



The U.S. Regulatory Review Process

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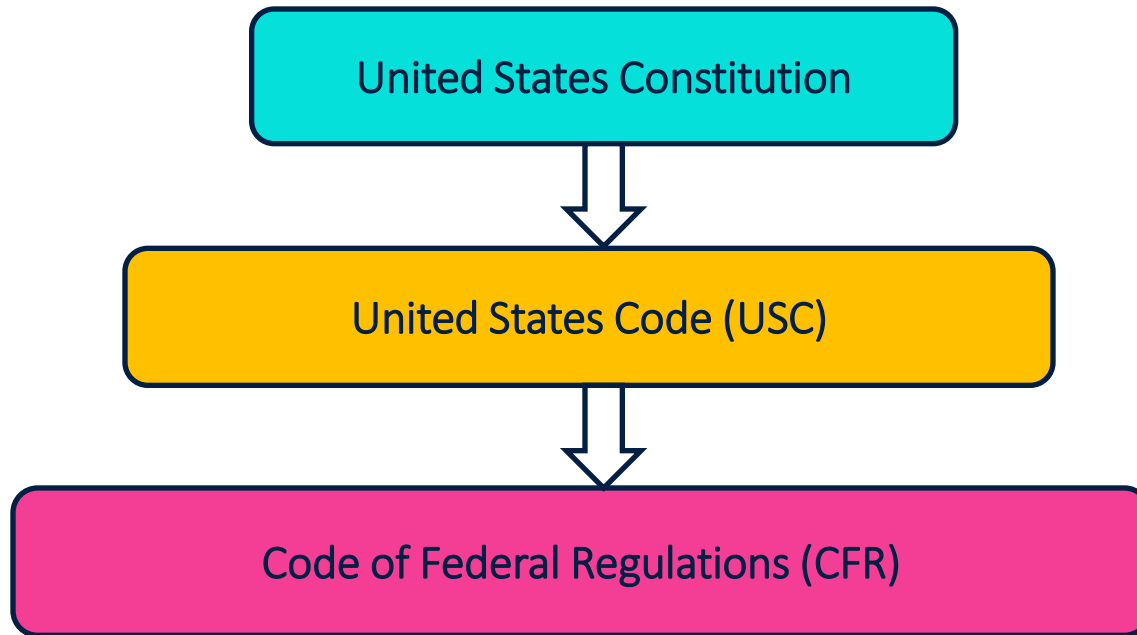
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Agenda

- Legal Framework for Rulemaking in the U.S.
- Executive Office of the President's Office of Information and Regulatory Affairs (OIRA)
- Executive Orders 12866 and 13771
- OIRA's Centralized Regulatory Review Process
- Regulatory Transparency and Participation



Legal Framework in the United States



Legislative Branch (Congress)

- Public Laws
- "Primary Legislation"

Executive Branch

- Regulations
- "Secondary Legislation"



Regulations in the United States

The Executive Branch can make law.

- Congress delegates authority to Executive Branch agencies to implement statutes through rulemaking.
- Some statutes are so broad that agencies can make new programs without new statutes.

Many important public policy decisions are made during rulemaking.

- Regulatory enforcement and allocation of resources.
- Grants, loans, and loan guarantees.
- Rights and responsibilities of the 50 States and the public.



Legal Framework for the U.S. Rulemaking Process

Administrative Procedure Act of 1946 (APA)

- The APA requires that agencies go through a notice and comment process open to all members of the affected public, both U.S. and foreign.
- Before agencies can issue a final regulation, they must first issue a proposed regulation for public comment. They must then respond to the public comments in the final regulation and make sure that the final regulation is a logical out-growth of the proposal and the administrative 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.



U.S. Rulemaking Process

Legislative Branch

Executive Branch

Judicial Branch

Congress passes law authorizing or requiring regulation. (www.Congress.gov)

Unified Agenda & Regulatory plans.

Agency drafts a proposed regulation. (www.RegInfo.gov & www.Regulations.gov)

If "significant," OMB reviews draft proposed regulation. (www.RegInfo.gov)

Agency publishes proposed regulation. (www.FederalRegister.gov & www.Regulations.gov)

Public reviews proposed regulation/docket and sends comments to agency. (www.Regulations.gov)

Agency reviews public comments drafts and final regulation.

If "significant" OMB reviews and draft final regulation. (www.RegInfo.gov)

Agencies submit all final regulations to Congress under the Congressional Review Act.

Agency publishes final regulation. (www.FederalRegister.gov & Regulations.gov)

The final regulation may be challenged in court.

Disapproval resolution passed and signed by the President.

Regulation takes effect. (www.FederalRegister.gov & Regulations.gov)

Court "vacates" all or part of rule.

Office of Management and Budget (OMB)

OMB, within the Executive Office of the President (EOP), assists the President in the development and implementation of budget, program, management, and regulatory policies.

- Develops the President's annual budget submission to Congress.
- Assists the President in managing the Executive Branch, developing the Administration's position on legislation before Congress and executing the law.
- Provides high quality regulatory analysis.



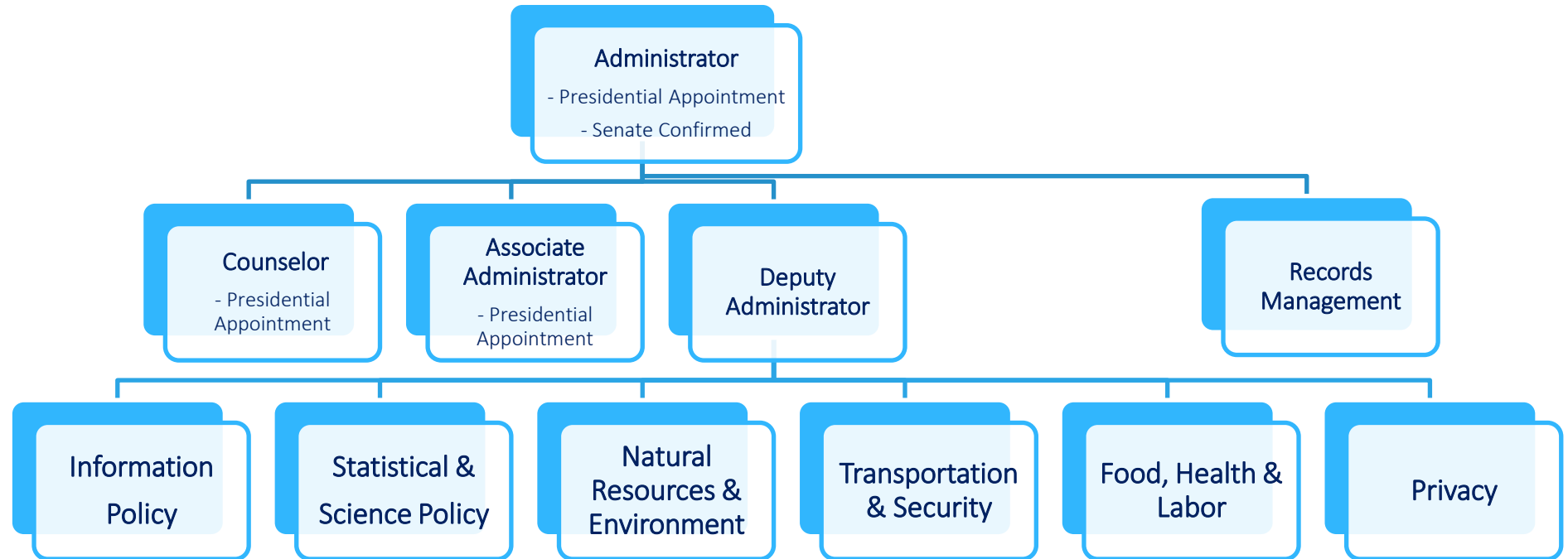
Interagency Coordination of Rulemaking: Office of Information and Regulatory Affairs (OIRA)

Role of the Office of Information and Regulatory Affairs:

- OIRA was established by the Paperwork Reduction Act of 1980, partially in response to the explosion in regulation that occurred in the 1970s and earlier in the U.S.
- As part of the Office of Management and Budget, OIRA is a central body, within the Executive Office of the President, that has special standing with the agencies.
- OIRA is the lead division of OMB for regulatory oversight and interagency review of “significant” regulations.
- OIRA also develops and oversees government-wide policies in the areas of information collection, information policy, privacy, and statistical and science policy.



Office of Information and Regulatory Affairs (OIRA)



Interagency Coordination of Rulemaking: Presidential Oversight

1970s

- **President Ford:** Required, for the first time, regulatory impact analysis (RIA) requirement for major regulations (over \$100 million in impact).
- **President Carter:** Established the Regulatory Analysis Review Group.

1980s

- **President Reagan:** Solidified regulatory oversight authority within the White House, issuing Executive Order 12291, which required OMB review and approval of rules.
- **President George H.W. Bush:** Continued the Reagan Executive Order.

1990s

- **President Clinton:** Issued Executive Order 12866, which focused OMB oversight on “significant” rules and increased the disclosure of contacts with outside parties.

2000s

- **President George W. Bush:** Maintained the Clinton Executive Order that requires the agencies to do RIAs and send significant regulations to OMB for review.
- **President Obama:** Issued Executive Order 13563, which affirms EO 12866 and outlines his regulatory strategy to support continued economic growth and job creation.
- **President Trump:** Issued Executive Order 13371 which outlines a regulatory budget and a requirement for identifying deregulatory rules before issuing regulatory rules, as allowed by law.



Executive Order 12866: “Regulatory Planning and Review”

Issued by President Clinton in October 1993.

- Governs OIRA’s centralized, interagency review of draft regulations.

Establishes principles of regulation.

- Regulation must be consistent with law.
- Regulations must identify nature and significance of problem.
- Alternatives to address the problem must be identified and assessed.
- The costs and benefits of each alternative must be assessed (regulatory impact analysis).
- The alternative selected should maximize net benefits to society.

These principles guide OIRA’s review of regulations.



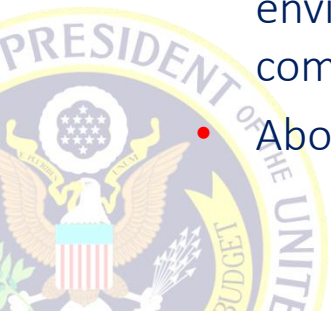
What regulations must OIRA review?

“Significant” Rules (Proposed and Final Rules)

- Create a serious inconsistency or otherwise interfere with another agency’s actions.
- Materially alter the budgetary impact of Federal programs.
- Raise novel legal or policy issues.
- OIRA reviews 500-700 proposed and final regulations per year—those we determine to be significant—out of about 6,500 that are published in the *Federal Register* (national gazette).

“Economically Significant” Rules (Proposed and Final Rules)

- Subset of “significant” rules.
- Annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.
- About 70-100 of the regulations reviewed are “economically significant.”



EO 12866: Important Requirements and Scope

EO 12866 has deadlines for OIRA review (usually 90 days).

EO 12866 requires economic analysis.

- Economically significant regulations require more analysis than smaller rules.
- OIRA examines the Regulatory Impact Analysis (RIA) and the regulation and makes suggestions to improve both the RIA and the rule's cost-effectiveness, ensure adherence to the Executive Order's principles, and consistency with the President's priorities.

Independent Regulatory Agencies are not covered.

- For example, Consumer Product Safety Commission, Federal Communications Commission, and the financial regulators.



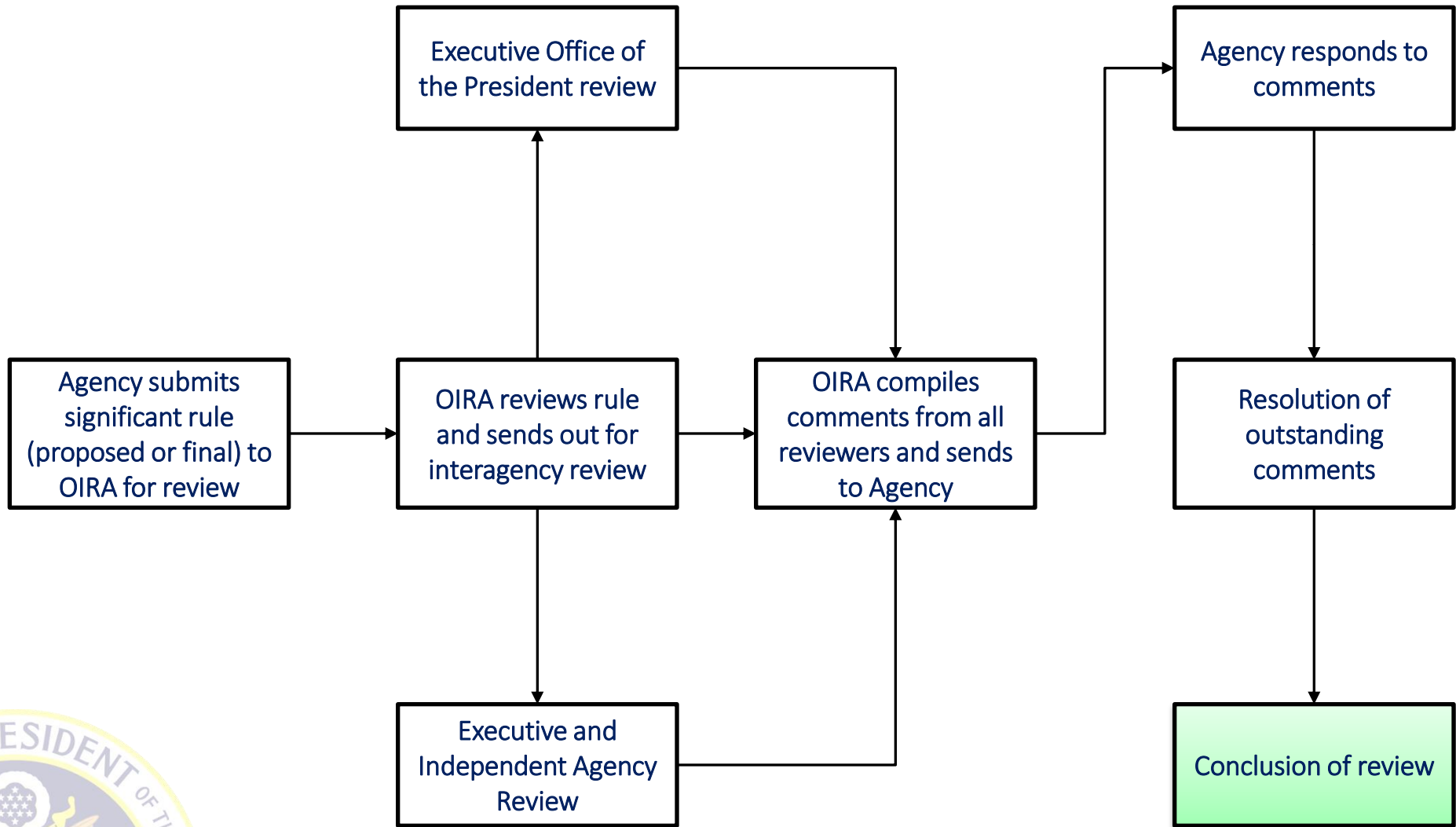
Executive Order 13771: “Reducing Regulation and Controlling Regulatory Costs”

Issued by President Trump in January 2017.

- Whenever an agency proposes for notice and comment or issues a new regulation, it shall identify at least two existing regulations to be repealed, unless prohibited by law.
- any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.
- Establishes annual regulatory costs for agencies and a role for the Office of Management and Budget (OMB) to set and maintain a regulatory budget.
- Requires approval by the Director of OMB if a regulation is not within the Unified Regulatory Agenda.



OIRA Centralized Regulatory Review Process



OIRA Centralized Regulatory Review Process (Cont'd)

Executive Office of the President

- Office of Management and Budget
- Council of Environmental Quality
- United States Trade Representative
- Council of Economic Advisors
- National Security Council
- Office of Science and Technology Policy
- National Economic Council
- Domestic Policy Council
- White House Counsel
- Office of the Vice President
- Office of the National Drug Control Policy
- Office of Public Engagement and Intergovernmental Affairs
- Office of the First Lady
- Office of Digital Strategy
- Other as necessary

Executive and Independent Agencies

- Department of Transportation
- Department of Labor
- Department of Interior
- Environmental Protection Agency
- Department of Energy
- Department of Health and Human Services
- Department of Justice
- Department of Homeland Security
- Department of Treasury
- Department of Commerce
- Department of State
- Department of Housing and Urban Development
- Department of Agriculture
- Federal Energy Regulatory Commission
- Nuclear Regulatory Commission
- Securities and Exchange Commission
- Federal Reserve Board
- Other as necessary



Possible Actions at the End of OIRA Review

Allow the agency to issue the rule.

- A rule is usually sent directly to the *Federal Register* at the conclusion of review.

Agency withdrawal of the rule.

- If we are unable to resolve issues during the review process, or the agency needs more time to make changes, the agency can withdraw the rule.

“Return Letter”

- OIRA may return a regulation for agency reconsideration to address OIRA concerns.
- Very public and very rare.



Regulatory Transparency and Participation

Disclosure of Information Under Executive Order 12866:

- The public can consult OMB's online "Regulatory Review Dashboard" to learn each day which rules are under formal review at OMB.
- Meetings with outside parties – OIRA and the issuing agency will meet with external stakeholders regarding rules under review. OMB's website notes which outside groups have met with OIRA, including the participants, and docket written materials provided to OIRA during the meeting.
- All written information given to us while a rule is under review is sent to the agency, placed in OIRA's docket, and posted online.
- Return letters sent to the agencies outlining our concerns with rules we send back are posted on our website.



References

- Administrative Procedure Act of 1946: <http://www.archives.gov/federal-register/laws/administrative-procedure/>
- Executive Order 12866: <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>
- Executive Order 13771: <https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-02451.pdf>

