



Overview of Best Practices in Impact Assessment

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Regulatory Impact Assessment:
Advancing the Economic & Commercial Strategic Partnership

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Agenda

Regulatory Impact Assessment: A Good Regulatory Practice

A Strong International Consensus

- APEC-OECD Integrated Checklist on Regulatory Reform
- Recommendation of the OECD Council on Regulatory Policy and Governance

Regulatory Impact Analysis

- Basic Goals
- Elements
- Why it Matters

Regulatory Transparency and Participation in the U.S.

- Administrative Procedure Act of 1946



Good Regulatory Practices (GRPs)

Coordinated, coherent “whole of government” approach to regulation

Analysis: tools to assess need/ impact of, proposed regulation (e.g. impact assessment, cost benefit analysis, risk assessment)

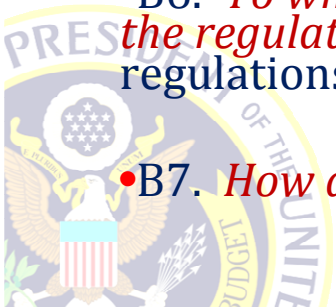
Transparency and public participation, considering stakeholder inputs



2005 APEC-OECD Integrated Checklist on Regulatory Reform

B. Regulatory Policy. Regulatory policies are designed to maximise the efficiency, transparency, and accountability of regulations based on an integrated rule-making approach and the application of regulatory tools and institutions.

- B2. *Are the legal basis and the economic and social impacts of drafts of new regulations reviewed?* What performance measurements are being envisaged for reviewing the economic and social impacts of new regulations?
- B3. *Are the legal basis and the economic and social impacts of existing regulations reviewed,* and if so, what use is made of performance measurements?
- B5. *Are there effective public consultation mechanisms and procedures* including prior notification open to regulated parties and other stakeholders, non-governmental organisations, the private sector, advisory bodies, accreditation bodies, standards-development organisations and other governments?
- B6. *To what extent are clear and transparent methodologies and criteria used to analyse the regulatory impact* when developing new regulations and reviewing existing regulations?
- B7. *How are alternatives to regulation assessed?*



2012 Recommendation of the OECD Council on Regulatory Policy and Governance

1. Commit at the highest political level to an explicit whole-of-government policy for regulatory quality. The policy should have clear objectives and frameworks for implementation to *ensure that, if regulation is used, the economic, social and environmental benefits justify the costs, the distributional effects are considered and the net benefits are maximised.*

2. Adhere to principles of open government, including transparency and participation in the regulatory process to ensure that regulation serves the public interest and is informed by the legitimate needs of those interested in and affected by regulation. This includes *providing meaningful opportunities (including online) for the public to contribute to the process of preparing draft regulatory proposals and to the quality of the supporting analysis.* Governments should ensure that regulations are comprehensible and clear and that parties can easily understand their rights and obligations.

4. Integrate Regulatory Impact Assessment (RIA) into the early stages of the policy process for the formulation of new regulatory proposals. *Clearly identify policy goals, and evaluate if regulation is necessary and how it can be most effective and efficient in achieving those goals.* Consider means other than regulation and identify the tradeoffs of the different approaches analysed to identify the best approach.



History of Regulatory Analysis in the U.S.

Executive Orders 12866 and 13563 require agencies to conduct a regulatory analysis for “economically significant” regulatory actions.

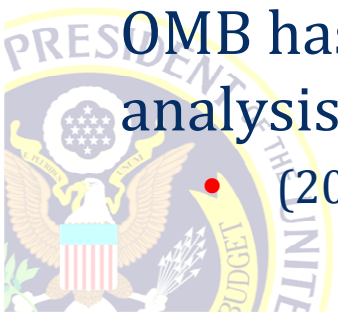
- (2011) Executive Order 13563
- (1993) Executive Order 12866
- (1981) Executive Order 12291

The “Regulatory Right to Know Act” requires OMB to “issue guidelines to agencies to standardize

- (1) measures of benefits and costs; and
- (2) the format of accounting statements.”

OMB has issued guidance on how to conduct regulatory impact analysis in place since the 1980s.

- (2003) OMB Circular A-4



Regulatory Impact Analysis (RIA): Goals

Basic Goals

- Maximize net benefits to society—or at least ensure that benefits justify costs.
- Promote economic efficiency by regulating only where markets fail, and when regulating, by using cost-effective and market-based approaches.
- Increase the transparency of the regulatory system.

RIA assesses the anticipated consequences a regulation and estimates associated benefits and costs.

- Helps to organize and consolidate all the possible impacts and elements for decisions at various stages of policy development.
- Provides clear and transparent methodologies and criteria for new or existing regulations.



Elements of an RIA

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 the market failure).
- Examination of alternative approaches to addressing the problem.
- Analysis of the costs and benefits of each alternative.

RIA is a flexible and adaptable tool that should always:

- Be proportional to the situation.
- Follow consistent guidance for complexity and level of analysis.



Why Does Regulatory Analysis Matter?

Good analysis helps provide a reasonable basis for rulemaking.

- Demonstrates whether a rule maximizes net benefits to society—or at least ensure that benefits justify costs.
- Demonstrates whether a rule promotes economic efficiency by regulating only where markets fail, and when regulating, by using cost-effective and market-based approaches.
- Increases the transparency of the regulatory system.

Good analysis is critical to inform stakeholders:

- Decision-makers
- Interested/Affected Parties (regulated entities and stakeholders)
- The Legislature
- The Public



Regulatory Transparency and Participation in the U.S.

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 respond to the public comments, make sure that the final regulation is a logical out-growth of the proposal and the administrative record, and is not arbitrary or capricious.

Federal Register

- The official daily publication for rules, proposed rules, and notices of Federal agencies and organizations
- Executive orders and other presidential documents are also published in the *Federal Register*.



Regulatory Transparency and Participation: Notice of Proposed Rulemaking (NPRM)

Preamble

- Legal authority for the regulation.
- A summary of the provisions in the regulatory proposal.
- A description of alternatives to the agency's proposal.
- Solicitation for public comments on the issues raised.
- Various legal and analytical assessments.

Regulatory Text

- Draft text that the agency proposes be codified in the Code of Federal Regulations (i.e., law).



Regulatory Transparency and Participation: Final Rule

Preamble

- Discussion of changes from the NPRM and why they were made.
- Responses to public comments on the NPRM.
- Various legal and analytical assessments.

Regulatory Text

- The text that will be codified in the Code of Federal Regulations (i.e., law).

Effective Date

- The APA requires at least 30 days from publication
- There are exceptions (including “good cause”).



Regulatory Transparency and Public Participation: Regulations.gov

The screenshot shows the homepage of Regulations.gov. At the top, the logo "regulations.gov" is displayed with the tagline "Your Voice in Federal Decision-Making". Navigation links for Home, Help, Resources, and Feedback and Questions are visible. A search bar and buttons for Browse and Learn are also present.

The main content area features a "Participate Today!" section with a call to action to submit comments on proposed regulations. Below this is a search bar with the text "SEARCH for: Rules, Comments, Adjudications or Supporting Documents:" and a "Search" button. To the right, there is a "Newly Redesigned Comment" section with an image of a laptop and a call to action to comment on a regulation today with the new form.

On the left side, there is a "What's Trending" section with a bar chart icon. It lists several trending items, including "Medicare Programs: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule and...", "Deepwater Port Licenses: Liberty Natural Gas, LLC, Port Ambrose Deepwater Port; Correction", "Oil and Gas: Hydraulic Fracturing on Federal and Indian Lands", "Endangered and Threatened Wildlife and Plants: Gray Wolf (Canis lupus), Mexican Wolf (Canis lupus bailey)", and "Endangered and Threatened Wildlife and Plants: Nonessential Experimental Population of the Mexican Wolf".

In the center, there is a "Comments Due Soon" section with a list of comments due today, next 3 days, next 7 days, next 15 days, next 30 days, and next 90 days. Below this is a "Newly Posted" section with a list of comments posted today, last 3 days, last 7 days, last 15 days, last 30 days, and last 90 days.

At the bottom, there is a navigation menu with links for Home, About Us, Resources, Help, and Connect With. The Connect With section includes social media icons for RSS, Facebook, Twitter, and YouTube, as well as a "Feedback and Questions" section with links for Privacy Notice, User Notice, and Accessibility Statement.

At the very bottom, there is a "Partner Sites" section with links to We the People, Federal Register, Reginfo, Thomas, USA.gov, E-Gov, and Opengov. A "Participate Today!" button is also visible in the bottom right corner.



References

2005 APEC-OECD Integrated Checklist on Regulatory Reform:
<http://www.oecd.org/regreform/34989455.pdf>

2012 Recommendation of the OECD Council on Regulatory Policy and Governance:
<http://www.oecd.org/gov/regulatory-policy/49990817.pdf>

Administrative Procedure Act: <http://www.archives.gov/federal-register/laws/administrative-procedure/>

Federal Register: www.FederalRegister.gov

Public Participation in the Regulatory Process: www.regulations.gov

