Chapter 1

INTRODUCTION TO LAWS AND REGULATIONS

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Introduction

American democracy is based on six essential principles. They are:

- The majority rules
- Protection of political rights of minorities
- Citizens agree to be ruled by a system of law
- Free exchange of ideas and opinions
- Equality of all citizens
- Government exists to serve the people.

In the United States, the combination of federal, state, and local laws, bodies, and agencies are responsible for carrying out operations. This combined group ensures that the people are the source of the government's authority by electing representatives to serve in the government in all levels and provides for checks and balances by sharing power between different levels of government. The President and Vice President are the only public officials elected by all the citizens of the United States. Each serve a 4-year term and are eligible for an additional 4-year term. Each President adds his personal touches to the Oval Office during his occupancy. More information about the president and vice president can be found on the white house website (http://www.whitehouse.gov).

A brief biography of each of the previous presidents can be found at http://www.whitehouse.gov/about/presidents.

Sources of American Law

There are four sources of American law: the Constitution, statutory law, common law, and equity.

The Constitution

JWST337-Curtis

The Constitution is the supreme law of the United States. It describes what powers the government has, as well as what rights US citizens have. All other laws must comply with the Constitution. It has six basic principles.

- 1. Popular sovereignty. The people have the power to govern. Likewise, the people must entrust this power to their government. People elect their congressmen, who make the laws that govern them.
- 2. Separation of powers. The US government is divided into three branches:
 - Legislative branch responsible for law making
 - Judicial branch responsible for law interpreting
 - Executive branch responsible for law enforcement.

Each of these branches has its own responsibilities, constituencies, and organization.

- 3. Checks and balances. No branch of the government can act completely on its own. Each branch has some control over the other two branches. In order to make a law, Congress (legislative branch) must get an okay from the President (executive branch) except in special cases.
- 4. Federalism. Allows federal, state, and local governments to exist and have their own powers. This separation of government power helps prevent abuse of that power. In general, state laws deal with matters that are contained to the state's borders. The state laws must be as stringent as the federal laws and must comply with the Constitution. For example, North Carolina Department of Agriculture is allowed to regulate food that is produced and sold within the state lines.
- 5. Supremacy of National Laws. When a federal and state law contradict, the federal law will be upheld.
- 6. Civilian control of government limits are placed on military power by putting control of the military into civilian hands. The President (a civilian) is the Commander-in-Chief, and only Congress can approve war and defense spending.

Statutory Law

Statutory law is written law that is passed by legislatures. Congress, state legislatures, and local governments all enact statutes. While constitutional law is broad and leaves room for interpretation, statutory law is generally more detailed and precise. Regulations passed by agencies are even more specific than statutes.

Common Law

The laws based on previous court ruling are called common, or case, law. This system dates back to 11th century England where judges contemplating a case would refer to previous case rulings. After seeing what was "common", he would then make his decision. When common law is in conflict with statutory law, the statutory law is upheld.

Equity

Equity cases deal with the 'fairness' or 'justice' of a situation. Judges decide the issues, and a jury is not present. The judge often orders injunctions to prevent the unfair act from happening again.

Public and Private Law

There are two branches of law in America (not to be confused with the three branches of government).

Private Law

This branch mainly deals with disputes between individuals, businesses, or other organizations. The outcome of these disputes is usually a fine or award of money as opposed to a jail sentence. Private law encompasses: property, contracts, family relations, and torts.

Public Law

Public laws deal with the relationship between the government and its citizens. The four categories of public law are Constitutional law, international law, criminal law, and administrative law. Administrative law encompasses the rules and regulations that governmental agencies make. The majority of the rules and regulations that control food quality and safety fall into this category.

Guide to US Food Laws and Regulations

Legislative Branch

The legislative branch is a bicameral system, which means that it is composed of two houses, the Senate and the House of Representatives, as outlined in the United States Constitution. The US Senate is made up of 100 Members, two elected from each state. The US House of Representatives is composed of 435 Members elected every 2 years from among the 50 States, apportioned to their total populations. These two houses together form the U.S. Congress and are mainly responsible for passing statutory, also known as legislative, laws.

The Constitution gives specific powers to Congress. These are:

- To levy and collect taxes
- To borrow money for the public treasury
- To make rules and regulations governing commerce among the states and with foreign countries
- To make uniform rules for the naturalization of foreign citizens
- To coin money, state its value, and provide for punishment of counterfeiters
- To set the standards for weights and measures
- To establish bankruptcy laws for the country as a whole
- To establish post offices and post roads
- To issue patents and copyrights
- To set up a system of federal courts
- To punish piracy
- To declare war
- · To raise and support armies
- To provide for a navy
- To call the militia to enforce federal laws, suppress lawlessness or repel invasions by foreign powers
- To make all laws for the District of Columbia and
- To make all laws necessary to enforce the Constitution.

The Vice President is the president of the Senate. He or she only has a vote in the case of a tie. A president *pro tempore* is chosen by the Senate to preside when the Vice President is absent. The House of Representatives chooses its speaker of the House.

Congress also has the power to investigate. This includes investigating the need for new legislation and the effectiveness of existing legislation, and evaluating the qualifications and performance of members of the executive and judicial branches. The House of Representatives is responsible for conducting impeachment proceedings, and the Senate is responsible

for impeachment trials. More information about the legislative branch can be found at http://www.whitehouse.gov/our-government/legislative-branch.

Judicial Branch

The Judicial Branch consists of the federal court system, with the Supreme Court being the top entity. It is its responsibility to interpret the 'intent' of laws, and to settle disputes. Its jurisdiction includes cases involving the Constitution, controversies when the US government is a party, and controversies between states or their citizens. In food law, this often includes disputes between an enforcing agency and a food company.

The US Congress has the power to create and abolish federal courts. It cannot abolish the Supreme Court, however. The President appoints US judges, who must then be confirmed by Congress. More information about the judicial branch can be found at http://www.whitehouse.gov/ourgovernment/judicial-branch.

Federal Court System

The Supreme Court

The Supreme Court is the highest court in the federal court system and was created by the Constitution. Its decisions cannot be overturned. About 10% of its cases get there by appeals. The rest of the cases get there through writs of certiorari (sir-shee-uh-RARE-ee). This is an order telling a lower court to send its records of a case to the Supreme Court for review. Writs of certiorari are issued for cases involving a serious constitutional issue or an error in the lower court. The Supreme Court consists of one chief justice and eight associates. More information about the Supreme Court can be found at http://www.supremecourt.gov.

Courts of Appeals

If someone feels that they did not get a fair trial, they can appeal their case to the courts of appeals. Here, a panel of judges who determine if the district court decision was correct reviews the case. If they need clarification on a point, they can ask to hear oral statements. These courts are also known as circuit courts, and they are arranged according to geography, with 12 circuits in all. In addition, the Court of Appeals for the Federal Circuit has nationwide jurisdiction to hear appeals in specialized

cases, such as those involving patent laws and cases decided by the Court of International Trade and the Court of Federal Claims.

US District Courts

There are 89 districts in the 50 states, and district courts also exist in Puerto Rico, the Virgin Islands, the District of Columbia, Guam, and the North Mariana Islands. In total there are 94 federal district courts. These courts have original jurisdiction over both criminal and civil federal laws. In criminal cases, a grand jury decides if there is enough evidence to try the case. Then a trial jury determines if the person is guilty. In civil cases, a trial jury can be used, or can be waived if both parties agree. In these cases, a federal judge makes the final decision. More information about the district courts can be found at http://www.uscourts.gov/Federal Courts/UnderstandingtheFederalCourts/DistrictCourts.aspx.

Special Courts

Congress has set up 'special' courts to deal with specific problems. One of these courts is the Court of Customs and Patent Appeals. This court handles issues involving the US Patent Office.

Executive Branch

The Executive Branch includes the President, the Cabinet, the Cabinet Departments, and independent agencies. The president has many powers. These include the power to:

- Introduce legislation to Congress
- · Veto legislation
- · Appoint federal judges
- Grant full and conditional pardons
- Call the National Guard into service
- Appoint ambassadors, ministers and consuls to aid in foreign relations
- Appoint heads of the executive departments and independent agencies.

The heads of the executive departments make up the President's 'Cabinet'. These Cabinet departments, along with independent agencies also in the executive branch, are responsible for enforcing laws passed by the legislative branch. The responsibility of food safety and quality is spread out among four Cabinet level departments and two independent agencies.

More information about the Executive Branch can be found at http://www.whitehouse.gov/our-government/executive-branch.

Sources of Legislation

For the purpose of this discussion, the word "law" refers to statutory law, or laws passed by Congress. As mentioned earlier, the US Congress is responsible for passing laws. The ideas for these laws can come from a variety of places:

- A member of Congress
- Constituents
- Citizen's groups
- A member of the President's Cabinet
- The President
- The executive agencies.

The idea is then drafted into a bill. A bill should contain three things:

- 1. Statutory provisions describe what legislation will prohibit, what is required, etc.
- 2. Administrative provisions describes who will be responsible for and enforce this statute, usually a department or agency.
- Judicial provisions describes which courts will handle disputes and aid enforcement These three provisions divide the responsibilities involved with the statute between the three branches.

Congressional bills are legislative proposals from the House of Representatives and Senate. There are six different types of bills. They are:

- House and Senate bills
 - Require the approval of both chambers (House and Senate) and the signature of the President to become law.
- Joint Resolutions
 - Require the approval of both chambers and the signature of the President.
 - Used for limited matters such as a single appropriation for a specific purpose or to propose an amendment to the Constitution.
- Concurrent Resolutions
 - Require the approval of both chambers but do not require the signature of the President and do not have the force of law
 - Generally used to make or amend rules that apply to both chambers.

Guide to US Food Laws and Regulations

- House and Senate Simple Resolutions
 - Address matters entirely within the prerogative of one chamber
 - Do not require the approval of the other chamber or the signature of the President
 - Do not have the force of law.

For more information about Congressional bills click on "About the Congressional Bills" at http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=BILLS.

How a Bill Becomes a Law

There are six main steps a bill goes through on its way to becoming a law:

- 1. Introduction
- 2. Considered in Committee
- 3. Reintroduction
- 4. Debate in Congress
- 5. Presidential Action
- 6. Enrollment.

Introduction

The introduction of the bill can take place in either the House or the Senate. The process is as follows:

- 'First Reading'. In the Senate, the bill is usually introduced by presenting it to the clerk at the Presiding Officer's desk. The Senator with a brief statement can introduce it from the floor. In the House of Representatives the bill is simply dropped in a hopper and printed in the Congressional Record.
- The bill is then numbered. Bills originating from the Senate are numbered S. #, while bills from the House of Representatives are numbered H.R. #.
- Assigned to a standing committee for consideration,
- And printed by the Government Printing Office.

Considered in Committee

Once in the standing committee, bills are often sent to a subcommittee. If it is a controversial or important topic, the subcommittee may hold a

public hearing to get more information. They will then prepare a report for the standing committee with their recommendations and amendments.

The committee will then consider the subcommittee's report and take one of the following actions:

- Pigeonhole the bill ("kill" the bill).
- "Report the bill out of committee favorably" (recommend to the house of origination that it be passed).
- "Mark up" the bill (amend the bill).
- Throw out the old bill and write a new one, called a "clean bill."
- "Report the bill out unfavorably." This happens in rare cases when a committee has political reasons for not killing a bill.

Once the bill is 'reported out' of the committee, it must then be placed on the calendar of the originating house. The Rules Committee decides exactly when and how the bill will be discussed.

Reintroduction

When it is the bill's turn on the calendar, it is reintroduced or "called up" by the standing committee to the full Senate or House. The bill is then considered "Reported out of Committee."

Debate in Congress

Once the bill is reintroduced, it has its "second reading." At this time, the Congress members can take one of several "actions" on it.

- Pass it as written.
- Table the bill. This removes the bill from further discussion, or "kills"
 it
- Send the bill back to committee. This often results in the bill being killed in committee.
- Amend the bill. All amendments are debated and voted on.

All actions on the bill are published daily in the Congressional Record. The bill then has its third reading and is voted on in its final form. If it gets a YES vote, it undergoes "engrossment" and graduates from being a bill to being an "act". The act is then passed on to the other house, where it undergoes the same process, starting again with the introduction of the act.

10

Guide to US Food Laws and Regulations

If the Senate and House of Representatives end up with different versions of the same act due to amendments, members are sent from each house to form a conference committee to resolve the differences. A report of the committee's results is sent to each house, and the act is voted on again.

Presidential Action

The President has three options when he is presented an act. He can:

- Approve and sign the act. It then becomes a law.
- Not act on it within 10 days, excluding Sundays. In that case it will automatically become a law unless Congress is out of session. In that case, it will be considered vetoed. This is called a "pocket veto."
- Veto the act by not signing it or sending it back to the House of origin for recommendations. The veto can be overridden if each house approves it by 2/3 vote.

Once the act becomes a law, it is printed as a Slip Law and is distributed to the public. If the law is a Public Law, then it is numbered consecutively with the Congress session number and the number of the law. Example: Pub. L. 113-4 is the 4th law passed by the 113th Congress.

Enrollment

The act is enrolled, or reprinted and submitted to the President after being signed by the Speaker of the House and the President of Senate. During every step of the legislative process, information about the bill or act is printed. A list of where the documentation for each step can be found is shown below.

The Legislative Process: Publications

- 1. Introduction: Bills of Resolutions
- 2. Considered in Committee: Hearings and Reports
- 3. "Calling Up" the Bill: Congressional Record
- 4. Debate: Congressional Record and Conference Report
- 5. Presidential Action: Slip Law or Veto Message
- 6. Enrollment: US Code.

Once the act becomes a law, it is then up to the regulatory agency to enforce it through the use of rules, regulations, policies, and guidelines.

It is possible to find much of the legal information you need on the internet. This is very convenient and allows you to get up to date JWST337-Curtis

information quicker. With the improvement of the online search at the Government Printing Office website, online searching has become much easier. At the time of publication, there was a three-part series of YouTube videos published by the John Marshall Law School's Louis L Biro Library. This three-part series provides easy to follow instructions on how to conduct research on the FDsys website (http://www.gpo.gov/fdsys/search/ home.action). The three instructional videos are:

- 1. How to Use US Government Websites to Research Federal Regulations1
- 2. How to Use the FDsys to Research Federal Regulations²
- 3. How to Use the Online Code of Federal Regulations (eCFR) to Research Federal Regulations³

Both the electronic means of finding legal information as well as the method of using indexes in the library will be discussed.

Where to Find Legal Information

The Federal government makes legal information available at Federal depository libraries and on the web. There are approximately 1200 Federal depository libraries throughout the United States and its territories. All provide free public access to a wide variety of Federal government information in both print and electronic formats, and have expert staff available to assist users. To locate a Federal Depository Library near you visit http://catalog.gpo.gov/fdlpdir/FDLPdir.jsp.

All of the government information available from the U.S. Government Printing Office's is available on their website (http://www.gpo.gov/ fdsys/search/home.action).

Each of the individual federal agency website also contain information regarding agency related laws and regulations.

Information about US laws is printed in many different publications. It is important to know what each one contains and how often it is updated when looking for current information. Some governmental publications of interest are described below.

¹http://www.youtube.com/watch?v=PKW_19KxKcc&list=UUX9qoSvd_ePtVDuC60ot7jQ &index=7

²http://www.youtube.com/watch?v=YGGEBeSlaLQ&list=UUX9qoSvd_ePtVDuC60ot7jQ

³http://www.youtube.com/watch?v=GOheBZaWiec&list=UUX9qoSvd_ePtVDuC60ot7jQ &index=5

12

Guide to US Food Laws and Regulations

Law-making Process

Consult the following resources when looking for information about the actually passing of a law. For example, what took place during debate about the law or when will the law be introduced to the House of Representatives or the Senate.

Congressional Record

The Congressional Record is the official record of the proceedings and debates of the United States Congress. It is published daily when Congress is session. It began publication in 1873 and is still in publication today. The Congressional Record consists of four sections:

- · Daily digest
 - Summarizes the day's floor and committee activities and serves as a table of contents for each issue.
- House section
 - o Contain proceedings for the House chambers.
- Senate section
 - Contain proceedings for the Senate chambers.
- Extension of remarks
 - Includes tributes, statements and other information that supplements statements made on the Congressional floor.

The FDsys contains Congressional Record volumes from 140 (1994) to present. The current year's Congressional Record is usually updated daily. The date of the publication refers to the date the proceedings were recorded. To browse the Congressional Record go to http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=CREC.

Congressional Calendar

The Congressional Calendars collection includes the Calendars of the US House of Representatives and History of Legislation and the Senate Calendar of Business. The House Calendar contains a history of both House and Senate bills and resolutions that have been reported or considered by either house. The issue for the first legislative day of each week that the House is in session includes legislative history of bills through conference, and index of short titles, and index of major subject headings, and an alphabetical index. The Senate Calendar of Business identifies bills and resolutions awaiting Senate floor actions. It is updated each day the Senate is in session. To browse the Congressional Calendars visit http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=CCAL.

The Laws

Once the laws have been passed, they can be found in the following forms.

Slip Laws

Public Laws are first printed as a slip laws. They can be found loose at Federal Reserve Libraries until the end of the year, when they are reprinted together as the Statutes at Large. They are referred to by their Public Law number (Pub. L. 113-4). GPO has the full text of Public Laws passed since the last Congress.

The Statutes at Large

The Statutes at Large (Stat.) is the official compilation of Federal Laws. It is published annually. It contains all laws, both public and private, passed in the United States. At the end of each congressional session, acts are printed into the Statutes at Large in the order in which they are printed in the statutes. The Statutes at Large present a chronological arrangement of the laws in the exact order that they have been enacted.

At the beginning of each volume there is a list of bills enacted into public laws, a list of public laws by number, a list of proclamations, a popular names index, and a subject index. Because the text of laws published as public laws and Statutes at Large are the same, there is not a Statutes at Large database on GPO. However, users may perform a search by Statutes at Large citation in both the public laws and US Code databases. The Statutes at Large can be found in Federal deposit libraries.

US Code

Every 6 years, public laws are incorporated into the *United States Code*. The *United States Code* is the codification by subject matter of the general and permanent laws of the United States based on what is printed in the *Statutes at Large*. It is divided by broad subjects into 50 titles and published by the Office of the Law Revision Counsel of the US House of Representatives. Of the 50 titles, only 23 have been enacted into positive (statutory) law. These titles are 1, 3, 4, 5, 9, 10, 11, 13, 14, 17, 18, 23, 28, 31, 32, 35, 36, 37, 38, 39, 44, 46, and 49. When a title of the Code was enacted into positive law, the text of the title became legal evidence of the law. Titles that have not been enacted into positive law are only *prima facie* evidence of the law. In that case, the Statutes at Large still govern.

The *US Code* also contains helpful indexes and tables. The General Index contains an alphabetical listing of useful subject headings. Entries are also listed under agency names. The *US Code* citation is given for each entry.

The US Code has nine tables found at the end of its volumes. A couple of particular interest is:

- Table 1 Revised Titles This table lists all the sections of the titles that have been revised since the last printing.
- Table 3 Statutes at Large Here all the public laws currently in effect and there corresponding US Code citation is listed. Statutes are cited in the US Code as, Title U.S.C. section (subsection). For example, 21 U.S.C. Sec. 301 (a)

A US Code Supplement is issued during each of the years between printings of the US Code. This contains additions to and changes in the general and permanent laws of the United States enacted during that Congress and session.

The US Code does not include regulations issued by executive branch agencies, decisions of the Federal courts, treaties, or laws enacted by State or local governments. Regulations issued by executive branch agencies are available in the Code of Federal Regulations (CFR). Proposed and recently adopted regulations may be found in the Federal Register (FR).

Since 1926, the *US Code* has been published every 6 years. In between editions, annual cumulative supplements are published in order to present the most current information.

When a section is affected by a law passed after a supplement's revision date, the header for that section includes a note that identifies the public law affecting it. In order to find the updated information, you must search the public laws databases for the referenced public law number. You may browse the *US Code* at http://www.gpo.gov/fdsys/browse/collectionUS code.action?collectionCode=USCODE.

You can search the *US Code* by subject or by citation. The GPO website contains the 1996-current year editions of the US Code. The List of CFR Sections Affected lists proposed, new, and amended Federal regulations that have been published in the Federal Register since the most recent revision date of a CFR title. Each LSA issue is cumulative and contains the CFR part and section numbers, a description of its status (e.g. amended, confirmed, revised), and the Federal Register page number where the change(s) may be found. The US Code on GPO website is the official version of the Code, however, two unofficial editions are available. These are the USCA (US Code Annotated) and the USCS (US Code Service). The USCA and USCS contain everything that is printed in the official US Code but also include annotations to case law relevant to the particular statute. While these unofficial versions may include annotations, they are not official and not available from the US Government Printing Office.

Code of Federal Regulations (CFR)

The Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each title is divided into chapters, which usually bear the name of the issuing agency. Each chapter is further subdivided into parts that cover specific regulatory areas. Large parts may be subdivided into subparts. All parts are organized in sections, and most citations in the CFR are provided at the section level. Titles 7 (Agriculture) and 21 (Food and Drug) contain most laws concerning food. Each volume of the Code of Federal Regulations is updated once each calendar year and is issued on a quarterly basis:

- Titles 1-16 (includes Title 7, Agriculture) 1 January Titles 17-27 (includes Title 21, Food and Drug) - 1 April
- Titles 28-41 1 July
- Titles 42-50 1 October.

CFR volumes are added to FDsys concurrent with the release of the paper editions. When revised CFR volumes are added, the prior editions remain on FDsys as a historical set. FDsys currently titles from 1996 to present.

Due to the update schedule of the CFR, the List of Sections Affected (LSA) provides a cumulative list of CFR sections that have been changed at any time since each CFR title was last updated.

Code of Federal Regulations Citations

The FDsys provides the following description of how information is contained in a CFR citation.

- Title: Is the numeric value to the left of "CFR".
- Part: Is the numeric value to the right of "CFR" and preceding the period (".").
- Section/Subpart: Is the numeric value to the right of the period
 - A subpart is a letter of the alphabet (A-Z) that is used to retrieve an entire subpart of the CFR rather than many individual sections. For example: Subpart E.
- **Revision Year:** The four-digit year from the "Revised as of" text represents the year being cited. The revision year is not always available when the CFR is cited.

16

Guide to US Food Laws and Regulations

The following example illustrates information contained in a CFR citation.

21 CFR 310.502 Revised as of April 1, 1997

Title: 21Part: 310Section: 502Year: 1997.

Conventional Search Method

In order to find a specific law using printed copies:

- 1. If the name of the law is known, look in the *US Code* Popular Names Index. This index contains Public Law Citations and *US Statutes* at Large citations for many laws. The Popular Names Index is found in the same volume as Title 50 in the 1994 Edition. If name of the law is not known, look in the *US Code* General Index for laws about a specific subject.
- 2. Find out the status of the law by using the *Statutes at Large* Table in the *US Code Tables* volume. This table lists laws by their Public Law Number and gives their *US Code* citation and their status.
- 3. Take the *US Code* citation given and use it to find the law.

Example Search

Online Search

- 1. Open a browser window and type in http://www.gpo.gov/fdsys/search/home.action that takes you to "FDsys" the Government Printing Office's Federal Digital System.
- 2. Select Advanced Search, which is located near the search box.
- 3. You can select specific dates for your search or search all dates.
- 4. Find "Public and Private Law" in the "Available Collections" box and select. Click the "Add" and "Public and Private Laws" should appear in the "Selected Collections" box.
- 5. In the "Search In" box choose "Full-Text of Publications and Metadata." For future searches you may want to be more selective and if so, you can click on the drop down menu for additional selections.
- 6. Perform a search for "Food Safety Modernization Act" by typing "Food Safety Modernization Act" into the box next to "for". Click the search button.
- 7. This search should return a number of results, one of which should be titled "Public Law 111-353."
- 8. By clicking "Public Law 111-353" you will be able to see complete text of the Act.

You can search the *United States Code*, *Federal Register*, etc., using a similar process. Simply select your search choice in the "Available Collections" box. Many searches can be done by simply typing in keywords in the FDsys search box without having to do an advance search.

You can also browse through the different collections (*US Code, Federal Register, Congressional Record*, etc.) by selecting the specific reference from the 'Featured Collections' listing on the FDsys home page and then continuing to select the year and then other selections as needed until you reach the specific publication you desire to browse.

How Regulations are Made

After the bill becomes a law, the agency or department listed in the administrative provisions is responsible for enforcing the statute. In order to do this, the agency must make rules and regulations. Rules are typically administrative in nature, while regulations deal more with scientific and technical issues. They both carry the force of the law, which means that if a rule or regulation is broken, then the statute is broken. For the purpose of this discussion, the terms "rule" and "regulation" will be used interchangeably.

Regulations are made in the following manner:

- 1. A regulation is proposed by the appropriate agency. It is then published in the *Federal Register*, which is the federal publication that notifies the public of changes in US laws and regulations. It is published as an "Advanced Notice of Proposed Rulemaking" or ANPR. ANPRs alert the public that the agency plans to make or change a regulation and asks for their comments.
- 2. Then there is a comment period during which people can write in with opinions and criticisms of the proposed regulation. These comments are taken into account when the final regulation is made and a summary of the comments is provided in the final rule. In addition, the agencies can have hearings where they bring in experts on a particular subject to aid their decision.
- 3. The regulation is printed in the *Federal Register* as a final rule along with the date it goes into effect.

A list of where in the *Federal Register* each step in this process is published can be found below.

The Rule-making Process and Publication

1. A rule is proposed in the "Proposed Rules" section of the *Federal Register*

- 2. A comment period is announced in the "Proposed Rules" section of the Federal Register
- 3. The final rule is published in the "Final Rules" section of the Federal Register
- 4. Rules are arranged according to subject Code of Federal Regulations. Regulations are compiled into the *Code of Federal Regulations*.

Example

An example of this process is the "Pathogen Reduction; Hazard Analysis Critical Control Point Systems Final Rule" published by the USDA. The public was first notified that the USDA was planning a new inspection system when the Advanced Notice for Proposed Rulemaking (ANPR) was published in the *Federal Register* of December 29, 1995 (60 FR 67469). This ANPR explained the regulation and requested comments from the public. There was an initial comment period of 120 days. The comment period was ultimately extended for 30 days, then reopened for another 95 days. During this time, seven informational briefings were held in seven cities around the United States to help interested parties prepare comments on the proposal. A panel of FSIS officials and scientists provided information on the proposed regulations and answered questions. All of this input assisted USDA in writing the final rule.

Anyone can comment on a proposal and your comments do make a difference. At regulations.gov (http://www.regulations.gov/#!home;tab= search) you can submit comments on proposed regulations and related documents published by the US Federal government. The website provides easy to follow instructions. The site also has links to regulations with comments due soon and newly posted regulations.

Code of Federal Regulations

All the final and interim regulations of the United States are compiled (or codified) into the Code of Federal Regulations (CFR). The CFR is updated yearly. The regulations are categorized into 50 titles. (Note: these are not the same titles as those in the US Code - that would be too easy!) These titles are subdivided into chapters, parts, sections and paragraphs. Regulations are referred to using those parts. An example citation for a regulation in the CFR is:

21 CFR Sec. 131.144 (a).

This would be read as Title twenty-one, part 131, section 144, paragraph a.

Titles of particular interest to Food Scientists are Title 9 - Animals and Animal Products and Title 21 - Food & Drugs. The CFR can be found on the internet at the FDsys website. The best way to become familiar with how these regulations are printed is to jump right in and look at them. Published along with the *Code of Federal Regulations* are the CFR Index and Finding Aids. These resources are available to help people find information located in the CFR. The CFR Index has appropriate CFR citations under subject headings and agency names.

Parallel Table of Authorities and Rules lists rulemaking authority for regulations codified in the CFR. It contains a section for *US Code* citations, *US Statutes at Large* citations, *Public Law* citations, and Presidential document citations. Within each segment the citations are arranged in numerical order.

A list of CFR Titles, Chapters, Subchapters, and Parts outlines what can be found in each section of the CFR. Each agency is listed alphabetically along with the CFR Title, Subtitle, or Chapter in which it is found.

The CFR also publishes a monthly publication, The List of CFR Sections Affected (LSA), which lists the sections of the CFR that have been changed by actions published in the *Federal Register*. This includes any new or proposed rules. Entries are by CFR title, chapter, part and section. The LSA should be consulted whenever looking for up-to-date regulations to ensure the CFR has not been changed. The *Federal Register* contains a cumulative List of Parts Affected. The page numbers to the right indicate where the specific amendments begin in the Federal Register. A table of *Federal Register* Issue Pages and Dates can be found at the back of the LSA.

Using the Code of Federal Regulations

In order to find a regulation in the Code of Federal Regulations:

- Look up the subject of the regulation in the CFR Index and Finding Aids.
- 2. Go to the source listed.
- 3. Check the LSA or the *Federal Register* for any recent changes to the regulation.

Example

Searching the Code of Federal Regulations Using the Internet

The *Code of Federal Regulations* can be searched via the internet from the GPO FDsys website. Selected books and titles of the CFR, keywords, or citations can be used to search the record.

20

Guide to US Food Laws and Regulations

- Open a browser window and type in http://www.gpo.gov/fdsys/ search/home.action that takes you to "FDsys" the Government Printing Office's Federal Digital System.
- 2. Select Advanced Search, which is located near the search box.
- 3. You can select specific dates for your search or search all dates.
- 4. Find "Code of Federal Regulations" in the "Available Collections" box and select. Click the "Add" and "Code of Federal Regulations" should appear in the "Selected Collections" box.
- 5. In the "Search In" box choose "Full-Text of Publications and Metadata." For future searches you may want to be more selective and if so, you can click on the drop down menu for additional selections.
- 6. Perform a search for "Food Safety Modernization Act" by typing "HACCP" into the box next to "for". Click the search button.
- 7. This search should return a number of results, one of which should be titled "9 CFR 417.2."
- 8. By clicking "9 CFR 417.2" you will be able to see complete text of the regulation.

You can also do a simple search at the FDsys website by typing HACCP into the search box on the home page of FDsys. You will probably need to refine your results by choosing "Code of Federal Regulations" from the "Narrow your Search" tool in the left column of your results.

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Additional Resources

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22 Guide to US Food Laws and Regulations

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