



# Regulatory Policy

## The United States Perspective

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*Disclaimer: This talk represents my personal views and is not a reflection or a statement of OMB policy or positions.*



# U.S. Approach to Regulatory Policy

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- ❑ Centralized Oversight and Leadership
  - ❑ Emphasizes the importance of and adherence to regulatory principles and procedures.
  
- ❑ Transparency and Accountability
  - ❑ Makes information available to the public and allows all interested parties to be heard.
  
- ❑ Regulatory Impact Analysis
  - ❑ Contributes to more informed policy decisions and promotes efficiency.
  
- ❑ Smarter Regulation/ Sound Science
  - ❑ Adopt good rules; modify and rescind existing rules to improve cost effectiveness.

# The U.S. Federal Government

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## Legislative Branch

- House of Representatives and Senate

## Executive Branch

### Power is vested to the President and delegated

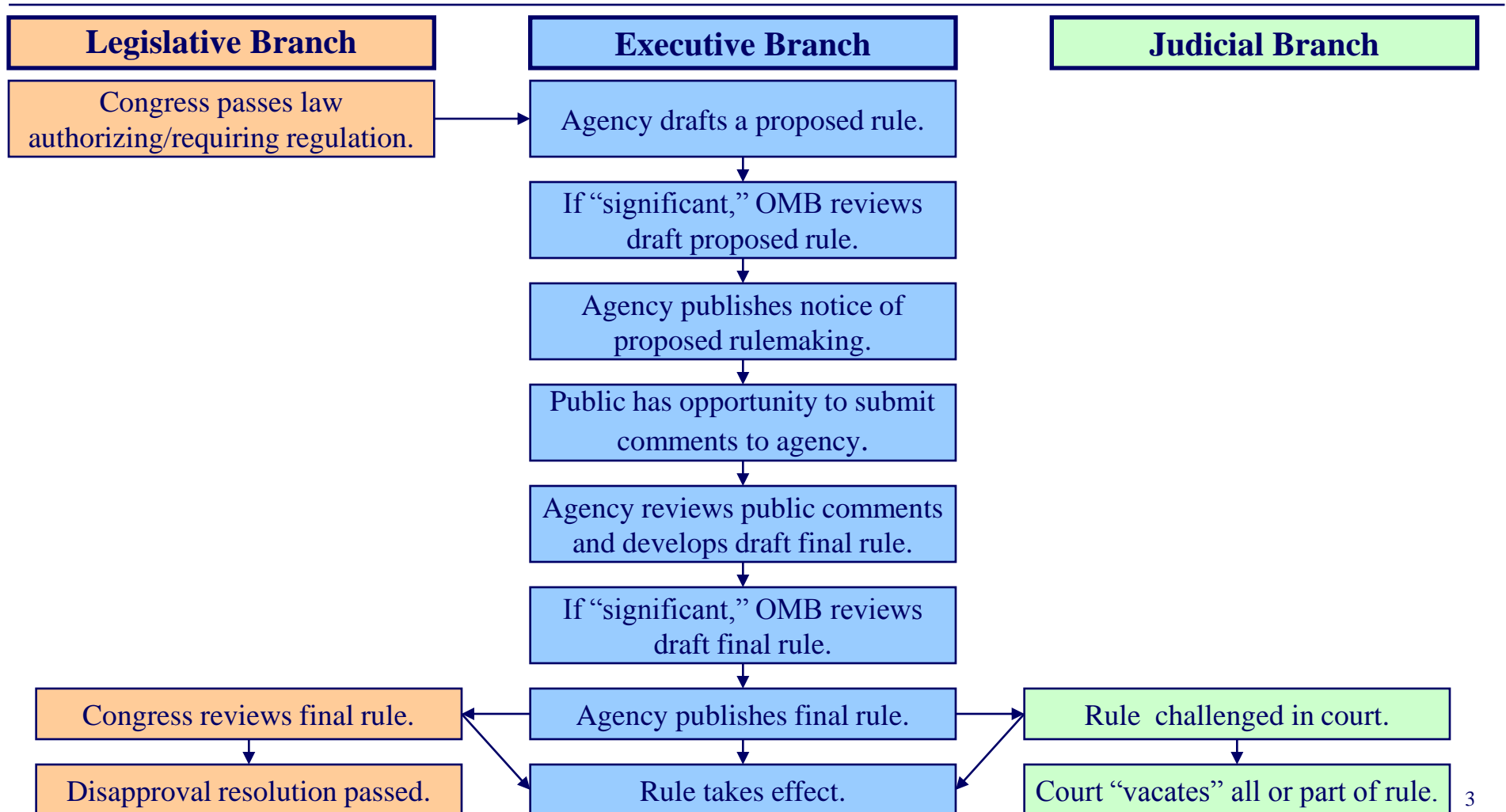
- 14 Cabinet Agencies
- Over 100 Agencies, Boards, and Commissions
- 4.8 million military and civilian employees
  - 244,210 full time equivalent workers employed to work on regulatory issues (2007)

## Judicial Branch

### US Federal Courts

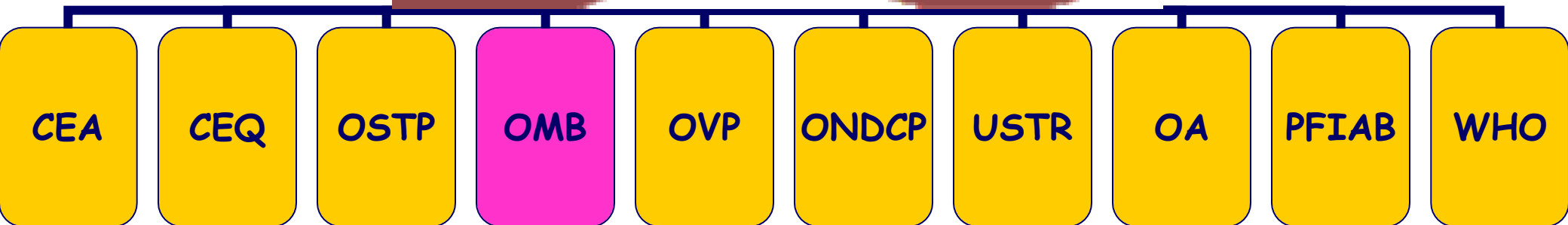
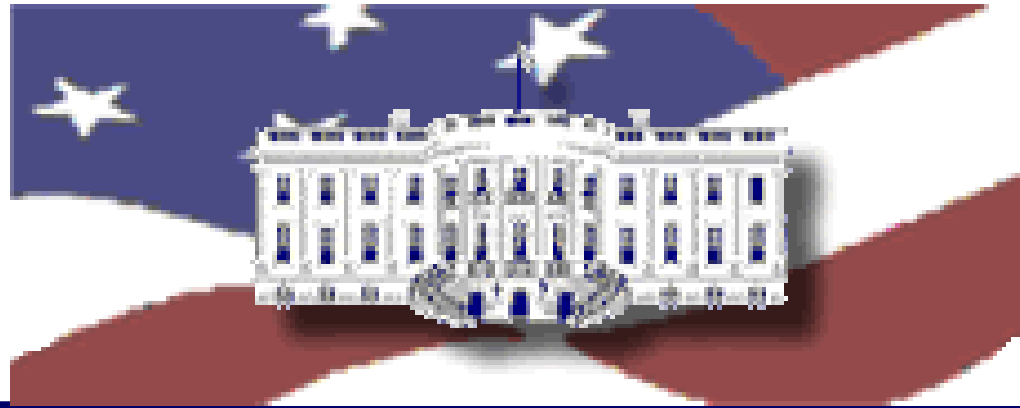
- Supreme Court
- 13 courts of appeals, 94 district courts, and two courts of special jurisdiction

# Federal Rulemaking Process



# The Executive Office of the President (EOP)

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# Office of Management and Budget (OMB)

Jacob Lew

## Support

General Counsel

Legislative Affairs

Communications

Administration

Economic Policy

Legislative  
Reference

Budget Review

## Resource Management

Natural Resources

Human Resources

General  
Government

National Security

## Statutory Offices

Financial Management

Procurement

E-Gov and IT

Information and  
Regulatory Affairs



# Extent of Federal Regulation Since 1980

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- 109,000 new rules
- 20,000 reviewed by OMB
- 1,000 estimated to cost > \$100 m

# Federal Rulemaking Process

Primary \*  
Legislation

Legislative Branch: Clean Air Act

Agency \*  
Rulemaking

Executive Branch: Diesel-Engine  
Exhaust Rule

Information &  
Enforcement

Executive and Judicial Branches:  
“Guidance” and “Certification”,  
Procedures for Engine Suppliers

Effects on  
Public

Cleaner Air (At a cost)

\*Public input is part  
of the process



# Federal Rulemaking Process

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## Legislative Checks on Regulatory Power

- Oversight: letters and hearings
- The purse string
- Senate confirmation of regulators
- Modify primary legislation
- Congressional review vote

## Scope of Judicial Review

- Agency compliance with administrative procedures
- “Arbitrary and capricious” decision making
- Adherence to primary legislation
- Constitutionality



# How Regulation Has Changed: 1980-2010

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- ❑ Decline of economic regulation
- ❑ Rise of regulation where science is critical determinant
- ❑ Majority of rules address public health, safety, environment, and homeland security
  - ❑ FDA, EPA, OSHA, CMS, NHTSA, DHS, FAA, USDA



# OIRA Responsibilities

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- ❑ OIRA coordinates statistical policies, budgets, standards, long-range plans, and international activities for the decentralized Federal statistical system.
- ❑ OIRA develops and oversees government-wide information policy and information technology policy.
- ❑ OIRA manages and coordinates regulatory policy in the Federal government.



# OIRA Responsibilities

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- Paperwork Reduction Act
- Executive Order 12866/13563
- Information Quality Guidelines
  - Peer Review Bulletin
  - Memorandum on Risk Analysis
- Review legislative proposals, policy proposals, and testimony
  
- Cost Benefit Report of Federal Regulations
- Unfunded Mandates Reform Act
- Congressional Review Act
- Small Business Regulatory Enforcement Act



# New Expertise at OIRA

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In addition to: Economics and Public Policy

- Toxicology
- Epidemiology
- Risk Modeling
- Engineering
- Environmental Science
- Public Health
- Health Economics

- Staff of approximately 45 career employees

# Presidential Executive Order 12866/13563 on Regulatory Planning and Review

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- ❑ Governs OMB's oversight of agency rulemaking, requiring OMB review of "significant" agency regulatory actions.
- ❑ Agencies submit draft significant regulations (both proposed and final) to OIRA for an up-to-90-day review before publishing them in the Federal Register.
- ❑ OIRA reviews about 600 regulations per year-those we determine to be significant- out of about 2,200 that are issued.
- ❑ About 70 of the 600 regulations are "economically significant" (over \$100 million per year in economic effects).



# 12866/13563 Review Process

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- ❑ OIRA sees all public comments for all regulatory actions under review.
- ❑ OIRA has 90-days for review after agency submits the proposed or final rule for review.
- ❑ OIRA coordinates Interagency review by other interested parties within the Executive Branch. This includes other EOP offices and other Agencies.



# Transparency and Accountability

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- The Administrative Procedures Act requires that agencies go through a notice and comment process open to all members of the affected public, both US and foreign. Notice of all proposed and final rules is published in the *Federal Register*
- Before agencies can issue a final regulation, they must respond to the public comments, make sure that the final regulation is a logical outgrowth of the proposal and the public record, and is not arbitrary or capricious.
- The public record is used by the courts in settling any challenge to the regulations brought by the affected public.





# Disclosure of Information

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- ❑ OMB's public website each day shows which rules are under formal review at OMB and which have been cleared. [www.reginfo.gov](http://www.reginfo.gov)
- ❑ OMB's website notes which outside groups have recently lobbied OIRA on rules under review: providing their names, organizations, date of the meeting, and the topic of discussion.
- ❑ All written information given to OMB while a rule is under review is sent to the agency, placed in our public docket and posted on our website.
- ❑ Return letters sent to the agencies outlining our concerns with rules we send back are posted on our website.

# Reginfo.gov

**RegInfo.gov** Where to find Federal Regulatory Information

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**AGENCIES WITH THE MOST REGULATORY ACTIONS CURRENTLY UNDER REVIEW**

Agency	Number of Pending Actions
EPA	19
USDA	9
DOT	8
DOL	7
HHS	6
VA	5
DOJ	4
HUD	4
DOD	3
FAR	3

Total Pending Actions: 88

**Pending Actions By Rule Stage**

Rule Stage	Count
Proposed Rule	38
Final Rule	36
Notice	9
Prerule	3
Interim Final Rule	2

View

**REGULATORY REVIEW**

Executive Order 12866 directs agencies to follow certain principles in rulemaking, such as consideration of alternatives and analysis of benefits and costs, and describes OIRA's role in the rulemaking process.

[More about Regulatory Review >>](#)

**INFORMATION COLLECTION REVIEW**

The Paperwork Reduction Act requires that agency information collections minimize duplication and burden on the public, have practical utility, and support the proper performance of the agency's mission.

**WHAT'S NEW**

**Regulatory Review**

- [Regulations under EO 12866 Review](#)
- [Regulatory Reviews Completed in Last 30 Days](#)

**Agenda**

The Unified Agenda and Regulatory Plan provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal government, covering over 60 departments, agencies, and commissions.

[More about Agenda >>](#)

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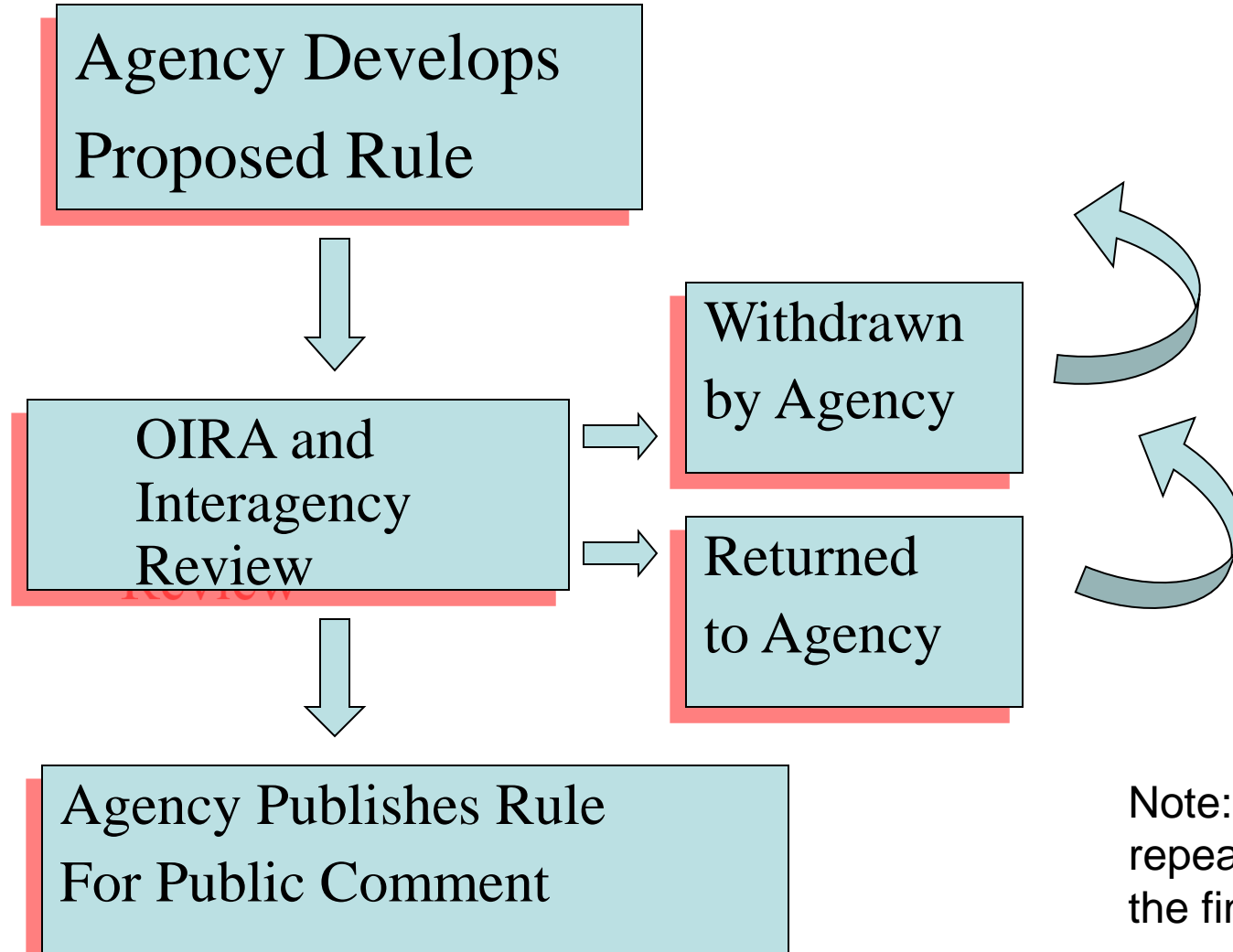
[Learn more about these organizations and their missions >>](#)

**The Reg Map** **Reg Map**

The Reg map gives an overview of the informal rule making process.

[Comment on Federal Rulemaking](#)

# How OIRA Review Works



Note: process repeats itself for the final rule



# Role of Scientific Review: Ensuring Quality

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- ❑ Scientific review enhances OMB's ability to evaluate the scientific underpinnings of regulatory impact analyses, risk assessments, and health and safety guidance.
- ❑ This process also engages scientists throughout the government.
- ❑ Ensures that agency science is presented in an accurate, clear, concise, and unbiased manner.



# Role of Review: Ensuring Quality and Utility

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- What OIRA looks at:
  - Is the rule based on best available, peer-reviewed science?
    - Where the performance standards of the Information Quality Guidelines and Peer Review Bulletin met?
  - Is the risk analysis transparent and appropriately conducted?
    - Were the Principles for Risk Analysis followed?
  - Are benefits and costs identified, quantified and weighed?
    - Was Circular A-4 followed?
  - Are regulatory alternatives considered?
  - Consistency with President's priorities
  - Need for the regulation, identification of market failure

# Regulatory Impact Analysis

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## Basic Goals

- Provide information to decision makers and the public on the costs, benefits, and impacts of the rule.
- Support the agency's determination that the benefits of the rule justify the costs.
- Increase the transparency of the regulatory system.

## Elements of a Regulatory Impact Analysis

- Statement of need for the proposed rule that identifies the nature and significance of the problem (e.g., identification of market failure).
- Examination of alternative approaches to addressing the problem.
- Analysis of the costs, benefits and impacts of each alternative.

# Regulatory Impact Analysis

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- ❑ Useful Information That the Public Can Provide
  - ❑ Information on current practices for purposes of correctly identifying the “baseline” against which regulatory impacts are measured.
  - ❑ Data to support/refute an agency’s cost, benefit, or impact estimates.
  - ❑ Additional data representing the best reasonably obtainable scientific, technical, economic, and other information.
  - ❑ Identification of reasonable alternatives to achieving regulatory objectives.
  - ❑ Identification of implementation challenges that the agency may not have considered.



# Emphasis on Sound Risk Assessment Principles

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- ❑ Consistency with 2007 Memorandum on Principles for Risk Analysis:
  - ❑ The depth or extent of the analysis of the risks, benefits and costs associated with a decision should be commensurate with the nature and significance of the decision.
  - ❑ Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.
  - ❑ Characterizations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative, consistent with available data. The characterizations should be broad enough to inform the range of policies to reduce risks.





# Emphasis on Sound Risk Assessment Principles

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- ❑ Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.
- ❑ Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximize its use.
- ❑ Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner.



# Emphasis on Sound Risk Assessment Principles

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- In choosing among alternative approaches to reducing risk, agencies should seek to offer the greatest net improvement in total societal welfare, accounting for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).



# Emphasis on Sound Risk Assessment Principles

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To maximize public understanding and participation in risk- related decisions, agencies should:

- a. explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
- b. describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;
- c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risk; and,
- d. provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.



# U.S. Framework Ensures Quality

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- ❑ Responsive, consultative, science-based system
  - ❑ Opportunity for the public at large to comment
- ❑ Operates synergistically within multiple layers of checks and balances
  - ❑ Involving social norms, market forces, liability law, and voluntary standards
- ❑ Benefits from executive, legislative and judicial oversight
- ❑ System allows for an iterative process of information collection, risk assessment, and risk management when regulating emerging risks

# References

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- ❑ Executive Order 12866  
[http://www.whitehouse.gov/omb/inforeg/eo12866/index\\_eo12866.html](http://www.whitehouse.gov/omb/inforeg/eo12866/index_eo12866.html)
- ❑ Executive Order 13563  
[http://www.reginfo.gov/public/jsp/Utilities/EO\\_13563.pdf](http://www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf)
- ❑ Government-Wide Information Quality Guidelines  
<http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>
- ❑ Information Quality Bulletin for Peer Review  
[http://www.whitehouse.gov/omb/fedreg/2005/011405\\_peer.pdf](http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf)
- ❑ Circular A-4  
<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>
- ❑ Bulletin for Agency Good Guidance Practices  
[http://www.whitehouse.gov/omb/fedreg/2007/012507\\_good\\_guidance.pdf](http://www.whitehouse.gov/omb/fedreg/2007/012507_good_guidance.pdf)
- ❑ OMB/OSTP Updated Principles for Risk Analysis  
<http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>