

New Ideas for Risk Based Regulation and Regulatory Governance in Mexico

A joint OECD / Mexico workshop

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Regulatory Policy Division, Directorate for Governance and Territorial Development, OECD Secretariat

Federal Commission for Protection against Health Hazards, Mexico

Vice-Ministry for Competitiveness and Business Regulation, Ministry of Economy, Mexico

Federal Regulatory Improvement Commission

The purpose of the workshop was to explore and develop ways of improving how risk-based regulations are designed and delivered in Mexico.

Risk-based regulation forms part of a responsive policy process that includes risk assessment, risk management and risk communication. Risk assessment is a key analytical tool to identify and assess the extent of a likely hazard and to estimate the probability and consequences of negative outcomes for humans, property or the environment. Risk management refers to the design and implementation of actions and remedies to address risks through a consideration of potential treatments and the selection of the most appropriate course, or combination of courses, of action. Risk communication is fundamental to the entire risk policy cycle, and assists in identifying the nature and extent of the risks as well as educating and informing the public about risks when making risk tradeoffs. Improving public understanding of the nature of the risks and the risk management measures can increase the public acceptance of the risk elements that cannot be reduced through further management.

The workshop examined the application of risk based regulation in the Mexican context. The term “risk based regulation” has been used in a number of OECD countries in at least two contexts: promoting better regulatory design and securing better regulatory compliance and enforcement. The first application concerns the design of regulations based on a rational scientific assessment of the consequences of the risk to society that the regulation is intended to avert. The second application of the term applies to the practice of using evidence based approaches to target enforcement and inspection resources based on a transparent assessment of the risks posed by the regulated entity to the public value objectives of the regulator. Both of these approaches were assessed during the workshop.

General questions for discussion included:

- What are the consistent features of good regulatory design, based on risk-based approaches, which can be applied across various kinds of regulatory frameworks?
- What is the appropriate scope for guidance on risk methodologies and who should be responsible for developing this guidance?
- How can governments ensure that regulators incorporate the features of systemic risk into their risk models?
- What is the nature of the relationship between the political sphere and the technical role of the regulator? How is this taken into account in the decision making processes of the regulatory agency? How does it affect policy development?

- How can sectoral regulatory and officials with regulatory oversight responsibilities co-operate to improve ex-ante procedures and ex-post evaluation?
- How can regulators demonstrate the links between good regulatory performance and beneficial social outcomes?

Programme

Welcome and Overview

Hector Nava, Head of the National Centre for Metrology

Alfonso Carballo, Head of the Federal Commission of Regulatory Improvement (COFEMER)

Josef Konvitz, Head of the Regulatory Policy Division, OECD Secretariat

Mikel Arriola, Head of the Federal Commission for the Protection of Health Hazards (COFEPRIS)

Session 1 – Risk based regulation and better regulatory design

Better integration of science, economics, and decision-making has long been a central concern in regulation. In recent years, a number of organisations including the OECD have made recommendations for changing how these issues are addressed by regulatory agencies. These recommendations, as well as other proposals and newer ideas for fundamental change, have significant implications for how environmental and numerous other risks are assessed and regulated. This session will discuss how to imbed risk assessment practices into policy-making and regulation in Mexico.

Speakers

[George Gray](#), Director of the Centre for Risk Science and Public Health, George Washington University, United States of America (*in English*)

[Julio Rocha](#), General Coordinator for Regulatory Reform of Economic Sectors, COFEMER, Mexico (*in Spanish*)

[Nancy Beck](#), Office for Information and Regulatory Affairs (OIRA), Office of Management and Budget, United States of America (*in English*)

[Christian Turegano](#), General Director of Technical Regulation, Ministry of Economy, Mexico (*in Spanish*)

Moderator: Manuel Gerardo Flores, Senior Economist, Regulatory Policy Division, OECD Secretariat

Questions

- What are the key features of a risk based approach to regulatory design?
- What are the institutional capacities needed to embed risks based approaches in COFEPRIS and other regulatory agencies in Mexico?
- What are the practical lessons that Mexico can garner from other OECD countries in the design of risk-based regulatory frameworks?

Session 2 – Risk based approaches to regulatory enforcement and compliance

Risk based approaches are central to regulatory enforcement and compliance in a number of OECD countries. Regulators use a number of methods to target enforcement and inspection resources based on an assessment of the risks posed by the regulated entity of non-compliance.

Such a risk based regulatory approach can have at least three benefits:

1. it contributes to regulatory efficiency by targeting the approaches of the regulator to allocate resources where risk is greatest;
2. it can systematically improve decision making processes by providing new evidence and insights into potential risk, and;
3. it can assist in providing defensible rationale for decision making, that can withstand external challenge from adversely affected parties, the courts, or potentially civil society.

Developing a methodology for the governance of risk, the case of COFEPRIS

[Patricio Caso Prado](#), Legal and Consultative General Coordinator, COFEPRIS, Mexico (*in Spanish*)

[Julio Sanchez y Tepoz](#), Chief of Staff of the Head of COFEPRIS, Mexico (*in Spanish*)

Discussants:

Professor George Gray, George Washington University, United States of America

Nancy Beck, Office for Information and Regulatory Affairs, Office of Management and Budget, United States of America

Moderator and Speaker: Nick Malyshev, Deputy Head, Regulatory Policy Division, OECD Secretariat

Questions:

- What are the respective roles of the Department of Health and COFEPRIS in implementing risk policy?
- How does COFEPRIS undertake risk management, particularly in relation to compliance and enforcement strategies?
- To what extent is COFEPRIS sufficiently reflexive to assess the success of risk based approaches?
- What key performance indicators can be applied to assess the conduct of COFEPRIS?
- How can the COFEPRIS (and other Mexican regulatory agencies) develop a program for the evaluation of regulatory performance?

Session 3- Regulatory Policy and Governance

The advent of a new OECD Recommendation on Regulatory Policy and Governance provides an opportunity to reconsider the regulatory development process in Mexico. This session will focus on the Ministry of Economy's role in prompting and reviewing domestic regulations as well as its requirements for regulatory analysis and evaluation. This panel will also explore the successes and failures of U.S. regulatory reform efforts, highlight opportunities to learn from each other's policy innovations, and examine options for increasing international cooperation.

Speakers

[Josef Konvitz](#), OECD Secretariat, “The draft OECD Recommendation on Regulatory Policy and Governance and its relevance to regulatory development in Mexico” (*in English*)

[Alfonso Carballo](#), COFEMER, Mexico, “Prompting and reviewing domestic regulations in Mexico” (*in Spanish*)

[Nancy Beck](#), Office for Information and Regulatory Affairs, Office of Management and Budget, United States of America, “International co-operation in evaluating and improving the quality of domestic policies and regulations” (*in English*)

Moderator: Rocío Alatorre Eden-Wynter, Commissioner for Evidence and Management of Risks, COFEPRIS, Mexico

Questions:

- How can the OECD Recommendation on Regulatory Policy and Governance be adapted to improve the work of regulators in Mexico?

Session 4 – Concluding Roundtable: The Future of Risked Based Approaches to Regulation in Mexico

This concluding session will invite government agency officials from Mexico and OECD countries, the OECD Secretariat and leading scholars to reflect on the results of the workshop, discuss the implications of the presentations, and identify the key issues to be addressed in the future.

Speakers (8 minutes each):

Jose Antonio Torre, Vice Minister of Competitiveness and Business Regulation, Ministry of Economy, Mexico

Alfonso Carballo, Head of COFEMER, Mexico

Mikel Arriola, Head of COFEPRIS, Mexico

Professor George Gray, George Washington University, United States of America

Nancy Beck, Office for Information and Regulatory Affairs, Office of Management and Budget, United States of America

Moderator and Speaker: Josef Konvitz, OECD Secretariat