



THE BRIDGE TO COOPERATION: GOOD REGULATORY DESIGN



U.S. CHAMBER OF COMMERCE

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U.S. CHAMBER OF COMMERCE

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THE BRIDGE TO COOPERATION: GOOD REGULATORY DESIGN

Interest in regulatory cooperation has grown in recent years, given the benefits that it can confer on a wide range of stakeholders. In order for regulatory cooperation to be effective, however, it is important that the process undertaken to develop regulation be comprised of internationally recognized best practices.

This guide outlines those best practices and serves as an overview for governments and stakeholders alike to assess to what degree internationally recognized best practices are adopted to form a foundation for cross-border regulatory cooperation initiatives. The guide proceeds as follows:

Chapter 1 – Good Regulatory Practices and Regulatory Cooperation

Chapter 2 – The Benefits from Successful Regulatory Cooperation

Chapter 3 – Key Components of Good Regulatory Practices

Chapter 4 – The Role of a Central Coordinating Body

Checklist – The Bridge to Cooperation, Step-by-Step

It is our hope that, when combined with discussions among interested governments and stakeholders, this guide can serve to harness the promise of international regulatory cooperation – delivering benefits to regulators, consumers and businesses alike.

Sean Heather

Vice President, Center for Global Regulatory Cooperation
U.S. Chamber of Commerce

1. Good Regulatory Practices and Regulatory Cooperation

What are Good Regulatory Practices?

The term Good Regulatory Practices (also referred to as GRPs, good regulatory design and regulatory coherence) speaks to the quality and consistency of the domestic rulemaking process. It refers to the internal coordination and review process under which the whole of government works to ensure that rules and regulations are crafted in an open, transparent and participatory manner, and that outcomes are risk-based and grounded in the best available data.

A proper system of GRPs involves the consistent implementation of best practices across the government. By implementing GRPs, government agencies are better coordinated and better able to work together to achieve identified policy objectives, thereby avoiding overlapping and inconsistent rules.

“GRPs ensure that rules and regulations are crafted in an open, transparent and participatory manner, and that outcomes are risk-based and grounded in the best available data.”

Three things to remember about Good Regulatory Practices

1. GRPs aren't about more regulation or less regulation. They're about facilitating better regulatory outcomes.
2. Political processes make directional decisions, but GRPs create a professional process to rule-making that follows the political course set. They achieve this by adhering to a transparent and participatory rule-making process, and to evidence-based decision making.
3. GRPs are an important precursor to regulatory cooperation. Only quality regulatory outcomes avail themselves of regulatory cooperation opportunities.

What is Regulatory Cooperation?

Regulatory Cooperation is any interaction between regulators from different countries that results in some form of cooperation, with a view towards increasing efficiency, while achieving the desired regulatory outcome. There are many different forms of regulatory cooperation. Some examples include:

Harmonization: The process by which technical guidelines are developed to be uniform across participating authorities. Harmonization is often not practical, nor is it necessary for regulatory cooperation to be success. It also has limits as it doesn't eliminate duplicative compliance burdens.

Regulatory Convergence: When different countries each decide to modify their existing or proposed regulatory frameworks to bring them into closer alignment. This may occur over time, but the timing of rulemaking in respective countries is often independent of each other and difficult to synchronize.

Mutual Recognition/Substitute Compliance: Here the focus is on compliance. This requires regulators to identify common regulatory objectives, followed by assurance that respective regulatory frameworks achieve similar outcomes, resulting in regulatory compliance within one framework to be adequate for the other.

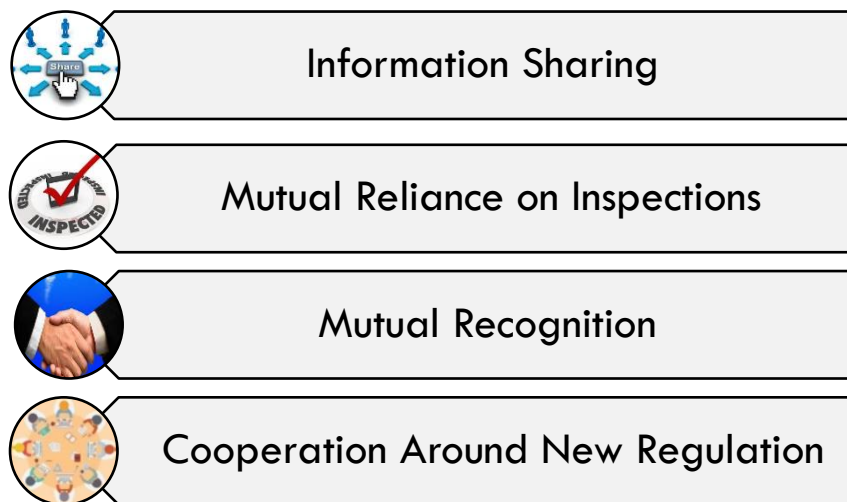


Image 1: Scaling Approaches to Regulatory Cooperation

All of these are fairly sophisticated levels of regulatory cooperation, but one should think of regulatory cooperation as a ladder of options that can occur during the design, monitoring, enforcement, or ex-post management of regulation (see *Image 1*).

In its most basic form, regulatory cooperation can be focused on information sharing, such as the filing of common paperwork by industry to regulators in multiple jurisdictions. It could also be more advanced, such as regulators' mutual reliance on the others' inspections.

Deeper cooperation comes in the form of accepting the regulatory determination of one jurisdiction in the other or through cooperation in the design of new regulation.

Regardless of the form that regulatory cooperation takes, regulatory cooperation efforts support greater regulatory compatibility. Regulatory compatibility is a somewhat generic term that suggests regulators have made efforts to reduce friction between regulations and compliance across -borders.

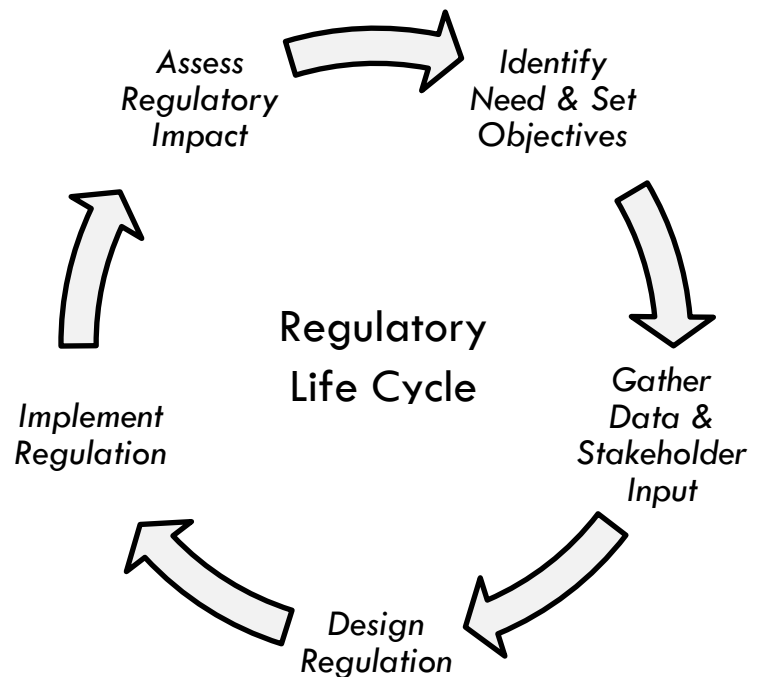


Image 2: Regulatory Life Cycle

Three things to remember about Regulatory Cooperation

1. Regulatory cooperation isn't about lowering or raising regulatory levels of protection. It is about working across countries to achieve the best regulatory outcomes in a trade facilitating manner.
2. There is a life cycle to regulation; regulatory cooperation is easier on the ex-ante side of the regulatory process rather than the ex-post side.
3. Regulatory cooperation is about trust. Without it, opportunities for cooperation between regulators are limited.

How are Good Regulatory Practices and Regulatory Cooperation connected?

It is very difficult for regulatory cooperation to be successful without the implementation of good regulatory practices. Good regulatory practices lead to good regulatory design and increase the probability of quality regulatory outcomes. The implementation of good regulatory practices alone is a significant step toward cooperation, since well-designed regulations produce outcomes that generate fewer cross-border challenges.

Regulatory cooperation is easier to achieve when working with quality regulatory outcomes from different jurisdictions. Those quality outcomes are often the result of adherence to good regulatory practices. In these instances, regulators can easily understand, trust and appreciate the quality of regulations. While good regulatory practices are important for regulatory cooperation, regulatory cooperation can also support the implementation of good regulatory practices. Any rule-making process is enhanced by information sharing; this extends to information sharing between regulators across borders. Deeper learning and approaches to problem solving gained through cooperation support better regulatory design.

In short, good regulatory practices are enhanced by regulatory cooperation, but without good regulatory practices, regulatory cooperation is often out of reach.

“The implementation of good regulatory practices alone is a significant step toward cooperation, since well-designed regulations produce outcomes that generate fewer cross-border challenges.”

2. The Benefits of Regulatory Cooperation

Benefits for Regulators

Regulators have important responsibilities and tough jobs. Markets, products and services move quickly and resources for regulators are strained. A good regulator cares about quality regulatory outcomes. Implementing GRPs and engaging in regulatory cooperation help to meet a regulator's needs through:

- ✓ Facilitating enhanced exchanges with an array of stakeholders to better understand a regulatory need and avoid unintended consequences.
- ✓ Implementing a process for analysis to determine regulatory options, maximizing benefits, minimizing costs and assessing impacts.
- ✓ Delivering quality regulations, which in turn lead to better compliance by industry, achieving the ultimate regulatory outcome.
- ✓ Enabling regulators to pool resources in support of streamlining regulatory approvals or to share responsibilities for conducting market surveillance.

Benefits for Consumers

Consumers expect regulators to help protect them. They also want the opportunity to make choices for themselves, however, as well as to have access to the latest products and services and at the lowest possible prices. For consumers, good regulatory practices and regulatory cooperation afford them:

- ✓ A higher degree of consumer confidence that regulations are providing the appropriate safeguards.
- ✓ Increased access to a wide choice of products and services at better prices.

Benefits for the Economy, Business & Foreign Direct Investment

In the absence of good regulatory practices and regulatory cooperation, manufacturers, service providers, retailers, SMEs and farmers face arbitrary, duplicative and oftentimes opaque regulatory processes that fail to take into account their views and experiences. Reducing these issues would lead to:

- ✓ Greater predictability with regard to regulatory frameworks and their enforcement.
- ✓ Sound regulatory outcomes that minimize compliance costs and inefficiencies.
- ✓ Regulation designed with sensitivities to global supply chains.
- ✓ A more prosperous business environment in which innovation thrives.
- ✓ A boost to the competitiveness of the economy.

Benefits for Trade

Despite the highly integrated nature of the global economy, regulatory frameworks are largely developed country-by-country. As such, products and services that cross borders face a growing array of regulations that can range from being opaque to duplicative to conflicting. Further, it has been estimated that while global tariffs are 5%, non-tariff barriers tied to regulatory frictions are equivalent to a 20% tariff¹. GRPs and regulatory cooperation can positively affect trade and investment by:

- ✓ Facilitating exports, especially for SMEs, who often don't have the scale to meet compliance challenges in foreign markets.
- ✓ Ensuring a transparent, predictable regulatory process that leads to quality outcomes, is foundational to the rule of law and fosters an attractive environment for foreign direct investment.
- ✓ Reducing regulatory trade frictions to allow more citizens and businesses access to new products, services and technology, leading to greater economic competitiveness and growth.

¹ Pascal Lamy – 'Looking Ahead: The New World of Trade', ECIPE, 9 March 2015

3. Key Components of Good Regulatory Practices

Since good regulatory practices are about creating and following a process for rule-making, it's imperative that the rule-making process incorporate controls to ensure accountability. Political decisions made by a government will limit the degree of freedom a regulator enjoys but, once the political objective has been set, good regulatory practices should guide the rule-making process.

1) Transparency & Stakeholder Involvement

It's important that the regulatory process be transparent and involve an array of stakeholders. In order to best achieve this, a rule-making process should include:

Regulatory Forecast: A central electronic publication, ideally updated every six months, of planned and ongoing regulatory activity. Such disclosure brings focus to the regulators, keeps stakeholders informed and previews upcoming considerations.

National Regulatory Register: A central electronic publication, issued with a regular frequency (weekly or monthly) that serves as a coordination mechanism, keeps stakeholders informed and solicits stakeholder input on active regulatory matters.

Opportunity for Public Comment: Following notification, ideally electronically through a national regulatory register, agencies should seek guidance prior to drafting regulation and publish draft rules for comment on a timetable that allows stakeholders to respond. Ideally this time period would be 60 days or more.

Publication of Evidence/Regulatory Analysis: It is not enough to simply publish a proposed rule online. It is also important to share with stakeholders the data that supports the draft rule, as well as the regulatory analysis that guided the regulator's initial determination.

Address and Respond to Stakeholder Input: Being transparent and seeking input includes a feedback loop. After a draft regulation has been published and before it is finalized, the regulatory process should require the regulator to evaluate the input it received and seek to modify the draft regulation accordingly. It is also important that, when a rule is finalized, a regulator communicates the reasoning behind changes that were made as a result of stakeholder input, as well as the rationale for changes that were not made. It's important for stakeholders to know that they were

heard and to enable them to better understand the thinking of the regulator. It is also important to guard against regulatory capture, which is the result of opaque influence on the regulatory process.

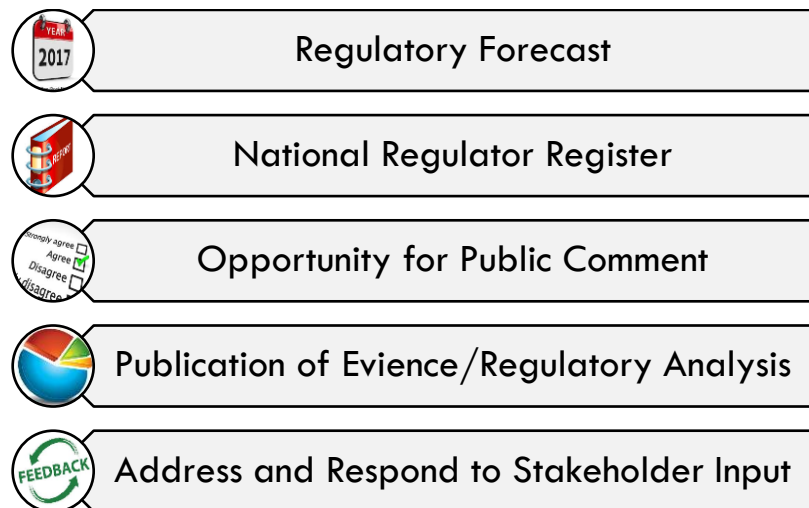


Image 3: Five Stages of Transparency & Stakeholder Involvement

2) Quality Data & Sound Science

A good rule-making process provides guidance to regulators on how to gather quality data and holds regulators accountable to using sound science to guide regulatory design. Bad input leads to bad outcomes. Gathering facts and using sound science leads to fact-based decision making and better regulatory results.

3) Risk Based Approach

Measuring risk and determining a path forward to manage risk in regulation is critically important. Calibrating the right approach to risk is critical as risk is inherent to everything. Efforts to eliminate all risk through regulation results in regulatory foreclosure, stifles innovation, and results in a drag on the economy. In contrast, no control for risk represents real dangers to achieving important regulatory outcomes. Good regulatory practices impose disciplines on the regulatory process to carefully consider risks involved and calibrate the appropriate regulatory approach.

4) Regulatory Impact Assessment (RIA)

Good regulations anticipate the impact a regulation will have on the market. They project the benefits, particularly economic benefits, that a given regulation will have on costs in the market. All regulations produce benefits and costs. Only the regulations where the benefits outweigh the costs should become law. Good regulatory practices guide regulators' efforts to better calculate costs and benefits by producing guidance and developing a common methodology used across regulatory agencies. The appendix to this publication includes a checklist developed for U.S. regulators to use when drafting and examining their RIAs.

5) Pro-Competitive Analysis

Often overlooked, a competition analysis is important to apply as part of regulatory design. Competition enforcement is typically thought of as being a discipline on private sector restraints that damage an economy. Government regulatory decisions routinely shape the economy, however, in ways that are often far more profound than any activity undertaken by a private actor. As a result, regulation can have an adverse impact on the market, picking winners and losers. It can prevent market entry and favor larger players over smaller ones. For this reason, looking at regulatory design through a competition lens as part of the regulatory process can be helpful in avoiding regulations that result in a stagnant economy.

“Looking at regulatory design through a competition lens...can be incredibly helpful in avoiding regulations that result in a stagnant economy.”

6) International Impact

Some products and services are largely dominated by imports and supply chains are sophisticated and global in nature. Accordingly, the regulatory process needs to recognize the degree to which a proposed regulation will have far-ranging impacts. Without question, products and services entering a country must comply with the regulatory requirements, but a regulator can ill-afford to develop regulation without considering an increasingly important international dimension, which needs to be built into regulatory design.

7) Role of Standards

Standards can play an important role in regulation. Standards are developed by public-private stakeholder groups to meet technical specifications and can be an effective tool that supports regulation when used by both regulators and industry. Governments are encouraged to maximize their use of private sector standards wherever possible as a basis for regulation, and to make normative reference to such standards in lieu of creating government-unique rules.

Governments can participate in standards development processes as a means for establishing rules for compliance that are promulgated faster, more cost effectively and with more quality than standards developed by governments alone. Such jointly-developed standards benefit from knowledge applicable to the latest technology and accordingly, are more applicable to the regulated product or service, while also increasing the effectivity and quality of the regulation. In the event a standard does not exist that meets a regulator's need, the best practice is for the regulator to ask industry to create the standard. Such an approach is highly effective as industry is motivated to respond, rather than have a standard imposed upon them.

“The WTO encourages governments to maximize their use of private sector standards and to make normative reference to such standards in lieu of creating government-unique rules.”

There is also an important link between the use of standards in regulation and trade commitments within the World Trade Organization (WTO), where there is a requirement that standards in regulation be not more trade restrictive than necessary to achieve legitimate regulatory objectives. The WTO encourages governments to maximize their use of internationally harmonized standards and to make normative reference to such standards in lieu of creating government- or region-unique rules, which can create technical barriers to trade. A reliance on standards developed by the private sector is not only a good regulatory practice, but also the best way to minimize unnecessary regulatory burdens, economic inefficiencies, the creation of technical barriers to exporters and non-compliance with international trade obligations. A good regulatory system places a premium on regulators looking to industry standards where possible.

8) Role of Conformity Assessment

In addition to standards, governments are encouraged to leverage private sector conformity assessment mechanisms as a means for enabling industry to demonstrate compliance with regulations and standards without resorting to the creation, maintenance and administration of government-only compliance regimes. Examples include third-party accreditation, testing, certification, inspection and supplier's self-declaration of conformity. The appropriate mechanisms depend on the level of risk of non-compliance, as determined by the regulator. Likewise, when a government seeks to develop a conformity assessment program, it should adhere to the same good regulatory practices as used in the development of regulations.

9) Ex-post Assessment

Good regulatory practices also extend to regulation that has gone into effect – sometimes referred to as a regulatory look-back. Regulations have life-cycles: challenges arise, regulations are drafted, regulations are imposed on the economy and those regulations have an impact. As time passes, new challenges arise and the regulatory process repeats. A cutting-edge regulatory process puts equal emphasis on ex-post evaluation of regulation and ex-ante regulatory design. This approach increases a regulator's understanding of how the regulated community responds to regulation, puts the regulator in a position to course correct its regulatory decisions and better informs future ex-ante impact assessments.

“A cutting-edge regulatory process puts equal emphasis on ex-post evaluation and ex-ante regulatory design. Doing so increases understanding of how the regulated community responds to regulation.”

10) Central Coordination

In order to ensure that the all good regulatory practices are well understood and followed across agencies, it is critical that a government have a central coordination and oversight body responsible for managing the regulatory process and ensuring adherence to best practices.

4. The Role of a Central Coordinating Body

Why should a government have a central coordinating body?

Putting in place regulatory practices that lead to good regulatory design is important, but ensuring they are implemented is often the larger challenge for governments. A central coordinating body which governs accountability and consistency in the regulatory process is increasingly seen as the most effective mechanism for implementing regulatory oversight and improving regulation.

“A central coordinating body...is increasingly seen as the most effective mechanism for implementing regulatory oversight and improving regulation.”

The benefits to a central coordinating body include:

Enhancing regulatory coordination

A central coordinating body provides regulators, which have focused missions, with an objective, cross-cutting perspective that enhances coordination between different ministries involved in the regulatory process. This helps to avoid the negative effects that arise under a fragmented administrative system.

Ensuring political accountability and regulatory credibility

A central coordinating body ensures that individual regulations support a government’s policy priorities, while maintaining the credibility of regulatory review through its independence and expertise. On the one hand, it can ensure proposed regulations serve a government’s policy goals by reviewing individual regulations and their RIAs, while also issuing agency guidelines based on privileged knowledge of the government’s agenda. On the other hand, when expert advice differs from a government’s priorities, the oversight body can explain the impacts and tradeoffs of political decisions over technical analysis to decision makers.

Improving regulatory consistency

A central coordinating body improves the quality of regulation by applying consistent and coherent quality control, as well as providing regulatory analysis, guidelines and support. It not only ensures the use of consistent and coherent criteria during the regulatory review process, but can also assist regulators in improving the quality of regulation by issuing guidance for sound analysis and consistent regulatory process.

Raising public awareness on regulation

A central coordinating body raises public awareness of regulatory quality and improvement. It is well positioned to engage in external communication, calling for stakeholder participation and aggregating diverse input to shape better regulation.

Facilitating international regulatory cooperation

With appropriate authority, a central coordinating body can facilitate and enhance international engagement by eliminating unnecessary regulatory divergences and barriers, while achieving the coordination of regulatory objectives across countries.

What should one consider when forming a central coordinating body?

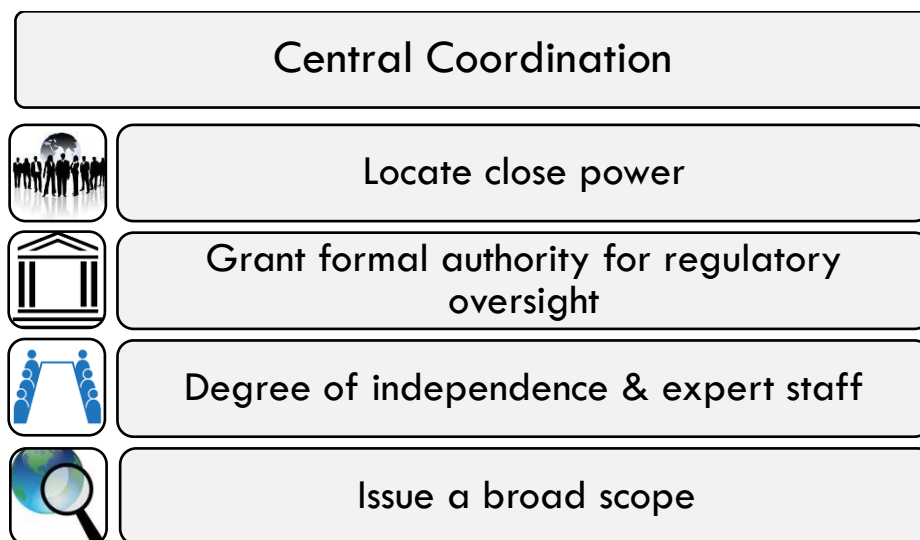


Image 4: Key factors to consider when forming a central coordinating body.

1) Location of a central coordinating body

A central coordinating body can be placed in an office of the President or Prime Minister, at a powerful ministry, or as an independent government watchdog office. Regardless of the location, a central oversight body exerts its authority most effectively and efficiently when it is located close to a locus of power in the government, with access to influential government decision makers.

Center of Government: Placing the central oversight body at the center of government is most common in OECD countries, including the Office of Information and Regulatory Affairs (OIRA) in the U.S., which is located in the Executive Office of the President. This oversight body is close to power (i.e. the President), which ensures political accountability and enables regulatory oversight to influence the decision-making process. It can also improve coordination across agencies, reduce redundancies, improve communication, and lead to more cohesive national policy priorities. Care must be taken, however, to avoid perceived or actual undue politicization of the process.

Ministry: Sometimes a central oversight body is placed in a ministry, usually clearly supported by the President or Prime Minister's Office, or directly linked to an economic or budgetary agency. This approach is typically used if the center of government lacks the institutional capacity and resources for regulatory oversight. Mexico's regulatory oversight body—COFEMER, under the Ministry of Economy—is an example of this approach.

2) Formal authority of regulatory oversight

Formal authority for a central coordinating body can come from legislation, executive order or other directives. Regardless of the vehicle, formal authority is most effective when it is well-defined and grants the review body real power to review and check regulation.

“Regardless of the vehicle, formal authority is most effective when it is well-defined and grants the review body real power to review and check regulation.”

Legislation: In the Czech Republic, the Republic of Korea and Mexico, legislation creates the formal authority for regulatory review. One clear benefit of including formal authority in legislation is that it institutionalizes regulatory review via law, making it less vulnerable to political cycles. Legislation authorizing regulatory review is most effective when the authority is both meaningful and clearly defined.

Executive Orders: In the U.S., centralized regulatory review has been established via executive orders, which are presidentially-issued documents that govern the executive branch. Executive Order 12866 has governed regulatory review in the U.S. since 1993 and established fundamental principles of regulation that are still in force today. Importantly, this order establishes OIRA as a gatekeeper on regulation by allowing OIRA to send back to agencies rules that do not meet high criteria for regulatory and analytical quality.

Five Key Things That E.O. 12866 Achieves

- ✓ Institutionalizes centralized regulatory review within the Office of Information and Regulatory Affairs (OIRA)
- ✓ Requires analysis of the benefits and costs of significant rules
- ✓ Requires agencies to consider alternative regulatory proposals
- ✓ Encourages agencies to involve the public in regulatory planning
- ✓ Establishes a governing regulatory philosophy and the principles of good regulatory practice by which agencies should operate

Other Directives: Regulatory review can also be established via a decree or guidelines from the Prime Minister (such as in Australia, Austria, France, Italy and the Netherlands), or via directive or resolution of the Cabinet or the government (such as in Canada, Denmark, Finland, Germany, Japan, and the UK).

3) Independence and expertise of staff

Staff expertise and political independence within a coordinating body ensure that regulatory review is a professionalized, rather than political, process.

Specialization: Staff may be economists or experts in specialized fields such as law, environmental science or social sciences, depending on the scope of regulatory oversight. In the U.S., for example, OIRA is equipped with roughly 45 professionals with backgrounds in economics, law, policy analysis, statistics and I.T. A number of them also specialize in public health, toxicology, epidemiology, engineering and other technical fields, enabling them to effectively review science-based regulation.

Independence: Expertise also helps to guarantee the objectivity and independence of regulatory oversight. In contrast, a staff lacking expertise may not be able to function as an intermediary between experts and political leaders. One means to help maintain independence is a permanent mandate: establishing formal review authority via legislation can make staff and regulatory review less vulnerable to political cycles.

4) Scope of oversight

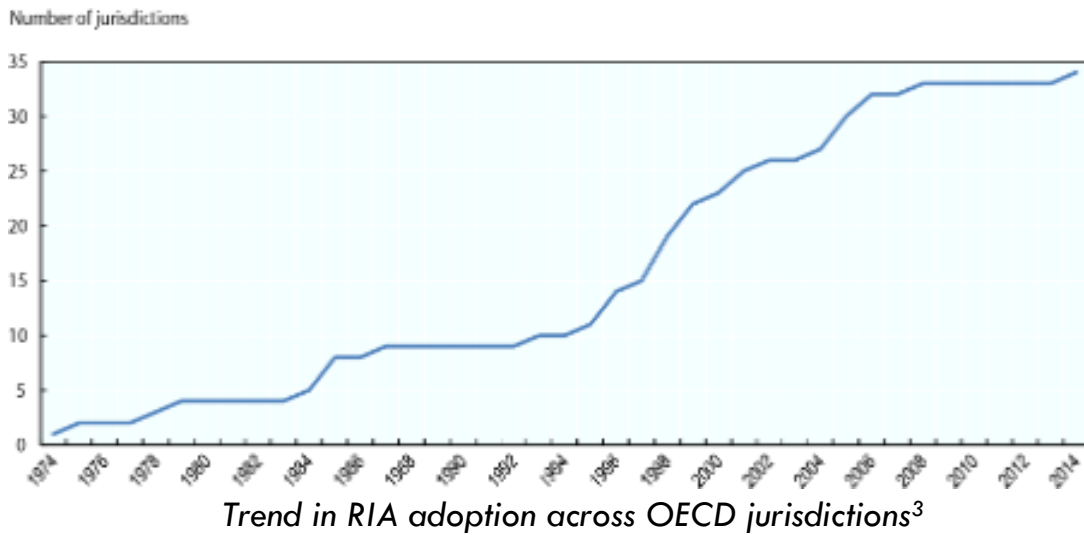
A central coordinating body can cover a diverse array of regulatory activities, which may include proposed legislation, proposed regulations, existing regulations and guidance documents. It may cover all activities or selected ones. The following attributes define part of the oversight scope.

Timing - ex-ante vs. ex-post: Review of regulation before it is finalized (ex-ante review) has been more common than review of existing regulation (ex-post review). Review at the proposal stage retains flexibility by incorporating feedback into a proposed regulation, which avoids the political costs of making changes at later stages. However, review of existing regulation can be beneficial as it can identify implementation problems and creates incentives for better rulemaking. From an administrative perspective, an ex-post review based on well monitored data and information can act as a check for an ex-ante analysis.

Type of legal action - legislation vs. regulation: In the U.S. and in many other countries, the scope of regulatory review is defined as regulations promulgated by federal regulatory agencies. In contrast, the European Union's regulatory oversight body—a recently established independent Regulatory Scrutiny Board²—reviews impact assessments for legislation proposed by the European Commission.

Reviews of both legislation and regulation have substantial benefits. Reviews of regulation directly improve the quality of regulation and helps achieve its objectives, while reviews of legislation improve the context to develop better future regulation. Typically, authority granted via legislation could lead to a broader review of future legislation, while authority granted by a presidential order usually results in a review of regulation within the executive branch.

² The EU's Regulatory Scrutiny Board replaced the former Impact Assessment Board which was established in 2006.



Threshold for review - all vs. selected: Ex-ante oversight of regulation can extend to all proposed regulations or only selected regulations, based on certain predefined criteria. There are examples of both options in the real world.

For example, France, Switzerland, and the Netherlands require RIA and oversight for all proposed regulations. In contrast, the U.S. only reviews “significant” regulations, which include about 400 proposed and final rules per year that are expected to have the greatest impact on society. Given the large amount of regulations issued annually in many countries, a specific threshold to define regulations subject to review is an effective way to guarantee credible regulatory oversight, given the frequently limited capacity and resources at the disposal of an oversight body.

³ 2014 OECD Regulatory Indicators Survey results, *Measuring Regulatory Performance*.
<http://www.oecd.org/gov/regulatory-policy/measuring-regulatory-performance.htm>

What are the key functions of a central coordinating body?

1) Establish good regulatory practices and principles of regulation

Central coordinating bodies should be responsible for establishing good regulatory practices and developing tools for regulators to improve regulation. The use of good regulatory practices is enhanced by providing regulatory agencies with guidelines on how to administer the regulatory process and conduct analysis.

In the U.S., memos known as “circulars” have been issued to provide regulators with guidelines on how to conduct regulatory impact assessments and how to discount future costs and benefits. These circulars, which incorporate best practices for regulatory analysis, are available to the public, which further enhances transparency in the rulemaking process and predictability for outside stakeholders.

Examples of U.S. Guidance

Circular A-119: Development and Use of Voluntary Consensus Standards

This guidance reinforces good regulatory practices and predictability by encouraging regulatory agencies to benefit from private industry standards rather than creating government-unique standards that do not rely on industry expertise. Pursuant to this circular, relying on private sector expertise and standards “remains the primary strategy for government engagement in standards development.”

Information Quality Act Guidance

This guidance to regulatory agencies strengthens transparency by providing policy and procedural direction for ensuring that the information and data disseminated by agencies meets standards for quality, objectivity, utility, and integrity.

2) Ensure forward looking planning of regulatory activity

Centralized coordinating bodies can increase regulatory transparency and accountability by pulling together regulatory plans and agendas from regulators from across the government – ensuring that outside stakeholders are aware of future regulatory actions. Making forward-looking regulatory agendas available to the public also informs international trading partners and enhances opportunities for international regulatory coordination. In the U.S., it's required by statute that agencies release two regulatory agendas per year, informing the general public which rulemakings are underway and which are planned in the next 12 months. In addition, as of 2008, regulatory agencies in the U.S. are instructed to highlight regulations in the regulatory agenda that are expected to have a significant impact on international trade and investment. This early notice system gives stakeholders ample opportunity to plan for regulatory developments and participate in the rulemaking process.

3) Review draft proposed and final regulatory measures before they are published

This review process helps to ensure that regulations are consistent with established principles and analytical requirements.

Regulatory Consistency: Regulatory review ensures individual regulations do not create inconsistencies with other regulations, programs of other agencies, or with an administration's policies and priorities. Review by a central coordinating body also ensures that regulations accomplish broad social objectives, rather than the objectives of a specific regulatory agency.

Regulatory Quality: Independent regulatory review safeguards the quality of regulations by ensuring that the analysis underpinning new rules is consistent with best practices and current guidelines. This quality check on regulatory analysis improves the quality of regulatory agencies' analyses and the resulting regulatory outcomes.

Regulatory Review by the Numbers

Review provides agencies with important feedback about the quality of their rules that leads to improved regulatory analysis and outcomes. For example, in the U.S., of the 319 final rules that were reviewed in 2016 over 90% underwent revisions as a result, and 6 final rules were withdrawn.

4) Coordinate international regulatory cooperation

Centralized review bodies are well-positioned to coordinate information about government-wide regulatory actions to stakeholders, including foreign stakeholders. Given their authorities and functions, centralized regulatory oversight bodies are able to develop and oversee work plans with other governments that address or prevent unnecessary differences in regulatory requirements in more than one jurisdiction. In the U.S., Executive Order 13609 grants the central coordinating body an important role in coordinating discussions regarding international regulatory cooperation across different regulatory agencies.

Checklist: The Bridge to Cooperation, Step by Step

Implementing Good Regulatory Practices

Transparency & Stakeholder Engagement

- Regulatory Forecast
- National Regulatory Register
- Opportunity for Public Comment
- Publication of Evidence / Regulatory Analysis
- Respond to Stakeholder Input

Other

- Use of Quality Data & Sound Science
- Risk-Based Approach
- Regulatory Impact Assessment (RIA)
- Pro-Competitive Analysis
- Assessment of International Impact
- Leverage Private Sector in the Development of Standards & Conformity Assessments
- Ex-Post Assessments of Regulatory Impacts

Central Regulatory Oversight Body

Structure

- Located Close to Important Government Decision Makers
- Given Formal Authority of Regulatory Oversight
- Staffed with Experts and Given Independence
- Given the Necessary Scope of Review to be Effective

Functions

- Establish and Foster Good Regulatory Practices and Principles of Regulation
- Ensure Forward Planning of Regulatory Activity
- Review Proposed and Final Regulatory Measures before they are Published
- Coordinate International Regulatory Cooperation

Appendix

Regulatory Impact Assessment Checklist for U.S. Regulators

1. Does the RIA include a reasonably detailed description of the need for the regulatory action?
2. Does the RIA include an explanation of how the regulatory action will meet that need?
3. Does the RIA use an appropriate baseline (i.e., best assessment of how the world would look in the absence of the proposed action)?
4. Is the information in the RIA based on the best reasonably obtainable scientific, technical, and economic information and is it presented in an accurate, clear, complete, and unbiased manner?
5. Are the data, sources, and methods used in the RIA provided to the public on the Internet so that a qualified person can reproduce the analysis?
6. To the extent feasible, does the RIA quantify and monetize the anticipated benefits from the regulatory action?
7. To the extent feasible, does the RIA quantify and monetize the anticipated costs?
8. Does the RIA explain and support a reasoned determination that the benefits of the intended regulation justify its costs (recognizing that some benefits and costs are difficult to quantify)?
9. Does the RIA assess the potentially effective and reasonably feasible alternatives?
 - Does the RIA assess the benefits and costs of different regulatory provisions separately if the rule includes a number of distinct provisions?
 - Does the RIA assess at least one alternative that is less stringent and at least one alternative that is more stringent?
 - Does the RIA consider setting different requirements for large and small firms?
10. Does the preferred option have the highest net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires a different approach?
11. Does the RIA include an explanation of why the planned regulatory action is preferable to the identified potential alternatives?
12. Does the RIA use appropriate discount rates for benefits and costs that are expected to occur in the future?
13. Does the RIA include, if and where relevant, an appropriate uncertainty analysis?
14. Does the RIA include, if and where relevant, a separate description of distributive impacts and equity?
 - Does the RIA provide a description/accounting of transfer payments?
 - Does the RIA analyze relevant effects on disadvantaged or vulnerable populations (e.g., disabled or poor)?
15. Does the analysis include a clear, plain-language executive summary, including an accounting statement that summarizes the benefit and cost estimates for the regulatory action under consideration, including the qualitative and non-monetized benefits and costs?
16. Does the analysis include a clear and transparent table presenting (to the extent feasible) anticipated benefits and costs (quantitative and qualitative)?

Appendix

EU Materials

EU Impact Assessment Guidelines

http://ec.europa.eu/smart-regulation/guidelines/ug_chap3_en.htm

EU Commission – Secretary General – Better Regulation

http://ec.europa.eu/info/law/law-making-process/better-regulation-why-and-how_en

Regulatory Scrutiny Board

http://ec.europa.eu/info/files/regulatory-scrutiny-board-rules-procedure_en

Transparency, Public Consultation Practices and Government Accountability in U.S. Rulemaking (authored by U.S. government official)

[http://www.europarl.europa.eu/RegData/etudes/IDAN/2015/536482/IPOL_IDA\(2015\)536482_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/IDAN/2015/536482/IPOL_IDA(2015)536482_EN.pdf)

International Materials

APEC – OECD *Integrated Checklist on Regulatory Reform*

<https://www.oecd.org/regreform/34989455.pdf>

OECD 2012 *Recommendation of the Council on Regulatory Policy and Governance*

<http://www.oecd.org/governance/regulatory-policy/2012-recommendation.htm>

OECD *Best Practices Principles for Governance of Regulators*

http://www.oecd-ilibrary.org/governance/the-governance-of-regulators_9789264209015-en

OECD *Regulatory Cooperation*

<http://www.oecd.org/gov/regulatory-policy/irc.htm>

WTO Agreement on Technical Barriers to Trade

https://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

U.S. Materials

Circular A-4

<https://www.federalregister.gov/documents/2003/10/09/03-25606/circular-a-4-regulatory-analysis>

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<https://www.federalregister.gov/documents/2016/01/27/2016-01606/revision-of-omb-circular-no-a-119-federal-participation-in-the-development-and-use-of-voluntary>

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https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

EO 13609

<https://www.gpo.gov/fdsys/pkg/FR-2012-05-04/pdf/2012-10968.pdf>

OIRA Website

<https://www.reginfo.gov/public/>

Unified Agenda

https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.jsp

https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.jsp



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