Contents

Preface XXI List of Contributors XXIII ٧

1 EU Legislation 1

Annette Schäfer

- 1.1 Introduction 1
- 1.2 Community Legislation 2
- 1.2.1 Horizontal Legislation 2
- 1.2.1.1 Framework Regulation 2
- 1.2.1.2 Good Manufacturing Practice 5
- 1.2.2 Specific Measures 6
- 1.2.2.1 Plastics 6
- 1.2.2.2 Recycled Plastics 10
- 1.2.3 Other Materials 11
- 1.2.3.1 Ceramic Articles 12
- 1.2.3.2 Regenerated Cellulose Film (Cellophane) 12
- 1.2.3.3 Rubber Teats and Soothers 12
- 1.2.3.4 BADGE, BFDGE, and NOGE in Coated Materials, Plastics, and Adhesives *13*
- 1.2.3.5 Active and Intelligent Materials and Articles 13
- 1.2.4 Control of Food Contact Materials in the EU 17
- 1.2.4.1 Role of the Business Operators: Food Industry and Packaging/ Contact Material Industry 17
- 1.2.4.2 Role of the Member States 17
- 1.2.4.3 Role of the European Commission 18
- 1.2.4.4 Methods for Sampling and Analysis in the Official Control 18
- 1.3 Specific National Legislation 19
- 1.4 Future Trends 20
- 1.4.1 Plastic 20

VI Contents

1.4.2	Nanomaterials 20
1.4.3	Risk Assessment 24
1.4.4	Other Materials 24
	References 24
2	Petitioning Requirements and Safety Assessment in Europe 27
	Paul Tobback and Rinus Rijk
2.1	Introduction 27
2.2	EFSA and its Role in Safety Evaluation of Food Contact Materials 28
2.3	Data Requirement on a Substance for its Safety Assessment
	by the EFSA 30
2.3.1	Introduction 30
2.3.2	Data to be Supplied within a Submission 31
2.3.2.1	General Information on the Substance 32
2.3.2.2	Information on Physical and Chemical Properties
	of the Substance 33
2.3.2.3	Information on the Intended Application of the Substance 35
2.3.2.4	Information on Authorization of the Substance 36
2.3.2.5	Information on the Migration of the Substance 36
2.3.2.6	Information on the Residual Content 39
2.3.2.7	Antimicrobial Substances 39
2.3.2.8	Toxicological Information 40
2.4	Evaluation Process of a Food Contact Substance 42
2.4.1	Re-Evaluation of Substances 44
2.5	Public Access to Data 46
	References 47
3	Council of Europe Resolutions 49
	Luigi Rossi
3.1	Introduction 49
3.2	Activity of CoE in the 1960s–1970s 50
3.2.1	Resolution on Plastics 50
3.2.2	Guidelines for the Evaluation of Substances 50
3.2.3	Estimation of Exposure 51
3.2.4	Conventional Classification of Food 52
3.3	EU Activity and Relationship Between EU and CoE 52
3.4	Resolutions of the CoE 52
3.4.1	Procedure for the Adoption of a Resolution and Guidelines
	and Technical Documents 52
3.4.2	
3.4.2 3.5	CoE Resolutions, Guidelines, and TDs 53
3.4.2 3.5	CoE Resolutions, Guidelines, and TDs 53 Status of the Packages (Resolutions, Guidelines,
	CoE Resolutions, Guidelines, and TDs 53

3.5.1.1 Inventory of the Documents 54

- 3.5.1.2 Chronological Development 54
- 3.5.1.3 Content of the Resolution 54
- 3.5.2 Resolutions on Control of Aids to Polymerization for Plastic 54
- 3.5.2.1 Inventory of the Documents 54
- 3.5.2.2 Chronological Development 55
- 3.5.2.3 Content of the Resolution 55
- 3.5.3 Resolution on Silicones 55
- 3.5.3.1 Inventory of the Documents 55
- 3.5.3.2 Chronological Development 55
- 3.5.3.3 Content of the Resolution 55
- 3.5.4 Resolution on Paper 56
- 3.5.4.1 Inventory of the Documents 56
- 3.5.4.2 Chronological Development 56
- 3.5.4.3 Content of Package 56
- 3.5.5 Resolution on Coatings 57
- 3.5.5.1 Inventory of the Documents 57
- 3.5.5.2 Chronological Development 57
- 3.5.5.3 Content of the Resolution 57
- 3.5.6 Resolution on Cork Stoppers and Other Cork Materials 58
- 3.5.6.1 Inventory of the Documents 58
- 3.5.6.2 Chronological Development 58
- 3.5.6.3 Content of the Resolution 58
- 3.5.7 Resolution on Ion Exchange and Adsorbant Resins Used in the Processing of Foodstuffs 58
- 3.5.7.1 Inventory of the Documents 58
- 3.5.7.2 Chronological Development 59
- 3.5.7.3 Content of the Resolution 59
- 3.5.8 Resolution on Rubber Products 59
- 3.5.8.1 Inventory of the Documents 59
- 3.5.8.2 Chronological Development 59
- 3.5.8.3 Content of the Resolution 59
- 3.5.9 Resolution on Packaging Inks 60
- 3.5.9.1 Inventory of the Documents 60
- 3.5.9.2 Chronological Development 60
- 3.5.9.3 Content of the Resolution 60
- 3.5.10 Guidelines on Metals and Alloys 61
- 3.5.10.1 Inventory of the Documents 61
- 3.5.10.2 Chronological Development 61
- 3.5.10.3 Content of the Guidelines 61
- 3.5.11 Guidelines on Glass 62
- 3.5.11.1 Inventory of the Documents 62
- 3.5.11.2 Chronological Development 62
- 3.5.11.3 Content of the Resolution 62

VIII Contents

3.5.12	Guidelines on Tissue Paper Kitchen Towels 62
3.5.12.1	Inventory of the Documents 62
3.5.12.2	Chronological Development 62
3.5.12.3	Content of the Guidelines 62
3.6	Transposition of the Resolutions, Guidelines, and
	Technical Documents 63
3.7	The Future of the CoE 63
3.7.1	Procedure of Authorization of a New Substance at
	National/CoE Level 64
3.8	Conclusions 64
	References 65
4	National Legislation in Germany 67
	Wichard Pump
4.1	Introduction 67
4.1.1	Commodities Defined in LFGB 67
4.1.2	Basic Requirements on Commodities 68
4.1.3	BfR Recommendations 69
4.1.4	Further Requirements 71
4.2	Legal Assessment of Different Materials Classes in
	Food Contact 71
4.2.1	Plastic Materials 71
4.2.2	Colorants 74
4.2.3	Plastics Dispersions (BfR Recommendation XIV) 74
4.2.4	Silicones (BfR-Recommendation XV) 75
4.2.5	Rubber and Elastomers (BfR Recommendation XXI) 75
4.2.6	Hard Paraffins, Microcrystalline Waxes and Mixtures of these with
	Waxes, Resins, and Plastics (BfR Recommendation XXV) 77
4.2.7	Conveyor Belts Made from Gutta-Percha and Balata (BfR
	Recommendation XXX) 77
4.2.8	Paper, Carton, and Board 77
4.2.8.1	XXXVI: Paper, Board for Food Contact 78
4.2.8.2	XXXVI/1: Cooking and Hot-filter Paper and Filter Layers 78
4.2.8.3	XXXVI/2: Papers, Cartons, and Boards for Baking Purposes 79
4.2.8.4	XXXVI/3: Absorber Pads based on Cellulosic Fibers for
	Food Packaging 79
4.2.9	Artificial Sausage Casings (BfR Recommendation XLIV) 79
4.2.10	Materials for Coating the Outside of Hollow Glassware
	(BfR Recommendation XLVIII) 80
4.2.11	Soft Polyurethane Foams as Cushion Packaging for Fruit
	(BfR Recommendation IL) 80
4.2.12	Temperature-Resistant Polymer Coating Systems for Frying,
	Cooking, and Baking Utensils (BfR Recommendation LI) 80
4.2.13	Fillers for Commodities Made of Plastic (BfR Recommendation LII) 80

Contents IX

 4.2.14 Absorber Pads and Packagings with Absorbing Function, in which Absorbent Materials Based on Cross-Linked Polyacrylates are Used, for Foodstuffs (BfR Recommendation LIII) 81 References 81

5 The French Regulation on Food Contact Materials 83 Jean Gauducheau and Alexandre Feigenbaum 5.1 Introduction 83 5.1.1 Basic Principles 84 5.1.2 Categories of Reference Binding Texts 84 5.1.2.1 Binding Texts: Lois (Laws), Décrets (Decrees), and Arrêtés (Orders) 84 Additional Information on the Texts 85 5.1.2.2 5.1.2.3 The Consumption Code (Code de la Consommation) 86 5.2 Integration of European Directives and Regulations on Food Contact Materials into the French Regulation 86 5.2.1 Main EU Regulations on Materials Intended for Contact with Food 87 5.2.2 Transposition of the Directives on Materials Intended to Come in Contact with Foodstuffs 87 Regenerated Cellulose Films 87 5.2.2.1 5.2.2.2 Plastic Materials 88 5.2.2.3 Ceramics 88 5.2.2.4 Rubber 88 5.3 Specific French Legislation on Plastic Materials Intended to Come in Contact with Food 89 5.3.1 Reference Texts on Coloring Agents for Plastic Materials 89 5.3.2 Reference Texts on Additives for Plastic Materials 89 5.3.2.1 Information Note of DGCCRF 2003-27 of 24 March 2003 89 Reference Texts on Recycled Materials 89 5.3.3 5.3.3.1 Avis of CSHPF Dated 1 June 1993 89 5.3.3.2 Avis of CSHPF Dated 7 September 1993 90 5.3.3.3 Avis of AFSSA of 27 November 2006 90 5.4 Supplementary French Legislation on Materials other than Plastics Intended to Come in Contact With Food 90 5.4.1 Introduction 90 5.4.2 Application of Regulations: the Decree 2007-766 of 10 May 2007 91 French Regulation on Materials in Paper and Board Intended to 5.4.3 Come in Contact with Food 91 5.4.4 French Regulation on Materials and Articles in Rubber Intended to Come in Contact with Food 93 5.4.4.1 Note of Information 2004-64 of DGCCRF, Chapter "Rubber" 93 5.4.5 French Regulation on Materials and Articles in Silicone Elastomers Intended to Come in Contact with Food 93 French Regulation on Materials and Articles in Glass and 5.4.6 Ceramics Intended to Come in Contact with Food 94

X Contents

5.4.7	French Regulation on Materials and Articles in Metals Intended to
J. . ./	Come in Contact with Food 94
5.4.7.1	General Case: Metallic Materials and Objects, Packaging 94
5.4.7.2	Household Metallic Articles and Parts of Industrial Materials 96
5.4.7.3	French Regulation on Materials and Objects in Wood Intended to
	Come in Contact with Food 99
5.4.7.4	French Regulation on Materials and Objects as Complexes
	Intended to Come in Contact with Food 100
5.5	French Regulation on Coatings Coming into Contact with
	Foodstuffs 100
5.6	French Regulation on Coloring Matters Used on or
	Within Food Packaging in Contact with Food 101
5.6.1	Preliminary Remarks 101
5.6.2	Basic Principles 101
5.6.3	French Regulation on Colorants Used in the Mass of
	Paper or Plastic Materials 102
5.6.3.1	Texts and Regulations 102
5.6.3.2	Instruction of 2 August 1993 102
5.6.4	French Regulation on Inks Used to Print Food Packaging 103
5.7	French Regulation on Requests for Authorization of Use of
	Constituents of Materials and Articles in Contact with Food 104
5.7.1	Advice of CSHPF of 9 December 1997 105
5.8	Conclusion 106
5.0	Conclusion 106
6	Dutch Legislation on Food Contact Materials 109
6	Dutch Legislation on Food Contact Materials 109 Rob Veraart
6 6.1	Dutch Legislation on Food Contact Materials 109 <i>Rob Veraart</i> Introduction 109 Plastics 111
6 6.1 6.2 6.2.1	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111
6 6.1 6.2	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics112
6 6.1 6.2 6.2.1 6.2.2	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112
6 6.1 6.2 6.2.1 6.2.2 6.3	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113113
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above 80 °C114
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1	Dutch Legislation on Food Contact Materials 109 Rob Veraart Introduction 109 Plastics 111 Nonepoxy Plastics 111 Epoxy Plastics 112 Paper and Board 112 Paper and Board for General Purpose 112 Overall Migration 113 Specific Migration 113 Paper for Filtering and Cooking Above 80 °C 114 Overall Migration 114
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2	Dutch Legislation on Food Contact Materials 109 Rob Veraart Introduction 109 Plastics 111 Nonepoxy Plastics 111 Epoxy Plastics 112 Paper and Board 112 Paper and Board for General Purpose 112 Overall Migration 113 Specific Migration 113 Paper for Filtering and Cooking Above 80 °C 114 Overall Migration 114 Specific Migration 114
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2 6.4	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above80 °C114Overall Migration114Specific Migration114Rubber114
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2 6.4 6.4.1	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above 80 °C114Overall Migration114Specific Migration114Categories114
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2 6.4 6.4.1 6.4.2 6.4.3 6.5	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above 80 °C114Overall Migration114Rubber114Categories114Positive List117Other Restrictions118Metals118
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2 6.4 6.4.1 6.4.2 6.4.3 6.5 6.5.1	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above 80 °C114Overall Migration114Specific Migration114Rubber114Categories114Positive List117Other Restrictions118Metals118Metals118
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2 6.4 6.4.1 6.4.2 6.4.3 6.5 6.5.1 6.5.2	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above 80 °C114Overall Migration114Rubber114Categories114Positive List117Other Restrictions118Metals118
6 6.1 6.2 6.2.1 6.2.2 6.3 6.3.1 6.3.1.1 6.3.1.2 6.3.2 6.3.2.1 6.3.2.2 6.4 6.4.1 6.4.2 6.4.3 6.5 6.5.1	Dutch Legislation on Food Contact Materials109Rob VeraartIntroduction109Plastics111Nonepoxy Plastics111Epoxy Plastics112Paper and Board112Paper and Board for General Purpose112Overall Migration113Specific Migration113Paper for Filtering and Cooking Above 80 °C114Overall Migration114Specific Migration114Rubber114Categories114Positive List117Other Restrictions118Metals118Metals118

- 6.6 Glass and Glass Ceramics 119
- 6.7 Ceramics and Enamels 119
- 6.7.1 Ceramics 119
- 6.7.2 Enamels 120
- 6.8 Textiles 120
- 6.9 Regenerated Cellulose 121
- 6.10 Wood and Cork *121*
- 6.11 Coatings 121
- 6.12 Colored Materials 122
- 6.13 Calculations 122 References 123

7 National Legislation in Italy 125

- Maria Rosaria Milana
- 7.1 Introduction 125
- 7.2 Decrees on General Principles 126
- 7.3 Decrees on Specific Materials 127
- 7.3.1 The Ministerial Decree 21 March 1973 and its Amendments 127
- 7.3.1.1 General Part 127
- 7.3.1.2 Specific Part 129
- 7.3.2 Ceramic 135
- 7.3.3 Tin Plate 135
- 7.3.4 Tin-Free Steel 136
- 7.3.5 Aluminum 137
- 7.3.6 Materials Without Specific Regulation 138
- 7.4 How to Get the List and the Text of the Italian Legislation 138 References 138

8 Switzerland 141

8.1

- Roger Meuwly and Vincent Dudler
- Legislative System 141
- 8.1.1 Availability of Legal Texts and Official Documents 142
- 8.1.2 Attestation of Conformity (Letter of No Objection (LNOs) 143
- 8.1.3 Council of Europe 143
- 8.2 Food Contact Materials and Articles 144
- 8.2.1 Plastic Materials and Articles 144
- 8.2.1.1 Limits on Migration 145
- 8.2.1.2 Recycled Plastic Materials 146
- 8.2.2 Regenerated Cellulose 146
- 8.2.3 Materials and Articles in Ceramic, Glass, Enamel, or Other Analogue Materials 147
- 8.2.4 Metals and Alloys 147
- 8.2.5 Materials and Articles in Paper and Board 147
- 8.2.6 Active and Intelligent Materials and Articles 147
- 8.2.7 Paraffin, Waxes, and Colorants 148

XII Contents

8.2.8	Silicone Materials and Articles 148
8.2.9	Inks 148
8.3	Conclusions 149
	References 149
9	Legislation on Food Contact Materials in the Scandinavian
	Countries and Finland 151
	Bente Fabech, Pirkko Kostamo, Per Fjeldal, and Kristina Salmén
9.1	Introduction 151
9.2	Legislation in Denmark 151
9.2.1	Public Control and In-House Documentation 152
9.3	Legislation in Finland 152
9.4	Legislation in Norway 153
9.4.1	The Packaging Convention of Norway and the EK Declaration 153
9.4.2	Paper and Board Food Contact Materials 154
9.4.3	Control of Critical Points 154
9.4.4	Metals in Ceramics, Glass, Metalwares, and Nonceramic Materials
	Without Enamel 155
9.5	Legislation in Sweden 157
9.5.1	Voluntary Agreement 157
10	Code of Practice for Coatings in Direct Contact with Food 161
	Peter Oldring
10.1	Introduction 161
10.2	Contents of the Code of Practice 163
10.3	Main Points of the Code of Practice 164
10.3.1	Scope of the Code of Practice: Article 1 164
10.3.2	Good Manufacturing Practice: Article 2 165
10.3.3	Substance Lists: Articles 3, 4, and 5 166
10.3.4	Dual Use Additives – Article 6 167
10.3.5	Restrictions of Substances and Testing – Articles 7, 8 and 11 168
10.3.6	Multilayer Coatings – Article 9 168
10.3.7	Declaration of Conformity – Article 10 168
10.3.8	Risk Assessment: Annex VI 171
10.4	How can the Code of Practice be Applied? 171
10.5	Conclusions 173
	References 173
11	Estimating Risks Posed by Migrants from Food
	Contact Materials 175
	Peter Oldring 175
11.1	Introduction 175
11.2	Hazard Assessment 176
11.2.1	Cramer Class I 177
11.2.2	Cramer Class II 177

Cramer Class III 177 11.2.3 11.3 Exposure Assessment 178 11.3.1 Introduction 178 11.3.2 What is Exposure? 179 What Data are Needed to Estimate Exposure? 180 11.3.3 Who Should be Protected in an Exposure Assessment? 11.3.4 180 11.3.5 Factors to Consider in an Exposure Assessment 181 11.3.6 Estimating Exposure to Migrants from Food Contact Articles 181 11.3.6.1 Simplistic 182 Deterministic 182 11.3.6.2 Probabilistic (Stochastic) Modeling 183 11.3.6.3 The US FDA Approach to Estimating Consumer Exposure to 11.3.7 Migrants from Food Contact Materials 184 11.3.8 Approaches to Determining Exposure to Migrants from Packaging of Foodstuffs that could be Used in the EU 185 11.3.8.1 Overview of Dietary Surveys 185 Concentration Data 187 11.3.8.2 11.3.8.3 Packaging of Foodstuffs Containing the Migrant(s) of Interest 189 11.4 FACET: Overview of Food Contact Material Work Package and Interactions with Other Work Packages 190 Conclusions 193 11.5 References 194 12 Compliance Testing, Declaration of Compliance, and Supporting Documentation in the EU 197 Rob Veraart 12.1 Introduction 197 Composition of the FCM 12.2 198 12.2.1 How to Demonstrate Compliance of Composition 198 12.3 Selection of Contact Conditions 199 Food Simulants 199 12.3.1 Substitute Fatty Food Simulants 12.3.1.1 201 12.3.1.2 Alternative Fatty Food Simulants 201 12.3.1.3 Reduction Factors 201 12.3.1.4 Future Developments 203 Selection of Time and Temperature Conditions 12.3.2 203 Migration Experiments 205 12.4 12.4.1 Contact Methods 205 12.4.2 Overall Migration 208 12.4.2.1 Overall Migration into Aqueous Food Simulants 208 12.4.2.2 Overall Migration into Fatty Food Simulants 208 Overall Migration into MPPO 210 12.4.2.3 Specific Migration 210 12.4.3 12.4.4 Mathematic Modeling 211 12.5 Residual Content 212

XIV Contents

I		
	12.5.1	Worst-Case Calculations 212
	12.5.2	Analytical Determination 212
	12.6	Miscellaneous 213
	12.6.1	Not Intentionally Added Substances 213
	12.6.2	Organoleptic Testing 214
	12.6.3	Other Tests 215
	12.6.3.1	Demonstrating the Absence of PAHs 215
	12.6.3.2	Color Release 216
	12.6.3.3	Colorants Purity 217
	12.7	Declaration of Compliance and Supporting Documentation 217
	12.7.1	Ceramics 218
	12.7.2	Plastic Materials 218
	12.7.3	Materials with BADGE 219
	12.7.4	Other Materials 219
		References 220
	13	Food Packaging Law in the United States 223
		Joan Sylvain Baughan and Deborah Attwood
	13.1	Introduction 223
	13.2	FDA Rules and Regulations 224
	13.2.1	Definition of a Food Additive 224
	13.2.2	Suitable Purity, the Delaney Clause, and FDA's
		Constituents Policy 225
	13.3	Exemptions 226
	13.3.1	"No Migration" 226
	13.3.2	Functional Barrier 228
	13.3.3	Prior Sanction 228
	13.3.4	GRAS 229
	13.3.5	Threshold of Regulation 229
	13.3.6	Housewares 230
	13.3.7	Basic Polymer/Resin Doctrine 232
	13.3.8	Mixture Doctrine 233
	13.4	The Food Contact Notification System: An Outgrowth of the
		Food Additive Regulation System for Food Contact Substances 233
	13.4.1	Introduction 233
	13.4.2	Prenotification Consultations 235
	13.4.3	Requirements for an FCN 235
	13.4.3.1	Comprehensive Summary 236
	13.4.3.2	Chemical Identity 236
	13.4.3.3	Intended Conditions of Use 236
	13.4.3.4	Intended Technical Effect 236
	13.4.3.5	Estimation of Dietary Intake 237
	13.4.3.6	Toxicity Information 237
	13.4.3.7	Environmental Information 237
	13.5	The Food Additive Petition Process 238

13.6 Conclusions 239 References 239

14Food Packaging Law in Canada – DRAFT243

- Anastase Rulibikiye and Catherine R. Nielsen
- 14.1 Introduction 243
- 14.2The Legal Structure244
- 14.2.1 The Agencies Involved 244
- 14.2.2 The Laws Involved 244
- 14.3 The Regulatory Scheme 245
- 14.3.1 Mandatory Requirements: Federally Registered Establishments 245
- 14.3.2 Not so Voluntary Requirements 246
- 14.3.2.1 The NOL Process 247
- 14.3.2.2 The Result 251
- 14.4 Enforcement 252
- 14.5 Conclusions 252
 - References 253

15 Food Packaging Legislation in South and Central America 255

Marisa Padula

- 15.1 South America 255
- 15.1.1 MERCOSUR 255
- 15.1.1.1 Plastic Materials 256
- 15.1.1.2 Elastomeric Materials 262
- 15.1.1.3 Adhesives 263
- 15.1.1.4 Waxes and Paraffins 264
- 15.1.1.5 Cellulosic Materials 264
- 15.1.1.6 Regenerated Cellulose Films 265
- 15.1.1.7 Regenerated Cellulose Casings 266
- 15.1.1.8 Metallic Materials 266
- 15.1.1.9 Glass 267
- 15.1.1.10 Legislation Update 268
- 15.1.1.11 Implementation of GMC Resolutions in the MERCOSUR Member States' National Legislations 268
- 15.1.2 Venezuela 269
- 15.1.3 Chile 271
- 15.1.4 Andean Community 271
- 15.2 Mexico 274
- 15.3 Central America 275
- 15.3.1 Costa Rica 276
- 15.3.2 El Salvador 276
- 15.3.3 Guatemala 276
- 15.3.4 Honduras 277
- 15.3.5 Belize 277
- 15.4 Cuba 277

/I	Contents
/	Contents

XVI	Contents	
	15.5	Conclusions 277 References 278
	16	Israel's Legislation for Food Contact Materials: Set for the Global Markets 283 Haim H. Alcalay
	16.1	Introduction 283
	16.2	The Standards: Legislative Process in Israel 284
	16.3	Technical and Expert Forums at SII 284
	16.4	Voluntary Standards and "Compulsory – Official Standards" 285
	16.5	Food Contact SI-5113 Provisions 286
	16.6	Documentation Requirements 287
	16.7	Approved Test Laboratories in Israel 287
	16.8	Introducing the New Standard in Israeli 288
	16.9	Imports of Packaging Materials into Israel 288
	16.10	Global Israeli Approach to Food Contact Legislation 289
	16.11	Kosher Regulations 289
	16.12	Implementation Issues (FAQ) 289
	16.13	Guiding Principles 290
		References 290
	17	Rules on Food Contact Materials and Articles in Japan 291 Yasuji Mori
	17.1	Introduction 291
	17.2	The Food Sanitation Law 292
	17.2.1	Articles of the Food Sanitation Law 292
	17.3	Specifications and Standards for Food and Food Additives (Notification No. 370) 295
	17.3.1	Contents 295
	17.3.2	Abstract of Restrictions for Packages/Containers 296
	17.3.2.1	General Restrictions (Abstracts) 296
	17.3.2.2	Specifications for each Material (Abstracts and Summary) 296
	17.3.2.3	Specifications for Packages/Containers for Specific Food Type (Abstract) 304
	17.3.2.4	Standards for Manufacturing of Apparatus and Packages/ Containers (Abstract) 306
	17.4	The Ordinance of Specifications and Standards for Milk and Milk Products 306
	17.4.1	Articles of the Ordinance of Specifications and Standards for Milk and Milk Products (Abstracts) 306
	17.4.2	Attached List (Specification and Standards for Milk and Milk Products) 307
	17.4.3	Specifications and Standards for Apparatus, Packages/Containers, Their Materials, and Methods of Manufacturing in Attached List (Abstract) 307

- Specifications and Standards for Apparatus, Packages/Containers, Their Materials and Methods of Manufacturing for Milk, Special Milk, Sterilized Goat Milk, Milk Making Adjustment for Constituent Part of Milk, Low-Fat Milk, No-Fat Milk, Processed Milk, and Cream (Group 1) 308
- 17.4.3.2 Specifications and Standards for Apparatus, Packages/Containers, Their Materials and Methods of Manufacturing for Fermented Milk, Lactic Acid Bacteria Drink, Milk Drink (Group 2) 310
- 17.4.3.3 Specifications and Standards for Apparatus, Package/Container, Their Materials and Methods of Manufacturing for Formulated Powder Milk (Group 3) 312
- 17.5 The Food Safety Basic Law and Relationship with the Food Sanitation Law *313*
- 17.6 Industrial Voluntary Rules 314
- 17.7 Sheets of Confirmation with Compliance 316
- 17.8 Conclusions 316 References 316

18 China Food Contact Chemical Legislation Summary 319

- Caroline Li and Sam Bian
- 18.1 Introduction 319
- 18.2 Current Status 319
- 18.3 China Food Safety Regulatory Entity 320
- 18.4 Regulations and Rules under the China Food Hygiene (Sanitary) Law 320
- 18.5 Hygiene Standards on Food Container and Packing Material 321
- 18.6 Hygiene Standards for Food Contact Substance (Indirect Additive) 323
- 18.7 Update in China Food Contact Chemical Regulation and Forecast on Future 326
- 18.7.1 Update of China Food Contact Chemical Legislation 326
- 18.7.2 Forecast on the New Food Contact Regulation in China 326
- 18.7.2.1 Expanded Food Contact Additive Positive List 327
- 18.7.2.2 The New Food Contact Substance Notification Procedure 327
- 18.7.2.3 Future Steps 328
- 18.8 Other Food Packaging Material-Related Regulation in China: Requirements for Local Manufacturing and Import of Food Contact Materials 328
- 18.8.1 Requirements for Local Manufacturing of Food Contact Materials 328
- 18.8.2 Requirements for Importing Food Contact Materials 329 References 335
- **19 Principal Issues in Global Food Contact: Indian Perspective** 337 Sameer Mehendale
- 19.1 The Indian Subcontinent: A Study in Contrast 337
- 19.2 Food Contact Legislation 337

XVIII Contents

19.3	General Guidelines 337
19.4	Condition for Sale and License 338
19.4.1	Conditions for Sale 338
19.5	Packing and Labeling of Foods 340
19.5.1	Package of Food to Carry a Label 340
19.5.1.1	
19.5.1.2	
19.5.1.3	5 5
19.6	Indian Standards for Direct Food Contact 343
19.7	Methods of Analysis and Determination of Specific
	and Overall Migration Limits 343
19.8	Acceptability Criteria 343
19.9	Future 344
20	Southeast Asia Food Contact 345
	Caroline Li and Sumalee Tangpitayakul
20.1	Singapore 345
20.2	Malaysia 346
20.3	Thailand 348
20.4	Conclusions 354
	References 354
21	Legislation on Food Contact Materials in the Republic of Korea 355
	Hae Jung Yoon and Young Ja Lee
21.1	Introduction 355
21.1 21.2	
21.2 21.3	Introduction 355
21.2	Introduction 355 Food Sanitation Act 355
21.2 21.3 21.3.1 21.3.2	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358
21.2 21.3 21.3.1 21.3.2 21.3.3	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358
21.2 21.3 21.3.1 21.3.2	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact
21.2 21.3 21.3.1 21.3.2 21.3.3 21.4	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365
21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366
21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366
21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6 21.7 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369 <i>Robert J. Steele</i>
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6 21.7 22 22.1 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369 <i>Robert J. Steele</i> Introduction 369
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6 21.7 22 22.1 22.2 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369 <i>Robert J. Steele</i> Introduction 369 Australia 370
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6 21.7 22 22.1 22.2 22.3 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369 <i>Robert J. Steele</i> Introduction 369 Australia 370 Australia's Regulatory Framework 370
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6 21.7 22 22.1 22.2 22.3 22.4 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369 <i>Robert J. Steele</i> Introduction 369 Australia 370 Australia's Regulatory Framework 370 Enforcement 372
 21.2 21.3 21.3.1 21.3.2 21.3.3 21.4 21.5 21.6 21.7 22 22.1 22.2 22.3 	Introduction 355 Food Sanitation Act 355 Food Code 357 General Provision 357 Common Standard and Specification for Food in General 358 Equipment, Containers, and Packaging for Food Products 358 Data and Information Required for Submission of Food Contact Material Prior to Use 364 Labeling Standard for Food and Food Additives 365 Requirements for Importing Food Contact Materials 366 The Future Direction for Packaging Material Regulations 366 References 367 Australia and New Zealand 369 <i>Robert J. Steele</i> Introduction 369 Australia 370 Australia's Regulatory Framework 370

- 22.7 New Zealand's Regulatory Framework 374
- 22.8 Relationship with Codex 375
- 22.9 Food Contact Legislation 375
- 22.10 Recycled Material 376
- 22.11 Food Recall Examples Under Section 1.4.3 of the FSANZ Code 377
- 22.12 Conclusions 377
 - References 378

Index 379