

A satellite-style world map showing the continents in green and brown, with the oceans in dark blue. The map is centered on the Atlantic Ocean.

Regulating Effectively in a Globalized World: Perspectives of the RPO

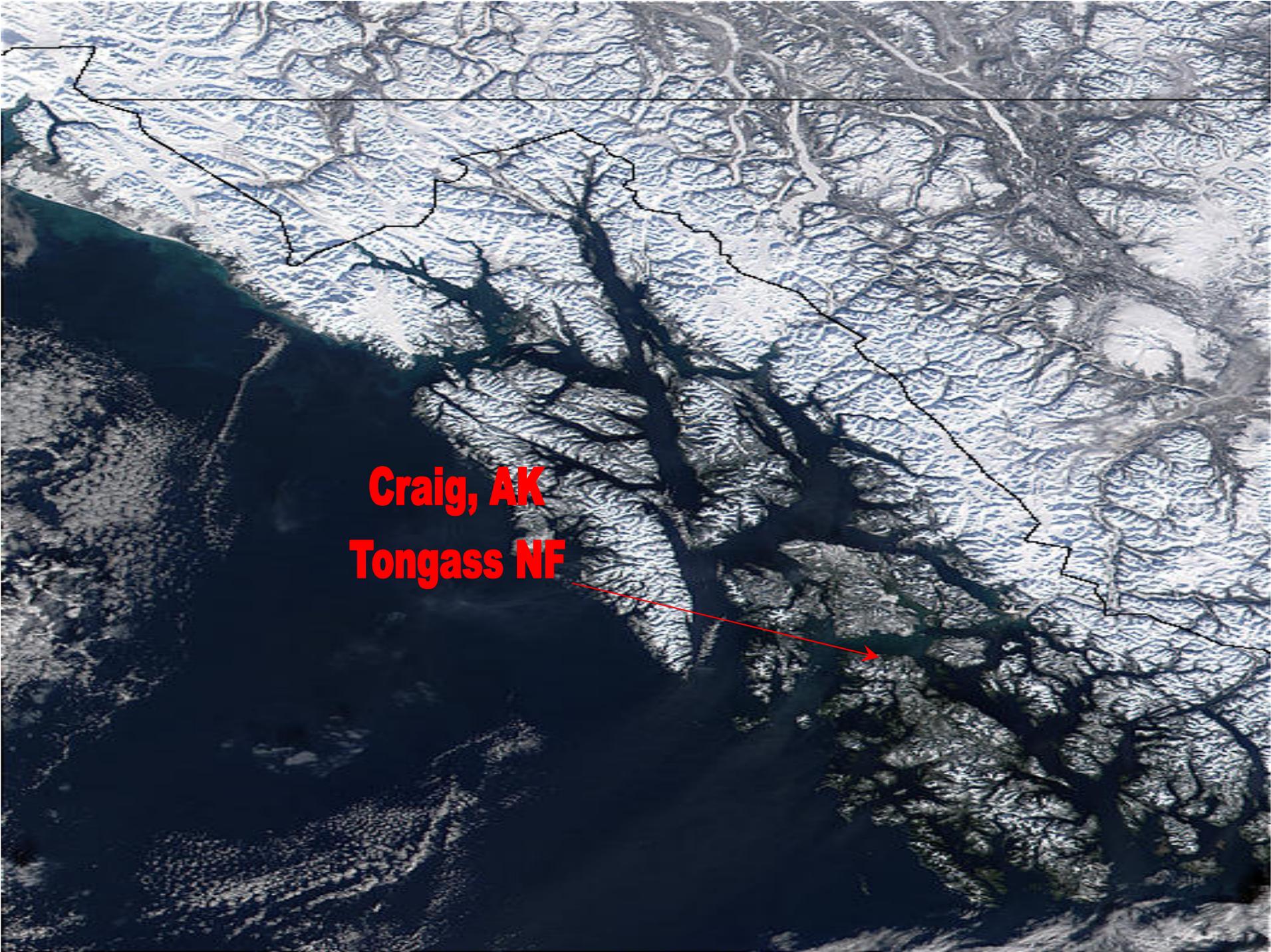


Marc L. Kesselman
General Counsel
United States Department of Agriculture









Craig, AK
Tongass NF

An aerial photograph of the Tongass National Forest in Alaska. The image shows a vast expanse of dense, green forest covering rolling hills and mountains. In the foreground, a large, winding body of water, likely a fjord or a large lake, is visible, surrounded by forested islands and peninsulas. The water is a deep blue-green color. In the background, snow-capped mountains rise against a clear sky. The text "Tongass National Forest" is overlaid in white, serif font across the upper middle portion of the image.

Tongass National Forest



PORT
CRAIG

04

PORT GROUP
CRAIG

S

CONSIGNEE
CITY OF CRAIG

N# **19549-6** **VS730**

BOOK # **449120**

A

327

Three Simple Steps for Regulating Effectively in a Globalized World*

- **T**ransparent Process
- **S**ound Analysis / Sound Science
- **D**eference / Judicial Restraint

* “Magic Ginzu” knife included

U.S. Rulemaking Process Is Open & Transparent

- **Congress**
 - Statutory authority for agency action
 - Process Requirements
- **Executive Branch**
 - The Office of Management and Budget (OMB)
 - Independent Analysis: OIRA
 - Coordinates for Executive Office of the President
 - Coordinates interagency comments
- **The Public**
 - Consumers
 - Producers
 - Interest Groups
- **The Courts**
 - Judicial review
 - Priority setting by mandating deadlines

Executive Branch Rules of the Road: E.O. 12866

- For regulatory actions designated as “significant” regulatory actions, Agencies must submit
 - the draft regulation and
 - an assessment of the potential costs and benefits of the regulatory action, including how the action is consistent with the statute, promotes President’s priorities and avoids interference with State, local and tribal governments
- OMB reviews the regulations according to the timelines and requirements within the Executive Order.
 - OMB typically has 90 days for its review
 - OMB can return a regulation

Problem:

Regulating Without Regulations

“The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.”

Appalachian Power Co. v. EPA, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment).

Solution:
**E.O. 13422 and OMB Bulletin on
Agency Good Guidance Practices**

- On January 18, 2007, the President signed Executive Order 13422 (amending Executive Order 12866 on Regulatory Planning and Review) to include agency issued guidance documents as part of the existing regulatory process.
- On that same date, OMB issued a bulletin entitled “Agency Good Guidance Practices” that establishes policies and procedures for the development, issuance, and use of “significant guidance documents” by Executive Branch departments and agencies.

OMB Bulletin on Agency Good Guidance Practices

Specifically, the Bulletin establishes:

- Criteria for identifying guidance documents;
- Requirements for displaying significant guidance documents on agency websites and providing an opportunity for public review and comment; and,
- Approval procedures for revising, withdrawing, or initiating significant guidance documents.

Guidance Documents Defined

“A statement of general applicability and future affect other than a rule that is made available to the public and sets forth a policy or interpretation of a statutory, regulatory, or technical issue.”

Significant Guidance Documents

A “significant” guidance document is a guidance document disseminated to regulated entities or the general public that “may reasonably” be anticipated to:

- Lead to an annual effect of \$100 million or more; or
- Create a serious inconsistency with an action taken or planned with another agency; or
- Alter budgetary impacts or rights of recipients of entitlements, grants, user fees, or loan programs; or
- Raise novel legal or policy issues arising out of legal mandates, Presidential priorities, or the principles set forth in E.O. 12866.

OMB has since indicated that any guidance document issued in support of a significant rule should be considered significant under the new policies.

Requirements

- **Public Comment:**
 - By August 23, 2007, agencies were required to make significant guidance documents currently in effect available on their websites for public comment.
 - Agencies do not need to respond to public comments on significant guidance documents.
- **Respond to Public Comment:**
 - Agencies must publish economically significant guidance documents in the *Federal Register* and respond to public comments prior to issuing them in final form.
- **Workplans:**
 - Since June 29, agencies have been required to submit workplans to revise, withdraw, or initiate significant guidance documents.
- **Publication on Web:**
 - New significant guidance documents must be posted on an agency website within 30 days of release.



You are here: Home / Laws and Regulations / USDA Significant Guidance Documents

Search

Search input field with a 'Go' button and a dropdown menu set to 'All USDA'.

- Advanced Search
- Search Tips

My USDA

- Login
- Customize | New User

Browse by Audience

Information For... dropdown menu

Browse by Subject

- Agriculture
- Education and Outreach
- Food and Nutrition
- Laws and Regulations**
- Marketing and Trade
- Natural Resources and Environment
- Research and Science
- Rural and Community Development
- Travel and Recreation
- USDA Employee Services

Laws and Regulations

USDA Significant Guidance Documents

On January 18, 2007, the President issued Executive Order 13422, "Amendment to Executive Order 12866 for Regulatory Planning and Review." On that same day, the Office of Management and Budget (OMB) issued a final Bulletin entitled, "Agency Good Guidance Practices." The primary focus of the Executive Order and Bulletin is to increase the quality and transparency of agency guidance practices and the significant documents produced through them.

The term "guidance document" means an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue. A discussion of this definition and various types of guidance documents and other background information is available at the following sites:

<http://www.whitehouse.gov/omb/fedreg/>

<http://www.whitehouse.gov/omb/memoranda/>

By August 23, 2007, in accordance with OMB's Final Bulletin for Agency Good Guidance Practices, USDA will make available to the public a list of significant guidance documents and invite public comment on those documents.

List of USDA Significant Guidance Documents:

- <http://www.ams.usda.gov/guidance>
- <http://www.aphis.usda.gov/guidance>
- <http://www.csrees.usda.gov/business/awards/guidance.html>
- <http://www.ers.usda.gov/AboutERS/ERSgrants.htm>
- <http://www.fns.usda.gov/oane/GoodGuidance.htm>
- <http://www.fs.fed.us/guidance/index.shtml>
- http://www.fsis.usda.gov/significant_guidance
- <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=iq&topic=guidance>
- http://www.nass.usda.gov/About_NASS/Regulations_Guiding_NASS/index.asp#guidance
- <http://www.rma.usda.gov/aboutrma/what/guidance.html>
- http://www.rurdev.usda.gov/regsign_list.html

Related Topics

- Biotechnology
- Commodity Standards and Grades
- 2007 Farm Bill
- Food Distribution
- Food Labeling and Packaging
- Homeland Security
- Organic Certification
- Patents and Licensing
- Quality Assurance
- Regulations and Directives
- Safety Inspections
- Small Business Non-Retaliation Policy
- Trade Policy and Procedures
- Transportation and Distribution
- USDA Significant Guidance Documents**

You are here: [Home](#) / Significant Guidance Documents

Search FSIS

Go

Browse by Audience

Information For... ▼

Browse by Subject

- ▶ Food Safety Education
- ▶ Science
- ▶ Regulations & Policies
- ▶ FSIS Recalls
- ▶ Food Defense & Emergency Response

Significant Guidance Documents

This information is provided to comply with the OMB Bulletin on Agency Good Guidance Practices. The bulletin requires agencies to maintain a current electronic list of all "significant guidance documents" as defined in the Bulletin and in Executive Order 13422. See the Federal Register Notice | PDF published January 25, 2007 (72 FR 3432-3440).

Additional background information is available in the memoranda at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-13.pdf> (PDF Only)

Contact Information

For questions about this program, please contact us by emailing the FSIS Office of Policy, Program and Employee Development (OPPED), Risk Management Division (RMD), at http://www.fsis.usda.gov/contact_us/Email_Form/index.asp?rcpt=FSISGuidanceDocumentComments@fsis.usda.gov

FSIS Significant Guidance Documents

- Supplementary Guidance on the Use of Antimicrobial Agents to Control *Listeria Monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products, (Feb 11, 2008; PDF Only)
- Compliance Guidelines to Control *Listeria monocytogenes* In Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products (May 2006; PDF Only)
- Compliance Guideline for Controlling *Salmonella* in Poultry, First Edition (Aug 2006; PDF Only)
- Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 (Apr 13, 2004; PDF Only)

Last Modified: February 11, 2008

I Want To...

- [Ask a Food Safety Question](#)
- [askFSIS an Inspection-Related Question](#)
- [Apply for a Grant of Inspection](#)
- [Find Resources for Small Plants](#)
- [Subscribe to Newsletters](#)
- [Watch a Food Safety Video](#)
- [Attend a Public Meeting](#)
- [Export or Import Meat, Poultry or Egg Products](#)
- [Report a Problem with Food](#)
- [More...](#)

Media Help

To view PDF files you must have Adobe Reader installed on your computer.

USDA Significant Guidance Documents

Examples of USDA significant guidance documents:

- APHIS National Animal Identification System (NAIS): A User Guide and Additional Information Resources, Draft Version.
- FNS Food Buying Guide for Child Nutrition Programs.
- RMA Standard Reinsurance Agreements.
- FSIS compliance guideline to small poultry plants regarding *Salmonella* control in poultry slaughter establishment in order to meet regulatory requirements.

False Controversy

- **ACUS / ABA Recommendations**

- Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. 305.92-2 (1992) (“Agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices.”);
- American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting, August 10-11, 1993, Vol. 118, No. 2, at 57 (“Before an agency adopts a non-legislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so.”).

- **FDA Good Guidance Practices**

- FDA Modernization Act of 1997
 - directed the FDA to issue a regulation by 2000 “specifying the policies and procedures of the [FDA] for the development, issuance, and use of guidance documents.”
- 21 C.F.R. § 10.115 (October 2000) – “FDA shall:
 - seek public comment on its guidance documents, and consider the comments;
 - make its guidance documents easily available to the public by posting on the Internet;
 - “not include [in its guidance documents] mandatory language such as ‘shall,’ ‘must,’ ‘required,’ or ‘requirement,’ unless FDA is using these words to describe a statutory or regulatory requirement”;
 - “have written procedures” in each FDA center and office “for the approval of guidance documents,” which procedures “must ensure that issuance of all documents is approved by appropriate senior FDA officials”;
 - provide members of the public with an opportunity to submit and seek resolution of a complaint “that someone at FDA did not follow the requirements in [the regulation] or . . . treated a guidance document as a binding requirement.”

Next Steps

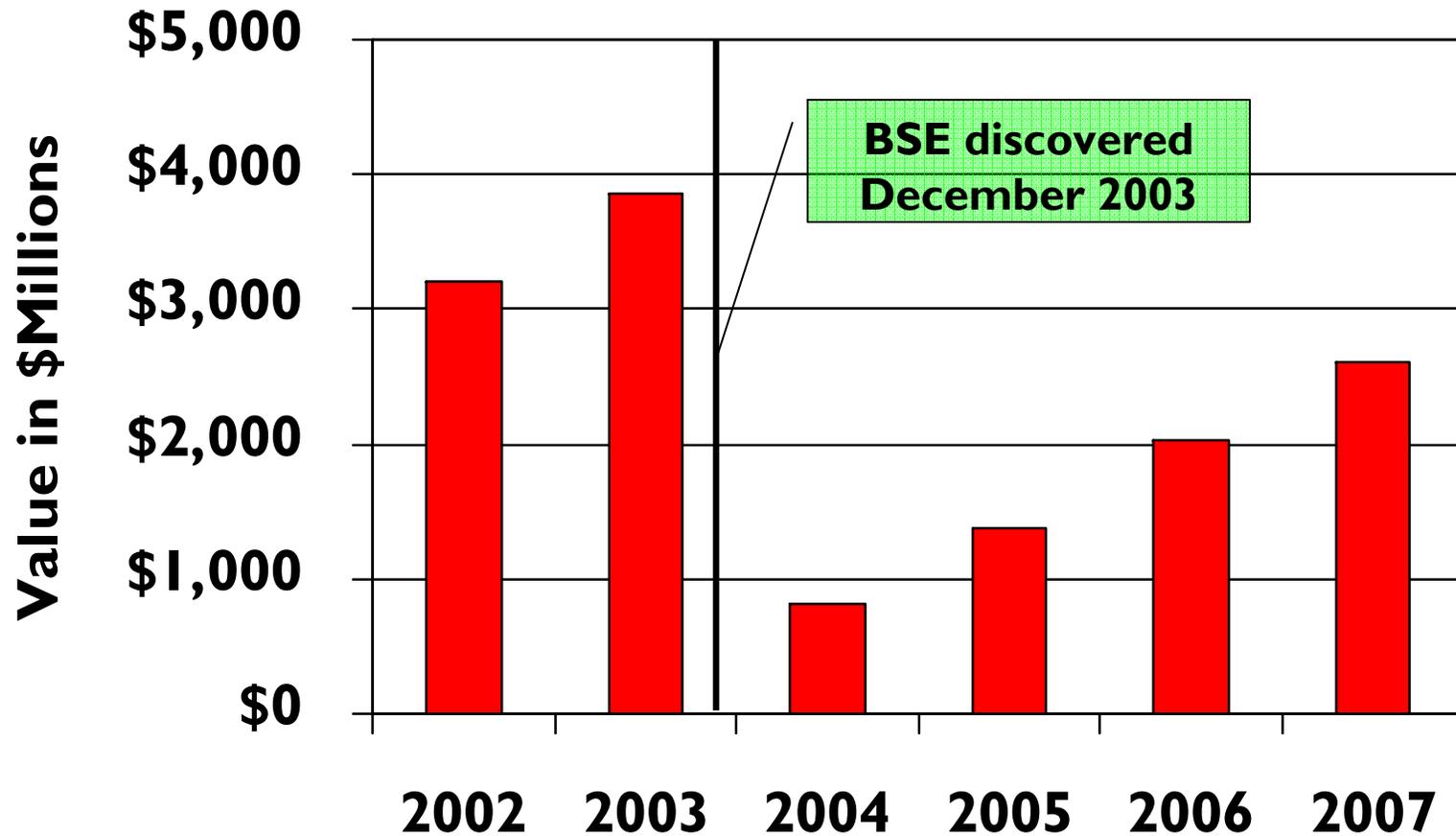
- Revised Departmental Regulations
- Public Utilization of New Process

Sound Science

- Public Confidence
- International Recognition
- Judicial Sustainability

Example: BSE Regulations

U.S. Beef and Beef Product Exports



Interlocking Safeguards

- **Feed Ban** -- The Food and Drug Administration feed ban was instituted in 1997 which prohibits ruminant protein from being fed to other ruminants.
 - The average age of animals slaughtered at this facility is 5 to 7 years of age, born after the 1997 feed ban.
- **Surveillance** -- We also have a robust ongoing BSE surveillance program that began before we experienced our first BSE positive cow in the U.S. in 2003, and we know that the prevalence in the U.S. herd is extremely low.
 - USDA ramped up its sampling in 2004, and has since sampled more than 759,000 animals. To date, only 2 animals have tested positive for BSE under our program. Both of those animals were born prior to initiation of the FDA feed ban.
- **SRM Removal** -- Since January 2004, specified risk materials (SRMs), such as the brain and spinal cord, must be removed and segregated so they do not enter the food supply.
 - Our on-site, continuous inspection ensures and verifies SRM removal which accounts for a 99 percent reduction in the risk of exposure to BSE as reported by the Harvard Risk Assessment.
- **Downer Ban** -- Since January 2004, non-ambulatory disabled cattle, or “downers,” are prohibited from the food supply.

OIE Recognition

- On May 22, 2007, the World Organization for Animal Health (OIE) **formally classified** the United States as a controlled risk country for bovine spongiform encephalopathy (BSE).
- This classification confirms that **U.S. regulatory controls are effective** and that U.S fresh beef and beef products from cattle of all ages can be safely traded due to our interlocking safeguards.
- The controlled risk status classification we have received provides strong support from an internationally recognized, standard-setting body that the **science-based mitigation measures** in place in the United States effectively protect animal health and food safety.
- Secretary Johanns' Statement:

“We appreciate OIE’s review of our application, as well as its leadership in **developing sound, science-based standards that will help countries standardize regulations and import requirements**. The U.S. is taking action to achieve compliance with OIE standards and we ask the same of our trading partners.

“**We will use this international validation to urge our trading partners to reopen export markets to the full spectrum of U.S. cattle and beef products**. We are notifying our trading partners of our expectation that they commit to a timeframe to amend import requirements and expand access to their markets to reflect this controlled risk determination. We will use every means available to us to ensure that countries rapidly take steps to align their requirements with international standards.”

R-CALF v. Johanns

- APHIS published the Minimal-Risk Region final rule (January 2005).
 - established a category of minimal risk regions for BSE and added Canada to that category.
 - allowed importation of cattle up to 30 months of age.
 - allowed the importation of beef from cattle of any age.
- R-CALF Challenge Filed (January 2005)
- Preliminary Injunction Issued (March 2005)
 - U.S. District Court for the District of Montana issued a preliminary injunction enjoining the rule from taking effect.
- Ninth Circuit Overturns PI (July 2005)
 - The importation of live cattle (under 30 months of age) and beef (derived from cattle under 30 months of age) from Canada begins immediately.

Deference

“When specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.”

Marsh v. Oregon Natural Resources Council, 490 U.S. 360
(1989)

“Hot” Regulatory Litigation

- R-CALF v. USDA and Creekstone Farms Premium Beef, LLC v. USDA
 - Challenge to APHIS regulation establishing minimal risk regions for BSE, and action to designate Canada as minimal risk region
 - USDA authority to prohibit use of BSE test kits by private entities
- Geertson Seed Farms v. Johanns
 - Challenge to APHIS Biotechnology Regulations
- California Avocado Comm. v. Johanns
 - APA challenge to APHIS regulation allowing importation of Haas avocados from Mexico
- Citizens for Better Forestry, et al. v. USDA and Defenders of Wildlife, et al. v. Johanns
 - Challenges to the Forest Service Planning Rule
- People of the State of California v. USFS and Wyoming v. USFS,
 - Challenges to the Forest Service Roadless Rule and the State Petitions Rule.
- Land’s Council v. McNair*
 - Challenge to Lolo post-burn project (NEPA)
 - Ninth Circuit recently granted *en banc* review

National Environmental Policy Act (NEPA)

NEPA is the national charter for environmental planning.

NEPA establishes an analytical process to incorporate environmental considerations into Federal agency decision making.

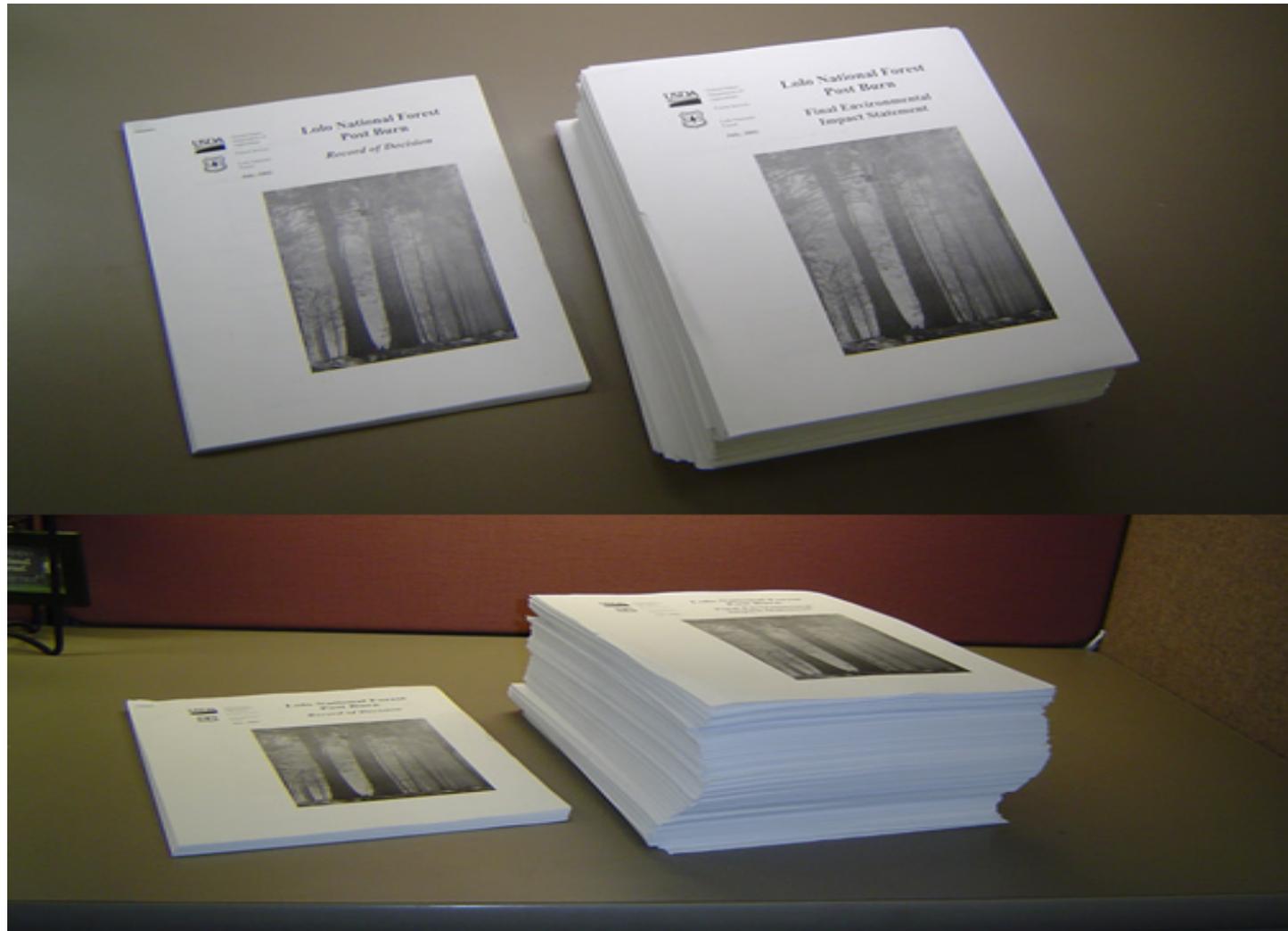
NEPA requires that for Federal actions having the potential to significantly impact the environment, agencies must:

- **Identify and analyze environmental consequences of proposed Federal actions in *comparable detail* to economic and operational analyses;**
- **Assess *reasonable alternatives* to agency proposed actions**
- **Document the environmental analysis and findings; and**
- **Make environmental information available to public officials and citizens *before* agency decisions are made;**

The Supreme Court On NEPA

- NEPA is a procedural, not a substantive statute.
 - Questions is “Did the agency follow the proper NEPA procedures?”
 - NOT: “Did the agency choose an environmentally sound alternative?”
- *Kleppe v. Sierra Club*, 427 U.S. 390 (1976)
 - “Once an agency has made a decision subject to NEPA's procedural requirements, the only role for a court is to insure that the agency has considered the environmental consequences; it cannot interject itself within the area of discretion of the executive as to the choice of the action to be taken.”

Lolo Post-Burn EIS and ROD



Admin. Record for Litigation



Lands Council v. McNair

- The Forest Service had not proven the reliability of its scientific methodology with regard to wildlife habitat restoration that includes timber harvest.
 - Cited *Ecology Center* (“Any action based on proof less than that followed by pharmaceutical companies for clinical drug trials is arbitrary and capricious agency decision making.”)
 - The court rejected the Forest Service’s key scientific study because it involved monitoring a “relatively small area” and because the agency inferred that harvest practices were maintaining suitable habitat *based upon the number of owl responses* the agency’s biologists did or did not hear.
- Judge Ferguson (for the court)

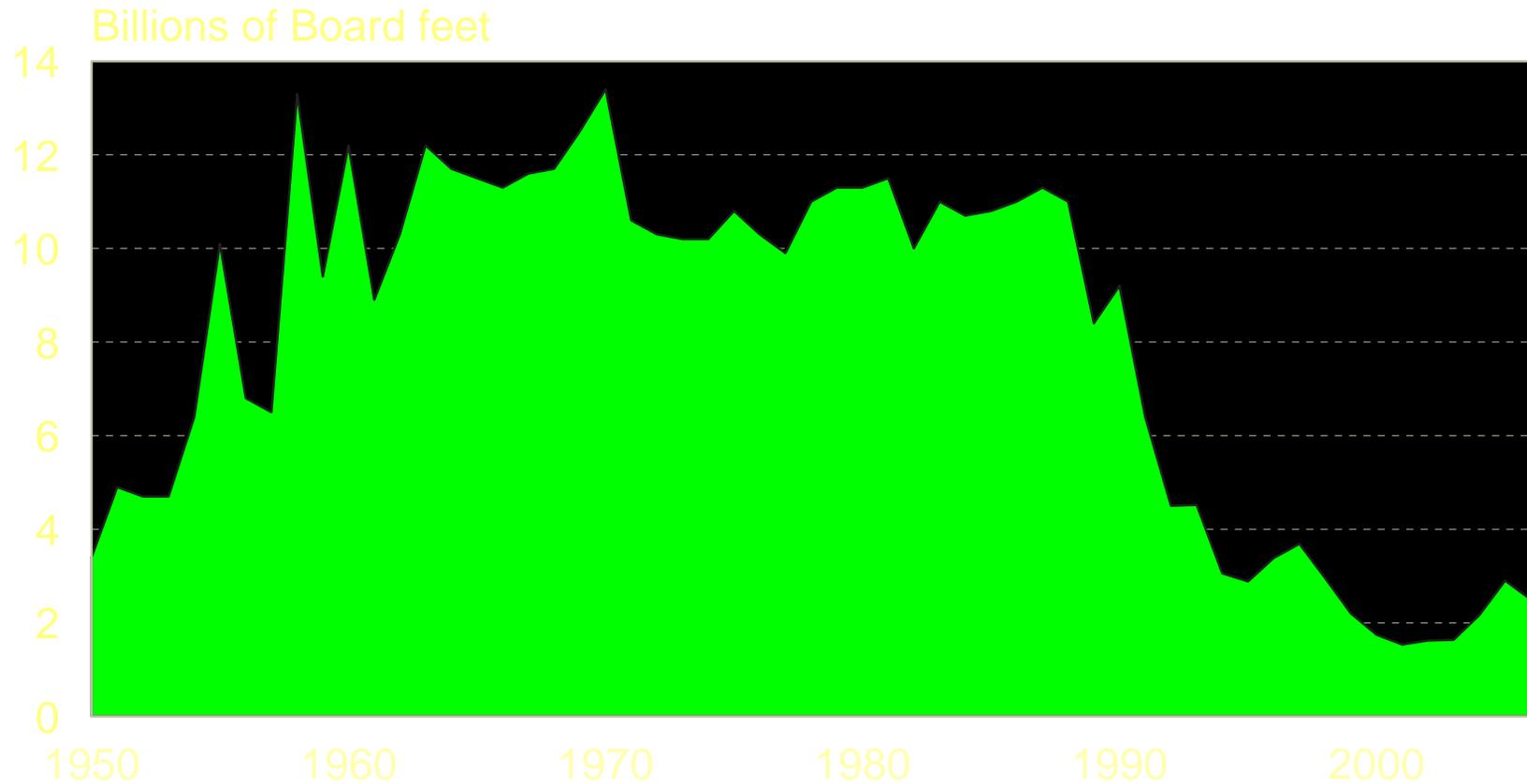
Lands Council v. McNair

- “By counting owl hoots, we are abandoning our role as reviewers under an “arbitrary and capricious” standard and **supplanting the Forest Service as decision makers.**
- If we do not grant the Forest Service appropriate deference in areas of scientific expertise, we **defeat the purpose of permitting the Forest Service to make administrative decisions in the first place**, and we intrude into areas far beyond our competence.”
- “It is not presently, and has never been, the policy of our national government under any administration to ban all logging in all of our national forests, and yet cases like *Ecology Center* make it **virtually impossible for logging to occur** under any conditions because the **Forest Service can never satisfy the constantly moving legal targets created by our circuit**, sometimes out of whole cloth.”

-- Judge Milan Smith (concurring)

National Forest Timber Sales

1950-2006



FS Cut and Sold Reports

Good
for the environment,
right?

Supply & Demand

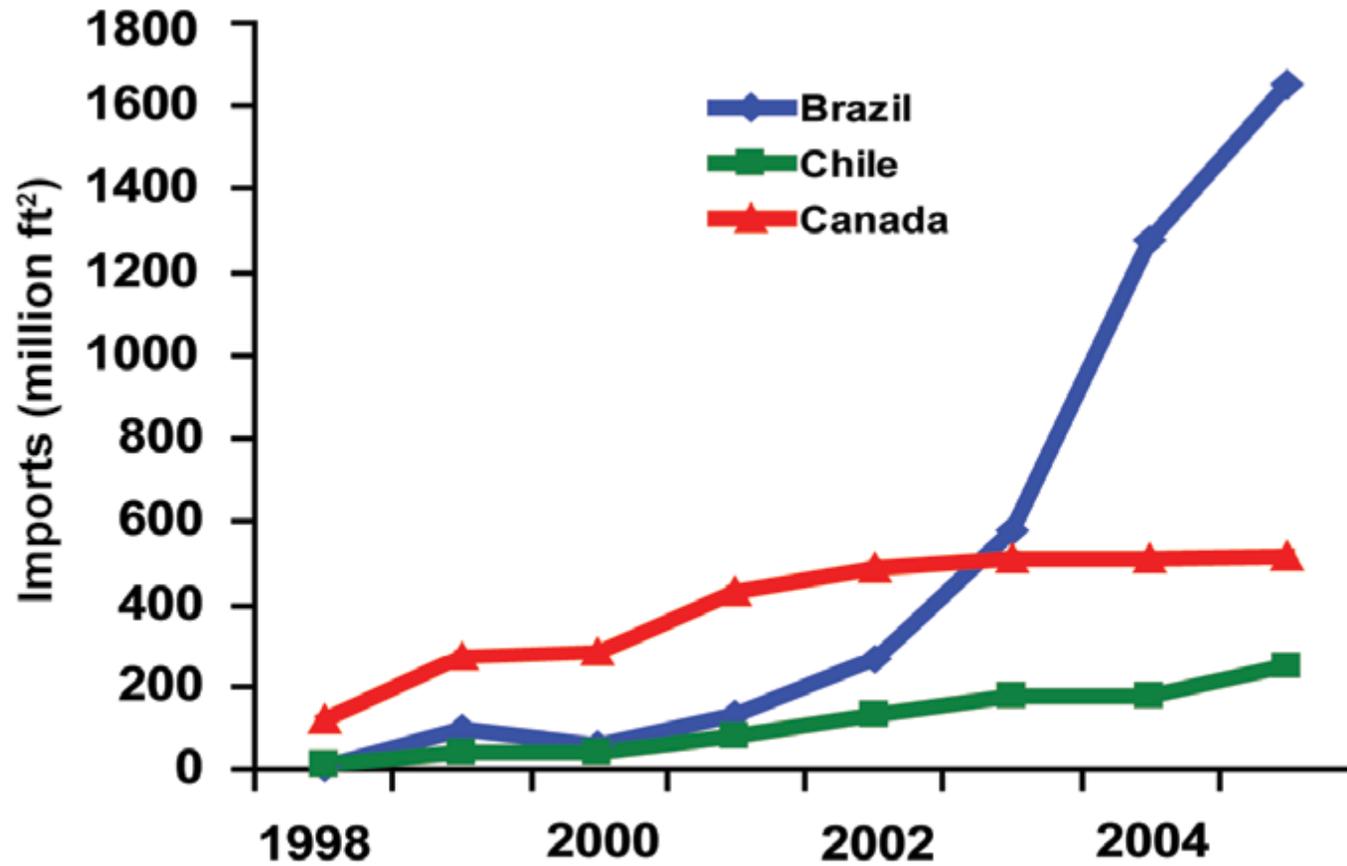
Increased Need

- Displacement of 9 billion board feet per year from NFS
- Increasing consumer demand

Potential Sources

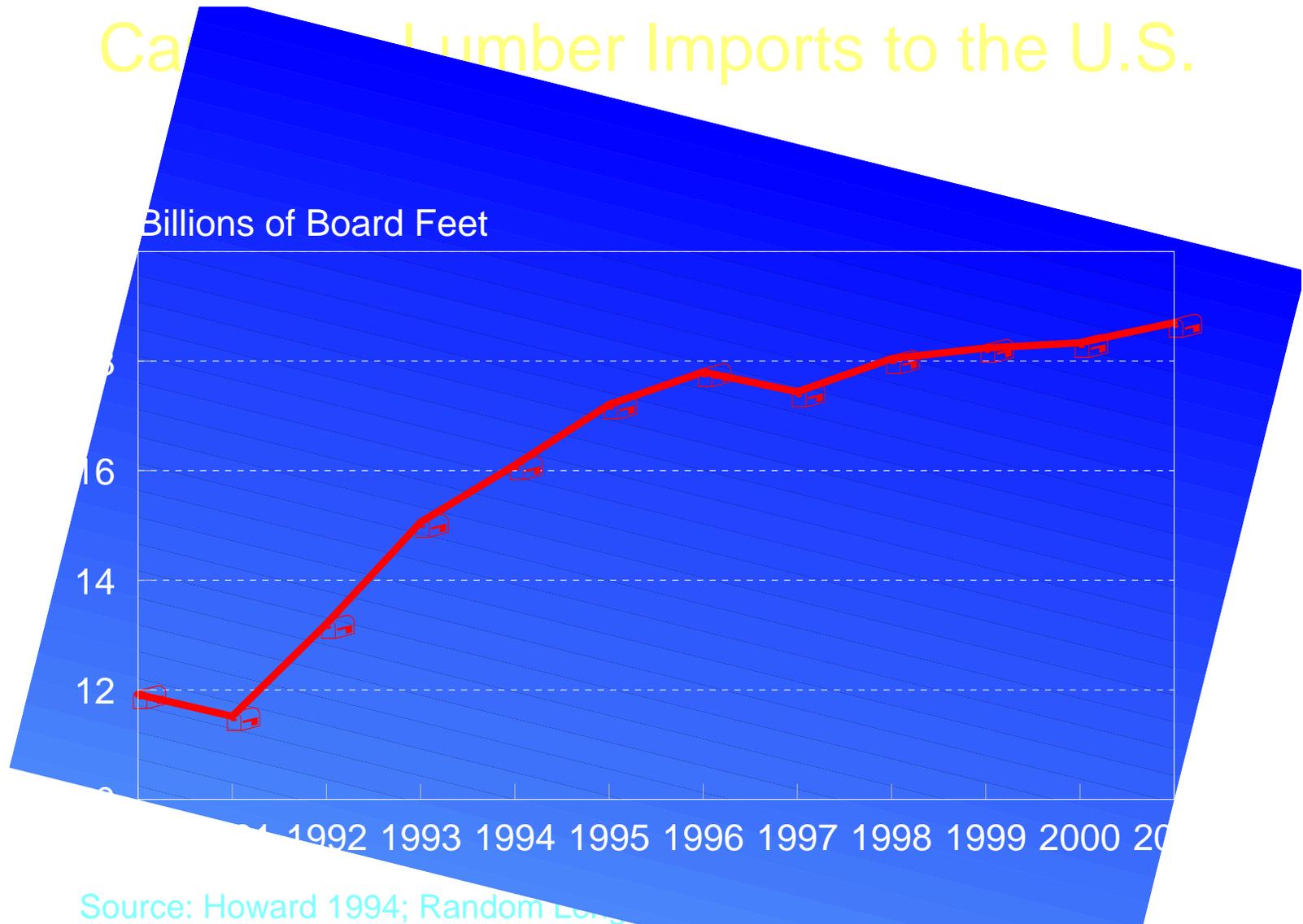
- Increase harvest from private lands
- Increase efficiency in manufacturing
- Shift to non-wood materials: plastics, aluminum, concrete, steel
- **Increase imports**

U.S. Plywood Imports, 1998-2005



In response to reduced NFS timber harvests, private harvests and Canadian imports to the U.S. have increased

Canadian Lumber Imports to the U.S.



Clearcutting of public lands to meet U.S. timber needs was not eliminated – it just moved north to the public forests of Canada



A clearcut in the boreal forest of northern Ontario within the traditional land use area of the Grassy Narrows Ojibway First Nation.

Photo from Taiga Rescue Network

China and the U.S. wood furniture industry

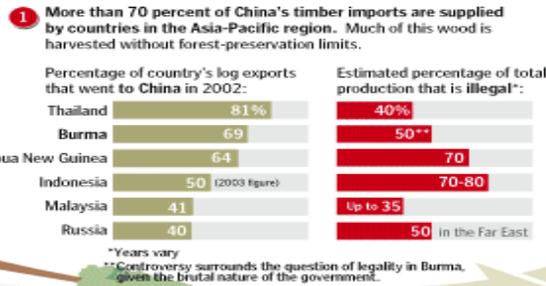
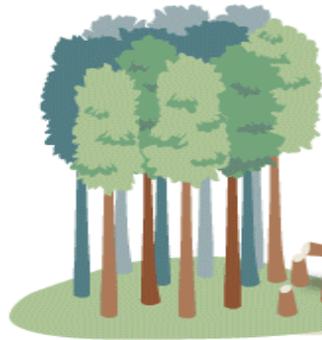
- Between 1995 and 2004, Chinese wood furniture exports rose 13 times, from \$682 million to \$8.7 billion
- At the same time, there were 250 furniture plant closures in the U.S., with a loss of 62,000 jobs
- Low labor rates, improved quality, and a favorable currency exchange were also significant factors in this growth
- But much of the hardwood material going into this furniture is from tropical forests having few management standards or is illegal

The Economic Effect of Illegal Wood

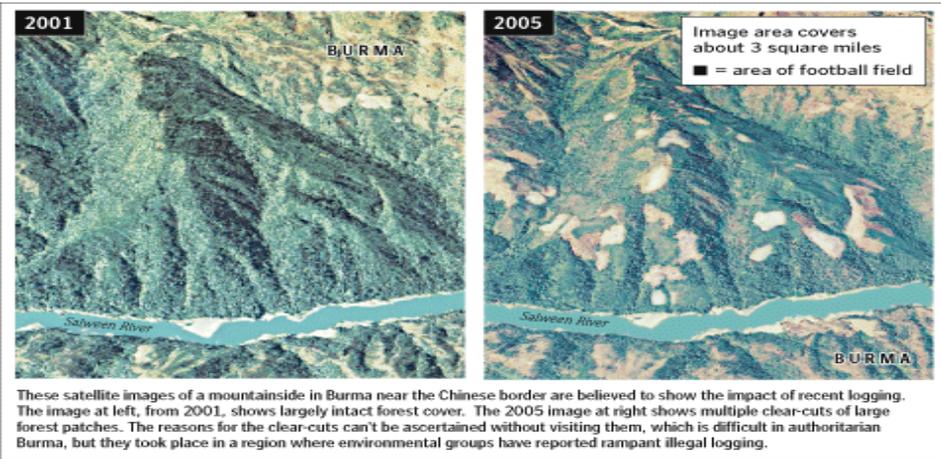
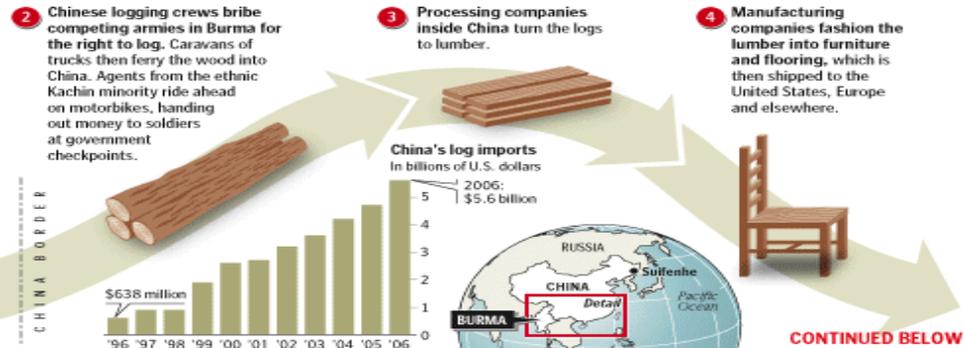
- The World Bank has estimated that the revenue losses to governments and legal producers due to illegal logging is between \$10-15 billion annually.
- An AF&PA study estimated that, absent illegally harvested wood, the value of U.S. produced wood could increase by over \$460 million
- The environmental cost of illegal logging is huge, as well, and the proceeds often support “dirty wars” and human rights abuses in third world countries

How illegal timber travels

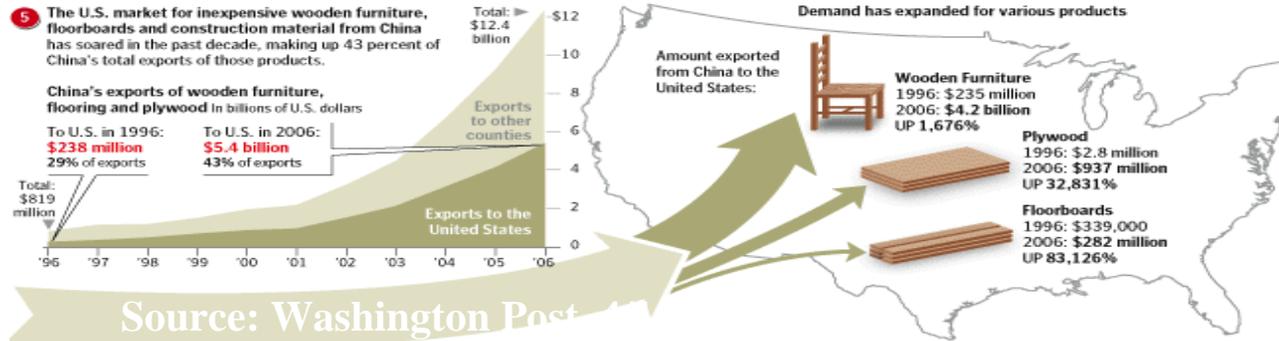
From Burma . . .



. . . Through China . . .



. . . to the United States



Source: Washington Post

CONTINUED BELOW



A satellite-style world map showing the continents in shades of green and brown, set against a dark blue ocean. The map is centered on the Atlantic Ocean.

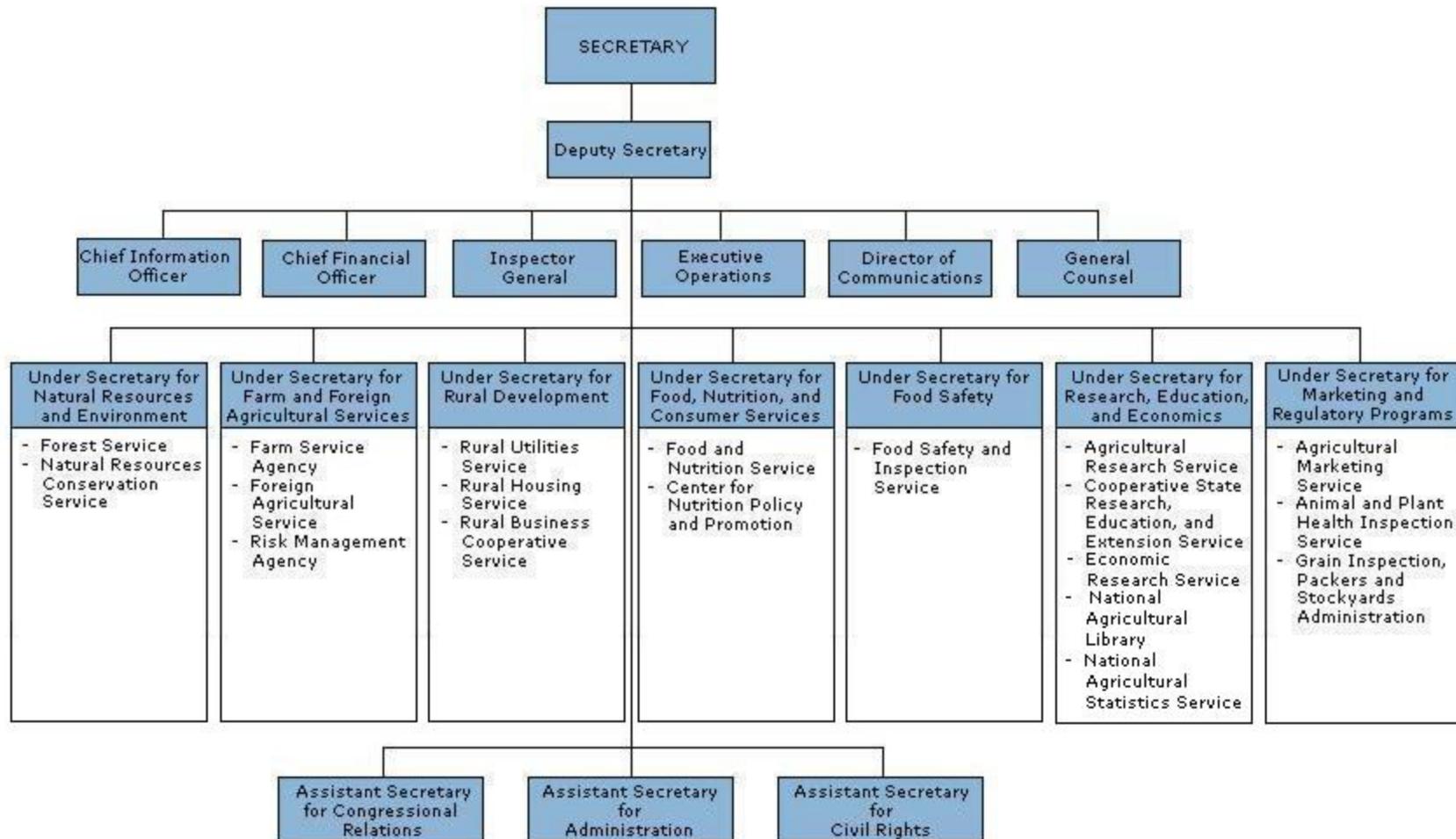
Regulating Effectively in a Globalized World: Perspectives of the RPO



Marc L. Kesselman
General Counsel
United States Department of Agriculture



U.S. Department of Agriculture



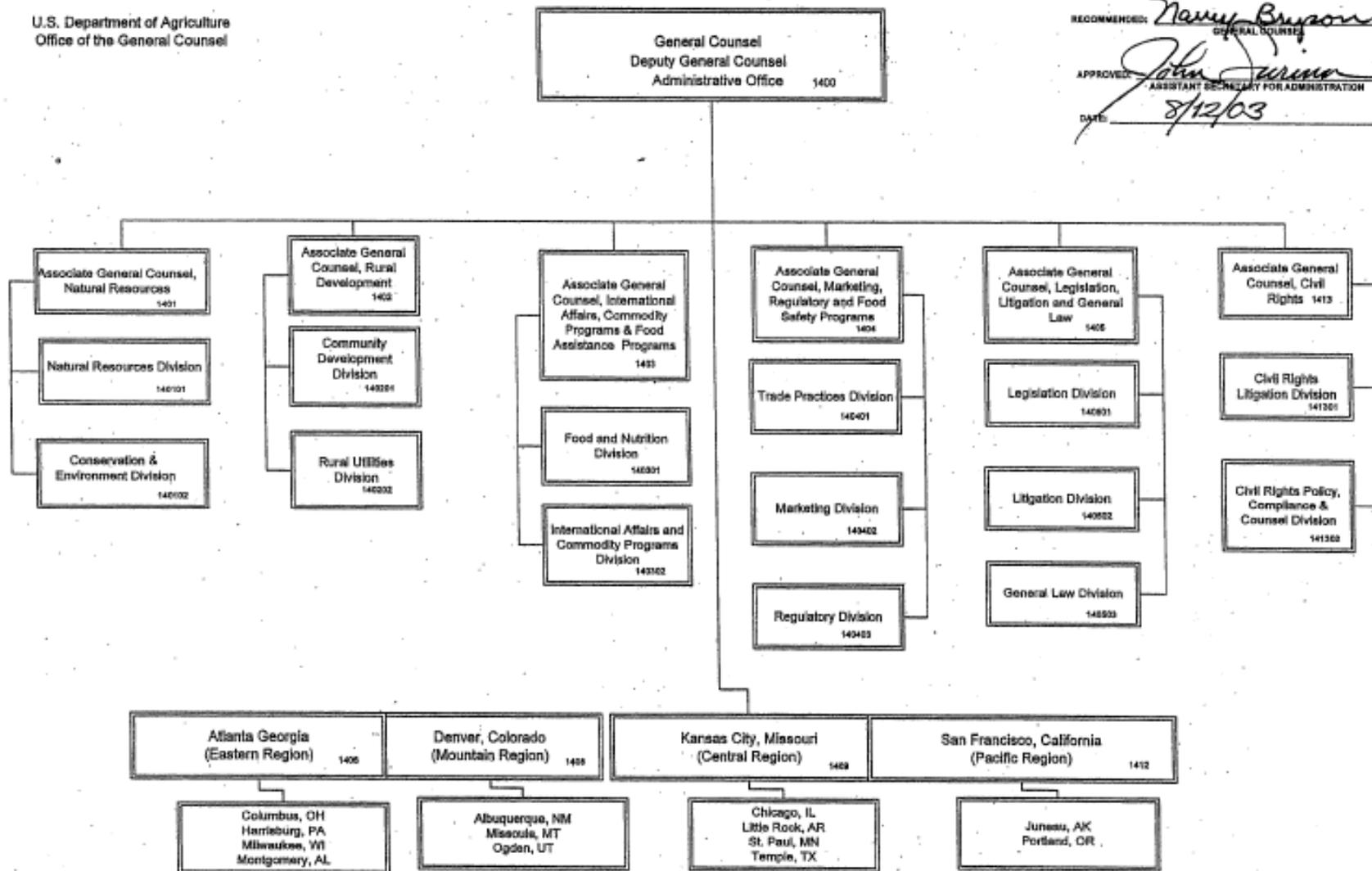
USDA OGC

U.S. Department of Agriculture
Office of the General Counsel

RECOMMENDED: *Nancy Brunson*
GENERAL COUNSEL

APPROVED: *John Jurena*
ASSISTANT SECRETARY FOR ADMINISTRATION

DATE: *8/12/03*



OMB: Interagency Coordination

- Identifies all interested governmental parties
- Coordinates review with other interested parties within the White House complex
 - Domestic Policy Council
 - National Economic Council
 - National Security Council
 - Council of Economic Advisors
 - U.S. Trade Representative
 - Office of Science and Technology Policy
- Coordinates review with other relevant Federal agencies (e.g., Commerce, State, Justice)

How does the Process Work?

Step 1: The Agency Determines Whether a Rule Is Needed

Step 2: The Agency Prepares a Proposed Rule and any required analyses.

- The Agency requests a designation from OMB
- The Agency may informally consult with other Federal agencies and OMB as they prepare their draft.
- The Agency gathers the supporting data and prepares, at the very least, initial drafts of the analyses required by E.O. 12866 and, if applicable, other Executive Orders and Laws.

How does the Process Work?

Step 3: OMB reviews the draft proposed rule

- 90-day review after agency submits proposed for 12866 review
- Internally review rule and coordinate with other agencies
- For all regulatory actions under review, we see public comments provided during review and those submitted to the agency during public comment period required by the Administrative Procedure Act
- OMB disclosure to public of formal submission

Step 4: The Agency publishes the proposed rule and requests public comment

Step 5: The Agency prepares a final rule

How does the Process Work?

Step 6: OMB reviews the draft final rule

- 90-day review after agency submits proposed for 12866 review
- Internally review rule and coordinate with other agencies
- For all regulatory actions under review, we see public comments provided during review and those submitted to the agency during public comment period required by the Administrative Procedure Act
- OMB disclosure to public of formal submission

Step 7: The agency publishes the final rule

Step 8: The agency submits the final rule to Congress

How is the Public Involved?

- The public may petition an agency to initiate a rulemaking
- The public may meet with the agency, OMB, and/or others within the Executive Branch to discuss their concerns.
- The public may formally comment on proposed rules and provide information and/or data to assist the agency in assessing the effect of the rule.
- After a rule goes into effect, affected parties can bring suit against the agency issuing the rule to have the courts reverse or mandate it back to the agency because the agency violated the APA's requirements, the statute that authorized the rule, or the U.S. Constitution.
 - “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”



- Glickman v. Wileman Brothers (June 25, 1997) -- marketing order for California peaches and nectarines
- United States v. United Foods (June 25, 2001) -- mushroom research and promotion program
- Johanns v. Livestock Marketing Association (May 23, 2005) -- beef research and promotion program
- Michigan Pork Producers Association, Inc., et al. v. Campaign for Family Farms (May 31, 2005) – pork research and promotion program



Worker in Mexico fills boxes with Avocados headed to market in United States.