



# VENABLE

## Regulatory Coherence in Mexico

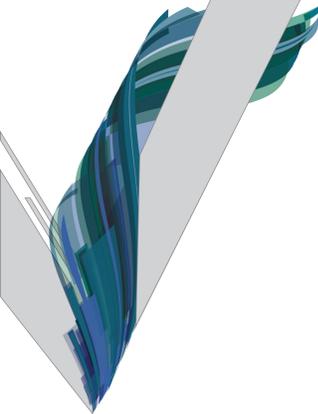
September 2018

By Jeffrey G. Weiss, Esq.

Partner, Venable LLP

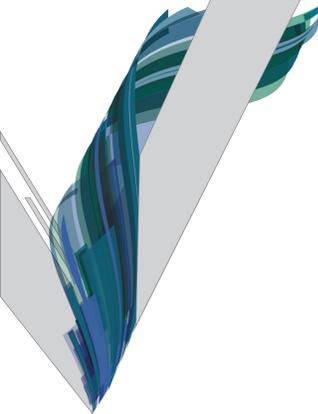
[JWeiss@Venable.com](mailto:JWeiss@Venable.com)

+1.202.344.4377



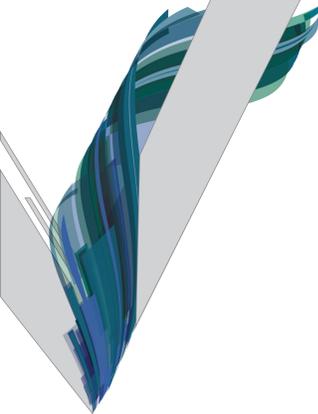
# Agenda

- Overview of the AdvaMed Standards Alliance Project
- Overview of Regulatory Coherence
- Central Coordination in Mexico
- Implementation of Good Regulatory Practices in Mexico
  - Regulatory Forecasting
  - National Regulatory Register
  - Public Comment Process
  - Regulatory Analysis
  - Entry into Force
  - Ex Post Assessment
  - Life Cycle of a Regulation
  - Standards
  - International Regulatory Cooperation
- New Developments: General Law on Regulatory Improvement
- Closing Thoughts



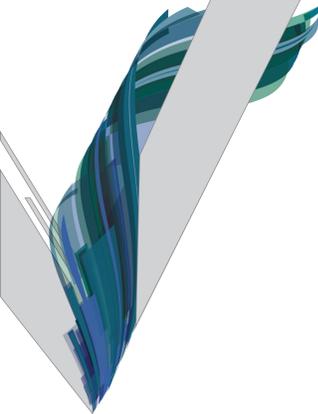
# Project Overview

- Regulatory Coherence in the Americas
- AdvaMed, in cooperation with ANSI, under USAID grant
- Promote regulatory coherence and provide capacity building to certain developing countries in Latin and South America
- Five country study: Colombia, Costa Rica, Mexico, Peru, USA
  - Tier 1: Regulatory Coherence Initiative
  - Tier 2: Medical Device Sector



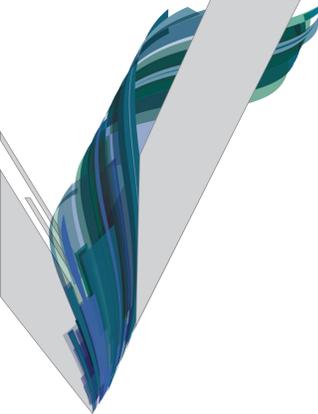
# Project Overview (continued)

- Tier 1: Regulatory Coherence Initiative
  - Phase 1: Develop Regulatory Coherence Implementation Guide
    - The Bridge to Cooperation: Good Regulatory Design (U.S. Chamber)
  - Phase 2: Regulatory Coherence Assessment and Gap Analysis
    - Elements of five-country study under Tier 1, Phase 2:
      - Examination of key legal instruments
      - Factual analysis of each regulatory system using the U.S. Chamber document as a guide
      - Step-by-step flow charts to track the life cycle of a typical regulation
      - Validation of findings through discussions with government officials
      - Presentation of findings



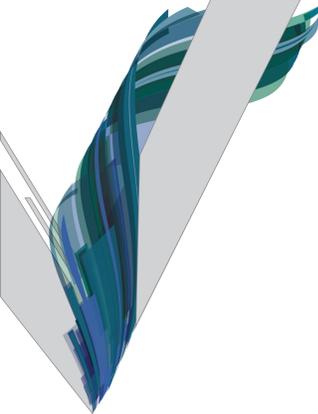
# Overview of Regulatory Coherence

- What do we mean by Regulatory Coherence?
  - Central Coordination
  - Good Regulatory Practices
- Why is Regulatory Coherence important?
  - Better regulatory outcomes
  - Enhance legitimacy and predictability
  - Avoid creating unnecessary obstacles to trade and unnecessary regulatory differences



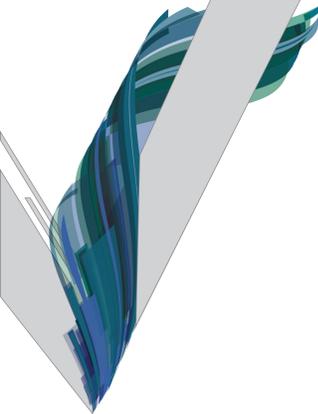
## Central Coordination in Mexico

- The National Commission for Regulatory Improvement (CONAMER) is the central coordinating body for regulation
- CONAMER, which is part of Economía, has the authority to:
  - review the national regulatory framework, draft regulatory measures, and the performance of regulations through the ex-post Regulatory Impact Assessment (RIA) process; and
  - make proposals to the President regarding improvements to the national regulatory framework



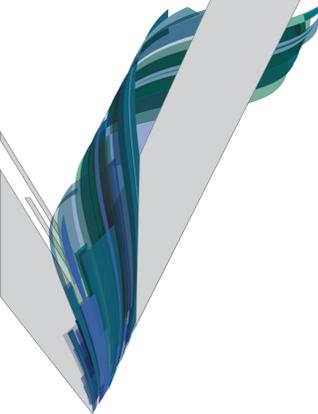
## Central Coordination in Mexico (continued)

- CONAMER's main role is to review draft regulatory measures (i.e., (i) general administrative acts and (ii) NOMs) and to promote interagency coordination and transparency in regulatory development
- CONAMER has authority to review all draft regulations from all Mexican federal agencies – irrespective of the level of economic impact – with certain exceptions
- CONAMER reviews and opines on draft regulations by assessing the measures themselves as well as regulatory impact assessments required from agencies proposing the measures
- CONAMER's non-binding opinion is not required to publish a draft regulatory measure for comment on SYRIA, but it is required before the agency can publish a final measure in the Diario Oficial de la Federación (DOF)



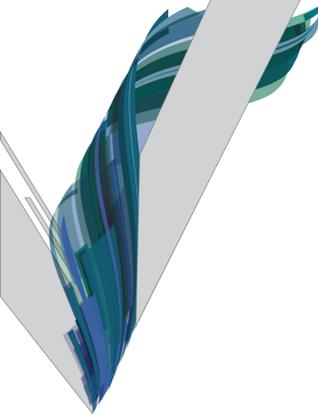
## Central Coordination in Mexico (continued)

- At a systemic level, CONAMER:
  - reviews existing regulatory measures with the objective of reducing the number of regulations and/or simplifying regulations;
  - develops draft laws and administrative programs to improve regulatory measures in specific economic sectors or activities;
  - promotes and encourages federal agencies to adopt best regulatory practices, such as use of RIAs; and
  - promotes regulatory improvement at the state and local level through collaboration agreements
- In the case of NOMs, Mexican law also incorporates some best regulatory practices for their preparation:
  - Representativity
  - Consensus
  - Transparency
  - Rationality
  - Review



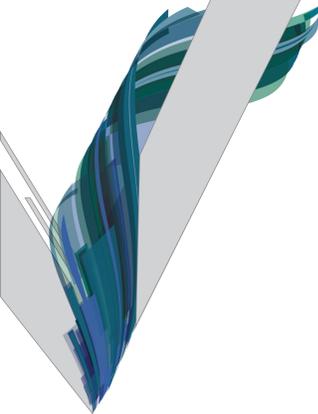
## Central Coordination in Mexico (continued)

- CONAMER must submit to the Congress an annual report that includes all regulatory measures it has reviewed during the past year.
- Under Mexican law, federal agencies should submit to CONAMER, at least every two years, a program for improving how they regulate, as well as reports on their progress.



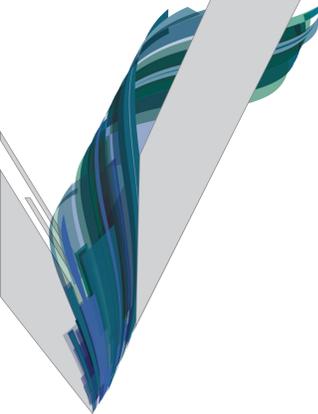
# Regulatory Forecasting

- Mexico does not maintain a regulatory forecast for measures of general applicability
- However, the General Directorate of Standards (DGN), which is part of Economía, manages the National Standardization Program (PNN)
  - The PNN lays out an annual plan for NOMs and NMXs (voluntary standards)
  - The information contained in the PNN is provided by regulatory agencies, national standardization bodies, and national standardization committees



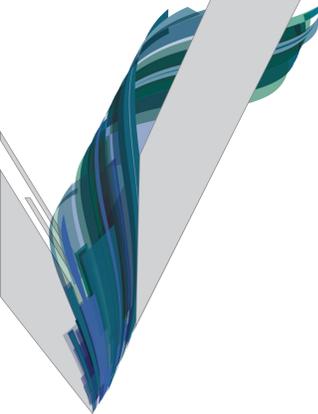
# National Regulatory Register

- All draft regulatory measures (including draft NOMs) are published online. The Mexican online system is called SYRIA:
  - Through SYRIA, Mexico publishes and informs all interested parties of the opportunity to comment on draft regulatory measures. The information provided on SYRIA includes:
    - 1) the draft regulatory measure;
    - 2) the corresponding RIA;
    - 3) public comments; and
    - 4) the opinions issued by CONAMER.
- In addition, draft and final NOMs, draft and final conformity assessment procedures (CAPs), as well as replies to public comments on such measures, are published in the NOMs Catalogue, and all draft and final NMXs are compiled online.
- All final regulatory measures are published in the DOF.



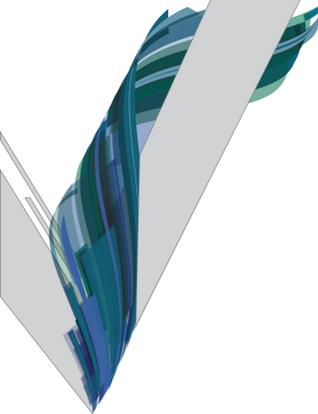
# Public Comment Process

- All draft regulatory measures and their corresponding regulatory impact assessments (“RIAs”) submitted to CONAMER are published on SYRIA and are later published in the DOF when finalized
  - Mexican law does not specify the duration of the comment period
  - However, CONAMER is required to consider comments submitted by interested parties through SYRIA when opining on a draft regulatory measure
  - The regulator must also demonstrate to CONAMER that it considered the comments and made changes to the measure as a consequence, and agencies are required to respond to comments submitted by interested parties
  - CONAMER publishes all comments on SYRIA, unless the commenter requests that its comments not be made public
  - CONAMER must consider all comments before finalizing its opinion on a draft regulatory measure



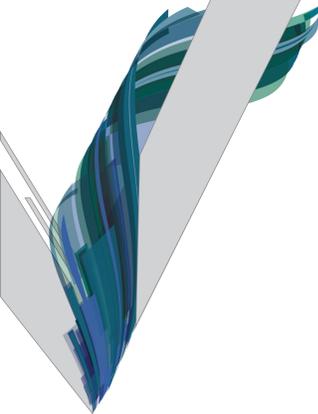
## Public Comment Process (continued)

- NOMs are developed by national standardization consulting committees (“CCNN”) in which private sector entities participate
- Mexican law and regulation require agencies to provide a minimum of 60 calendar days for public comments on draft NOMs
- At the end of the comment period, the CCNN that oversees the process of developing the draft NOM must consider and respond to the comments received, including explaining why certain comments were not taken into account in the final NOM
- All draft NOMs are also notified to the WTO by Mexico’s National Contact Point



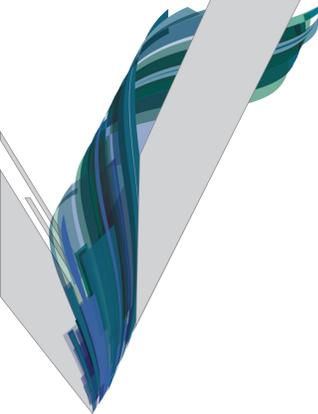
# Regulatory Analysis in Mexico

- Mexican law requires agencies to submit all draft regulatory measures to CONAMER and to attach a corresponding RIA where the measure would impose compliance costs on citizens
- CONAMER's RIA Manual lists the different types of RIAs that may be required to be submitted with the draft regulatory measure and the content that each RIA must include, depending on the level of anticipated impact that the draft measure will have
  - Interested parties may submit comments related to the draft regulatory measure and/or its corresponding RIA
  - If the RIA does not satisfy CONAMER, CONAMER may request corrections from the agency before issuing a final opinion on the draft regulatory measure
  - A final opinion is required before the final regulatory measure is published in the DOF



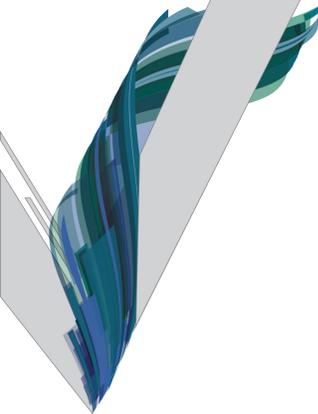
## Regulatory Analysis in Mexico (continued)

- To determine the types of RIA analysis that an agency must prepare and submit to CONAMER, agencies are required to use four primary tools:
  - Regulatory Impact Calculator
  - Competition Impact Checklist
  - Risk Impact Checklist
  - Foreign Trade Impact Checklist



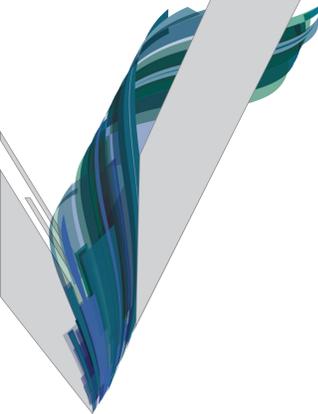
## Regulatory Analysis in Mexico (continued)

- The regulator may need to perform one, two, three, or all four of these analyses in an RIA
- As a result, there are numerous potential types of RIAs that an agency may need to complete and submit to CONAMER
- A regulator may be required to prepare two other types of RIAs:
  - a periodic updating RIA
  - an emergency RIA
- Mexican law also requires that an RIA be submitted with a draft NOM



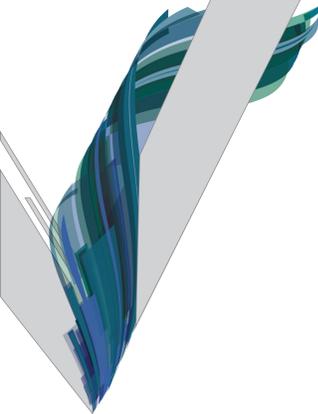
## Regulatory Analysis in Mexico (continued)

- Science Policy
  - The RIA Manual requires that a risk analysis be undertaken when the high-impact RIA form is used for a draft regulation
  - The Manual also encourages agencies to, whenever possible, include the empirical (statistical or scientific) information backing their assertions, as well as sources



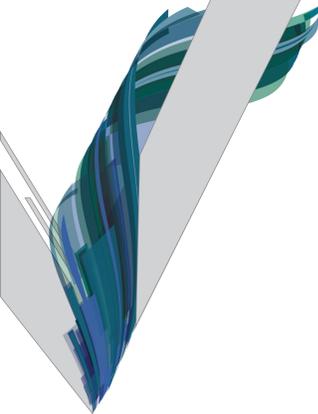
# Regulatory Analysis in Mexico (continued)

- Competition Analysis
  - Coordination between CONAMER and the Federal Commission for Economic Competition (“COFECE”) is governed by their Collaboration Agreement
    - COFECE will issue opinions regarding provisions of draft regulatory measures that could affect competition and free operation of markets
    - COFECE may also require a competition analysis in instances in which COFECE determines that a draft regulation will impact competition but the calculator did not detect it
- Analysis of International Impacts
  - In addition to the Foreign Trade Impact Analysis the regulator must complete when certain conditions are met, a draft regulation can only be issued if it complies with Mexico’s international obligations, pursuant to the Regulatory Quality Agreement (ACR)



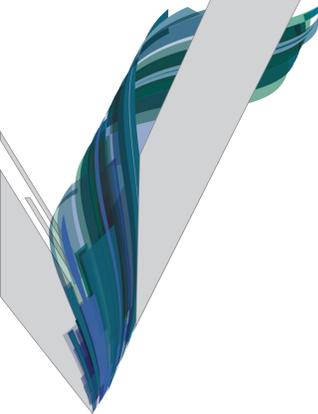
## Regulatory Analysis in Mexico (continued)

- Before issuing its opinion, CONAMER analyzes the draft regulation and its RIA to determine whether the draft regulation complies with the Regulatory Quality Agreement (ACR)
  - The ACR requires that the draft regulation be issued only under the following conditions:
    - the regulator has complied with its legal obligations;
    - the draft regulation complies with Mexico’s international obligations; and
    - the draft regulation’s competition and market efficiency benefits exceed its costs.



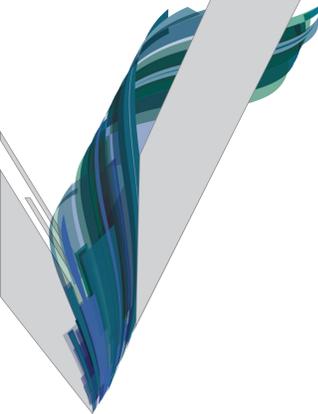
# Use of Standards in Regulation

- Under Mexican law, Mexico has long relied on standards developed by certain bodies – e.g., ISO, IEC, and Codex – but not others
  - Recent trade agreements (i.e., Pacific Alliance and CPTPP) contain a provision that defines “international standard” as a standard that fulfills the TBT Committee’s six principles, so the definition of international standard in Mexico is potentially wider now
- Two potential entry points for standards into the Mexican regulatory system:
  - When developing a draft measure, DGN (in the case of NOMs) and other regulators consider the use of international standards, as well as NMXs
  - Stakeholders can participate in the process through which Mexican national standards bodies develop NMXs
    - DGN has recognized 10 bodies in Mexico to develop NMXs, and each has a specific scope that it is not permitted to exceed (at least in theory). For example, ANCE is the national standards body for the electrical sector.



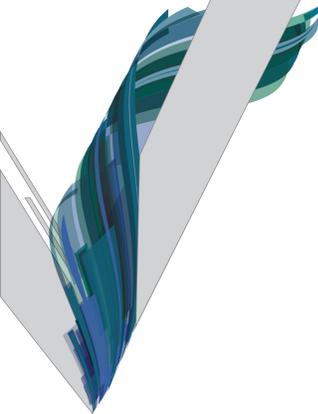
# Entry into Force

- Reasonable Period of Time
  - Mexican law establishes that a general administrative act enters into force on the date it is published in the DOF, unless the regulator decides otherwise
  - NOMs, on the other hand, do not enter into force for at least 60 days after they have been published in the DOF
    - In some instances, international agreements require that a NOM normally enter into force no sooner than 6 months after publication



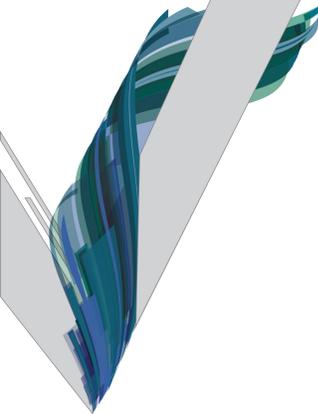
## Ex-Post Assessment in Mexico

- CONAMER created an ex post RIA procedure for agencies to evaluate whether a regulation has met its objectives after it has been in force for a certain time
  - Ex post evaluation for general administrative acts is voluntary
- However, Mexican law requires that NOMs are reviewed every 5 years when they were analyzed with a high-impact RIA



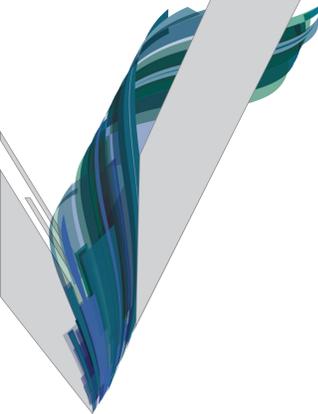
# Life Cycle of a Regulation in Mexico

- Sources of authority to regulate: regulation is required by law or promulgated under an agency's general authority
- STEP 1: Development of a Draft Regulation
  - To develop the draft regulation, the regulator creates a working group that may include interested stakeholders
  - The regulator is required to prepare an RIA for any draft regulation that would add costs for citizens
  - To determine whether a draft regulation adds a cost to the citizen, CONAMER examines four areas of the draft regulation:
    - Does the draft regulation create new or stricter obligations for citizens?
    - Does the draft regulation add to or modify an administrative burden?
    - Does the draft regulation reduce or restrict citizens' rights?
    - Could the draft regulation affect citizens' rights or obligations or impose administrative burdens in the future?
  - Assuming that the regulator must complete an RIA, it must determine which type of RIA to conduct, using the Regulatory Impact Calculator
    - When regulator submits its responses, the system indicates if the draft measure needs to be notified to the WTO and alerts DGN and Economia



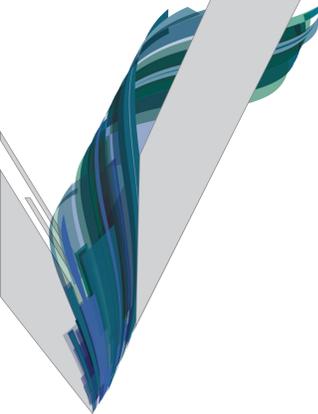
## Life Cycle of a Regulation (continued)

- STEP 2: Draft Regulation is Subject to Public Comment
  - The regulator must submit the draft regulation and its corresponding RIA to CONAMER at least 30 business days before the draft regulation is expected to enter into force
  - Unless the regulator received an exemption from CONAMER (i.e., the draft regulation does not add costs), CONAMER publishes the draft regulation and its corresponding RIA for public comment on SYRIA
  - The SYRIA website includes, for each draft regulation:
    - the text of the draft regulation;
    - the draft regulation's RIA;
    - the public comments; and
    - opinions issued by CONAMER
  - The regulator considers the comments



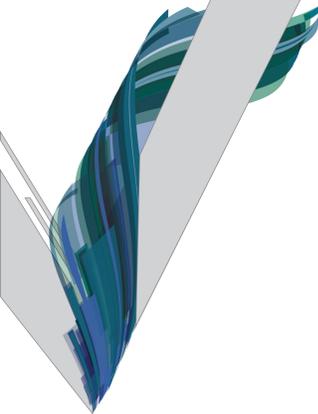
## Life Cycle of a Regulation (continued)

- **STEP 3: CONAMER Analyzes the Draft Regulation**
  - CONAMER analyzes the revised regulation, its corresponding RIA, and the regulator’s consideration of the public comments, and determines whether the draft regulation complies with the ACR
  - As part of its review, CONAMER reviews the cost-benefit analysis, the regulator’s use of standards, its consideration of alternatives, and other factors
  - CONAMER must provide one of the following opinions based on its review:
    - Approve the regulation, which means that the regulation can be published in the DOF; or
    - Request additional information from the regulator that justifies the draft regulation



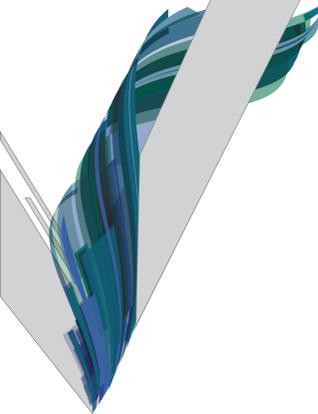
## Life Cycle of a Regulation (continued)

- STEP 4: Regulator Publishes the Regulation in the Official Gazette
  - Once CONAMER issues a final opinion, the regulator finalizes the regulation, publishes it in the DOF and, if it's not a technical regulation, it enters into force
    - RIA and correspondence between CONAMER and the regulator are made public on SYRIA
  - If the regulation is a technical regulation, DGN notifies it to the WTO for a 60-day comment period
    - The regulator is required to take the comments into account
    - If the regulator substantially revises the regulation, it is obliged to send it back to CONAMER to repeat Step 3, but this does not always occur
    - The regulator publishes the final regulation in the DOF, normally with an effective date of not less than six months from publication



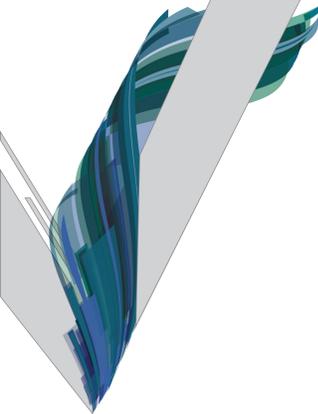
# International Regulatory Cooperation

- Responsibilities are divided as follows:
  - CONAMER leads on “horizontal” regulatory cooperation
  - DGN participates in specific or sectoral regulatory cooperation activities when NOMs are involved
  - The Undersecretariat of Foreign Trade of Economía negotiates Chapters on Regulatory Cooperation as part of FTA negotiations



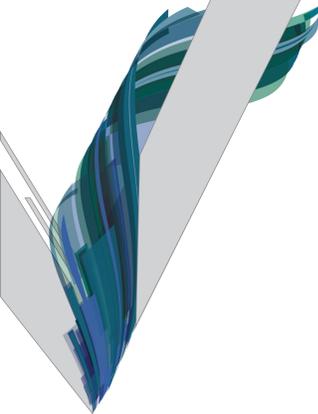
# New development: General Law on Regulatory Improvement

- On May 18, the General Law was promulgated and published in the Official Gazette.
  - The power of central coordination was extended throughout the entire territory of Mexico, creating arguably the most powerful central coordinating authority for regulation in the world
  - COFEMER became CONAMER, a national regulatory improvement commission with the authority to review regulatory measures developed at the federal level and perform a number of coordination activities with respect to state and municipal regulatory activities
  - As part of the new architecture, the General Law will require each state and municipality to create a central coordinating authority on regulatory improvement headed by a high-level official



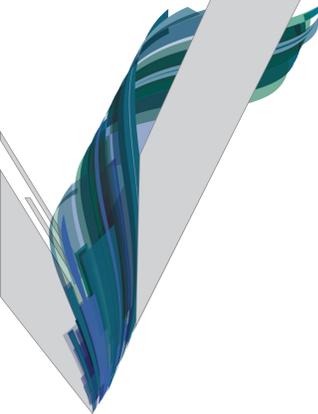
# General Law on Regulatory Improvement (continued)

- With respect to the regulatory process, the new General Law will:
  - define regulation in a broad manner, to cover any legal instrument of general application issued by federal, state, and municipal regulators;
  - oblige all regulators at the federal, state, and municipal levels to publish a Regulatory Agenda twice per year and request public comment;
  - provide regulatory improvement authorities at the federal, state, and municipal levels with the power to block the issuance of a regulation in cases where the regulator does not modify its RIA to reflect the recommendations of the regulatory improvement authority;
  - mandate regulators at federal, state, and municipal levels to conduct ex-post RIAs every five years for regulations that impose compliance costs; and
  - require regulators at the federal, state, and municipal levels to modify or repeal one regulatory obligation or act before promulgating a new one



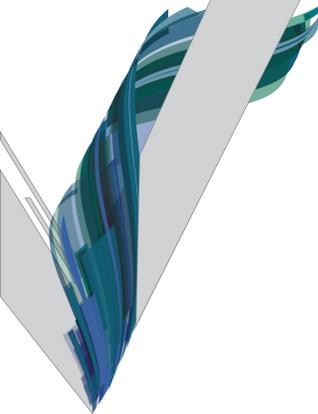
## General Law on Regulatory Improvement (continued)

- The General Law will also establish a National Council, which will:
  - Comprise several Ministers (Secretaries), a representative of the President of Mexico, the President of the Regulatory Improvement Observatory, the Heads of five State Regulatory Improvement Authorities, and the Head of CONAMER;
  - Develop an implementing regulation for the General Law, including revised guidance for conducting regulatory impact analyses; and
  - Be required to propose a National Regulatory Improvement Strategy with a 20-year vision to the Council



# General Law on Regulatory Improvement (continued)

- Other elements of note:
  - Establishment of a National Observatory of Regulatory Improvement
  - New state laws and installation of State Regulatory Improvement Authorities
  - Creation of an electronic catalogue
  - Implementation of a new complaint mechanism ("Citizen's Protest")
  - Ascension of CONAMER to become Mexico's international authority for regulatory improvement



# Closing Thoughts on Mexico

- Implementation of the General Law
- NAFTA
- Possible areas for additional work
  - Standards
  - Pacific Alliance

# Questions?



**Jeffrey G. Weiss**  
**Partner**

**Venable LLP**

[jweiss@venable.com](mailto:jweiss@venable.com)

+1 (202) 344-4377