
FOOD REGULATION

**LAW, SCIENCE, POLICY,
AND PRACTICE**

Neal D. Fortin, J.D.

Professor and Director, Institute for Food Law & Regulations,
Michigan State University

Adjunct Professor of Law, Michigan State University College of Law

 **WILEY**

A JOHN WILEY & SONS, INC., PUBLICATION

TABLE OF CONTENTS

SUMMARY OF CONTENTS	xxi
PREFACE	xxiii
ACKNOWLEDGMENTS	xxix
PART I: INTRODUCTORY CHAPTERS	1
1. Introduction to Food Regulation in the United States	3
1.1 Introduction	3
1.2 A Short History of Food Regulation in the United States	3
1.2.1 Why Do We Have Food Laws?	3
1.2.2 The 1906 Pure Food and Drug Act	5
1.2.3 Evolution of the Food Statutes	6
1.3 The U.S. Legal System	8
1.3.1 The Constitution	9
1.3.2 Statutes	9
1.3.3 Regulations	10
1.3.4 Case Law and Common Law	10
1.3.5 Federalism	11
1.4 Agency Procedural Regulation	13
1.4.1 The Administrative Procedure Act	14
1.4.2 Rulemaking	14
1.4.3 Adjudication	15
1.4.4 Judicial Review	16
1.4.5 Federal Advisory Committee Act (FACA)	16
1.4.6 Freedom of Information Act (FOIA)	17
1.4.7 Constitutional Limitations on Agency Power	17
1.5 Agency Jurisdiction	23
1.5.1 Food and Drug Administration	24
1.5.2 Centers for Disease Control and Prevention	24
1.5.3 USDA Food Safety and Inspection Service (FSIS)	25
1.5.4 U.S. Environmental Protection Agency	25
1.5.5 National Marine Fisheries Service (NMFS)	26
	vii

1.5.6	Alcohol and Tobacco Tax and Trade Bureau (TTB)	26
1.5.7	U.S. Customs Service	26
1.5.8	U.S. Department of Justice	27
1.5.9	Federal Trade Commission	27
1.5.10	State and Local Governments	28
1.6	Major Federal Laws	29
1.6.1	The Statutes	29
1.6.2	Other Statutes	30
1.6.3	The Regulations	31
1.7	Informational Resources	32
1.7.1	Government Agencies	32
1.7.2	Associations and Trade Groups	32
1.7.3	Other Sources	32
	Appendix	33
2.	What Is a Food?	35
2.1	Introduction to the Food, Drug, and Cosmetic Act	35
2.1.1	Definitions	35
2.1.2	FDA's Jurisdiction and the Definition of Food	38
2.1.3	Specific Food Classifications	39
2.2	What Makes an Article a Food or a Drug?	40
	<i>Nutrilabs, Inc. v. Schweiker</i>	40
2.3	The Central Role of Intended Use	43
2.4	Other Considerations	44
2.4.1	Products Ordinarily Considered Foods	44
2.4.2	Products Intended to Be Processed into Food	45
2.4.3	Products No Longer Fit for Food	45
2.4.4	Packaging Materials	45
2.4.5	Evidence of Intended Use	46
	PART II: REGULATION OF LABELING AND CLAIMS	47
3.	Food Labeling	49
3.1	Introduction	49
3.2	Legal Authorities	50
3.3	Labeling Terminology	51
3.3.1	Label versus Labeling	52
3.3.2	The Scope of Labeling	53
	<i>Kordel v. United States</i>	53
3.3.3	Labeling versus Food Advertising	56
3.3.4	The Internet and Labeling	57

3.4	Affirmative Label Requirements	59
3.4.1	Principle Display Panel (PDP)	59
3.4.2	Information Panel	59
3.4.3	Statement of Identity	60
	<i>Federation of Homemakers v. Butz</i>	61
3.4.4	Net Quantity	65
3.4.5	Ingredient Labeling	67
3.4.6	Name and Address of the Responsible Party	70
3.4.7	Product Dates and Codes	71
3.5	Misbranded Food: Prohibited Representations	71
3.5.1	Section 403 on Misbranded Food	71
	<i>United States v. 95 Barrels of Alleged Apple Cider</i>	74
3.5.2	False or Misleading as a Matter of Law	77
	<i>United States v. 432 Cartons Individually Wrapped Candy Lollipops</i>	78
3.6	Deceptive Packaging	80
	<i>United States v. 174 Cases Delson Thin Mints</i>	80
3.7	Warning Statements: Products Requiring Warning Labels	82
3.8	Allergens	85
3.9	Alcoholic Beverages	88
3.9.1	Wine Coolers versus Flavored Wine	89
3.9.2	A Double Standard	89
3.10	USDA	90
3.10.1	Labeling Approval	90
3.10.2	“Generic” Approvals (Labels without Prior Approval)	90
3.10.3	Safe Food-Handling Instructions	90
3.10.4	Additional Information Required	90
3.10.5	Record Keeping	91
3.11	Optional Label Information	91
3.11.1	Health Claims and Nutrient Level Claims	91
3.11.2	Grades	91
3.11.3	Trademarks and Copyrights	91
3.11.4	Religious Symbols	92
3.11.5	Universal Product Code	92
3.11.6	Organic	92
4.	Nutritional Labeling, Nutrient Level Claims, and Health Claims	93
4.1	Introduction	93
4.1.1	Nutrition and Public Health Expenditures	94

4.1.2	McFat Litigation	95
	<i>Pelman et al. v. McDonald's Corp.</i>	95
4.2	The Nutrition Labeling and Education Act (NLEA)	101
4.3	Nutrient Level Claims	103
4.3.1	Meals and Main Dishes	106
4.3.2	Standardized Foods	106
4.3.3	Healthy	106
4.4	Nutrition Panel Format	106
4.5	<i>Trans</i> Fats	111
4.5.1	Background on <i>Trans</i> Fat	112
4.5.2	Petition to Ban Hydrogenated Oil	112
4.5.3	Highlights of the <i>Trans</i> Fat Rule	113
4.6	Health Claims	113
4.6.1	General Well-Being Claims	114
4.6.2	Classical Nutrient-Deficiency Disease and Nutrition	115
4.6.3	Structure-Function Claims	115
4.6.4	Pre-approved Health Claims (NLEA)	116
4.6.5	Authoritative Statements—FDA Modernization Act of 1997	124
4.6.6	Qualified Claims— <i>After Pearson v. Shalala</i>	125
	<i>Pearson v. Shalala</i>	127
4.6.7	Nutritional Claims Grading Proposed	138
4.6.8	Substantiation of Claims	139
4.7	NLEA and Restaurants	142
	<i>Public Citizen and CPSI v. Shalala</i>	142
4.8	Advertising	145
4.8.1	Federal Trade Commission	145
4.8.2	Deceptive Advertising and Unfairness	146
4.8.3	Overview of Other Regulatory Aspects of Advertising	146
5.	Economic and Aesthetic Adulteration	149
5.1	Introduction	149
5.2	Definitions	149
5.2.1	Food	149
5.2.2	Adulterated	150
5.2.3	Misbranded	151
5.3	Food Standards: Regulation of Food Identity and Quality	152
5.3.1	Historical Overview	153
5.3.2	FD&C Act § 401, Power to Set Food Standards of Identity	157

	<i>Corn Products Co. v. Dept. of HEW</i>	161
	<i>Libby, McNeil & Libby v. United States</i>	166
5.3.3	Current Issue	169
5.3.4	Penalties	169
5.3.5	Temporary Marketing Permits	169
5.4	Sanitation and Aesthetic Adulteration	170
	<i>U.S. v. 1,500 Cases . . . Tomato Paste</i>	170
5.4.1	GMPs	173
5.4.2	Waiter, There's a Fly in My Soup—FDA Defect Action Levels	174
5.4.3	The FDA Food Defect Level Handbook	175
5.4.4	Blending	179
5.4.5	<i>De minimis</i> Filth	179
	<i>United States v. 484 Bags, More or Less</i>	179
	<i>United States v. Capital City Foods, Inc.</i>	181
5.4.6	Decomposition	183
	<i>United States v. An Article of Food . . . 915 Cartons of Frog Legs</i>	183
5.4.7	Insanitary Conditions	186
	<i>U.S. v. 1,200 Cans Pasteurized Whole Eggs by Frigid Food Products</i>	187
5.4.8	Good Manufacturing Practices (GMPs)	189
	<i>United States v. Nova Scotia Food Products Corp.</i>	189
5.4.9	Otherwise Unfit for Food	194

PART III: FOOD SAFETY REGULATION **195**

6. Food Safety Regulation **197**

6.1	Introduction	197
6.1.1	Background—The Nature and Cost of Foodborne Illness	198
6.1.2	Poisonous and Deleterious Substances	200
6.1.3	Added Substances	201
	<i>United States v. Lexington Mill & Elevator Co.</i> <i>232 U.S. 399 (1914)</i>	201
6.1.4	Nonadded Substances	204
	<i>U.S. v. 1,231 Cases American Beauty Brand Oysters</i>	204
6.1.5	Tolerances for Unavoidable or Necessary Poisonous and Deleterious Substances	208
	<i>Young v. Community Nutrition Institute et al.</i>	209
6.2	Pesticide Residues	212

6.2.1	FIFRA and EPA	213
6.2.2	FQPA and Risk Assessment	213
6.3	Environmental Contaminants	214
	<i>United States v. Anderson Seafoods, Inc.</i>	215
6.4	Tampering: The Anti-tampering Act	220
6.5	Carcinogens: The Delaney Clause	221
	<i>Scott v. FDA</i>	222
	<i>Public Citizen v. Young</i>	225
6.6	HACCP	240
6.6.1	HACCP's History	241
6.6.2	The Advantages of HACCP	241
6.6.3	The Nature and Cost of Foodborne Illness	242
	<i>Supreme Beef Processors, Inc. v. USDA</i>	245
7	Food Additives, Food Colorings, Irradiation	253
7.1	Introduction	253
7.2	Background	253
7.3	Food Additives	260
7.3.1	The Food Additive Amendment of 1958	261
7.3.2	FD&C Act Definition	262
7.3.3	Additive Safety and Approval	264
7.3.4	Prior Sanctioned Substances	266
7.3.5	GRAS (Generally Recognized as Safe)	267
7.3.6	Proving GRAS Status	268
	<i>United States v. An Article of Food, Coco Rico, Inc.</i>	268
7.3.7	Indirect Additives	272
	<i>Natick Paperboard Corp. v. Casper Weinberger and FDA</i>	273
7.3.8	The FDA Modernization Act of 1997 (FDAMA)	277
7.3.9	MSG	278
7.3.10	Preservatives	283
7.3.11	Botanicals and Other Novel Ingredients	289
7.4	Color Additives	293
7.4.1	Color Additive Amendments	293
7.4.2	Provisional Listing	294
	<i>United States v. An Article of Food Consisting of 12 Barrels . . . Lumpfish Roe</i>	302
7.5	Food Irradiation	306
7.5.1	Irradiation as a Food Additive under FD&C Act	306
7.5.2	Labeling	313
7.5.3	Agricultural Pests	314

PART IV: SPECIALIZED FOOD REGULATION	321
8. Dietary Supplements	323
8.1 Introduction	323
8.2 Background	323
8.2.1 What Are Dietary Supplements?	323
8.2.2 Background to DSHEA	324
8.3 The Statutory Definition	326
8.3.1 What Is a Dietary Supplement	328
8.3.2 What Is Not a Dietary Supplement	329
<i>United States v. Ten Cartons of Ener-B Nasal Gel</i>	330
<i>Pharmanex v. Shalala</i>	344
8.4 Approval and Safety	352
8.4.1 Presumption of Safety	352
8.4.2 No Food Additive Approval	355
8.4.3 New Dietary Ingredients (Post-1994)	355
8.4.4 Adulteration	356
8.5 Enforcement	357
8.5.1 Hurdles for the FDA	357
8.5.2 Adverse Publicity	358
8.5.3 Other Tools	358
8.6 Good Manufacturing Practices (GMPs)	359
8.7 Labels	360
8.7.1 Basic Labeling Requirements	360
8.7.2 Literature and Labeling	362
8.8 Health Claims	363
8.8.1 Background	364
8.8.2 DSHEA Authorized Health Claims	367
8.8.3 Permitted Health Claims	368
<i>Whitaker v. Thompson</i>	370
<i>Pearson v. Shalala</i>	380
8.9 Problem Supplements	388
8.9.1 Ephedra	388
8.9.2 Androstenedione—Mark McGwire’s Tonic	390
8.9.3 FDA Warnings	390
8.9.4 Third-Party Certification	391
8.10 “Street Drug Alternatives”	391
<i>United States v. Undetermined Quantities of Articles of Drug</i>	392
8.11 Advertising	399
8.11.1 Truthful and Not Misleading	399
8.11.2 Claim Substantiation	400

9. Biotechnology and Genetically Engineered Organisms	413
9.1 Introduction	413
9.1.1 Background	413
9.1.2 Regulatory Overview	415
9.2 Food Safety	417
9.3 FDA Policy	422
9.3.1 Labeling	423
9.3.2 The Proposed New FDA Approach	428
9.3.3 Enhancing the FDA’s Oversight	429
9.4 USDA’s Role	429
9.5 EPA’s Role—The Safety of Pesticides in Bioengineered Plants	431
9.5.1 Pesticidal Substances in Food	431
9.5.2 StarLink Corn Investigation and Recall	432
9.6 The Right to Know	434
<i>International Dairy Foods Ass’n v. Amestoy</i>	436
<i>Alliance for Bio-Integrity v. Shalala</i>	443
10. Food Terrorism	457
10.1 The U.S. Food Safety System	457
10.2 The Threat	459
10.2.1 Illness and Death	459
10.2.2 Economic and Trade Effects	460
10.2.3 Social and Political Implications	460
10.3 Examples of Contamination	461
10.3.1 A <i>Salmonella</i> Tainted Election	461
10.3.2 Pesticide Poisoning in Michigan	462
10.4 The Bioterrorism Act and FDA’s New Powers	465
10.4.1 Food Facility Registration	466
10.4.2 Prior Notice of Food Imports	466
10.4.3 New Penalties	466
10.5 Conclusions	467
11 Importation and Exportation	469
11.1 Introduction	469
11.2 The Major Federal Agencies	470
11.3 The FDA Import Process	470
11.3.1 Basic Import Procedure	471
11.3.2 Prior Notice of Import	472
11.3.3 Import Food Facility Registration	473

11.3.4	Additional Forms for Certain Canned Foods, Milk, Cream, and Infant Formula	473
11.3.5	When a Violation Is Found	474
11.3.6	When a Notice of Action Is Issued	474
11.3.7	Request for Authorization to Relabel or Perform Other Acts	475
11.3.8	Inspection after Reconditioning or Relabeling	476
11.3.9	Good Agricultural Practices (GAPs)	476
11.3.10	Enforcement	477
11.4	USDA's Import System	477
11.4.1	Food Safety Inspection Service (FSIS)	477
11.4.2	Animal and Plant Health Inspection Service (APHIS)	480
11.5	Other Import Controls	480
11.5.1	Customs (CBP)	480
11.5.2	Environmental Protection Agency	482
11.5.3	Alcohol and Tobacco Tax and Trade Bureau (TTB)	482
11.5.4	National Oceanic and Atmospheric Administration (NOAA)	482
11.6	Country-of-Origin Labeling	483
11.7	Challenges Facing Import Regulation	484
11.8	Export	487
11.8.1	Export Exemption	487
11.8.2	Import for Export <i>U.S. v. 76,552 Pounds of Frog Legs</i>	488 489
11.8.3	Export Certificates	491

PART V: INSPECTION AND ENFORCEMENT **493**

12. Federal Enforcement **495**

12.1	Introduction	495
12.1.1	A Note on Materials	495
12.1.2	The Role of States	496
12.1.3	Public Records	497
12.2	Statutory Authorities	497
12.2.1	Prohibited Acts	497
12.2.2	FDA's Enforcement Discretion	498
12.2.3	Role of the Justice Department	498
12.3	Enforcement Jurisdiction	499

12.3.1	Introduction into Interstate Commerce	499
12.3.2	Held for Sale after Shipment in Interstate Commerce	500
	<i>United States v. 40 Cases . . . “Pinocchio Brand . . . Blended . . . Oil”</i>	500
12.3.3	FD&C Act Interstate Commerce Presumption	503
12.3.4	FDA Jurisdiction over Restaurants	503
12.4	Administrative Enforcement	504
12.4.1	List of Inspectional Observations	504
12.4.2	Warning Letters	504
12.4.3	Recalls	510
12.4.4	Debarment	511
12.4.5	Import Detentions	512
12.4.6	Civil Penalties	512
12.4.7	Withdrawal of Product Approvals	513
12.4.8	Inspection-Related Enforcement Powers of FSIS	513
12.5	FDA Civil Court Actions	514
12.5.1	Seizure	514
12.5.2	USDA	515
12.5.3	Injunction	517
12.5.4	Contempt Action	518
12.5.5	Destruction of Products without a Hearing <i>North American Cold Storage Co. v. City of Chicago et al.</i>	518
12.6	Criminal Actions	524
12.6.1	Strict Liability <i>United States v. Park</i>	526
12.6.2	Fines, Prison	532
12.7	Other Remedies and Concerns	533
12.7.1	Publicity	533
12.7.2	Referral to State Agencies	533
12.7.3	Postenforcement Compliance Monitoring	533
12.7.4	Criminal Code Charges	533
13.	Inspections	537
13.1	Introduction	537
13.2	Constitutional Limits	538
13.2.1	Statutory Power for Inspections	539
13.2.2	Record Access under the Bioterrorism Act	541
13.2.3	The Warrantless Inspection Exception <i>United States v. Jamieson-McKames Pharmaceuticals, Inc.</i>	542

13.2.4	Consent to Inspect	546
	<i>United States v. Thriftmart, Inc.</i>	547
13.2.5	Statements by Firm Representatives	549
13.2.6	Scope of Inspections	550
13.2.7	Photographs	551
13.3	Planning for the Inspection	564
13.3.1	Policies	564
13.3.2	Training	564
13.3.3	FDA's Notice of Inspection	565
13.3.4	Inspectional Observations (FDA Form 483)	565
13.3.5	Times of Inspection	566
13.3.6	Samples	566
13.3.7	Follow-up Information	567
13.3.8	Etiquette for Dealing with FDA Inspectors	567
13.4	FSIS Inspection Authority	567
13.4.1	Major Enforcement Powers	568
13.4.2	Records Access	570
13.4.3	FSIS' International Inspection Activities	571
13.4.4	Supreme Beef v. USDA	571
	<i>Supreme Beef Processors, Inc. v. USDA</i>	572
14.	State Laws and Their Relationship to Federal Laws	575
14.1	Introduction	575
14.1.1	Overview of the Role of States	575
14.1.2	FDA Jurisdiction over Restaurants	576
14.1.3	FSIS	576
14.1.4	Related Authorities	576
14.1.5	National and State Cooperation	577
14.1.6	Organizations Fostering Uniformity	577
14.2	State Inspection and Enforcement Powers	579
14.2.1	Summary Seizure and Condemnation	579
14.2.2	Destruction of Products without a Hearing	579
14.3	State Warning Requirements	580
14.4	Federal Preemption of States	580
14.4.1	Express Preemption of Inconsistent State Law	582
14.4.2	Comprehensive Federal Scheme That Occupies the Field	583
	<i>Florida Lime and Avocado Growers, Inc. v. Paul</i>	583
	<i>Hillsborough Co. v. Automated Medical Labs, Inc.</i>	588
14.4.3	Direct Conflict between Federal and State Law	593

14.4.4	State Law an Obstacle to the Purposes and Objectives of Congress <i>Jones v. Rath Packing Co.</i>	593 594
14.4.5	Unreasonable Burden on Interstate Commerce	603
14.5	Federal Laws Delegating Authority to the States	604
15.	Private Actions	605
15.1	Introduction	605
15.2	Products Liability	606
15.2.1	The Hot Coffee Case	606
15.2.2	Products Liability	606
15.2.3	Foreign-Natural Test versus Reasonable Expectation <i>Porteous v. St. Ann's Café & Deli</i> <i>Jackson v. Nestle-Beich, Inc.</i>	609 610 615
15.2.4	Negligence Per se <i>Orthopedic Equipment Co. v. Eutsler</i> <i>Blommer Chocolate Co. v. Bongards Creameries, Inc.</i>	621 621 625
15.3	Preemption of Tort Claims	630
15.3.1	Generally	630
15.3.2	State Law	631
15.4	The False Claims Act	632
15.5	No Private Cause of Action under the FD&C Act <i>Florida ex rel. Broward Co. v. Eli Lilly & Co.</i> <i>Merrell Dow Pharmaceuticals, Inc. v. Thompson</i>	633 633 635
PART VI:	GENERAL CHAPTERS	637
16.	International Food Law	639
16.1	Introduction	639
16.2	International Food Standards	640
16.2.1	Codex Alimentarius	640
16.2.2	The WTO and International Trade Agreements	643
16.2.3	Jurisprudence	645
16.3	Foreign Regulatory Systems	645
16.3.1	Background on the European Union	646
16.3.2	EU Food Issues with the United States	646
16.3.3	The GE Food Fight	647
16.3.4	The Precautionary Principle	648
16.3.5	EU Requirements on GE Food	649
16.3.6	EU Labeling	650
16.3.7	The U.S. Response to the European Union	650

17. Ethics	653
17.1 Professionalism and Ethics	653
17.2 Ethical Practice Pointers	656
17.3 Attorney Rules of Ethics	656
17.4 Criminal Statutes Related to Ethics	660
17.5 Resources	661
TABLE OF ABBREVIATIONS	663
TABLE OF CASES	669
INDEX	671
ABOUT THE AUTHOR	677