

**Draft Risk Assessments of
Salmonella Enteritidis
in Shell Eggs and *Salmonella*
spp. in Egg Products**



Contributors to the Risk Assessments for *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products

(In alphabetical order)

MARGARET COLEMAN¹

ERIC EBEL¹

NEAL GOLDEN¹

ALLAN HOGUE¹

ABDEL KADRY¹

JANELL KAUSE¹

HEEJEONG LATIMER¹

HARRY MARKS²

NATHAN QUIRING¹

WAYNE SCHLOSSER¹

CARL SCHROEDER¹

¹Risk Assessment Division, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700

²Regulations and Directives Development Staff, Office of Policy, Program and Employee Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700

This page intentionally left blank

Peer Reviewers

SCOTT FERSON

Applied Biomathematics
Setauket, New York
United States of America

TOM HUMPHREY

Division of Food Animal Science
School of Clinical Veterinary Science
University of Bristol
Bristol, United Kingdom

CHRISTINE LITTLE

Health Protection Agency
Centre for Infections
Communicable Disease Surveillance Centre
London, United Kingdom

JOHN MAURER

Department of Avian Medicine
University of Georgia
Athens, Georgia
United States of America

MAARTEN NAUTA

Microbiological Laboratory for Health Protection
National Institute for Public Health and the Environment
Bilthoven, The Netherlands

Acknowledgements

Completion of these risk assessments was facilitated by constructive comments and suggestions provided by experts from the following agencies. The U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS); the USDA Economic Research Service; the U.S. Department of Health and Human Services (DHHS) Food and Drug Administration, Center for Food Safety and Applied Nutrition; the DHHS Centers for Disease Control and Prevention; the National Advisory Committee on Microbiological Criteria for Foods; and the Interagency Food Risk Assessment Consortium.

We are grateful to the following individuals for their comments. Ken Anderson, Tristan Cogan, Victor Cook, Phillip Derfler, Uday Dessai, Terry Disney, Daniel Engeljohn, Richard Gast, Roger Glasshoff, Elke Jensen, Dolores Hill, Walt Hill, Peter Holt, Karen Hulebak, Tom Humphrey, Michael Kasnia, Lynn Larsen, Priscilla Levine, Victoria Levine, Carol Maczka, Ronald Meekhof, Celine Nadon, Bharat Patel, Merle Pierson, Heather Quesenberry, Louise Ryan, Patricia Schwartz, Amelia Sharar. We also thank Tristan Cogan, Richard Gast, and Tom Humphrey for generously sharing unpublished data with us.

Notwithstanding the considerable help and valuable expertise provided by the abovementioned, responsibility for the content of this report rests solely with USDA FSIS.

This page intentionally left blank

Contents

EXECUTIVE SUMMARY	1
BACKGROUND	1
STRUCTURE AND SCOPE OF THE ASSESSMENTS	2
RESULTS	3
UNCERTAINTY AND SENSITIVITY ANALYSIS	3
RESEARCH NEEDS	4
SUMMARY	4
REFERENCES	5
1 INTRODUCTION.....	6
SALMONELLA AND EGG SAFETY	7
Regulatory Context	7
The 1998 Salmonella Enteritidis Risk Assessment	8
PURPOSE AND SCOPE OF THE RISK ASSESSMENTS	9
RISK ASSESSMENT COMPONENTS	10
AUDIENCE AND STRUCTURE OF THE REPORT	12
SUMMARY	12
REFERENCES	13
2 HAZARD IDENTIFICATION	15
INTRODUCTION	15
THE PATHOGEN	15
Epidemiology of Salmonella	15
SUMMARY	21
REFERENCES	22
3 EXPOSURE ASSESSMENT.....	27
EXPOSURE ASSESSMENT OF SALMONELLA ENTERITIDIS IN SHELL EGGS	27
Introduction.....	27
Overview of the Shell Egg Exposure Assessment Model.....	29
Exposure Assessment Results: SE in Shell Eggs	85
EXPOSURE ASSESSMENT OF SALMONELLA SPP. IN EGG PRODUCTS	97
Introduction.....	97
Overview of the Egg Products Exposure Assessment Model	98
Exposure Assessment Results: Salmonella spp. in Egg Products	112
SUMMARY	125
REFERENCES	127
4 HAZARD CHARACTERIZATION	129
INTRODUCTION	129
DATA SOURCES	130
Generic Data Sources	130
Dose-response Data.....	130
ESTIMATES FROM SURVEILLANCE DATA	137
Estimating Illness from Salmonella Enteritidis in Eggs.....	139
Estimating Hospitalizations from Salmonella Enteritidis in Eggs.....	140
Estimating Deaths from Salmonella Enteritidis in Eggs.....	141
Estimating Sequellae from Salmonella Enteritidis in Eggs.....	142
SUMMARY	143
APPENDIX	144
REFERENCES	148
5 RISK CHARACTERIZATION.....	152

RISK CHARACTERIZATION FOR <i>SALMONELLA</i> ENTERITIDIS IN SHELL EGGS.....	154
<i>Modeling Illnesses per Egg</i>	154
<i>Generating Baseline Estimates</i>	155
<i>Answers to Risk Management Questions</i>	156
<i>Stability of the Baseline Model</i>	164
<i>Sensitivity Analysis</i>	165
<i>Validation of the Shell Egg Model</i>	184
RISK CHARACTERIZATION FOR <i>SALMONELLA</i> SPP. IN EGG PRODUCTS.....	185
<i>Modeling Illnesses per Serving</i>	185
<i>Generating Baseline Estimates</i>	186
<i>Anchoring the Egg Products Model</i>	187
<i>Answers to Risk Management Questions</i>	190
<i>Stability of the Baseline Model</i>	197
<i>Sensitivity Analysis</i>	197
<i>Validation of the Egg Products Model</i>	207
SUMMARY.....	208
REFERENCES.....	210
6 RESEARCH NEEDS.....	211
INTRODUCTION.....	211
STUDIES IN PROGRESS.....	212
NEW RESEARCH NEEDS.....	214
SUMMARY.....	220
ANNEX A: GENERAL INTRODUCTION TO THE ANNEXES	
ANNEX B: DISTRIBUTION OF <i>SALMONELLA</i> PREVALENCE IN HENS AND EGGS	
ANNEX C: INITIAL CONTAMINATION OF <i>SALMONELLA</i> ENTERITIDIS IN SHELL EGGS	
ANNEX D: ESTIMATION OF EXPONENTIAL COOLING RATES FOR SHELL EGGS	
ANNEX E: MODELING GROWTH OF <i>SALMONELLA</i> ENTERITIDIS IN EGGS	
ANNEX F: LEVELS OF <i>SALMONELLA</i> SPP. IN EGG PRODUCTS	
ANNEX G: PASTEURIZATION OF LIQUID EGG PRODUCTS AND SHELL EGGS	
ANNEX H: EGG CONSUMPTION BY DIFFERENT AGE GROUPS IN THE UNITED STATES	
ANNEX I: FAO/WHO HAZARD CHARACTERIZATION OF <i>SALMONELLA</i> SPP.	