United States of America
National Coordination Procedures, Transparency, WTO Notifications and Capacity Building

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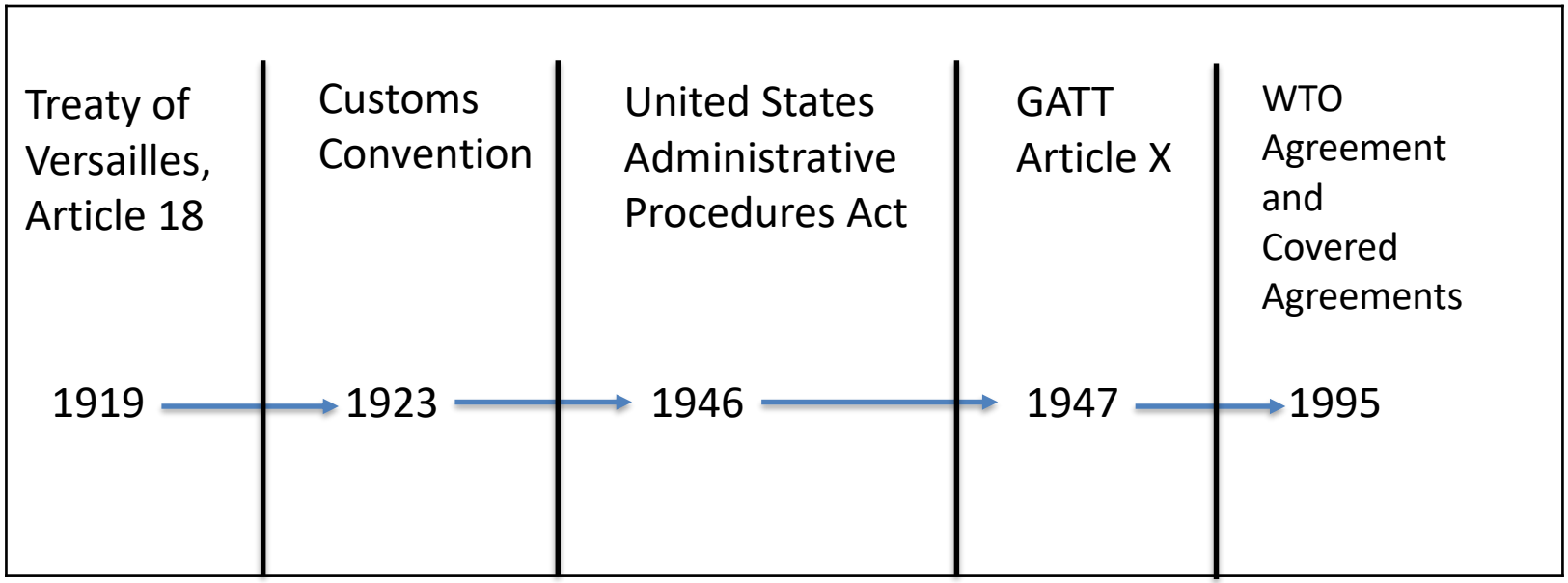
International Foundations for Transparency Provisions



United States
Administrative Procedures Act (APA) of 1946

- Governs administrative procedures for all U.S. federal agencies
- Notice and comment rulemaking solicits input from the public
- Public is informed of agency procedures and rules
- Fosters an administrative culture of transparency
- The APA is the legal framework that supports U.S. notifications to the WTO

WTO Agreements

- Transparency Provisions
  - Article X of the GATT
  - Article 7 of the Agreement on the Application of Sanitary and Phytosanitary Measures
  - Article III of the General Agreement on Trade in Services
  - Article 12 of the Customs Valuation Agreement
  - Article 63 of the Agreement on Trade-Related Aspects of Intellectual Property Rights

United States
Interagency Trade Policy Mechanism

- Trade Expansion Act of 1962 – created the interagency trade policy mechanism
  - Two Processes:
    1) Trade Policy Review Group (TPRG) and
    2) Trade Policy Staff Committee (TPSC)
- Uruguay Round Agreements Act (1994)

Implementing Uruguay Round Agreements into U.S. Law

Office of Information and Regulatory Affairs (OIRA)

- Established by Congress in 1980 Paperwork Reduction Act (44 U.S.C. Chapter 35)
- Part of Office of Management and Budget (OMB) within Executive Office of the President
- Reviews draft proposed and final regulations under Executive Order 12866
- OIRA consults with relevant agencies & departments in EO 12866 reviews
- Reviews for consistency with international obligations

Transparency in Development and Implementation of Regulations

- Consistency with the APA requirements
- Interagency Review and Comment
- Public Notice and Comment Period – Proposed Rule on public docket (Regulations.gov)
- Notification to the WTO
- Review of public comments submitted to public docket
- Agency Review
- Public Notice and Comment Period -- Final Rule

How FDA develops regulations

Development of policy through Rulemaking or Guidance

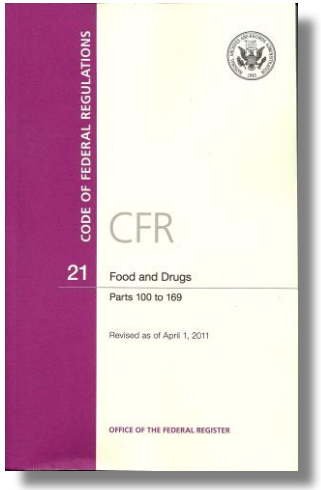
Amendments enacted into law

For example, Federal Food, Drug, and Cosmetic Act

As Amended <date>

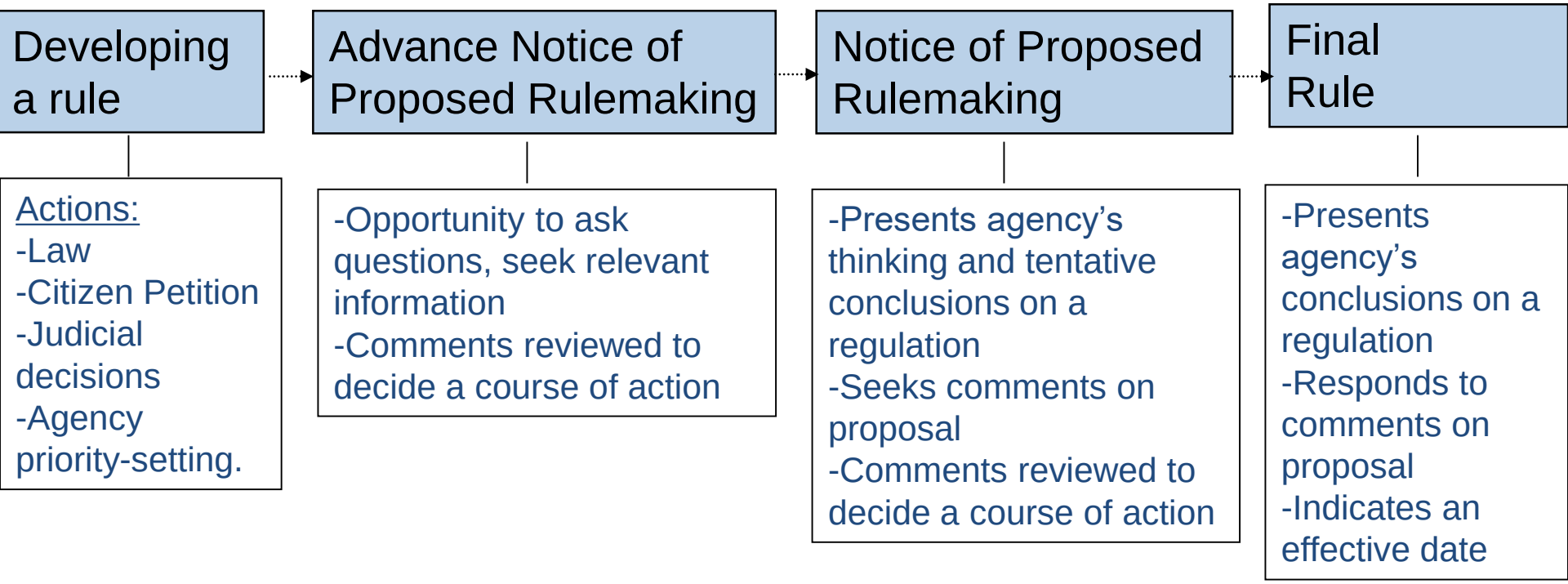
Steps for Notice and Comment

Title 21 of the Code of Federal Regulations



Guidance for Industry
www.fda.gov

Potential steps for development of a regulation



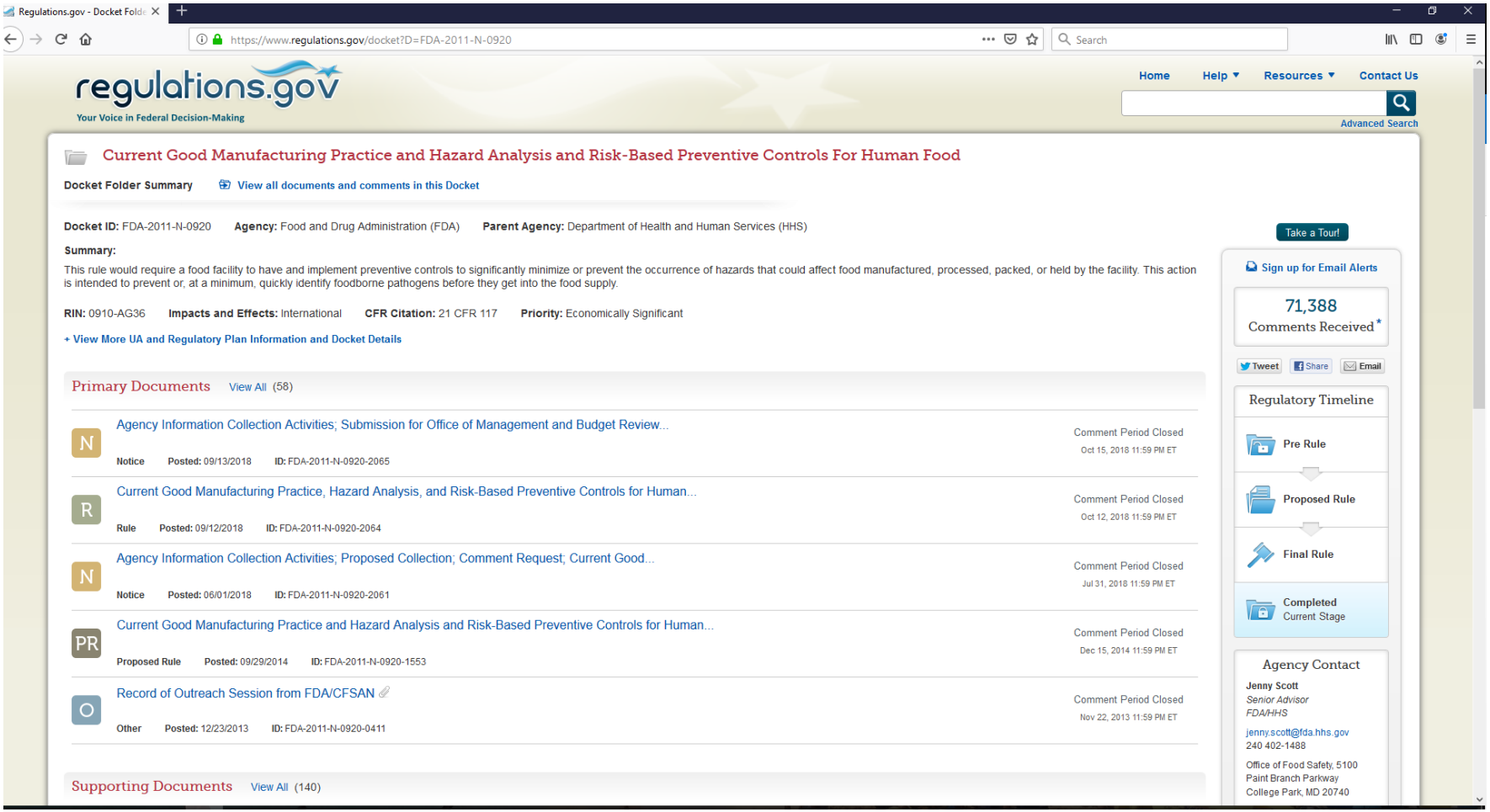
Note: At each step the agency can decide to proceed, not to proceed, or consider a new course of action.

Public Outreach

- FDA undertakes significant public outreach on new rules, policies and activities.
- Public hearings, information (listening) sessions and public meetings are held across the United States.
- FDA hosted several webinars with trading partners on the Food Safety Modernization Act (FSMA) and made the rules available in several languages.

Stakeholder comments

- FDA establishes a docket for the Proposed Rule public comment (www.regulations.gov)
- FDA receives thousands of comments for some rules
  - 71,388 (Preventive Controls for Human Food)
  - 39,887 (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption)
  - 289,653 (Revision of the Nutrition and Supplement Facts Labels)
- For Final Rules, FDA publishes responses to significant comments received and the rationale for the course of action taken


Regulations.gov - Docket Folde
https://www.regulations.gov/docket?D=FDA-2011-N-0920
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Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food
Docket Folder Summary
View all documents and comments in this Docket
Docket ID: FDA-2011-N-0920
Agency: Food and Drug Administration (FDA)
Parent Agency: Department of Health and Human Services (HHS)
Summary:
This rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. This action is intended to prevent or, at a minimum, quickly identify foodborne pathogens before they get into the food supply.
RIN: 0910-AG36
Impacts and Effects: International
CFR Citation: 21 CFR 117
Priority: Economically Significant
+ View More UA and Regulatory Plan Information and Docket Details
Primary Documents
View All (58)
N
Agency Information Collection Activities; Submission for Office of Management and Budget Review...
Notice
Posted: 09/13/2018
ID: FDA-2011-N-0920-2065
Comment Period Closed
Oct 15, 2018 11:59 PM ET
R
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human...
Rule
Posted: 09/12/2018
ID: FDA-2011-N-0920-2064
Comment Period Closed
Oct 12, 2018 11:59 PM ET
N
Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good...
Notice
Posted: 06/01/2018
ID: FDA-2011-N-0920-2061
Comment Period Closed
Jul 31, 2018 11:59 PM ET
PR
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human...
Proposed Rule
Posted: 09/29/2014
ID: FDA-2011-N-0920-1553
Comment Period Closed
Dec 15, 2014 11:59 PM ET
O
Record of Outreach Session from FDA/CFSAN
Other
Posted: 12/23/2013
ID: FDA-2011-N-0920-0411
Comment Period Closed
Nov 22, 2013 11:59 PM ET
Supporting Documents
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Paint Branch Parkway
College Park, MD 20740

Comments are considered before issuing Final Rule

- Preventive Controls for Human Food
  - Many comments argued for increased flexibility in application of preventive controls
    - FDA provided flexibility by clarifying that preventive control management components (monitoring, corrective actions/corrections and verification activities) depend on the role of the preventive control in the facility's food safety system and the nature of the preventive control
  - From other comments received:
    - FDA provided for use of "exception records" (in which a record is made only when a deviation occurs) for monitoring preventive controls where appropriate
    - FDA provided for the reanalysis of an applicable portion of the food safety plan rather than the complete food safety plan in certain circumstances

WTO NOTIFICATIONS

- FDA notifies:

  - Proposed and Final Rules
    - FDA meets WTO obligation to provide a minimum of 60 days for comment
    - Proposed and Final Rules typically have 60-90 days or longer for interested parties to submit comments

Coordination and comments

- FDA coordinates with the U.S. National Notification Authority to ensure timely notification of the measure to the WTO
- WTO members may submit comments through the docket (instructions given in the notification) that will be reviewed and considered with all other stakeholder comments

U.S. FDA Supports Transparency Efforts Through Partnerships

- Standards and Trade Development Facility (STDF)
- Asia Pacific Economic Cooperation (APEC)
- Food and Agriculture Organization (FAO)
- World Health Organization (WHO)
- Global Food Safety Partnership (GFSP)


FDA
U.S. FOOD & DRUG
ADMINISTRATION