FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

EXPLANATORY STATEMENT

PROPOSAL P301

PRIMARY PRODUCTION & PROCESSING STANDARD FOR EGGS & EGG PRODUCTS

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/foodstandards/changingthecode/

EXECUTIVE SUMMARY

Purpose

FSANZ has prepared this Final Assessment Report[1] on Proposal P301 which includes draft variations 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. An impact analysis of the risk management options has been conducted and a preferred option recommended.

FSANZ's decision is to vary the Code by introducing a primary production and processing standard for eggs and egg products (Standard 4.2.5) to augment the Chapter 4 Standards. Minor amendments are also recommended to Standard 1.1.1 – Preliminary Provisions, Standard 1.6.1 – Microbiological Limits for foods, Standard 1.6.2 - Processing Requirementsand Standard 2.2.2 – Eggs and Egg Products.

Introduction

This Final Assessment Report represents the final stage in addressing food safety within the egg supply chain. The work has progressed with the advice and guidance of a Standard Development Committee comprising representatives from the egg industry, government regulators and consumers.

The Problem

Contaminated eggs and egg products are suspected as the causeof an unacceptably high number of foodborne illness outbreaks in Australia. An economic valuation of these illnesses is anestimated total cost of $44 million to the Australian economy each year.

FSANZ undertook a scientific assessment of the public health and safety of eggs and egg products in Australia[2]. The assessment concluded that the main microbiological hazard associated with these products is *Salmonella*.*Salmonella* are bacteria that can infect laying birds and are pathogenic to humans, causing gastroenteritis.

The likelihood that clean, intact eggs are contaminated with *Salmonella* is very low. However, the risk is increased in eggs with visible surface faecal contamination and/or which are cracked. Damage to the shell allows *Salmonella* to penetrate into the egg contents. Egg pulp that is inadequately heat-treated is also more likely to be contaminated because cracked eggs are usually used in its production.

[1] This Report has been prepared according to the FSANZ standard development process as was in force prior to 1 July 2007.

[2] *Risk Assessment of Eggs and Egg Products*, FSANZ, Sep 2009. Available from http://www.foodstandards.gov.au/foodstandards/proposals/proposalp301primaryp3426.cfm

Salmonellosis is the second most commonly reported foodborne illness in Australia. Where the cause of foodborne illness can be identified, eggs are the most commonly identified food vehicle. The main cause of egg-related illness is the consumption of food containing raw or lightly cooked eggs. The current lack of traceability for eggs, once they are removed from their packaging, has compounded difficulties in investigating egg related illness.

Salmonella may be introduced into a laying flock from several sources including feed, water, pests e.g. rodents and insects, the environment, personnel, new laying stock and equipment. The Risk Assessment concluded that identification of factors that have the greatest impact on flock contamination was not possible due to the multi-factorial nature of transmission of *Salmonella* spp. into laying flocks and a lack of quantitative data.

There are significant variations in the size of the egg layer industry in Australia, ranging from small producers with less than 100 birds to large enterprises with more than 300,000 birds. The large producers supply the major supermarket chains. However, the smaller producers supply small retailers, farmers markets and sell at the farm gate.

Industry food safety assurance schemes, such as the national egg industry scheme (known as Egg Corp Assured), are voluntary and industry reports that the uptake amongst small producers is low. Currently, there are approximately 30% of egg businesses registered in the program capturing 93% of the national layer flock and 80% of eggs sold.

There are currently no national regulatory measures in place to minimise the likelihood of eggs, or egg pulp produced on-farm, being contaminated on-farm or during grading, washing or packaging. Three States, Queensland, Tasmania and New South Wales (as of 18 June 2010), have already introduced their own legislation to control egg safety on-farm. In Queensland, the legislation includes a requirement to identify individual eggs for traceability purposes.

The Code contains Australia-only processing requirements for specified egg products. The Risk Assessment concluded that treatments specified in the Code for liquid whole egg were more than sufficient to inactivate any *Salmonella* likely to be present. The Code also contains prohibitions on the availability of cracked eggs for retail sale. Stakeholders report that the current Code requirements are generally unclear as to their application and obligations on egg businesses.

There is no nationally-agreed set of egg safety messages for consumers although advice is reasonably consistent. There are indications that some consumers do not follow the advice.

Objective

The objective of this Proposal is to reduce the incidence of foodborneillness from *Salmonella* by minimising the prevalence and concentration of this pathogen in eggs and egg products.

Options

In order to decide the most cost-effective approach for achieving the objective, FSANZ proposed risk management options. These options included the *status quo* as a comparative measure against which appropriate non-regulatory and regulatory approaches can be assessed. Three options were proposed.

Option 1A – Reject the Proposal – maintain the status quo

No change made to the existing regulatory regime.

Option 1B – Reject the Proposal - industry self-regulation (including education)

Industry to implement measures whereby all producers and processors ensure contaminated eggs and eggs products do not enter the market place and that eggs and eggs products are traceable. It would also include an education campaign targeted at consumers to improve the safe handling of eggs.

Option 2– Approve the draft Standard – government regulation

All egg producers and processors would be required to comply with regulatory requirements for the production and processing of egg and egg products by way of 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 options 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.

Option 1A (*reject the Proposal thus maintaining the status quo*) does not introduce any new measures to lower the likelihood of the community contracting salmonellosis from the consumption of eggs and egg products. The adoption of the *status quo* option is estimated to cost the community around $44 million annually, which is the estimated current cost burden, associated with illness from eggs and egg products contaminated with *Salmonella*.

Option 1B could reduce egg associated illness from *Salmonella.* The advice and evidence provided by the SDC, however, indicates that it is unlikely that small producers will participate in such a program to the extent that it will have a positive impact on the health and safety issues raised. Moreover, cost projections indicate that such an option would not deliver a net benefit to the community. Over a five year period, at net present value, it may instead impose a cost burden of about $26 million.

Option 2 is the preferred option as it represents the most cost effective way of lowering the likelihood of the community contracting salmonellosis from the consumption of eggs and egg products. It will reduce the incidence of illness by anything between 20 and 50 per cent. Over the first five years of implementation, it is expected to deliver a net benefit of between $26 million and $75 million to the Australian community.

Decision

To approve draft Standard 4.2.5 – Primary Production and Processing Standard for Eggs and Egg Products and make consequential amendments to Standard 1.1.1 – Preliminary Provisions –Application, Interpretation and General Provisions, Standard 1.6.1 – Microbiological Limits for Food, Standard 1.6.2 – Processing Requirementsand Standard 2.2.2 – Egg and Egg Products.

Reasons for Decision

At Final Assessment, FSANZ has approved draft variations to the Code. The amendments:

- address public health and safety concerns raised in the Risk Assessment of Eggs and Egg Products in Australia
- 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 and Territory 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.

Implementation and review

An 18 month implementation timeframe has been recommended. This means the Primary Production and Processing Standard for Eggs and Egg Products will commence eighteen months after the Standard is gazetted.

Implementation of the Code is the responsibility of the States and Territories. The Implementation Sub-Committee (ISC) is facilitating the consistent national implementation of the Primary Production and Processing Standard for Eggs and Egg Products. ISC has developed an implementation package for the consistent implementation of the Standard. It has undertaken to review the effectiveness and impact on regulators and businesses of the implementation package in enhancing consistent implementation of the Standard following its implementation.

CONTENTS

SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Final Assessment Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/proposals/proposalp301primaryp3426.cfm

SD1: Regulatory impact statement

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. FSANZ has developed primary production and processing standards for seafood, poultry meat and processed dairy products for inclusion in the *Australia New Zealand Food Standards Code* (the Code). Standards for meat (beef, pork, sheepmeat and goat meat), raw milk products and seed sprouts are currently under development[3].

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[4] in Australia that extends from production on the farm through to sale to the consumer.

The Final Assessment Report describes the second stage of the assessment of Proposal 301, Primary Production and Processing Standard for Eggs and Egg Products. The objective of the Proposal is to improve the safety of shell eggs and egg products for sale in Australia.

Implementation of primary production and processing standards is the responsibility of the State and Territory Governments. During the progress of the Proposal, the State and Territory Governments have developed a national plan for implementing the proposed new requirements for eggs and egg products in the Code. Information on the implementation plan is included in this report.

1. Scope of the Proposal

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 does not extend to businesses keeping breeding stock that produce eggs for hatching as laying hens5 or producers of speciality egg products such as Salted, Century[6] and Balut[7] eggs and embryonic quail eggs[8].

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[3] Further information on these Proposals is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/proposals/

[4] 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.

[5]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.

[6] A Century or Thousand-year egg is a Chinese cuisine ingredient made by preserving duck, chicken or quail eggs in a mixture of clay, ash, salt, lime and rice hulls for several weeks to several months, depending on the method of processing (www.wikipedia.org, August 2010).

2. The egg and egg products production chain

The general flow of activities related to egg production and processing is illustrated in Figure 1.

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.

Eggs may be transported long distances for grading, with some farms up to 500 kilometres from grading facilities[9].

The activities of individual producers vary 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[10], 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 free-range market share increasing over the past few years (20%) and barn-laid market share decreasing slightly (5.1%)[11].

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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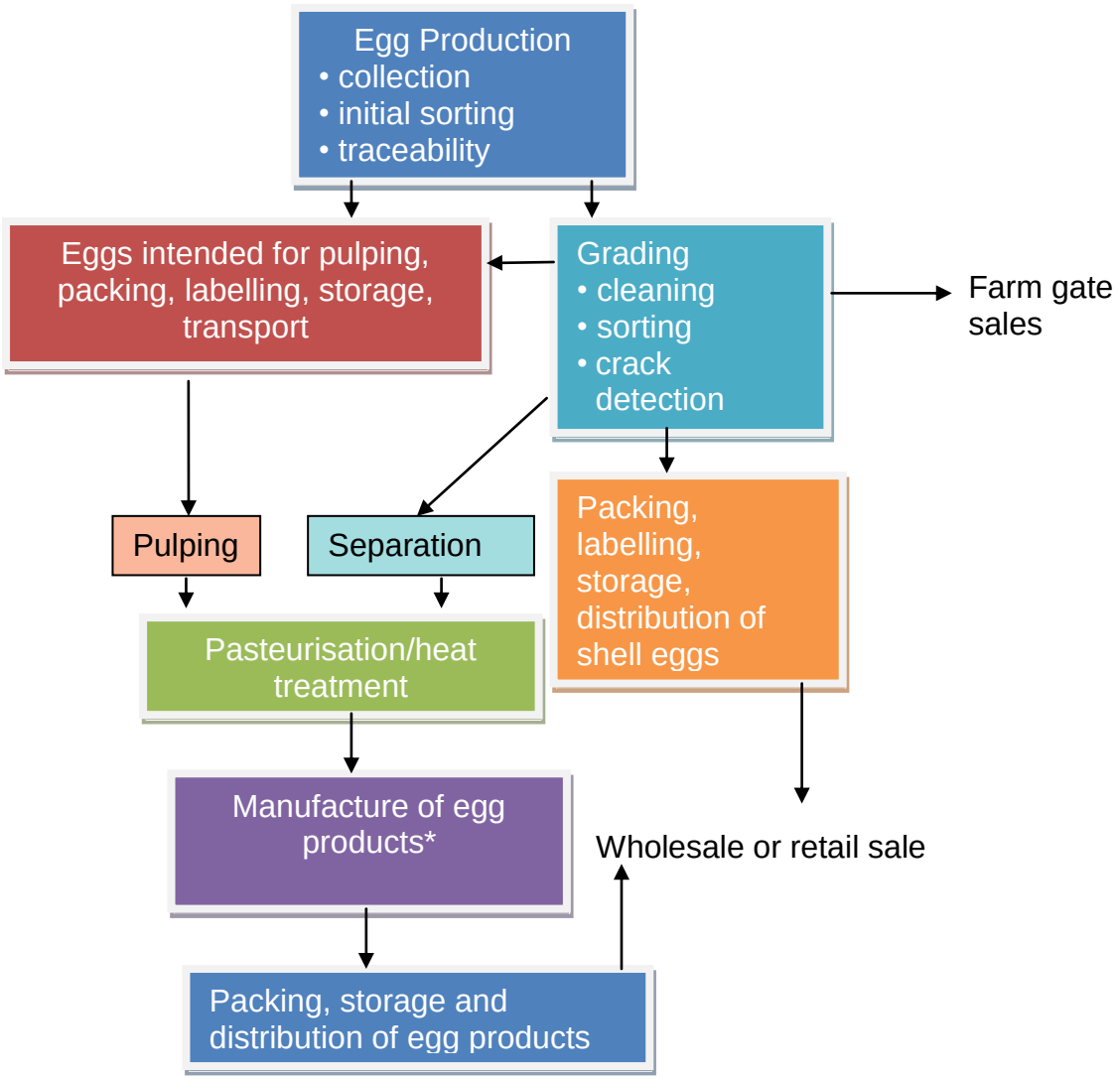
[7] A balut is a fertilised duck (or chicken) egg with a nearly-developed embryo inside that is boiled and eaten in the shell (www.wikipedia.org, August 2010).

[8] Manufacturers of speciality eggs are required to comply with the NSW Egg Food Safety Scheme, which is currently being implemented.

[9] 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.http://www.daff.gov.au/animal-plant-health/animal/livestock_movement_in_australia_and_emergency_disease_preparedness

[10] 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.

[11] AECL Annual Report 2008 http://www.aecl.org/images/File/AECL%20Annual%20Report%20web.pdf



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

Figure 1: Production chain for eggs and egg products

3. The Problem

Australia has an unacceptable number of cases of foodborne illness caused by contaminated eggs and egg products. These illnesses result in socialand economic costs estimated to be $43.88m annually. The existing regulatory and non-regulatory measures are not adequate to prevent these egg-related foodborne illnesses.

3.1 Cost of foodborne illness attributable to eggs

Based on information from previous egg-associated outbreaks, the impact analysis estimates that the egg and egg products industry in Australia could be incurring costs amounting to $6.53m annually as a consequence of reputation damage, inefficiencies and product recall.

Government annual costs due to recalls, compliance and investigation due to outbreaks of egg-related foodborne illness are estimated to be $1.75m annually.

The total costs to the community attributed to egg-related foodborne salmonellosis, is about $36.68m annually. This includes health related costs, loss of income and/or leisure, in addition to a monetary value attributed to pain and suffering. Therefore, the total cost of foodborne illness attributable to eggs is estimated to be in the order of $44.99m annually.

3.2 Public health risk

The Risk Assessment[12] concluded that the main microbiological hazard associated with eggs and egg products is *Salmonella.*Consumption of food containing contaminated raw eggs or lightly cooked eggs for example, sauces and desserts, and food contaminated as a result of handling contaminated raw eggs, are the main causes of egg-related illness. The likelihood that clean, intact eggs are contaminated with *Salmonella* is very low. However, the risk is increased if eggs that have visible surface faecal contamination and/or are cracked are used.

Salmonella are bacteria that can infect laying birds;many serovars 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[13] were associated with outbreaks attributed to consumption of eggs contaminated with *Salmonella*.

Salmonellosis is the second most commonly reported foodborne disease in Australia. In 2009, there were 9,527 notifications of human infection to health authorities, equivalent to a rate of 44 cases per 100,000 population14. 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 foodborne diseases is often unknown. Additionally, many cases of foodborne disease are not reported. However, where the food vehicle has been identified through investigations of foodborne disease outbreaks, eggs have been the most commonly identified food vehicle for salmonellosis.

In 2007, of the 149 foodborne outbreaks reported, 24 (16%) were associated with eggs15. TheNew South Wales Food Authority reported 13 outbreaks in New South Wales in 2008/2009 financial year attributable to *Salmonella* contaminated eggs[16].
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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[12]FSANZ Sep 2009 *Risk Assessment of Eggs and Egg Products*, Available from www.foodstandards.gov.au.
[13]*Risk Assessment of Eggs and Egg Products*, FSANZ, Sep 2009. Available from www.foodstandards.gov.au.
[14]National Notifiable Diseases Surveillance System (NNDSS), Australian Government Department of Health and Ageing, http://www9.health.gov.au/cda/Source/Rpt_2_sel.cfm (accessed January, 2011).
[15] OzFoodNet 2008 *Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual report of the OzFoodNet Network*,http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/$FILE/cdi3204.pdf(accessed August 2010)
[16] New South Wales Food Authority *Submission to the Draft Assessment Report Proposal 301 Primary Production and Processing Standard for Eggs and Egg Products.* Available from FSANZ.

3.3 Factors contributing to risk

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. The Risk Assessment concluded that identification of factors that have the greatest impact on flock contamination was not possible due to the multi-factorial nature of transmission of *Salmonella* spp. into laying flocks and a lack of quantitative data.

Collaborative work between the Tasmanian Department of Primary Industries and Water and FSANZ[17] confirmed that *Salmonella* may be present in the poultry farm environment in manure, feed, egg belts, walkways and egg shells.

The Risk Assessment concluded that limiting the opportunity for flocks to become infected with *Salmonella* from on-farm sources will 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 raw eggs that have been stored under time and temperature conditions that have allowed *Salmonella* to grow in the yolk.

If the flock is infected, 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 the majority of 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 egg shell and cuticle form the first line of defence against horizontal transmission of microorganisms into the egg contents. However, the shell is porous to enable exchange of respiratory gases and water vapour and presents a route for microorganisms to gain entry into the egg. In addition to the shell and cuticle, the egg has internal membranes which limit the movement of microorganisms from the egg albumen (egg white) to the yolk.

[17] Department of Primary Industries, Parks, Water and Environment 2008 *Tasmanian Egg Shell Survey*, unpublished.

The albumen contains bacteriostatic compounds that inhibit, although not necessarily prevent, the growth of microorganisms. The egg yolk provides an ideal growth medium for *Salmonella* if eggs are stored at temperatures that allow its growth i.e. above 7˚C.

Factors that impact on the likelihood of horizontal transmission of *Salmonella* spp. into the egg contents includes the presence and load of external contamination (*e.g.* faecal material), temperature differential between the egg and the environment, humidity, and condition of the shell (*e.g.* cracks), cuticle and membranes. Practices during the production of eggs that increase the likelihood of shell contamination, such as contact with contaminated litter, and cracking of the shell through rough handling, will increase the likelihood of transmission of *Salmonella* into the egg contents.

The Risk Assessment acknowledged that in Australia, clean, intact shell eggs are rarely associated with foodborne illness. However, there is a very low likelihood that apparently clean, intact eggs may still be contaminated because surface contamination may be invisible to the naked eye. Cracks in the shell may also be invisible and yet allow penetration of bacteria into the egg contents.

The length of storage in association with the storage conditions is also a risk factor. During storage the membranes separating the albumen and yolk break down and this increases the likelihood that *Salmonella* in a contaminated egg can penetrate the yolk. The warmer the temperature that the eggs are stored, the shorter the time the membranes will remain intact.

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.

Washing eggs increases the risk of contamination if the washing is not carried out correctly. 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. However, washing of eggs, if carried out under the appropriate conditions, results in a reduction in the microbial load on the egg surface.

During grading and prior to washing eggs are checked for cracks and cracked eggs are diverted for making into pulp (liquid whole egg). Pulp is also made from intact shell eggs. Liquid egg white and liquid egg yolk are made from intact eggs that are separated usually by machine. During the production of liquid whole egg, liquid egg white and liquid egg yolk there are opportunities for contamination of egg contents because of possible contact with the shell. If the shells are dirty then the likelihood of contamination is increased. 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 7ºC.

Egg products could be contaminated after processing if heat treatment is not adequate to destroy pathogens and the products are not protected from contamination or are stored at temperatures that allow bacterial growth.

Although the frequency of eggs contaminated with *Salmonella* is very low, there remains an increased risk of foodborne illness if cracked or dirty eggs, which have a higher likelihood of being contaminated with *Salmonella*, are used in the home or in food service establishments and are consumed raw or lightly cooked (e.g. runny eggs). Cracked and dirty eggs have been available for sale to consumers and were the cause of a consumer level recall of eggs in Queensland in March 2007. Use of eggs with cracked shells by bakeries was noted in the FSANZ 2007 Food Handling Survey[18]. Use of cracked and/or dirty eggs by consumers was also recorded in the FSANZ consumer handling and egg consumption survey[19].

The use of raw eggs used in uncooked foods (e.g. eggnog, home-made ice cream, mayonnaise) is also a risk factor though the risk is very low. The New South Wales Food Authority in its submission at Draft Assessment provided a summary of 2008/2009 (financial year) egg associated outbreaks which included an outbreak caused by a raw-egg dessert sauce served at a Sydney festival in April 2009.
The Authority identified that, where the type of eggs used were able to be identified, the majority of outbreaks were associated with using intact eggs, not cracked eggs. The FSANZ consumer handling survey reported that 5% of consumers that eat eggs or foods containing eggs would consume uncooked eggs. Also, 54% of households that use eggs always or almost always sample raw batter when making cakes. The Department of Human Services Victoria[20] and the New South Wales Food Authority carried out consumer research in 2009 on egg safety awareness and egg handling. These studies corroborated the findings of the FSANZ consumer survey with regard to egg storage and food safety behaviours.

Unhygienic practices during preparation of food containing egg have also been reported as contributing factors to the risk of foodborne illness. The New South Wales Food Authority submission gave examples of illness caused by cross contamination and temperature abuse of raw egg dishes. 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[21]

The current inability to identify eggs once they are removed from their packaging has compounded difficulties in investigating egg related illness because the business producing the eggs, could not always be identified. Consumers prefer egg cartons that are not sealed so that they can check for cracked eggs prior to purchasing. This means that eggs can be moved to different cartons. A lack of traceability back to the producer potentially means that any deficient on-farm practices cannot be addressed. It also could result in an inability to advise consumers as to which eggs to avoid using or to return in the event of a recall.

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[18] FSANZ November 2008 *2007 National Food Handling Survey Final Report, Evaluation Report Series No. 19*
[19]FSANZ 2009 *Quantitative survey of consumer behaviour and egg consumption www.*http://www.foodstandards.gov.au/_srcfiles/_srcfiles/P301_%20DAR%20_SD21.pdf
[20]FSANZ 2009 *Quantitative survey of consumer behaviour and egg consumption www.*http://www.foodstandards.gov.au/_srcfiles/_srcfiles/P301_%20DAR%20_SD21.pdf
[21]Local Authorities Co-ordinators of Regulatory Services(LACORS) and the Health Protection Agency (HPA) undated *Microbiological Study on Salmonella Contamination of Pooled Raw Shelled Egg Mix and Environmental Samples from Catering Establishments*http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1245309914251

3.4 How is the risk addressed under current regulatory and non-regulatory measures?

3.4.1 Control measures that could manage the risk

FSANZ referred to several sources, including the Codex[22]Code of Hygienic Practice for Eggs and Egg Products[23] and industry Codes of Practice in order to assess whether control measures to address the risk of contamination of eggs and egg products are included in regulatory and non- regulatory measures.[24] The key control measures are summarised in Table 1 below.

Table 1: Key control measures to manage the hazards at egg production and processing.

Step	Hazard	Control measure
Egg production on-farm	Transmission of pathogens from infected flock Contamination from inputs (feed, water, agricultural and veterinary chemicals), from pests and vermin and from waste including used litter, manure and dead birds	Managing bird health and not obtaining eggs from infected birds. Management of inputs and other factors on-farm that could introduce contamination to eggs.
Grading, washing and packing of whole shell eggs		Carry out grading, washing and packing in a manner that avoids contamination Sorting of eggs to separate dirty and cracked eggs and divert them for cleaning and/or processing.
Processing, Separating yolks from whites and centrifuging to remove shell Heat treatment and subsequent packaging, storage and transport	*Salmonella* contaminated eggs and egg products Survival and growth of *Salmonella* in heat treated products	Carry out processing in a manner that avoids contamination Heat treating (or equivalent) to destroy *Salmonella* and ensure egg products are protected from post-processing contamination and stored under temperature control
Retail sale and use in food service	*Salmonella* contaminated eggs and egg products	Only clean, intact eggs and treated egg products are available for use in raw or lightly cooked foods.

[22] The Codex Alimentarius commission develops food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.
[23] The Codex Code is available on the Codex Alimentarius website www.codexalimentarius.net
[24] The existing industry schemes, Egg Corp Assured and Hen Care, Codes of Practice and guidance material developed by the States and Territories were sources of information on control measures.

3.4.2 Regulatory measures

3.4.3.1 On-farm (egg production)

There are currently no national regulatory measures in place to minimise the likelihood of eggs, or egg pulp produced on-farm, being contaminated on-farm.

Three States have introduced legislation to control egg safety on-farm. Queensland requires all egg businesses to identify its eggs and to have a documented food safety program in place to manage hazards[25]. Tasmania also requires egg producers to have a documented program in place that manages egg safety[26]. The Tasmanian legislation 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). New South Wales has recently (June 2010) commenced an Egg Food Safety Scheme which requires egg producers to implement certain food safety requirements[27].

South Australia is also developing similar requirements for egg producers[28].

3.4.3.2 Grading, washing and packaging of whole shell eggs

There are no national regulatory measures in place to manage the likelihood of eggs or egg pulp being contaminated during grading, washing or packaging of eggs if these activities take place on the premises where the eggs are produced.

Where these activities take place off the farm, the Code requirements in Chapter 3, Standard 3.2.2 -Food Safety Practices and General Requirements and Standard 3.2.3- Food Premises and Equipment apply. These Standards 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. Chapter 3 Food Safety Standards apply in Australia only and apply to all food businesses, other than primary production businesses[29], involved in the handling of food intended for sale.

Standard 3.2.2 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.

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[25] Information on the Queensland Food Safety Scheme for Eggs and Egg Products, is available from the Safe Food Production Queensland website, http://www.safefood.qld.gov.au.

[26] Information on the Tasmanian Egg Industry Act 2002 and associated regulations is available from the Tasmanian Department of Primary Industries website, http://www.dpiw.tas.gov.au.

[27] The NSW Egg Food Safety Scheme is currently being implemented. For information on the Scheme see http://www.foodauthority.nsw.gov.au.

[28] 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.

[29] 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 3.2.3 has requirements for premises and equipment that facilitates compliance with Standard 3.2.2[30].

The Queensland Food Safety Scheme for eggs extends to processing including grading, washing and packaging of whole shell eggs. The food safety program of the business must cover these activities. The NSW Egg Food Safety Scheme also extends to the grading, washing and packaging of whole shell eggs. Egg graders must implement a food safety program.

3.4.3.3 Processing of liquid egg, liquid white and liquid yolk and other egg products

The Code contains processing requirements for specified egg products in Standard 1.6.2 Processing Requirements. This Standard does not apply in New Zealand. 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.

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 - Microbiological Limits for Food which states that pasteurised egg products must be free of *Salmonella* in 25 g. 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 requirements in the Standard are also 'subject to this exemption'.

Standard 2.2.2 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.

Standards 3.2.2 and 3.2.3, referred to in section 1.3.4.2, apply to egg processors.

The Queensland and NSW food safety schemes extend to the production of liquid egg products and their treatment. In NSW, egg processors must implement a food safety program. 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.

3.4.3.4 Manufacturing foods containing eggs, food service and retail sale

The food Standards in Chapter 1 apply to all food sold or traded at retail and wholesale level in Australia. 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.

[30] More information on the Food Safety Standards, Standards 3.2.2 and 3.2.3, is available from the FSANZ website http://www.foodstandards.gov.au/.

Chapter 2, Standard 2.2.2 prohibits the availability of cracked eggs for retail sale or for catering purposes. Cracked or dirty eggs cannot be sold as 'eggs' due to the definition of an egg in Standard 2.2.2. The definition states that the shell of an egg must be free from visible cracks, faecal matter, soil or other foreign matter.

Standards 3.2.2 and 3.2.3, referred to in section 1.3.4.2, apply to egg processors.

3.4.3.5 Traceability

There are no provisions in the Code for producers or processors of eggs to have systems to identify where their products have come from or where they are supplied to i.e. traceability systems. For the seafood, dairy and poultry sectors, a requirement for a traceability system has been included in the primary production and processing Standards for these sectors.

Queensland requires all egg businesses to state in their food safety programs how they identify their eggs. All eggs must be identified with a unique identifier.

3.4.4 Non-regulatory measures

3.4.4.1 On-farm

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 developed 'Hen Care' a quality assurance system that includes a guide to through-chain food safety practices.

There are two Codes of Practice developed by the egg industry 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*[31].

In response to foodborne illness outbreaks in Australia attributable to eggs, the South Australian Government issued advice to South Australian commercial egg producers in 2007 on the minimum requirements for food safety[32]. New South Wales and other States also provide similar advice.

[31] AECL 2005 *Code of Practice for Shell Egg, Production, Grading, Packing and Distribution* and the *Code of Practice for Manufacture of Egg Products*http://www.aecl.org/index.asp?pageid=486 (accessed July 2009).
[32]Department of Health South Australia *Food Industry Bulletin No 1/07*http://www.health.sa.gov.au/pehs/Food/070504-egg-FIB-directive.pdf .

3.4.4.2 Food businesses

State governments provide advice to wholesalers, distributors and retailers of eggs on safe handling of eggs. Advice is also provided to the food service industry on handling eggs and using them as an ingredient. For example, the Victorian Government in association with the Victorian Farmers Federation has produced brochures for the various sectors with include four main messages – handle eggs carefully, buy clean intact fresh eggs, keep them cool and cook them well.

3.4.4.3 Consumers

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.

3.4.5 International measures

The Codex Alimentarius Commission adopted the *Code of Hygienic Practice for Eggs and Egg Products (*CAC/RCP 15 – *1976)*(Codex Egg Code)in 1976 and most recently revised it in 2007. The objective is to ensure the safety and suitability of eggs and egg products by applying the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1- 1969) to eggs and egg products. The Codex Egg Code describes the specific considerations for food hygiene and safety associated with all methods of primary production and processing of eggs and egg products, including the adequate measures for small-scale producers and processors.

The Codex Egg Code applies to the primary production, sorting, grading, storing, transport, processing, and distribution of eggs in shell and egg products of such eggs produced by domesticated birds and intended for human consumption. Traditional delicacy eggs (e.g. Balut and Century or Thousand-year eggs) are not within the scope of the Codex Egg Code.

The World Organisation for Animal Health (OIE) Terrestrial Animal Health Code (2010) also provides guidance on farm biosecurity and specific control of *S. Enteritidis* and *S. Typhimurium* on-farm[33].

3.5 Do the current regulatory and non-regulatory measures adequately address the risk?

The management of risks and perceived gaps in current regulatory and non-regulatory measures are detailed in this section and a summary presented in Table 2.

[33] OIE Terrestrial Animal Health Code 2010
http://www.oie.int/international-standard-setting/terrestrial-code/access-online/
Relevant chapters on measures for control of Salmonella in poultry and/or eggs (on-farm):Chapter 6.4 Hygiene and disease security procedures in poultry breeding flocks and hatcheries, and Chapter 6.5 Prevention, detection and control of Salmonella in poultry.

Table 2: Summary of perceived gaps in regulatory and non-regulatory requirements

Production/processing step	Management of risks and perceived gaps in current measures
Bird Management	Only adequately addressed by Qld and Tas legislation and industry schemes where implemented. In the main, small businesses have not implemented the industry programs.
Collection and initial sorting	No requirements in the Code for collecting or sorting eggs. Currently restrictions on the sale of cracked and dirty eggs are unclear. The hazards are adequately addressed by Qld and Tas legislation and industry schemes where implemented. In the main, small businesses found not to comply.
Cleaning /washing and drying of intact shell eggs ; and Packing, storage and transport of cracked eggs and raw pulp	Current requirements do not apply if these activities take place at the egg production facility. Only adequately addressed by Qld and Tas legislation and industry schemes where implemented.
Pulping (Commercial off-farm)	Only adequately addressed by Qld legislation. There is a gap in industry scheme which does not apply to processing of egg products.
Pasteurisation	The Code has requirements for pasteurisation however clarification is required.
Storage and distribution of treated (pasteurised products)	There is a regulatory gap in that processed egg products need to be stored or transported under time/temperature control.
Use of eggs and egg products by manufacturing businesses/caterers and other types of food businesses; and Retail sale of shell eggs and egg products	The regulatory requirements are unclear (for example, whether unpasteurised pulp can be sold for use in other foods and whether businesses can use cracked eggs in products that are subsequently heat treated.)
Traceability	There are only traceability requirements in one State (Qld).
Skills and knowledge of food handlers	There is a gap in the need for skills and knowledge for egg producers who may handle cracked and dirty eggs or raw egg pulp.

3.5.1 Regulatory measures

3.5.1.1 Managing risk on-farm

Except in Queensland, New South Wales and Tasmania there are no regulatory measures to manage risks associated with egg production for example, from inputs such as contaminated feed or from birds, waste, personnel, premises and equipment.

3.5.1.2 Managing risk during grading, washing and packing of eggs

The general food safety requirements in Standards 3.2.2 and 3.2.3 only apply where grading and other activities, such as using cracked eggs for pulp, take place off the premises where the eggs are produced because of the definition of primary production in the Code. In those States that have no requirements on farm (States other than Queensland and Tasmania) there are no food safety controls on farm to manage the risks associated with these activities.

Standards 3.2.2 and 3.2.3 are adequate to manage the risks where they can be applied.

3.5.1.3 Processing liquid egg products

The Risk Assessment concluded that pasteurisation treatments specified in the Code for liquid whole egg were more than sufficient to inactivate any *Salmonella* likely to be present. Pasteurisation requirements for liquid yolk and albumen were predicted to provide lower inactivation. However, the Risk Assessment estimated the predicted probability of liquid yolk and albumen failing to meet the *Salmonella* limit in the Code is low.

Standard 1.6.2 which contains the pasteurisation requirements allows exemptions and cross references Standard 2.2.2. Advice from industry, jurisdictions and the SDC is that the pasteurisation requirements are difficult to interpret because of the cross references and the wording is not straightforward. Specifically, there is confusion as to whether untreated liquid egg can be sold to manufacturers such as bakeries where it could be used in raw or lightly cooked products or provide a source of *Salmonella* which could be transferred to ready to eat foods.

Standards 3.2.2 and 3.2.3 apply to processing activities and are adequate to manage the risk of contamination and temperature control of eggs and egg products.

3.5.1.4 Processing of other egg products

Standards 3.2.2 and 3.2.3 apply to these processing activities and are adequate to manage the risk of contamination and temperature control of eggs and egg products.

3.5.1.5 Retail sale of eggs and use of eggs in catering and food service.

Standards 3.2.2 and 3.2.3 apply to food businesses likely to use eggs and egg products such as restaurants and bakeries and are adequate to manage the risk of contamination and temperature control of products containing eggs.

However, although Standard 2.2.2 prohibits the availability of cracked eggs for retail sales there is evidence that cracked eggs are still being sold. In March 2008 a former Queensland egg producer was fined for supplying cracked and dirty eggs into the marketplace[34].

Two submissions at Draft Assessment indicated anecdotally that cracked and dirty eggs are available for sale. There are also indications that cracked eggs are used in catering. For example, the New South Wales Food Authority in its submission at Draft Assessment refers to an outbreak in an aged care facility attributable to using cracked eggs.

The SDC advise that a factor in these eggs being available is that the restrictions on selling and using cracked eggs in the Code are not clearly expressed.

Dirty eggs are sometimes available for sale at farmers markets and similar events. Advice from jurisdictions is that the Code is not clear as to whether dirty eggs can be sold because the requirement for them to be clean is contained in the definition of 'egg'.

[34] SafeFood Production Queensland 26 March 2008 Media release, *Queensland egg producer doesn't fall through the Cracks* 2008.

It would be clearer if there was an explicit prohibition on selling dirty eggs to the public (because of their higher risk) rather than depending on a definition.

3.5.1.6 Traceability

The current requirement for traceability in Queensland is supported by the Queensland egg industry. The main national egg suppliers have also advised they would support a national requirement for traceability. However, currently only eggs produced and packaged in Queensland have to bear identifiers and eggs supplied packaged from interstate do not. Industry and governments have noted that this makes it difficult to trace potentially contaminated eggs and to remove them from sale.

The egg industry includes many small producers who supply small retailers, farmers markets and sell at the farm gate. The FSANZ consumer study indicated that 11% of consumers sourced eggs from farmers and growers markets and 5% from producers with a small number of hens in their backyard or from their own chickens (5%). Some respondents (22%) obtain their eggs from multiple sources. Advice from industry and the SDC is that some small producers do not implement safety measures and supply cracked or dirty eggs to businesses and consumers but the lack of national traceability obligations makes it difficult to identify offenders.

3.5.1.7 Temperature control during distribution and display at retail

Standard 3.2.2 requires potentially hazardous foods to be stored under temperature control. Current advice in the FSANZ guide to Standard 3.2.2, *Safe Food Australia*[35], is that intact shell 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.

Several submissions at Draft Assessment noted that storing intact, clean shell eggs at low storage temperatures would reduce the likelihood of foodborne illness. The Risk Assessment considered the additional information provided at Draft Assessment on outbreaks of egg related illness and concluded that there remains very little epidemiological data to implicate clean, intact eggs as the source of egg-associated illness and the prevalence of Salmonella contaminated eggs in Australia is very low (imported raw shell eggs for food are not permitted). Therefore, temperature, and time at that temperature, of shell eggs is important to ensure quality but is not a key factor in ensuring safety. Additionally, there are limitations on shell egg shelf life for quality reasons and current industry practice is to recommend that eggs are stored chilled.

3.5.2 Non-regulatory measures

3.5.2.1 Industry schemes

The national egg industry scheme, Egg Corp Assured (ECA) requires a business to implement a food safety program to control the hazards associated with egg production.

[35]FSANZ 2001 *Safe Food Australia 2nd Edition January 2001* http://www.foodstandards.gov.au/scienceandeducation/publications/scienceandeducation/publications/safefoodaustralia2nd519.cfm.

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[36].

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

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 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.

The South Australian government carried out a survey in 2007[37] 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.

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.

3.5.2.2 Consumer information

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.

[36]AECL personal communication.
[37]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.

However, several of the messages differ for example, NSW recommends that children under 2 years old[38] 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.
There are indications that some consumers do not follow the advice. For example, Victoria's Better Health website advises[39] 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.

3.5.3 Summary of the problem

This Proposal deals with the problem of foodborne illness caused by the consumption of eggs and egg products. These illnesses are estimated to cost the Australian economy about $44 million a year.

A scientific assessment undertaken by FSANZ of the public health and safety of eggs and egg products in Australia[40] identified *Salmonella* as the main microbiological hazard.Salmonellosis is the second most commonly reported foodborne illness in Australia. Where the cause of foodborne illness can be identified, eggs are the most commonly identified food vehicle.

Eggs become contaminated during lay and at subsequent steps in primary production i.e. at the laying farms and subsequent activities, such as washing and grading may contribute to contamination. Cracked and dirty eggs have a higher likelihood of being contaminated with *Salmonella* and uncontrolled handling or processing increases the risk of consumerscontracting salmonellosis. Egg pulp is also more likely to be contaminated because it is usually made with cracked eggs and also, the egg contents are in contact with the shell.

The Risk Assessment concluded that transmission of *Salmonella* spp. into laying flocks is multi-factorial in nature, including feed, water, pests (rodents and insects), the environment, personnel, new laying stock and equipment. The main cause of egg-related illness is the consumption of food containing raw or lightly cooked eggs.

The main problems that this proposal seeks to address are the prevalence of dirty and/or cracked eggs in the market, the absence of a national traceability system for eggs and gaps in regulatory and non-regulatory requirements. This problem is exacerbated by the large number of small producers who do not have on-farm safety measures in place and often supply unidentified sub-standard eggs to small retail outlets.

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[38] 'Enjoy eggs safely' NSW Food Authority website 3 July 2006.
[39] www.betterhealth.vic.gov.au(http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Food_safety_storing_eggs?open) (accessed July 2009.
[40] *Risk Assessment of Eggs and Egg Products*, FSANZ, Sep 2009 http:// www.foodstandards.gov.au

There is a need to ensure that cracked and dirty eggs do not enter the market. Systems are also needed to divert unsuitable eggs to pulping (which typically involves pasteurisation) or their complete exclusion from the food supply where they are unsuitable to be pulped.

Traceability makes possible the targeted recall of suspect eggs, as opposed to industry-wide recall, thereby reducing the financial loss to the egg industry that an outbreak of illness causes. A national health and safety program and traceability scheme will also provide the consistency that an industry which operates across state boundaries requires in order to ensure consumer confidence.

Currently three States, Queensland, Tasmania and New South Wales have their own legislation to control egg safety on-farm, and in Queensland it includes identifying individual eggs for traceability purposes. However there are no national regulatory measures in place to minimise the likelihood of eggs, or egg pulp produced on-farm, being contaminated on-farm or during grading, washing or packaging. The absence of such a national regime means that there is no assurance that eggs moving across state boundaries conform to any minimum standard of safety. Given that the major suppliers have interstate operations and supply across state borders, national inconsistency has potential cost implications.

There is support from industry and Australian governments for regulatory measures to reduce the likelihood of contaminated eggs reaching the market, resulting in a reduction of egg related cases of illness, by putting in place traceability systems and to improve national regulatory consistency.

OBJECTIVE

4. Objective of the Proposal

The objective of this Proposal is to reduce the incidence of foodborneillness 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 liquid egg (egg pulp) is treated to control *Salmonella*.

5. Statutory considerations

There are specific legislative constraints on FSANZ as a standard-setting body. These constraints have been considered in the analysis of risk management options.

5.1 *Food Standards Australia New Zealand Act 1991*

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 Food Standards Australia New Zealand Act (FSANZ Act) 1991. 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.

5.2 Policy guidelines

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) *Overarching Policy Guideline on Primary Production and Processing Standards* specifies a number of high order principles that must be considered where a standard is developed.

These principles state that standards will be outcomes-based, address food safety across the entire food chain where appropriate, ensure the cost of the overall system should be commensurate with the assessed level of risk and provide a regulatory framework that only applies to the extent justified by market failure.

RISK MANAGEMENT OPTIONS

In order to determine the most effective and efficient approach for achieving the objective,FSANZ has considered various risk management options. At Draft Assessment three options were identified. These options were the *status quo* (the situation if no action is taken) as a comparative measure against appropriate non regulatory (education), self regulatory (industry) and regulatory (government) approaches.

The preferred option at Draft Assessment was for a regulatory approach for the primary production of eggs and for processing. The Code would be amended to include a primary production and processing standard in Chapter 4. Submissions at Draft Assessment Report supported this option and no additional options have been identified during Final Assessment.

At Final Assessment the options are:

Option 1A	Reject the Proposal - maintain the status quo
Option 1B	Reject the Proposal – industry self regulation (including education)
Option 2	Approve the draft Standard – government regulation

6. Option 1A–Reject the Proposal – maintain the status quo

This option reflects the current situation whereby there is a combination of State-based regulation, self-regulation and some national requirements in the Code. Governments and industry would continue to provide egg safety messages through education campaigns, leaflets etc.

Egg producers that sell eggs direct from the farm gate or at farmers' markets would be 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 be expected to comply with existing requirements in the Code which would remain unchanged as a result of this Proposal.

Industry could continue to choose to follow industry based codes and food safety programs such as the Egg Corp Assured program.

7. Option 1B–Reject the Proposal – industry self regulation (including education)

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.

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.

8. Option 2 – Approve the draft Standard – government regulation comprising regulatory elements on farm and on processers

FSANZ would include a Primary Production and Processing Standard for Eggs and Egg Products (Egg Standard) 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.

The Egg Standard would specify food safety obligations for producing and processing eggs and egg products for human consumption.

At the primary production stage, egg producers would be required to identify and control the food safety hazards associated with the productions of eggs. Specific requirements have also been included for:

- the control of inputs
- waste disposal

- health and hygiene
- ensuring producers have the necessary food safety skills and knowledge
- the design, construction and maintenance of premises, equipment and transportation vehicles
- bird health
- traceability of eggs including a requirement for individual eggs to be marked with the producers' unique identification
- sale or supply of unsuitable eggs and egg pulp.

At the processing stage, egg processors would be required to identify and control the food safety hazards associated with the processing of eggs and egg products. Specific requirements have also been included for:

- receiving unacceptable eggs
- control of inputs
- waste disposal
- ensuring persons engaged in egg processing have the necessary food safety skills and knowledge
- design, construction and maintenance of premises, equipment and transportation vehicles
- traceability of eggs and egg products
- processing of egg products
- storage and transport of processed egg product
- sale or supply of unacceptable eggs or egg product.

The proposed draft Standard is at Attachment 1 and the explanatory memorandum is at Attachment 2.

IMPACT ANALYSIS

The impact analysis is included in Supporting Document 1: Regulation Impact Statement (RIS).

The RIS states that both the status quo and the industry self regulation option/education option are not adequate to address the public health and safety concerns arising out of cracked and dirty eggs.

The RIS concluded that even at a conservative level of 20% efficacy, the benefits outweigh the costs. The total cost over 5 years is $20m compared with benefits estimated at $47 million, taking into account health, welfare and productivity.

In summary, regulation of the egg industry has the greatest potential to deliver maximum net benefits to the community. This would be in the range of $25 million to $75 million, in the first five years of implementation.

CONSULTATION AND COMMUNICATION

9. Consultation

FSANZ established a Standard Development Committee (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.

FSANZ also 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.

FSANZ carried out 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 undertook the first round of public consultation on this Proposal in December 2006 and a second round in September 2009. The Draft Assessment Report included a list of submitters on the Initial Assessment Report, their comments and a response by FSANZ to these comments.

9.1 Submissions received at Draft Assessment

A summary of issues raised at Draft Assessment is provided below. Further information is provided at Attachment 3.

Twenty-five submissions were received including three late submissions[41]. Overall the response indicated support for including a primary production and processing Standard in Chapter 4.

Submissions were received from ten government agencies which supported the development of a primary production and processing Standard in the Code. There was considerable input from industry which overall supported development of national requirements although there were reservations as to impact and costs compared with the benefits that would be achieved, particularly from industry and government in Victoria.

The main issues raised were:

[41] FSANZ is not obliged to consider submissions received after the close of the consultation period. However, in this case, the issues raised had been raised in other submissions and have been considered.

- the scope and application of the various standards in the Code to different types of egg businesses and to different size businesses (in terms of layers kept or eggs produced)
- the cross references to Chapter 3 Standards within the draft Standard
- the focus of the draft Standard is on managing cracked and dirty eggs whereas egg related illness outbreaks have been associated with whole, clean eggs
- the costs of compliance to small businesses and practicalities of enforcement when there are numerous small businesses
- the specific nature of the traceability requirement in that it required shell eggs to be stamped and the cost of national register of unique identifiers
- re-use of egg packaging with associated problems of labelling and contamination
- hazards addressed includes some that are biosecurity issues rather than food safety issue
- ineffectiveness of current egg safety education initiatives
- specificissues on the drafting of the draft Standard.

9.2 Post- Draft Assessment consultation

In May 2010, the Department of Primary Industries Victoria conveyed its concerns regarding the impact a PPP Standard would have on small egg producers, including duck and quail farms. They also had concerns that the number of small producers had been underestimated.

In order to address these concerns and to ensure that the Regulatory Impact Statement accurately reflected the cost burdens a standard would impose on small producers, FSANZ called for data from the Egg SDC members on small producers. The following comments were received:

New South Wales Food Authority (NSWFA) responded with information on the industry profile and licensing fees applicable to the State. NSWFA is of the opinion that compliance costs computed by FSANZ and used in the RIS tend to be excessive. On the issue of the number of small egg producers state-wide, they did not provide any specific data.

Safe Food Production Queensland (SFPQ) provided extensive information on the Egg Food Safety Scheme operated by the State. This included a unique identification system that is carried out in the State. They also provided costs associated with the implementation of this scheme, based on a recent survey which covered 85% of accredited businesses. SFPQ costs regarding the stamping of eggs were used to revise the cost structure in the RIS.

The Department of Primary Industries and Resources, South Australia (PIRSA) provided data on the size of hen flocks in the State, including the number of egg producers and possible implementation and enforcement costs. PIRSA provided an overview of the smaller producers and described their operations. While no data was provided on the actual number of very small farms in South Australia, Biosecurity SA used information from fodder stores to estimate the possible number of such farms. This range provided a guide to the estimate used in the RIS.

The Department of Primary Industries, Victoria (DPI Vic) provided comprehensive information on small hen, duck and quail producers Australia-wide. DPI Vic examined the kind of interests and operation of different categories of small producers, including duck and quail farms, as well as the markets to which they cater.

DPI Victoria provided industry estimates of the number of very small farms in Victoria. These figures were used in the RIS. DPI Vic also made cost estimates on the initial outlay required for a State-wide unique identifier system. This figure was extrapolated to make an estimate of setup costs Australia-wide.

Farm Pride Foods Ltd Victoria provided estimates of the cost of setting up and implementing an egg stamping facility. These figures helped with estimating the costs used in the RIS.

Australian Egg Corporation Limited (AECL) provided a detailed profile on the egg industry. This was both historical as well as descriptive. The report explained the difficulties encountered in determining the precise number of very small egg producers. Therefore, the AECL estimate of the number of such producers Australia-wide is based on ABS data. This information was used in the RIS.

In revising the RIS, we took into consideration both the estimates made regarding the number of small egg producers, as well as the anticipated cost burden imposed on them when complying with the Standard. While available data cannot estimate the precise number of small and very small egg producers in Australia, by carefully considering the above submissions, and studying the industry profile in different States, it was possible to make an informed estimate of the number of small commercial (hen, duck and quail) egg farms as 1,225 Australia-wide.

The cost estimates provided enabled us to revise the ongoing traceability/stamping costs for small (including very small) producers from $660,000 (at DAR) to $858,000 per annum.

9.3 Consultation with New Zealand

New Zealand is represented on the SDC 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. Standard 1.1.1 contains definitions relevant to these Standards.

Chapter 3 and Chapter 4 Standards 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[42]. New Zealand has food safety requirements in the *Food Act 1981* and the *Animal Product Act 1999*.

At Draft Assessment, New Zealand supported the draft variations to Standards 1.1.1 and 1.6.1. New Zealand agreed with making Standard 2.2.2 a Standard that applied to Australia because New Zealand legislation already adequately managed the matters included in that Standard.

[42]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.

9.4 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 draft Standard has been developed recognising internationally agreed Codex and OIE guidelines. These include guidance on the safe production of eggs and egg products in the Codex Code of Hygienic Practice for Eggs and Egg Products, and on farm biosecurity in the OIE Terrestrial Animal Health Code (2010). However, there may be minor implications for imported egg products. Australia notified the WTO of the draft Standard on 23 September 2009 (G/SPS/N/AUS 238) with an initial closing date of 15 December 2009 which was extended to 16 January 2010. No comments were received on the notification.

10. Communication

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.

General communication messages about the outcomes of the Proposal will be developed following the public release of the Final Assessment Report. More specific messages will subsequently be developed to coincide with full implementation of the Standard.

CONCLUSION

11. Conclusion andDecision

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

Self-regulation (Option 1B) is not a viable option for egg production 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.

For processing, jurisdictions would not support removing regulatory requirements in the Code for public health reasons. Also some States have introduced 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 2: to approve draft variations to the Code to include 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 mentioned inSection 4 and detailed in SD1, the total cost over 5 years is $20m compared with benefits estimated at $47 million, taking into account health, welfare and productivity. 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 foodborne 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. 20% - 50%.

Decision

To approve draft Standard 4.2.5 – Primary Production and Processing Standard for Egg and Egg Products and make consequential changes to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Provisions, Standard 1.6.1– Microbiological Limits for Food, Standard 1.6.2 – Processing Requirements and Standard 2.2.2 – Egg and Egg Products

11.1 Reasons for the Decision

At Final Assessment, FSANZ has approved draft variations to the Code. These amendments:

- address public health and safety concerns raised in the *Risk Assessment of Eggs and Egg Products* in Australia
- 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.

IMPLEMENTATION AND REVIEW

12. Implementation

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

A recent initiative of ISC is to harmonise the processes of standard development by FSANZ and implementation by the States and Territories by developing an implementation plan during the standard development process. This means that the Ministerial Council can be presented with implementation information with the approved draft Standard. Therefore, Ministers would be informed on 'how' the Standard is to be implemented at the time the Standard is provided for consideration.

The implementation packagefor the primary production and processing Standard for eggs and egg productsis being finalised by ISC. All documents within the implementation package are not legal documents in their own right, but provide the direction for consistent implementation of the Standard in the States and Territories.The implementation package comprises:

- compliance plans which describe how compliance with the national food standard will be demonstrated and/or measured
- guideline food safety management statements
- reference materials which are existing industry and government guidance material on producing and processing eggs and egg products
- response materials which are documents that provide direction to government in facilitating national consistency in response to specific incidents.

An18-month period will be provided from the date the Standard is gazetted and registered as a legislative instrument to enable industry and the jurisdictions adequate time to put measures in place to implement the Standard.

When the finalised implementation package is publicly available, FSANZ will provide a link to ir on the FSANZ website.

13. Review

FSANZ is committed to undertaking evaluation of the impact of implementing key new food regulatory measures and outlines the program for evaluation activities in its Evaluation Strategy documents available on the FSANZ website.

ISC has developed an implementation package for the consistent implementation of the Standard. It has undertaken to review the effectiveness and impact on regulators and businesses of the implementation package in enhancing consistent implementation of standard following its implementation.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Explanatory Memorandum
3. Summary of, and responses to, submissions received at Draft Assessment.

Attachment 1

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: 18 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 products*, 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

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 purposes or retail sale.

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

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 or other equivalent methods, 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 eggs or egg pulp.

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

(a) pulping, separating, grading, packing, washing, candling, assessing for cracks or oiling eggs received from an egg producer; or
(b) storing or transporting eggs in association with any of the activities in paragraph (a); or
(c) 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.

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) a cracked egg or a dirty egg; or
(b) egg product which has not been processed in accordance with clause 21; or
(c) egg product which contains a pathogenic micro-organism, whether or not the egg product has been processed in accordance with clause 21.

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) A person involved in egg production 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.

(3) Subclauses (1) and (2) do not apply to eggs or egg pulp sold or supplied to an egg processor (**the supplied product**)if that egg processor complies with clause 20 in respect of the supplied product.

(4) In addition to subclauses (1) and (2), an egg producer must have a system to identify to whom eggs or egg pulp is sold or supplied.

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 of Food Safety Standards

Standards 3.2.2 and 3.2.3 apply to processing under clause 21 and storage and transport under clause 22, but not to any other processing activities.

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 or egg product unsafe or unsuitable.

Editorial note:

See Standard 4.1.1 for the definition of 'inputs'.

16 Waste disposal

(1) An egg processor must store, handle or dispose of waste in a manner that will not make the eggs or egg product unsafe or unsuitable.

(2) For subclause (1), waste includes sewage, waste water, unacceptable eggs or egg product and garbage.

17 Skills and knowledge

An egg processor must ensure that persons undertaking or supervising the processing of eggs or egg product 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) A person involved in egg processing must exercise personal hygiene and health practices that do not make the eggs or egg product 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 or egg product 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 processor's or producer's 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 processor's or the producer's unique identification.

(3) In addition to subclauses (1) and (2), an egg processor must have a system to identify –

(a) from whom eggs were or egg pulp was received; and
(b) to whom eggs or egg product was supplied.

21 Processing egg product

(1) An egg processor must process egg product by –

(a) pasteurising; or
(b) heatingusing any other time and temperature combination of equivalent or greater lethal effect on any pathogenic micro-organisms in the egg product; or
(c) using any other process that provides an equivalent or greater lethal effect on any pathogenic micro-organisms in the egg product.

(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) A process described in paragraph 1(b) or (c), if 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 (^{o}C)**	**Retention time to be no less than (minutes)**	**Maximum temperature to be immediately rapidly cooled to (^{o}C)**
Egg pulp (without any sugar or salt)	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 control the growth of pathogenic micro-organisms.

23 Sale or supply

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

(2) Subclause (1) does not apply to an egg processor thatsells 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.

Attachment 2

Explanatory Memorandum

Primary Production and Processing Standard for Eggs and Egg Products

These variations commence 12 months after the date on which they are gazetted.

Item [1] – Standard 1.1.1

This item inserts a definition of **egg product** in Standard 1.1.1. The definition is being inserted into Standard 1.1.1 so that it may be applied across all of the standards in the Code.

Item [2] – Standard 1.6.1

This item inserts a definition of **processed** in Standard 1.6.1. It also omits the reference to **pasteurised egg product** in Schedule 1 of that Standard, and substitutes **processed egg product**. The intent of this item is to align the terminology in Standard 1.6.1 with the terminology in Standard 4.2.5.

Item [3] – Standard 1.6.2

This item deletes clause 3 of Standard 1.6.2. This is a consequential amendment as a result of processing requirements now being located in Standard 4.2.5.

Item [4] – Standard 2.2.2 (Australia only)

This item omits Standard 2.2.2 and substitutes a new standard. The purpose of each of the clauses is explained below.

Clause 1
This clause contains the definitions. Subclause (1) makes it clear that the definitions in Standard 4.2.5 apply to Standard 2.2.2. Subclause (2) sets out definitions for **catering purposes** and **retail sale**.

Clause 2
The intent of this clause is to prohibit the sale of unacceptable eggs either for catering purposes or retail sale. **Unacceptable egg** is defined in Standard 4.2.5.

Clause 3
The purpose of this clause is to ensure that eggs for retail sale or for catering purposes are marked with the producer's or processor's unique identification.

Item [5] – Standard 4.2.5 (Australia only)

This item inserts a new Standard 4.2.5 in the Code. The purpose of each of the clauses is explained below.

Clause 1

This clause makes it clear that Standard 4.2.5 does not apply to any retail sale activities except for the direct sale to the public of eggs by an egg producer. The intent 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 clause provides that the producer is still able to sell clean whole eggs direct to the public, such as at the farm gate or by the egg producer at farmers markets.

Clause 2

This clause contains the definitions for this Standard. The purpose of subclause (1) is to apply the definitions in Chapter 3 of the Code (the Food Safety Standards) unless there is a specific definition in Standard 4.1.1 or Standard 4.2.5 to override them.

Subclause (2) contains a number of definitions for words used in this Standard. The definition of **egg pulp** makes it clear that egg pulp is all, or a portion of the contents found inside eggs separated from the shell, with or without added salt or sugar. The intent of the definition of **food safety management statement** is to clarify that a food safety management statement is a document written and owned by an egg producing or processing business, and approved or recognised by the relevant jurisdictional authority, that shows how the egg producing or processing business is controlling identified food safety hazards within their operations.

The definition of **unacceptable eggs**makes it clear that eggs are unacceptable if they have cracks in their shells or which are dirty. It also includes egg product which has not been processed in accordance with clause 21, or egg product containing pathogenic micro-organisms, whether or not it has been processed in accordance with clause 21.

Clause 3

Subclauses (1), (2), and (3) set out the elements that an egg production business must develop and incorporate in a food safety management statement. This statement becomes the vehicle whereby egg producers demonstrate compliance with the elements of the Standard as well as allowing the relevant regulatory authority to monitor the businesses' compliance.

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 relevant state, territory or commonwealth regulatory authority which legally enforces or implements primary production and processing Standards.

Clause 4

This clause imposes an obligation on egg producers to make sure inputs do not make the eggs unsafe or unsuitable. When preparing the food safety management statement, producers are required to examine and show how they are managing the inputs into their production system to ensure they do not introduce a source of contamination to eggs. For example producers must indicate how they manage stock feed used to feed layer hens, prior to providing to birds, to ensure that it does not introduce a source of contamination to eggs.

Clauses 5, 6, 7 and 8

Clauses 5, 6, 7, and 8 are general requirements similar to those set out in Chapter 3 but have been tailored to egg production activities. These requirements, amongst others in this Standard, must be addressed by the production business when developing their management statement under clause 3.

Clause 9

The intent of this clause is to ensure that eggs for human consumption are only sourced from birds that may be considered to not be afflicted with a disease or other condition capable of contaminating eggs. Subclause (2) makes it clear that the definition of 'condition' in Standard 3.2.2 does not apply to clause 9.

Clause 10

The intent of this clause is to require egg producers to implement a system within their operations to allow each individual egg sold or supplied by the business to be to be rapidly accounted for in the event of a food safety incident, by requiring each individual egg sold or supplied by an egg producer to be marked with the producers unique identifier.

The only exception provided is the sale of eggs to an egg processing business that will then mark each individual egg on the producer's behalf before it may be sold onto another business.

This clause also establishes traceability requirements for egg pulp in that each package or container of unpasteurised egg pulp sold by an egg producer to an egg processor that processes egg product will need to be marked with the producer's unique identifier.

An exemption is provided for the sale of egg pulp to an egg processing business that processes egg product, which will then mark the individual container or package of egg pulp on the producer's behalf before it is sold to another business.

This clause needs to be addressed in the management statement.

Clause 11

The intent of the clause is to prevent egg producers from selling or supplying unacceptable eggs (i.e. eggs with cracks in their shells, eggs with visible faecal contamination or other foreign matter contamination on their shells or unpasteurised egg pulp) for human consumption. This clause places a clear prohibition on the sale and supply of an inherently dangerous food for human consumption.

A specific exemption is provided for the sale or supply of unacceptable eggs (i.e. cracked eggs, dirty eggs, unpasteurised egg pulp) to an egg processor for processing in accordance with clause 21 of this Standard. It is further noted that dirty eggs may be sold to an egg processor for cleaning under this clause, as this is not sale or supply for human consumption.

Clause 12

This clause clarifies that Standards 3.2.2 – Food safety practices and general requirements and Standard 3.2.3 – Food premises and equipment of the Code only apply to the activity of processing egg product in accordance with clause 21 of this Standard, or to the storage or transport of egg product that has been processed in accordance with clause 21 of this Standard.

Clause 13

Subclauses (1), (2), and (3) set out the elements that an egg processing business must develop and incorporate in a food safety management statement. This statement becomes the vehicle whereby egg processors demonstrate compliance with the elements of the Standard as well as allowing the jurisdictions to monitor the businesses' compliance.

The egg processor 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 relevant State, Territory or Commonwealth regulatory authority which legally enforces or implements primary production and processing Standards.

Clause 14

The intent of this clause is to make it clear that unacceptable eggs may only be received by an egg processor that is capable of treating such material so that it is no longer unacceptable (i.e. not dirty or processed as egg product so that it does not contain any pathogenic microorganisms).

Clause 15

When preparing the food safety management statement, processors are required to examine and show how they are managing the inputs into their processing system, for example, how they deal with water that is used to clean eggs.

Clause 16, 17, 18 and 19

Clauses 16-19 are specific requirements similar to those set out in Chapter 3 but have been tailored to egg processing activities, other than those involving the processing of egg product. These requirements, amongst others in this Standard, must be addressed by the processing business when developing their management statement under clause 13.

Clause 20

The intent of this clause is the same as for clause 10 but applies to an egg processor. It is noted that this clause applies to the processing of eggs as well as to the processing of egg products.

Clause 21

The intent of this clause is to require egg product to be processed to eliminate pathogenic micro-organisms. The processing requirements in the table included in this clause have been transferred from Standard 1.6.2 – Processing Requirementsto this Standard (4.2.5).
It is noted that any process used by an egg processor to process egg product must be validated as capable of ensuring that that egg product is not unacceptable following processing (i.e. it does not contain pathogenic microorganisms).

Clause 22

The intent of this clause is to ensure that egg products processed under clause 21 do not become contaminated with pathogenic microorganisms during storage or transport to another business in the human food supply chain.

Clause 23

The intent of the clause is to prevent egg processors from selling or supplying unacceptable eggs (i.e. cracked or dirty eggs, unpasteurised egg pulp, or egg product containing pathogenic microorganisms) for human consumption. This clause places a clear prohibition on the sale and supply of inherently dangerous foods for human consumption.

It is noted that this clause provides specific exemption for the sale or supply of unacceptable eggs (i.e. cracked eggs, dirty eggs, unpasteurised egg pulp) to an egg processor for processing in accordance with clause 21 of this Standard.

Attachment 3

Summary of, and responses to, submissions received at Draft Assessment

Following is a summary of, and responses to, submissions received in response to the release of the Draft Assessment report and the draft Primary Production and Processing Standard for Eggs and Egg Products.

Twenty-five submissions were received including three late submissions[43]. The submitters were:

1. Blue Mountain Creek Pty. Ltd
2. Free Range Farmers Association (Vic) Inc
3. Hens of Hallora
4. Mr Bob Tatnell and Ms Angie Bowen
5. Food Technology Association Australia
6. Australian Government Department of Agriculture, Fisheries & Forestry
7. The Commercial Egg Producers Association of Western Australia (Inc)
8. Department of Health and Human Services and the Department of Primary Industries, Parks, Water & Environment, Tasmania
9. New Zealand Food Safety Authority
10. New South Wales Food Safety Authority
11. Free Range Egg & Poultry Australia Ltd.
12. Ms Maree Bachmann
13. Golden Egg Farms
14. Australian Egg Corporation Ltd.
15. Department of Health and the Department of Primary Industries, Victoria
16. Department of Health, South Australia
17. Victorian Farmers Federation Egg group
18. Department of Health, Western Australia
19. Queensland Health
20. Australian Government Department of Health and Ageing
21. Safe Food Production Queensland
22. Sunny Queen Australia
23. Qld Egg Farmers Association Inc
24. Free Range Egg and Poultry Association of Australia Inc
25. Free Range Poultry Association Queensland Inc

Overall the response indicated support for including a primary production and processing standard in Chapter 4 of the Code and progressing the Proposal on that basis.

Submissions were received from ten government agencies. These government agencies all supported the development of a primary production and processing standard in the Code. In some cases the support was qualified, particularly in the case of Victoria.

[43] FSANZ is not obliged to consider submissions received after the close of the consultation period. However, in this case, the issues raised had been raised in other submissions and have been considered.

There was considerable input from industry with submissions from six individuals/companies and six industry associations. The majority supported development of national, whole-of-chain requirements in the Code. Four submissions were received from individuals; 'small' egg producers.

In general, they supported greater management of egg supplies through-chain and through government intervention but raised issues on practicalities of such action and the costs to small producers.

Industry associations also raised many issues on behalf of their members. The industry associations overall supported developing national, whole-of-chain requirements in the Code. However, there was also support for self-regulation from the Victorian based industry associations. The Free Range Egg and Poultry Australia Ltd (FREPA) was not convinced that regulation on egg producers would achieve any better food safety outcome than the current arrangements in Victoria, where there is a certification program based on standards. There were also concerns that the inclusion of a standard in the Code would be costly. This was also the view of the Victorian Farmers Federation Egg Group (VFF) which indicated that it represented small and large producers, in all production systems, with 3.7 million of the 4 million birds in the Victorian egg industry.

The Australian Egg Corporation Ltd (AECL), representing approximately 400 commercial egg producers across Australia (including cage eggs, barn-laid eggs, free range eggs and specialist eggs) and the Commercial Egg Producers' Association of Western Australia supported the development of whole-of-chain and nationally consistent legislation. Support was also received from the Queensland Egg Farmer Association and two free-range associations in Queensland.

The main issues raised were:

- How do the different standards i.e. Standards 1.1.1, 1.6.1, 1.6.2, 2.2.2[44] and the draft primary production and processing standard for eggs and egg products in combination, apply across the industry sectors for example, to food service, bakeries and manufacturing and also to farmers markets, community markets and road side stalls.

The proposed standard does not apply to retail sale activities (except the direct sale of eggs to the public by an egg producer). This approach is common across the primary production and processing standards because retail sale activities are covered by Chapter 3 of the Code. Standard 2.2.2 makes it clear that unacceptable eggs cannot be sold at retail.

- The Standard was not clear that it applied to businesses regardless of the number of layers or eggs produced.

The explanatory memorandum (Attachment 2) clarifies this point.

[44] Standard 1.1.1 Preliminary Provisions - Application Interpretation and General Prohibitions
Standard 1.6.1 Microbiological Limits for Food
Standard 1.6.2 Processing Requirements (Australia only)
Standard 2.2.2 Egg and Egg Products

- The focus of the draft Standard is on managing cracked and dirty eggs whereas egg related illness outbreaks have been associated with whole, clean eggs

In the review of epidemiological data included in the risk assessment, the use of visually soiled (dirty) eggs was identified as a common risk factor in reported egg-associated outbreak. It also concluded that cracked and dirty eggs have an increased likelihood of penetration of Salmonella spp. into the egg contents, and subsequent potential for growth compared with clean intact eggs.

Although the draft Standard contains specific requirements for cracked and dirty eggs, the intent of the Standard is to manage food safety hazards from all eggs and egg products. Businesses are required to control all the food safety hazards identified with their particular operations.

- The costs of compliance to small businesses are a concern.

The issues have been addressed in the impact analysis.

- Several submitters raised concerns about the specific nature of the traceability requirement in that it required shell eggs to be stamped. This could impose undue costs, particularly on small businesses. The cost of a national register of unique identifiers was also raised.

These issues have been addressed in the impact analysis

- Re-used packaging may be contaminated by its previous use and transfer this contamination to the eggs.

Producers and processors are required by the draft Standard to describe how they control their hazards which would include contamination if the business chooses to re-use packaging.

- Information on the packaging may not apply to the eggs in the package if packaging is re-used.

Information on the package must comply with the requirements in the Code.

- There may be some confusion as to the application of Chapter 3 standards in the draft Standard.

The draft Standard has been amended to clarify that Standards 3.2.2 and 3.2.3 only apply to processing under clause 21 and transport under clause 22, but not to other processing activities.

- Some of the hazards described in the Draft Assessment Report are biosecurity risks, rather than food safety risks.

The intent of the Standard is to control hazards in relation to eggs not the health of layers. The business must not obtain eggs from birds if the bird is affected by a disease or condition that presents a hazard to eggs.

- Existing education initiatives are not working effectively and this is a fundamental concern for susceptible consumers. Further education on eggs to change consumer behaviour, possibly including labelling pending the outcomes of the review on labelling[45], is suggested.

FSANZ has considered non-regulatory approaches... The ISC Food Communicators Group will be asked to consider education of consumers and industry as part of the communication strategy for the release of the Standard and the need for general advice on egg food safety will be discussed with the Food Safety Information Council.

FSANZ will await the findings of the labelling review before considering any changes to labelling requirements.

- Specific issues were raised on the drafting of the draft Standard.

Specific issues on individual clauses in the Standard were taken into account in amending the draft Standard. Members should note that an explanatory memorandum prepared by the FSANZ Office of Legal Counsel is provided Attachment 2 and is intended to assist in interpreting the Standard by explaining the intent of each clause.

[45] The Council of Australian Governments (COAG) and the Australia and New Zealand Food Regulation Ministerial Council undertaken a comprehensive review of food labelling law and policy. Information on the review is available on the Food Labelling Review website at www.foodlabellingreview.gov.au.