## Contents

**List of Contributors**  xi

1  **Introduction and Overview**  1  
   *Richard Podolak and Darryl G. Black*
   - Introduction  1
   - Definition of Low-Moisture Foods (LMF) and Water Activity Controlled Foods  2
   - *Salmonella* as a Continuing Challenge and Ongoing Problem in Low-Moisture Foods  4
   - Foodborne Outbreaks of *Salmonella* spp. and Other Implicated Microbial Pathogens in Low-Moisture Foods  6
   - Major Safety Concerns in Low-Moisture Foods  16
   - Content and Brief Book Chapter Review  17
   - Goal of the Book  21
   - How to Use the Book  21
   - References  22

2  **Regulatory Requirements for Low-Moisture Foods – The New Preventive Controls Landscape (FSMA)**  29  
   *Jeffrey T. Barach and George E. Dunai*
   - Introduction  29
   - FSMA Sanitation and cGMPs  32
   - FSMA Preventive Controls  34
   - Process Controls  35
   - Sanitation Controls  36
   - Supplier Controls  37
   - Summary of Requirements for Low-Moisture FSMA Regulated Products  38
   - References  39

3  **Potential Sources and Risk Factors**  41  
   *Elizabeth M. Grasso-Kelley, Ai Kataoka and Lisa Lucore*
   - Introduction  41
   - Raw Ingredients Control and Handling  43
   - Identifying Vulnerable Ingredients  43
   - Supplier Management  44
3.2.3 Receiving and Transport 46
3.2.4 Segregation/Isolation of Raw, Vulnerable Ingredients 47
3.2.5 Assessment of Remediation Practices after Loss of Control (Potential Contamination of Facility) or Assessing Sanitation Practice Effectiveness 48
3.3 Pest Control 49
3.3.1 Integrated Pest Management 50
3.3.2 Web Resources for More Information 52
3.3.3 Choosing a Pest Control Partner 54
3.4 Salmonella Harborage in the Facility 55
3.4.1 Sanitation Practices that may Lead to the Spread of Pathogens 56
3.4.2 Equipment Sources 58
3.4.3 Hygienic Sources 59
3.4.4 Management Practices for Cleaning Equipment 60
3.4.5 Rolling Stock 61
3.4.6 Raw Materials 61
3.5 Conclusions 62
References 62

4 Persistence of Salmonella and Other Bacterial Pathogens in Low-Moisture Foods 67
Elena Enache, Richard Podolak, Ai Kataoka and Linda J. Harris
4.1 Introduction 67
4.2 Factors Affecting Survival of Salmonella and Other Pathogens in Low-Moisture Foods 67
4.2.1 Water Activity (a_w) 68
4.2.2 Temperature 73
4.2.3 pH 73
4.2.4 Other Factors 73
4.3 Recovery of Salmonella Cells Stressed by Low-Moisture Foods 75
4.4 Mechanism of Salmonella Survival in Food Product and Processing Environment 75
4.4.1 Viable but Nonculturable (VBNC) 76
4.4.2 Filamentation 76
4.4.3 Osmoprotectants 77
4.4.4 Biofilm Formation 78
4.4.5 Outer Membrane Porins 78
4.4.6 Other Mechanisms 78
4.4.6.1 Activation of Genes for \( \sigma^E \) or \( \sigma^S \) Pathways 78
4.5 Other Vegetative Pathogens 79
4.6 Summary 79
References 80

5 Best Industry Practices to Control Salmonella in Low-Moisture Foods 87
Lisa Lucore, David Anderson, Elizabeth M. Grasso-Kelley and Ai Kataoka
5.1 Introduction 87
5.2 Sanitation Practices 89
  5.2.1 Dry Cleaning 89
  5.2.2 Wet Cleaning 92
  5.2.3 Cleaning Pattern/Planning 93
  5.2.4 Chemical Selection and Specific Options 94
    5.2.4.1 Oxidizers 96
    5.2.4.2 Surfactants 97
    5.2.4.3 Alcohols 98
  5.2.5 Validation and Verification 99
    5.2.5.1 Validation Methods and Considerations 99
    5.2.5.2 Verification of Appropriate Cleaning and Sanitization 100
  5.2.6 Facility Equipment and Design 101
    5.2.6.1 Hygienic Facility Design 102
    5.2.6.2 Facility Condition 103
    5.2.6.3 Grounds 104
    5.2.6.4 Other Facility Considerations 105
    5.2.6.5 Penetration Points 105
    5.2.6.6 Contractors 106
    5.2.6.7 Employees 107
    5.2.6.8 Rolling Stock/Moving Stock 107
    5.2.6.9 Waste 108
    5.2.6.10 Ingredients 108
    5.2.6.11 Vending/Employee Meals 108
    5.2.6.12 Personnel Health 109
    5.2.6.13 Sanitation 109
  5.2.7 Hygienic Equipment Design 109
  5.3 Current Good Manufacturing Practice 112
  References 114

6 Heat Resistance of Salmonella and Other Bacterial Pathogens in Low-Moisture Foods 121
Richard Podolak, Lisa Lucore and Linda J. Harris
6.1 Introduction 121
6.2 Factors Affecting Heat Resistance of Foodborne Pathogens 122
  6.2.1 Strain of Bacteria 122
  6.2.2 Surrogate Organisms for In-Plant Validation 124
  6.2.3 Culture Conditions 125
  6.2.4 Properties of the Food 128
  6.2.5 Inoculation Procedures 129
  6.2.6 Food Storage Conditions 130
  6.2.7 Recovery Conditions 131
6.3 Use of Published Heat Resistance Data to Establish Lethal Process Lethality in Low-Moisture Foods 133
6.4 Summary 143
  References 143
7 Validation Requirements in Heat-Processed Low-Moisture Foods  149
David Anderson, Nathan Anderson, Linda J. Harris and Wilfredo Ocasio
7.1 Introduction  149
7.2 Definitions  150
7.3 Tasks of Validation  150
7.4 Task 1: Assemble a Validation Team  151
7.5 Task 2: Identify the Hazard to be Controlled Through Hazard Analysis  151
7.6 Task 3: Identify a Validation Approach for the Control Measure  152
7.6.1 Generally-held Historical Knowledge  153
7.6.2 Published “Safe Harbor” Processes  153
7.6.3 Regulatory Documents such as Performance Standards  156
7.6.4 Published Industry Processing Guidelines  158
7.6.5 Peer-Reviewed Scientific Literature or Technical Data  159
7.6.6 Scientifically-Valid Experimental Data such as a Microbiological Challenge Study  160
7.6.7 Previous Validation Studies  160
7.6.8 Scientific Pathogen Models; Mathematical Modeling  161
7.6.9 Operational Data and Surveys  163
7.7 Task 4: Conduct the In-Production Validation  163
7.8 Task 5: Write the Results of the Validation in a Validation Report  165
7.10 Task 6: Implement the Control Measure, Monitors and Record Review  167
7.11 Task 7: Verify that the Control Measure is Operating as Intended  168
7.12 Task 8: Re-evaluate the Control Measure Periodically  169
7.13 Conclusion  170
References  171

8 Test Methods for Salmonella in Low-Moisture Foods  175
Elena Enache, Shaunti Luce and Lisa Lucore
8.1 Introduction  175
8.2 Sampling Plans  175
8.2.1 Product Testing  176
8.2.2 Environmental Monitoring Sampling Plans  177
8.2.2.1 Establishing the Monitoring Plan  178
8.2.2.2 Zone Assignment  182
8.2.2.3 Sampling Frequency  183
8.2.2.4 Track and Trend Results  183
8.2.2.5 Conclusion  184
8.3 Types of Methods  184
8.3.1 Traditional Cultural Methods for Qualitative Analysis  184
8.3.2 Rapid Methods  187
8.3.3 Quantitative Methods  190
8.3.4 Strain Identification Methods  190
8.4 Matrices Testing Challenges  192
8.5 Conclusion  194
References  194
9  Techniques to Determine Thermal Inactivation Kinetics for Pathogenic Bacteria and their Surrogate Organisms in Low-Moisture Foods  197
Shirin J. Abd, Carrie M.H. Ferstl and Wilfredo Ocasio
9.1  Introduction  197
9.2  Kinetics of Microbial Destruction  198
  9.2.1  The D-value  198
  9.2.2  The z-value  199
  9.2.3  Nonlinear Microbial Destruction Kinetics  200
  9.2.4  The F-value  200
9.3  Experimental Design and Execution  200
  9.3.1  Selection of the Target Organism  200
  9.3.2  Experimental Matrix (Selection of the Product)  201
  9.3.3  Test Culture Preparation  202
  9.3.4  Product Inoculation  203
  9.3.5  Selection of TDT Sample Container and Heat Transfer (Minimizing Come-Up Times)  205
  9.3.6  TDT Study Design: Selection of Study Parameters (Times and Temperatures to Use)  207
  9.3.7  Conducting the Heat Treatment (Capturing Product Temperature Data)  208
  9.3.8  Recovery and Enumeration of Bacterial Cells Post-Heat Treatment (Including Sublethally Injured Cells)  210
  9.3.9  Data Analysis  210
  References  215

10  Modeling and Statistical Issues Related to Salmonella in Low Water Activity Foods  219
Sofia M. Santillana Farakos, Michelle Danyluk, Donald Schaffner, Régis Pouillot, Linda J. Harris and Bradley P. Marks
10.1  An Introduction to Modeling Salmonella in Low Water Activity Foods  219
10.2  Developing a Predictive Model for Salmonella in Low Water Activity Foods  220
  10.2.1  Primary Models  222
  10.2.2  Criteria for Choosing the Best Applicable Model  224
  10.2.3  Primary Model Fits  224
  10.2.4  Secondary Models  224
  10.3  Model Validation  226
  10.4  Models in Risk Assessment  228
    10.4.1  The Risk Assessment Model  228
    10.4.2  The Monte Carlo Analysis  230
    10.4.3  Sensitivity Analysis  231
    10.4.4  Modeling Variability and Uncertainty  232
    10.4.5  Available Tools in Risk Assessment  233
  10.5  Summary  234
  References  234
11 Spoilage Microorganisms in Low-Moisture Foods 241
   Melinda Hayman and Richard Podolak

11.1 Introduction 241
11.2 Microorganisms Associated with the Spoilage of Low-Moisture Foods 241
   11.2.1 Halophilic Organisms 241
   11.2.2 Xerophilic Fungi 242
11.3 Factors Influencing Heat Resistance of Fungi in Low-Moisture Foods 244
   11.3.1 Effect of Solutes 244
   11.3.2 Effect of pH 245
   11.3.3 Effect of Strains and Age of Spores 246
   11.3.4 Effects of Growth Substrate and Medium Composition 246
   11.3.5 Heat Resistance and Aflatoxin Production 246
11.4 Heat Resistance of Fungi in Low-Moisture Foods 247
11.5 Heat Resistance of Yeasts in Low-Moisture Foods 247
11.6 Preventing and Reducing Spoilage in Low-Moisture Foods 247

11.7 Conclusions 251

References 251

Index 255