Rule Making Process in the US

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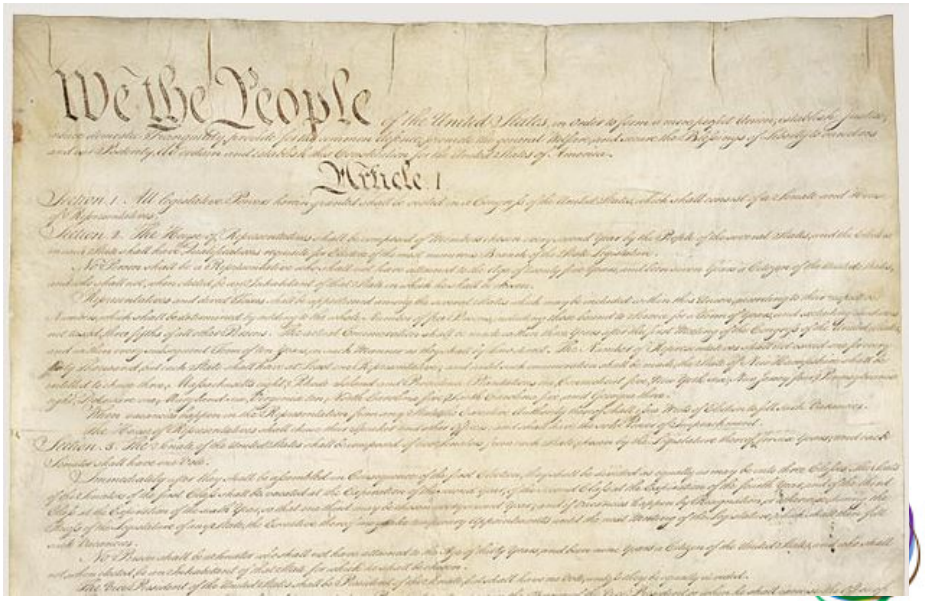
US Sources of Law

- Constitution
- Legislatures
- Executive
- Administrative agencies
- Courts

US Constitution

- Defines the authorities of Federal and State government

- Laws determined by elected officials



Legislative (Congress) Branch

- Comprised of elected representatives who set public policy
  - Approve presidential appointments
  - Can override presidential vetoes
  - Control appropriations

Executive Branch

- Led by an elected official
  - president at the federal level

- Role is to implement or execute the statutes enacted by the legislative branch
- Appoint judges to fill vacancies in the court
- Can grant reprieves and pardons

Administrative Agencies

- Created by legislature
  - Delegated powers
- Regulate certain activities
  - Enact rules
  - Adjudicate
- Federal
  - USDA, FDA, EPA, etc

Judicial Branch

- Role is to resolve disputes and interpret the "law“
- Interpret laws and Presidential actions

Federal Regulatory Process

Congress enacts statute

President signs it into law

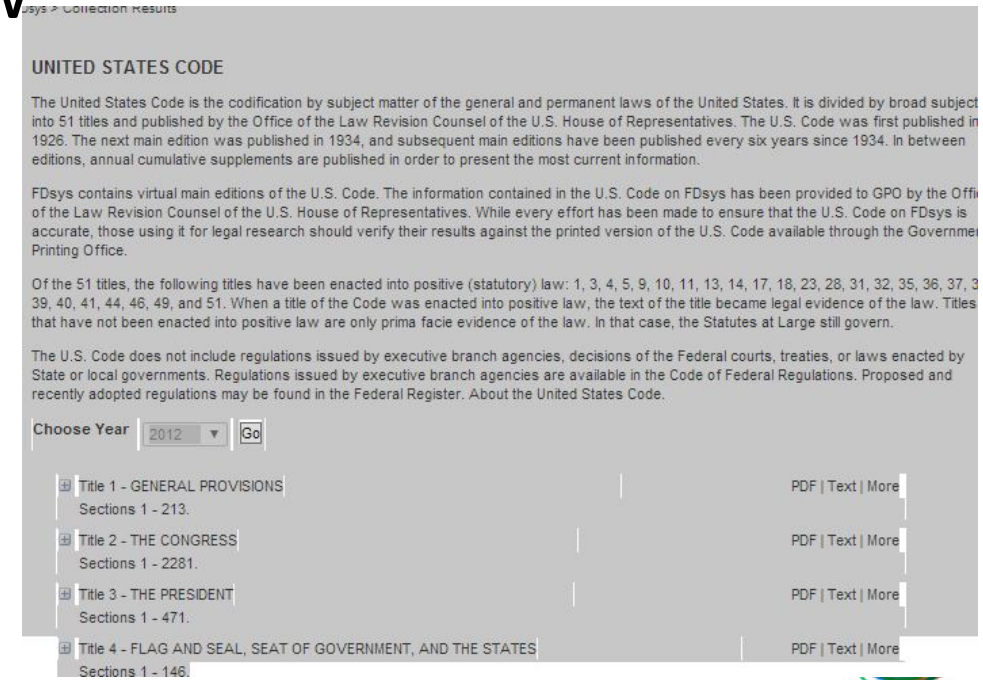
Statute delegates authority to a Federal administrative agency

Agency issues regulations based on the delegation of regulatory authority

United States Code

- Contains all federal statutes currently in effect; it is organized into 50 major topics (titles); Title 21 contains most federal statutes pertaining to food law

code of federal regulations



UNITED STATES CODE

The United States Code is the codification by subject matter of the general and permanent laws of the United States. It is divided by broad subject into 51 titles and published by the Office of the Law Revision Counsel of the U.S. House of Representatives. The U.S. Code was first published in 1926. The next main edition was published in 1934, and subsequent main editions have been published every six years since 1934. In between editions, annual cumulative supplements are published in order to present the most current information.

FDsys contains virtual main editions of the U.S. Code. The information contained in the U.S. Code on FDsys has been provided to GPO by the Offi of the Law Revision Counsel of the U.S. House of Representatives. While every effort has been made to ensure that the U.S. Code on FDsys is accurate, those using it for legal research should verify their results against the printed version of the U.S. Code available through the Governme Printing Office.

Of the 51 titles, the following titles have been enacted into positive (statutory) law: 1, 3, 4, 5, 9, 10, 11, 13, 14, 17, 18, 23, 28, 31, 32, 35, 36, 37, 3 39, 40, 41, 44, 46, 49, and 51. 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 U.S. 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. Proposed and recently adopted regulations may be found in the Federal Register. About the United States Code.

Choose Year 2012 Go

Title 1 - GENERAL PROVISIONS PDF | Text | More
Sections 1 - 213.

Title 2 - THE CONGRESS PDF | Text | More
Sections 1 - 2281.

Title 3 - THE PRESIDENT PDF | Text | More
Sections 1 - 471.

Title 4 - FLAG AND SEAL, SEAT OF GOVERNMENT, AND THE STATES PDF | Text | More
Sections 1 - 146.

Steps in creating a law

Step 1: Congress Writes a Bill

A member of Congress proposes a bill. A bill is a document that, if approved, will become law.

Step 2: The President Approves or Vetoes the Bill

If both houses of Congress approve a bill, it goes to the President who has the option to either approve it or veto it. If approved, the new law is called an act or statute.

Step 3: The Act is Codified in the *United States Code*

Once an act is passed, the House of Representatives standardizes the text of the law and publishes it in the *United States Code* (U.S.C.). The U.S.C. is the codification by subject matter of the general and permanent laws of the United States.

Regulations

- General statement issued by an agency, board, or commission that has the force and effect of law
- Federal regulations are created through a process known as "rulemaking," which is governed by the Administrative Procedure Act (APA),
  - requires Agencies to seek public comment in process of rule making
  - Agencies need to publish proposed rule and make changes if necessary prior to the rule becoming final and respond to comments

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Establishment of Rulemaking Process

EO 12866 – 1993 (All agencies)

- Required agencies to estimate net impact of benefits and costs of a regulation on society
- Required analysis to include the effect of proposed rule on state, local, tribal governments and businesses of different size

Federal Crop Insurance Reform (FCIR) and Dep .Agriculture Reorganization Act – 1994

- USDA required to conduct a regulatory risk assessment and cost-benefit analysis under any proposed rule designated as major (over $100 mill. In 1994 $)
- Analysis had to make clear
  - Nature of risk
  - Alternative ways to mitigate the risk
  - Reason for justifying the proposed rule
  - Comparison of the likely costs and benefits of reducing the risk of the proposed rule

Rule Making Process (cont.)

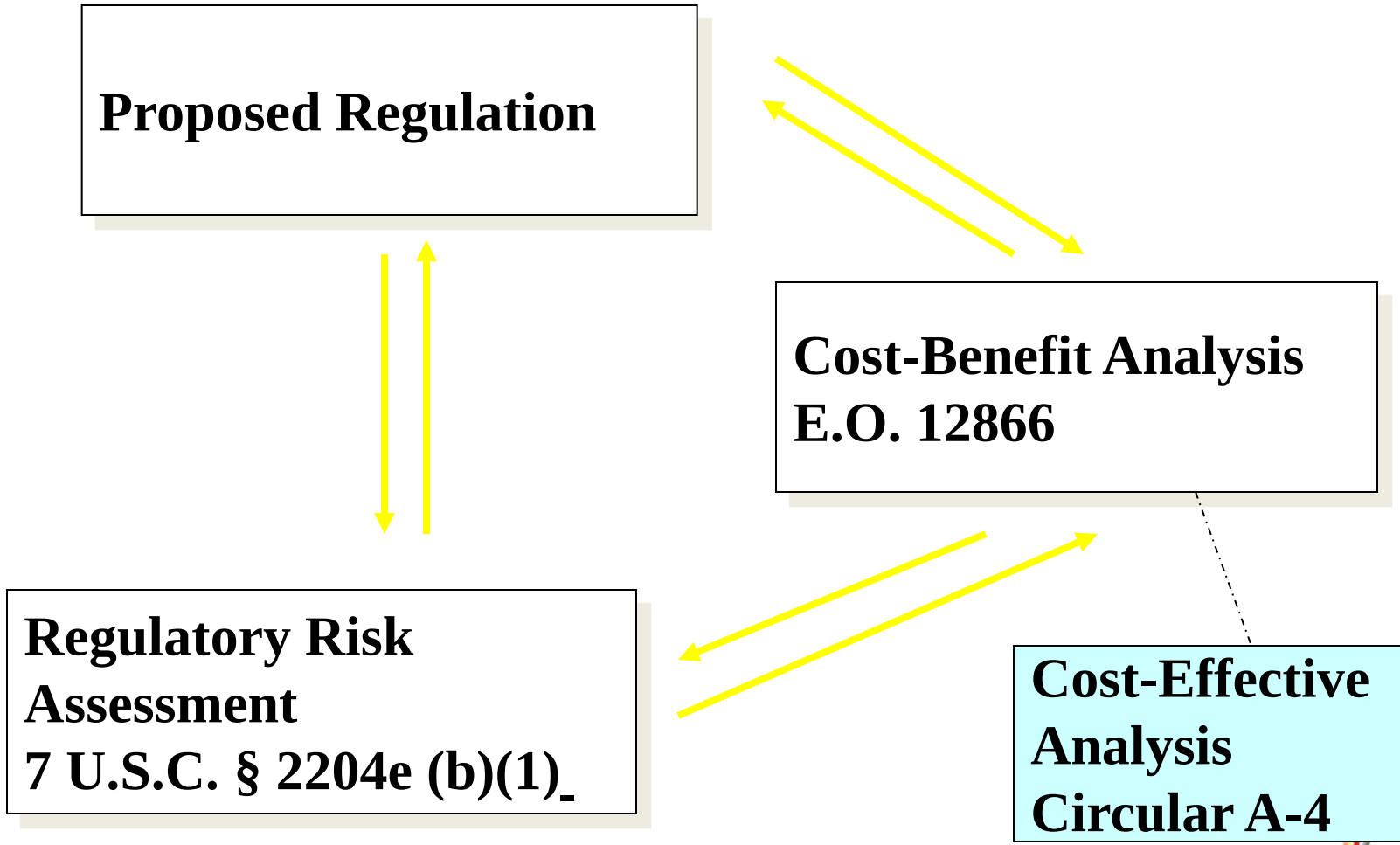
OMB –Circular A-4: Encourages agencies to conduct a cost-effectiveness analysis whenever possible

- Required for all major rulemakings for which primary benefits are improved public health and safety where valid effectiveness measures can be developed and benefits can not be measured.
  - Proposed rules as of Jan 1 2004
  - Final rules as of Jan 1 2005

Executive Order 13563 Improving Regulation and Regulatory Review - January 18, 2011

- Retrospective review of existing rules

Major Components of the Regulatory Impact Assessment



Purpose of Analyses

To aid decision makers in choosing the best risk reduction strategy and allocating scarce resources to reduce health, safety, and environmental risks.

- Risk assessments look at the likelihood of an event and provide a set of risk mitigation options.
- Cost-benefit analyses quantify the changes in societal welfare that result from the imposition of a regulation (or other policy, action, or decision).
- Cost-effective analysis quantify the effectiveness of different mitigation options on societal welfare

Combined these analyses, consistent or not, makeup important components of decision-making.

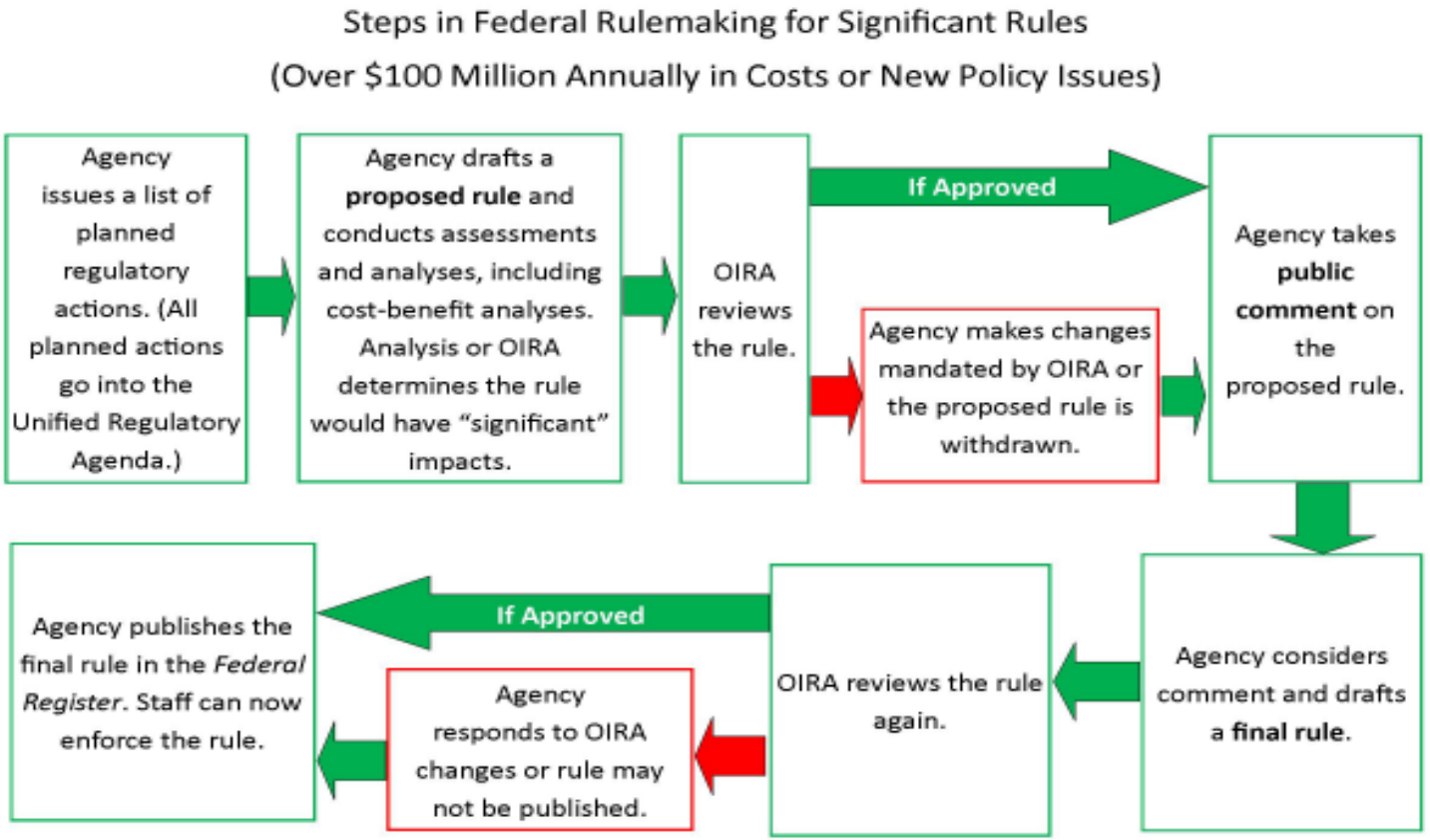
Rule Making Process Transparent

- Proposed Rules, Final Rules, and emergency rules are published

- During the comment period (and afterwards) they are often criticized by special interest groups
  - Domestic/international
  - Public/private actors

Figure 1. Federal Rulemaking Process

Source: Center for Effective Government



Note: OIRA does not review rules submitted by independent regulatory agencies (e.g, the Consumer Product Safety Commission or the Consumer Financial Protection Bureau).

Due to the government shutdown, information on this website may not be up to date. You can still submit comments to agencies using Regulations.gov during the shutdown.

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Help improve Federal regulations by **submitting your comments**.

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Comments Due Soon

Today (54)
Next 3 Days (55)
Next 7 Days (220)

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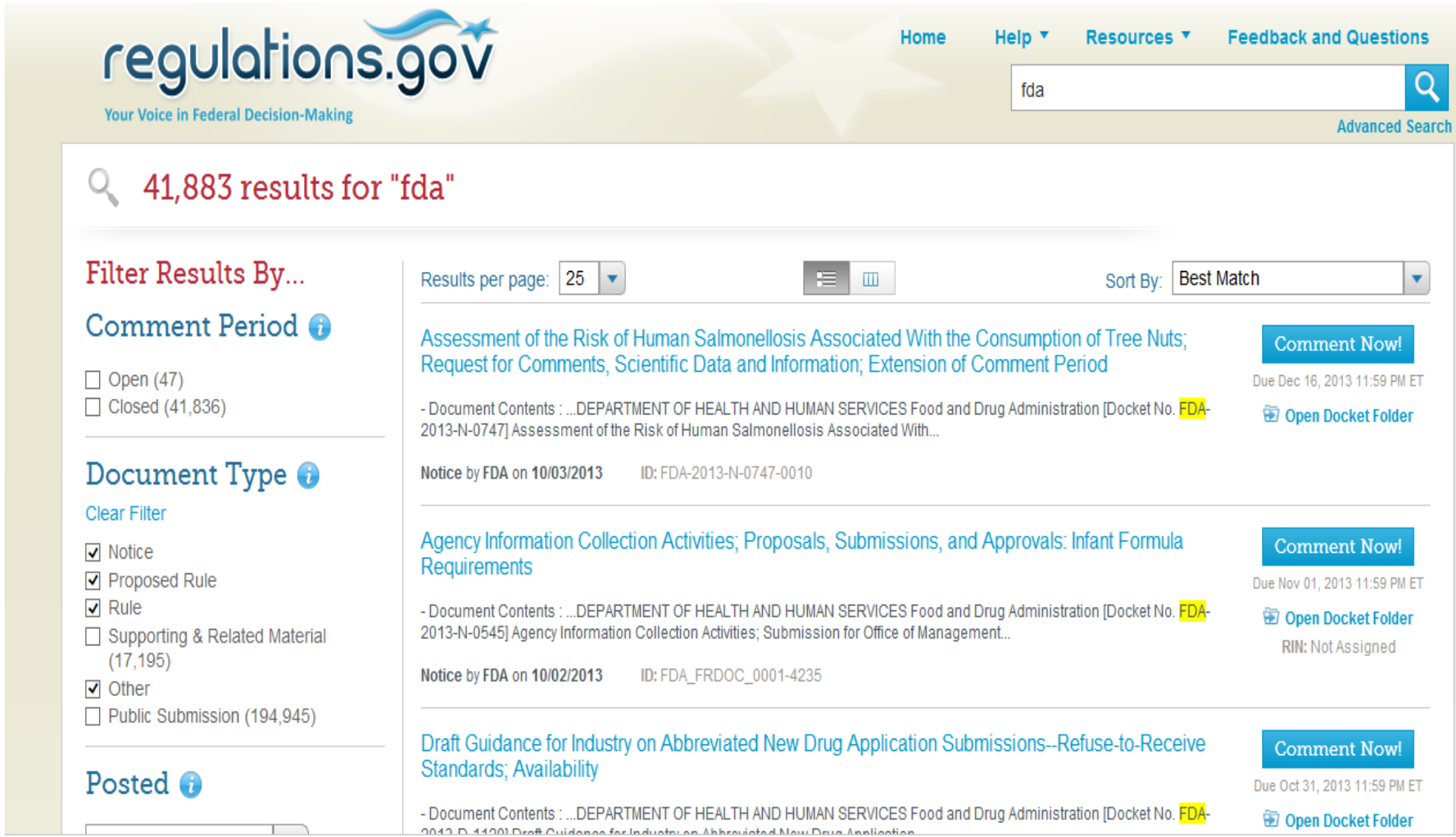
Click the links below to get started.

- What can I find on this site?
- How do I find a rule?
- How do I submit a comment?
- How do I find my comment?
- Do my comments make a difference?

Newly Redesigned Comment

Site Enhancements

Comment Period



Reality

Rules

- Developed within tight deadlines.
- Efforts may be conducted under separate chains of command, even within the same agency.

INCONSITENCIES open the rule making to "attack."

- Reasons Rule Making Come Under Attack

Inconsistencies between documents.

- Premises
- Options considered
- Assumptions made
- Facts used
- Conclusions made

Despite Regulations May Be Challenged

- Arbitrary and capricious or abuse of discretion (no rational basis)
- NEPA analysis not sufficient
- Didn't provide background material, respond to FOIA request, or answer questions in timely manner to comment
- Not authorized by statue
- Not sufficient to protect from pest or disease or otherwise achieve its purpose
- Faulty risk assessment

Ex. Baur v. Veneman, 12/16/03

- Statute – Federal Meat Inspection Act; Federal Food, Drug and Cosmetic Act
- Ban on use of downer livestock requested
- Justification based on Risk Assessment
- The appellate court found Baur had standing to bring a federal suit.
- The 0.00011% chance of exposure to BSE from contaminated beef is a sufficient injury in fact.

Ex. Harlan Land Co. v. USDA, 9/27/01

- Statute – Plant Quarantine Act
- Petitioner concerned about rule allowing importation of citrus from Argentina
- Justification based on Supplemental plant risk assessment -1997
- Cause of action- Admin. Proc. Act - arbitrary and capricious agency action based on Sec. 706 because APHIS failed to identify a negligible level of risk
- Action - Suspension of APHIS rule

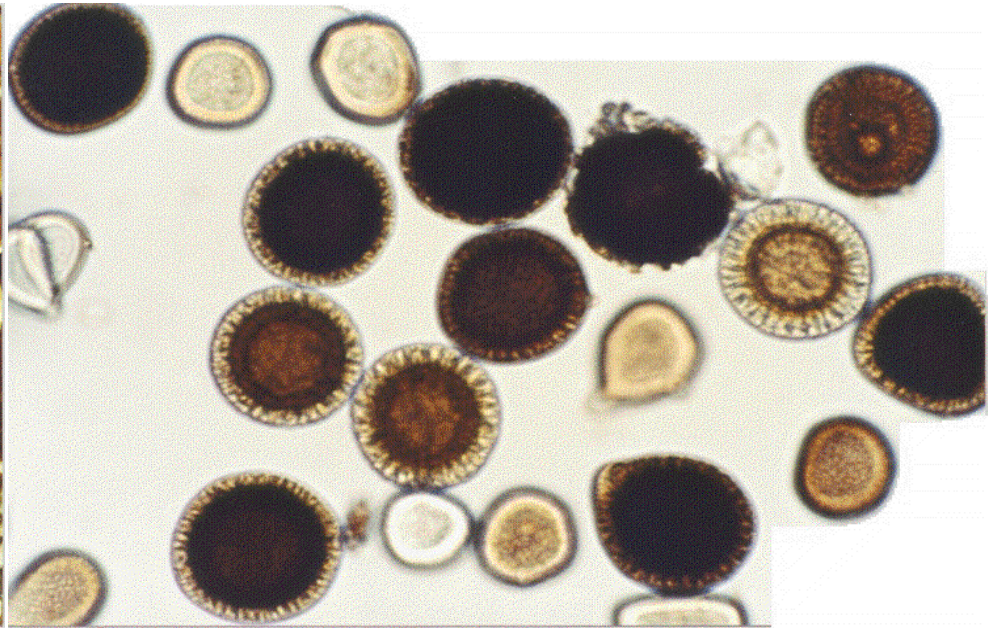
Plant Growers v. APHIS, 10/8/96

- Statute - Plant Quarantine Act; Federal Plant Pest Act
- Petitioner concerned over rule allowing importation in growing media of Rhododendron; Anthurium etc.
- Justification based on the Risk Assessment
- Cause of action: Administrative procedure Act - arbitrary and capricious agency action based on Sec. 706 because APHIS failed to provide all background documents relied upon for rule - namely studies & reports from APHIS Risk Management Group
- Action: None required – APHIS rule stands

Cost of Getting it Wrong

- Politics – always there
- Overestimating/underestimating the risk or cost
- Mitigation
- Compensation

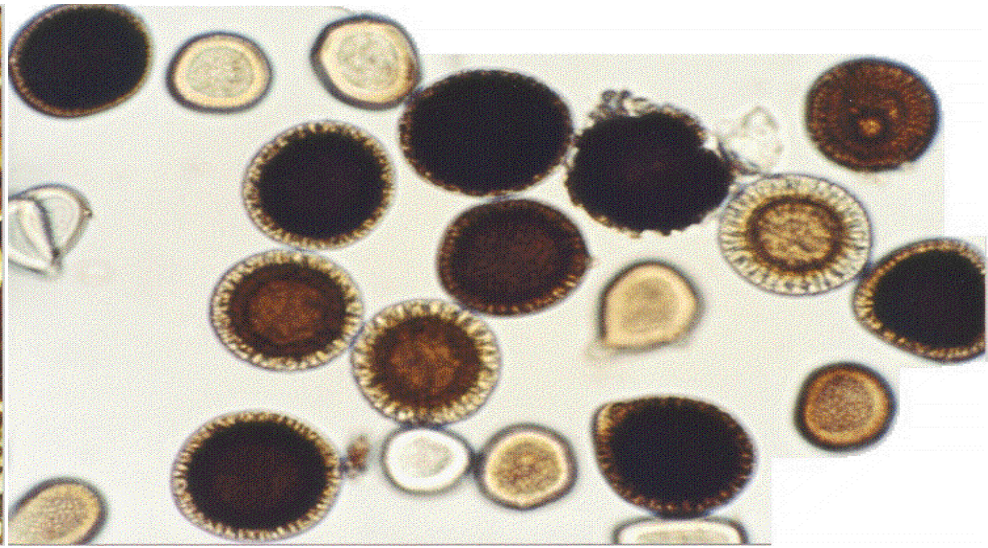
Karnal Bunt Example



Used:
RA from Podleckis/Firko,
CBA published in the Fed. Register

Karnal Bunt (KB) History

- KB is a disease affecting wheat, rye, and triticale (a hybrid of wheat and rye) caused by *Tilletia indica* Mitra
- Poses no risk to human health
- Can cause production losses to wheat
  - reduced yields and reduction of quality of wheat flour
  - generally wheat containing more that 3% of bunted kernels is considered unsatisfactory for human consumption because of fishy odor



Spread of KB

- 1931 - detected in Haryana, India near city of Karnal
- 1931-1970's spread to Pakistan, Iraq, Afghanistan, Nepal, and Iran
- 1970 appeared in Mexico (Sonora, Sinaloa, and Baja California Sur)
- 1982 wheat kernel infected with KB were intercepted in wheat imported from Mexico

Impact of this Detection at the Borders of the US

- 1982 -USDA took action to prevent the importation of host plant material (including seed and grain) and any other articles that might spread the disease - as preventive action (7 CFR 319.59)

- 1983 -actions were made permanent and restrictions on wheat were made for all countries where Karnal bunt was known to occur (7 Code of Federal Regulations 319.59)

Early Risk Assessments

- 1988 - because of the close proximity of wheat growing areas of Arizona and California to infested areas in Mexico "transport of the KB pathogen is extremely likely"
- 1991 -KB was a high risk pest, primarily because "wheat from infested areas would probably be denied or restricted access in the export market"
- Recommended that in the event of introduction of the KB pathogen national quarantines should be established to restrict distribution so as to protect integrity of U.S. wheat export market.

KB Detected in US

- March 8, 1996, KB detected in Arizona during a seed certification inspection
- March 20, 1996, a “Declaration of Extraordinary Emergency” signed authorizing the Secretary to take emergency action with regard to KB within Arizona, New Mexico and Texas
- April 12, 1996 the quarantine was extended to Imperial and Riverside counties in California

Regulations to Prevent Spread of KB

- Plow down and seed distruction
- Cleaning and disinfection
- Restrictions on the movement and use of conveyances, harvesters, and/or marketing

Objectives of KB Regulations

(1) To protect U.S. wheat producers in KB free areas

(2) To protect U.S. export markets

(3) To provide the best possible options for producers in quarantined areas who are affected by the KB detections

Each regulation has a cost

Potential Pathways

- Millfeed
- Export elevators
- Seed originating in the quarantined area
- Railcars transporting grain from the quarantined area to domestic mills
- Export elevators
- Grain storage facilities
- Combines
- Other harvesting machinery

*** Ambient risk not considered**

Various Protocols

1) Restrictions on the movement of positive-tested grain and seed outside the quarantine area, but allows all negative-tested grain and seed to move without significant additional restrictions
2) Requirements that all railcars be cleaned after delivery of wheat from the quarantined area
3) Restrictions on the movement of negative-tested seed outside of the quarantine area
4) Requirements for heat treatment of millfeed from quarantine-area wheat

The effects of various protocols on the risk of Karnal Bunt outbreak

Protocol	Probability of an outbreak 1/	
	For individual pathway	Overall
Railcar cleaning:		
- with	6.43×10^{-4}	2.14×10^{-3}
- without	5.18×10^{-2}	5.67×10^{-2}
Restrictions on the movement of negative-testing seed:		
- with	0	5.53×10^{-2}
- without	1.40×10^{-3}	5.67×10^{-2}
Millfeed treatment:		
- with	1.66×10^{-8}	5.66×10^{-2}
- without	6.59×10^{-5}	5.67×10^{-2}

1/ Evaluated at mean.

Greatest overall effect

Greatest individual risk reduction, but doesn't change overall risk at all

Original analysis on considered individual pathway

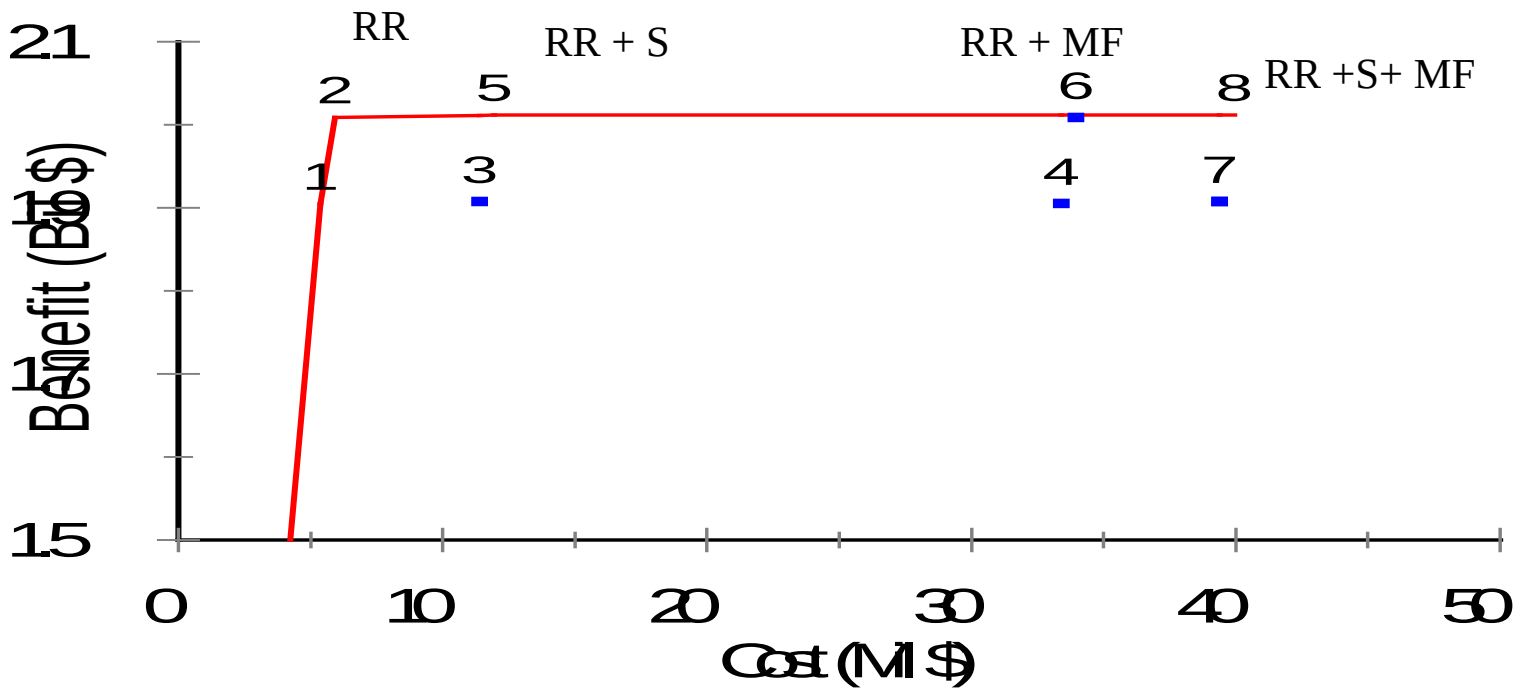
Table 7–Expected costs and benefits of alternative quarantine actions (million dollars)

Quarantine Option	Expected benefits	Expected costs	Net
Option 1--Baseline 1/	1,901.5	5.4	1,896.1
Option 2--Railcar cleaning	2,011.4	6.0	2,005.5
Option 3–Restrictions on seed movement	1,904.3	11.4	1,892.9
Option 4–Millfeed treatment	1,901.7	33.4	1,868.3
Option 5–Railcar cleaning; restrictions on seed movement	2,014.3	12.0	2,002.3
Option 6–Railcar cleaning; millfeed treatment	2,011.6	34.0	1,977.6
Option 7–Restrictions on seed movement; millfeed treatment	1,904.3	39.4	1,864.9
Option 8–Railcar cleaning; restrictions on seed movement; millfeed treatment	2,014.5	40.0	1,974.5

1/ Includes prohibition of movement of positive testing grain and seed from quarantined area; all negative testing grain and seed moved in sealed hopper cars; all combines disinfected before leaving quarantined area.

Figure 2

Karnal Bunt Quarantine Alternatives



Railroad car cleaning most beneficial

Karnal Bunt

- In 1996 USDA imposed quarantine on SW durum wheat producers to prevent the spread of Karnal bunt, a minor disease of wheat.
- Goal was to protect integrity of U.S. wheat export market
- Imposed substantial costs on those affected by regulations.
- USDA conducted numerous risk assessments that examined the probability of outbreak given various regulatory decisions and provided detailed cost/benefit analyses of their regulatory decisions.
- However, little attempt to integrate the two.
- Had they done so, arguably different regulatory strategy.

Conclusions

- The original regulatory impact analyses also failed to look at the expected marginal benefits and costs of various quarantine alternatives
  - If expected costs and benefits had been considered, two of the more controversial protocols--seed restrictions and the millfeed requirements--may have received closer scrutiny
- Cost to society of these actions (including compensation) was $350- $390 million

Implications for the future

- Where possible, integrate risk assessments to analyze *expected* costs and *expected* benefits (or expected effectiveness Circ. A-4)
- Proper measurement of baseline risks
- Explicit assumptions on risk premium
- Compensation should be used to ensure compliance—not to offset suboptimal policy

Executive Order 13563 Improving Regulation and Regulatory Review - January 18, 2011

- Retrospective review of existing rules

Federal Agency Plans for Retrospective Reviews of Rules

9/1/2011

Retrospective Review of Rules

On Aug. 23, the Obama administration released a set of "look-back" plans from federal agencies that will reform or jettison outdated or ineffective rules. The 26 plans were drafted in response to a January executive order (E.O. 13563) that created a regulatory review initiative and instructed federal agencies to review existing regulations and revise those that are outdated, redundant, or "unnecessarily burdensome."