

# Food Regulation

*Law, Science, Policy, and Practice*

*Neal D. Fortin, JD*



 WILEY

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# FOOD REGULATION

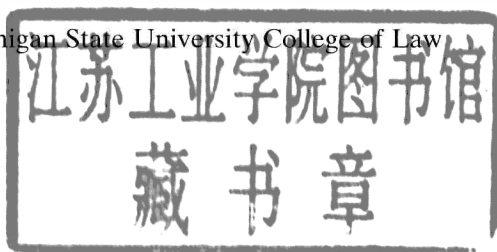
LAW, SCIENCE, POLICY,  
AND PRACTICE

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## SUMMARY OF CONTENTS

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### Part I: Introductory Chapters

- 1 Introduction to Food Regulation in the United States** A short history of food and drug regulation in the United States. An overview of government agency jurisdictions and authority over food.
- 2 What Is a Food?** Introduction to the Food, Drug, and Cosmetic Act (FD&C Act). What makes an article a food, a drug, a device, or a product outside the scope of the Act?

### Part II: Regulation of Labeling and Claims

- 3 Food Labeling** The basic requirements of food labeling, misbranding, legal authorities, labeling terminology, affirmative label requirements, prohibited representations, deceptive packaging, warning statements, and allergens.
- 4 Nutritional Labeling, Nutrient Level Claims, and Health Claims** The requirements for nutritional labeling and health claims on food plus an overview of the regulation of advertising. The Nutritional Labeling and Education Act (NLEA).
- 5 Aesthetic and Economic Adulteration** Key definitions, adulteration, food (unfit for food, packaging materials), esthetic adulteration, defect action levels, GMPs, standards of identity, and economic adulteration.

### Part III: Food Safety Regulation

- 6 Food Safety Regulation** Poisonous or deleterious substances, pesticides, the Delaney Clause, the Food Quality Protection Act (FQPA), foodborne illnesses, HACCP, and tampering law. Current issues in foodborne illness, such as mad cow disease.
- 7 Food Additives, Color Additives, and Irradiation** The regulation of food additives, color additives, and irradiation.

## **Part IV: Specialized Food Regulation**

- 8 Dietary Supplements** The regulation of this special class of food that is regulated neither as conventional food nor as food additives. Dietary Supplement Health and Education Act of 1994 (DSHEA), ephedrine; “street drug alternatives,” and dietary supplement ads on the Internet.
- 9 Biotechnology and Genetically Engineered Organisms** The regulation biotechnology, genetically modified foods, and cloning.
- 10 Food Terrorism** A look at food security and the federal government’s new bioterrorism powers.
- 11 Importation and Exportation** The regulation of U.S. food imports and exports, including harmonization of domestic and foreign trade restrictions, and agency enforcement authority.

## **Part V: Inspection and Enforcement**

- 12 Federal Enforcement** An overview of the enforcement tools of the FDA and USDA-FSIS with a focus on seizures, recalls, and penalties.
- 13 Inspections** An overview of the FDA and state inspections, and Fourth Amendment, and practical issues.
- 14 State Laws and Their Relationship to Federal Laws** A discussion of state enforcement, the state food and drug laws, and federal pre-emption.
- 15 Private Actions** Private causes of actions and their regulatory role.

## **Part VI: General Chapters**

- 16 International Food Law** The implications of international trade, international treaties, and the Codex Alimentarius.
- 17 Ethics** Discussion of ethical issues in food law and in government regulation.

## PREFACE

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Knowledge is the food of the soul.  
—Plato

Food regulation is a complex and fascinating field. Study in this area is richly rewarding. From a human-interest perspective, the range of products regulated touches the lives of nearly every American every day. Food regulatory issues often warrant headline news because this is a subject that commands the public's attention, whether it be a news flash on a foodborne illness outbreak or information on diet that can help one live a longer and healthier life.

In addition the regulation of food provides a snapshot of the political, social, and economic currents in our society. Thus the study of food law provides a incisive look at important policy decisions on vital aspects of people's everyday lives.

### ABOUT THE TEXT

This text is designed to provide an accessible guide the United States food regulation—to be enlightening, without being light. While the text contains in-depth discussion of the federal statutes, regulations, and the regulatory agencies, the material is not dense, and remains accessible to the average reader. For this reason the text is appropriate for a wide audience of students and professionals.

A modified casebook method is used. The black letter law is livened with discussion of emerging issues and trends plus case studies that explore important issues. These materials explore not only regulation, but the science, policy, and practice. The reader is challenged to move beyond theory into application of the theory.

The focus is on the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. section 321 *et seq.*, and the Food and Drug Administration (FDA). A good number of the cases and references in this text are to pharmaceuticals, medical devices, and cosmetics. The FD&C Act regulates all these products, and there are commonalities in the regulatory framework for all. In fact, some

drug or medical device cases illustrate a point about food law better than any case directly about food.

This casebook presents diverse materials from pertinent sources. Commentary and context are provided as needed, but often the materials can be digested without these aids. The novice may feel challenged at first to understand the materials, but after jumping around the various writing styles and contexts, and the relative value and weight of each source should become discernable. Stay with it, and you will find that the materials become easier.

## **A ROAD MAP FOR READING THE MATERIALS IN THIS COURSE**

In keeping with the way information is encountered in practice, not all readings in this text are equal. Some may be read quickly, while some require close scrutiny. Moreover, materials come in varying levels of formality. Some materials I have condensed to make them easier to read.

Readers new to this teaching style may be disconcerted at first. Do not let this throw you. Persist and trust your instincts, and you will find that your effort quickly pays dividends. In the end, you will learn much more than the mere rules, but develop and hone critical skills that are not only vital in legal analysis but are extremely useful in winnowing through the mountains of information available on the Internet. In addition law and regulation are not static subjects, so developing these dynamic skills will be beneficial in the end.

Here are a few tips to readers who are new to this teaching method:

1. Review your road map of each chapter. Review the chapter title, the other headings, and the table of contents before reading. These will provide you with an overview of how the chapter material relates to the overall text.
2. Put the material in context. Note the source of the material quoted. Who wrote the material will tell you what type of perspective is offered. Often regulations reconcile conflicting interests, and understanding both sides can be key to a complete picture. Note the date when the material was written, as the date may indicate that the material is provided for historical perspective, or that part of the information may be pertinent but part may be outdated.
3. The statutes and regulations are the primary source of our food law. That is, food regulatory law is largely bound by statutes and regulations. Therefore these materials should be the beginning of your research to answer a food law question. Often a problem is solved by examination of the statutory definitions (particularly key definitions, e.g., food, drug, misbranding, and adulterated).

4. In reading the cases, develop the ability to understand how the court reasoned through the conflict to a solution. Identify the particular factors used by the court to decide the case the way it did. Check to see if those factors are present in a problem with which you are dealing. If the factors are not present, then ask yourself if that justifies a different result. If there are any changes in the social or economic conditions that surrounded an earlier decision, ask how that affects the problem now at hand.

In short, learn to analyze the materials, rather than merely read and memorize rules.

## **EDITING**

I have edited out the footnotes and citations from most of the cases. Remaining footnotes may be renumbered with my own footnotes. Unless otherwise indicated, any footnotes with cases are those of the court. In addition materials may be edited for typographic style without notation in the text.

## **STATUTORY RESEARCH USING THE FEDERAL REGISTER, CFRs, AND STATUTES**

Food regulation in the United States is primarily based on statutory law. So it is generally best to read or review the statutory language before reading the cases and secondary materials, which serve mainly to explain statutory issues. When reading the statutes or regulations, be sure that you also review the definitions of defined terms used—particularly the key definitions in section 201 [321], such as “food” and “drug,” and the definitions of “adulterated” and “misbranded.” In addition, when reading the statutory language, obtain at least a general idea of what is covered by any statutory cross-references.

## **A NOTE ON STATUTE CITATIONS**

All federal statutes in force in the United States are codified in the United States Code (U.S.C.). The U.S.C. is organized into subject matter titles with numbering that is unique from the section numbering in the statutes as they were enacted into the public acts. For example, section 1 of the Food, Drug, and Cosmetic Act is codified as 21 U.S.C. § 301. You may also find this section cited with one or the other or both reference numbers, such as “Sec. 1 [301].”



Statutory citations used in this material are to the FD&C Act statutory sections (which is the way practitioners refer to them). The citation within the brackets is the U.S.C. number. Nonetheless, occasionally you will see reference to a United States Code citation.

## FD&C ACT REFERENCES

Four free online locations for reference to the FD&C Act follow:

Cornell's LII: [www4.law.cornell.edu/uscode/21/ch9.html](http://www4.law.cornell.edu/uscode/21/ch9.html)

FDA: [www.fda.gov/opacom/laws/fdact/fdctoc.htm](http://www.fda.gov/opacom/laws/fdact/fdctoc.htm)

GPO Access: <http://www.gpoaccess.gov/uscode/index.html>

University of Virginia: [www.uvm.edu/nusc/nusc237/ffdcac.html](http://www.uvm.edu/nusc/nusc237/ffdcac.html)

Of course, Westlaw and Lexis-Nexis provide access to the most up to date text of the FD&C Act.

## DISCUSSION QUESTIONS

The Discussion Questions are designed to encourage thought on the material presented or for class discussion. Often there is not a right or wrong answer but multiple viewpoints on these issues or public policy questions. A great deal of insight can be gained by having candid discussions of these different perspectives.

## PROBLEM EXERCISES

The Problem Exercises are designed to encourage critical thinking. They take on a variety of forms, but usually revolve around a public policy question in food law.

## INTERNET CITATIONS

The fluid nature of Internet addresses creates difficulty for a textbook of this nature. The food regulation information available on the Internet is far too valuable not to include many Internet addresses. Inevitably, however, some of these addresses will have changed or the documents will have been removed within days of this book's printing.

However, learning what *types* of materials are available is more valuable than finding a specific document. When you find a broken Internet address,

take the opportunity to use search engines to find the new location, or to find similar material on the Web.

In the types of materials reference in this text, most of the broken Internet addresses result from reorganization of large document repositories. If search engines cannot find a particular document—and you believe it contains vital information—you may be able to find the document using Internet archives.<sup>1</sup> Nonetheless, this text offers a complete and appetizing menu for understanding food regulation in the United States.

## **CITATION FORMAT**

Citations in this text generally follow *The Bluebook: A Uniform System of Citation (18th Ed.)*. However, some conventions are modified to save space and repetition.

I hope you find this text offers a complete and appetizing menu for understanding food regulation in the United States.

<sup>1</sup>For example, the Wayback Machine, which contains 55 billion Web pages archived from 1996, available at: <http://www.archive.org/web/web.php> (last accessed Sept. 12, 2006).

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- Food and Drug Law Institute: Neal Fortin, *The Hang-up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD AND DRUG LAW JOURNAL 565–594 (2003).
- International Food Information Council: FDA/IFIC, *Food Additives* (1992).
- Journal of Food Law and Policy: Neal Fortin, *Is a Picture Worth More Than 1,000 Words?* 1 JOURNAL OF FOOD LAW AND POLICY 239–268 (Fall 2005).
- Thompson-West: JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION (2d ed. 2004).

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