Rule Making Process in the US
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.
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

www.Regulations.gov
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
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

Proposed Regulation

Regulatory Risk Assessment
7 U.S.C. § 2204e (b)(1)

Cost-Benefit Analysis
E.O. 12866

Cost-Effective Analysis
Circular A-4
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

Steps in Federal Rulemaking for Significant Rules
(Over $100 Million Annually in Costs or New Policy Issues)

- Agency issues a list of planned regulatory actions. (All planned actions go into the Unified Regulatory Agenda.)
- Agency drafts a proposed rule and conducts assessments and analyses, including cost-benefit analyses. Analysis or OIRA determines the rule would have “significant” impacts.
- OIRA reviews the rule.
- If Approved
  - Agency makes changes mandated by OIRA or the proposed rule is withdrawn.
  - Agency takes public comment on the proposed rule.
- If Approved
  - Agency publishes the final rule in the Federal Register. Staff can now enforce the rule.
- OIRA reviews the rule again.
  - Agency responds to OIRA changes or rule may not be published.
  - Agency considers comment and drafts a final rule.

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.

Participate Today!

Submit your comments on proposed regulations and related documents published by the U.S. Federal government. You can also use this site to search and review original regulatory documents as well as comments submitted by others.

Help improve Federal regulations by submitting your comments.

SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

What's Trending

Animal Care Resource Guide: Policy #3, Veterinary Care

Comments Due Soon
Today (54)
Next 3 Days (55)
Next 7 Days (220)
Comment Period

regulations.gov

41,883 results for "fda"

Filter Results By...

Comment Period

- Open (47)
- Closed (41,836)

Document Type

- Clear Filter
- Notice
- Proposed Rule
- Rule
- Supporting & Related Material (17,195)
- Other
- Public Submission (194,945)

Results per page: 25

Sort By: Best Match

Assessment of the Risk of Human Salmonellosis Associated With the Consumption of Tree Nuts; Request for Comments, Scientific Data and Information; Extension of Comment Period

- Document Contents: ...DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2013-N-0747] Assessment of the Risk of Human Salmonellosis Associated With...

Notice by FDA on 10/03/2013 ID: FDA-2013-N-0747-0010

Agency Information Collection Activities; Proposals, Submissions, and Approvals: Infant Formula Requirements

- Document Contents: ...DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2013-N-0545] Agency Information Collection Activities; Submission for Office of Management...

Notice by FDA on 10/02/2013 ID: FDA_FRDOC_0001-4235

Draft Guidance for Industry on Abbreviated New Drug Application Submissions--Refuse-to-Receive Standards; Availability


Notice by FDA on 10/02/2013 ID: FDA-2013-P-1403-0000
Reality

Rules

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

INCONSISTENCIES 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 statute
- 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 than 3% of bunted kernels is considered unsatisfactory for human consumption because of fishy odor.
• 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 destruction
• 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

<table>
<thead>
<tr>
<th>Protocol</th>
<th>For individual pathway</th>
<th>Overall</th>
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<tbody>
<tr>
<td><strong>Railcar cleaning:</strong></td>
<td></td>
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<tr>
<td>- with</td>
<td>6.43 x 10^-4</td>
<td>2.14 x 10^-3</td>
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<td>- without</td>
<td>5.18 x 10^-2</td>
<td>5.67 x 10^-2</td>
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<tr>
<td><strong>Restrictions on the movement of negative-testing seed:</strong></td>
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<tr>
<td>- with</td>
<td>0</td>
<td>5.53 x 10^-2</td>
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<tr>
<td>- without</td>
<td>1.40 x 10^-3</td>
<td>5.67 x 10^-2</td>
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<tr>
<td><strong>Millfeed treatment:</strong></td>
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<td></td>
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<tr>
<td>- with</td>
<td>1.66 x 10^-8</td>
<td>5.66 x 10^-2</td>
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<tr>
<td>- without</td>
<td>6.59 x 10^-5</td>
<td>5.67 x 10^-2</td>
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</table>

1/ Evaluated at mean.

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)

<table>
<thead>
<tr>
<th>Quarantine Option</th>
<th>Expected benefits</th>
<th>Expected costs</th>
<th>Net</th>
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<td>Option 1--Baseline 1/</td>
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<td>Option 3–Restrictions on seed movement</td>
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<td>Option 4–Millfeed treatment</td>
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<td>1,868.3</td>
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<td>Option 5–Railcar cleaning; restrictions on seed movement</td>
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<td>Option 6–Railcar cleaning; millfeed treatment</td>
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<td>Option 7–Restrictions on seed movement; millfeed treatment</td>
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<td>1,864.9</td>
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<td>Option 8–Railcar cleaning; restrictions on seed movement; millfeed treatment</td>
<td>2,014.5</td>
<td>40.0</td>
<td>1,974.5</td>
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</tbody>
</table>

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.
Railroad car cleaning most beneficial
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 rescind 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."