What is the CFR?

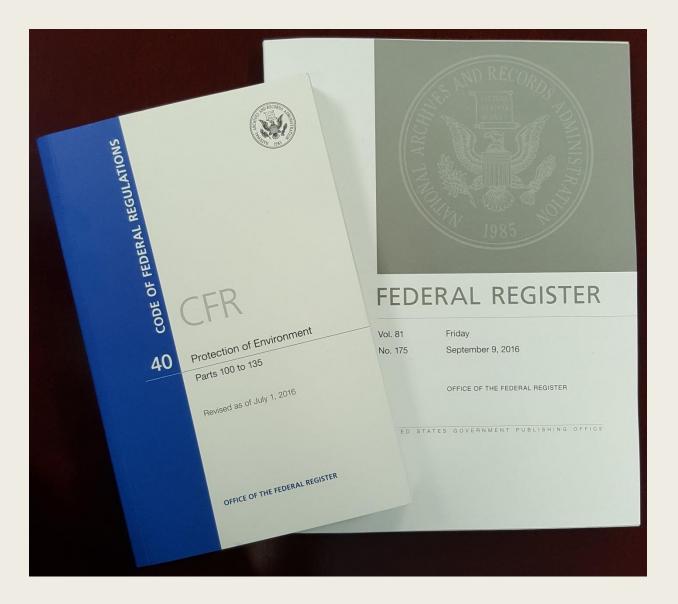
Office of the Federal Register National Archives and Records Administration

2018

What topics will this workshop cover?

- Historical background and legal basis of the CFR
- Relationships among Public Laws, the Federal Register and CFR
- Organization of the CFR
 - Research tools and Finding Aids
- Where to find it online

Historical Background & Legal Basis



Why was the Federal Register System Established ?

New Deal Legislation

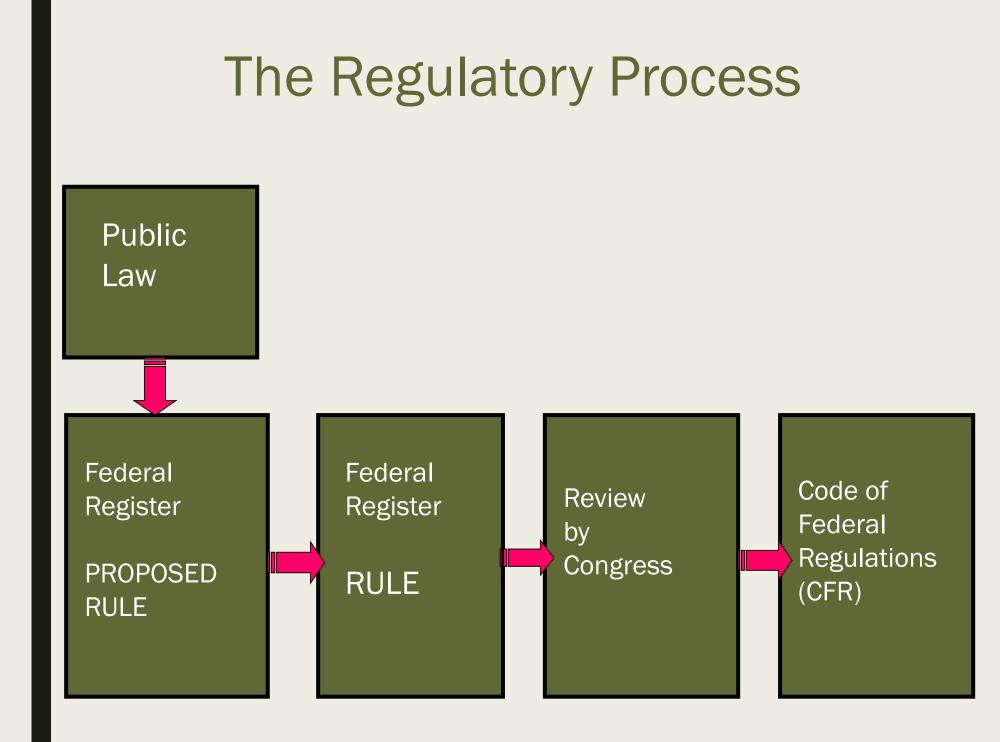
- A growing government
- New agencies regulating new areas
- Lack of Process
 - No centralized publication system
- Lack of Access
 - No centralized filing system
- Lack of Organization
 - No organization to the system
- Constitutional Issues
 - Separation of Powers
 - Due Process
 - Fairness

Federal Regulatory Process – the Congressional Response

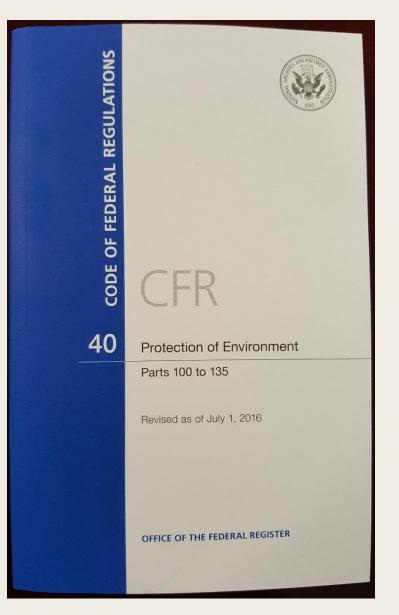
Legal structure:

- The Federal Register Act
- The Administrative Procedure Act (APA)
- Congressional Review Act
- Other individual laws

Designed to allow Federal agencies to <u>issue</u> <u>and enforce</u> legally effective regulations



The CFR – Organization and Contents



What is the Code of Federal Regulations ?

The CFR contains Federal rules that have:

- <u>General applicability</u> to the public
- <u>Current and future effect</u> as of the date specified

Always published first in the FR as <u>amendments to the CFR</u>

The CFR is published in a set of over 240 volumes

- Printed soft cover books
- Microfiche
- Online at: govinfo.gov

How is the CFR organized ?

Federal regulations are organized into:

- <u>50 titles</u>
- Broad subject matter categories
 - Environment, Defense, Public Health, Transportation

Each title is completely revised and reissued once each year on a staggered schedule.

- Titles 1 16 updated as of January 1
- Titles 17 27 updated as of April 1
- Titles 28 41 updated as of July 1
- Titles 42 50 updated as of October 1

What is the CFR numbering system?

The CFR has a <u>uniform numbering system</u>

• Titles 3, 41, and 48 have significant variations

The section is the basic unit of the CFR

Cite the CFR by title and section: 12 CFR 303.1

Text is divided into descending levels of units

CFR Structure

- Title12Broad subject area of regulations
- Chapter III Rules of individual agency
- Part 303 Rules on a single program or function
- Section 303.1 One provision of program/function rules

Paragraph 303.1(a)

Detailed, specific requirements

Paragraph Levels

Sections may contain up to 6 levels of paragraphs.

• We strongly recommend no more than 3 levels.

<u>Paragraph</u>	Designations	Cite paragraph as
Level 1	(a), (b), (c), etc.	§ 303.1(a)
Level 2	(1), (2), (3), etc.	§ 303.1(a)(1)
Level 3	(i), (ii), (iii), etc.	§ 303.1(a)(1)(i)
Level 4	(A), (B), (C), etc.	§ 303.1(a)(1)(i)(A)
Level 5	(1), (2), (3), etc.	§ 303.1(a)(1)(i)(A)(1)
Level 6	(<i>i), (ii), (iii)</i> , etc.	§ 303.1(a)(1)(i)(A)(1)(i)

Material Approved for Incorporation By Reference (IBR) (5 U.S.C. 552(a) and 1 CFR Part 51)

IBR material has the force of law as though it were published in full text the FR & CFR

Congress authorized IBR to enforce voluntary standards already used in science & industry

Under the FOIA, the Director of the Federal Register must approve IBR to give it force and effect of law

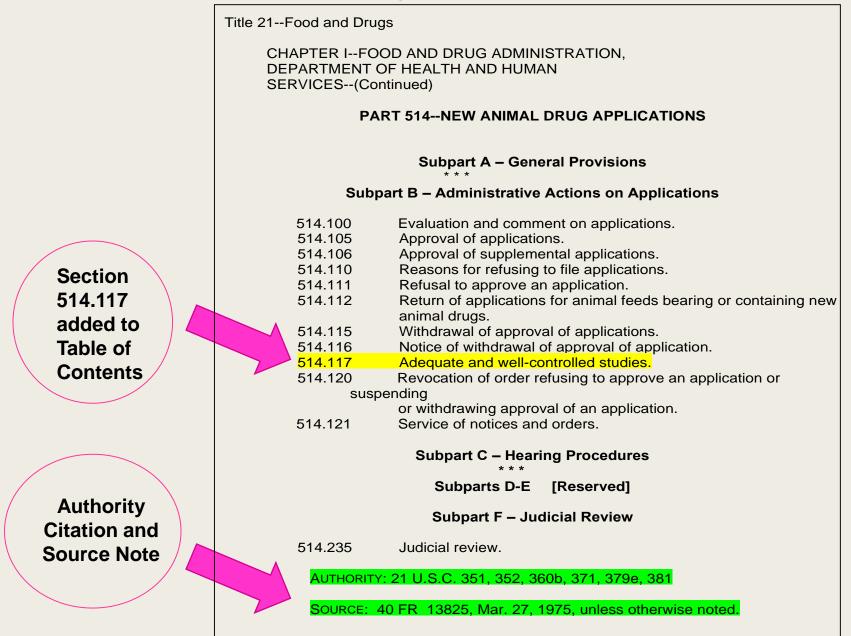
Part Level Table of Contents, Authority Citations, and Source Notes

A new entry in the <u>table of contents</u> at the part level to reflect the newly added section of regulatory text

The <u>authority citation</u> below the table of contents

The source note below the authority cite

Table of Contents, Authority Cite, Source Note

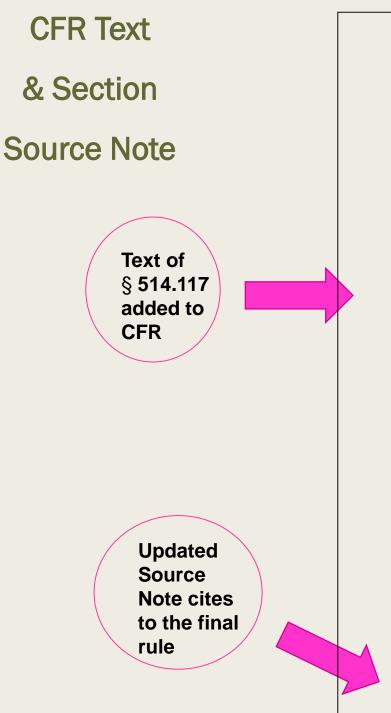


CFR Text, Section Level Source Notes, and Authority Citations

The <u>text of new section 514.117</u> inserted into CFR Title 21, Chapter I, Part 514, Subpart B

A source note

No separate authority citation for this section



TITLE 21--FOOD AND DRUGS

CHAPTER I-FOOD AND DRUG ADMINISTRATION, DE AND HUMAN SERVICES--(Continued)

PART 514--NEW ANIMAL DRUG APPLICATIONS--Table

Subpart B--Administrative Actions on Applications

\S 514.116 Notice of withdrawal of approval of application.

When an approval of an application submitted pursuant to section 512 of the act is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

\S 514.117 Adequate and well-controlled studies.

(a) *Purpose*. The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well controlled, as used in the phrase adequate and well controlled, emphasizes an important aspect of adequacy. The Food and Drug Administration (FDA) considers these characteristics in determining whether a study is adequate and well controlled for purposes of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). Adequate and wellcontrolled studies, in addition to providing a basis for determining whether a new animal drug is effective, may also be relied upon to support target animal

CFR Cover Color

Each year is given its own cover color to distinguish it from other years on the shelf.

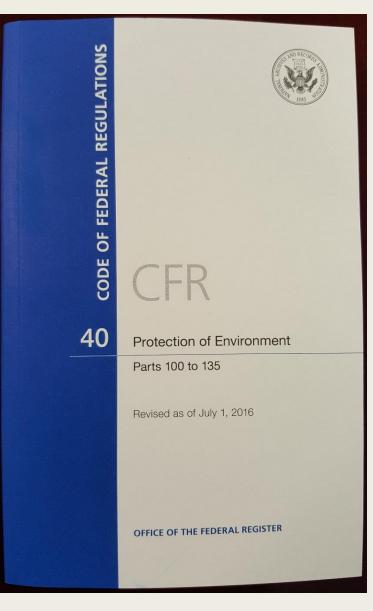
2012	"Update Slate"	Pantone 433U
	A dark gray.	
2013	"Regulatory Red"	Pantone 186U
75 year anniversary	Brick red to look nice with a navy-	
	colored seal.	
2014	Charley Barth purple	Pantone 266U
2015	Hyrum Green	Pantone 355U
	(selected by new Managing Editor)	
2016	Royal Blue	Pantone 293U
2017	Orange	Pantone 1655U
2018	Flint	Pantone 5497U

Title 3

Title 3 – The President

- This title is not codified, it is compilation of the Presidential Documents Published in the Federal Register during that year
- Because it is an annual compilation the paper volume should be retained as a permanent reference source
- Its cover color is reversed from the other books in the CFR

CFR Research Tools in Print and On-line



Tables of Contents Incorporation by Reference Tables Table of CFR Titles and Chapters Alphabetical List of Agencies Appearing in the CFR Redesignation Tables

e-CFR

What research tools are in each printed volume of the CFR ?

At the front of each CFR volume, look for:

- Tables of contents to all material within the book
- Tables of contents to the title, subtitle(s), chapter(s), and subchapter(s) within the book

At the back of each CFR volume, look for:

- "Table of CFR Titles and Chapters"
- "Alphabetical List of Agencies Appearing in the CFR"
- Redesignation Tables
- "List of CFR Sections Affected"

Table of Contents to a Subtitle

Table of Contents shows page numbers for the beginning of each part

Subtitle A—Office of the Secretary of Agriculture

Part		Page
1	Administrative regulations	5
1a	Law enforcement authorities	95
1b	National Environmental Policy Act	96
1c	Protection of human subjects	98
2	Delegations of authority by the Secretary of Agri- culture and general officers of the Department	108
3	Debt management	238
4	[Reserved]	
5	Determination of parity prices	258
6	Import quotas and fees	263
7	Selection and functions of Agricultural Stabiliza- tion and Conservation State, county and commu-	
	nity committees	282
8	4-H Club name and emblem	295
9-10	[Reserved]	
11	National Appeals Division rules of procedure	298
12	Highly erodible land and wetland conservation	309
13	[Reserved]	
14	Determining the primary purpose of certain pay- ments for Federal tax purposes	331
15	Nondiscrimination	334
15a	Education programs or activities receiving or ben- efitting from Federal financial assistance	366
15b	Nondiscrimination on the basis of handicap in pro- grams and activities receiving Federal financial assistance	382
15e	Enforcement of nondiscrimination on the basis of handicap in programs or activities conducted by the United States Department of Agriculture	404
15f	Adjudications under section 741	404
16	[Reserved]	410
10	[reserved]	
	3	

Part Level Table of Contents

Table of **Contents** lists the sections in the part and subparts

PART 1-ADMINISTRATIVE REGULATIONS

Subpart A-Official Records

- 1.1 Purpose and scope.
- 1.2 Policy.

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- 1.3 Agency implementing regulations. 1.4 Implementing regulations for the Office
- of the Secretary.
- 1.5 Public access to certain materials. 1.6 Requests for records.
- 1.7 Aggregating requests.
 - Agency response to requests for records.
- 1.9 Search services.
- 1.10 Review services.
- 1.11 Handling information from a private business.
- 1.12 Date of receipt of requests or appeals. 1.13 Appeals.
- 1.14 Extension of administrative deadlines.
- 1.15 Failure to meet administrative dead-
- lines.
- 1.16 Fee schedule.
- 1.17 Exemptions and discretionary release.
- 1.18 Annual report.
- 1.19 Compilation of new records. 1.20 Authentication.
- 1.22 Records in formal adjudication proceedings.
- 1.23 Preservation of records.
- APPENDIX A TO SUBPART A-FEE SCHEDULE

Subpart B-Departmental Proceedings

- 1.26 Representation before the Department of Agriculture.
- 1.27 Rulemaking and other notice procedures
- 1.28 Petitions.
- 1.29 Subpoenas relating to investigations under statutes administered by the Secretary of Agriculture

Subpart C-Judicial Proceedings

1.41 Service of process.

Subpart D—Claims

1.51 Claims based on negligence, wrongful act or omission

Subpart E-Cooperative Production of **Television Films**

- 1.71 Purpose
- 1.72 Policy.
- 1.73 Responsibility.
- 1.74 Basis for special working relationships.
- 1.75 General stipulations.
- 1.76 Department cooperation.
- 1.77 Assignment of priorities.
- 1.78 Development of special working rela-
- tionships. 1.79 Credits.

Subpart G-Privacy Act Regulations

- 1.110 Purpose and scope.
- 1.111 Definitions.
- 1.112 Procedures for requests pertaining to individual records in a record system.
- 1.113 Times, places, and requirements for identification of individuals making requests
- 1.114 Disclosure of requested information to individuals.
- 1.115 Special procedures: medical records.
- 1.116 Request for correction or amendment to record.
- 1.117 Agency review of request for correction or amendment of record.
- 1.118 Appeal of initial adverse agency determination on correction or amendment.
- 1.119 Disclosure of record to person other than the individual to whom it pertains. 1.120 Fees.
- 1.121 Penalties.
- 1.122 General exemptions.
- 1.123 Specific exemptions.
- APPENDIX A TO SUBPART G-INTERNAL DIREC-TIVES

Subpart H-Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes

- 1.130 Meaning of words.
- 1.131 Scope and applicability of this subpart.
- 1.132 Definitions.
- 1.133 Institution of proceedings.
- 1.134 Docket number.
- 1.135 Contents of complaint or petition for review.
- 1.136 Answer.
- 1.137 Amendment of complaint, petition for review, or answer; joinder of related matters.
- 1.138 Consent decision.
- 1.139 Procedure upon failure to file an answer or admission of facts
- 1.140 Conferences and procedure. 1.141 Procedure for hearing.
- 1.142 Post-hearing procedure.
- 1.143 Motions and requests.
- 1.144 Judges.
- 1.145 Appeal to Judicial Officer.
- 1.146 Petitions for reopening hearing; for rehearing or reargument of proceeding; or for reconsideration of the decision of the Judicial Officer.
- 1.147 Filing; service; extensions of time; and computation of time.
- 1.148 Depositions.
 - 1.149 Subpoenas.
 - 1.150 Fees of witnesses.
 - 1.151 Ex parte communications.

Table of CFR Titles and Chapters

A list of all CFR titles, subtitles, chapters, and part spans in numerical order – titles 1 to 50

Includes the names of agencies assigned to CFR chapters

A more detailed list is located in the CFR Index and Finding Aids, a separate publication

Alphabetical List of Agencies Appearing in the CFR

A list of all agencies that publish in the CFR

References to sub-agencies under main agencies

Location of the regulations of each agency and sub-agency appear in the CFR by title, subtitle and chapter

Redesignation Tables

A Redesignation Table helps you find the new location of parts and sections of regulations

An agency publishes this table when it has done extensive reorganization and renumbering

The table appears in the preamble of the rule document and is then included as a research tool in the back of the CFR

List of CFR Sections Affected (in a specific CFR volume)

This list helps you track amendments in each CFR volume for the previous five years with FR page numbers

Lists the type of amendment and the text affected down to the paragraph level

For earlier years, use the *List of CFR Sections Affected* (LSA)

A cumulative, monthly LSA is also published separately

CFR Books Online

- PDF version of paper CFR books online at www.govinfo.gov
- Updated once a year staggered by the 4 groups
- From 1996 through present

Electronic Code of Federal Regulations (e-CFR)

www.ecfr.gov

Unofficial

 Authoritative (source files are used for the printed books)

e-CFR Features

- Updated daily to incorporate all changes
- Includes links to published amendments that will be effective at a future date
- 2-3 day lag
- "Point-in-Time" view back to January 1, 2015
- Fully Searchable
- Searchable by specific category of information (CFR element)

New eCFR Website in Development

- https://ecfr.criticaljuncture.org
- Based on XML version of daily eCFR
- Recent changes
- Compare feature
- Once the website is live, users can create a personal account for notification related to MyFR account

Federal Register Online Resources

CFR Volumes Online

- <u>www.govinfo.gov</u>
- Electronic Code of Federal Regulations (e-CFR)
 - <u>www.ecfr.gov</u>
- New ECFR in development
 - ecfr.criticaljuncture.org
- Federal Register
 - <u>www.federalregister.gov</u>
- National Archives OFR Home Page
 - <u>www.archives.gov/federal-register</u>
- Public Participation in Rulemaking
 - <u>www.regulations.gov</u>

Thank you!

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- e-mail: johnhyrum.martinez@nara.gov