
Contents

1	Introduction to Statutory Framework and Case Law	1
1.1	The Need for Food Law.....	1
1.1.1	Our Own Experience with Food.....	1
1.1.2	In Food we Trust.....	2
1.1.3	History and the Courts’ View of Food Drug and Cosmetic Act (FD&C).....	3
1.1.4	Organization of this Text.....	5
1.2	Introduction.....	6
1.3	Overview of the U.S. Legal System.....	6
1.3.1	Federalism and the Structure of Government.....	6
1.3.2	The Role of the Constitution in Food Law.....	7
1.3.3	The Role of Judicial Opinions in Food Law.....	8
1.4	Food Law and Regulation.....	9
1.4.1	Sources of Food Law.....	9
1.4.2	Primary and Secondary Agencies.....	10
1.5	What is Food? FDA Jurisdiction and Authority.....	12
1.5.1	The Role of Definitions.....	12
1.5.2	Intended Use.....	22
1.6	What are Meat, Poultry and Eggs? USDA/FSIS Jurisdiction and Authority.....	23
1.6.1	Jurisdictional Overlap.....	24
1.6.2	The Impact of the Food Safety Modernization Act (FSMA).....	27
1.6.3	The Tale of Two Agencies.....	27
1.7	Comparative Law—Food Agencies Around the World.....	28
1.8	Chapter Summary.....	28
1.9	Discussion Questions.....	29
	References.....	29
2	Federal Inspections and Enforcement	31
2.1	Introduction.....	31
2.2	FSIS inspection Authority and Enforcement Tools.....	31
2.2.1	Statutory Authority and Early Origins of Inspection Authority.....	31
2.2.2	Continuous Mandatory Inspection Requirement.....	32
2.2.3	Inspection Methods.....	32
2.2.4	Organization and Evolution of FSIS.....	33

2.2.5	Enforcement Toolkit	34
2.2.6	Lessons from FSIS's History— Food Law is a Floor Not a Ceiling	38
2.3	Overview of FDA Inspection Process and Enforcement Tools	39
2.3.1	Evolution of Inspection Authority	39
2.3.2	Where we Find the FDA	41
2.3.3	FDA Criminal Division	42
2.3.4	The Role of Form 483.....	42
2.3.5	Warning Letters as Enforcement Instruments.....	44
2.3.6	Other Enforcement Mechanisms	46
2.3.7	Impact of FSMA	53
2.3.8	Comparing and Contrasting Inspection Models.....	53
2.4	Constitutionality of Warrantless Inspections.....	54
2.4.1	Introduction to Challenging Enforcement Actions.....	54
2.4.2	Constitutional Questions of Warrantless Inspections Conducted by the FDA	54
2.4.3	The Fourth Amendment	55
2.4.4	Waiving a Challenge by Consenting to a Search	55
2.4.5	Administrative Warrant Requirement under the <i>Camara-See</i> Principle.....	57
2.4.6	<i>Collonade-Biswell</i> and the Pervasively Regulated Business Doctrine	58
2.4.7	The Evolution of <i>Colonnade-Biswell</i> Doctrine.....	59
2.4.8	Outstanding Constitutional Challenges and Open Questions.....	60
2.4.9	Broader Lessons from <i>Camara, See, Colonnade, and Biswell</i>	62
2.5	Statutory Challenges to Inspections and Enforcement.	62
2.5.1	Administrative Procedure Act Challenges.....	62
2.5.2	APA and Import Alerts	64
2.5.3	Statute Specific Challenges	64
2.6	Comparative Law— International Inspection Methods	66
2.7	Chapter Summary	67
2.8	Discussion Questions.....	67
	References	67
3	Adulteration	69
3.1	Introduction	69
3.1.1	Defining Adulteration.....	69
3.2	Types of Adulteration	74
3.2.1	Economic Adulteration	75
3.2.2	Indirect Adulteration—Filth and Insanitary Conditions ...	78
3.2.3	Intentional Adulteration.....	80
3.3	Added Substances and Adulteration	81
3.3.1	Defining Added for the FDA	81
3.3.2	Added and Meat and Poultry.....	83
3.3.3	May Render Injurious to Health Standard.....	83
3.3.4	Tolerances.....	87

3.4	Non-Added Substances and Adulteration	89
3.4.1	Ordinarily Injurious Standard	89
3.4.2	Ordinarily Injurious and the USDA	92
3.5	Amendments Controlling Specific Adulterations	93
3.5.1	Pesticide Residues Amendment of 1954	93
3.5.2	Food Additive Amendments of 1958	94
3.5.3	Delaney Clause	95
3.5.4	Color Additives Amendment	96
3.5.5	Animal Drug Amendments of 1968	97
3.6	Comparative Law	97
3.7	Chapter Summary	98
3.8	Discussion Questions	98
	References	99
4	Misbranding	101
4.1	Introduction	101
4.1.1	Defining Misbranding	102
4.1.2	Overview of Constitutional Challenges	103
4.1.3	The USDA and Misbranding	104
4.2	Defining the Label	106
4.2.1	When Written Material Becomes Labeling	106
4.2.2	Regulatory Components of a Label	110
4.3	What Constitutes Misbranding	111
4.3.1	Misleading Labels	112
4.3.2	Common or Usual Name of Food	116
4.3.3	Country of Origin Labeling	118
4.3.4	Allergen Labeling	119
4.3.5	Organic and Natural Food Labeling	121
4.4	Labeling Claims and Misbranding	122
4.4.1	Types of Claims	122
4.4.2	Restrictions on Claims	124
4.5	Constitutional Challenges	124
4.5.1	Freedom of Speech and Choice	124
4.5.2	Preemption and Private Litigation	126
4.6	Comparative Law	127
4.7	Chapter Summary	128
4.8	Discussion Questions	129
	References	129
5	Regulation of Dietary Supplements and Other Specialized Categories	131
5.1	Introduction	131
5.2	Dietary Supplements	132
5.2.1	Regulation 1906–1994	132
5.2.2	Regulation Under DSHEA	145
5.2.3	Free Speech and Labeling Claims	156
5.3	Other Areas of Specialized Regulations	160
5.3.1	Seafood and Juice HACCP	160
5.3.2	Eggs	160

5.3.3	Water and Ice	161
5.3.4	Milk	161
5.3.5	Food Safety Modernization Act (FSMA) Overview ...	161
5.4	Comparative Law	162
5.5	Chapter Summary	163
5.6	Discussion Questions	164
	References	164
6	Food Additives	165
6.1	Introduction	165
6.1.1	Defining Food Additive.....	166
6.1.2	Generally Recognized as Safe.....	167
6.1.3	USDA and Food Additives	167
6.2	Regulatory Framework	168
6.2.1	Components of Food.....	168
6.2.2	Indirect Food Additives.....	170
6.2.3	Dietary Supplements	176
6.3	Generally Recognized as Safe.....	177
6.3.1	Defining GRAS.....	178
6.3.2	FDA's GRAS List	179
6.3.3	FDA Approved GRAS.....	181
6.3.4	Self-Affirming GRAS.....	182
6.4	Approval Procedures	183
6.4.1	Prior Sanctions Exceptions	183
6.4.2	Food Additive Petitions	184
6.4.3	Color Additive Petitions	186
6.4.4	Irradiation.....	190
6.4.5	Interim Food Additives.....	192
6.4.6	Limitations from Delaney Clause	193
6.5	Comparative Law	194
6.6	Chapter Summary	195
6.7	Discussion Questions	195
	References	195
7	Private Actions and Personal Liability	197
7.1	Introduction	197
7.2	Private Actions.....	198
7.2.1	Personal Liability for Food Borne Illnesses.....	198
7.2.2	Labeling Litigation.....	201
7.3	Criminal Actions.....	218
7.3.1	Dotterweich Doctrine.....	219
7.3.2	Park Doctrine	225
7.3.3	Modern Applications of the Park Doctrine.....	228
7.4	Comparative Law	230
7.5	Chapter Summary	231
7.6	Discussion Question.....	231
	References	231
	Index	233