AUSTRALIAN EGG
CORPORATION LIMITED

National Food Safety Risk Profile of Eggs and Egg Products

Part 1: Final Report

Part 2: Attachments

A report for the Australian Egg Corporation Limited

by
B. Daughtry, J. Sumner, G. Hooper, C. Thomas,
T. Grimes, R. Horn,
A. Moses, A. Pointon

July 2005

AECL Publication No 05/06
AECL Project SAR-47

ISBN 1 920835 24 5
ISSN 1448-1316

National food safety risk profile of eggs and egg products
Publication No.05/07
Project SAR-47

Researcher Contact Details

Name:	Andrew Pointon
Address:	SARDI 33 Flemington St Glenside SA 5065
Phone:	08 8207 7838
Fax:	08 8207 7854
Email:	pointon.andrew@saugov.sa.gov.au

In submitting this report, the researcher has agreed to AECL publishing this material in its edited form.

AECLContact Details:
Australian Egg Corporation Limited
A.B.N: 6610 2859 585
Suite 4.02, Level 4
107 Mount Street
North Sydney NSW 2060

Phone:	02 9409 6999
Fax:	02 9954 3133
Email:	enquiries@aecl.org
Website:	http://www.aecl.org

Published in July 2005

Foreword

This project aimed to conduct a through chain food safety risk profile for the Australian egg industry. Risk profiling is now recognised as an important first step that is essential for effective food safety risk management. It has recently been defined as 'a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions' (Codex Alimentarius Commission). Risk profiling involves the systematic collection of information needed to make a decision on what will be done next and where resources should be allocated to more detailed scientific assessment. The risk profiling process typically provides information on: the hazard, exposure to the hazard, adverse health effects, public health surveillance information, appropriate options for control, and other information relevant to risk management decision-making. The provision of a comprehensive description of the food safety problem associated with the pathogen(s):commodity combination(s) from farm to fork is recommended. This process is increasingly being adopted across Australia by jurisdictions responsible for protecting public health.

This report identifies:

- hazards that entered any point of the food chain for eggs and egg products produced in Australia and ranks them in terms of health risk to the consumer
- hazards of potentially high risk where too little information exists for a confident ranking of risk and "what if" scenarios raised by risk managers during the expert consultations
- potential management strategies for the identified high risk hazards
- product/pathogen combinations in which further risk analysis might be required by risk managers.

An extensive process of expert consultations between risk managers and assessors was used to guide management of the project. This was to ensure the outputs adequately address the major food safety concerns and were provided in a timely manner to support current and pending risk management processes.

This project was funded from industry revenue which is matched by funds provided by the Federal Government.

This report is an addition to AECL's range of research publications and forms part of our R&D program, which aims to support improved efficiency, sustainability, product quality, education and technology transfer in the Australian egg industry.

Most of our publications are available for viewing or downloading through our website:

www.aecl.org

Printed copies can be purchased by faxing or emailing the downloadable order form from the web site or by phoning (02) 9409 6999.

James Kellaway
Managing Director
Australian Egg Corporation Limited

Acknowledgments

Contributors and Attendees at Workshops 1 & 2

George Arzey	NSW DPI
Narelle Brown	Pace Farms
Steve Colegate	CSIRO
Duncan Craig	FSANZ
Michael Dack	FSANZ
Ben Daughtry	SARDI
Liz Dean	FSANZ
Chris Devine	SafeFood Qld
Nora Galway	DAFF
Irene Gorman	AECL
Tom Grimes	Grimes Consulting
Greg Hargreave	Poultry Nutritionist
Greg Hooper	Hooper Associates
Rowly Horn	Financial Consultant
Martyn Kirk	OzFoodNet
David Miles	NSW Food Authority
Abe Moses	Industry Consultant
Frank Pace	Pace Farms
Andrew Pointon	SARDI
Peter Scott	Melbourne University/Industry Veterinarian
Barry Shay	Food Safety Consultant
Jo Slade	SARDI
Phil Steel	Golden Egg/AECL Board
John Sumner	Food Safety Consultant
Agnes Tan	Melbourne Diagnostic Unit
Connor Thomas	The University of Adelaide
Joe Vella	Industry Consultant
Jonathan Webber	JJ Webber Consulting
Sarah Wilson	FSANZ

About the Authors

The risk profile report was prepared by a multi-disciplinary team including risk modelling, food microbiology, chemical risk assessment, veterinary public health, industry and hazard experts. For the Hazard Identification the Project Manager (Andrew Pointon) consulted extensively with public health surveillance specialists.

Contents

List of Tables

Part 1

Part 2

List of Figures

Part 1

Part 2

Abbreviations

ABS	Australian Bureau of Statistics
ADI	Acceptable Daily Intake
AECL	Australian Egg Corporation Limited
AEIA	Australian Egg Industry Association
ANZFA	Australia New Zealand Food Authority (now FSANZ)
APVMA	Australian Pesticides and Veterinary Medicines Authority
ArfD	Acute Reference Dose
CAC	Codex Alimentarius Commission
CDN-ANZ	Communicable Diseases Network - Australia New Zealand
CFU	Colony Forming Unit
CI	Confidence Interval
CSIRO	Commonwealth Scientific & Industrial Research Organisation
CTs	Corynetoxins
DAFF	Department of Agriculture, Fisheries and Forestry
DANMAP	Danish Integrated Antimicrobial Resistance Monitoring and Research Programme
DON	Deoxynivalenol
ELISA	Enzyme-Linked Immunosorbent Assay
FAO	Food and Agriculture Organisation (United Nations)
FDA	Food & Drug Administration (USA)
FHB	Fusarium Head Blight
FSA	Food Science Australia
FSANZ	Food Standards Australia New Zealand (formerly ANZFA)
FSIS	Food Safety and Inspection Service (USA)
HACCP	Hazard Analysis and Critical Control Point
ICMSF	International Commission on Microbiological Specifications of Foods
IMVS	Institute of Medical and Veterinary Science
JETACAR	Joint Expert Technical Advisory Committee on Antibiotic Resistance
MDU	Microbiological Diagnostic Unit
MLST	Multi-Locus Sequence Typing
MRL	Maximum Residue Level
NARM	National Antibacterial Residue Minimisation Program
NEPSS	National Enteric Pathogen Surveillance Scheme
NEQAP	National Egg Industry Quality Assurance Program
NNDSS	National Notifiable Diseases Surveillance System
NORM	National Organochlorine Management Program
NRS	National Residue Survey
OIE	Office International des Epizooties
PAs	Pyrrolizidine alkaloids
PATs	Plant-Associated Toxins
PT	Phage Type
QA	Quality Assurance
QRA	Quantitative Risk Assessment
RDNC	Reacts Does Not Conform
RH	Relative Humidity
RIRDC	Rural Industries Research and Development Corporation
SARDI	South Australian Research and Development Institute
SCARM	Standing Committee on Agriculture and Resource Management
SE	*Salmonella enterica* serotype Enteritidis
SVARM	Swedish Veterinary Antimicrobial Resistance Monitoring
USDA	United States Department of Agriculture
WHO	World Health Organisation

YMT	Yolk Mean Time

Executive Summary

In establishing the Terms of Reference for the Egg Risk Profile, AECL stated that: "Although a qualitative assessment of on-farm food safety risks was undertaken during the development of National Egg Quality Assurance Program no comprehensive qualitative or quantitative food safety risk profile has been performed for eggs and egg products on a 'through-chain' basis i.e. from farm to consumer in the Australian situation".

Risk profiling is an activity in preliminary risk management that is defined as 'a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions' (Codex Alimentarius Commission, 2002). This process typically provides information about: the hazard, exposure to the hazard, adverse health effects, public health surveillance information, control measures, and other information relevant to risk management decision-making. As such, risk profiling provides a comprehensive review and evaluation of recognised hazards and the effectiveness of industry and regulatory risk management programs, as well as control options that might be considered.

In preparing this report, two expert consultations between risk managers and assessors were held to thoroughly assess the feasibility of risk profile work, ensure risk management questions were clearly articulated, provide ongoing review of technical outputs for relevance against these objectives and modify/expand expected outputs in terms of opportunities created by early findings. This process ensured the work was completed within the predetermined 6-month timeframe and that the outputs remained relevant to current risk management needs.

Risk ranking of hazard:product combinations was achieved using both an established quantitative and a qualitative methodology, that embodied established principles of food safety risk assessment from farm-to-fork. Uncertainties identified in the risk-rating process were used to identify data gaps that might be considered for further R&D (Section 5.2).

Risks associated with existing and potential biological, chemical and physical hazards were examined as part of the risk profiling process. Based on available information, there is no evidence that pesticides, veterinary medicines or other contaminants, chemical or physical present a food safety or public health risk. In general, eggs are residue free and no egg samples have been found to have heavy metal residues of any food safety consequence. A chemical risk assessment is provided in Attachment 13. Potential for transfer of antimicrobial resistance via eggs is predicted to be low (Attachment 9.3). Background information for a broad range of potential hazards is provided in Section 3 and Part 2 (Attachments).

Review of foodborne outbreaks in which eggs were implicated to various degrees and through-chain hazard monitoring data, identified *Salmonella* as the principal biological hazard. For the purpose of risk analysis, the presence of any *Salmonella* serotype in egg or egg products (excluding *S.* Sofia) has been assumed to have potential to initiate foodborne infections[1]. To assess the impact of infections of different severity, ratings of "Mild" (sometimes requiring medical attention) and "Moderate" (often requiring medical attention) were used (Table 17).

Scenario egg-use and consumption pathways (Exposure Assessment) were modelled (n=33) to establish hazard:egg and egg product combinations (Attachment 2, Figures 2.1, 2.2 and 2.3; Part 1, Tables 6 and 16). Considerations included:

- Egg and egg product and sales/supply chain pathways for commercial shell eggs and pulp products, and non-commercial eggs (Attachment 1)

[1] Industry stakeholders reported that there is a tendency within industry to disregard all but contamination with *S.* Typhimurium, and that this may lead to added risk.

- Commercial egg handling and storage practices (expressed as time and temperature combinations) that lead to potential for growth in the yolk (YMT)
- Use in home, manufacturing and food service sectors
- End use pathways for shell and processed commercial eggs (either as an ingredient or egg-based meal)
- Effect of meal preparation (cooking) as a variable (Table 6).

A number of egg end-use pathways were modelled, with three outputs: Risk rating (between 0-100), Predicted annual illness and predicted illnesses per million servings. The Risk Rating is a logarithmic scale with each 6 unit change in the Risk Rating scale representing a factor of 10 difference in the absolute risk estimate. It should be noted that the risk rating is independent of the human population size but reflects relative risk to an individual within a population (Ross and Sumner, 2002). Consequently, end-use pathways (Scenarios) may have the same risk rating but different numbers of predicted illnesses. A Sensitivity Analysis of Risk Ranger inputs is presented in Attachment 10. This analysis investigates the relative impact of various changes in the input values to the risk estimate. Assumptions used are detailed in Attachment 14 for transparency.

Note that Scenarios 25 and 26 represent circumstances associated with well-publicised outbreaks associated with egg butter and unpasteurised egg pulp (see Attachment 14). Cold desserts containing egg/egg product have been responsible for several hundred illnesses aboard flights leaving an Australian airport. Scenario 26 is built around anecdotal evidence that around 500kg of unpasteurised egg pulp enters the food service sector each week in one area of Australia (the scenario spreads this product among an assumed localised population of 130,000).

While such Scenario analysis provides opportunity for large risk models, it brings uncertainty, particularly in relation to dose response information. As a result the predicted number of illnesses should be used to compare scenarios only. However, "what may be more important than an absolute measure of risk is the relative *change* in magnitude of risk outcomes resulting from changing some parameter in the food chain" (Lammerding 2005).

Objective 1. Identify public health hazards that enter any point of the food chain for eggs and egg products produced in Australia and rank them in terms of risks to the consumer (Risk Characterisation).

Risk ratings for *Salmonella* were low when commercial eggs which had not undergone pathogen growth (YMT unresolved[2]) were used for egg meals in which there was some pathogen reduction. That is, for the vast bulk of shell-egg utilisation, risk ratings were low with no predicted illness.

A medium risk rating (41-55) was obtained for eggs that had undergone pathogen growth (YMT resolved, enabling hazard growth in the yolk) which were used for egg meals and egg-based dishes which had been lightly cooked (2 log reduction e.g. poached and boiled still with liquid yolk and lightly scrambled). In this scenario, significant numbers of illnesses are predicted, depending on the source of the eggs[3]:

- Commercial non-cracked eggs – Scenario 4 (Risk Rating=49, predicted illnesses/10^6 servings=4, predicted illnesses 702/annum)
- Non-commercial non-cracked eggs – Scenario 10 (Risk Rating=49, predicted illnesses/10^6 servings=4, predicted illnesses 72/annum)
- Non-commercial cracked eggs – Scenario 16 (Risk Rating=48, predicted illnesses/10^6 servings=400, predicted illnesses 60/annum)

[2] YMT or Yolk Mean Time is an estimate of the time taken for the yolk membrane to destabilise. Once the YMT is exceeded, bacteria present in albumen can freely migrate into the yolk.

[3] Note that commercial cracked eggs cannot legally be sold and therefore are not considered for this scenario set.

The target population differs for commercial and non-commercial use, with the former considered to embrace the entire Australian population and the latter an estimated 10% of the entire population. To place this into perspective, the predicted illnesses per million servings is shown in Table 16. This data indicates that use of cracked eggs presents a 100-fold increase in cases of salmonellosis when compared to non-cracked eggs (Scenarios 10 and 16).

For eggs used in foods in which the egg component was uncooked (e.g. raw egg drinks, cold desserts – Tables 6 and 9-14), there are a number of possible medium to high risk scenarios. All of these were associated with eggs in which pathogen growth in the shell egg had occurred (YMT resolved). The implicated egg source and scenarios are as follows:

- Commercial non-cracked eggs – Scenario 20 (Risk Rating=48, predicted illnesses/10^6 servings=40, predicted illnesses 585/annum)
- Non-commercial non-cracked eggs – Scenario 22 (Risk Rating=51, predicted illnesses/10^6 servings=40, predicted illnesses 180/annum)
- Non-commercial cracked eggs – Scenario 24 (Risk Rating=44, predicted illnesses/10^6 servings=400, predicted illnesses 12/annum)
- Non-commercial, cracked eggs used for egg butter – Scenario 25 (Risk Rating=57, predicted illnesses/10^6 servings=4, predicted illnesses 9/annum)
- Unpasteurised pulp used in cold puddings – Scenario 26 (Risk Rating=51, predicted illnesses/10^6 servings=250, predicted illnesses 10/annum)
- Commercial pulp (0.2% contaminated) used in cold puddings – Scenario 30 (Risk Rating=38, predicted illnesses/10^6 servings=0.2, predicted illnesses 9/annum)

The risk from use of (non-commercial) cracked eggs in terms of predicted illnesses per million servings increased 100x when compared with (non-commercial) non-cracked eggs when used in egg meals in which meal preparation produces only a slight reduction of assumed growth (Scenarios 16 and 10). A 10x increase in illnesses per million servings is predicted when cracked versus non-cracked eggs are used in raw egg drinks and cold desserts (Scenarios 24 and 22). This finding is consistent with reports of increased risk of outbreaks of 3 – 90 times when cracked eggs were used (Todd, 1996).

If *Salmonella* Enteritidis became endemic in Australia the level of risk has been estimated to increase by 6 units for shell egg scenarios (Table 16) and the predicted illnesses per annum and per million servings would increase by 10x. However, this estimate would be more rigorous with knowledge of time and temperature handling of eggs from lay to retail (and probably consumption).

Uncertainties and potential R&D

Areas of uncertainty (data gaps) and the associated R&D that might be considered to improve the reliability of risk estimates are:

- Source of *Salmonella* Typhimurium – As reviewed in Section 3.1 and AECL Project SAR-42A there is considerable uncertainty about the source of *S.* Typhimuium in egg pulp. More recent data (Table 5) may indicate regional differences in isolation rates exist. Industry adoption of the proposed SE monitoring program (Attachment 15) could lead to collection of data to fill this knowledge gap. (Information on all serovars of *Salmonella* isolated from all regions would be extremely valuable for assessing risk associated with graded shell eggs.) Serotype and phage typing data obtained for all isolates as part of routine post-processing QA would also provide valuable information for risk assessment purposes.

- Risk associated with non-cage egg production systems – The number of *Salmonella* that contaminate the shell surface before the barrier effect of the cuticle is established (Attachment 15), is an important determinant of contamination of the contents of barn laid and free range eggs. The lack of information about contamination of the contents of ungraded eggs from non-cage systems, limits this assessment. However, the cost of obtaining this data is likely to be prohibitive. Alternatively, it may be possible to use ratios (surface:contents) from Attachment 6,

Table 6.2 to infer prevalence of contaminants in egg contents from these layer systems. Data from broiler breeder operations may also provide a useful insight.

- The time:temperature profile of eggs post egg grading floor to retail – This affects the proportion of contaminated eggs that might support growth in the yolk (see Section 5.1), particularly for high volume shell egg use pathways (Table 16, Scenario 4) where incomplete cooking fails to overcome contamination in eggs where growth has occurred due to the Yolk Mean Time being exceeded. If this data were available (through the use of temperature loggers) it could be utilised in more sophisticated quantitative predictive models (as developed in AECL Project SAR-42A) to better quantify risk and its credible range. Such information is considered essential for a rigorous risk analysis of *Salmonella* Enteritidis if it became endemic in Australian layer flocks.
- Effect of food matrix on infective dose – A lower infective dose may apply with the ingestion of fatty foods (eg egg butter). Allowance for this effect is best achieved within a quantitative risk model (as developed in AECL Project SAR-42A).
- Effect of egg washing on internal contamination – Egg washing was widely used by egg processors in Australia in 2002 (Attachment 15). Data describing the efficacy of washing procedures in terms of reduction of surface contaminants was not collected. It is not known whether washing procedures are consistent with reduction of bacterial contamination or indicative of conditions that might lead to increased internal contamination (Attachment 15).

Objective 2. Identify hazards of potential high risk where too little information exists for a confident ranking of risk.

- Risk from *Salmonella* in non-cage production systems – information about serovars, phage types and egg shell prevalence (to infer prevalence in contents – see Section 5.1).
- No other recognised microbial hazards were identified (Section 3.1).
- Chemicals in use for which no Maximum Residue Level or Acceptable Daily Intake established (potential hazards - Attachment 13).

Objective 3. Identify potential management strategies for the identified hazards. The implications and recommendations for the identified medium to high risk combinations are presented as options for industry risk managers to consider.

(A) Commercial, non-cracked eggs where growth is assumed to have been possible due to the expiry of the yolk membrane defences when lightly cooked (Scenario 4) or used in raw egg drinks and uncooked desserts (Scenario 20) present a higher risk. The higher risk rating is a result of the combination of the large volume of eggs used in this end-use pathway and the fact that reduction in numbers of contaminants during meal preparation is either incomplete or negligible. Potential control options (Recommendations) are:

- Management of the shell egg cool chain at 16^0C from lay to retail, with the bulk of eggs targeted for consumption or consumer refrigerated storage by 25 days post-lay.
- Implementation of education and/or audited quality programs for caterers, particularly those which service institutions. These programs should emphasise adoption of egg preparation methods that eliminate presence of liquid yolk, and promote use of pasteurised egg products for dishes containing uncooked egg.
- Encourage all processors to stamp Julian dates on all eggs to verify grading (i.e. as confirmation of removal of off-farm cracked eggs and as a method for the food industry to ensure non-commercial eggs are avoided).

(***B) Non-commercial, non-cracked eggs have a higher risk rating when growth is assumed (YMT resolved) and meal preparation results in only slight reduction of numbers of contaminants (Scenario 10).*** While the risk rating is medium the number of predicted illnesses is reduced due to lower exposure (being independent of population exposed). Potential control options (Recommendations) are:

- These eggs should not be used by caterers (industry feedback indicates a significant proportion of these non-commercial eggs are used in catering).
- Catering HACCP plans should prevent use of these eggs. Being ungraded, by definition (Attachment 1) they will contain cracked eggs, the use of which is illegal (see Scenario 16).

(C) Non-commercial cracked eggs are higher risk when growth is assumed to have occurred (YMT resolved) and meal preparation results in only slight reduction of numbers of contaminants (Scenario 16). Potential control options (Recommendations) are:

- These findings support the intent of the FSANZ Standard 2.2.2 Egg and Egg Products.
- Jurisdictions should develop programs (e.g. education, audits) with industry, caterers and food manufacturers to ensure cracked eggs are not used illegally.
- Backyard/non-commercial producers should be advised to discard cracked eggs.

(D) Non-commercial, non-cracked eggs are higher risk when growth is assumed to have occurred and these eggs are used in raw egg drinks and cold desserts (Scenario 22). Potential control options (Recommendations) are:

- Education to non-commercial producers to keep eggs refrigerated at all times.
- Catering HACCP plans should reject use of these eggs.

(E) Non-commercial, cracked eggs are higher risk when growth is assumed to have occurred and these eggs are used in raw egg drinks and cold desserts (Scenario 24). Potential control options (Recommendations) are:

- These findings support the intent of the FSANZ Standard 2.2.2 Egg and Egg Products.
- Jurisdictions should develop programs (e.g. education, audits) with industry, caterers and food manufacturers to ensure cracked eggs are not used illegally.
- Backyard/non-commercial producers should be advised to discard cracked eggs.

Preliminary data indicates the prevalence of *Salmonella* in the Australian egg industry is low on-farm (Attachment 9.1) and on eggs (Attachment 6). This report endorses current and proposed industry schemes to ensure *Salmonella* levels remain low (NEQAP, Attachment 15) and are monitored (SE Surveillance Program, Attachment 15).

Objective 4. Identify product:pathogen combinations in which further risk analysis might be performed. In the context of salmonellosis, priorities for consideration include:

- Evaluate the food safety risk resulting from the implementation of non-cage egg production systems (Section 5.1; Attachment 10)
- Use time:temperature data post-grading floor to retail to improve the reliability of Quantitative Risk models (as per AECL Project SAR-42A). Robust models will enable a more reliable identification of risk and credible ranges resulting from marketing practices in Australia (Section 3.3 and Attachment 3)
- Comparison of risk from unwashed and washed shell eggs under Australian commercial industry production and processing conditions (Attachments 10 and 15)
- Potential risk of *Salmonella* Enteritidis in shell eggs: this would utilise some of this data but would specifically require data on time:temperature handling of eggs from lay to retail (and possibly consumption).

1. Objectives

1.1 Terms of Reference

The project objectives specified by AECL were specifically to:

- Identify public health hazards that enter any point of the food chain for eggs and egg products produced in Australia and rank them in terms of health risk to the consumer
- Identify hazards of potentially high risk where too little information exists for a confident ranking of risk
- Identify potential management strategies for the identified hazards
- Identify product:pathogen combinations in which further risk analysis might be required.

2. Introduction

2.1 Definitions

- A ***public health risk*** is defined in this report as a recognised hazard that causes disease as a result of eating eggs or egg products. Consumer susceptibilities are taken into consideration.
- ***Foodborne hazards*** included in the scope of this report include biological (micro-organisms, natural toxins), physical (foreign matter, animal derived) and chemical (residues, metals) hazards.
- ***Potential hazards*** include those that may result in public health, social and/or economic impact but for which evidence is lacking; i.e. the hazard is currently present in Australia, but whether it causes illness is unknown.
- The ***entire food chain*** is defined from egg production on farm through to food preparation and consumption.
- ***Risk profile*** is defined as 'a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions' (Codex CX/FH 01/7-Alinorm 03/13). The provision of a comprehensive description of the food safety problem associated with hazard:product combinations has more recently been advocated (Codex, 2003).

2.2 Risk Assessment

A requirement of the project is to follow the risk assessment approach.

The Codex Alimentarius Commission (1999) has the Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment that applies to risk assessment of microbiological hazards in food. Risk assessment, along with risk management and risk communication, forms the process of risk analysis. Risk assessment itself comprises the four steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation. The approach for this Risk Profile project follows the risk assessment framework.

Hazard identification – The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard characterisation – The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Exposure assessment – The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

Risk characterisation – The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.

2.3 Risk Profiling Approach: Farm to Consumption Rationale

Risk profiling is one activity in preliminary risk management. This has been defined as 'a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions' (Codex Alimentarius Commission, 2002). It involves the systematic collection of information needed to make a decision on what will be done next and where resources should be allocated to more detailed scientific assessment. Typically, the risk profiling process provides information on: the hazard, exposure to the hazard, adverse health effects, public health surveillance information, control measures, and other information relevant to risk management decision-making. The provision of a comprehensive description of the food safety problem associated with hazard:product combinations has more recently been advocated (Codex Alimentarius Commission, 2003). As such, risk profiling provides a comprehensive review and evaluation of recognised hazards and the effectiveness of industry and regulatory risk management programs.

The Terms of Reference for the present project reflect the following statement by AECL: "Although a qualitative assessment of on-farm food safety risks was undertaken during the development of the National Egg Quality Assurance Program no comprehensive qualitative or quantitative food safety risk analysis has been performed for eggs and egg products on a 'through-chain' basis i.e. from farm to consumer in the Australian situation".

The through-chain approach which produces risk ratings for hazard:product combinations reflects the requirements of the present study (as specified by AECL) and accepted processes for risk profiling by standards setting agencies both nationally (by FSANZ) and internationally (Codex Alimentarius Commission, 2003). This iterative process is useful in prioritising strategic food safety issues to ensure protection of consumers and provides a justifiable basis for the application of mitigations where they reduce consumer risk and avoid inappropriate measures and costs across the supply continuum.

2.4 Risk Profile Process

This risk profile (Codex, 2001; 2003) followed the Principles and Guidelines for the Conduct of a Microbial Risk Assessment (Codex 1999 CAC/GL-30) with functional separation of risk management and risk assessors to ensure objectivity, transparency and avoidance of bias. However, to facilitate an accurate risk assessment, a more iterative process of two expert consultations between risk managers and assessors was implemented (Codex, 2004a; 2004b; Buchanan *et al.*, 2004). This was seen as desirable to thoroughly assess the feasibility of the risk profile work, ensure risk management questions were clearly articulated, to provide ongoing review of technical outputs for relevance against these objectives and modifying/expanding the expected outputs in light of opportunities created by early findings.

In order to achieve the agreed milestones the project manager was required to provide a written monthly report which identified progress against the work plan, resources required to address unforeseen issues and guidance needed on planning the expert consultations. Draft reports including data gaps and assumptions were provided to stakeholders prior to each consultation. This open and transparent process provided confidence for a broad range of stakeholders to engage strongly with the risk profile project and assured informed and consistent feedback was forthcoming throughout. This engagement and the expert consultations provided a process for ensuring the requirements were appropriately resourced to ensure the work was completed within the predetermined 6 month timeframe. This ensured the outputs remained relevant to current risk management needs.

3. Methodology

3.1. Hazard Identification

Objective 1. **Identify public health hazards that enter any point of the food chain for eggs and egg products produced in Australia** and rank them in terms of risks to the consumer.

Introduction

Under the Codex Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (CX/FH 01/7) hazards fall into three categories, namely microbial, chemical and physical. An interrogation of relevant databases including OzFoodNet, National Residue Survey, Total Dietary Survey and FSANZ recalls indicates illness to be restricted to microbial hazards. Richardson *et al.* (2000) identified the following recognised and potential hazards associated with eggs and egg products. These hazards along with the contributing factors listed below are addressed in this report.

PRODUCT	***HAZARD/ POTENTIAL HAZARD***
Shell egg	Contamination with *Salmonella spp.* (non *S.* Enteriditis)
	Growth of *Salmonella spp.*
	Contamination with other pathogens
	Penetration of pathogens during egg production and handling
	Pathogen survival due to undercooking
	Development of antibiotic resistant pathogens
	Mycotoxins
	Pyrrolizidine alkaloids from feed transferred to eggs
	Heavy metals
	Agricultural and veterinary chemicals
	Pesticide residues (eg: organochlorines) in free range and backyard eggs
	Dioxins/Polychlorinated biphenyls
	Packaging contaminants
	Eggs cracked in transit after grading and packaging
Liquid and dried eggs	
	Contamination with *Salmonella spp.* or other pathogens
	Pathogen survival due to inadequate process treatment
	Cross contamination of raw and processed product with toxins, heavy metals, agricultural and veterinary chemicals

Food recalls

Food recalls are prompted either by the manufacturer when a problem is detected, or by regulators following complaints of an outbreak of illness or other problem requiring compulsory recall.

From January 1989 to July 2004 there have been 642 recalls by FSANZ; of these 14 (2.2%) were for egg-associated reasons (pers comm. Scott Crerar, FSANZ). In all instances the reason for recall was due to failure of labelling to declare the presence of egg or egg components (i.e. presence of undeclared allergens).

Microbiological hazards

In general, the principal microbial hazards associated with eggs and egg products are limited to a few genera. This section provides a brief review of the micro-organisms potentially associated with this food source.

Campylobacter

As poultry is considered to be a major reservoir of human campylobacteriosis, a leading cause of bacterial foodborne illness in developed countries including Australia (Source: CDN-ANZ – NNDSS, 2000), a review by Sahin *et al.* (2003) attempted to better understand the ecology of this organism, and in particular endogenous transmission via the egg. Studies have shown egg-borne transmission is unlikely because of the limited ability of *Campylobacter* to invade via the shell external surface. Moreover, this organism does not survive well on the egg surface or in the air sac and albumen. This is further supported by lack of detection of *Campylobacter* in eggs even when hens were actively shedding this organism (Sahin *et al.*, 2003, Kollowa and Kollowa, 1989).

Illness due to *Campylobacter* attributed to the consumption of eggs has not been reported in Australia (M. Kirk OzFoodNet, pers. comm.). An extensive literature search revealed one outbreak in the US (Finch and Blake, 1985) where isolates of *Campylobacter* recovered from hens at the implicated egg farm were serologically identical to an isolate recovered from an ill person. Unfortunately no information was reported on the possible involvement of ungraded, cracked eggs. Chaudhary *et al.* (1989) observe that cracked eggs are easily penetrated by *Campylobacter* when cooled to 4°C from a high summer temperature (in India) of 42°C. However, egg white prevents growth due to its' antimicrobial systems, but growth can occur when yolk is mixed with whites. Lowest penetration was observed at 25°C reduced to 4°C. No Campylobacter were recovered from the inner or outer membranes or egg contents for eggs after 72 hours of storage at either 25 or 42°C. A similar study by Doyle (1984) found that *Campylobacter* inoculated onto the surface egg shells were not recovered from the contents, inner or outer membranes of the inner shell after 5 hours when stored at 25 or 37°C, and was not detected in eggs equilibrated at 37°C and subsequently stored at 4°C after 10 days. *C. jejuni* was not isolated from the egg contents. Doyle concluded that *C. jejuni* is not likely to contaminate sound (uncracked) eggs. From these data, consumer risk may only arise from *Campylobacter* when severely cracked eggs (i.e. inner yolk membranes ruptured) are lightly cooked; an unlikely scenario.

Clostridium botulinum

Botulism has occasionally been associated with consumption of home-pickled eggs (Anon 2000). *Clostridium botulinum* type B and type B toxin was detected in the pickled egg mixture. Although the pH (pH 3.5) of the pickling liquid was sufficient to prevent germination of *C. botulinum* spores and production of toxin, the pH of the egg yolk was not determined.

E coli O157:H7

Foodborne outbreaks due to *E coli* O157:H7 have been linked to a number of sources. The potential for infection from eggs as the primary source was investigated by Schoeni and Doyle (1994) who reported that chicks may become persistently infected, resulting in contamination of the shells but not the yolks or whites. From this they conclude that chickens and hens eggs can serve as vehicles for this pathogen, however no reports of outbreaks associated with this pathogen arising from eggs was found.

Fungal contaminants

In the Terms of Reference it is "noted that in parts of Australia, fungal growth on eggs can occur under certain environmental conditions (Davis and Stephenson, 1991)". These authors reported summer and winter temperature and relative humidity conditions in northern Queensland but did not provide details on fungal contamination of the egg shell. Anecdotal evidence exists for "moulds" on discarded 12 week old eggs held at 12°C and 80% relative humidity (RH) (pers comm, Rowly Horn). In extension advice from the Queensland Department of Primary Industries (1990) it is recommended that to avoid "fungus or mildew on shells", eggs "must be stored at or below 15ºC and a humidity under 80%; a practice generally followed by industry (Attachments 7 and 8). Factors that contribute to fungal growth relate primarily to poor hygiene and storage eg. soiled egg handling equipment, incorrect use of egg sanitisers, and use of "old eggs". Spoilage of shell eggs has been more recently

reviewed by Cox (2001) who details the causes and the influence of production and processing factors as a basis for prevention.

Listeria monocytogenes

No foodborne outbreak reports due to *Listeria monocytogenes* attributed to primary contamination of eggs were found. However, *Listeria monocytogenes* can survive normal commercial egg wash-water conditions and can be found in commercial egg wash plants (Laird *et al.*, 1991). *Listeria monocytogenes* was also found commonly in raw liquid whole egg but not pasteurised product (Moore and Madden, 1993; Leasor and Foegeding, 1989). Light cooking of eggs ("sunnyside up") results in little reduction of counts whereas frying scrambled eggs at 70-73°C results in elimination (Brackett and Beuchat, 1992).

Salmonella

For the purpose of the Hazard Identification, 26 outbreaks investigated by OzFoodNet (http://ozfoodnet.org.au/index.htm), in which the investigators identified an epidemiological link with eggs, were used. These are reviewed in AECL Project SAR-42A (Appendix 2) and a summary is provided in Attachment 11 of this report. The outbreaks are summarised in Attachment 11 by cross-tabulating the egg-specific criteria along with details of other contributing factors. The only hazard identified from these outbreak descriptions was *Salmonella*. *S.* Typhimurium accounted for 73% of the outbreaks and *S.* Heidelberg 11.5%. In relation to duck eggs, an outbreak of *Salmonella* Typhimurium PT9 was reported in 2004 (OzFoodNet, 2004). The implication that *Salmonella* is the principal risk for eggs is also consistent with a previous report to the Australian Egg Industry that *Salmonella* is the major foodborne hazard for the egg industry as a whole (Dawson *et al.*, 2001). In a review of the food safety of cracked egg, only *Salmonella* were considered to be a hazard (Todd 1996) (see Attachment 9.2). Furthermore, other (microbial) hazards have not been identified in foodborne outbreaks associated with eggs in Australia (M Kirk pers. comm.).

Salmonella Enteritidis Phage Type 4 (PT4) has not been isolated from intact eggs in Australia and extensive government agency epidemiological evidence does not support locally acquired infection with this phage type. Hence *S.* Enteritidis PT4 is not considered an identified hazard, or potential hazard, within the current Australian context (reviewed in AECL SAR-42A). Furthermore, while *S.* Enteritidis PT26 is evident in environmental sources in Queensland and has been recovered from chicken litter (AECL Project SAR-42A Appendix 2), food-borne illness associated with eggs has not been reported.

In relation to certainty of attribution, proving the chain-of-evidence in investigations is often difficult due to the retrospective and non-point source circumstances of some outbreaks and the low level of *Salmonella* contamination in eggs (Attachment 6). Attribution to eggs is further complicated by factors such as potential cross-contamination from other ingredients or the kitchen environment, temperature abuse of the implicated food and lack of a regional database on serovars found in commercial layer environments. Expert opinion at Workshop 1 concluded that in relation to attribution of these outbreaks, "strong evidence" could only be claimed for a third or less of the outbreaks presented for evaluation. This was based on case histories in which a combination of factors such as isolation of the same *Salmonella* serovar and phage type from farm and/or food and patients (Attachment 11). Enhancements to attribution are suggested in Attachment 12.

Data supporting the association of *Salmonella* with eggs comes from several sources. Data from 1976 reveals contamination of bulked unpasteurised liquid egg was common (15% of batches) with a broad range of serovars (n=29) (Peel 1976). A survey in the 1990s on levels of *Salmonella* contamination of pooled unpasteurised egg pulp from multiple farms in Queensland found a much higher proportion of batches to be contaminated with *Salmonella* (95%), with 23% of individual farm egg pulp samples positive (Cox *et al.*, 2002). The serovars isolated from egg pulp (*S.* Singapore 25% of all isolates, *S.* Mbandaka (23%), *S.* Cerro, subspecies 1 serovar 16.1,v, *S.* Kottbus, *S.* Oranienburg, *S.* Typhimurium (untypable) and *S.* Infantis) reflected those found in stock-feeds. Similarly, the

relative frequency of serovars found in the NSW layer environment monitoring also reflects those found in stock-feeds (Table 1). Considering the prevalence of these serovars in annual salmonellosis statistics, they are not considered to play any major role in human illness (NEPSS Human Annual Report, 2002a and 2003a). A through-chain perspective of *Salmonella* contamination is provided in Attachment 9.1.

In relation to faecally contaminated eggs, expert industry opinion estimated that only 10% of eggs are produced by the non-commercial sector (Attachment 1); egg washing of commercial shell eggs in Australia is practiced on the majority of production (AECL Project SAR-42A). While it is possible that faecally contaminated eggs/egg products may enter the food chain via the non-commercial pathway, there is no data on the likely proportion of eggs faecally contaminated or on the likely proportion of these contaminated with human pathogens.

By contrast, analysis of NEPSS data for *Salmonella* isolated from egg products indicated that *S.* Typhimurium serovars represent 43.5% of 154 isolates (Table 1). NEPSS data are not based on any statistical sampling basis and tested pulp may not always be limited to eggs from commercial layers, therefore the source of this contamination is uncertain (a more complete categorisation of NEPSS data is presented in Attachment 9). However, the predominance of *S.* Typhimurium associated with egg products is further supported by the isolation of *S.* Typhimurium PT 9 and PT 108 from 15% and 26% respectively of 27 commercial raw egg pulp samples (Table 5) tested prior to pasteurisation over a 3 month period in 2004 (Murray 2004). More recent data on isolates from commercial raw egg pulp samples reveals a broad range of serovars, including a number of *S.* Typhimurium Phage Types listed in the outbreaks summarised in Attachment 11 (Murrary 2005a,b). While this commercial product testing data does not allow estimation of prevalence, it raises the potential of flock infection with *S.* Typhimurium in areas other than Qld and NSW (see above). Clarification of this potential temporal and geographic variability in flock colonisation as a source of egg product contamination and public health risk may arise from data generated nationally from the proposed *Salmonella* Enteritidis surveillance scheme (Sergeant *et al* 2003). Alternatively, this may reflect pulp contamination post-farm gate from sources other than eggs; in Risk Assessment terms this remains an area of uncertainty.

The relatively minor symptoms associated with infections by these serovars are consistent with the estimate of 38:1 for under reporting in the USA (<3% of salmonellosis cases reported symptoms) (Mead *et al.*, 1999). On the other hand, the under reporting ratio of Wheeler *et al*. (1999) of 3.2:1 is based on a study which is considered the "gold standard". Case reports in Australia appear to lie somewhere between these estimates. Kirk (pers. comm.) estimates an under reporting ratio of 10-15:1 is more likely.

Nevertheless, the severity of symptoms caused by infection are important indicators of the public health risk associated with consumption of contaminated food products. Risk Ranger (Ross and Sumner, 2002) categorises severity of illness according to the following:

- **Severe** hazard - causes death in most victims
- **Moderate** hazard - requires medical intervention in most cases
- **Mild** hazard - sometimes requires medical attention
- **Minor** hazard – patient rarely seeks medical advice

In view of the above definitions stakeholders at Workshop 2 decided to use both Mild and Moderate hazard severity for the purposes of Risk Ranger, and that all *Salmonella* should be assumed to be of equivalent virulence, including the likely outbreak serovars (*S.* Typhimurium, Heidelberg and Virchow – Section 3.1; Attachment 11). For Question 6: Probability of contamination of raw product per serving, the assumed prevalence estimate was not limited to just the outbreak serovars (Attachment 11) but used the prevalence from scenarios for all serovars (excluding *S.* Enteritidis) (Attachment 6).

Table 1: *Salmonella* isolates and phage types from raw egg and processed egg products and notified to NEPSS from laboratories across Australia over the period 2000-2003 (Source NEPSS, Non-human data)

	Raw egg pulp	Heat-processed egg fractions	Egg product (mainly mayonnaise)	Unspecified egg products
Agona[1,2]	5	1		
Anatum[1]	4			
Bovismorbificans PT24[2]	2			
Cerro[1]	12	2		
Infantis[1,2]	2	1		
Johannesburg	1			
Kiambu[1,2]	1			
Mbandaka[1,2]	2	1		
Ohio[1,2]	6	4		
Oranienburg	1			
Orion[1,2]	2			
Singapore[2]	4	23		
Tennessee[1,2]		1		
Typhimurium PT8			1	
Typhimurium PT 9	15	2	13	
Typhimurium PT 102		1		
Typhimurium PT 126			3	
Typhimurium PT 135	13	1	3	3
Typhimurium PT 170		1		
Typhimurium RDNC	1			
Typhimurium untype[2]	9	1		
Virchow PT 34	8	3		
Subsp 1 ser 1,3,19:-:-[2]	1			
Total	**89**	**42**	**20**	**3**

[1] Relatively commonly isolated from stock feeds (meat meal and meat and bone meal predominantly) compared with other serovars, (NEPSS 2000-2002)

[2] Isolated from commercial layer flock environments in NSW (Attachment 9.1)

In relation to the consumers affected, national data on the notification rates per 100,000 population indicated infants 0-4 years (Blumer *et al.*, 2003) are more commonly affected. This may be a result of increased susceptibility to infection or a result of exposure from additional non-food source pathways (e.g. pets, child care etc.). Interestingly, the notification rate for other groups expected to be susceptible, such as the elderly (>65 years), is the same as for the remainder of the population. The perceived increased susceptibility of this age group may be a reflection of the increased likelihood of outbreaks in aged care facilities, where the outcome of food-borne infections may be more severe due to concurrent illnesses, rather than a lower infective dose.

Staphylococcus aureus

No human cases of foodborne illness attributable to staphylococcal enterotoxins in egg products have been reported. However, the growth and survival of *Salmonella* spp. and *Staphylococcus aureus* in steamed and scrambled eggs has been investigated (Yang *et al.*, 2001). Although *Salmonella* spp. and *Staphylococcus aureus* grow better in steamed eggs than scrambled eggs, production of staphylococcal enterotoxin was higher in scrambled egg than steamed egg. The destruction of both organisms was rapid when these egg-based dishes were held at 60ºC. However, as staphylococcal

enterotoxins are heat stable they represent a problem with freshly prepared pasta (Agnes Tan pers. comm.).

Chemical Hazards

A detailed risk assessment of agricultural and veterinary chemicals used in the Australian egg industry is provided in Attachments 9.3 and 13. In summary, it is concluded that chemicals present a low risk, however, a thorough assessment is provided in the context of their ability to severely disrupt market access.

Some 20 pesticides and veterinary drugs were identified as being of importance to the Australian egg industry. These included the insecticides azamethiphos, carbaryl, maldison and permethrin, the antibiotics amoxycillin, bacitracin, chlortetracycline, lincospectin and tiamulin, the coccidiostats amprolium, lasolosid, monensin and salinomycin and dewormers such as levamisole and piperazine. There were also 21 pesticides that, on the basis of detection in the NRS grains program and/or their lipophilic nature, were identified as chemicals that had the potential to carryover into eggs through the diet. With the exception of methoprene, MRLs were set by the Australian Pesticides and Veterinary Medicines Authority for all chemicals with carryover potential (formerly NRA, www.apvma.gov.au).

There were no chemicals identified where the level of residue detected in monitoring programs was above the MRL (NRS, www.affa.gov.au). However, a number of chemicals identified as being of importance to the egg industry did not have MRLs established for eggs. Furthermore, in a number of instances, no ADI had been set.

The Australian Total Diet Survey (ANZFA, 1996; FSANZ, 2002, 2004) confirmed that for individual chemicals of interest (and where included within the scope of the Survey) actual residue intake was well below the established ADI and that in several cases, no residue was detected in any foods, including eggs. Levels of contamination by heavy metals and dioxins were low.

Based on the available information, there is no evidence that residues of pesticides, veterinary medicines or other contaminants present a food safety or public health risk. In fact the results suggest that eggs are generally residue-free.

With the exception of antibiotic use, there is, at this time, no known public health concern associated with any of the specific products identified as being of importance to the egg industry. The issue of antibiotic use and the potential for development and spread of resistance to bacteria of public health significance has been investigated through JETACAR (1999) with the cooperation of user industries. As a result, regulatory processes have been modified and specific product reviews are currently underway. The outcome of the review may have implications for the egg industry should antibiotic products be withdrawn from the market. From an international perspective, there is concern about organophosphates and carbamate insecticides that may result in further regulatory reviews (such as that currently underway in respect to carbaryl) and possible removal of some products over time. The potential for antibiotic resistance causing a risk in consumers via eggs is considered low (Attachment 9.3).

A range of plant associated toxins that are/may be transmissible to eggs have been identified in livestock feed-grain produced in Australia (Attachment 9.4). These include;

- Corynetoxins resulting from contaminated ryegrass seeds in stockfeed (ANZFA, 1997).
- Pyrrolizidine alkaloid (PA) contamination of feed grain occurred several years ago in Australia when between 100,000 to 200,000 chickens and 1000 to 4000 pigs died from PA poisoning as a result of heliotrope-contaminated stock feed (Gaul *et al*., 1994). One literature report (Edgar and Smith, 2000) identifies PAs from *Echium* sp. and *Heliotropium* sp. in eggs at levels that would exceed current regulations in some countries.

- Deoxynivalenol (DON), also known as vomitoxin is a secondary metabolite of some species of the fungal genus Fusarium. Fusarium infections of wheat heads produce the disease known as Fusarium Head Blight (FHB) or Scab and the concomitant production of DON. DON contamination is often at low levels in wheat crops but in some years FHB outbreaks overseas have occurred in durum wheat on the Liverpool Plains in Northern NSW (Southwell *et al*., 2003). Aflatoxins (known human liver carcinogens) are usually present at low frequency and concentration in maize grown in temperate regions of Qld and NSW, but occasional samples contain high concentrations (ANZFA, 1999). After nuts, maize produced in Australia registered the next highest level of contamination. Residues of Aflatoxin B1 in laying hens diets has been demonstrated to be transmitted to eggs at a ratio of feed to eggs of 5000:1 (Bintvihok *et al.*, 2002; Oliveira *et al.*, 2000).

Allergens

Allergy to egg is widely recognised with an estimated prevalence among Australian infants at 2 years of age of 3.2% (Hill *et al.*, 1997). A large study in Norway (Eggesbo *et al.*, 2001) of infants of a similar age found 1.6% (CI 1.3-2.0) point prevalence with an upper estimate of cumulative incidence by this age of 2.6% (CI 1.6-2.6). Loss of allergy to eggs is common, as 65% to 80% of egg-sensitive infants tolerate eggs at age 5 (Juchet *et al.*, 2003). However, among 1070 sufferers of bronchial asthma, aged between 3 and 70 years, 27.3% were allergic to egg white (Tsai-Jaw *et al.*, 1999). Bakery and confectionary workers are also at risk of respiratory allergy from airborne egg proteins (Leser *et al.*, 2001). Allergy to egg white protein is the most prevalent allergy among children and adolescents in USA and Spain relative to other food allergens (Pascual *et al.*, 2000).

Severe egg allergy manifests within a few minutes as anaphylaxis, and requires strict avoidance of all traces of egg to avoid future, and potentially fatal, allergic responses. Typical reactions include a rash, hives or swelling around the mouth, immediate runny nose, sneezing and itchy watery eyes, breathing difficulties and abdominal pains. Ovalbumin, ovomucoid and an unidentified protein, antigen 22, of hen egg white were classified as major allergens by Langeland (1982).

Under the Food Standards Code 1.2.3 there is a mandatory requirement to declare (label) the presence of allergenic ingredients. Listing eggs as an ingredient is considered adequate; although some manufacturers use bold print for allergens named in ingredient lists. Among an Australian consumer survey in which there was a household member “at risk” of an adverse or allergic reaction to food, 90% of respondents always read food labels carefully (FSANZ Food Labelling Survey 2004a). Under the new Code, 67% of respondents noticed some specific labelling changes. Food manufacturers now have the capacity to monitor (presence/absence) of egg-associated allergens in products through the use of rapid ELISA test kits (Anon, 2004) as a means of verifying HACCP plans.

Physical Hazards

A review of the literature indicates larvae of *Ascardia galli* may be found in the oviduct of chickens (Norton and Ruff, 2003) which may explain the anecdotal reports of worms in eggs. Extension advice from the Queensland Department of Primary Industries (Coutts and Wilson, 1990) reported occurrence of intestinal roundworms that migrate from the cloaca into the oviduct where they may become enclosed within the egg. Use of barn and free-range production re-introduces potential for this type of, probably rare, physical contamination. This represents an aesthetic or wholesomeness issue rather than a primary public health risk.

Hungerford (1969) reported that not infrequently, foreign bodies such as roundworm or a piece of manure, may be carried up into the oviduct by antiperistaltic waves and be included in the egg white. Sometimes grey, stone-like particles produced by abnormal function of the shell glands may be produced and included in the egg. Portions of shell membranes may also be included. Candling of commercial eggs should prevent eggs containing physical contaminants from entering the market.

None of the 642 FSANZ recalls over the last 15 years were for foreign objects eg plastic or metal in egg pulp (pers. comm. Scott Crerar, FSANZ).

Food Products Considered

The types of food products considered for risk rating reflects whether eggs are:

- commercially or non-commercially produced (Attachment 1)
- consumed as shell eggs or processed egg products as ingredients (Attachment 2)
- the degree of cooking (kill-step/bacterial inactivation) prior to consumption (Attachment 2)
- the likelihood of extended periods between lay and dispatch from the egg grading floor (Attachments 7 and 8).

Consequently, groups of like cooked/processed foods were considered (Attachment 2) rather than all the types of recipes in which eggs are used. This process ensured the food products identified as potential foodborne illness vehicles in the outbreaks reviewed (Attachment 11), were considered in the risk rating process.

Conclusion

Based on the foregoing, *Salmonella* appears to be the principal hazard associated with eggs and egg products. There are several hazards of low concern, with one outbreak attributed to *Campylobacter*. Consequently, due to lack of food-borne evidence and data from commercial egg production (prevalence, location of contamination, counts) there is little value in estimating risk other than for *Salmonella*:egg and egg product combinations.

3.2 Hazard Characterisation

Two methods have been selected for the process of risk rating of hazard:product combinations. One of these, Risk Ranger, is spreadsheet based and embodies established principles of food safety risk assessment (Ross and Sumner, 2002). A qualitative risk rating approach based on ICMSF (2002) has also been employed (Chapter 4.3). In this and following sections, inputs for Risk Ranger are identified.

A summary of the original Risk Ranger spreadsheet tool inputs with weighting values used in the current model (V.1) [Ross and Sumner, 2002] is provided as background to the development of input answers in the following text. Modifications to customise its' application to eggs are provided in Section 4.2.

		Comment
1. Hazard severity		
SEVERE hazard—causes death to most victims	1	arbitrary weighting factors
MODERATE hazard—requires medical intervention in most cases	0.1	
MILD hazard—sometimes requires medical attention	0.01	
MINOR hazard—patient rarely seeks medical attention	0.001	
2. How susceptible is the consumer?		
GENERAL—all members of the population	1	100% of population
SLIGHT—e.g., infants, aged	5	20% of population
VERY—e.g., old, very young, diabetes, alcoholic etc.	30	3% of population
EXTREME—e.g. AIDS, transplants recipients, cancer patients, etc.	200	0.1% of population
		arbitrary weightings, but based on relative susceptibility to listeriosis, population estimates based on Australian health statistics
3. Frequency of consumption		
daily	365	simple algebra
weekly	52	
monthly	12	
a few times per year	3	
once every few years	0.3	
4. Proportion of population consuming		
all (100%)	1	arbitrary weighting factors
most (75%)	0.75	
some (25%)	0.25	
very few (5%)	0.05	
5. Size of population of interest		User selected or specified
6. Proportion of product contaminated?		
Rare (1 in a 1000)	0.001	0.01% of samples
Infrequent (1%)	0.01	1% of samples
Sometimes (10%)	0.1	10% of samples
Common (50%)	0.5	50% of samples
All (100%)	1	all samples
OTHER	user input	
7. Effect of process		
The process RELIABLY ELIMINATES hazards	0	arbitrary weighting factors

The process USUALLY (99% of cases) ELIMINATES hazards	0.01	
The process SLIGHTLY (50% of cases) REDUCES hazards	0.5	
The process has NO EFFECT on the hazards	1	
The process INCREASES (10x) the hazards	10	
The process GREATLY INCREASES (1000x) the hazards	1000	
8. Is there a potential for recontamination?		
NO	0	arbitrary weighting factors
YES—minor (1% frequency)	0.01	
YES—major (50% frequency)	0.50	
OTHER	user input	
9. How much increase from level at processing is required to reach an infectious or toxic dose for the average consumer?		
none	1	arbitrary weighting factors
slight (10-fold increase)	0.1	
moderate (100-fold increase)	0.01	
significant (10,000-fold increase)	0.000 1	
OTHER	user input	
10. How effective is the post-processing control system?		
WELL CONTROLLED—systems in place, audited, well-trained staff	1	arbitrary weighting factors
CONTROLLED—systems in place, audited, well-trained staff	3	
NOT CONTROLLED—no systems in place, untrained staff	10	
GROSS ABUSE OCCURS	1000	
NOT RELEVANT—level of risk agent does not change	1	
11. Effect of preparation for meal		
Meal preparation RELIABLY ELIMINATES hazards	0	arbitrary weighting factors
Meal preparation USUALLY ELIMINATES (99%) hazards	0.01	
Meal preparation SLIGHTLY REDUCES (50%) hazards	0.50	
Meal preparation has NO EFFECT on the hazards	1.00	
OTHER	user-input value	

Infections with zoonotic *Salmonella* are characterised by gastroenteritis i.e. diarrhoea, fever, vomiting and malaise. Symptoms generally appear within 12 to 24h after infection and continue for 2 to 7 days. In a certain percentage of cases invasive disease develops resulting in septicaemia and infection of the organs, bones or joints. Complications such as reactive arthritis and persistent abdominal pain may occur as a result of infection. Human salmonellosis is generally a zoonotic disease and strains with reduced sensitivity to antibiotics are detected in farm animals and the human population. A more detailed hazard characterisation has been undertaken by the WHO/FAO drafting group on Risk Assessment of *Salmonella* in broilers and eggs (this characterisation can be viewed at http://www.who.int/fsf/Micro/Scientific_documents/mra03.pdf).

For the purpose of this report, all *Salmonella*, excluding *S.* Sofia in Australia are regarded as pathogenic. Furthermore, it was the opinion of stakeholders present at Workshop 2, including public health experts, that the disease outcome should be regarded as "Mild" for this risk rating exercise. Consequently, this input definition has been specified for Risk Ranger. However, for comparative purposes, the stakeholders also requested that risk ratings be calculated for eggs and egg products using a "Moderate" severity of illness rating (Table 17).

Inputs to Risk Ranger

Question 1: Severity of *Salmonella* as a hazard
Based on the foregoing, the pathogen was ascribed a severity rating of "Mild" with the commentary that it sometimes requires medical attention.

For comparison a severity rating of "Moderate" was requested.

For food-borne illness, the infectious dose has been reported to be about 10^6 cells. This estimate is based on human feeding trials from the 1940s and 1950s (FAO/WHO, 2002). However, other factors such as age (especially children and the elderly) and food composition (eg high fat foods such as cheese or chocolate), may reduce the infectious dose to less than 100 cells (Table 2).

Table 2: Examples of salmonellosis produced by serovars at low dosage (after D'Aoust, 1994)

Vehicle	Serovar	Infectious dose
Chocolate	*S.* Eastbourne	100
Chocolate	*S.* Napoli	10-100
Chocolate	*S.* Typhimurium	<10
Cheese	*S.* Heidelberg	100
Cheese	*S.* Typhimurium	1-10
Hamburger	*S.* Newport	10-100

Thus the food matrix, especially its fat content, is important and all the foods listed in Table 2 have high fat contents which apparently protect the salmonellas from mammalian gastric secretions. In the present study, however, the fat content of eggs (3.5%) and egg products does not nearly approach that of the high-fat food matrices in Table 2. Consequently, an infective dose associated with infection and illness in 50% of those who consume the food (ID_{50}) has been adopted. The infective dose selected for the present study owes much to the work of FAO/WHO (2002). Figure 1 presents consolidated dose-response data (2002) based on outbreak data, that suggests an ID_{50} of about 10,000 cells. Allowance for the effect of food matrix can be included in the quantitative predictive model developed in AECL project SAR-42A.

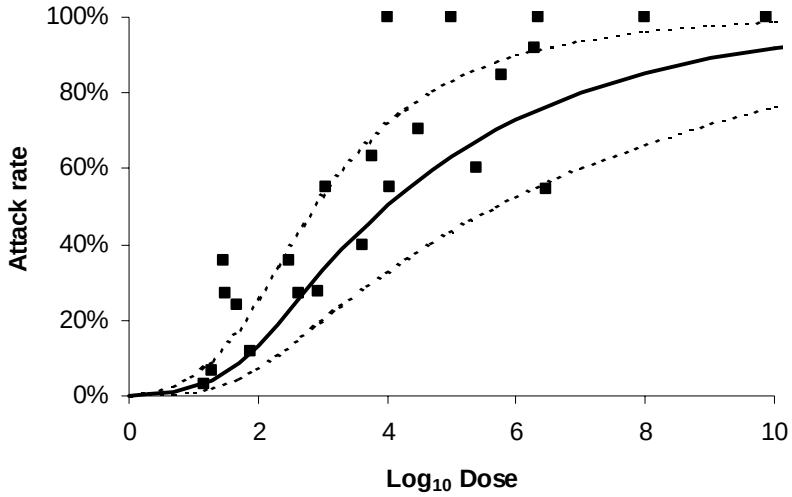

Figure 1: Dose-response curve derived from outbreak data (after FAO/WHO, 2002)

The dose response relationship (logarithm of dose vs probability of illness) is presented in Attachment 10.

Table 3 summarises ID_{50} estimates (FAO/WHO, 2002) that are consistent with an ID_{50} of about 10,000 cells.

Table 3: Estimated ID_{50}

Estimated median infective dose, ID_{50}	Data source	Reference
23,600	Human feeding trials	FAO (2002)
9,600	Human outbreak data	FAO (2002)

An important input to Risk Ranger is the fold increase in numbers of *Salmonella* cells required to reach an infective dose. The fold increase, among other factors, is used by Risk Ranger to estimate risk. The higher the fold increase required the lower the risk associated with the raw product and vice versa. For the purpose of this risk assessment, stakeholders indicated that an estimate of ID_{50} for all *Salmonella* should be 10,000 cells, consistent with Table 3. Note that this estimate is for normal healthy individuals and takes no account of food composition, or other factors that may influence infective dose. Thus the increase to infective dose depends on the number of *Salmonella* cells in the raw product. Using the example of a 55g cracked egg (50g content) containing 1 cfu/g (from Question 6 of Risk Ranger, see Attachment 14), the egg would contain a total of 50 *Salmonella* cells. Consequently the fold increase to an infectious dose of 50,000 cells, would be 1000x. This figure is inserted at Question 10 (see Exposure assessment section for the rationale behind estimating concentrations of *Salmonella* in eggs and egg fractions).

Inputs to Risk Ranger

Question 2: How susceptible is the consumer
General has been used; all sub-populations are subsumed within this input e.g. infants, elderly etc.

Question 10: Increase required to infective dose
Uncracked eggs: 10,000-fold
Cracked eggs: 1,000-fold

3.3 Exposure Assessment

Prevalence of *Salmonella* in shell eggs

Information on prevalence of *Salmonella* on and in Australian shell eggs comes primarily from a pilot survey (Thomas and Daughtry unpublished) conducted in 2002 (Table 4).

Table 4: Pilot Prevalence of *Salmonella* in Australian eggs

Egg type	Pilot prevalence 95% CI[A]			Overseas non-SE average (95% CI) [C]
	Total tested	Sensitivity 0.7[B]	Sensitivity 1.0	
Shell eggs ungraded - external				
- Caged	2,160	0 – 0.2%	0 – 0.2%	0.21% (0.04-0.62%)
- Free range[D]	1,200	0 – 0.4%	0 – 0.3%	
- Barn laid[D]	1,200	0 – 0.4%	0 – 0.3%	
Shell eggs - graded				
- Caged external	6,476	0 – 0.08%	0 – 0.06%	0.03% (0.01-0.07%)
- Caged internal contents	20,000	0 – 0.03%	0 – 0.02%	0.004% (0.001-0.008%)

[A] All cultures negative
[B] Assumes a 0.7 sensitivity due to culturing pools of 20 eggs
[C] References in Attachment 6
[D] Sample size for free range and barn laid too small to confidently estimate prevalence

Salmonella was not isolated from the external shell surface of any of the 11,036 eggs sampled. By conservatively assuming the upper limit of the 95% Confidence Interval to be the estimate of the true prevalence, the results for contamination of external surfaces (for eggs from all production systems) reflects the average prevalence recorded internationally for non *S.* Enteritidis serovars; this applies to both ungraded and graded (washed) eggs.

Similarly, *Salmonella* was not isolated from the internal contents of eggs. However, insufficient eggs were tested in this pilot study to obtain a rigorous estimate of prevalence. Accordingly, for the purposes of the present study, it is assumed that the prevalence may be assumed to also reflect international levels of non SE *Salmonella* considering the low and similar prevalence of external contamination.

A summary of overseas prevalence surveys of all non-SE *Salmonella* in egg contents is presented in Attachment 6. From this data, we have proposed that a prevalence of 0.004% for all non-SE *Salmonella* in the contents of eggs be used. Prevalence data for barn laid and free range eggs which represent approximately 10% of commercial production (Attachment 1) are unknown and are assumed to be the same as cage laid for the purpose of these risk ratings, although in practice they are likely to be higher. This data gap is considered important and is discussed under Sections 5.1, 5.2 and 6.

While cracked eggs form a component of the industry there is no information on prevalence of salmonellas. Accordingly, for the present study, cracked eggs were considered to have a 10-fold increased prevalence compared with uncracked eggs.

Inputs to Risk Ranger

Question 6: Prevalence of *Salmonella* in egg contents.
Uncracked eggs 0.004%
Cracked eggs 0.04%

Concentration of *Salmonella* in shell eggs

No publicly available data describing concentration of *Salmonella* in Australian eggs[4] was found. A further complication is whether pathogens are distributed homogeneously within individual eggs or through batches of egg pulp product. While some risk assessments (Bemrah *et al*., 1999; FDA/FSIS, 2000) have noted that pathogens are probably heterogeneously distributed in some foods, all to date have assumed that pathogens present in foods are distributed homogenously. This is a clearly a simplification. The assumption may be appropriate for pasteurised and/or homogenised liquid egg products.

A consequence of the assumption of homogeneity is that prevalence and concentration of pathogens (cfu/g) in foods are often considered to be related properties particularly at very low concentrations. The observed prevalence will depend on the sample size and the extent of contamination of the batch. If the batch is contaminated at a level of >1cfu/g, there is high probability that, in each 25g sample, the pathogen of concern would be detected. If, however, the sample size were only 1g, some samples would not contain cells of the pathogen. If the contamination level were 1/100g, we would expect only one in four 25g samples to "test positive", and it is then more usual to describe this concentration as "25% prevalence". This is especially true in the case of pasteurised egg products.

In fact, the distribution of bacteria in a sample is likely to follow a Poisson distribution. In that case, if the mean concentration is X per gram, and there are Y grams per sample the count per sample is Poisson distributed with mean X*Y. More importantly, the probability of a positive result for a sample of Y grams is then: 1 - exp(-X*Y). Thus, for large amounts of product, prevalence and concentration are related and the estimate of the prevalence depends on the level of contamination and the sample size.

Similarly, products that permit the growth of pathogens may exhibit a low prevalence of contamination at the point of production and a higher prevalence at the point of consumption. This is not necessarily due to re-contamination, but may be due to subsequent growth in the product that in turn leads to an increase in the probability of detection.

For the present study, a concentration of 1 cfu/egg has been assumed for uncracked eggs and 10 cfu/egg for cracked eggs. Note that Risk Ranger does not allow concentration of the target pathogen as an input. However, an appreciation of the concentration of bacteria present in a sample is needed to calculate the increase to infective dose in Question 10.

Condensation on eggs due to removing eggs from storage at 4°C to ambient temperature, while not a hazard in its' own right, provides opportunity for bacterial survival and penetration of the shell (reviewed by Messens *et al.,* 2005). Moisture is needed to allow penetration, hence any stage of production where both moisture and a positive temperature differential may be present provides an opportunity for bacterial invasion. When eggs are removed from refrigerated storage and placed at room temperature, they may "sweat" due to condensation of water droplets on the egg surface. Consequently, industry quality assurance practices aim to prevent temperature changes that may

[4] Surveys of naturally contaminated eggs for the presence of *Salmonella* Enteriditis have established that levels are typically <10 cfu/egg (Humphrey *et al.*, 1991). In the absence of published data it is assumed that vertical transmission will give a concentration 10x greater than by horizontal transmission.

cause condensation to form on the egg surface. The risk will be reduced for washed eggs due to reduction of bacterial loads on the shell surface (reviewed in Attachment 15).

Inputs to Risk Ranger

Question 6: Concentration of *Salmonella* in egg contents.
Uncracked eggs 1 cfu/egg
Cracked eggs 10 cfu/egg

Salmonella growth in shell eggs

As eggs age weakening of the vitelline membrane allows bacteria to migrate from the albumen into the yolk, or the leakage of yolk contents into the albumen. These changes have been suggested to be factors that can lead to significant growth of *Salmonella* in eggs (Humphrey *et al.*, 1991). Thus, the number of *Salmonella* in eggs may increase greatly as a result of invasion and growth in the yolk. Typically, at ambient room temperatures increases in cell counts are not observed until the eggs are stored for periods in excess of three weeks. This growth lag correlates with weakening of the yolk membrane.

Experimental evidence for growth and persistence of *Salmonella* in albumen and yolk support observations of the behaviour of *Salmonella* in naturally contaminated eggs. *Salmonella* inoculated into albumen grows very slowly, if at all. Lock and Board (1992) found that only 15/27 *Salmonella* serovars grew in albumen stored at 20°C. Generation (doubling) times ranged from 2 to 19 days. Of the remaining 12 serovars, only *S.* Pullorum did not remain viable at the end of 42 days of storage. Baron *et al.* (1997) identified ovotransferrin as the key compound responsible for inhibiting the growth of *Salmonella* in egg albumen.

Yolk, by contrast to albumen, is an excellent growth medium for *Salmonella* and does not contain the inhibitory compounds found in albumen. Typical generation times for *Salmonella* in yolk of <2 hours at 25°C have been reported, with counts as high as 10^9 cfu/g egg pulp (Humphrey *et al.*, 1994).

The term Yolk Mean Time (YMT) (Whiting *et al.*, 2000; USDA/FSIS 1998) has been coined to define the period during which salmonellas present within the egg will be prevented from multiplying due to natural inhibitory and physical barriers. The term provides a useful expression of the interaction of storage time and temperature and capacity for growth from farm to retail for *Salmonella*[5]. This relationship for *Salmonella* has been constructed for Australian industry practices by surveying lay-to-retail time/temperature characteristics of the egg supply chain. Estimates for on-farm temperature:time data (Attachment 7) and egg grading floors are provided (Attachment 8) which indicate that smaller operations have longer holding times on farm. Data on the proportion of egg grading floor throughput held for the "maximum" periods quoted were not collected. In the draft Australian Quantitative Risk Assessment model for *Salmonella* it was estimated the YMT for eggs stored at 16°C is 26 days and for those stored at 20°C, 17 days (AECL project SAR-42A).

The time:temperature handling of eggs post egg grading floor to retail is unknown but represents important information about the proportion of contaminated eggs that could support growth in the yolk (see Sections 5.1, 5.2 and 6). If this data were available, it could be utilised to develop more sophisticated predictive models and risk assessments similar to those prepared for AECL Project SAR-42A.

Inputs to Risk Ranger

Question 7: Effect of process
The process (grading floor) has no effect on hazards

Question 8: Is there potential for recontamination?
No (shell eggs)

[5] This rep… MT is the same for a…

For the present context the best-by date used by different egg producers was found to range from 28-42 days. This is well past the (approximately) 25 days (lay to consumption) where YMT is probably resolved under storage at ambient temperatures. Importantly, ambient storage was considered by industry sources to be the "norm" for major supermarkets. For the present risk profile, therefore, it is assumed that YMT had expired in 25% of shell eggs (resulting from expert opinion at Workshop 2, i.e. that 75% of eggs are either consumed or refrigerated post-retail before YMT resolves allowing growth) and that growth was possible in only 0.001% of shell eggs (i.e. *Salmonella* prevalence of 0.004% x 25% of eggs exceeding their YMT – refer to Inputs to Risk Ranger Question 6). This assumption is supported by Humphrey (1994) who showed that no growth of *Salmonella* occurs prior to expiration of the YMT.

Consequently, the input to Risk Ranger (Question 9) is assumed to be either no increase in numbers, where YMT is not resolved, or an increase in numbers of *Salmonella* of 5-log (100,000-fold) to describe growth after resolution of YMT under conditions of temperature abuse. Clearly where growth does occur, this will be temperature dependent. As Risk Ranger is a risk rating tool and not a risk modelling tool, the rate and final concentration of *Salmonella* cannot be determined in absolute terms. Where no growth occurs the multiplier is 1 and the risk rating is not increased. However, under conditions of gross abuse, the multiplier of 100,000 is used to calculate a risk rating.

This multiplier was selected as a value representative of the growth in numbers of *Salmonella* that could occur under conditions of temperature abuse. It is based on observations of Humphrey (1994), who observed log increases in numbers of SE of this magnitude at room temperature, in naturally contaminated eggs after expiration of YMT. While these results are for SE, the growth rates of non-SE serovars in yolk are similar (Messens *et al*., 2004; Takase *et al*., 1999).

Inputs to Risk Ranger

Question 9: How effective is the post-process control system
YMT not resolved: Well controlled (no increase)
YMT resolved: Gross abuse (5-log increase)

Prevalence of *Salmonella* (non-SE) in egg fractions

A summary of results obtained from laboratory testing of shell eggs and processed eggs at NEPSS and the Institute of Medical and Veterinary Science (IMVS) in SA is provided in Tables 1 and 5. In addition, as part of the present project, five egg processors across Australia were surveyed for the frequency of testing for the presence of *Salmonella* in liquid egg products. The processors reported sampling between two and 10 times per week, depending on the quantity of liquid egg pasteurised.

The main serovars isolated in egg pulp surveys in Queensland in the 1990s were *S*. Singapore, *S*. Mbandaka, *S*. Cerro and *S*. Infantis (Cox *et al.*, 2002). Contamination of raw whole egg pulp sampled over 14 months at a single egg processing facility in Queensland was high (95% of 110 samples), presumably due to pooling across farms. In contrast 23% of 856 farm egg pulp samples were positive indicating contaminated pulp from a single farm may contaminate the rest of the pulp. The isolation

of *S.* Infantis, particularly from egg yolk product, is of concern due to its public health significance in other countries (Cox *et al.,* 2002). Concerns raised in relation to *S.* Infantis have not materialised to date as outbreaks attributed to *S.* Infantis have not been reported in Australia (Attachment 11). More recent data on isolates from commercial raw egg pulp samples reveals a broad range of serovars, including a number of *S.* Typhimurium Phage Types listed in the outbreaks summarised in Attachment 11 (Murrary 2005a,b). While this commercial product testing data does not allow estimation of prevalence, it raises the potential of flock infection with *S.* Typhimurium in areas other than Qld and NSW (see above). Systematic national data is required to address this uncertainty. Alternatively, this may reflect pulp contamination post-farm gate from sources other than eggs; in Risk Assessment terms this remains an area of uncertainty.

Table 5: IMVS Food Lab *Salmonella* testing of shell eggs and processed eggs (1998-2004)

Product	Year(s)	Number of samples	Number of samples in which *Salmonella* was detected	Reference
Eggs & processed eggs*	Jan 1998-Dec 2001	339	0	Murray (2002)
Processed egg*	Jan-Dec 2002	41	0	Murray (2003a)
Egg (AQIS)	Jan-Dec 2002	27	0	Murray (2003a)
Raw egg pulp**	Jan-March 2003	6	2***	Murray (2003d)
Raw egg pulp	April-June 2004	27	23****	Murray (2004)

* pasteurised egg product
** commercial unpasteurised pulp, not outbreak related
*** *S.* Bovismorbificans PT24: also reported in Attachment 9 Table 9.1.3
**** Includes 7x *S.* Typhimurium phage type 108 and 4 x *S.* Typhimurium phage type 9

Inputs to Risk Ranger

Question 6: Prevalence of raw product contamination by *Salmonella* (non-SE)
Raw pulp fractions: 25% (based on Cox *et al.,* 2002)
Concentration 0.1 cfu/g (assumed)

Consumption of eggs and egg products

Initial feedback at and since Workshop 1 raised issues regarding the complexity of the range of egg end uses. Variables considered in the revision of the hazard:egg and egg product combinations (Attachment 2; Figures 1, 2 and 3; Tables 6 and 16) included:

- Egg and egg product and sales/supply chains pathways for commercial shell eggs and pulp products, and non-commercial eggs (Attachment 1)
- Commercial egg handling and storage practices (expressed as YMT - Attachment 3)
- Use in home, manufacturing and food service sectors
- End use pathways for shell and processed commercial eggs (either as an ingredient or egg-based meal
- Effect of meal preparation (cooking) as a variable (Table 6).

A series of scenarios recommended during the expert consultations were also considered. Consumption was estimated at 2.8 billion eggs annually (Attachment 5);

Utilisation pathways

The end use pathway process categorised egg meals and dishes into four groups based on the degree of pathogen reduction in meal/dish preparation (Table 6). Further information is provided in Attachment 2; Figures 1, 2 and 3. To evaluate the effect of different cooking times and temperatures on inactivation of *Salmonella*, data describing inactivation rates of *Salmonella* Typhimurium Phage Types have been used (Humphrey *et al.*, 1989; Bates and Spencer, 1995).

The current implementation of Risk Ranger allows for 4 meal preparation effect categories as inputs (Attachment 10 - adjusted Question Q11. Reliably Eliminates, Substantially Reduces (99.999%), Moderately Reduces (99%), and No Effect). These have been modified (Attachment 10) for the use of Risk Ranger for eggs (Table 6) to better reflect the extent of inactivation of *Salmonella* during meal preparation (Humphrey *et al.*, 1989).

With eggs, the same meal can end up in more than one category depending on meal preparation procedures; for example boiled eggs could be both hard boiled ("RE - reliably eliminates") and lightly boiled where some of the yolk remains liquid ("MR - moderately reduces"). Use of the "meal preparation effect" approach allows aggregation of meals and dishes into risk-based groupings (Table 6). Risk ratings of these groupings have been prepared to enable comparison of risk.

Table 6: Thermal inactivation of *S*. Typhimurium in typical egg meals (after Humphrey *et al*., 1989; Bates and Spencer, 1995)

Thermal treatment	Decimal reduction	Descriptor	Types of meal
None		No effect (NE)	Raw egg drinks, some desserts
Light cooking	100-fold	Moderate reduction (MR)	*Boiled 4 min, fried ("sunny side up"), microwave
Medium cooking	10,000-fold	Substantial reduction (SR)	Fried ("easy over"), lightly scrambled or omelette, pasta
Heavy cooking	1,000,000,000	Reliably eliminates (RE)	Hard boiled or scrambled, cakes, biscuits

* Where some liquid yolk remains

End-use pathways for pulp products have also been identified that cover the full range of commercial egg consumption in Australia. As described previously, categories for products prepared from pulp (Attachment 2; Figure 2) have been developed on the basis of meal preparation effects (Humphrey *et al.*, 1989).

Non-commercial eggs (Attachment 2; Figure 3) are considered in a similar manner. In this instance the additional risk from use of cracked eggs in meals is included.

While this approach is useful in describing the full set of scenarios describing product and end-use pathways (Attachment 2), it results in the description of many pathways that are either little used or represent little risk. The meals/dishes selected for the preliminary risk ratings in this report include:

- Examples of high volume usage
- Potential high-risk pathways eg use of cracked eggs and unpasteurised egg pulp in the food industry
- Foods implicated in outbreak investigations.

Where practical, groups of like meals/dishes based on different meal preparation impacts (Table 6) were evaluated against combinations of egg source and potential for growth (Yolk Mean Time in Attachment 3). Results of the analysis are provided in Table 16.

Consumption volumes

Calculations were made of the number of servings of eggs and egg products consumed for each product type, based on pathogen inactivation treatment. Thus, for consumption of shell eggs the total consumption of 176 million dozen is divided into four streams, based on pathogen reduction: No effect (NE), Moderate reduction (MR), Substantial reduction (SR) and Reliable reduction (RE). The premise for this characterisation is that an "easy-over" egg undergoes similar pathogen reduction whether eaten at home or in the food service sector. Similarly, baking results in reliable reduction of pathogens whether done in the home oven or in a commercial oven.

The assumed flow of egg volume into each category is presented in Table 7. Primary flows are:

- Commercial shell eggs for home use (123.2 million dozen and for processing/food service 52.8 million dozen)
- Commercial egg pulp for processing and food service (31 million dozen)
- Non-commercial shell eggs for home consumption (23 million dozen)
- Unpasteurised egg pulp (500kg/week).

Consumption of meals which have undergone similar pathogen reduction

The end use split for shell eggs in Tables 7 and 8 is based on feedback from stakeholders with 70% of eggs assumed to be used in the home and 30% in processing and food service sectors. Table 8 lists estimates of the proportion of each category of shell eggs that receive similar pathogen reduction during meal preparation/processing. Note the descriptors (NE, MR, SR and RE) are defined in Table 6.

Table 7: Primary egg and egg product flows (figures shown are million dozen)

Egg production 231								
Commercial shell eggs 176				**Non-commercial shell eggs** 23		**Processed pulp** 31		**Unpasteurised pulp** 500kg/week
Home use 123.2		**Processing and food service** 52.8		**Home use** 23		**Processing and food service** 31		**Processing and food service** 500kg/week
Ingredients 61.6	Egg meals 61.6	Ingredients (manufacturing) 26.4	Egg meals (food service) 26.4	Ingredients 11.5	Egg meals 11.5	Ingredients (manufacturing) 15.5	Egg meals (food service) 15.5	Ingredients (manufacturing) 500kg/week

Table 8: Assumed distribution of servings of shell eggs according to pathogen reduction regime in cooking/processing (figures shown are million dozen)

Commercial shell eggs 176				**Non-commercial shell eggs** 23	
Home use 123.2		**Processing and food service** 52.8		**Home use** 23	
Ingredients	Egg meals	Ingredients (manufacturing)	Egg meals (food service)	Ingredients	Egg meals
61.6	61.6	26.4	26.4	11.5	11.5
NE (10%)	NE (5%)	NE (10%)	NE (5%)	NE (10%)	NE (5%)
MR (15%)	MR (40%)	MR (15%)	MR (40%)	MR (15%)	MR (40%)
SR (25%)	SR (40%)	SR (25%)	SR (40%)	SR (25%)	SR (40%)
RE (50%)	RE (15%)	RE (50%)	RE (15%)	RE (50%)	RE (15%)

Table 9 shows estimates of the number of servings (an egg is considered one serving) of commercial eggs that have not undergone pathogen growth (no resolution of YMT); this proportion is estimated at 75% of total egg production.

Estimates in Table 9 are used as inputs to Questions 3 and 4 of Risk Ranger for commercial eggs that have not undergone resolution of YMT. Table 10 lists corresponding estimates for eggs that have undergone 5-log growth following resolution of YMT.

Table 9: Servings of commercial shell eggs which have not undergone resolution of YMT cooked to different extents

			Input to Risk Ranger
Total serves	**176m x 12 x 0.75[6]**	**1584m**	
NE meals* (7.5%)	1584m x 0.075	118.8m	Most people eat Monthly
MR meals (27.5%	1584m x 0.275	425.6m	Most eat Weekly
SR meals (32.5%)	1584m x 0.325	514.8m	Most eat Weekly
RE meals (32.5%)	1584m x 0.325	514.8m	Most eat Weekly

* See Table 6 for descriptors and meal types

Table 10: Servings of commercial shell eggs which have undergone resolution of YMT cooked to different extents

			Input to Risk Ranger
Total serves	**176m x 12 x 0.25[7]**	**528m**	
NE meals* (7.5%)	528m x 0.075	39.6m	A few people eat Weekly
MR meals (27.5%	528m x 0.275	145.2m	Most eat Monthly
SR meals (32.5%)	528m x 0.325	171.6m	Most eat Monthly
RE meals (32.5%)	528m x 0.325	171.6m	Most eat Monthly

* See Table 6 for descriptors and meal types

Table 11 lists estimates of servings used as inputs for Questions 3 and 4 of Risk Ranger for non-commercial eggs which have not undergone resolution of YMT. Table 12 contains corresponding estimates for non-commercial eggs that have undergone 5-log growth following resolution of YMT.

[6] Millions of dozens of eggs x 12 eggs per dozen x proportion of eggs that have not undergone resolution of YMT.

[7] Millions of dozens of eggs x 12 eggs per dozen x proportion of eggs that have undergone resolution of YMT.

Table 11: Servings of non-commercial shell eggs, which have not undergone resolution of YMT, cooked to different extents (figures shown are millions)

			Input to Risk Ranger
Total serves	**21m x 12 x 0.75[8]**	**189m**	
NE meals* (7.5%)	252m x 0.075	14.1m	Most eat Monthly
MR meals (27.5%	252m x 0.275	51.9m	Most eat Weekly
SR meals (32.5%)	252m x 0.325	61.4m	Most eat Weekly
RE meals (32.5%)	252m x 0.325	61.4m	Most eat Weekly

* See Table 6 for descriptors and meal types

Table 12: Servings of non-commercial shell eggs, which have undergone resolution of YMT, cooked to different extents

			Input to Risk Ranger
Total serves	**21m x 12 x 0.25[9]**	**63m**	
NE meals* (7.5%)	63m x 0.075	4.7m	Some eat Monthly
MR meals (27.5%	63m x 0.275	17.3m	Most eat Monthly
SR meals (32.5%)	63m x 0.325	20.4m	Most eat Monthly
RE meals (32.5%)	63m x 0.325	20.4m	Most eat Monthly

* See Table 6 for descriptors and meal types

Table 13 contains estimates used as inputs for Questions 3 and 4 of Risk Ranger for cracked non-commercial eggs that have not undergone resolution of YMT. Table 14 contains corresponding data for eggs which have undergone 5-log growth following resolution of YMT.

Table 13: Servings of non-commercial cracked shell eggs which have not undergone resolution of YMT cooked to different extents

			Input to Risk Ranger
Total serves	**2m x 12 x 0.75[8]**	**18m**	
NE meals* (7.5%)	18m x 0.075	1.35m	Every few years
MR meals (27.5%	18m x 0.275	4.95m	Few times
SR meals (32.5%)	18m x 0.325	5.85m	Few times
RE meals (32.5%)	18m x 0.325	5.85m	Few times

* See Table 6 for descriptors and meal types

Table 14: Servings of non-commercial cracked shell eggs which have undergone resolution of YMT cooked to different extents

			Input to Risk Ranger
Total serves	**2m x 12 x 0.25[9]**	**6m**	
NE meals* (7.5%)	6m x 0.075	0.45m	Every few years
MR meals (27.5%	6m x 0.275	1.65m	Every few years
SR meals (32.5%)	6m x 0.325	1.95m	Every few years
RE meals (32.5%)	6m x 0.325	1.95m	Every few years

* See Table 6 for descriptors and meal types

[8] Millions of dozens of eggs x 12 eggs per dozen x proportion of eggs that have not undergone resolution of YMT.

[9] Millions of dozens of eggs x 12 eggs per dozen x proportion of eggs that have undergone resolution of YMT.

Egg pulp pasteurisation

Cox (2002) indicated the prevalence of *Salmonella* in egg fractions was around 23%. Consequently, the prevalence of *Salmonella* in raw egg fractions will be set at 25%. In the Australian industry, temperature:time parameters of pasteurisation are as presented in Table 15. These parameters reflect the need to pasteurise certain egg fractions at a lower temperature for longer times for quality reasons.

Table 15: Temperature:time parameters reported by Australian processors for pasteurising egg fractions (2004)

Product	Temperature (°C)	Time (min)
Whole egg	64-65	3.5
High solids	64-65	4.3
Egg whites	55.4-56	10.0
Plain yolks	60.9-63	7.0
10% sugar yolk	63.9-66	5.75
Scramblers	54.9-56	10.0
Albumen		
Scrambled egg mix	64-65	7.0

Using a bench-scale pilot pasteuriser, Robertson and Muriana (2004) have measured D-values for egg fractions. Using the most conservative values, parameters used by the Australian industry appear to give >20-log reduction in *Salmonella* during pasteurisation.

However, NEPSS data indicate that a range of serovars, including *S*. Typhimurium, have been isolated from pasteurised egg products. Whether these contaminants are the result of under processing or recontamination is unknown.

Processors have reported occasional detection of *Salmonella* positive samples over the past 5 years in pasteurised liquid and powdered egg products[10]. However, it is claimed these incidents reflect failure in cleaning. Furthermore, from the industry data provided it is apparent that very low levels of post-processing contamination may occur at very low rates across all product types. Processors implement complex batch-based sampling plans (packaged end product) are weighted toward batches at the start and end of a processing run. Intensity of sampling is increased if there is uncertainty for any reason. All *Salmonella* positive batches are discarded, though there is no implication that contaminated batches do not reach the downstream industry.

With powdered products, pasteurisation holding times are extended for whole egg and yolk; the product is then dried. Powdered albumen product is first dried then held for days at temperatures higher than whole egg pasteurisation temperatures (64-65°C).

Use of unpasteurised pulp

There is anecdotal evidence that 500kg/week of unpasteurised pulp may be used.

Post-process contamination

Issues associated with recontamination are very difficult to model and advice is required on identifying suitable scenarios where recontamination may be an issue.

[10] (Collaborating processors have requested that the data supplied on >13 000 tests on eggs and egg products over 5 years on 65% of national production, and processing procedures, is to be kept confidential). General observations are presented from examination of these data.

4. Risk Rating Results

4.1 Risk Characterisation

A required output of the Egg Risk Profile (Section 2) is to:

Identify public health hazards that enter any point of the food chain for eggs and egg products produced in Australia and rank them in terms of risks to the consumer

Two methods were selected for the risk ranking of hazard:product combinations including Risk Ranger, a spreadsheet software format that embodies established principles of food safety risk assessment (Ross and Sumner 2002). This was repeated using a qualitative risk rating approach based on ICMSF (2002) (M Cole pers comm. and FSA 2000) for all hazard:product combinations.

4.2 Risk Ranger

The tool is in spreadsheet software format and embodies established principles of food safety risk assessment, i.e., the combination of probability of exposure to a foodborne hazard, the magnitude of hazard in a food when present, and the probability and severity of outcomes that might arise from that level and frequency of exposure. The tool requires the user to select from qualitative statements and/or to provide quantitative data describing factors that that will affect the food safety risk for a specific population, arising from a specific food product and specific hazard, during the steps from harvest to consumption. The spreadsheet converts the qualitative inputs into numerical values and combines them with the quantitative inputs in a series of mathematical and logical steps using standard spreadsheet functions. Those calculations are used to generate indices of the public health risk. Shortcomings of the approach are discussed, including the simplifications and assumptions inherent in the mathematical model, the inadequacy of data currently available, and the lack of consideration of variability and uncertainty in the inputs and outputs of the model. Possible improvements are suggested.

The model underpinning the tool is a simplification of the harvest to consumption pathway. Nevertheless, the tool provides a rapid and simple means of comparing risk associated with diverse foods and food products. Consequently, Risk Ranger is useful for ranking and prioritising risks. It can be used to screen foodborne risks and identify those requiring more rigorous assessment. It also serves as an aid to structured problem solving and can help to focus attention on those factors in food production, processing, distribution and meal preparation that most affect food safety risk, and that may be the most appropriate targets for risk management strategies (Ross and Sumner, 2002). For example, Risk Ranger has been used to generate a Risk Ranking as part of a semi-quantitative risk assessment of 10 seafood hazard/product combinations in Australia (Sumner and Ross, 2002).

For the purpose of this risk analysis, modifications of the spreadsheet were necessary for inputs to *"Q6 Probability of contamination of raw product per serving"* and *"Q11Effect of preparation before eating"* and the calculation of probability of illness (Attachment 10).

Risk Ranking Output Interpretation

A number of scenarios were modelled, with three outputs:

- Risk rating between 0-100
- Predicted annual illness
- Predicted illnesses per million servings

The Risk Ranking incorporates a number of factors that act to influence the risk from a hazard in a particular food. These factors include:

- Severity of the hazard
- Likelihood of an infectious dose of the hazard being present in a serving
- Probability of exposure to the hazard in a defined period of time

The Risk Ranking obtained is a logarithmic scale between 0 and 100. A value of 0 represents no risk, while 100 represents a situation where every member of the population consumes a serving that contains a lethal dose every day. Each 6 unit change in the Risk Ranking scale is approximately a factor of 10 difference in the absolute risk estimate. It should be noted that the risk rating is independent of the population size but reflects relative risk to an individual within a population (Ross and Sumner 2002). Consequently combinations may have the same risk rating but different numbers of predicted illnesses. For example for any set consumer population an increase in 10 times in prevalence will result in a 10x increase in exposure for that population (except for cases where heavy cooking reliably eliminates the hazard – Table 6).

Two additional outputs are included for comparison between *Salmonella*:product combinations: Predicted annual illness and predicted illnesses per million servings. The predicted illnesses per million servings are included to allow for comparison between utilisation pathways with large differences in exposure. Predicted annual illness estimates the total burden of illness from each pathway.

Modifications to Risk Rating Spreadsheet Tool

In order to accommodate egg-specific issues into the Risk Ranger approach (Table 10.1), the designer was consulted and the following modifications inserted.

Following a request by stakeholders a sensitivity analysis has been included to enable better appreciation of the relative impact on risk that might result from changes to input values.

Question 6: Probability of Contamination of Raw Product per Serving

The original Risk Ranger values for the probability of contamination of raw product are too large when compared to surveys of *Salmonella* contamination in eggs. The probability of finding *S.* Typhimurium in egg contents is of the order of 1 in 100,000 eggs; a probability of only 0.001% (Attachment 6). One 'built-in' option is to use the Other option. This allows the user to manually enter the required probability each time a scenario is developed. An alternative approach was to modify the Risk Ranger weightings to better reflect the probabilities of contaminated eggs found in surveys directly (Tom Ross, pers. comm.). The original and alternative probabilities are presented in the table below. The selected probabilities were selected to adequately cover the range of probabilities for *Salmonella* contamination of eggs. The Other option is maintained to allow for the possibility of different contamination probabilities.

Comparison of original and alternative Risk Ranger options for Q6

Original	Alternative
Rare (1 in 1000)	1 in 100,000 or 0.001%
Infrequent (1%)	1 in 50,000 or 0.002%
Sometimes (10%)	1 in 25,000 or 0.004%
Common (50%)	1 in 12,500 or 0.008%
All (100%)	1 in 10,000 or 0.01%
Other	Other

Question 11: Effect of preparation before eating

The second Risk Ranger input that required modification was the question relating to the effect of preparation before eating. Experimental studies of egg meal preparation (Humphrey *et al*., 1989; Bates & Spencer 1995; Table 1) have found that different cooking practices result in large variations in the amount of *Salmonella* inactivation achieved. The original Risk Ranger input options were modified to reflect the experimental studies, especially the results of Humphrey *et al*. The original and alternative probabilities are presented in the table below. The new options are RELIABLY ELIMINATES (100% elimination), SUBSTANTIALLY REDUCES (5 log reduction in numbers, 99.999%), MODERATELY REDUCES (2 log reduction in numbers, 99%) and NO EFFECT.

Comparison of original and alternative Risk Ranger options for Q11

Original	**Alternative**
RELIABLY ELIMINATES hazards	RELIABLY ELIMINATES hazards
USUALLY ELIMINATES (99%) hazards	SUBSTANTIALLY REDUCES (5 log) hazards
SLIGHTLY REDUCES (50%) hazards	MODERATELY REDUCES (2 log) hazards
NO EFFECT on the hazards	NO EFFECT on the hazards
Other	Other

Calculation of the probability of illness

Risk Ranger has a log-linear dose response relationship between dose, the probability of illness and risk. This relationship implies that if the dose increases by a factor of ten, then the probability of illness and risk also increase by a factor of ten. However, the log-linear dose response relationship does not hold for all doses. For doses greater than the median infective dose, ID_{50}, the probability of becoming ill is taken to be 1. The probability of a consumer becoming ill following the consumption of a contaminated serving is the "Probability of Contamination of Raw Product per Serving" (value of Question 8) x "Probability of becoming ill from the consumption of a contaminated serving".

As there is no possibility of post-processing contamination, the probability of a consumer becoming ill following the consumption of a contaminated serving is given by:

$$\text{MIN}\left(\begin{array}{l}\text{the proportion of product contaminated (value of Q6) x}\\ 1,\\ \text{the effects of processing (value of Q7) x}\\ \text{the effect of post-processing handling/storage (value of Q9) x}\\ \text{the increase in the initial level of the factor required to reach } ID_{50} \text{ (value of Q10) x}\\ \text{the effect of preparation prior to eating (value of Q11)}\end{array}\right)$$

Results

Risk rating results of *Salmonella*:egg meal and egg-base dishes are presented in Table 16. Details of the inputs used for each scenario can be found in Attachment 14 where the use of assumptions or data for each question is specified.

Scenarios 1-24 refect the use of commercial and non-commercial shell eggs under the full range of growth and meal preparation effects.

Scenario 25 presents hypothetical circumstances where non-commercial, cracked eggs are used in "egg butter" (raw egg and oil). This is constructed to provide risk managers with an insight into the risk associated with this illegal use of eggs if it were to occur.

Scenarios 26-29 are presented to reflect the risk that might be associated with the use of unpasteurised egg pulp with varying levels of pathogen reduction from meal preparation. Use of this product without a hazard reduction step equivalent to pasteurisation would constitute illegal use (Egg Standard 2.2.2 – Attachment 15). Scenarios 25-29 are presented to support the intent of existing standards, and the inclusion of these scenarios is not evidence that they reflect current practice. Scenarios 25 and 26 in particular reflect worst-case scenarios as it is unlikely that the majority of egg butter nationally is made from non-commercial cracked eggs or that unpasteurised egg pulp is mainly used in uncooked foods.

Stakeholders requested Scenarios 30-33 be developed for the use of commercial pulp which had a low level of pasteurisation failure or recontamination. Current Standards require discarding of test positive material, and the inclusion of this Scenario in no way reflects current practice.

Feedback at Workshop 2 indicated the need to provide an indication of the impact on risk rating arising from changes to inputs to Risk Ranger questions (i.e. a "sensitivity analysis", Attachment 10). While this is discussed in the previous text, the inclusion of "Moderate" severity for the hazard was requested to be included in Table 16 ("Moderate" in brackets in column 4) to enable this comparison.

Table 16: Risk ratings and predicted illnesses from consumption of eggs and egg-based meals which have undergone various pathogen reduction regimes (*refer to Table 6 for examples of egg and egg-based meal "cooking effect" groupings)

Scenario	Pathogen growth	Pathogen reduction	Risk Rating Mild* (Moderate)	Predicted illnesses per million servings	Predicted annual illnesses
A. Subjected to pathogen reduction					
1. Commercial, non-cracked eggs	None	2-log (MR)*	24 (30)	$4x10^{-5}$	$3.04x10^{-2}$
2. Commercial, non-cracked eggs	None	5-log (SR)	7 (12)	$4x10^{-8}$	$3.04x10^{-5}$
3. Commercial, non-cracked eggs	None	8-log (RE)	0 (0)	0	0
4. Commercial, non-cracked eggs	**5-log**	**2-log (MR)**	**49 (54)**	**4**	**702**
5. Commercial, non-cracked eggs	5-log	5-log (SR)	32 (37)	$4x10^{-3}$	$7.02x10^{-1}$
6. Commercial, non-cracked eggs	5-log	8-log (RE)	0 (0)	0	0
7. Non-commercial, non-cracked eggs	None	2-log (MR)	24 (30)	$4x10^{-5}$	$3.12x10^{-3}$
8. Non-commercial, non-cracked eggs	None	5-log (SR)	7 (12)	$4x10^{-8}$	$3.12x10^{-6}$
9. Non-commercial, non-cracked eggs	None	8-log (RE)	0 (0)	0	0
10. Non-commercial, non-cracked eggs	**5-log**	**2-log (MR)**	**49 (54)**	**4**	**72**
11. Non-commercial, non-cracked eggs	5-log	5-log (SR)	32 (37)	$4x10^{-3}$	$7.20x10^{-2}$
12. Non-commercial, non-cracked eggs	5-log	8-log (RE)	0 (0)	0	0
13. Non-commercial, cracked eggs	None	2-log (MR)	22 (27)	$4x10^{-3}$	$1.20x10^{-3}$
14. Non-commercial, cracked eggs	None	5-log (SR)	0 (10)	$4x10^{-6}$	$1.20x10^{-6}$
15. Non-commercial, cracked eggs	None	8-log (RE)	0 (0)	0	0
16. Non-commercial, cracked eggs	**5-log**	**2-log (MR)**	**48 (54)**	**400**	**60**
17. Non-commercial, cracked eggs	5-log	5-log (SR)	31 (37)	0.4	$6.00x10^{-2}$
18. Non-commercial, cracked eggs	5-log	8-log (RE)	0 (0)	0	0
B. Consumed without pathogen reduction in raw egg drinks and cold desserts					
19. Commercial non-cracked eggs	None	None (NE)	29 (35)	$4x10^{-3}$	$2.34x10^{-1}$
20. Commercial, non-cracked eggs	**5-log**	**None (NE)**	**48 (54)**	**40**	**585**
21. Non-commercial, non-cracked eggs	None	None (NE)	32 (37)	$4x10^{-3}$	$7.20x10^{-2}$
22. Non-commercial, non-cracked eggs	**5-log**	**None (NE)**	**51 (57)**	**40**	**180**
23. Non-commercial, cracked eggs	None	None (NE)	27 (33)	0.4	$1.20x10^{-2}$
24. Non-commercial, cracked eggs	**5-log**	**None (NE)**	**44 (50)**	**400**	**12**
25. Non-commercial, cracked eggs in egg butter	**3-log**	**None (NE)**	**57 (62)**	**4**	**9**

Table 16 (continued)

Scenario	Pathogen growth	Pathogen reduction	Risk Rating Mild* (Moderate)	Predicted illnesses per million servings	Predicted annual illnesses
C. Commercial pulp					
26. Commercial, unpasteurised pulp	**1-log**	**None (NE)**	**51 (56)**	**250**	**10**
27. **Commercial, unpasteurised pulp**	**1-log**	2-log (SR)	41 (47)	$2.50x10^{0}$	$1.95x10^{-1}$
28. **Commercial, unpasteurised pulp**	**1-log**	5-log (RE)	24 (30)	$2.50x10^{-3}$	$2.44x10^{-4}$
29. **Commercial, unpasteurised pulp**	**1-log**	8-log (MR)	0 (0)	0	0
30. **Commercial, pasteurised pulp**	None	**None (NE)**	**38 (44)**	**0.2**	**9**
31. **Commercial, pasteurised pulp**	None	2-log (SR)	27 (33)	$2.00x10^{-3}$	$1.17x10^{-1}$
32. **Commercial, pasteurised pulp**	None	5-log (RE)	10 (16)	$2.00x10^{-6}$	$1.17x10^{-4}$
33. **Commercial, pasteurised pulp**	None	8-log (MR)	0 (0)	0	0

NE: No Effect **MR**: Moderated Reduction **SR**: Substantial Reduction **RE**: Reliably Eliminates

*Arbitrary aggregation of Risk Ranger rankings are: <40 – Low; 41-55 – Medium; >55 High.

For "Moderate" (Severity = II) Scenarios 22 & 26 the risk rating will increase from Medium to High

4.3 Qualitative Risk Rating Approach

This is a qualitative exercise with different hazard:product combinations being allocated a low, medium or high risk rating (ICMSF 2002: M Cole pers. comm. and FSA 2000).

In general, insufficient data is available to characterise risk according to risk assessment criteria (CAC 1999). For this reason, a qualitative approach for the rating of risk has been developed by the International Commission on Microbiological Specifications of Foods (ICMSF 2002, M. Cole, pers comm. and FSA 2000).

For the purpose of this project all egg and egg dish categories are listed. These are given a risk rating of low, medium or high (Table 17). The information used to arrive at a risk rating for each product is as follows:

Microbiological, Physical and Chemical Hazards

Microbiological, Physical and Chemical Hazards are identified in Chapters 3 on the basis of being a known hazard or potential hazard associated with specific egg or egg product.

Severity

The Severity of the identified hazards is classified according to the latest International Commission of the Microbiological Specifications of Food (ICMSF 2002: M Cole pers comm. and FSA 2000). The level of severity is defined as follows:

IA. Severe hazard for general population, life threatening or substantial chronic sequelae or long duration.

IB. Severe hazard for restricted populations, life threatening or substantial chronic sequelae or long duration.

II. High hazard; incapacitating but not life threatening; sequelae rare; moderate duration. (For Risk Ranger this equates to a “Moderate” input).

III. Moderate, not usually life threatening; no sequelae; normally short duration; symptoms are self limiting; can be severe discomfort**.** (For Risk Ranger this equates to a “Mild” input).

Microbiological hazards may have more than one severity rating depending on the population that consumes the product and the levels of the hazard or toxin in the product. For example, *Salmonella* spp. is rated as III in the general population, but when associated with infants less than 5 years old is rated IB. A severity rating of II was requested by stakeholders for comparison (Table 17).

Occurrence risk

Occurrence risk is classified as low, medium or high. The occurrence risk is the occurrence of microbial hazards in Australia. This is low for contents of non-cracked egg (Attachment 6) and medium for cracked eggs.

Growth

An indication of whether growth of the pathogen in the product is required to cause disease is given. In general, microbiological hazards need to grow in the product to produce an infective dose (Attachment 3).

Production, processing or handling of food

The production, processing or handling of the food may increase (↑), decrease (↓) or not affect (→) the hazard.

Consumer terminal step

Is a consumer terminal step, such as cooking, applied to the product? This is particularly important for eggs as egg meals may be cooked to varying degrees (Table 6).

Epidemiology

Is the hazard:product combination recorded as a cause of food poisoning?

Comments

Are there any other factors that may affect the risk rating of the hazard? For example *Salmonella* growth in eggs increases as the stability and defences of the yolk membrane decline (Attachment 3) with prolonged storage.

Derivation of Qualitative Risk Ratings

In the ICMSF approach (ICMSF 2002: M Cole pers comm. and FSA 2000) the process of arriving at the risk rating for each hazard:product combination was qualitative. Most emphasis was placed on a combination of the occurrence risk, potential for growth, the effect of consumer terminal step (i.e. little or no reduction during meal preparation). The severity of the hazard was considered to be the same for all scenarios considered. The epidemiological link is limited to scenarios where outbreaks indicate specific products, and is limited by many of the scenarios potentially causing sporadic cases which fall under the sensitivity of the public health surveillance system for detection. The approach also fails to take into consideration the volume of the product consumed.

For example in Scenario 4 (Table 17) a Medium rating results from the assumption of growth to an infective dose in older eggs stored at ambient temperature during processing and handling, with only a 2 log reduction in consumer terminal step.

For Scenario 25 a High rating resulted from a medium occurrence risk (assumes exposure of 75% of the population a few times a year to cracked eggs – Attachment 14, Table 14.8), an assumed 3 log increase in numbers due to temperature abuse and no consumer terminal step. Scenario 25 presents hypothetical circumstances where non-commercial, cracked eggs are used in “egg butter”. This is constructed to provide risk managers with an insight into the risk associated with this illegal use of eggs if it were to occur.

In contrast the risk rating of Scenario 24 is lower than Scenario 25, even though there is an assumed greater log increase. The reason for this is the assumption that only 5% of the population is exposed once every few years (Attachment 14, Table 14.7) i.e. low occurrence risk. The population exposed has a profound impact on risk rating. The consumption frequency and population exposed assumptions in Scenarios 24 and 25 also explain the higher Risk Ranking value for Scenario 25 when compared to Scenario 24. It should also be noted that Scenario 25 is a hypothetical sub-set of Scenario 23; cracked eggs sourced from non-commercial production systems, resulting in a lower population exposed.

Qualitative risk rating results for all scenarios is presented in Attachment 16, Table 16.1. Results for scenarios in which a medium or high rating was determined are presented in Table 17.

Table 17: Qualitative microbiological hazard risk rating for egg and egg products (ICMSF 2002: M Cole pers comm. and FSA 2000).

A. Subjected to pathogen reduction

Product*	**Severity**	**Occurr. Risk**	**Growth in product required to cause disease**	**Prod^{n}/process/ handling ↑↓→ hazard**	**Consumer terminal step**	**Epidem. link**	**Comments/ other factors affecting significance**	**Risk Rating****
A. Subjected to pathogen reduction								
1. Commercial, non-cracked eggs	III (II)	Low	Yes	→	Yes (2 log)	No		Low
2. Commercial, non-cracked eggs	III (II)	Low	Yes	→	Yes (5 log)	No		Low
3. Commercial, non-cracked eggs	III (II)	Low	Yes	→	Yes (>8 log)	No		Low
4. Commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	Yes (2 log)	No		Medium
5. Commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	Yes (5 log)	No		Low
6. Commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	Yes (8 log)	No		Low
7. Non-commercial, non-cracked eggs	III (II)	Low	Yes	→	Yes (2 log)	No		Low
8. Non-commercial, non-cracked eggs	III (II)	Low	Yes	→	Yes (5 log)	No		Low
9. Non-commercial, non-cracked eggs	III (II)	Low	Yes	→	Yes (>8 log)	No		Low

Product*	**Severity**	**Occurr. Risk**	**Growth in product required to cause disease**	**Prod^{n}/process/ handling ↑↓→ hazard**	**Consumer terminal step**	**Epidem. link**	**Comments/ other factors affecting significance**	**Risk Rating****
10. Non-commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	Yes (2 log)	No		Medium
11. Non-commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	Yes (5 log)	No		Low
12. Non-commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	Yes (>8 log)	No		Low
13. Non-commercial, cracked eggs	III (II)	Low	Yes	→	Yes (2 log)	No		Low
14. Non-commercial, cracked eggs	III (II)	Low	Yes	→	Yes (5 log)	No		Low
15. Non-commercial, cracked eggs	III (II)	Low	Yes	→	Yes (>8 log)	No		Low
16. Non-commercial, cracked eggs	III (II)	Medium	Yes	↑ (5 log)	Yes (2 log)	No		Medium
17. Non-commercial, cracked eggs	III (II)	Medium	Yes	↑ (5 log)	Yes (5 log)	No		Low
18. Non-commercial, cracked eggs	III (II)	Medium	Yes	↑ (5 log)	Yes (>8 log)	No		Low

Table 17 (cont): Qualitative microbiological hazard risk rating for egg and egg products (ICMSF 2002: M Cole pers comm. and FSA 2000)
B. Without pathogen reduction in raw egg drinks and cold desserts

Product*	Severity	Occurr. Risk	Growth in product required to cause disease	Prod^{n}/process/ handling ↑↓→ hazard	Consumer terminal step	Epidem. link	Comments/ other factors affecting significance	Risk Rating**
B. Without pathogen reduction in raw egg drinks and cold desserts								
19. Commercial non-cracked eggs	III (II)	Low	Yes	→	No	No		Low
20. Commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	No	Yes		Medium
21. Non-commercial, non-cracked eggs	III (II)	Low	Yes	→	No	No		Low
22. Non-commercial, non-cracked eggs	III (II)	Low	Yes	↑ (5 log)	No	No		Medium
23. Non-commercial, cracked eggs	III (II)	Medium	Yes	→	No	No		Low
24. Non-commercial, cracked eggs [A]	III (II)	Low	Yes	↑ (5 log)	No	Yes		Medium
25. Non-commercial, cracked eggs in egg butter [B]	III (II)	Medium	Yes	↑ (3 log)	No	Yes	Built around outbreaks but include assumptions	High

[A] Scenario 24 is lower than Scenario 25, even though there is an assumed greater log increase. The reason for this the assumptions that only 5% of the population is exposed once every few years (Attachment 14, Table 14.7) i.e. low occurrence risk.
[B] Scenario 25 has a High rating which results from a medium occurrence risk (assumes 75% of the exposed sub-population a few times a year are exposed to cracked eggs – Attachment 14, Table 14.8). Scenario 25 presents hypothetical circumstances where non-commercial, cracked eggs are used in "egg butter".

Table 17 (cont): Qualitative microbiological hazard risk rating for egg and egg products (ICMSF 2002: M Cole pers comm. and FSA 2000)
C. Commercial pulp

Product*	Severity	Occurr. Risk	Growth in product required to cause disease	Prod^{n}/process/ handling ↑↓→ hazard	Consumer terminal step	Epidem. link	Comments/ other factors affecting significance	Risk Rating**
C. Commercial pulp								
26. Commercial unpast pulp	III (II)	High	Yes	↑ (1 log)	No	Yes	Built around outbreaks but include assumptions	Medium
27. Commercial unpast pulp	III (II)	High	Yes	↑ (1 log)	Yes (2 log)	No		Medium
28. Commercial unpast pulp	III (II)	High	Yes	↑ (1 log)	Yes (5 log)	No		Low
29. Commercial unpast pulp	III (II)	High	Yes	↑ (1 log)	Yes (>8 log)	No		Low
30. Commercial past pulp	III (II)	Low	Yes	→	No	No		Low
31. Commercial past pulp	III (II)	Low	Yes	→	Yes (2 log)	No		Low
32. Commercial past pulp	III (II)	Low	Yes	→	Yes (5 log)	No		Low
33. Commercial past pulp	III (II)	Low	Yes	→	Yes (>8 log)	No		Low

* ICMSF approach does not take product volume into account though Occurrence Risk reflects a combination of the amount of product and likely combination etc
** Low risk rating mostly due to yes for 'consumer terminal step'
*** Arbitrary aggregation of Risk Ranger rankings are: <40 – Low; 41-55 – Medium; >55 High.
For "Moderate" (Severity = II) Scenarios 22 & 26 the risk rating will increase from Medium to High

4.4 Comparison of Risk Rating Approaches

A comparison of outputs from each risk rating approach is provided in Table 18. While concordance of results is evident, it is reliant on the arbitrary aggregation of Risk Ranger rankings as <40 – Low; 41-55 – Medium; >55 High. However, with Risk Ranger, risk increases ten times for each 6 points. Consequently, this greater discrimination of risk across the Medium category assists Risk Managers prioritise *Salmonella*:egg and egg product combinations for review or establishment of mitigations. Therefore, despite their appealing consensus-building properties, flexibility, and thoughtful process in input requirements, qualitative rating systems often do not provide sufficient information to discriminate accurately between quantitatively small and quantitatively large risks (Cox *et al.*, 2005).

Table 18: Comparison of risk ratings of eggs and egg-based meals by Risk Ranger and the Qualitative methods (Sources: Tables 14.1-10 and 16.1)

Scenario	Risk Ranger Rating (*)	Qualitative Risk Rating
A. Subjected to pathogen reduction		
1. Commercial, non-cracked eggs	24 (Low)	Low
2. Commercial, non-cracked eggs	7 (Low)	Low
3. Commercial, non-cracked eggs	0 (Low)	Low
4. Commercial, non-cracked eggs	**49 (Medium)**	**Medium**
5. Commercial, non-cracked eggs	32 (Low)	Low
6. Commercial, non-cracked eggs	0 (Low)	Low
7. Non-commercial, non-cracked eggs	24 (Low)	Low
8. Non-commercial, non-cracked eggs	7 (Low)	Low
9. Non-commercial, non-cracked eggs	0 (Low)	Low
10. Non-commercial, non-cracked eggs	**49 (Medium)**	**Medium**
11. Non-commercial, non-cracked eggs	32 (Low)	Low
12. Non-commercial, non-cracked eggs	0 (Low)	Low
13. Non-commercial, cracked eggs	22 (Low)	Low
14. Non-commercial, cracked eggs	0 (Low)	Low
15. Non-commercial, cracked eggs	0 (Low)	Low
16. Non-commercial, cracked eggs	**48 (Medium)**	**Medium**
17. Non-commercial, cracked eggs	31 (Low)	Low
18. Non-commercial, cracked eggs	0 (Low)	Low
B. Consumed without pathogen reduction in raw egg drinks and cold desserts		
19. Commercial non-cracked eggs	29 (Low)	Low
20. Commercial, non-cracked eggs	**48 (Medium)**	**Medium**
21. Non-commercial, non-cracked eggs	32 (Low)	Low
22. Non-commercial, non-cracked eggs	**51 (Medium)**	**Medium**
23. Non-commercial, cracked eggs	27 (Low)	Low
24. Non-commercial, cracked eggs	**44 (Medium)**	**Medium**
25. Non-commercial, cracked eggs in egg butter	**57 (High)**	**High**
C. Commercial pulp		
26. Commercial, unpasteurised pulp	**51 (Medium)**	**Medium**
27. Commercial, unpasteurised pulp	**41 (Medium)**	**Medium**
28. **Commercial, unpasteurised pulp**	24 (Low)	Low
29. **Commercial, unpasteurised pulp**	0 (Low)	Low
30. **Commercial, pasteurised pulp**	38 (Low)	Low
31. **Commercial, pasteurised pulp**	27 (Low)	Low
32. **Commercial, pasteurised pulp**	10 (Low)	Low
33. **Commercial, pasteurised pulp**	0 (Low)	Low

* Arbitrary aggregation of Risk Ranger rankings are: <40 – Low; 41-55 – Medium; >55 High.

5. Discussion and Conclusions

Objective 1. Identify public health hazards that enter any point of the food chain for eggs and egg products produced in Australia and **rank them in terms of risks to the consumer.**

5.1 Risk Ranking

The risk ratings and predicted illnesses per million servings for each *Salmonella*:egg meal and egg-based dish enabled comparison of "like with like" and ranking in terms of their relative importance. The predicted illnesses per annum provides an indication of overall burden, but does not include a multiplier for outbreaks. Unfortunately this quantitative spreadsheet approach does not enable the calculation of "credible ranges" for these estimates; this is best achieved using a quantitative risk model as developed in SAR-42A. An indication of the relative impact of changing various inputs (sensitivity analysis) is provided in Table 16 and Attachment 10.

A summary of risk ratings are presented in Table 16 and full inputs to Risk Ranger in Attachment 14. Low risk ratings were obtained for commercial eggs that had not undergone pathogen growth (YMT unresolved) when used for egg meals that were cooked in a manner that resulted in some pathogen reduction and no predicted illness. This scenario is estimated to apply to the bulk of shell-egg utilisation.

A medium risk rating (41-55) was obtained for eggs that had undergone pathogen growth (YMT resolved, enabling hazard growth in the yolk) which were used for egg meals and egg-based dishes which had been lightly cooked (2 log reduction e.g. poached and boiled still with liquid yolk and lightly scrambled). In this scenario, significant numbers of illnesses are predicted, depending on the source of the eggs[11]:

- Commercial non-cracked eggs – Scenario 4 (Risk Rating=49, predicted illnesses/10^6 servings=4, predicted illnesses 702/annum)
- Non-commercial non-cracked eggs – Scenario 10 (Risk Rating=49, predicted illnesses/10^6 servings=4, predicted illnesses 72/annum)
- Non-commercial cracked eggs – Scenario 16 (Risk Rating=48, predicted illnesses/10^6 servings=400, predicted illnesses 60/annum)

The target population differs for commercial and non-commercial use, with the former considered to embrace the entire Australian population and the latter an estimated 10% of the entire population. To place this into perspective, the predicted illnesses per million servings is shown in Table 16. This data indicates that use of cracked eggs presents a 100 fold increase in cases of salmonellosis when compared to non-cracked eggs (Scenarios 10 and 16).

For eggs used in foods in which the egg component was uncooked (e.g. raw egg drinks, cold desserts – Tables 6 and 9-14), there are a number of possible medium to high risk scenarios. All of these were associated with eggs in which pathogen growth in the shell egg had occurred (YMT resolved). The implicated egg source and scenarios are as follows:

- Commercial non-cracked eggs – Scenario 20 (Risk Rating=48, predicted illnesses/10^6 servings=40, predicted illnesses 585/annum)
- Non-commercial non-cracked eggs – Scenario 22 (Risk Rating=51, predicted illnesses/10^6 servings=40, predicted illnesses 180/annum)
- Non-commercial cracked eggs – Scenario 24 (Risk Rating=44, predicted illnesses/10^6 servings=400, predicted illnesses 12/annum)

[11] Note that commercial cracked eggs cannot legally be sold and therefore are not considered for this scenario set.

- Non-commercial, cracked eggs used for egg butter – Scenario 25 (Risk Rating=57, predicted illnesses/10^6 servings=4, predicted illnesses 9/annum)
- Unpasteurised pulp used in cold puddings – Scenario 26 (Risk Rating=51, predicted illnesses/10^6 servings=250, predicted illnesses 10/annum)
- Commercial pulp (0.2% contaminated) used in cold puddings – Scenario 30 (Risk Rating=38, predicted illnesses/10^6 servings=0.2, predicted illnesses 9/annum)

Note that Scenarios 25 and 26 represent circumstances associated with well-publicised outbreaks (see Attachment 14). In Scenario 25 egg butter (egg and oil emulsion) was implicated in an outbreak of salmonellosis as an ingredient of pork rolls made in a restaurant in Melbourne. More than 100 illnesses and one death resulted from this outbreak. Scenario 25 assumed that:

- Most consumers (75% of a relatively small population size of 10,000) consume product a few times a year
- Cracked, non-commercial eggs are used as the source

Because the butter needs to be warm to spread easily, some temperature:time abuse is likely and has been assumed in the calculation of risk rating.

Cold desserts containing egg/egg product have been responsible for several hundred illnesses aboard flights leaving an Australian airport. Scenario 26 is built around anecdotal evidence that around 500kg of unpasteurised egg pulp enters the food service sector each week in one area of Australia (the scenario spreads this product among an assumed localised population of 130,000).

The foregoing discussion relates to direct exposure resulting from contaminated egg contents. The relative contribution from contamination from the surface of shell eggs is unknown. In Australia the estimated prevalence of *Salmonella* that contaminate the shell surface of ungraded and graded (washed) eggs was found to be 0%, with an upper 95% Confidence Interval of 0.2% and 0.06%, respectively (Attachment 6). While data on concentration is not published and the viability of *Salmonella* on the shell surface declines with drying (Nasim *et al.*, 1982) and washing (Attachment 15), it is likely that the level will be below an infective dose. In this circumstance, the capacity of bacteria on the shell surface to cause illness relies on cross-contamination of uncooked foods or cooked foods combined with temperature abuse sufficient to allow growth to a level that contains an infective dose. This source of risk has not been rated in this project due to critical uncertainties in relation to cross-contamination (discussed in Section 3). For similar reasons, the role of cross-contamination of dishes containing eggs by *Salmonella* from other ingredients, the food preparation environment or food preparers, cannot be estimated. Nevertheless, these factors are indicated as issues in many outbreaks (Section 3 and Attachment 11).

The risk presented by barn laid and free-range eggs is uncertain (reviewed in Attachment 3) as comprehensive data is unavailable. For non-cage egg production systems, the combined effects of a potential increase in prevalence of *Salmonella* for egg contents, and potential increases in egg production are estimated in Attachment 10 (Figure 10.2). These estimates can be used to provide a perspective of the impact on risk if these variables were to change. However, it is recognised that better data is needed.

Furthermore, a sensitivity analysis is provided in Attachment 10 to indicate to risk managers the relative impact of changing inputs to Risk Ranger on the risk rating, predicted illnesses per million servings and predicted illnesses per annum.

One critical assumption of this risk profile, is that the prevalence of contamination of egg contents remains the same irrespective of the commercial production system used (i.e. cage, barn laid and free range). It is also assumed that penetration of the shell by *Salmonella* may occur in the first hours post-lay and that the bacteria migrate from contaminated faeces on the shell surface (Sparks 1985; Sparks and Broad 1985). The ratio between the prevalence of *Salmonella* contamination of the shell surface of ungraded eggs and that of contents of ungraded and graded eggs may be inferred from

industry data to be, approximately 50:1 and 100:1, respectively (see Attachment 6, Table 6.2). Similar data for barn laid and free range eggs are unavailable, but would assist risk assessment of eggs laid from these alternative production systems (see Section 5.1). If the prevalence of *Salmonella* for these alternative systems is greater than that for cage produced eggs, the associated food safety risk should be reviewed in the context of adoption of alternative production systems. On this basis it is recommended that further risk analysis be undertaken to determine the impact of adoption of non-cage production systems on food safety (Section 6).

The assumptions that all *Salmonella* serovars (excluding *S.* Sofia) represent potential risk to the industry and that for the purpose of this risk analysis that all are of equivalent virulence was considered by stakeholders at the workshops to be of considerable significance. It was reported (Peter Scott pers. comm.) that there is a tendency within industry to disregard all isolations except for *S.* Typhimurium, and that this may lead to underestimation of risk.

There is an increased risk that results from the use of cracked non-commercial eggs compared with intact non-commercial eggs. This is evident from a 100 fold increase in predicted illnesses per million servings when these eggs are used for meals subjected to cooking that results in only a slight reduction of hazard (Table 16, Scenarios 10 and 16). A 10x increase in illnesses per million servings is predicted when cracked versus non-cracked eggs are used in raw egg drinks and cold desserts (Scenarios 22 and 24). Todd (1996) found an increased risk of outbreaks of 3 – 90 times when cracked eggs were used.

At Workshop 2 industry stakeholders requested that the risk of eggs cracked in transit after washing/grading should be assessed. It is predicted that between 1 – 2 cases of salmonellosis per year may result from this outcome (Attachment 14).

If *Salmonella* Enteritidis became endemic in Australia the level of risk has been estimated to increase. If the same Risk Ranger inputs in Sections 3.2 and 3.3 were used with an estimated 10 fold increase in prevalence of *Salmonella* in egg contents (Attachment 6), the Risk Rating would increase by 6 units for shell egg scenarios (Table 16) and the predicted illnesses per annum and per million servings would increase by 10x. This increased risk may warrant additional risk management control strategies to be considered. However, this estimate would be more rigorous with knowledge of time and temperature handling of eggs from lay to retail (and probably consumption).

5.2 Uncertainties and R&D

Areas of uncertainty (data gaps) and the associated R&D that might be considered to improve the reliability of risk estimates are:

- Source of *Salmonella* Typhimurium – As reviewed in Section 3.1 and SAR-42A there is considerable uncertainty about the source of *S.* Typhimurium in egg pulp. More recent data (Table 5 and Section 3.1) may indicate regional differences in isolation rates exist. Industry adoption of the proposed SE monitoring program (Attachment 15) could lead to collection of data to fill this knowledge gap. (Information on all serovars of *Salmonella* isolated from all regions would be extremely valuable for assessing risk associated with graded shell eggs.) Serotype and phage typing data obtained for all isolates as part of routine post-processing QA would also provide valuable information for risk assessment purposes.
- Risk associated with non-cage egg production systems – The number of *Salmonella* that contaminate the shell surface before the barrier effect of the cuticle is established (Sparks 1985; Sparks and Broad 1987; Attachment 15), is an important determinant of contamination of the contents of barn laid and free range eggs. The lack of information about contamination of the shell surface of ungraded eggs from non-cage systems, limits this assessment (Attachment 10). However, the cost of obtaining this data is likely to be prohibitive. Alternatively, it may be possible to use ratios (surface:contents) from Attachment 6, Table 6.2 to infer prevalence of

contaminants in egg contents from these layer systems. Data from broiler breeder operations may also provide a useful insight.

- The time:temperature profile of eggs post egg grading floor to retail – This affects the proportion of contaminated eggs that might support growth in the yolk (see Section 5.1), particularly for high volume shell egg use pathways (Table 16, Scenario 4) where incomplete cooking fails to overcome contamination in eggs where growth has occurred due to the Yolk Mean Time being exceeded. If this data were available (through the use of temperature loggers) it could be utilised in more sophisticated quantitative predictive models (as developed in AECL Project SAR-42A) to better quantify risk and its credible range. Such information is considered essential for a rigorous risk analysis of *Salmonella* Enteritidis in the Australian context.
- Effect of food matrix on infective dose – A lower infective dose may apply with the ingestion of fatty foods (eg egg butter). Allowance for this effect is best achieved within a quantitative risk model (as developed in AECL Project SAR-42A).
- Effect of egg washing on internal contamination – Egg washing was widely used by egg processors in Australia in 2002 (Attachment 15). Data describing the efficacy of washing procedures in terms of reduction of surface contaminants was not collected. It is not known whether washing procedures are consistent with reduction of bacterial contamination or indicative of conditions that might lead to increased internal contamination (Attachment 15). The impact of improper washing on risk is predicted in Attachment 10, however, data is required.

5.3 Sensitivity Analysis

A sensitivity analysis has been provided to illustrate how Risk Ranger inputs influence the three outputs: the Risk Ranking, the predicted illnesses per year and the predicted number of illnesses per million serving (Attachment 10). For each of the 10 Risk Ranger questions the numerical values were varied by a factor of 10 (eg Hazard Severity was changed from Mild to Moderate and Minor, see Ross and Sumner, 2002 Attachment 10, Table 10.1) and the changes in the outputs recorded. Summaries of the sensitivity analysis for two scenarios, where yolk growth has not occurred and cooking occurs during preparation (Scenario 1) and where yolk growth has occurred and no inactivation occurs during preparation (scenario 20), are presented in Attachment 10, Tables 10.2 and 10.3. The two scenarios (1 and 20) were selected as they represent egg utilisation pathways for a low dose (Scenario 1) and a high dose (Scenario 20).

A factor of 10 change in inputs was chosen for the sensitivity analysis as many of the weighting factors are set as 10-fold increments (eg Hazard severity). Also, as a 6 unit change in the Risk Ranking corresponds approximately to a factor of 10 difference in the absolute risk estimate, it is simple to assess the outputs using 10-fold changes in input values. Each factor was changed one at a time.

The effect of Q8 Potential for recontamination for shell eggs has not been considered in this analysis as it depends on the combined values of Q6 and 7. In relation to the efficacy of current washing practices this has been identified as an area that might be considered for further risk analysis.

The effect of Q8 Potential for recontamination of pasteurised commercial pulp has been considered in Attachment 16, Table 16.1 (Scenarios 30-33).

Recontamination in the context of cross-contamination of egg dishes from other ingredients or the food preparation environment/process has not been included due to this being essentially unrelated to eggs and the lack of information on its' incidence, though it is likely to occur (Attachment 11).

In both scenarios the population size has no influence on the Risk Ranking. This is because the Risk Ranking is independent of population size and reflects the relative risk to an individual within a population. For the low dose scenario all other inputs result in a 6 unit change in the Risk Ranking.

For the high dose scenario the dose consumed is greater than the median infective dose, ID_{50}. As a result all of those people consuming a contaminated serving will become ill.

5.4 Conclusions

Given uncertainty around the dose response information, users of this report are urged to place greatest emphasis on the relativity of the risk ratings for the scenarios considered. This provides a standardised basis that considers the elements of likelihood and severity (Ross and Sumner, 2002) on which to prioritise early risk management responses and R&D priorities.

While such scenario analysis provides opportunity for large risk models, it brings uncertainty, particularly in relation to dose response information. As a result the predicted number of illnesses should be used to compare scenarios only. However, "what may be more important than an absolute measure of risk is the relative *change* in magnitude of risk outcomes resulting from changing some parameter in the food chain" (Lammerding, 2005).

This Risk Profiling approach is strongly supported by the Codex Alimentarius Commission, Committee on Food Hygiene which has recently updated its' guidelines for Risk Management (CCFH 05/37/6 Annex II). In this framework commodity Risk Managers are advised to initially conduct a Risk Profile that may provide sufficient information to take an immediate and/or provisional decision. Alternatively it may indicate priorities for further data gathering or provide a mandate for risk assessors.

6. Implications and Recommendations: Risk Management Priorities

Project objectives 2, 3 and 4 are addressed in this section.

Objective 2. Identify hazards of potentially high risk where too little information exists for a confident ranking of risk.

- Risk from *Salmonella* in non-cage production systems – information about serovars, phage types and egg shell prevalence (to infer prevalence in contents – see Section 5.1)
- No other recognised microbial hazards were identified (Section 3.1)
- Chemicals in use for which no Maximum Residue Level or Acceptable Daily Intake established (potential hazards - Attachment 13).

Objective 3. Identify potential management strategies for the identified hazards.

The implications and recommendations for the identified medium to high risk combinations are presented as options for industry risk managers to consider.

(A) Commercial, non-cracked eggs where growth is assumed to have been possible due to the expiry of the yolk membrane defences when lightly cooked (Scenario 4) or used in raw egg drinks and uncooked desserts (Scenario 20) present a higher risk. The higher risk rating is a result of the combination of the large volume of eggs used in this end-use pathway and the fact that reduction in numbers of contaminants during meal preparation is either incomplete or negligible. Potential control options (Recommendations) are:

- Management of the shell egg cool chain at 16^0C from lay to retail, with the bulk of eggs targeted for consumption or consumer refrigerated storage by 25 days post-lay. This target could be reinforced by labelling of egg cartons with "best before" dates to promote this timeframe.
- Implementation of education and/or audited quality programs for caterers, particularly those which service institutions. These programs should emphasise adoption of egg preparation methods that eliminate presence of liquid yolk, and promote use of pasteurised egg products for dishes containing uncooked egg.
- Encourage all processors to stamp Julian dates on all eggs to verify grading (i.e. as confirmation of removal of off-farm cracked eggs and as a method for the food industry to ensure non-commercial eggs are avoided).

(***B) Non-commercial, non-cracked eggs have a higher risk rating when growth is assumed (YMT resolved) and meal preparation results in only slight reduction of numbers of contaminants (Scenario 10).*** While the risk rating is medium the number of predicted illnesses is reduced due to lower exposure (being independent of population exposed). Potential control options (Recommendations) are:

- These eggs should not be used by caterers (industry feedback indicates a significant proportion of these non-commercial eggs are used in catering).
- Catering HACCP plans should prevent use of these eggs. Being ungraded, by definition (Attachment 1) they will contain cracked eggs, the use of which is illegal (see Scenario 16).

(C) Non-commercial cracked eggs are higher risk when growth is assumed to have occurred (YMT resolved) and meal preparation results in only slight reduction of numbers of contaminants (Scenario 16). Potential control options (Recommendations) are:

- These findings support the intent of the FSANZ Standard 2.2.2 Egg and Egg Products.

- Jurisdictions should develop programs (e.g. education, audits) with industry, caterers and food manufacturers to ensure cracked eggs are not used illegally.
- Backyard/non-commercial producers should be advised to discard cracked eggs.

(D) Non-commercial, non-cracked eggs are higher risk when growth is assumed to have occurred and these eggs are used in raw egg drinks and cold desserts (Scenario 22). Potential control options (Recommendations) are:

- Education to non-commercial producers to keep eggs refrigerated at all times.
- Catering HACCP plans should reject use of these eggs.

(E) Non-commercial, cracked eggs are higher risk when growth is assumed to have occurred and these eggs are used in raw egg drinks and cold desserts (Scenario 24). Potential control options (Recommendations) are:

- These findings support the intent of the FSANZ Standard 2.2.2 Egg and Egg Products.
- Jurisdictions should develop programs (e.g. education, audits) with industry, caterers and food manufacturers to ensure cracked eggs are not used illegally.
- Backyard/non-commercial producers should be advised to discard cracked eggs.

Preliminary data indicates the prevalence of *Salmonella* in the Australian egg industry is low on-farm (Attachment 9.1) and on eggs (Attachment 6). This report endorses current and proposed industry schemes to ensure *Salmonella* levels remain low (NEQAP, Attachment 15) and are monitored (SE Surveillance Program, Attachment 15).

Objective 4. Identify product:pathogen combinations in which further risk analysis might be required.

In the context of salmonellosis, priorities for consideration include:

- Evaluate the food safety risk resulting from the implementation of non-cage egg production systems (Section 5.1; Attachment 10)
- Use time:temperature data post-grading floor to retail to improve the reliability of Quantitative Risk models (as per AECL Project SAR-42A). Robust models will enable a more reliable identification of risk and credible ranges resulting from marketing practices in Australia (Section 3.3 and Attachment 3)
- Comparison of risk from unwashed and washed shell eggs under Australian commercial industry production and processing conditions (Attachments 10 and 15)
- *Salmonella* Enteritidis and shell eggs: this would utilise some of this data but would specifically require data on time:temperature handling of eggs from lay to retail (and possibly consumption).

7. References

ACMSF (Advisory Committee on the Microbiological Safety of Food) (2000) In-shell egg pasteurisation. Thirty eighth meeting of the Advisory Committee on the Microbiological Safety of Food. ACM/490. http://archive.food.gov.uk/pdf_files/papers/acm490.pdf (last viewed September 3, 2004)

Ali MR, Borhanuddin M, Rahman MM, Choudhury KA (1987) Incidence of microorganisms in market shell eggs and their impact on public health. Bangladesh Veterinary Journal 21, 9-13.

Allen JG, Creeper JH, Forshaw D, Kabay MJ, Main DC Richards RB (2002) Plant-associated Diseases, Either New or New to the State, Encountered over the Last Decade (1991-2001) in Western Australia. In Proceedings of the 6th International Symposium on Poisonous Plants (Ed. T. Acamovitch *et al*.) CABI Press, in press.

Anon (2000) Foodborne botulism from eating home-pickled eggs – Illinois, 1997. MMWR 49(34):778-780

Anon (2000) Australian Government Response to the Report of the JETACAR. Commonwealth Department of Health and Aged Care, Commonwealth Department of Agriculture, Fisheries and Forestry - Australia. August 2000. Accessed at http://www.health.gov.au/pubhlth/strateg/jetacar/index.htm

Anon (2004) Egg Residue ELISA. ELISA Systems, Windsor, Queensland

ANZFA (1996) The Australian market basket survey 1996. Australian New Zealand Food Authority, Canberra.

ANZFA (1997) Corynetoxins: A toxicological review. Australia New Zealand Food Authority.

ANZFA (1999) Proposal P158 – Review of the maximum permitted concentrations of non-metals in food (April 1999)

ANZFA (2000) Phomopsins in Food: A Toxicological review and risk assessment (May 2000)

ANZFA (2001) The 19th Australian Total Diet Survey. Australian New Zealand Food Authority, Canberra.

ASM (American Society for Microbiology) (1999) Antimicrobial resistance an ecological perspective. American Society for Microbiology, Washington, DC.

Australian Egg Industry Association (1998) Code of Practice for the manufacture of egg products. Issued 6th July 1998

Australian Egg Industry Association (1998) Code of Practice for shell egg, production, grading, packing and distribution. Issued 6th July 1998

AVPA (2001) Code of Practice for the Use of Antibiotics in the Poultry Industry. Australian Veterinary Poultry Association Accessed at http://www.jcu.edu.au/school/bms/avpa/code_of_prac_jul_2001.pdf

Baker RC, Goff JP, Mulnix EJ (1980) Salmonellae recovery following oral and intravenous inoculation of laying hens. Poultry Science, 59 (5), 1067-72.

Baker RC, Goff JP, Timoney JF (1980) Prevalence of salmonellae on eggs from poultry farms in New York State. Poultry Science, 59, 289-92

Baker RC, Quereshi RA, Sandhu TS, Timoney JF (1985) The frequency of salmonellae on duck eggs. Poultry Science, 64, 646-652.

Baron F, Gautier M, Brule G (1997) Factors involved in the inhibition of growth of *Salmonella* enteritidis in liquid egg white. Journal of Food Protection, 60, 1318-1323.

Bates CJ, Spencer RC (1995) Survival of *Salmonella* species in eggs poached using a microwave oven. Journal of Hospital Infection, 29, 121-127

Bemrah N, Sara M, Cassin MH, Griffiths MW, Cerf O (1999) Quantitative risk assessment of human listeriosis from consumption of soft cheese made from raw milk. Preventive Veterinary Medicine, 37, 129-145.

Bintvihok A, Thiengnin S, Doi K, Kumagai S (2002) Residues of aflatoxins in the liver, muscle and eggs of domestic fowls. J. Vet. Med. Sci., 64, 1037-1039.

Blumer C, Roche P, Spencer J, Lin M, Milton A, Bunn C, Gidding H, Kaldor J, Kirk M, Hall R, Della-Porta T, Leader R, Wright P (2003) Australia's notifiable diseases status, 2001: Annual

Report of the Natonal Notifiable Diseases Surveillance System. Communicable Diseases Intelligence, 27, 1-78.
Bourke CA, Carrigan MJ (1993) Experimental tunicamycin poisoning in cattle, sheep and pigs. Aust. Vet. J 70, 188 – 189.
Brackett RE, Beuchat LR (1992) Survival of *Listeria monocytogenes* on the surface of egg shells and during frying of whole and scrambled eggs. Journal of Food Protection, 55, 862-865.
Bruce J, Drysdale L (1994) Trans-shell transmission, In: Board, R.G., Fuller, R. (Eds.) Microbiology of the avian egg. Chapman and Hall, London, pp. 63-91.
Bryden WL, Trengove CL, Davis EO, Giesecke PR, Curran GC (1994) Corynetoxicosis of livestock: A nematode-bacterium disease complex associated with different grasses. In: Colegate SM and Dorling PR (eds) Plant-associated Toxins: Agricultural, Phytochemical and Ecological Aspects, CAB International, Wallingford UK, pp.410-415.
Buchanan RL, Dennis S, Miliotis M (2004). Initiating and managing risk assessments within a risk analysis framework: FDA/CFSAN's practical approach. Journal of Food Protection, 67 (9), 1824-1828.
Chaudhary A, Gupta LK, Sharma S (1989) Penetration of *Campylobacter jejuni* at different storage temperatures in membranes and contents of cracked eggs. MIRCEN Journal 5, 199-204.
Chowdhury SPC, Bhattacharyya AK, Gupta PD (1976) Studies on incidence of *Salmonella* in egg shell of duck. Indian Journal of Animal Health 15, 169.
Codex Alimentarius Commission (1999) Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL 30
Codex Alimentarius Commission (2001) Report of the 34th Session of the Codex Committee on Food Hygiene. Codex CX/FH 01/7-Alinorm 03/13
Codex Alimentarius Commission (2002) Proposed draft principles and guidelines for the conduct of microbiological risk management (at step 3 of the procedure). CX/FH 03/7. Joint FAO/WHO Food Standards Programme.
Codex Alimentarius Commission (2003) Proposed draft process by which the Codex Committee on Food Hygiene could undertake its work in microbiological risk assessment/risk management. CX/FH 03/6. Joint FAO/WHO Food Standards Programme.
Codex Alimentarius Commission (2004a) Annex II. Iterative process between the Codex committee on food hygiene and the FAO/WHO joint expert group on microbiological risk assessment (JEMRA) for the conduct of microbiological risk assessment. In: Report of the 36th session of the Codex Committee on food hygiene. Alinorm 04/27/13. FAO/WHO, Washington.
Codex Alimentarius Commission (2004b) Proposed draft principles and guidelines for the conduct of microbiological risk management. CX/FH 04/6. MRM Drafting Group of the Codex Committee on Food Hygiene, Brussels. 28-30 September 2004
Codex Alimentarius Commission (2005) Joint FAO/WHO Food Standards Programme Codex Committee on Food Hygiene, 37th Session, Buenos Aires, Argentina, March 14-19, 2005 http://www.codexalimentarius.net/web/reports.jsp?lang=en <http://www.codexalimentarius.net/download/report/638/al28_13e.pdf>.
Cogan TA, Domingue G, Lappin-Scott HM, Benson CE, Woodward MJ, Humphrey TJ (2001) Growth of *Salmonella* enteritidis in artificially contaminated eggs: the effects of inoculum size and suspending media. International Journal of Food Microbiology, 70 131-141.
Cogan TA, Jorgensen F, Lappin-Scott HM, Benson CE, Woodward MJ, Humphrey TJ (2004) Flagella and curli fimbriae are important for the growth of *Salmonella* enterica serovars in hen eggs. Microbiology 150, 1063-1071.
Colegate SM, Edgar JA, Stegelmeier BL (1998) Plant-associated Toxins in the Human Food Supply, in Environmental Toxicology : Current Developments (Ed. J. Rose), Gordon and Breach Science Publishers, pp 317 – 344.
Coutts JA, Wilson GC (1990) Egg Quality Handbook. Pig and Poultry Branch, Qld Dept of Primary Industries.
Cox JM (1993) *Salmonella enteritidis* – the threat, better defined. In: Ninth Australian Poultry and Feed Convention. Gold Coast, Queensland. pp216-222
Cox JM (2001) Eggs and Egg Products. In: Spoilage of Processed Foods: Causes and Diagnosis. AIFST Inc (NSW Branch) Food Microbiology Group. NSW

Cox JM, Woolcock JB, Sartor AL (2002) The significance of *Salmonella*, particularly *S.* infantis, to the Australian Egg Industry. RIRDC Project Report No. UQ-19E.

Cox LA, Babayev D, Huber W (2005) Some limitations of qualitative risk rating systems. Risk Analysis, 25, 651-662.

Daenicke S, Ueberschaer K-H, Halle I, Mattes S, Valenta H, Flachowsky G (2002) Effect of addition of a detoxifying agent to laying hen diets containing uncontaminated or Fusarium toxin-contaminated maize on performance of hens and on carryover of zearalenone. Poultry Science, 81(11), 1671-1680.

DANMAP (2002) Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food of animals, foods and humans in Denmark. Danish Institute for Food and Veterinary Research. ISSN 1600-2032. Available from http://www.dfvf.dk/Files/Filer/Zoonosecentret/Publikationer/Danmap/Danmap_2002.pdf

D'Aoust JY (1994) *Salmonella* and the international food trade. International Journal of Food Microbiology, 24(1-2), 11-31.

Dawson RC, Cox JM, Almond A, Moses A (2001) Food Safety Risk Management in Different Egg Production Systems (RIRDC Publication No 01/111).

De Buck J, Van Immerseel F, Haesebrouck F, Ducatelle R (2004). Colonization of the chicken reproductive tract and egg contamination by Salmonella. Journal of Applied Microbiology, 97 233-245.

de Louvois J (1994) *Salmonella* contamination of stored hens eggs PHLS Microbiology Digest 11: 203-205.

D'Mello JPF, MacDonald AMC (1998) Fungal Toxins as Disease Elicitors, in Environmental Toxicology : Current Developments (Ed. J. Rose), Gordon and Breach Science Publishers, pp 317 – 344.

Dorner JW, Cole RJ, Erlington DJ, Suksupath S, McDowell GH, Bryden WL (1994) Cyclopiazonic acid Residues in Milk and Eggs. Journal of Agriculture and Food Chemistry, 42(7), 1516-1518.

Dunlop RH, McEwen SA, Meek AH, Clarke RC, Black WD, Friendship RM (1998) Associations among antimicrobial drug treatments and antimicrobial resistance of fecal *Escherichia coli* of swine on 24 farrow-to-finish farms in Ontario, Canada. Preventive Veterinary Medicine; 34:283-305.

Edgar JA, Frahn JL, Cockrum PA, Anderton N, Jago MV, Culvenor CCJ, Jones AJ, Murray K, Shaw KL (1982) Corynetoxins, causative agents of annual ryegrass toxicity; their identification as tunicamycin group antibiotics. Journal of the Chemical Society, Chemical Communications, 222-224.

Edgar JA, Smith LW (2000) Transfer of Pyrrolizidine Alkaloids into Eggs: Food Safety Implications, In Proceedings of the 3rd International Symposium on Natural Toxins (Gaffield W and Tu E, Eds), Boston, USA, ACS Symposia, pp. 118 - 128.

Eggesbø M, Botten G, Halvorsen R, Magnus P (2001) The prevalence of allergy to egg: a population-based study in young children. Allergy 56, 403-411.

Erdogrul OT, Ozkan N, Cakiroglu E (2002) *Salmonella* enteritidis in quail eggs. Turk Veterinerlik ve Hayvancilik Dergisi 26, 321-323.

Eroksuz H, Eroksuz Y, Ozer H, Yaman I, Tosun F, Akyuz Kizilay C, Tamer U (2003) Toxicity of *Senecio vernalis* to laying hens and evaluation of residues in eggs. Vet. Human Toxicol., 45(2), 76-80.

Everist SL (1974) In: *Poisonous Plants of Australia, 2nd Edition*, Angus&Robertson.

Fatma AM, Bastawrows AF, Abd-El-Gawad AM, Nawal GK (2001) Bacteriological studies on the causative agents of low hatchability and infertility of quail eggs in Assiut Governorate. Assiut Veterinary Medical Journal 44, 257-274.

Finch MJ, Blake RA (1985) Foodborne outbreaks of Campylobacteriosis: the United States experience. Am J Epidem 122(2), 262-268

FDA (2001) Food labelling: safe handling statements, labeling of shell eggs; refrigeration of shell eggs held for retail distribution. Small entity compliance guide (US Food and Drug Administration. Center for Food Safety and Applied Nutrition). www.cfsan.fda.gov/~dms/eggsguid.html (last viewed September 3, 2004)

FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment, Geneva, 1-5 December 2003. Accessed at http://www.who.int/foodsafety/publications/micro/nov2003/en/

FAO/OIE/WHO 2nd Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Management Options, Oslo, Norway, 15-18 March 2004. Accessed at http://www.who.int/foodsafety/publications/micro/mar04/en/

FAO/WHO (2002) Risk assessments of *Salmonella* in eggs and broiler chickens.

FDA/FSIS (2000) Risk Assessment of the Public Health Impact of Foodborne *Listeria monocytogenes*.

FSA (2000) Final Report - Scoping study on the risk of plant products (SafeFood NSW).

FSANZ (Food Standards Australia New Zealand). (2003).The 20th Australian Total Diet Survey. Food Standards Australia New Zealand, Canberra.

FSANZ (Food Standards Australia New Zealand). (2004a) Food Labelling Issues: Quantitative consumer survey on allergen labelling. Evaluation report series no. 7. February 2004. Food Standards Australia New Zealand, Canberra.

FSANZ (Food Standards Australia New Zealand). (2004b) Food Standards Code. Accessed August 2004. http://www.foodstandards.gov.au/foodstandardscode/

Gast RK, Holt PS (2000) Influence of the level and location of contamination on the multiplication of *Salmonella* enteritidis at different storage temperatures. Poultry Science, 79 559-563.

Gast RK, Holt PS (2001) Multiplication in egg yolk and survival in egg albumen of *Salmonella* enterica serotype enteritidis strains of phage types 4, 8, 13a, and 14b. Journal of Food Protection, 64 (6), 865-868.

Gaul KL, Gallagher PF, Reyes D, Stasi S, Edgar JA (1994) Poisoning of pigs and poultry by stock feed contaminated with heliotrope seed, in Plant-associated Toxins: Agricultural, Phytochemical and Ecological Aspects, Colegate, S.M. and Dorling, P.R., Eds, CAB International, UK, Chapter 26, 137.

Ghosh H, Das R, Batabyal K (2002) Identification and antibiogram of *Salmonella* enteritidis from duck and hen eggs. Indian Journal of Poultry Science 37, 301-302.

Grimes T, Jackson C (2001) Code of practice for biosecurity in the egg industry. RIRDC Publication No. 01/102. Project No. MS001-02

Hill DJ, Hosking CS, Zhie CY, Leung R, Baratwidjaja K, Iikura Y (1997). The frequency of food allergy in Australia and Asia. Environ Toxicol Pharmacol, 4 101-10.

Hou H, Singh RK, Muriana PM (1995) Pasteurization of shell eggs for salmonella reduction using water bath and hot air oven heating. In: Proc Inst Food Technol. Book of Abstracts, p. 146.

Horn R (2004) Australian Egg Industry Annual Statistical Publication 2003. Australian Egg Corportion Ltd. Publication No. 04/01. Project No. ROW-1A

Humphrey TJ, Greenwood M, Gilbert RJ, Rowe B, Chapman PA (1989) The survival of salmonellas in shell eggs cooked under simulated domestic conditions. Epidemiol Infect 103, 35-45.

Humphrey TJ, Whitehead A, Gawler AH, Henley A, Rowe B (1991) Numbers of *Salmonella* enteritidis in the contents of naturally contaminated hens' eggs. Epidemiology and Infection, 106(3), 489-496.

Humphrey TJ (1994) Contamination of egg shell and contents with *Salmonella* enteritidis: a review. International Journal of Food Microbiology 21, 31-40.

Hungerford TG (1969) Disease of Poultry including Cage Birds and Pigeons. Angus and Robertson. Sydney

Hutchison ML, Gittins J, Walker A, Moore A, Burton C, Sparks N (2003) Washing table eggs: a review of the scientific and engineering issues. World's Poultry Science Journal. 59:233-248.

ICMSF (2002) Microorganisms in Foods: 7 Microbiological testing in food safety management. Kluwer Academic/Plenum Publishers, New York.

IMVS (2004) Food Safety Summary April – June 2004. Food and Environmental Laboratory.

Indar L, Baccus-Taylor G, Commissiong E, Prabhakar P, Reid H (1998) Salmonellosis in Trinidad: evidence for transovarian transmission of *Salmonella* in farm eggs. West Indian Med J, 47 (2), 50-53.

Jago MV, Payne AL, Peterson JE, Bagust TJ (1983) Inhibition of glycosylation by corynetoxin, the causative agent of annual ryegrass toxicity: a comparison with tunicamycin. Chemical and Biological Interactions 45, 223-234.

Jago MV, Culvenor CCJ (1987) Tunicamycin and corynetoxin poisoning in sheep. Australian Veterinary Journal 64, 232-235.

JETACAR. (1999) The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans. Commonwealth Department of Health and Aged Care, Commonwealth Department of Agriculture, Fisheries and Forestry, Canberra.

Ji TJ, Chang CW, Tsai JJ, Chen WC (1999) Relation of different food allergens to different age of asthmatic patients. Journal of Microbiology, Immunology and Infection 32, 47-51.

Juchet A, Chabbert-Broue A, Micheau P, Piot M, Bremont F (2003) Natural history of food allergy in children. Revue Francaise d'Allergologie et d'Immunologie Clinique 43, 186-191.

Keller LH, Schifferli DM, Benson CE, Aslam S, Eckroade RJ (1997) Invasion of chicken reproductive tissues and forming eggs is not unique to *Salmonella* Enteritidis. Avian Dis. 41, 535-539.

Kingston DJ (1981) A comparison of culturing drag swabs and litter for identification of infections with *Salmonella* spp. in commercial chicken flocks. Avian Diseases, 25 (2), 513-516.

Kollowa T, Kollowa C (1989) Occurrence and survival of *Campylobacter jejuni* on the shell surface of hens' eggs. Monatshefte fur Veterinarmedizin. 44(2):63-65

Laird JM, Bartlett FM, McKellar RC (1991) Survival of Listeria monocytogenes in egg washwater. International Journal of Food Microbiology, 12, 115-122.

Lammerding AM (2005) Modelling and Risk Assessment for *Salmonella* in meat and Poultry. Journal of AOAC International. Special issue, in press.Langeland T (1982) A clinical and immunological study of allergy to hen's egg white. IV. Specific IGE-antibodies to individual allergens in hen's egg white related to clinical and immunological parameters in egg-allergic patients. Allergy, 37, 521-530.

Larkin T, Heilbron SG, Murphy T (2001) A Strategic Study of the Interdependence and Integration of the Egg, Processed Food and Food Service Industries. RIRDC. June 2001. RIRDC Project No: INS-4A

Leach SA, Williams A, Davies A, Wilson J, Marsh P, Humphrey TJ (1999) Aerosol route enhances the contamination of intact eggs and muscle of experimentally infected laying hens by *Salmonella* Typhimurium DT104. FEMS Microbiology Letters 171 203-207.

Leasor SB, Foegeding PM (1989) Listeria species in commercially broken raw liquid whole egg. Journal of Food Protection, 52, 777-780.

Leser C, Hartman AL, Praml G, Wuthrich B (2001) The "egg-egg" syndrome: occupational respiratory allergy to airborne egg proteins with consecutive ingestive egg allergy in the bakery and confectionery industry. Journal of Investigational Allergology and Clinical Immunology 11, 89-93.

Lock JL, Board RG (1992) Persistence of contamination of hens' egg albumen in vitro with *Salmonella* serotypes. Epidemiology and Infection, 108(3), 389-396.

Mattocks AR (1986) In Chemistry and Toxicology of Pyrrolizidine Alkaloids, Academic press, London, 153.

Mattocks AR, Jukes R (1990) Recovery of the pyrrolic nucleus of pyrrolizidine alkaloid metabolites from sulfur conjugates in tissues and body fluids, Chem.-Biol. Interactions, 75, 225.

Mead PS, Slutsker L, Dietz V, McCraig LF, Bresee JS, Shapiro C, Griffin PM, Tauxe RV (1999) Food-related illness and death in the United States. Emerging Infectious Diseases. 5:607-625.

Mermelstein NH (2001) Pasteurization of shell eggs. FoodTechnology 55, 72-73,79.

Messens W, Duboccage L, Grijspeerdt K, Heyndrickx M, Herman L (2004) Growth of *Salmonella* in hens' egg albumen as affected by storage prior to inoculation. Food Microbiology 21, 25-32.

Messens W, Grijspeedt K, Herman L (2005) Eggshell penetration by *Salmonella*: a review. World's Poultry Science Journal, 61, 71-85.

Miokovic B, Njari B, Wittner V (2003) Bacteriological quality of duck eggs. In: V Simpozij Peradarski Dani 2003, Croatia, pp. 207-209.

Molyneux RJ, Johnson AE, Stuart LD (1988) Delayed manifestation of Senecio-induced pyrrolizidine alkaloidosis in cattle: case reports, Vet. Hum. Toxicol., 30, 201.

Moore J, Madden RH (1993) Detection and incidence of Listeria species in blended raw egg. Journal of Food Protection, 56, 652-654.
Murray C (2002) *Food Safety Summary: Cumulative data from January 1998 to December 2001*. Food and Environmental Laboratory, Institute of Medical and Veterinary Science, Adelaide.
Murray C (2003a) *Food Safety Summary: Full Year 2002*. Food and Environmental Laboratory, Institute of Medical and Veterinary Science, Adelaide.
Murray C (2003b) *Food Safety Summary: Jan – Mar 2003*. Food and Environmental Laboratory, Institute of Medical and Veterinary Science, Adelaide.
Murray C (2004) *Food Safety Summary: Apr – Jun 2004*. Food and Environmental Laboratory, Institute of Medical and Veterinary Science, Adelaide.
Murray C (2005a) *Food Safety Summary: Jan - Mar 2005*. Food and Environmental Laboratory, Institute of Medical and Veterinary Science, Adelaide.
Murray C (2005b) *Food Safety Summary: Apr - Jun 2005*. Food and Environmental Laboratory, Institute of Medical and Veterinary Science, Adelaide.
Nasim Z, Afzal H, Ashfaque M, Akhta F, Hur G (1982). Isolation and survival of *Salmonella* typhimurium from egg shells. Pakistan Vet. J., 2 (3), 108-109.
NEPSS (2000) National Enteric Pathogens Surveillance Scheme. Non-Human Annual Report 1999 Issue No. 5/00. November 2000. Microbiological Diagnostic Unit, The University of Melbourne.
NEPSS (2001) National Enteric Pathogens Surveillance Scheme. Non-Human Annual Report 2000. Issue No. 3/01. November 2001. Microbiological Diagnostic Unit, The University of Melbourne.
NEPSS (2002a) National Enteric Pathogens Surveillance Scheme. Human Annual Report 2001 (Microbiological Diagnostic Unit, The University of Melbourne).
NEPSS (2002b) National Enteric Pathogens Surveillance Scheme. Non-Human Annual Report 2001 Issue No. 2/02. December 2002. Microbiological Diagnostic Unit, The University of Melbourne.
NEPSS (2003a) National Enteric Pathogens Surveillance Scheme. Human Annual Report 2002 (Microbiological Diagnostic Unit, The University of Melbourne).
NEPSS (2003b) National Enteric Pathogens Surveillance Scheme. Non-Human Annual Report 2002 Issue No. 2/02. October 2003. Microbiological Diagnostic Unit, The University of Melbourne.
NORM/NORM-VET 2001 Consumption of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Norway. Norwegian Zoonoses Centre. Accessed at http://www.zoonose.no/NormNormVet_2001.pdf
Norton RA, Ruff MD (2003) Internal Parasites. In:Saif Y.M (editor-in chief) Diseases of Poultry. 11th Edition. Iowa State Press.
Obrien TF (2002) Emergence, spread and environmental effect of antimicrobial resistance: how use of an antimicrobial anywhere can increase resistance to any antimicrobial anywhere else. Clinical Infectious Diseases; 34(Suppl 3):S78-S84.
Okamura M, Miyamoto T, Kamijima Y, Tani H, Sasai K, Baba E (2001). Differences in abilities to colonize reproductive organs and to contaminate eggs in intravaginally inoculated hens and in vitro adherences to vaginal explants between *Salmonella* enteritidis and other *Salmonella* serovars. Avian Diseases, 45 (4), 962-71.
Oliveira CAF, Kobashigawa E, Reis TA, Mestieri L, Albuquerque R, Correa B (2000) Aflatoxin B1 residues in eggs of laying hens fed a diet containing different levels of the mycotoxin. Food Additives and Contaminants 17, 459-462.
Ostlund K (1971a). Bacteriology of washed and unwashed eggs. I Bacterial counts of egg contents after storage. Acta Vet Scand, 12 467-478.
Ostlund K (1971b). Bacteriology of washed and unwashed eggs. II Penetration of *Salmonella* bacteria through the eggshell. Acta Vet Scand, 12 479-488.
OzFoodNet Working Group (2003) Foodborne disease in Australia: incidence, notifications and outbreaks. Annual Report of the OzFoodNet network, 2002. Communicable Diseases Intelligence 27: 209-243.
OzFoodNet (2004) OzFoodNet: enhancing foodborne disease surveillance across Australia: quarterly report, January to March 2004. CDI. 28(2):207
Pass DA (1982) Heliotrine poisoning of broiler chickens: an experimental clinicopathologic study of low dose intoxication, Avian Pathology, 11, 81. Perales I. Audicana A. (1989). The role of hens'

eggs in outbreaks of salmonellosis in north Spain. International Journal of Food Microbiology, 8 (2), 175-180.
Patrick ME, Adcock PM, Gomez TM, Altekruse SF, Holland BH, Tauxe RV, Swerdlow DL (2004) *Salmonella* Enteritidis infections, United States 1985-1999. Emerging Infectious Diseases 10: 1-7.
Peel B (1976) Occurrence of Salmonellas in raw and pasteurised liquid whole egg. Queensland Journal of Agricultural and Animal Sciences, 33, 13-21.
Phillips I, Casewell M, Cox T, De Groot B, Friis C, Jones R, Nightingale C, Preston R and Waddell J. (2004) Does the use of antibiotics in food animals pose a risk to human health? A critical review of published data. Journal of Antimicrobial Chemotherapy 53: 28-52
Prakash AS, Pereira TN, Reilly PEB, Seawright AA (1999) Pyrrolizidine alkaloids in the human diet, Mutation Res. 443, pp 53 – 67. Radkowski M (2001). Occurrence of *Salmonella* spp. in consumption eggs in Poland. International Journal of Food Microbiology, 64 189-91..
Richardson K, Tompkins B, Morris S (2000) Final Report – Scoping study on the risk of plant products (prepared for Safe Food NSW) 131-141
Robertson W, Muriana PM (2004) Reduction of *Salmonella* by two commercial egg white pasteurization methods. Journal of Food Protection, 67, 1177-1183.
Ross T, Sumner J (2002) A simple, spreadsheet-based, food safety risk assessment tool. International Journal of Food Microbiology 77, 39-53.
Ruzickova V (1994). Growth and survival of *Salmonella* enteritidis in selected egg foods. Veterinarni Medicina, 39 (4), 187-195.
Saeed AM (1998) USAHA Annual Meeting, October 2-9, 1998. Minneapolis, Minnesota
Sahin O, Kobalka P, Zhang Q (2003) Detection and survival of Campylobacter in chicken eggs. Journal of Applied Microbiology. 95:1070-1079
Saitanu K, Jerngklinchan J, Koowatananukul C (1994) Incidence of salmonellae in duck eggs in Thailand. Southeast Asian J. Trop. Med. Public Health 25, 328-331.
Sergeant ESG, Grimes TM, Jackson CAW Baldock FC, Whan IF (2003) *Salmonella* enteritidis surveillance and response options (Canberra, RIRDC). RIRDC Project No. AUV-1A
Schoeni JL, Doyle MP (1994) Variable colonization of chickens perorally inoculated with *Escherichia coli* O157:H7 and subsequent contamination of eggs. Applied and Environmental Microbiology, 60, 2958-2962.
Schlosser WD, DJ Henzler *et al*. (1999) In AM Saeed (ed) *Salmonella* enterica Serovar Enteritidis in Humans and Animals. Iowa State University Press.
Schoeni JL, Glass KA, McDermott JL, Wong ACL (1995). Growth and penetration of *Salmonella* enteritidis, *Salmonella* heidelberg and *Salmonella* typhimurium in eggs. International Journal of Food Microbiology, 24 385-396.
Schutze GE, Fawcett HA, Lewno MJ, Flick EL, Kirby RS (1996). Prevalence of *Salmonella* enteritidis in poultry shell eggs in Arkansas. South Med J., 89 (9), 889-91.
Shareef AM, Al-Sanjary RA, Hassan AA (1997) Recovery of two types of Salmonellae from eggs of free range-rearing hens and ducks. Iraqi Journal of Veterinary Sciences 10, 125-128.
Shirota K, Katoh H, Murase T, Ito T, Otsuki K (2001) Monitoring of layer feed and eggs for *Salmonella* in eastern Japan between 1993 and 1998. Journal of Food Protection, 64, 734-737.
Shojaee AliAbadi F, Lees P (2000) Antibiotic treatment for animals: effect on bacterial population and dosage regimen optimisation. International Journal of Antimicrobial Agents; 14:307-13.
Southwell RJ, Moore KJ, Manning W, Hayman PT (2003) An outbreak of *Fusarium* head blight of durum wheat on the Liverpool Plains in northern New South Wales in 1999. Australasian Plant Pathology, 32, 465-471.
Sparks NHC (1987) The hen's eggshell: a resistance network. PhD, Bath University.
Sparks NHC, Board RG (1985). Bacterial penetration of the recently oviposited shell of hens' eggs. Australian Veterinary Journal, 62 (5), 169-170.
Stadelman WJ, Singh RK, Muriana PM, Hou H (1996) Pasteurization of eggs in the shell. Poult Sci 75:1122-1125.
Stege H, Bager F, Jacobsen E, Thougaard A (2003). VETSTAT-the Danish system for surveillance of the veterinary use of drugs for production animals. Preventative Veterinary Medicine 57: 105-115.
Stegelmeier BL, Edgar JA, Colegate SM, Gardner DR, Schoch TK, Coulombe RA, Molyneux RJ (1999) Pyrrolizidine alkaloid plants, metabolism and toxicity, J. Nat. Toxins 8, pp 95 - 116.

Sumner J, Ross T (2002) A semi-quantitative seafood safety risk assessment. International Journal of Food Microbiology 77, 55-59.
SVARM (2002) Swedish Veterinary Antimicrobial Resistance Monitoring. National Veterinary Institute, Uppsala, Sweden. Accessed at http://www.sva.se/pdf/svarm2002.pdf
Swartz MN (2002) Human diseases caused by foodborne pathogens of animal origin. Clinical Infectious Diseases; 34(Suppl 3):S122.
Sypecka Z, Kelly M, Brereton P (2004) Deoxynivalenol and zearalenonein eggs of laying hens fed with a naturally contaminated diet: Effects on egg production and estimation of transmission rates from feed to eggs. Journal of Agriculture and Food Chemistry, 52(17), 5463-5471.
Takase K, Nakayama T, Kawai T, Fujikawa H (1999) Growth of *Salmonella* typhimurium and *Salmonella* enteritidis in egg yolks from highly immunized hens. J Vet Med Sc. 61, 959-960.
Todd ECD (1996) Risk assessment of use of cracked eggs in Canada. International Journal of Food Microbiology 30:125-143.
Turnidge J (2004) Antibiotic use in animals – prejudices, perceptions and realities. Journal of Antimicrobial Chemotherapy 53, 26-27
USDA-FSIS (1998) *Salmonella* Enteritidis Risk Assessment. Shells Eggs and Egg Products. Final Report. Prepared by the Salmonella Enteritidis Risk Assessment Team. 268 pp.
van Lith LAJT, Putirulan FF, Mulder RWAW (1995) Pasteurization of table eggs to eliminate salmonellae. Arch. Gefluegelkunde 59.
Wang H Slavik MF (1998). Bacterial penetration into eggs washed with various chemicals and stored at different temperatures and times. J Food Prot, 61 (3), 276-279.
Wegener H (2003) Antibiotics in animal feed and their role in resistance development. Current Opinion in Microbiology 6: 439-445
Wheeler JG, Sethi D, Cowden JM, Wall PG, Rodrigues LC, Tompkins DS, Hudson MJ, Roderick PJ (1999) Study of infectious disease in England: rates in the community, presenting to general practice, and reported to national surveillance. British Medical Journal 318:1046-1050
Whiting RC, Hogue A, Schlosser WD, Ebel ED, Morales RA, McDowell RM (2000) A Quantitative Process Model for *Salmonella* Enteritidis in Shell Eggs. Journal of Food Science, 65 (5), 864-869.
WHO (1997) The medical impact of antimicrobial use in food animals. Report of a WHO meeting. Berlin, Germany, 13-17 October, 1997.World Health Organisation, Geneva.
WHO (2001) WHO global strategy for containment of antimicrobial resistance. Switzerland: WHO.
WHO (2002) Consultation. Monitoring antimicrobial usage in food animals for the protection of human health, Norway.
Wilks C, Parkinson G,. Young P (2000) International review of *Salmonella* Enteritidis (SE) epidemiology and control policies. RIRDC 00/145
Williams L, Chou MW Yan J, Young JF, Chan PC, Doerge DR (2002) Toxicokinetics of riddelliine, a carcinogenic pyrrolizidine alkaloid, and metabolites in rats and mice, Toxicol. Appl. Pharmacol. 182, 98 – 104.
Wilson IG, Heaney JC, Powell GG (1998) *Salmonella* in raw shell eggs in Northern Ireland: 1996-7. Communicable Disease and Public Health / PHLS 1(3): 156-160.
Woo J, Sigurdsson ST, Hopkins PB (1993) DNA interstrand cross-linking reactions of pyrrole-derived, bifunctional electrophiles: evidence for a common target site in DNA, J. Am. Chem. Soc.,115, 3407.
Yang SE, Yu RC, Chou CC (2001) Influence of holding temperature on the growth and survival of *Salmonella* spp. and *Staphylococcus aureus* and the production of staphylococcal enterotoxin in egg products. International Journal of Food Microbiology. 63:99-107