products are joint standards with New Zealand: Standards 1.6.1 and Standard 2.2.2. The Chapter 3 and Chapter 4 Standards in the Code do not apply in New Zealand as food safety requirements are outside the scope of the arrangements between Australia and New Zealand for a joint Code<sup>89</sup>. New Zealand has food safety requirements in the *Food Act 1981* and the Animal *Product Act 1999*.

The *Animal Product Act 1999* requires egg producers to have a risk management program to control hazards and other risk factors so that shell eggs are fit for their intended purpose. The program must cover their primary processing operations (from laying farm through to packing of shell eggs). Requirements for programs are contained in the Egg Producers Federation of New Zealand Inc Code of Practice<sup>90</sup>.

New Zealand has shown support for Option 3, the development of a through chain egg and egg product Standard.

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<sup>&</sup>lt;sup>89</sup> Under the Trans-Tasman Mutual Recognition Arrangement, the Australian Government, State and Territory Governments and the Government of New Zealand have common food standards (the Code), but New Zealand develops its own food standards for residues of agricultural and veterinary chemicals, food safety and primary production and processing.

http://www.nzfsa.govt.nz/animalproducts/publications/consultation/egg-cop/egg-cop.pdf (accessed July 2009)

#### 10.6 World Trade Organization

As members of the World Trade Organization (WTO), Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The proposed Standard for Eggs and Egg Products in Chapter 4 has been developed recognising the internationally agreed guidelines for the safe production of eggs and egg products in the Codex Code of Hygienic Practice for Eggs and Egg Products. Subsequently there may be minor implications for imported egg products. Notification will therefore be made in accordance with Australia's obligations under the Sanitary and Phytosanitary Measures (SPS) Agreement. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

#### 11. Communication

#### 11.1 Communication plan

A communication sub-committee was established by the SDC at its first meeting with membership from jurisdictions and industry. The sub-committee worked with FSANZ to develop and implement a communication plan. The aim of the plan was to ensure that all sectors of the egg industry were aware of the Proposal, had access to information about its progress and were informed as to when they would have an opportunity to provide formal comments.

Activities in communicating work on the Proposal have included:

- presenting information about the egg and egg product primary production and processing proposal at conferences and workshops
- development of a contact database of interested parties to be kept informed of the progress of the proposed standard
- the production of five fact-sheets, trade journal articles and a generic PowerPoint presentation to inform the industry and public about the standard development work.

The sub-committee will continue developing material to reflect progress as the Proposal moves to Final Assessment. Preliminary discussions have been held with the Food Safety Information Council to develop safe egg handling advice for consumers, in association with the egg industry.

# **IMPLEMENTATION AND REVIEW**

Implementation of the Code is the responsibility of the State and Territory Governments. ISC facilitates the consistent national implementation of the Code and is responsible for developing nationally consistent implementation approaches.

ISC is conducting a pilot exercise<sup>91</sup> on the proposed primary production and processing Standard for Eggs and Egg Products to trial a concept in better aligning implementation arrangements for food standards with the national food standards development processes<sup>92</sup>.

The intention is to provide information and guidance to industry and consumers on how a standard will be implemented at the same time as a proposed standard is presented for endorsement by the Ministerial Council.

The pilot Implementation Model developed for the egg standard comprises a Compliance Plan, a Response Plan and an Implementation Guide (support materials and reference materials.)

The Compliance Plan describes how compliance with a national food standard will be demonstrated and/or measured. For industry, examples of tools within the Compliance Plan may include food safety programs templates or statements of management. For food regulators, examples of tools that may be used are auditing, inspection and improvement notices. Details of the Compliance Plan are provided in Attachment 4.

The Response Materials identify the enforcement options and strategies that may be used by food regulators in response to apparent breaches of the standard93. Available tools include written warnings, penalty notices and prosecutions.

The Implementation Guide will comprise support and reference materials. Support materials include documents that may be used by industry to assist in meeting requirements of the national standard.

FSANZ and ISC are jointly consulting on the option to develop a primary production and processing standard and the draft Compliance Plans through the release of this Draft Assessment Report.

FSANZ will address comments received on the options and the proposed draft standard and ISC will address comments on implementation matters.

A 12 month period will be provided from the date the proposed primary production and processing Standard for Eggs and Egg Products is gazetted in the Code to enable industry and the jurisdictions adequate time to measures in place to implement changes to the Code. This 12 month implementation period is a departure from the usual lead in time for primary production and processing standards.

This is due to time savings which have been identified through the implementation process and additionally, industry has indicated strong support for the commencement of the standard as soon as possible.

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<sup>&</sup>lt;sup>91</sup> Through the Egg Implementation Model Working Group, a working group of ISC.

<sup>92</sup> http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc.htm (accessed July 2009)

<sup>&</sup>lt;sup>93</sup> The Response Materials are taken to be the National Food Incident Response Protocol and draft Australia New Zealand Enforcement Policy agreed upon by ISC July 2009.

# **Attachments**

- 1. Draft variations to the Australia New Zealand Food Standards Code
- 2. Draft Explanatory Memorandum for draft Standard 4.2.5 Primary Production and Processing Standard for Eggs and Egg Products
- 3. Summary of issues at Initial Assessment
- 4. Draft Compliance Plans for the Egg and Egg Products Primary Production and Processing Standard

#### Draft Variations to the Australia New Zealand Food Standards Code

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunsetting.

#### To commence: 12 months from gazettal

- [1] **Standard 1.1.1** of the Australia New Zealand Food Standards Code is varied by inserting in clause 2
  - **egg product** means the contents of an egg in any form including egg pulp, dried egg, liquid egg white and liquid egg yolk.
- [2] **Standard 1.6.1** of the Australia New Zealand Food Standards Code is varied by –
- [2.1 inserting in clause 1
  - **processed** in relation to egg product means pasteurised or subjected to an equivalent treatment.
- [2.2] omitting from the Schedule, Pasteurised egg product, substituting –

Processed egg product

[3] **Standard 1.6.2** of the Australia New Zealand Food Standards Code is varied by omitting clause 3, substituting –

#### 3 Deleted

[4] The Australia New Zealand Food Standards Code is varied by omitting Standard 2.2.2, substituting –

# STANDARD 2.2.2

#### **EGGS**

# (Australia only)

# **Purpose and commentary**

This Standard prohibits the sale or supply of unacceptable eggs for catering and retail sale purposes and requires that eggs for retail sale or catering purposes must be marked with the producers' or processors' unique identification. These requirements do not apply in New Zealand.

#### **Table of Provisions**

- 1 Interpretation
- 2 Sale or supply of unacceptable eggs
- 3 Traceability

#### **Clauses**

# 1 Interpretation

- (1) The definitions in Standard 4.2.5 apply to this Standard.
- (2) In this Standard –

**catering purposes** includes food supplied to catering establishments, restaurants, canteens, schools, hospitals, and institutions where food is prepared or offered for immediate consumption.

retail sale means sale to the public.

# 2 Sale or supply of unacceptable eggs

Unacceptable eggs must not be sold or supplied for catering or retail sale purposes.

#### **Editorial note:**

Under Standard 4.2.5 an 'unacceptable egg' is a cracked (including broken) egg or a dirty egg or unprocessed egg pulp. See Standard 4.2.5 for definitions of cracked eggs and dirty eggs.

#### 3 Traceability

Eggs for retail sale or for catering purposes must be individually marked with the producers' or processors' unique identification.

#### **Editorial note**

This Standard does not apply in New Zealand as it relates to matters outside the scope of the Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System.

[5] The Australia New Zealand Food Standards Code is varied by inserting –

### STANDARD 4.2.5

# PRIMARY PRODUCTION AND PROCESSING STANDARD FOR EGGS AND EGG PRODUCT

# (Australia only)

#### **Purpose and commentary**

This Standard sets out a number of food safety requirements for the primary production and processing of eggs, egg pulp and other egg product for human consumption. At the primary production stage, businesses that produce eggs must implement measures to control the food safety hazards and must be able to trace their individual eggs for sale. Businesses that process eggs or egg product must control their food safety hazards and must be able to trace their individual eggs and the egg pulp. It is the responsibility of these businesses not only to comply with this Standard but also to be able to demonstrate compliance.

#### **Table of Provisions**

Division 1 –	Preliminary
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- 1 Application
- 2 Interpretation

# Division 2 – Primary production of eggs

- 3 General food safety management
- 4 Inputs
- 5 Waste disposal
- 6 Health and hygiene requirements
- 7 Skills and knowledge
- 8 Design, construction and maintenance of premises, equipment and transportation vehicles
- 9 Bird health
- Traceability
- 11 Sale or supply

# Division 3 – Processing of eggs and egg pulp

- 12 Application
- General food safety management
- 14 Receiving unacceptable eggs
- 15 Inputs
- Waste disposal
- 17 Skills and knowledge
- Health and hygiene requirements
- Design, construction and maintenance of premises, equipment and transportation vehicles
- 20 Traceability
- 21 Processing egg product
- 22 Storing and transport of processed egg product

#### Sale or supply

#### Clauses

# **Division 1 – Preliminary**

# 1 Application

This Standard does not apply to retail sale or catering activities other than the direct sale of eggs to the public by an egg producer.

# 2 Interpretation

- (1) Unless the contrary intention appears, and subject to Standard 4.1.1, the definitions in Chapter 3 of this Code apply in this Standard.
- (2) In this Standard –

**cracked egg** means an egg which has a cracked shell which is visible, or visible by candling, and includes a broken egg.

dirty egg means an egg that has visible faeces, soil or other matter on it.

egg means an egg from any avian (bird) species, except ratites.

**egg producer** means a business, enterprise or activity that involves the production of eggs, whether or not the business grades, packs, washes, candles or assesses for cracks, oils, pulps for supply to the processor for pasteurisation or stores or transports.

egg processor means a business, enterprise or activity that involves –

- (a) grading, packing, washing, candling, assessment for cracks or oils eggs; or
- (b) receiving eggs from an egg producer to undertake any of the activities listed in paragraph (a); or
- storing or transporting eggs in association with any of the activities in paragraph (a); or
- (d) processing egg product under clause 21 of this Standard.

egg pulp means the contents of an egg, which may contain sugar or salt.

**food safety management statement** means a statement, which at a minimum, has been approved or recognised by the relevant authority and subjected to ongoing verification activities by an egg producer or egg processor and the relevant authority.

#### **Editorial note:**

'Authority' is defined in draft Standard 4.1.1 as –

the State, Territory or Commonwealth agency or agencies having the legal authority to implement and enforce primary production and processing Standards.

**liquid egg white** means the white of egg separated as effectively as practicable from the yolk in liquid form.

**liquid egg yolk** means the yolk of egg separated as effectively as practicable from the white in liquid form.

**premises** means an egg production premises or a processing premises.

unacceptable refers to unacceptable eggs.

**unacceptable egg** means a cracked or dirty egg, or egg pulp which has not been processed in accordance with clause 21.

**verification** means the application of methods, procedures, tests and other tools for evaluation to determine compliance with the relevant requirement.

#### **Editorial note:**

Standard 1.1.1 defines 'egg product' as the contents of an egg in any form including egg pulp, dried egg, liquid egg white and liquid egg yolk.

# **Division 2 – Primary production of eggs**

# **3** General food safety management

- (1) An egg producer must systematically examine all of its production operations to identify potential hazards and implement control measures to address those hazards.
- (2) An egg producer must also have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented.
- (3) An egg producer must 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.

#### 4 Inputs

An egg producer must take all reasonable measures to ensure inputs do not make the eggs unsafe or unsuitable.

#### **Editorial note:**

See the definitions of 'safe' and 'suitable' in Standard 3.1.1.

See the definition of 'inputs' in Standard 4.1.1 which includes feed, water and chemicals used in or in connection with the primary production activity.

# 5 Waste disposal

- (1) An egg producer must store, handle or dispose of waste in a manner that will not make the egg unsafe or unsuitable.
- (2) For subclause (1), waste includes sewage, waste water, used litter, dead birds, garbage and eggs which the proprietor, supervisor or employee of the egg producer knows, ought to reasonably know or to reasonably suspect, are unsafe or unsuitable.

# 6 Health and hygiene requirements

- (1) An egg handler must exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.
- (2) An egg producer must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.

# 7 Skills and knowledge

An egg producer must ensure that a person who engages in or supervises the primary production of eggs has –

- (a) skills in food safety and food hygiene; and
- (b) knowledge of food safety and food hygiene matters;

commensurate with their work.

# 8 Design, construction and maintenance of premises, equipment and transportation vehicles

An egg producer must –

- (a) ensure that premises, equipment and transportation vehicles are designed and constructed in a way that minimises the contamination of the eggs, allows for effective cleaning and sanitisation and minimises the harbourage of pests and vermin; and
- (b) keep premises, equipment and transportation vehicles effectively cleaned, sanitised and in good repair to ensure the eggs are not made unsafe or unsuitable.

#### 9 Bird health

- (1) 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 bird is affected by disease or a condition that makes the eggs unsafe or unsuitable.
- (2) The definition of 'condition' in Standard 3.2.2 does not apply to this clause.

# 10 Traceability

- (1) An egg producer must not sell eggs unless each individual egg is marked with the producers' unique identification.
- (2) An egg producer who supplies egg pulp must mark each package or container containing the pulp with the producers' unique identification.

# 11 Sale or supply

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

#### **Editorial note:**

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

# **Division 3 – Egg Processing**

#### 12 Application

Standards 3.2.2 and 3.2.3 do not apply to processing activities other than those in clause 21 and 22 of this Standard.

#### 13 General food safety management

- (1) An egg processor must systematically examine all of its processing operations to identify potential hazards and implement control measures to address those hazards.
- (2) An egg processor must also have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented.
- (3) An egg processor must 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.

#### 14 Receiving unacceptable eggs

An egg processor must not receive unacceptable eggs for human consumption unless -

- (a) in the case of dirty eggs they are to be cleaned;
- (b) in the case of cracked eggs they are to be processed in accordance with clause 21; or
- (c) in the case of egg pulp, the product is to be processed in accordance with clause 21.

#### 15 Inputs

An egg processor must take all reasonable measures to ensure inputs do not make the eggs unsafe or unsuitable.

#### **Editorial note:**

See Standard 4.1.1 for the definition of 'inputs'.

#### Waste disposal

- (1) An egg processor must store, handle or dispose of waste in a manner that will not make the eggs or egg products unsafe or unsuitable.
- (2) For subclause (1), waste includes sewage, waste water, unacceptable eggs or egg products and garbage.

# 17 Skills and knowledge

An egg processor must ensure that persons undertaking or supervising the processing of eggs or egg products have –

- (a) skills in food safety and food hygiene; and
- (b) knowledge of food safety and food hygiene matters;

commensurate with their work.

#### 18 Health and hygiene requirements

- (1) An egg handler or processor must exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.
- (2) An egg processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.

# 19 Design, construction and maintenance of premises, equipment and transportation vehicles

An egg processor must –

- (a) ensure that premises, equipment and transportation vehicles are designed and constructed in a way that minimises the contamination of the eggs or egg products, allows for effective cleaning and sanitisation and minimises the harbourage of pests and vermin; and
- (b) keep premises, equipment and transportation vehicles effectively cleaned, sanitised and in good repair to ensure the eggs or egg products are not made unsafe or unsuitable.

# 20 Traceability

- (1) An egg processor must not sell eggs unless each individual egg is marked with the processors' or producers' unique identification.
- (2) An egg processor must not sell or supply egg product unless each package or container containing the egg product is marked with the processors' or the producers' unique identification.

# 21 Processing egg product

- (1) An egg processor must process egg product by
  - (a) pasteurising; or
  - (b) heating, using any other time and temperature combination of equivalent or greater lethal effect on any pathogenic micro-organisms in the egg pulp; or
  - (c) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms.
- (2) For paragraph (1)(a), the egg product listed in Column 1 of the Table to this clause must be pasteurised to the time and temperature combinations in Column 2, Column 3 and Column 4.
- (3) For paragraphs (1)(b) and (1)(c), the process used must be validated by the egg processor.
- (4) In this clause, 'validate' means
  - (a) confirming a control measure for a critical control point or process is effective to minimise a food safety hazard; and
  - (b) providing objective evidence to confirm paragraph (a).

Table to clause 21

Column 1	Column 2	Column 3	Column 4
Egg product	Retention temperature to be no less than (°C)	Retention time to be no less than (minutes)	Maximum temperature to be immediately rapidly cooled to (°C)
Egg pulp	64	2.5	≤ 7
Liquid egg yolk	60	3.5	≤ 7
Liquid egg white	55	9.5	≤ 7

#### **Editorial note:**

For subclause 21(1), Standard 1.6.1 regulates microbiological limits for processed egg products.

# 22 Storage or transport of processed egg product

A processor must ensure that egg product processed under clause 21 is stored or transported under time and temperature conditions that prevent, reduce or control pathogenic growth.

# Sale or supply

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

#### **Editorial note:**

Standard 1.2.3 requires unpasteurised egg products to be labelled with a statement that the product is unpasteurised.

# **Draft Explanatory Memorandum for draft Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products**

#### **OUTLINE**

The purpose of this standard is to minimise the microbiological and chemical contamination of eggs and egg products and to enable the use of cracked eggs only in processing. Dirty eggs will be allowed to go to the table egg market following cleaning, or can be sent for processing.

This standard applies to all businesses that produce and process eggs, including those businesses which produce eggs and sell them at the farm gate, road side or farmers markets.

The application clause in draft Standard 4.1.1<sup>94</sup> clarifies that this draft Standard does not apply to New Zealand. While there is an agreement between Australia and New Zealand to establish one joint food standard-setting system for the two countries, the agreement specifically excludes food safety provisions (Chapter 3 and Chapter 4). New Zealand maintains and develops its own food safety regulatory measures.

The draft Standard has three Divisions. Division 1 – Preliminary, contains definitions; Division 2 – Primary production of eggs, has requirements that apply to egg primary production businesses and Division 3 – Egg Processing, has requirements that apply to businesses that process eggs.

In this Draft Explanatory Memorandum:

- The text of the Standard is included in bold Times New Roman type and clause, subclause and paragraph numbering and lettering are the same as those in the Standard.
- The meaning of the definitions used in the standard are explained where it is thought that more explanation may be necessary.
- The intent behind every requirement in the Standard is explained.

The Explanatory Memorandum does not specify ways in which egg producers or processors can comply with the requirements in the standards; this information is provided in the Compliance Plan (see Attachment 4).

<sup>&</sup>lt;sup>94</sup> Draft Standard 4.1.1 contains definitions used in all Chapter 4 Standards (see SD7)

#### NOTES ON CLAUSES

## **Division 1 – Preliminary**

This Division includes application provisions and definitions used within this standard.

### 1 Application

This Standard does not apply to retail sale or catering activities other than the direct sale of eggs to the public by an egg producer.

This standard does not apply to any retail sale activities. The exemption to this is the direct sale to the public of eggs by an egg producer, such as at the farm gate or by the egg producer at farmers markets. This is to ensure that unacceptable eggs are not sold to the public and therefore consumers will not be able to buy cracked and dirty eggs direct from the producer. The producer is still able to sell clean whole eggs.

#### 2 Interpretation

The terms used in Standard 4.2.5 are defined here. In the absence of a definition in the *Australia New Zealand Food Standards Code* (the Code), reference should be made to the definition in *The Macquarie Dictionary* (latest edition).

# (1) Unless the contrary intention appears, and subject to Standard 4.1.1 the definitions in Chapter 3 of this Code apply in this Standard.

Terms used in Standard 4.2.5 are generally defined within the Code. As in the case of other primary production and processing Standards, the definitions used in the Chapter 3 Food Safety Standards, apply to Chapter 4. Draft Standard 4.1.1 has been established to define preliminary provisions which apply to the primary production and processing Standards contained in Chapter 4. Terms developed for use specifically in Standard 4.2.5 are defined in the standard.

#### (2) In this Standard –

# cracked egg means an egg which has a cracked shell which is visible, or visible by candling, and includes a broken egg.

The definition intends to capture eggs with grossly visible cracks, including broken eggs, and eggs with micro cracks that may be made visible for example, by shining a light behind the egg (i.e. by candling). For cracked eggs, the membrane on the inside of the shell may be either intact or broken.

dirty egg means an egg that has visible faeces, soil or other matter on it.

A dirty egg has visible bird faeces on it or other matter such as feathers, manure, soil or egg yolk.

#### egg means an egg from any avian (bird) species, except ratites.

In this Standard, an egg may come from any avian species such as a chicken, duck, goose, turkey, quail or pigeon. The Standard does not include eggs from ratites, such as emus or ostriches.

egg producer means a business, enterprise or activity that involves the production of eggs, whether or not the business grades, packs, washes, candles or assesses for cracks, oils, pulps for supply to the processor for pasteurisation or stores or transports.

An egg producer is a business which maintains birds to produce eggs.

If the egg producer grades, packs, washes, candles, assesses for cracks or oils eggs, or receives eggs from another egg producer to carry out any of these activities, or stores or transports in association with these activities, then this business is also an egg processor, as well as an egg producer (see definition of 'egg producer' below). Similarly, if the egg producer also pasteurises egg pulp then the business is both an egg processor and an egg producer.

If the business does not maintain birds, but rather receives eggs or egg pulp from another source, then it is an egg processor, and not an egg producer.

#### egg processor means a business, enterprise or activity that involves –

- (a) grading, packing, washing, candling, assessment for cracks or oils eggs; or
- (b) receiving eggs from an egg producer to undertake any of the activities listed in paragraph (a); or
- (c) storing or transporting eggs in association with any of the activities in paragraph (a); or
- (d) processing egg product under clause 21 of this Standard.

An egg processor is a business that grades, packs, washes, candles, assess for cracks, oils eggs or processes egg products in accordance with clause 21. They may also store, transport or receive eggs in association with these activities. Egg product is generally defined in Standard 1.1.1 and 'means the contents of an egg in any form including egg pulp, dried egg, liquid egg white and liquid egg yolk'.

A business that *only* stores and transports eggs or receives eggs from another business (i.e. do not do activities listed in (a) or (d)) is *not* an egg processor.

## egg pulp means the contents of an egg, which may contain sugar or salt.

Egg pulp is all, or a portion of the contents found inside eggs separated from the shell, with or without added salt or sugar, intended for human consumption. See Standard 1.1.1 (or 'egg processor' above) for the general definition of 'egg product'.

food safety management statement means a statement, which at a minimum, has been approved or recognised by the relevant authority and subjected to ongoing verification activities by an egg producer or egg processor and the relevant authority.

#### **Editorial note:**

'Authority' is defined in draft Standard 4.1.1 as -

the State, Territory or Commonwealth agency or agencies having the legal authority to implement and enforce primary production and processing Standards.

A food safety management statement is a document written by the business, and approved or recognised by the relevant jurisdiction, showing that the business is controlling all identified food safety hazards associated with the business.

liquid egg white means the white of egg separated as effectively as practicable from the yolk in liquid form.

liquid egg yolk means the yolk of egg separated as effectively as practicable from the white in liquid form.

premises means an egg production premises or a processing premises.

unacceptable refers to unacceptable eggs

Unacceptable eggs are ones which cannot be sold at retail or wholesale (for example, to the table egg market or food service) in their current state. These unacceptable eggs or egg pulp can be made acceptable by processing carried out by an egg processor.

unacceptable egg means a cracked or dirty egg, or egg pulp which has not been processed in accordance with clause 21.

Eggs with cracks, or which are dirty, and pulp which has not been processed, are defined as 'unacceptable eggs'. The Standard has provisions in regard to the use of unacceptable eggs.

verification means the application of methods, procedures, tests and other tools for evaluation to determine compliance with the relevant requirement.

Verification means the ongoing activities of an egg producer or egg processor necessary to ensure that the control measures, monitoring, corrective actions and other matters in regard to compliance with the Standard, and described in the food safety management statement, are in place and operating as described.

#### **Editorial note:**

Standard 1.1.1 defines 'egg product' as the contents of an egg in any form including egg pulp, dried egg, liquid egg white and liquid egg yolk.

## **Division 2 – Primary production of eggs**

This Division governs activities related to the production of eggs. The outcome of the requirements in this Division is that eggs leave the egg production business in a safe and suitable condition for human consumption. That is, the eggs do not have levels of pathogenic micro-organisms or chemicals that would make them unsafe or unsuitable for human consumption or for processing. Also, eggs that are cracked are supplied for processing only and dirty eggs are cleaned (or sent for cleaning) before supplying to the table egg market or alternatively they are supplied for processing.

The concepts of safe and suitable food are already used in the Code (see Chapter 3).

In general terms, food is not safe if it would cause physical harm to a person provided it was used for its intended purpose. For whole, clean eggs, eggs are 'safe' because there is a very low likelihood that the content will be contaminated with *Salmonella* which could cause food-borne illness. 'Suitability' includes characteristics of products that make them unfit to eat even though they may not cause physical harm to the consumer. These eggs are unsuitable eggs for both the table egg market and for egg processing and must be disposed of.

Eggs that have cracked shells, and therefore are damaged, are unfit for sale to the table egg market. In this Standard, cracked eggs are termed 'unacceptable' and may only be sent for processing into egg pulp. Dirty eggs are also termed 'unacceptable'; they may be cleaned prior to sale to the table egg market, or may be sent for processing.

An egg producer in this Standard includes a business which carries out the following activities: the production, collection and sorting of eggs.

### **3** General food safety management

- (1) An egg producer must systematically examine all of its production operations to identify potential hazards and implement control measures to address those hazards.
- (2) An egg producer must also have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented.
- (3) An egg producer must 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.

The intent of this requirement encompasses activities related to the production of eggs. An egg producer is a business, enterprise or activity that involves the primary production of eggs, whether or not the business also collects, sorts, candles, cleans, grades, oils, packs, or stores eggs for human consumption, or pulps eggs for further processing.

The intent is that primary production businesses ensure the safety of their eggs by developing and implementing control measures to address the hazards that could potentially occur in their business i.e. taking into account the operations in the context in which they deal with eggs. The sorts of operations that a producer would carry out include bird management, egg collection, packing, transport and storage of eggs.

A business ensures its products are safe by identifying and addressing hazards during production and does not depend on another business further along the chain to potentially address food safety problems that are more effectively addressed earlier in the chain.

The egg producer will need to prepare a food safety management statement setting out how the requirements of this Division are being complied with. This statement must be approved or endorsed by the state, territory or commonwealth agency which legally enforces or implements primary production and processing Standards.

## 4 Inputs

An egg producer must take all reasonable measures to ensure inputs do not make the eggs unsafe or unsuitable.

#### Editorial note:

See the definitions of 'safe' and 'suitable' in Standard 3.1.1.

See the definition of 'inputs' in Standard 4.1.1 which includes feed, water and chemicals used in or in connection with the primary production activity.

The intent is that the egg producer ensures that eggs are made safe and suitable by making sure that they are not contaminated due to the consumption, imbibition or uptake of inputs by the birds during production and subsequent transfer to eggs. The inputs must not render the eggs damaged or deteriorated or expose them to biological or chemical agents that are foreign to the eggs.

The terms 'unsafe' and 'unsuitable' are defined in Standard 3.1.1.

Inputs are defined in Standard 4.1.1 to include any feed, water, chemicals and other substances used in, or in connection with, the primary production or processing of eggs.

The definition of unsuitable covers chemical levels that are not in accordance with Standard 1.4.2 – Maximum Residue Limits. For example, levels of permitted antibiotics introduced in the feed or water, may make the eggs unsuitable. Contaminants or adulterants, such as melamine or lead, which potentially may be introduced for example, through animal feed or through processing, may make the eggs unsuitable.

#### 5 Waste disposal

- (1) An egg producer must store, handle or dispose of waste in a manner that will not make the egg unsafe or unsuitable.
- (2) For subclause (1), waste includes sewage, waste water, used litter, dead birds, garbage and eggs which the proprietor, supervisor or employee of the egg producer knows, ought to reasonably know or to reasonably suspect, are unsafe or unsuitable.

The intent is to ensure that the potential contamination of eggs by waste is minimised.

Contamination includes direct contamination of eggs for example at time of lay (by faeces), or indirect, because the waste may potentially contaminate, for example, the water supply, stored litter or feed.

Waste products are risk factors for the introduction of *Salmonella* and contact of eggs with dirty litter, faeces or dead birds will increase the probability of contamination. Eggs which may not have been collected on the day of lay and are of uncertain age, may get damaged by hens and could also contaminate freshly laid eggs.

#### 6 Health and hygiene requirements

- (1) An egg handler must exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.
- (2) An egg producer must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.

The intent is that the egg handler is responsible for ensuring that his or her practices do not adversely affect eggs safety or suitability.

In addition, the egg producer must ensure that eggs are not made unsafe or unsuitable due to contamination from personnel and visitors. Egg producers, other farm staff and visitors may introduce *Salmonella* (or other contaminants) into the laying environment and contaminate eggs.

#### 7 Skills and knowledge

An egg producer must ensure that a person who engages in or supervises the primary production of eggs has -

- (a) skills in food safety and food hygiene; and
- (b) knowledge of food safety and food hygiene matters;

#### commensurate with their work.

The intent is to improve the safety of eggs by ensuring that egg producers (including supervisors) have the skills and knowledge to handle, clean and grade eggs and, for example, recognise unhealthy birds.

The obligation is on the business to ensure that the egg producers have relevant skills and knowledge. The skills and knowledge required are associated with the specific tasks carried out or supervised by the person. For example, staff would need the skills and knowledge of how to collect eggs so that they do not get cracked and thus prevent contamination; or to recognise dirty eggs which need cleaning prior to sale to the table egg market or to being processed. Staff would also need to be able to recognise which eggs are unsafe and unsuitable, for example, those eggs which are excessively dirty and cannot be cleaned and therefore should not be sent for the table egg market for human consumption.

# 8 Design, construction and maintenance of premises, equipment and transportation vehicles

An egg producer must -

- (a) ensure that premises, equipment and transportation vehicles are designed and constructed in a way that minimises the contamination of the eggs, allows for effective cleaning and sanitisation and minimises the harbourage of pests and vermin; and
- (b) keep premises, equipment and transportation vehicles effectively cleaned, sanitised and in good repair to ensure the eggs are not made unsafe or unsuitable.

The intent is that premises, equipment and transportation vehicles are maintained in good condition, can be kept clean and do not provide harbourage for pests. Also, the business must ensure that the design and construction of premises, equipment and transport vehicles minimises opportunities for contamination. In addition, the intent is that eggs are not made unsafe due to premises, equipment or transport vehicles which cannot be cleaned or sanitised appropriately. Cleaning or sanitation should be commensurate with the activity being undertaken. For example, not all equipment is amendable for sanitation, but should be kept as clean as possible.

#### 9 Bird health

- (1) 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 bird is affected by disease or a condition that makes the eggs unsafe or unsuitable.
- (2) The definition of 'condition' in Standard 3.2.2 does not apply to this clause.

The intent of this clause is to ensure that eggs are produced by healthy birds. In this clause, 'disease' refers to birds which show clinical signs of a disease (i.e. the bird looks sick) and 'condition' refers to the state of health of the bird (i.e. where the bird shows no clinical signs of a disease). The inclusion of 'condition' in this clause addresses birds for example, which may be suffering from the effects of chemical ingestion and not affected by a 'disease'.

Eggs from diseased animals would be considered unsuitable (under the definition in Standard 3.1.1 Clause 2(c) which states that food is not suitable if it is the product of a diseased animal). Additionally, diseased birds may exhibit increased faecal shedding and therefore increase the probability of external contamination of eggs with *Salmonella*.

#### 10 Traceability

- (1) An egg producer must not sell eggs unless each individual egg is marked with the producers' unique identification.
- (2) An egg producer who supplies egg pulp must mark each package or container containing the pulp with the producers' unique identification.

The intent is that the source of each egg and egg pulp is readily identifiable. Identification of each egg or egg pulp is necessary if the eggs are to be prevented from being sold or processed (in the case of a recall or withdrawal) or, if already sold or processed, to be prevented from distribution in the event of a food safety problem.

## 11 Sale or supply

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

#### **Editorial note:**

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

The intent is to ensure that egg producers do not sell eggs that are cracked or dirty (i.e. are unacceptable) to the table egg market, or supply them (i.e. transfer them) to other sectors of the industry even if the businesses are the same company. This does not apply to unacceptable eggs which are sold or supplied for processing. These eggs, if intended for human consumption, can only be sent for processing into egg pulp. Dirty eggs may be cleaned prior to sale or supply to the table egg market, or may be sent for processing.

Whole, clean shell eggs may also be sold or supplied to manufacturers who make other shell egg products, such as speciality eggs. For example, duck and quail eggs are often used in the production of specialty eggs. Duck and quail egg producers can sell or supply only whole clean eggs to specialty egg manufacturers. The manufacturing of specialty eggs is addressed under Standards 3.2.2 and 3.2.3. Food additives and processing aids used in the manufacture of products for sale are addressed in Standards 1.3.1 and 1.3.3 respectively. Contaminants and natural toxicants and maximum residue limits in foods for retail sale are addressed in Standards 1.4.1 and 1.4.2 respectively.

To ensure that the potential for the contamination or cross-contamination of *Salmonella* (associated with unacceptable eggs) is minimised, egg producers are not allowed to sell or supply unacceptable eggs to businesses which are not egg processors. This is to prevent the sale or supply to businesses that do not process the eggs in accordance with the standard.

'Sell' is defined in Standard 3.1.1 and is intended to cover all circumstances in which food is provided in exchange for money or other benefit (including bartering). It does not include food that is given away and for which nothing is expected in return for example, food prepared in the home for family and friends.

'Supply' is defined in Standard 4.1.1 to include intra-company transfer of product. However, the sale or supply may occur if the product is intended for disposal, pet food or non-food use, noting that business should comply with any biosecurity provisions on disposal of diseased birds

# Division 3 – Egg processing

This Division addresses activities related to processing eggs and egg pulp for human consumption. The outcome of the requirements in this Division is that eggs and egg pulp leave the egg processing business in a safe and suitable condition for human consumption. That is, the eggs and egg pulp do not have levels of pathogenic micro-organisms or chemicals that would make them unsafe or unsuitable for human consumption. The intent is also to ensure that egg processors only sell or supply eggs that are not unacceptable.

#### 12 Application

Standards 3.2.2 and 3.2.3 do not apply to processing activities other than those in clause 21 and 22 of this Standard.

Standards 3.2.2 – Food safety practices and general requirements, and Standard 3.2.3 – Food premises and equipment, do not apply to primary production. Although they do generally apply to processors, clause 12 specifies that Standards 3.2.2 and 3.2.3 only apply to the activities in clauses 21 (Processing egg product) and 22 (Storage or transport of processed egg product).

Standard 3.2.2 sets out requirements on food businesses and food handlers that, if complied with, will ensure that food does not become unsafe or unsuitable. The Standard specifies process controls that cover receipt of food, storage, processing, display, packaging, transport and disposal of food that may be unsafe or unsuitable. The applicable clauses are those that apply to the activities of processing, storage and transport of processed egg products.

Standard 3.2.3 sets out requirements for food premises which, if complied with, will facilitate compliance with Standard 3.2.2. The Standard has requirements on food businesses to use premises, equipment and vehicles that are adequate for the purpose and are designed and constructed to be able to be effectively cleaned and sanitised. The Standard also ensures that there is an adequate supply of potable water and that garbage, waste water and sewage are disposed of so as not to contaminate food. The business must provide facilities and equipment to enable food handlers to comply with health and hygiene requirements.

For general guidance on Standard 3.2.2 and Standard 3.2.3 refer to the guide 'Safe Food Australia' which is available on the FSANZ website.

#### 13 General food safety management

- (1) An egg processor must systematically examine all of its processing operations to identify potential hazards and implement control measures to address those hazards.
- (2) An egg processor must also have evidence to show that a systematic examination has been undertaken and that control measures for those identified hazards have been implemented.
- (3) An egg processor must 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.

The intent relates to general food safety requirements associated with the processing of eggs and egg pulp.

The egg processor will need to demonstrate that it operate s according to a food safety management statement which is approved or recognised by the state, territory or commonwealth agency which legally enforces or implements primary production and processing Standards.

The egg processor will need to prepare a food safety management statement describing how the business will comply with the Division. This statement must be approved or recognised by a State, Territory or Commonwealth agency which legally enforces or implements primary production and processing Standards and is subject to ongoing verification activities by the egg processor and the relevant authority.

## 14 Receiving unacceptable eggs

An egg processor must not receive unacceptable eggs for human consumption unless -

- (a) in the case of dirty eggs they are to be cleaned;
- (b) in the case of cracked eggs they are to be processed in accordance with clause 21; or
- (c) in the case of egg pulp, the product is to be processed in accordance with clause 21.

This requirement relates to the types of eggs and egg pulp which may be received by an egg processor. Eggs and egg pulp which can be received for processing are only those that can be treated in a manner which results in a safe product. The business needs to be aware of the intended use of the product and process the eggs accordingly. Examples of eggs (and egg pulp), their intended use and process required to ensure the safety of the product, are presented in the following table:

Product received	Intended use	Example of processing operation
Whole clean eggs	Table egg market	Crack detection
Whole dirty eggs	Table egg market	Cleaning
		Crack detection
Cracked or dirty eggs	Processed pulp	Pulping
		Processing (as per clause 21)
Unpasteurised pulp	Processed pulp	Processing (as per clause 21)

Whole, clean eggs are unlikely to be contaminated, do not present a hazard and therefore do not require specific control measures.

Dirty eggs present a greater risk of internal contamination than intact clean eggs. Therefore, all faecal matter and dirt must be removed from eggs before they are sent for crack detection, prior to sending to the table egg market. Dirty eggs may also be received for processing into pulp. As pathogenic contamination (through dirt and faecal matter) of the outer shell may contaminate the internal content of eggs during pulping or separation, appropriate controls are required to ensure that the requirements of clause 21 are met.

#### 15 Inputs

An egg processor must take all reasonable measures to ensure inputs do not make the eggs unsafe or unsuitable.

#### **Editorial note:**

See Standard 4.1.1 for the definition of 'inputs'.

The intent is that the egg processor ensures that eggs are made safe and suitable by ensuring that they are not contaminated due to inputs used during processing, for example, cleaning chemicals. The inputs must not render the eggs damaged or deteriorated, expose them to biological or chemical agents that are foreign to the eggs or cause the eggs to make someone unwell if eaten.

- Waste disposal
- (1) An egg processor must store, handle or dispose of waste in a manner that will not make the eggs or egg products unsafe or unsuitable.
- (2) For subclause (1), waste includes sewage, waste water, unacceptable eggs or egg products and garbage.

The intent is to control contamination of egg products by waste. Waste products are risk factors for the introduction of *Salmonella* and contact of egg pulp with waste, for example waste wash water, will increase the probability of contamination.

#### 17 Skills and knowledge

An egg processor must ensure that persons undertaking or supervising the processing of eggs or egg products have –

- (a) skills in food safety and food hygiene; and
- (b) knowledge of food safety and food hygiene matters;

#### commensurate with their work.

The intent is to improve the safety and suitability of eggs by ensuring that egg processors (including supervisors) have the skills and knowledge to handle eggs, including cleaning, grading, processing and pasteurising egg pulp, for example, the egg processor should understand time and temperature issues associated with potentially hazardous foods such as egg pulp.

The obligation is on the business to ensure that the egg producers have relevant skills and knowledge. The skills and knowledge required are associated with the specific tasks carried out or supervised by the person.

## 18 Health and hygiene requirements

(1) An egg handler or processor must exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.

(2) An egg processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make the eggs unsafe or unsuitable.

Intent as per clause 6

19 Design, construction and maintenance of premises, equipment and transportation vehicles

An egg processor must -

- (a) ensure that premises, equipment and transportation vehicles are designed and constructed in a way that minimises the contamination of the eggs or egg products, allows for effective cleaning and sanitisation and minimises the harbourage of pests and vermin; and
- (b) keep premises, equipment and transportation vehicles effectively cleaned, sanitised and in good repair to ensure the eggs or egg products are not made unsafe or unsuitable.

Intent as per clause 8

## 20 Traceability

- (1) An egg processor must not sell eggs unless each individual egg is marked with the processors' or producers' unique identification.
- (2) An egg processor must not sell or supply egg product unless each package or container containing the egg product is marked with the processors' or the producers' unique identification.

Intent as per clause 10

- 21 Processing egg product
- (1) An egg processor must process egg product by
  - (a) pasteurising; or
  - (b) heating, using any other time and temperature combination of equivalent or greater lethal effect on any pathogenic micro-organisms in the egg pulp; or
  - (c) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms.
- (2) For paragraph (1)(a), the egg product listed in Column 1 of the Table to this clause must be pasteurised to the time and temperature combinations in Column 2, Column 3 and Column 4.
- (3) For paragraphs (1)(b) and (1)(c), the process used must be validated by the egg processor.

- (4) In this clause, 'validate' means
  - (a) confirming a control measure for a critical control point or process is effective to minimise a food safety hazard; and
  - (b) providing objective evidence to confirm paragraph (a).

Table to clause 21

Column 1	Column 2	Column 3	Column 4
Egg product	Retention temperature to be no less than (°C)	Retention time to be no less than (minutes)	Maximum temperature to be immediately rapidly cooled to (°C)
Egg pulp	64	2.5	≤ 7
Liquid egg yolk	60	3.5	≤ 7
Liquid egg white	55	9.5	≤ 7

#### **Editorial note:**

For subclause 21(1), Standard 1.6.1 regulates microbiological limits for processed egg products.

Egg products must be processed (for example, by pasteurisation) to control pathogenic organisms. Different time/temperature combinations may be used other than those in the table, provided they are validated by the business. The requirements also enable alternative technologies to be used, providing they are equivalent. The processing requirements have been transferred from Standard 1.6.2 – Processing Requirements to this standard (4.2.5). Products are required to be immediately rapidly cooled to 7°C or less as 7°C is the minimum temperature at which *Salmonella* will grow.

Standard 1.6.1 – Microbiological Limits for Food contains a limit for *Salmonella* in processed egg products.

#### 22 Storage or transport of processed egg product

A processor must ensure that egg product processed under clause 21 is stored or transported under time and temperature conditions that prevent, reduce or control pathogenic growth.

The intent of this clause is to ensure that processed egg products are stored and transported under temperature control. Standard 3.2.2 applies to the activities in this clause and it contains requirements relating to temperature control and protection of food from contamination

#### Sale or supply

(1) An egg processor must not sell or supply eggs or egg pulp for human consumption if the processor knows, ought to reasonably know or to reasonably suspect, that the eggs are unacceptable.

- (2) Clause (1) does not apply to an egg processor that sells or supplies unacceptable eggs to an egg processor for processing in accordance with clause 21.
- (3) An egg processor must not sell liquid egg white or liquid egg yolk unless it is processed in accordance with clause 21.

#### **Editorial note:**

Standard 1.2.3 requires unpasteurised egg products to be labelled with a statement that the product is unpasteurised.

The intent of this clause is that businesses are not permitted to sell eggs that are cracked or dirty, or egg pulp, unless it is processed, or they are being sold to another egg processor.

Egg processors that process egg pulp are permitted to process cracked and dirty eggs. Processors will be able to directly sell egg pulp, made from cracked or dirty eggs, to another processor for processing.

The sale or supply of cracked or dirty eggs to businesses other than egg processors is permitted if the product is intended for disposal, pet food or non-food use, noting that the business must comply with any restrictions or requirements on the use of egg pulp for animal feed or other uses.

## **Summary of issues at Initial Assessment**

The Initial Assessment Report for Proposal P301 was released for an eight week consultation period from 13 December 2006 until 21 February 2007. Twenty-five submissions were received from the following:

- Australian Egg Corporation Limited
- Australian Department of Agriculture Fisheries and Forestry
- Farm Pride Foods Ltd
- Food Technology Association of Victoria Inc.
- Fraser Coast Free Range
- Free Range Farmers Association Inc.
- FSANZ Consumer Liaison Committee
- Private individual; Mr Gary Bielby
- Private individual: Mr Ivan Jeray
- McLean Farms
- Metcash
- Micro-Range Farmers Association
- New South Wales Food Authority
- Pace Farms
- Queensland Egg Farmers Association Inc
- Oueensland Health
- Queensland Retail Traders & Shopkeepers Association
- Safe Food Production Queensland
- Smalls Trading Co
- South Australian Department of Health and Primary Industries and Resources South Australia
- Sunny Queen Pty Ltd
- Tasmanian Egg Working Group
- The New Zealand Food Safety Authority
- Victorian Department of Primary Industries
- Victorian Farmers Federation

The major issues raised are discussed below and are listed by submitter in Table 1.

#### **Issues raised in submissions**

FSANZ's response is in italics.

#### <u>Scope</u>

The Initial Assessment Report described the scope of the Proposal as activities from on-farm production of eggs through to retail sale, including production of liquid and dried egg products and speciality eggs such as Balut eggs. The majority of submissions stated that the scope of the Proposal was acceptable. Some qualified this by stating that the Standard itself should not necessarily include all the elements considered in the Proposal.

The Proposal has considered production of eggs through to retail sale and handling by the consumer. The preferred option i.e. development of a draft standard, proposes controls for activities that are higher risk.

It was suggested that the scope of the Proposal include bakeries and other retail establishments using cracked and unpasteurised eggs and egg products (e.g. cracked eggs and egg pulp in the production of foods such as cakes, meringues, biscuits, hamburger patties and custard tarts).

Use of cracked eggs and unpasteurised pulp in these sectors has been included in the scope. The draft Standard has clarified existing provisions in the Code relating to the use of cracked eggs and liquid egg to ensure that cracked eggs and unpasteurised pulp must be treated to destroy pathogens by an egg processor.

It was suggested that businesses involved in the transport and storage of unpasteurised egg pulp and cracked eggs be included in the scope of the Proposal.

These businesses have been included in the scope of the Proposal. Hazards associated with transport and storage would be controlled under the general food safety management requirement on the egg producer and the egg processor to control hazards.

There was general support for the inclusion of specialty eggs in the Proposal, however, it was suggested that there should be a separate proposal for these products as these industries and processes would require a specialist team with expertise in the specialty egg product market. It was requested that FSANZ take into consideration that specialty eggs constitute a very small amount to the total consumption of eggs and any subsequent risk management practices should be proportional to the overall risk.

FSANZ does not intend to prepare a separate Proposal for specialty eggs. This decision is based on the finding from the risk assessment that the physical properties of these eggs would prevent growth of Salmonella and, where they are cooked, the cooking process would destroy Salmonella. Following further consultation with the SDC, FSANZ considers that the production of specialty eggs are adequately covered by the provisions within Standard 3.2.2, Standard 3.2.3 and Standard 1.4.2. The production of eggs that will be used for specialty eggs is however considered in the draft Standard.

The risk assessment did find, however, that the processes used to make some uncooked specialty eggs would not destroy any Salmonella that were present. Therefore, these eggs must be made with clean, intact eggs. Under the draft Standard, manufacturers of specialty eggs will not have access to cracked or dirty eggs as cracked and dirty eggs may only be sold or supplied for processing and processed in accordance with the draft standard.

Some jurisdictions stated that food safety issues associated with egg layer breeding stock could not be included in the scope of the Proposal as they may not be covered under the definition of food in some Food Acts, and therefore management may not be enforceable in some States.

FSANZ agrees that only businesses that are involved in egg production should be included in the scope of the draft Standard. However, all inputs into the egg production businesses must be managed and the inputs would include the day old chicks or pullets to be grown for egg laying.

It was also suggested that there be broader consultation with other industry groups who share the responsibility of food safety along the egg production chain.

In addition to publishing information and fact sheets on the progress of the work, FSANZ has also discussed the standard development process and scope of Proposal P301 with the larger supermarket chains, the Australian Food and Grocery Council and other relevant industry bodies.

#### Sale of cracked and dirty eggs and unpasteurised pulp

Submissions from both industry and jurisdictions expressed concern over the sale and use of cracked eggs. It was suggested that the current requirements for the sale of cracked and dirty eggs need review and that these eggs, as well as unpasteurised pulp should only be sent to an egg processor.

FSANZ agrees that cracked and dirty eggs and unpasteurised eggs are potentially hazardous foods which require special processing by an egg processor. This has been clearly addressed in the draft Standard 4.3.5 and in consequential amendments to Standard 2.2.2.

## Refrigerated storage and transport of eggs

Many submissions from both industry and government raised the issue of through-chain refrigeration of eggs.

A major retailer and a retailer association presented arguments against refrigeration at retail stating that there is little evidence that non-refrigeration at retail causes food-borne illness and that Chapter 3 standards were considered adequate. There were concerns with the cost and practicality of installing refrigeration units in all retail outlets and that this would deter retailers from selling eggs. It was also noted by a submitter that refrigeration at 4°C in supermarkets could result in condensation on eggs when they are taken into warmer ambient temperatures by consumers.

A government submitter noted industry concerns that fluctuating temperature and humidity could pose a food safety risk and sought an assessment of this risk.

The AECL supported through-chain refrigeration at a lower temperature than the current industry standard of 20°C.

Standard 3.2.2 applies to the storage, distribution and display of food at wholesale and retail. It requires potentially hazardous food to be store, transported and displayed under temperature control. However, intact, clean shell eggs have not been considered potentially hazardous and therefore do not have to be stored under temperature control.

FSANZ reaffirms that it considers that clean, intact eggs are not potentially hazardous foods and therefore do not need to be stored under temperature control.

The risk assessment concluded that there is very little epidemiological data to implicate clean, intact eggs as the source of egg-associated illness and the prevalence of Salmonella in eggs is likely to be low. FSANZ, with advice from the SDC, considers that storage and distribution temperatures for clean, intact eggs are a quality issue, rather than a food safety issue and that Standard 3.2.2 is adequate.

The risk assessment found that fluctuations in temperature should be minimised along the egg supply chain. Hazards associated with fluctuations in temperature would be controlled under the general food safety management requirements on the egg producer or egg processor. In proposed Standard 4.2.5, Standards 3.2.2 and 3.3.3. will only apply to processing of egg product and storage or transport of processed egg product.

#### **Traceability**

Industry and the jurisdictions raised issues regarding traceability. Jurisdictions generally supported requirements for traceability through-chain to aid recalls and investigation of foodborne illness. Industry was concerned that re-use of cartons meant that eggs could not be traced in the event of a recall and the financial burden to the egg industry of requiring traceability systems was also raised. Some specific suggestions were made to improve traceability, for example, tamper-proof sealing (to ensure integrity), stamping of eggs and a carton source identification system.

FSANZ supports traceability as a tool to assist effective recall of product and investigation of food-borne illness or other food safety issues back to the source of the product and has included requirements in the draft standard. Consultation with industry and jurisdictions, and advice from the SDC, indicates that through-chain traceability is a key measure to include in a draft standard. The financial implications of regulatory requirements to identify eggs have been taken into consideration in the impact analysis.

#### Labelling

A few submissions raised concerns about inaccurate and misleading information the method of production on egg cartons and incorrect information on re-used cartons.

FSANZ is not addressing information on cartons as to the method of production as part of the Proposal. Businesses are required to be truthful in the statements made on labels and comply with any State or Territory specific requirements as to labelling of method of production. Where a business re-uses a carton it must ensure that the information on the carton is applicable to the contents.

#### Date marking

Clarification was sought on whether eggs available at retail should have a 'use by date' or a 'best before date'.

Requirements for date marking of food are in Standard 1.2.5. Apart from specific exemptions, a label must contain either a 'use by date' or a 'best before date'. A 'use by date' is required where the food should not be consumed after the given date because of health and safety reasons.

A 'best before date' indicates that the product will retain its quality until this date. Any storage conditions that are necessary to ensure that the food keeps until these dates must also be included on the label. Clean, intact shell eggs would normally be expected to display a 'best before date' to indicate their quality as they are unlikely to be a risk to health and safety.

## Re-use of packaging

Several submissions raised concerns that the re-use of egg cartons may be a significant source of contamination of eggs. It was suggested that FSANZ review different types of packaging and that the new Standard stipulate that new packaging only be used.

FSANZ supports that egg packaging, that has been used already, may be contaminated and, if contaminated, should not be re-used. The consumer survey commissioned by FSANZ indicated that the main users of previously used cartons were small (backyard) producers and sellers at farmers markets. These retailers are required to comply with the packaging requirements in Standard 3.2.2 which prohibits the use of packaging material that is likely to cause contamination. Other businesses, for example, operating grading floors, are unlikely to re-use packaging. If they do, they must address any hazards under the general food safety management requirements in the draft standard.

#### Size of production systems

Several submissions raised concerns that food safety practices could differ with the size of the production facility. Large egg marketers and processors are likely to have more sophisticated procedures for food hygiene than small producers. Small or backyard producers may not clean, grade or assess their eggs for cracks and therefore compromise the safety of their produce.

FSANZ agrees that any regulatory obligations should apply to egg producers irrespective of the size of the operation. This is reflected in the draft Standard.

#### Washing practices

A submitter questioned whether wet washing with potable water without chemical detergents or sanitisers, as practiced by organic producers, was adequate.

The risk assessment concluded that the effective use of detergents and sanitisers, which increased pH, combined with other factors such as temperature of wash and rinse waters were key factors in ensuring the efficacy of washing to reduce overall surface microbial contamination.

It was also suggested that the Proposal investigate the practice of hand cleaning eggs and whether this is adequate.

The risk assessment concluded that dry cleaning, such as wiping with a clean dry cloth or more abrasive materials such as a scouring pad or steel wool, will remove debris such as feathers and faecal material. However, these practices damage the cuticle and could cause contamination from one egg to the next.

#### Current Code requirements for pasteurisation

Concerns were raised that the current Chapter 1 and 2 Standards relating to eggs may not be adequate to ensure that all egg products are pasteurised prior to use including product made from cracked eggs.

FSANZ agrees that the current requirements in the Code could lead to confusion as to whether egg products must be pasteurised or receive equivalent treatment.

Currently, Standard 1.6.2 contains time and temperature requirements for pasteurising liquid egg products. Standard 2.2.2 requires all egg products to be pasteurised but contains exemptions to these requirements provided that the food that contains the egg products will be processed to achieve the same outcome.

The processing requirements in Standard 1.6.2 have been relocated into the draft standard and amendments to Standard 1.6.2 and Standard 2.2.2 have been proposed. The draft Standard clarifies that all cracked eggs and unpasteurised pulp including liquid whole egg, liquid egg yolk and liquid egg white, must be pasteurised in accordance with the times and temperatures in the Standard or receive an equivalent treatment.

The Standard also allows for the use of innovative equivalent technologies (which have been validated) which enable pathogen reduction, for example, high pressure processing.

#### Adequacy of Chapter 3 standards pertaining to eggs and egg products

Several submissions contended that the Chapter 3 Food Safety Standards do not adequately control food safety of eggs and egg products. For example, the use of pulp and cracked eggs in other products (for example, by bakeries and restaurants) was not thought to be sufficiently controlled by Chapter 3 standards covering general food hygiene. On the other hand, a few submissions were satisfied with Chapter 3 and the current level of control of food safety of eggs and it was requested that requirements are not duplicated in the Code.

FSANZ considers that the standards in Chapter 3 are adequate to control food handling operations of businesses that use eggs and egg products. Therefore, no amendment of these standards is necessary. Specific measures for egg pulp and cracked eggs are included in the draft standard with references to Chapter 3 standards only where necessary.

## Australian export and import requirements

FSANZ was asked by the Australian Government Department of Agriculture, Fisheries and Forestry to ensure that the impact of the standard on imported products was considered.

Whole shell eggs are not permitted to be imported under quarantine. Any businesses that use imported egg products, and are egg processors under the Standard, must comply with the standard in regard to these eggs. FSANZ is working closely with the Australian Quarantine and Inspection Service (AQIS) to ensure imported products meet the same health and safety requirements of domestically produced product.

In addition, AQIS stated that it strongly supports a robust standard that will provide the basis (Tier 1) for export requirements.

The Standard should reflect requirements in the Codex Code of Hygienic Practice for Eggs and Egg Products to further harmonize domestic and export standards. Any requirements for food safety programs should reflect HACCP principles documented in the Codex HACCP guidelines.

In drafting the draft Standard, FSANZ endeavored to ensure harmonisation with the Codex Code of Hygienic Practice for Eggs and Egg Products to further harmonise domestic and export standards.

### Communication, training and education

It was suggested that additional training of producers and farmers may be required to explain 'what, how and why' hazards need controlling.

FSANZ agrees that skills and knowledge in food safety is important in ensuring that hazards are controlled. The draft Standard requires egg producers and egg processors to ensure their staff have these skills and knowledge. This may be gained through in house or on the job training or through attending formal training courses.

It was suggested in both government and industry submissions that an education campaign aimed at the retail and food service sector regarding good handling practices would be beneficial. Also, that the public be alerted to certain misconceptions about eggs, for example, some consumers may think that eggs are sterile, and that correct handling and storage practices are important, for example, handling of raw eggs in conjunction with ready to eat foods to avoid potential cross contamination.

Whilst agreeing that public health education is important, FSANZ notes that the scope of the Proposal does not include education. Some jurisdictions responsible for food safety have already produced fact sheets and information for food service businesses and the public to make them aware of good handling practices. The FSANZ survey on consumer behaviour towards eggs indicates that there are varying levels of understanding regarding correct handling and storage practices. For example, only 39% of households would not use a cracked egg and 47% would wash a dirty egg. On the other hand, over half of Australian households report that they nearly always wash their hands after handling eggs. One of the risk management options that FSANZ has suggested is to raise an education campaign in conjunction with industry self regulation. The information from the consumer survey would then be used to help develop the education campaign.

#### Diet of organic hens

The diet of organic layers was raised in a few submissions, including variances between the National Standard of Organic and Bio-dynamic Produce and the Model Code of Practice for the Welfare of Animals. It was also stated that The National Standard of Organic and Bio-dynamic Produce could potentially adversely affect organic egg producers who do not export their product as they would not be able to add methionine to the hen feed.

The scope of the draft Standard is to ensure safety and suitability of eggs and egg products. The draft Standard requires egg producers to control inputs to ensure that the safety and suitability of eggs is not adversely affected and 'inputs' includes feed.

#### Potential for vertical transmission of S. Typhimurium

The issue of the potential for vertical transmission of some strains of *S. Typhimurium* and other paratyphoid salmonella was also raised in the submissions. This could potentially have more serious food safety ramifications resulting in the need for through-chain refrigeration of eggs for example, or a national vaccination program.

The risk assessment investigated reports of the potential for vertical transmission of Salmonella, which could potentially change the risk profile of egg safety. This was found to be a very low risk. The draft Standard includes a clause which pertains to bird health and states that eggs for human consumption may only be obtained from birds which do not have a disease or condition that could make the eggs unsafe or unsuitable. The proposed drafting realistically reflects the necessary precautions for the current level of bird health in Australia and subsequent egg safety.

The risk assessment reviewed the scientific literature on the potential vertical transmission of non-Salmonella Enteritidis (S.E.) Salmonella serovars (such as S. Typhimurium). This confirmed that while infection of the ovaries with non S.E. serovars has been observed, there is little, if any, evidence of transmission of these serovars into the egg contents during formation (see SD1, p. 23).

#### Use of genetically modified feed or genetically modified hens in the production of eggs

One submitter suggested that genetically modified (GM) feed or the use of GM hens in the production of eggs ought to be prohibited.

GM foods in Australia are regulated under Standard 1.5.2 – Food produced using Gene Technology. This Standard requires that before any GM food may enter the food supply FSANZ must conduct a mandatory pre-market assessment process evaluating the safety of the GM food. This process ensures that there is no risk to public health and safety from consumption of the GM food.

Scientific evidence published so far indicates that feeding GM plant material to poultry does not affect the nutritional value or safety of the meat and eggs derived from these animals.

However, as many animal feeds are derived from the same GM food crops that are used for human consumption, there is some concern that the inadvertent co-mingling of crops intended for animal feed with those intended for human consumption may result in unapproved GM products entering the food supply. For this reason, it is current Australian policy to avoid 'split use' approvals in relation to GM plants. A 'split use' approval is where a GM plant receives approval for use as animal feed but not for human food. This policy is also adhered to in the United States and Canada, which are sources of imported GM foods and food ingredients into Australia and New Zealand.

Therefore, it is now common practice for GM plants intended primarily for feed use to also undergo food safety assessment and approval for human food use. This minimises the risk of unapproved and unassessed products entering the food supply as a result of inadvertent comingling of grain/seeds during transport and storage, and also ensures that their use as feed will not pose indirect risks to humans.

The use of GM hens to produce eggs would be regulated under Standard 1.5.2. Currently no food from GM animals has been approved either in Australia or anywhere else in the world.

#### *Use of steroids and growth promotants in egg production*

One submitter was concerned about the use of steroids and growth promotants in egg production and suggested that such practises be prohibited.

The use of veterinary medicines in laying hens is regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). No hormones are registered for use in laying hens and there are no hormone Maximum Residue Levels (MRLs) included in Standard 1.4.2. This is consistent with poultry industry practices which have not seen the use of hormones as growth promotants since the 1960s.

Other registered veterinary medicines may be used in laying hens subject to APVMA assessment and establishment of MRLs. Egg producers are required to use only registered products and to comply with label instructions such as observing the appropriate withholding periods.

## Potential chemical contamination of free-range eggs from contaminated soil

One submitter expressed concern that free-range eggs may be contaminated by environmental contaminants from the land on which the hens are permitted to roam. It was proposed by this submitter that free-range egg farms be tested to ensure that the land is not contaminated.

Inputs, and therefore potential sources of contamination, may vary between cage, barn and free-range eggs. If hens are permitted to roam on highly contaminated sites, there is a potential for the eggs from these hens to have higher levels of contaminants compared to eggs from hens in less polluted environments.

Surveys of contaminants (e.g. heavy metals, dioxins, polybrominated diphenylethers) in Australian eggs indicate that eggs are not a major source of exposure to these chemicals, however sample sizes have generally been small and surveys have not distinguished between cage, barn and free-range eggs.

A requirement of the proposed egg primary production standard is that egg producers must control potential food safety hazards by implementing a documented food safety program. The food safety program must manage the hazards arising along the production chain from inputs (including feed, water, agricultural and veterinary chemicals, and environment). Therefore, if appropriate, under the new Standard, consideration should be given to previous use of land and the potential for chemical contamination from this use.

#### Use of peanut husks for livestock feed

One submitter questioned whether the use of 'high-protein milled peanut husks' and other 'side stream residues' are safe to use as stockfeed.

The provision of adequate and nutritionally balanced diets for layers, whether these are pelletised diets or combinations of grains, pulses, oilseeds etc, is the responsibility of individual egg producers.

The use of materials such as peanut husks (also known as hulls or shells), would be at the discretion of the producer and as part of a nutritionally appropriate diet.

Peanut husks contain over 60% crude fibre and may interfere with digestion, especially of protein, unless they are fed in very small amounts<sup>95</sup>. MRLs for several agricultural chemicals used in peanut cultivation have been set for peanut hulls used as animal feed<sup>96</sup>. It would also be important not to use mouldy hulls as these may contain aflatoxins which are detrimental to bird health and productivity and may cause a food safety issue if residues are present in eggs.

Whole peanuts and peanut meal are considered valuable poultry feed as they are high in protein<sup>97</sup>.

#### Presence of agricultural chemicals and phytotoxins in stockfeed

The Victoria Government expressed concern that weed seeds and agricultural chemicals in stockfeed be considered as part of the chemical risk assessment.

These issues have been discussed as part of the chemical risk assessment. The APVMA has established MRLs for some chemicals in stockfeed commodities<sup>98</sup>. In addition, the different States and Territories of Australia have different regulations covering stockfeed. For example, the Queensland Agricultural Standards 1998<sup>99</sup> have limits for certain toxin containing weed seeds, mycotoxins and other contaminants in stockfeed. Other States and Territories have different regulations, and work is being done to harmonise these across Australia.

Feed contaminated with these toxins will potentially have significant detrimental effects on animal health and cause subsequent production losses. Concentrations which do not manifest in systemic toxicity in birds are unlikely to result in concentrations of concern in eggs.

**Table 1: Summary of issues raised in public submissions** 

Submitter	Comments
Australian Egg Corporation Limited	• Considers through-chain refrigeration should be considered for adoption into the Standard; this was considered at the AECL Industry Forum. It suggests
Corporation Ellinted	that a lower temperature range than 20°C should be adopted in the medium term.
Department of	Supports the development of the Standard.
Agriculture, Fisheries	• Recommend that the new Standard is consistent with the:
and Forestry	- Overarching policy guideline on primary production and processing
	Standards developed by the Ministerial Council
	- Australia New Zealand Food Standards Code
	- existing State and Territory based regulations and Codes of Practice Codex
	- Code of Hygienic Practice and other international standards
	• In relation to the proposed regulation for Specialty eggs, it is recommended
	that regulation be the minimum necessary to ensure food safety.

<sup>95</sup> http://www.fao.org/ag/aga/AGAP/FRG/AFRIS/Data/489.HTM Accessed on 10 April 2007

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<sup>&</sup>lt;sup>96</sup> http://www.apvma.gov.au/residues/downloads/TABLE04.pdf. Accessed on 10 April 2007

<sup>97</sup> http://www.fao.org/ag/aga/AGAP/FRG/AFRIS/Data/489.HTM Accessed on 10 April 2007

<sup>98</sup> http://www.apvma.gov.au/residues/downloads/TABLE04.pdf. Accessed on 10 April 2007

<sup>99</sup> http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/A/AgrStandR97.pdf

Submitter	Comments
	<ul> <li>Also, in relation to imported specialty eggs, there should be sufficient flexibility to prevent the imposition of new food safety requirements.</li> <li>Supports harmonisation of domestic, export and import standards for food production in Australia.</li> </ul>
Farm Pride Foods Ltd	Expressed concern over the sale and use of cracked eggs, egg washing, egg storage temperatures and microbial contamination.
Food Technology Association of Victoria Inc.	Endorses and accepts the draft proposal without any additional comments.
Fraser Coast Free Range	<ul> <li>Commented on points in relation to organic egg production.</li> <li>Disagrees with the issue of poultry welfare only being considered as part of the risk management options if the welfare of the bird is a contributory factor to food safety.</li> </ul>
Free Range Farmers Association Inc.	<ul> <li>Raised the issue of re-packaging of whole shell eggs into second hand cartons. This occurs frequently in Victoria, particularly amongst independent small producers that directly retail to the public via the farm gate or non food safety system audited grocers as well as those that sell at Farmers Markets. Concerns were expressed that these producers may not be aware of, or practice, safe food cleaning, candling, grading and cool room requirements of the AECL Code of Practice for Shell Egg, Production, Grading, Packing and Distribution.</li> <li>Re-used cartons are often stained which is indicative of foreign liquid contamination. Furthermore, the labelling of re-used cartons presents problems in the event of a recall.</li> <li>The word 'organic' does not appear to be adequately protected by law in Australia.</li> <li>Suggests consideration for a mandatory requirement for all eggs to be supported on request or public domain by a feed input certification or listing in the case of specialty types of eggs.</li> <li>Eggs from major stakeholders are regularly shipped interstate. For example, eggs coming into Victoria, from Queensland and NSW, carry another code system above the Best Before date, as it has been noted that some major packers in Victoria do not have a code system. It is assumed that this system is to assist the product recall and audit trail.</li> <li>Suggests that the Queensland/NSW carton source identification system should be mandated but within a national register which will trace back to the source farm.</li> </ul>
FSANZ Consumer Liaison Committee	<ul> <li>No significant issues from consumer perspectives in relation to the Standard.</li> <li>Issues were raised in relation to the labelling differences between organic and free range eggs.</li> </ul>
Gary Bielby	<ul> <li>Supports FSANZ in its approach to avoid undue social or economic costs.</li> <li>Raised the issue of traceability, indicating that stamping of each egg will have an effect (financial burden) on small egg producers.</li> </ul>
Ivan Jeray	• Provided comments in relation to concerns with genetically modified animal feed used in egg production.
McLean Farms	<ul> <li>Discussed the increase in both free range and barn lay operations in Australia.</li> <li>Considers that wholesale storage and distribution centres should be addressed separately as there are several organisations that purchase and resell eggs/egg products wholesale.</li> <li>Considers organic eggs as a separate production system.</li> </ul>
Metcash	In relation to refrigeration, commented that there is little evidence that the non-refrigeration of eggs at retail level is the major cause of the small number of food-borne illness outbreaks.

Submitter	Comments
	Any requirement for retailers to store or display eggs under refrigeration
	would impose an unnecessary cost to the industry.
	Opposes the introduction of legislation which would require the refrigeration
	of eggs at the point of retail sale.
	• Expressed concern in relation to governing the retail sale of eggs, particularly
	at markets and sale by smaller operators.
Micro-Range Farmers	Expressed concern in relation to the testing of soils of herbicide and pesticide
Association	contamination amongst free range egg farmers.
	In relation to organic egg production, it was suggest that there be controlled
	feeding practices i.e. hens kept in hencoops, which will assist consumers in
N G 4 W 1	purchasing decisions between free range and organic eggs.
New South Wales	Supports FSANZ's approach to developing a primary production and
Food Authority	processing standard.
	• Expressed concern in relation to the availability and sale of un-pasteurised egg
	pulp and cracked eggs within the scope of the Standard.
	• Suggest the use of a consistent definition for specialty eggs in the Standard as
	only salted, century and Balut eggs are covered by this definition.
	Advises consideration of egg layer breeding stock in the Standard as it is not assured under the definition of food in the Act.
	covered under the definition of food in the Act.
	Suggests the inclusion in the standard of bakeries and other retail     ortablishments using expelsed and upperturized eggs and egg products (e.g.,
	establishments using cracked and unpasteurised eggs and egg products (e.g.
	egg pulp in the production of foods such as cakes, meringues, biscuits, hamburger patties and custard tarts). As well as businesses involved in the
	transport and storage of unpasteurised egg pulp, pasteurised egg products or
	cracked eggs.
	<ul> <li>Expressed concern in relation to traceability for table eggs.</li> </ul>
	<ul> <li>Expressed concern in relation to traceability for table eggs.</li> <li>Expressed concern in relation to Salmonella Enteritidis, as the serotype can</li> </ul>
	enter eggs via the trans-ovarian route, thus contaminating intact eggs. Though
	no evidence of this serotype is present in egg laying birds in Australia,
	however continued strict biosecurity measures are necessary to maintain this
	status.
	Suggests heightened management to reduce the risk of food-borne illnesses
	through other Salmonella serovars.
	Suggests that specific consideration be given to biological hazards associated
	with the processing of Balut eggs.
	Expressed concern in regards to the microbiological hazards associated with
	ponds on free-range duck farms and the sanitary conditions of the water used
	in the processing of salted and century eggs.
	Suggests that the new Standard considers the introduction of new
	technologies, such as high pressure processing.
New Zealand Food	Welcomes the Proposal and will need to concurrently consider the impacts of
Safety Authority	any proposed changes may have on the New Zealand regulatory framework as
	it may necessitate a change to subordinate legislation under the New Zealand
	Animal Products Act 1999 and/or the Food Act 1981 to fill any resultant gaps
	in coverage and/or to ensure that requirements achieve equivalent outcomes.
	As well as the impact on its import and export requirements.
	Agrees that most labelling issues are already covered by the requirements of
	the Code, but for eggs and egg products, additional consideration could be
	given to the following:
	- relationship between shelf life, actual storage temperatures and resulting food
	safety outcomes especially microbiological
	- labelling necessary to aid traceability during recall situations, especially
	within the production sector where farm identification may be desirable but

Comments
may not be mandated by the lot identification requirements in the generic
labelling Standards in the Code.
<ul> <li>Organic producers may wish to wet wash with just potable water (without</li> </ul>
chemical detergents or sanitisers).
<ul> <li>Supports the need for outcome based assessments for the production of egg and egg product through the food chain from pullet egg to consumer.</li> <li>Suggests that to ensure product safety and integrity, we must also ensure that cracked and dirty eggs and unpasteurised pulp are only sold to egg processors.</li> <li>Commented that a new Standard should not significantly financially burden egg and egg product businesses or consumers.</li> <li>Expressed concern in relation to the egg product specification testing, suggesting that testing for <i>E. coli</i> should be included.</li> <li>Suggests that the work undertaken in the National Residue Survey is sufficient to demonstrate physical hazards.</li> <li>Requests clearer definitions of Standard 2.2.2 to ensure that only egg processors use cracked/dirty eggs, and sought further clarification of 'equivalent' forms of pasteurising egg products.</li> </ul>
<ul> <li>Acknowledged FSANZ's intent to treat layer welfare issues within current</li> </ul>
Welfare Codes of Practice.
• Expressed concern in relation to the production levels of different systems,
feed protein levels and potable water.
<ul> <li>In relation to packaging, it was noted that many eggs are sold for retail/wholesale or for further processing on open fibre trays used for collection.</li> </ul>
• Expressed concern in relation to the reuse of egg cartons as it is a traceability risk in relation to providing effective recall measures.
<ul> <li>Expressed concern in relation to labelling issues differentiating between free range, barn and cage eggs.</li> </ul>
<ul> <li>Provided information in regards to the relationships between different food safety management programs such as the Safe Food Production Queensland legislation.</li> </ul>
Supports the development of the Proposal.
<ul> <li>Expressed concern in relation to cracked, dirty and broken eggs.</li> </ul>
<ul> <li>Agreed that the Standard should relate to avian eggs and products made from eggs available for human consumption.</li> </ul>
<ul> <li>Agreed that the assessment addresses shell eggs, processed egg products and specialty egg products such as salted, century and Balut eggs.</li> </ul>
<ul> <li>Supports FSANZ in not considering labelling as part of the proposal.</li> </ul>
Acknowledged that traceability is an issue, and the matter should be
investigated with evidence.
• In relation to the retail sector, it was stated that the current requirements of
Chapter 3 adequately control the safety of eggs at retail level.
• Stated that the retail sector is not convinced of the effectiveness of
refrigeration. Queensland Legislation does not require eggs to be refrigerated
at the retail level.  • Stated that the economic estimate of refrigeration in QLD, with approximately 7000 supermarkets was estimated to be approximately \$AUD100m. If eggs were needed to be refrigerated, it would lead to a substantial increase in the price, not only of eggs, but of other food products to recoup the outlay, which may lead to a reduction in the sale of eggs. Furthermore, it was thought that refrigeration may potentially reduce the number of outlets where eggs are sold, also resulting in a reduction in sales by the egg industry.

Submitter	Comments
	Very few small to medium retailers would then continue to stock this product
	range once they have determined the initial cost of a unit/s, as well as
	installation cost and the ongoing operating and maintenance costs.
	Stated that if there were problems with eggs (before use) they can be readily
	identified and that 98% of all eggs consumed are cooked individually,
	collectively or with other products so that any possible risk is minimised.
	• Questioned that if a decision was made to refrigerate at retail, then what would
	be the situation relating to flea markets and farmers markets?
	The retail industry totally opposes any consideration to require eggs to be kept
	under refrigeration at retail level.
Safe Food Production	Supports FSANZ's approach to developing a primary production and
Queensland	processing standard.
	Expressed concern in relation to cracked and dirty eggs, the use of
	unpasteurised egg product, lack of traceability and preparedness for egg borne
	disease.
	Indicated that a regulatory approach is needed for on farm activities in relation
	to Quality Assurance programs, supply and sales of cracked and dirty eggs via
	on-farm sales and at markets and the need for Quality Assurance programs to
	address the identification, separation and management of cracked and dirty
	eggs.
	Expressed concern in relation to egg carton labelling and traceability.
	Queensland would support an egg traceability regulatory approach to be
G 11 T 1' G	consistently applied across all states and territories to improve investigations.
Smalls Trading Co	• Stated that for small producers there are several issues in relation to the
	washing of the egg.
	Process details were provided.  Provided comments in relation to the suidelines of the AECL Code of Provided.  Provided comments in relation to the suidelines of the AECL Code of Provided.
	• Provided comments in relation to the guidelines of the AECL Code of Practice
	for Shell Egg, Production, Grading, Packing and Distribution which need to be
South Australian	<ul> <li>updated to include different production lines.</li> <li>Supports the development of a food safety standard addressing food safety</li> </ul>
Department of Health	risks in eggs and egg products.
and Primary	Supports a through-chain outcomes-based approach to managing risks
Industries and	associated with eggs and egg products.
Resources SA	Supports the intended scope of the proposal.
Resources 571	Suggests provision of further consideration of particular strains of <i>Salmonella</i>
	that have the ability to be vertically transmitted.
	Provided several suggestions in relation to potential hazards in wash systems,
	non-candled and non-graded eggs, transportation hazards and cracked and
	dirty eggs.
	The difference between 'use by' and 'best-before' dates may warrant advice
	dependent on any storage temperature requirements that may be mandated in
	the proposed Standard.
	In relation to grading floors and egg cleaning and sanitising, consideration
	must be given to existing premises and equipment which may be unable to be
	washed and will affect the ability of that business to meet that Standard.
Sunny Queen Pty Ltd	National Standards of Organic and Bio-dynamic produce (2005) should not be
	included as a Code of Practice for Egg & Egg Products, as the Standard is
	based on food safety and not exporting Organic products. In addition the
	Standard hardly quotes organic eggs and contrasts with the Model Code of
	Practice for the Welfare of Animals – Domestic Poultry.
	If the Organic Standard is included it may affect organic growers who do not
	export their product as they will not be able to add methionine to their hen
	feed, which may result in adverse effects of hen welfare.

Submitter	Comments
	<ul> <li>In relation to grading floors, amendments have been made to Trade Measurement Legislation in Queensland and Victoria. Egg packers are no longer required to mark on the carton the individual weight of egg.</li> <li>In relation to the determination of the 'Best Before' or 'Use By' dates, the AECL Code of Practice for Shell Egg Production recommends a Best Before date of 35 days from point of lay. However, through a shelf life trial, a Best Before date of 50 days was found to be suitable for eggs if they are stored</li> </ul>
Tasmanian Egg Working Group	<ul> <li>Working Group participants were generally satisfied with the accuracy and the comprehensiveness of the information provided.</li> <li>Concern in relation to the re-use of egg cartons due to hygiene, traceability and misleading information for the consumer regarding the egg producer.</li> <li>Concerns that the Standard 2.2.2 does not clearly state that all egg products</li> </ul>
Victorian Department of Primary Industries	<ul> <li>(including egg pulp from cracked eggs) should be pasteurised prior to use.</li> <li>Supports the intended scope of the proposal.</li> <li>Provided comments in relation to the establishment of risk management practices of delicacy eggs as it is an area of minimum impact.</li> <li>Suggests that consideration be given to traditional delicacy egg products in a separate proposal, as these industries would require a specialist team and personnel with expertise in those markets.</li> <li>Expressed concern in relation to traceability, particularly within packing sheds where co-mingling of eggs from different farms occurs.</li> <li>Expressed concern with the incorrect labelling of reused egg cartons.</li> <li>Raises concerns in relation to chemical and microbiological hazards.</li> <li>Expressed concern in relation to the lack of data pertaining to consumption rates of raw egg containing products by consumers and the use of raw egg in food products by retail businesses.</li> <li>In relation to refrigeration, a key concern for industry is the food safety risk associated with inconsistent and fluctuating temperatures and humidity throughout the supply chain. Supports an assessment and impact of refrigeration throughout the supply chain compared with consistent ambient</li> </ul>
Victorian Farmers Federation	<ul> <li>Provided an overview of the egg system in Victoria</li> <li>Supports a national Standard providing it ensures the use of the principle of minimum effective regulation.</li> <li>Does not support a system where there are additional costs to the production and selling of eggs.</li> <li>In relation to the Food Safety Programs and the current effectiveness of the Shell Egg Codes - stated that jurisdictions may have different regulations, but many are following the Victorian Shell Egg Code.</li> <li>Prefers to have specialty hen eggs and eggs from other avian species dealt with in a separate proposal.</li> <li>Concerned about the incorrect labelling of reused egg cartons as it is both a trade and food safety issue.</li> <li>Provided comment in relation to chemicals used for poultry, as well as the significant microbiological risks that are imposed and how the Victorian Shell Egg Code is utilised to minimise any possible disease transmissions.</li> <li>Farmers in Victoria are trained in chemical use by passing a ChemCert course.</li> <li>In relation to egg safety and packaging, the industry uses clean cardboard and plastic trays for on-farm use and only uses new cardboard or plastic carton for retail use.</li> <li>Retail storage of eggs is set at 20°C, if eggs are kept at 4°C in supermarkets – they will sweat when taken out of the store, which is a potential hazard.</li> </ul>

#### **Attachment 4**

## Draft Compliance Plans for the Egg and Egg Products Primary Production and Processing Standard

The following activity groups have been identified by the EIMWG and are covered by Compliance Plans A and B attached. The following activity groups are:

- 1. Egg Producer: grows only, may transport, supplies direct to a processor and may sell acceptable eggs off farm once received back from processor.
- 2. Egg Producer: grows and grades eggs, may transport and store, may sell acceptable eggs off farm, may supply unpasteurised egg pulp to a processor for pasteurisation.
- 3. Processor: grows and grades their own eggs, as well as grading other people's eggs and may transport and store. May supply egg pulp to a processor for pasteurisation.
- 4. Processor: Does not grow, grades eggs, may transport and store, may supply unpasteurised egg pulp to processor for pasteurisation.
- 5. Processor: pasteurises egg product only.

Two compliance plans have been developed to promote consistent implementation of the standard for these various activities. The plans are draft and subject to any changes that may occur in the standards development process:

- describe the key issues of compliance,
- contain minimum requirements for compliance with the standard,
- provide a jurisdiction's intent for implementing the standard.

Compliance plan	Applies to activity group(s)
A	1-4
В	5

#### **Notes:**

Some egg producers/processors may not fit exactly into one of the above groupings. Each Compliance plan should be applied where applicable to their operation. For example, Group 1 would not be required to set out details in relation to grading. If groups 2-4 undertake pasteurisation, Compliance plan B will also apply.

Further details describing acceptable means of compliance will be found in the guideline document (under development).

For the purpose of this material 'grades/grading activity' includes the following - grades (sort into size), packs, washes, candles or assess for cracks, oils, pulps eggs for supply to a processor for pasteurisation, or stores.

## Compliance plan - A: Egg production (grows eggs, may also grade eggs).

Compliance requirement - Industry	Monitoring requirements - Industry	Monitoring requirements - Government
The food safety management statement must set out how a business proposes to manage the identified hazards associated with the following:		
- Collection, supply, storage and transport of eggs (e.g. identify collection process and conditions).	Evidence/records to be kept to demonstrate that:	Regulator to instigate appropriate monitoring arrangements.
- Identification, segregation and control of unacceptable eggs (e.g. send to processor, or cleaning/washing process, effective crack detection method e.g. candling).	- Control measures have been implemented and are monitored (e.g. distribution records, withholding periods for agricultural &	e.g. may include inspection or Audit, or other monitoring arrangement depending on
- <i>Inputs</i> (e.g. stockfeed, pesticides and veterinary medicines, water, chicks, litter).	veterinary chemicals);	regulator's legislation.
- <i>Waste disposal</i> , system to deal with waste (e.g. removal of dead birds, litter, garbage, manure and disposal of unacceptable eggs).	- Verification checks (e.g. internal audits, visual inspections) have been made of the food safety management statement to confirm	The frequency of monitoring will be based on risk and performance.
- Health and hygiene (e.g. egg handler personal hygiene and practices).	operating as per the management statement;	
- Skills and knowledge (e.g. demonstration of competency).	- Corrective action/s have been taken when necessary (e.g. description of actions for	
<i>-Premises equipment and transport</i> , (e.g. design, construction, cleaning and maintenance of premises, equipment and transport vehicles, pest control program, cleaning program).	restoration of control, dealing with unacceptable eggs, and prevention of recurrence).	
- Bird Health (e.g. active surveillance of flock, identification of treated birds).		
- Sale and supply (e.g. Distribution records).		
-Traceability Egg producers must not sell eggs unless each individual egg and each carton or package is marked with egg producers unique identification; e.g. stamping Egg producer who supplies egg pulp must mark each package or container containing the pulp with the producers' unique identification.	- Each producer must have evidence to show compliance with the traceability requirements.	

# Compliance plan – B. Egg Processor: Pasteurises egg products

Inherent risk: Unpasteurised egg product.

Compliance requirement - Industry	Monitoring requirements - Industry	Monitoring requirements - Government
The food safety management statement must set out how a		
business proposes to manage the identified hazards in		
accordance with the following criteria:		
<ul> <li>(a) systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the business;</li> <li>(b) identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control;</li> <li>(c) provide for the systematic monitoring of those controls;</li> <li>(d) provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control;</li> <li>(e) provide for the regular review of the statement by the food business to ensure its adequacy; and</li> <li>(f) provide for appropriate records to be made and kept by the business demonstrating action taken in relation to, or in compliance with, the food safety management statement.</li> </ul>	Evidence/records to be kept to demonstrate that:  - Control measures have been implemented and are monitored (e.g. time/temperature records).  - Verification checks (e.g. internal audits, visual inspections, final product microbiological monitoring) have been made of the food safety management statement to confirm operating as per the management statement.  - Corrective action has been taken when necessary (e.g. description of actions for restoration of control, dealing with unacceptable eggs, and prevention of recurrence).	Regulator to instigate appropriate monitoring arrangements.  e.g. may include inspection or Audit, or other monitoring arrangement depending on regulator's legislation.  The frequency of monitoring will be based on risk and performance.
Examples of key operations that should be included in a business's statement include:  (a) Collection, storage and transport conditions for unpasteurised egg product.  (b) Storage and transport conditions for pasteurised egg product, e.g. time and temperature.  (c) Critical limits and validation process for pasteuriser.  Note that pasteurised egg products are required to comply with Standard 1.6.1- Microbiological limits for food, contained within the Australia New Zealand Food Standards Code.  Standards 3.2.2 and 3.2.3 apply to businesses undertaking pasteurisation processes. The following major issues are managed by these standards:	Verification check to demonstrate compliance with the Standards 3.2.2 and 3.2.3.	

a) Skills and knowledge b) Food handling c) Health and hygiene d) Cleaning, sanitation and maintenance e) Design and construction of premises (includes water and waste disposal). f) Alternative methods of compliance g) Floors, walls and ceilings h) Fixtures, fittings and equipment i) Transport vehicles		
Traceability  Egg processors must not sell eggs unless each individual egg and each carton or package is marked with egg processors' or producers' unique identification; e.g. stamping  Egg processors' who supplies egg product must mark each package or container containing the product with the processors' or producers' unique identification.	Each processor must have evidence to show compliance with the traceability requirements	Check processor's records to confirm that egg pulp pasteurised by the business is traceable.