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Federal Regulation of the Food Industry—Part 1: The Regulatory Process[1]

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This fact sheet is intended to enhance understanding of federal regulations and provide a general overview of the regulatory process.

I. Introduction

The regulation of the food industry impacts a wide range of products and industries, from the wheat in a farmer's field to the nutrition label on the cereal box in the grocery store. Generally, the term "food" encompasses articles and components of articles that are food and drink, including water. The dominant jurisdictions of food regulations are (1) protecting public health and safety, (2) stopping consumer fraud, and (3) suppressing unfair competition.

Licensing, labeling, and inspection of food products and producers are accepted means of regulating the food industry. Depending on the specific violation, both civil and criminal penalties can be utilized if food regulations are violated. The validity of federal food legislation often rests upon Congress' power to regulate interstate commerce, and in keeping interstate commerce free from misbranded and tainted food products.

The regulation of the food industry often encompasses agricultural industry. Generally, the term *agriculture* includes all activities involved in and supporting farming. Such activities include soil cultivation, livestock raising, lumber operations, agricultural product storage and marketing, and even bee keeping. Both federal and state law reflects a strong and long-standing policy of promoting and protecting agriculture. Regulation of the agricultural and food industries is justified as a means of protecting public health and safety. Legislation exists to protect existing farmlands; provide varied public aid to agriculturists as necessary; and favorable tax classifications for agriculturists, their products, and their market practices. Furthermore, regulations protect the public and the agricultural industry from the spread of disease, destruction from pests, and spread of noxious vegetation. Regulations of the food industry protect the food supply from the presence of unwholesome or harmful chemical, physical, or biological residues; from unsanitary manufacturing and handling conditions; and from false representation or mislabeling with regard to formulation and content.

II. Federal Acts

General Definitions

An action by Congress is required prior to the passage of acts (or laws) (e.g. Federal Food, Drug and Cosmetic Act [FDCA]) or of amendments (or modifications) to these acts (e.g. Food Additives Amendment to FDCA). Acts are carefully written to clearly state their intent. Specified federal agencies are empowered with the enforcement of these acts.

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Passage of Acts and Amendments

The three requirements for good lawmaking are that a law must have a meaningful purpose, be just and fair to all concerned, and be enforceable. The precursor to an act is a *bill* in the Senate or the House of Representatives. The US Library of Congress maintains an up-to-date internet listing of congressional bills at https://www.loc.gov/.

For a bill to become an act, it must be:

- introduced by one or more members of the legislature,
- numbered or codified,
- considered by an assigned committee through public hearings and executive session,
- reintroduced,
- debated and voted upon by the Senate and the House,
- enrolled as an act or submitted to the president, and
- acted upon by the president.

Codification, Documentation, and Publication of Federal Acts

All public acts and laws are published in two federal publications, the *United States Statutes at Large* and the *US Code* [see www.gpo.gov]. The codification and citation system are as follows:

- ***Current Acts or Laws not yet Published***. The terminology used is *Public Law*—followed by the codification number (e.g. *Public Law 94-561*).
- ***US Statutes at Large***. This publication is the permanent chronological record of all federal acts and laws cited as follows: *Chapter, Statute, Paragraph* (e.g. *52 Stat. 1040)* followed by number or date of enactment.
- ***US Code***. In this publication, federal acts and laws are arranged by subject matter or "Titles" (e.g. Title 7, Agriculture; Title 21, Food & Drugs; Title 27, Intoxicating Liquors; Title 42, Public Health and Welfare). The citation is as follows: *Title, U.S.C., Paragraph*. Thus, the *Federal Food, Drug and Cosmetic Act* would be found at *21 U.S.C. 301*.

III. Federal Regulations

Federal acts empower specific federal agencies to promulgate *enabling regulations* as deemed necessary for enforcement of the act. *Regulations* (a.k.a. *rules*) are involved in the application of acts, and once finalized have the force and effect of law and must be observed. They usually are enacted to improve understanding, to increase specificity, to update, and to improve public communication. Passage of regulations requires that an agency publish its intent and proposed timetable to allow that the public voice is heard through town meetings, hearings, and comment requests.

Codification, Documentation, and Publication

Two federal publication documents are important to the enactment of regulations. These include the *Federal Register (FR)* and the *Code of Federal Regulations (CFR).* They can be readily accessed at the US Government Printing Office website (www.gpo.gov).

THE FEDERAL REGISTER

The *Federal Register,* a daily publication, is used by federal agencies to declare their intent to promulgate regulations as well as to inform the public on other issues. Agency summaries, notices, and proposed and final rules are published in the *Federal Register*. The *Federal Register* is organized into four parts as follows:

- *Presidential Documents*, executive orders or proclamations;
- *Rules and Regulations*, new documents and final rules;
- *Proposed Rules*; and
- *Notices*, miscellaneous agency announcements.

The citation system used for the *Federal Register* is *Volume F. R. Page #*. For example, a citation listed as *42FR 6834* would indicate volume 42, page 6834.

THE CODE OF FEDERAL REGULATIONS (CFR)

The *Code of Federal Regulations (CFR)*, published annually, is the official publication of federal regulations.

A. CFR Organization

The CFR is organized into *titles,* representing broad subject areas. The *titles* affecting regulations for food and agriculture are presented in Table 1.

CFR *titles* are subdivided into c*hapters, subchapters, parts*, s*ections, paragraphs*, and s*ubparagraphs*.

- *Chapters*, internal divisions of t*itles* numbered in Roman numerals (e.g. I, II), usually assigned to an individual agency;
- *Subchapters*, internal divisions of *chapters* (where needed). Given capital letters (e.g. A, B);

- *Parts*, internal divisions of *chapters.* Given Arabic numbers (e.g. 1, 2), consist of a unified body of regulations applying to a single function;
- *Sections*, internal divisions of *parts.* Cited using the number of the *part*, set off by a decimal point and preceded by the symbol § (For example, a *section* under *Part 25* would be designated §25.3);
- *Paragraphs*, internal divisions of *sections*. Designated by small letters set in parentheses [e.g. (a), (b)]; and
- *Subparagraph,* internal divisions of *paragraphs*. Designated by numbers in parentheses [e.g. (1), (2)].

B. Examples of CFR citations

Examples of CFR citations are presented in Table 2.

The Rulemaking Process

GENERAL ACTIONS OR EVENTS

The following actions or events are usually followed by federal agencies when putting out regulations:

1. Biennial summary of agency plans

Twice each year, the federal government publishes a summary (in the *Federal Register*) of its activities and any plans to issue new rules. This *regulatory agenda* or *snapshot* provides a heads up about the various programs being implemented by the agency.

2. Pre-rule phase

In this phase, the agency uses a variety of methods to collect pertinent information regarding the potential regulation. The pre-rule phase usually begins with information gathering, which may include informal solicitation or formally scheduled events (e.g. town meetings). The information gathering is usually followed by publication of an *Advance Notice of Proposed Rulemaking (ANPRM)*, or Pre-rule, in which an agency more definitively describes plans to propose certain requirements and solicits comments.

3. Proposed rule phase

In proposed rules, forthcoming regulations are outlined in proposal form and published in the *Federal Register*. The public is invited to submit comments within a specified period. Hearings are typically held within the "notice and comment" period. Comments received are carefully weighed and may or may not be incorporated into the final rule. Agencies are required to respond to comments on a proposed rule. The format and required sections of a proposed rule include:

- *Preamble*, background and intent are described; *Proposed Rule*, specific proposed requirements are spelled out in similar detail to how it would be published in the final rule; *Listing of Acts and Regulations Affected*, all acts and regulations that will be modified are listed; and *Proposed Timetable*, specific timetable for comment period and for proposed implementation is provided.

4. Final rule phase

A *final rule* is the final version of a regulation and is also published in the *Federal Register*. Final rules are incorporated into the next printing of the *Code of Federal Regulations (CFR)*. However, they have the effect of law upon the date of implementation listed on the final rule (which may precede publication in the *CFR*). The format of a final rule includes the following:

- *Preamble*, background and intent are described;
- *Response to Comments*, all comments on the proposed rule are addressed and responded to;
- *Final Rule*, specific requirements are spelled out in detail in CFR format and as they would appear in the final regulation published in the CFR;
- *Listing of Acts and Regulations Affected*, all acts and regulations that are modified are listed along with how they are modified; and
- *Implementation Timetable*, specific timetable with effective date.

A RULEMAKING EXAMPLE

To illustrate the rulemaking process, it might be helpful to review and summarize the procedures and actions used by the Food and Drug Administration (FDA) when issuing the regulations to require the hazard analysis critical control point (HACCP) system for the manufacture of fruits and vegetable juice products. These procedures and actions are as follows:

1. Pre-rule phase

Following a well-publicized foodborne illness outbreak associated with fresh apple juice, the FDA initiated the pre-rule process by publishing a notice in the *Federal Register* (61 FR 60290, November 26, 1996) to announce a public meeting to solicit input on the current science and safety factors related to juice products. Participants in the public meeting and interested parties were given until January 3,

1997, to submit written comments (the comment period was later extended to February 3, 1997). After consideration of these comments, the FDA published an ANPRM on August 28, 1997 (62 FR 45593), which again invited comment on the appropriateness of its proposed strategy to initiate, among other things, rulemaking on a mandatory HACCP program for juice products.

2. Proposed rule phase

The proposed rule, *Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice*; *Proposed Rule*, was published on April 24, 1998 (63 FR 20449). In this proposed rule, comments and concerns addressed in the ANPRM were thoroughly discussed and responded to and a proposed format, framework, and timetable of the regulations were delineated. Written comments from interested persons regarding the proposed rule were requested by July 8, 1998. On November 23, 1999 (64 FR 65669), the comment period on the proposed rule was reopened until January 24, 2000.

3. Final rule phase

The final rule, *Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule*, was published January 19, 2001 (66 FR 6137). In addition to the detailed final rule, as it would be published in the CFR with appropriate citations, this publication included an in-depth background discussion about the ANPRM, the proposed rule, response to comments, significance, economic impact, and a comparison of the final rule to the proposed rule. The juice HACCP regulations became effective on January 22, 2002, for most juice facilities; on January 21, 2003 for small businesses; and on January 20, 2004 for very small businesses.

IV. Additional Considerations

Economic Impact and the General Accounting Agency (GAO)

The General Accounting Agency (GAO) essentially examines how the federal government spends taxpayers' dollars. Known as the *congressional watchdog*, the GAO is an agency of Congress that investigates federal agencies' use of federal funds (audits agencies expenditures), determining whether agency programs and policies are both effective and efficient. The GAO issues evaluative reports and recommends actions, reporting both to Congress and the heads of executive agencies. GAO reports address varied and specific issues, such as fraud in the Food Stamp program. Most often, GAO reports are initiated at the request of congressional committees and individual congressional members. The GAO also regularly issues legal decisions and opinions regarding federal funding, among other matters. Also, the GAO provides Congress timely reports on rules proposed by federal agencies.

The GAO's recommendations and reports often influence congressional decisions. Congress is the final arbiter of federal funds. Subsequently, congressional funding decisions can impact the programs and policies of federal agencies.

Orientation and Language Style

As it is important that regulations be understood, they must be written in clear, concise, and appropriate (legal) language and terminology. For example, directive terminology (e.g. *shall*) is used to describe required actions. The word *should* is used for recommendations or suggested actions.

Regulations are also written in an active (not passive) language style that identifies the actor. The difference between active and passive writing can be seen in the following examples:

- *Active—Food employees* shall wear clean outer clothing.
- Passive—The outer *clothing of food employees shall be clean.*

V. References

Food and Drug Administration. Accessed November 20, 2024. www.fda.gov

Library of Congress. 2024. Accessed November 20, 2024. https://www.loc.gov/

U. S. Government Printing Office. Accessed November 20, 2024. www.gpo.gov

Table 1. Code of Federal Regulations (CFR) subject titles related to food and agricultural regulations.

Title	Subject
Title 7	Agriculture
Title 9	Animals & Animal Products
Title 21	Food & Drugs
Title 27	Alcohol, Tobacco & Firearms
Title 40	Environmental Protection
Title 42	Public Health
Title 50	Wildlife & Fisheries

Table 2. Examples of CFR citations.

Name Listing Requirements for Food Ingredients [21CFR101.4 (a)(1)]: Title 21, Food and Drugs; Chapter I, Food and Drug Administration (FDA)/Department of Health and Human Services (DHHS); Part 101, Food Labeling Section 4, Food; designation of ingredients Paragraph (a) Subparagraph (1)
Hazard Analysis Critical Control Point (HACCP) Plan Requirements for Meat Plants [9CFR417.2 (b)(1)] Title 9, Animals and Animal Products Chapter III, Food Safety and Inspection Service, Department of Agriculture Part 417, Hazard Analysis and Critical Control Point (HACCP) Systems Section 2, Hazard Analysis and HACCP Plan Paragraph (b) Subparagraph (1)