

# **UNITED STATES FOOD LAWS, REGULATIONS, & STANDARDS**



**Volume I,  
Second Edition**

**Y.H.Hui**

# **United States Food Laws, Regulations, and Standards Volume I**

**SECOND EDITION**

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A Wiley-Interscience Publication •

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## PREFACE

The major objective of this book is, as stated in the preface to the first edition, "... to provide a basic understanding of the major food regulatory agencies in the United States and of the regulations they promulgate concerning food inspections, standards, specifications, and related matters." By providing information missing in the first edition, this second edition makes the above objective the more important.

Before you proceed further, please read the preface to the first edition. The information there applies to the second edition with the following exceptions:

1. The organizational structure of each agency discussed is described in general terms instead of actual legal and administrative titles. This avoids the inevitable renaming with each new political administration. Also, how a small agency is related to a larger agency is not discussed. For example, this edition does not provide an organizational chart detailing the placement of the Food and Drug Administration under the Department of Health and Human Services. Information of this nature confuses the reader especially when changes occur after publication. Other-

wise, it must be emphasized that the organization unit of each agency mentioned in this book is discussed to its fullest extent in relation to the role of food control.

2. Camera reproduction of examples of standards and specifications in the appendix has been replaced by direct incorporation of the materials into the text. This was done because original materials in the first edition were both difficult to read and inconvenient to look up.
3. The materials in this second edition are more sophisticated in terms of scientific, technical and legal explanation and comprehensiveness. The decision to expand the first edition has been determined by the general background of the majority of the users.
4. The deletion of first edition material was necessary for a number of reasons, including the obvious one of outdatedness. However, this edition does not include the Bureau of Alcohol, Tobacco, and Firearms and the Environmental Protection Agency for the following reasons. First, a survey of the users of this book indicates that very few of them are involved with alcoholic beverages or environmental protection. Second, there are not sufficient changes in these organizations to warrant revision. Third, probably most important, space limitations make it essential that this edition be related directly to food and the people involved.
5. Inclusion of new material in the second edition is characterized by the following:
  - a. The discussion of the Food and Drug Administration and the Department of Agriculture is at least twice as large in depth and breadth. This is a direct reflection of the needs of the majority of the users.
  - b. New chapters are included for the postal service and medical fraud, customs service for imports and exports, food transportation, and occupational safety and health in food plants. No reference book on the market discusses these materials in one convenient source. It is hoped that this edition will fill the void.

Since this second edition has two volumes, the following points will help the readers use the book more efficiently:

1. All chapter, table, and figure cross-references include I or II to indicate the volume. For example, Chapter I-2 refers to Chapter 2 in Volume I and Chapter II-2 refers to Chapter 2 in Volume II.

2. All figure and table enumeration is preceded by I for Volume I and II for Volume II.
3. Each volume contains the tables of contents of both volumes.
4. An index for both volumes is provided in each volume.

Those of us who follow the scientific literature are familiar with such words as "repetitions" and "duplications" used by book reviewers. This applies especially to books with more than one volume. These two volumes also contain duplications. Every attempt has been made to assure that such occurrences are intentional. Because the work of federal agencies overlaps, it is almost impossible to discuss one without some minimal references to the specific work of another. However, a careful estimate places such duplication at less than 5% of the material presented.

Occasionally, the government, academia, industries, and the general public use different terms for the same item of information, object, fact, etc. In the presentation of materials, no attempt has been made to normalize this practice. However, the reader will have no trouble in delineating the meanings, which are defined by the context.

Certain materials in the preface to the first edition are briefly reiterated here for emphasis. Federal Register and Food Chemical News are still the major publications to keep current with new developments in the field. The new address for the latter is 1101 Pennsylvania Avenue SE, Washington, D.C. 20003.

Because of the present economic situation, practically all government publications are now priced items. Again, materials in this book are not meant to teach the practice of law. An attorney-at-law should be consulted for professional assistance. The legal information contained in this book cannot and should not be used as prima facie evidence in a court of law. To assure accuracy in the author's paraphrasing, always use the original sources cited.

Although this edition covers many subjects, it actually represents only a small fraction of the voluminous information on food laws and regulations. Again, this second edition does not attempt to provide a comprehensive discussion of the entire legal food system in this country.

After years of planning and preparation, two sets of correspondence courses have been developed using these two volumes as basic texts. One set is designed for educating and

training personnel in a foreign firm that exports food and beverages to the United States. The courses help them to comply with U.S. importing laws and regulations. The second set is appropriate for training food protection officials of foreign governments. Some countries improve their food protection systems by studying those of the United States. Inquiries about these courses should be directed to:

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Much work and thought have been given to the preparation of this edition, so that it will serve as a handy reference source for professionals and the public. It is the author's hope that it will "... provide a basic understanding of the major food regulatory agencies in the United States and of the regulations they promulgate concerning food inspections, standards, specifications, and related matters."

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June 1986

## **PREFACE TO FIRST EDITION**

In the absence of a modern reference source, it is difficult for an interested person to obtain basic information on and to understand the system of federal food regulations in the United States, its complexity, and its comprehensiveness. For example, one might ask: What are the types of legislation that exist with regard to food standards and inspections? What legislations regulate the standards for drinking water and alcoholic beverages, the use of food additives in food, or the safety of food preparation equipment? Other questions might be different in form, such as: Which federal agencies are involved in the enforcement of such legislations? How are they organized, what types of work do they perform, and what are their specific statutory responsibilities? Further, what is the relationship of two federal agencies that may have jurisdictional conflicts? What kind of cooperation exists between a federal agency and a state authority in regard to food regulations? Other interests might revolve around the legal requirements for television claims of the nutritive values of food products, the ingredients or nutritional composition of pet foods, the occurrence of "unavoidable" food contaminants, and the marketing of powdered forms of alco-



holic beverages. All these questions and more might be raised.

There is no recent publication that discusses United States food laws and regulatory agencies in a coordinated and systematic manner, especially regarding the queries mentioned above. The pertinent information does not exist in a cohesive form but is scattered in various federal publications, making it difficult to assemble and study the materials. Hopefully, this book helps to fill the existing vacuum. Its chief purpose is to provide a basic understanding of the major food regulatory agencies in the United States and of the regulations they promulgate concerning food inspections, standards, specifications, and related matters.

This book is divided into 7 chapters, each describing a federal agency that has at least some degree of statutory responsibility in enforcing food laws, especially in regard to food standards, definitions, and inspections. Food is defined by the Congress to include food and drink for human and animal consumption.

Each book contains part or all of the following information: (1) a brief description of the organizational structure of the agency, with a simplified chart attached to the appendix; (2) the agency's role in food inspection and the establishment of food grades and standards; (3) relevant statutory responsibilities assigned to the agency; (4) a list of lay and professional publications issued by the agency and related to food inspections and standards; (5) a discussion of some of the food regulations promulgated by the agency; (6) a list of food standards established by the agency, with some specific examples attached to the appendix; (7) the relationship to other governmental agencies in the performance of specific statutory responsibilities; (8) foreseeable changes in the organization of the agency, the food inspection regulations and standards promulgated by the agency, and the inclusion of new statutes; (9) directions for obtaining the original sources of material discussed in the book and in other related publications; (10) methods of enforcement; and (11) miscellaneous information such as important Supreme Court Decisions, controversial microbiological quality standards, problems of corporate responsibility, major jurisdictional conflicts, standardization of food package sizes, and other related materials.

Each chapter is provided with an appendix that may include such information as examples of definitions, standards,

specifications, and grades for selected food items, subpart and section titles of some relevant parts contained in the Code of Federal Regulations, and organization charts of the federal agencies discussed in the book.

There are a number of legal terms and documents that are used and referred to frequently in this book. Most individuals and organizations that are involved in this specialized area of food laws are familiar with them already. However, they are briefly explained here so that the information serves as a reminder for some and as background material for others. Specifically, the meanings of Statutes at Large, Public Law, United States Code, Federal Register, and the Code of Federal Regulations are presented in the following paragraphs.

Laws enacted by the Congress are published in the final and permanent form in Statutes at Large. This publication is issued in volumes, each of which contains those laws passed during a calendar year, although some old issues may contain varying periods of legislation. Statutes at Large divides all the legal papers into groups such as proclamations, treaties, and executive agreements, concurrent resolutions, private acts and resolutions, and public acts and resolutions. All the materials belonging to one group are assembled in a continuous series for the entire period covered by the volume. When a specific statute is cited, an abbreviation is used. For example, the citation "84 Stat. 1620 et seq." means Volume 84 of the Statutes at Large, starting from page 1620 and continuing with the following pages. These pages are concerned with the Egg Products Inspection Act. The abbreviation "Sec. 3, 84 Stat. 1620" means Section 3 of page 1620 in Volume 84 of the Statutes at Large; Section 3 is the Declaration of Policy for the Act.

It is difficult to define the difference between Public Law and Private Law. "Legislation classed generally as public may be listed as that in which the interest of the government is paramount, particular, or outweighs the other considerations of the act; that in which by the nature and scope of the act, the interest of the public as a whole is affected." This was stated in 1950 by the General Services Administration, which was and still is partially responsible for the editing and compiling of the Statutes at Large. In general, most food laws, especially those relating to food standards and inspections, are public laws. For example, PL 91-597 was enacted on December 20, 1970. This means that Public Law

number 597 was enacted during the 91st Congress of the United States on the date shown. The act was entitled "Egg Products Inspection Act".

At the time of current writing, the United States Code is in its 9th edition. It contains a consolidation and codification of all the general and permanent laws of the United States that were in force in January 1977. By statutory authority this edition may be cited "U.S.C. 1976 ed."

The authority for preparing and publishing this publication was issued under Section 202(c) of Title 1 of the Code. Previous editions were published in 1926, 1934, 1940, 1946, 1952, 1958, 1964, and 1970. Because many of the general and permanent laws required to be incorporated in this code are redundant, obsolete, and inconsistent, the Judiciary Committee of the House of Representatives is currently revising and enacting the Code into law, title by title. As the project proceeds, bills have been passed to revise, codify, and enact into law various titles of the Code. When this work is completed all the titles of the Code will be legal evidence of the general and permanent law of the United States, and recourse to the numerous volumes of Statutes at Large for this purpose will be unnecessary.

Each year a supplement to the latest edition is published, and this supplement contains the general and permanent laws of the United States enacted during the sessions of Congress of that particular year.

The United States Code is divided into titles that are expected to number 50. The citation "21 U.S.C. 1031 to 1056" refers to Title 21 of the United States Code, Sections 1031 to 1056. Title 21 is related to food and drugs, whereas Sections 1031 to 1056 are concerned with the Egg Products Inspection Act.

The Federal Register is published daily, Monday through Friday, and there is no publication on Saturdays, Sundays, or on official federal holidays. It is published by the Office of the Federal Register, National Archives and Records Service, and the General Services Administration, under the Federal Register Act (49 Stat. 500, as amended, and 44 U.S.C. Chapter 15) and the regulations of the Administrative Committee of the Federal Register (Title 1 of the Code of Federal Regulations, Chapter 1). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office.

The Federal Register provides a uniform system for making available to the public regulations and legal notices issued by the federal agencies. These include Presidential Proclamations and Executive orders and federal agency documents having general applicability and legal effect, documents required to be published by the Act of Congress, and other federal agency documents of public interest. There are no restrictions on the republication of material appearing in the Federal Register.

Again, abbreviation is used in the citation of information appearing in the Federal Register. The citation "36 FR 9814" (sometimes a date may accompany the citation, such as May 28, 1971) refers to Volume 36 of the Federal Register, page 9814, and such a page number was published on May 28, 1971. The regulations for enforcing the Egg Products Inspection Act as promulgated by the Food Safety and Inspection Service of the United States Department of Agriculture began on that page.

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government. The Code is divided into 50 titles, each of which is subdivided into chapters that usually carry the name of the issuing agency. Each title represents broad areas subject to federal regulation, and each chapter is further sectioned into parts that cover specific regulatory areas.

The Code is revised annually, and the dates of issue for the new revisions are as follows: January 1, Titles 1-16; April 1, Titles 17-27; July 1, Titles 28-41; and October 1, Titles 42-50. The cover of each volume should be consulted for the revision date. The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507), and the Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

Individual issues of the Federal Register keep the Code up to date. To determine the latest version of any given rule, these two publications must be used together. Further, the cumulative "List of CFR Sections Affected" (issued monthly) and the "Cumulative List of Parts Affected" (appearing daily in the Federal Register) together may assist a user to ascertain if there have been any amendments since the revision date of the specific Code volume.

Each volume of the Code of Federal Regulations contains amendments published in the Federal Register since the last

revision of that volume. Note that effective dates and publication dates in the Federal Register are usually not the same and that care must be exercised in determining the actual effective date. In instances where the effective date is beyond the cut-off date for the Code a note is inserted to reflect the future effective date.

The subject index to the Code, which is revised annually and supplemented periodically, is contained in a separate volume entitled General Index. This volume also contains a table of Code of Federal Regulations titles, chapters, and parts, an alphabetical list of subtitles and chapters, and lists of current and superseded volumes.

Again, reference to materials in the Code is usually given in abbreviation. For example, the citation "7 CFR 2859" means Part 2859 of Title 7 of the Code of Federal Regulations. Title 7 is "Agriculture," and Part 2859 is entitled "Inspection of eggs and egg products." Sometimes the citation may indicate a section, such as Section 2859.900 (or 7 CFR 2859.900), which has a section title of "Requirements for importation of egg products or restricted eggs into the United States."

This is a reference book and, as such, can be used by a large audience. It is expected, however, that the materials will be of special interest to the following individuals and organizations.

1. College or university students and instructors in the following fields: food science, food chemistry, dietetics, nutrition, public health, and law.
2. Federal and state regulatory officers at the administrative, technical, and field levels, who are assigned the responsibility of establishing and enforcing standards and regulations relating to food, drinking water, agriculture and health.
3. Physicians and scientists engaged in public health disciplines.
4. Ranking corporate officers in the food industry with supervisory roles in production, quality control, advertising, sanitation, regulatory affairs, and related responsibilities.
5. Government and private attorneys who have recently engaged in the practice of this specialty—food law. It is noted that a lawyer experienced with and specializing in food laws is usually very familiar with one particular

aspect of this book. However, it is hoped that this book serves as a good reference source for information about agencies and statutes that he or she is not working with and may be interested in.

6. Libraries of major universities, especially those with government document centers and law schools.

This book is not a comprehensive treatment of the total system of federal food regulations in the United States. Basic limitations on the size of a book of this nature confine the discussion to only a selected number of federal agencies and statutes. The selection is based on their direct bearing on and relative importance to food standards, inspections, and related regulatory aspects as they exist in this country. The omission of any material should be judged in this light. Two such examples of omission are the Occupational Safety and Health Administration (Department of Labor) and the Bureau of Customs (Department of the Treasury). The first has authority over the setting of safety regulations in food processing plants that have as their aim the protection of the workers. The second issues many special regulations governing the importation and exportation of food and drink for human consumption.

Federal statutes require all federal agencies to use federal specifications and standards for the procurement of subsistence items. Thus, for example, the General Services Administration, the Department of Defense, and the Veterans Administration all issue their own food product specifications and standard documents. This book does not deal with this type of information because of the lack of space and the scheduled massive federal government reorganization in procurement practices, including the issuance of food specifications and standards. However, interested parties may obtain the necessary information from the following documents, which are available at the time of current writing. (1) Publications issued by the Department of Defense: Consolidated Stock List, FSC Group 89 subsistence, Federal Supply Classification Listing of the Department of Defense Specifications and Standardization Documents; and Microbiological Requirements and Methodology for Food in Military and Federal Specifications. (2) Index of Federal Specifications and Standards issued by the General Services Administration. (3) Federal Hospital Subsistence Guide issued by the Veterans Administration.

There are certain kinds of information that this book either does not deal with or is concerned with only to a limited extent. For example, statutes concerning food stamps, food prices, and other monetary or economic aspects are not discussed. In addition, apart from a limited number of special situations, in general the book is not concerned with the legal analyses of specific court cases.

This book contains a fair amount of legal and technical information, most of which is paraphrased from original documents, and the interpretation is entirely the author's. Every reasonable effort has been made to assure accurate interpretation and paraphrasing. Because of the voluminous amount of materials involved, the author does not assume any liability for errors or omissions. Persons using this source should always consult the original document referenced to obtain further details and should use their own interpretation when necessary. Furthermore, the legal information contained herein cannot and should not be used as prima facie evidence in a court of law. The book is not meant to teach the practice of law, and, if legal advice is needed, the professional service of an attorney-at-law should be obtained.

Since one of the book's objectives is to make the information available to scientists, among others, some of the discussion and examples given are related to mathematical, chemical, physical, and/or biochemical data. The use of scientific and technical terms assumes certain basic background in these fields, but, for the most part, this use has been kept to a reasonable minimum.

The United States Government Manual provides a limited account of practically every federal agency in the country. It is published annually by the Office of the Federal Register, the National Archives and Records Service, and the General Services Administration, and it may be obtained from the Superintendent of Documents. A small amount of information appearing in this book is obtained from this publication, in which case it is cited as the Government Manual.

Because practically all the resource materials discussed are government publications, it is useful to attend to the question of the length of time it takes to obtain such materials from a government source. When requesting information it is fair to allow at least one month for a government reply. The answer may be faster if a request is sent to a specific individual in a federal agency soliciting specific and standard information. On the other hand, the purchase of any material



from the Government Printing Office may take longer. Addresses of government agencies discussed are given in Appendix 8. Those of private organizations are given in the text.

A book of this nature always suffers one inherent disadvantage—change. All federal laws, regulations, documents, and agencies undergo change constantly. Though it is not possible to avoid this obvious handicap, an attempt is made to minimize its impact. The information is presented in such a manner that only extensive and major changes will affect the content of this book. It is expected that no changes can influence its most important objective: "... to provide a basic understanding of the major food regulatory agencies in the United States and of the regulations they promulgate concerning food inspections, standards, specifications, and related matters." But it would be useful to remember that to obtain any of the reference sources discussed, one should always request the latest issue or edition.

In order to keep abreast of new developments in food laws, food regulations, and agency changes, one should read the Federal Register and the Food Chemical News (published weekly by Food Chemical News, Inc. 420 Colorado Building, 1341 G Street NW, Washington, D. C. 20005). The first publication is a well-known government document and is available in most major university government document centers and in law school libraries. It is too expensive for a personal subscription, though most food industries and law firms engaged in this specialty are subscribers. The Food Chemical News is a private publication, has been in existence since 1959, and is also too expensive for a personal subscription. Interested individuals, law firms, food industries, and university libraries subscribe to this publication.

Unless otherwise specified, the Code of Federal Regulations discussed in this book is the 1977 edition.

In the presentation of materials, the author is neutral, adheres to facts, and avoids personal opinions. Any controversial legal or scientific issues mentioned is accompanied by pro and con discussion.

Y. H. Hui  
Arcata, California  
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My neighbor Mrs. Leta Wilson deserves an A for her contribution in proofreading the chapter on the Food and Drug Administration. She did more than check for typographic mistakes; she also caught a few technical and legal errors. I appreciate her many years of experience as a clerk in a court house and I am grateful to her meticulous nature and dedication to the work she agreed to do.

The continuous support of the editors at Wiley, T. Leger and S. Kudzin, has been most gratifying. The readers are the