

VENABLE

**Regulatory Coherence:
Comparative Analysis of Colombia, Costa
Rica, Mexico, Peru, and the USA**

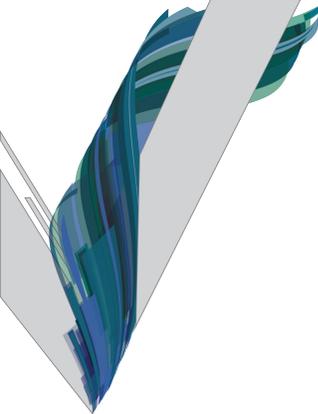
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Jeff Weiss

Partner, Venable LLP

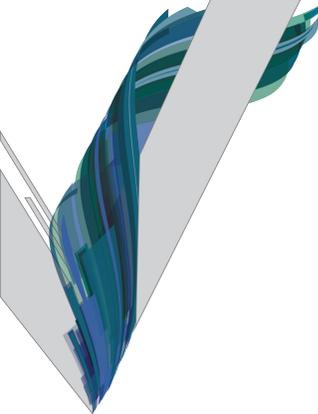
JWeiss@Venable.com

+1.202.344.4377



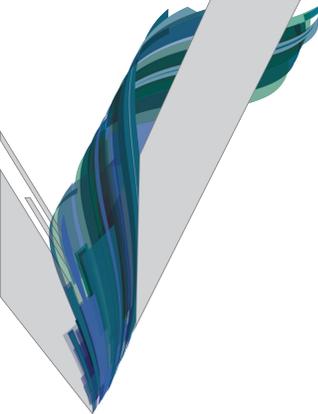
Agenda

- Overview of the AdvaMed Standards Alliance Project
- What Is Regulatory Coherence?
- Regulatory Coherence in Colombia, Costa Rica, Mexico, Peru, and the USA
 - Key Influences and Drivers of Regulatory Coherence
 - Central Coordination
 - Regulatory Forecasting
 - National Regulatory Register
 - Public Comment Process
 - Regulatory Analysis
 - Standards
 - Entry into Force
 - Judicial Review
 - Ex Post Assessment
- Things to Watch



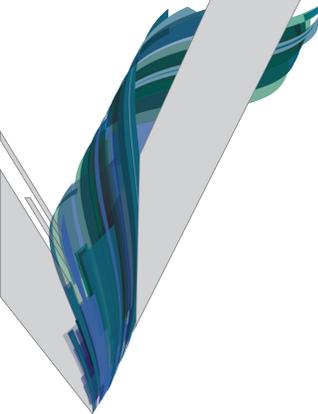
Project Overview

- 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



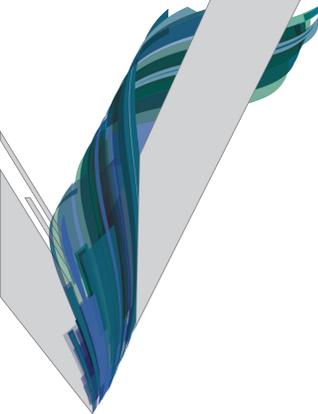
Project Overview (continued)

- 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



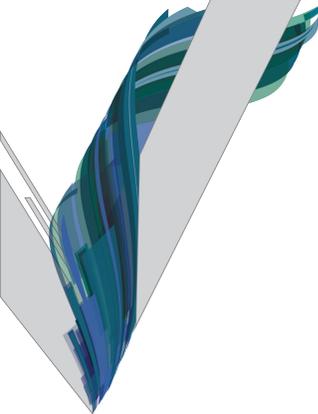
Overview of Regulatory Coherence

- 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



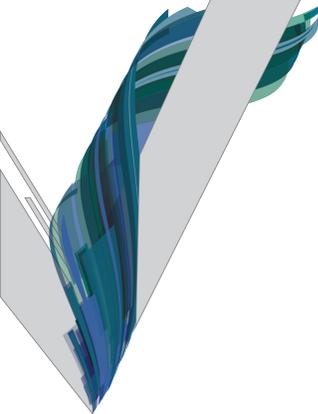
Key Influencers and Drivers of Regulatory Coherence

- Key Internal Drivers
 - Need to improve environmental, health, and safety protection
 - Desire to grow, attract investment, promote innovation
 - Efforts to combat corruption
 - Constraints on resources/staffing
- Key External Drivers
 - Compliance with WTO rules (e.g., Agreement on Technical Barriers to Trade (TBT Agreement))
 - OECD accession
 - Major influencers
 - USA
 - United Kingdom
 - Mexico



Central Coordination

- Still in its infancy, evolving
- Three different organizational structures
 - 1) One central coordinating body
 - 2) One central coordinating body, with a second agency in a strong supporting role for technical regulations
 - 3) No central coordinating body; several bodies performing coordination functions
- 1) One central coordinating body
 - USA: OMB/Office of Information and Regulatory Affairs



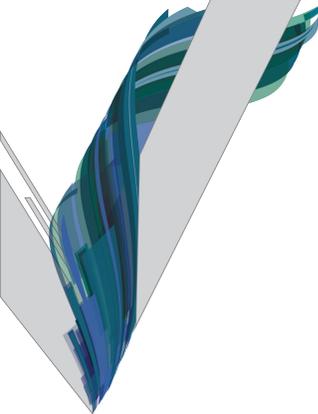
Central Coordination (continued)

2) One central coordinating body, with a second agency in a strong supporting role for technical regulations

- Mexico: CONAMER, plus DGN for NOMs
 - NOMs are RTs, but other Mexican regulations can be RTs as well
- Costa Rica: MEIC/DMR, plus ORT for RTs
 - Two separate regulatory development processes: ORT oversees development of RTs, whereas DMR oversees development of all other regulations

3) No central coordinating body; several bodies performing coordination functions

- Peru: PCM, CCR, and CCV
- Colombia: DNP/OMR, Función Pública, MINCIT, and SIC



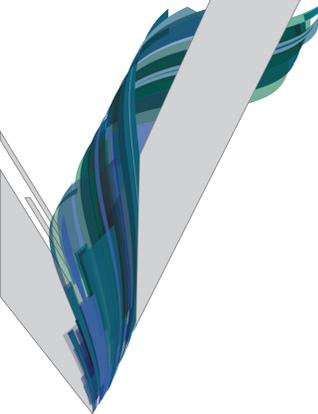
Central Coordination (continued)

Location of central coordinating body

- Coordinating functions are exercised by bodies within:
 - (1) econ ministries (Mexico and Costa Rica) or
 - (2) ministries in charge of central government planning (USA and Peru)
 - Colombia is trying to move toward (2)
 - All things being equal, central planning ministries tend to have more authority than econ ministries

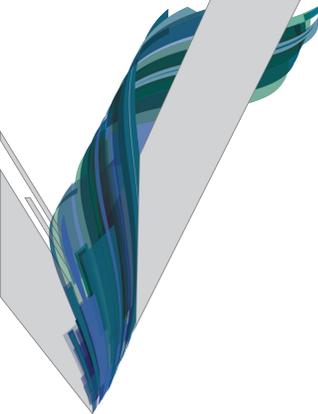
Staffing of central coordinating body

- Mexico (approximately 120) and USA (approximately 40) are the largest
- Peru and Costa Rica: less than a dozen staffers



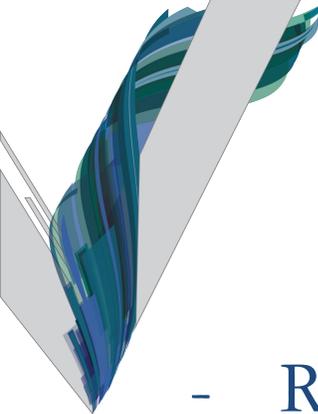
Central Coordination (continued)

- Scope of central coordination differs
 - Mexico: all regulations
 - RIA calculator is used to determine level of review
 - USA: significant regulations
 - OIRA determines significance, based on published criteria for determining significance, but application can vary for a variety of reasons
 - Costa Rica: regulations that add or modify an administrative burden
 - Peru: regulations that add or modify an administrative burden and/or require approval of three or more regulatory agencies
 - Colombia: regulations that require the President's signature
- One key similarity: all five countries have independent agencies



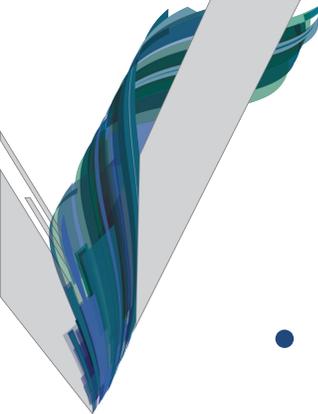
Central Coordination (continued)

- Reviewing authority: is it binding or not?
 - **USA:** yes, at both the proposed and final rule stages (OIRA and interested interagency actors review the regulation twice)
 - **Mexico:** yes, and also new authority for CONAMER at the sub-federal level (TBD)
 - **Costa Rica:** yes, both ORT (RTs) and DMR (other regulations)
 - **Peru:** yes, three sets of clearance are needed: (1) CCR; (2) MEF (budgetary and economic impacts), MINJUS (constitutionality and legality), and PCM (administrative simplification); and (3) CCV
 - **Colombia:** no, but for decrees, MINCIT (international trade) and Función Pública (administrative burdens) issue binding opinions and SIC (competition) issues a non-binding opinion



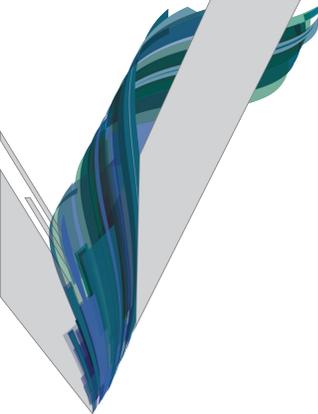
Central Coordination (continued)

- Regulatory Budgeting
 - Only in the USA (through executive order) and Mexico (by law)
- International Regulatory Cooperation
 - In general, the lead on IRC is shared between central coordinating authorities and economic/trade ministries, and regulators work with their counterparts through those agencies and/or directly
 - Central coordinating authorities tend to focus on regulatory improvement discussions and initiatives between countries and in intergovernmental bodies and fora (e.g., APEC, OECD)
 - Trade/econ ministries tends to focus on regulatory and standards issues in trade agreements (e.g., WTO TBT Committee, NAFTA, Pacific Alliance, CPTPP)



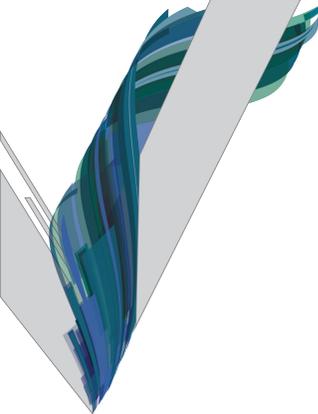
Regulatory Forecasting

- Annual regulatory agenda:
 - USA: Regulatory Plan (annual) and Unified Agenda of Regulatory and Deregulatory Actions (twice annually)
 - Colombia: Regulatory Agenda
- No annual regulatory agenda, but:
 - Mexico: DGN puts out an annual plan for NOMs and NMXs as part of the National Standardization Program
 - Costa Rica: MEIC publishes a four-year National Plan of Technical Regulations, and INTECO puts out an annual National Standardization Plan
 - Peru: agencies are required to submit an annual Strategic Standardization Plan to INACAL



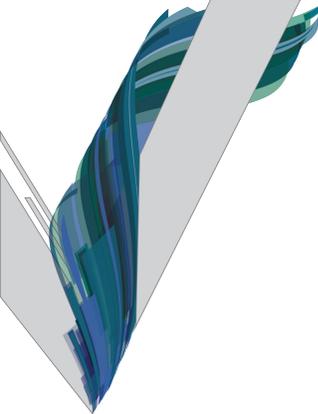
National Regulatory Register

- Official Journal
 - Peru (El Peruano)
 - USA (Federal Register)
 - Colombia (Diario Oficial)
 - Mexico (Diario Oficial de la Federación)
 - Costa Rica (Diario Oficial La Gaceta)
- Some have an online portal for commenting on draft regulations
 - Costa Rica (SICOPRE/ReglaTec)
 - Mexico (SYRIA)
 - Colombia (SUCOP is under construction)
 - USA (regulations.gov)



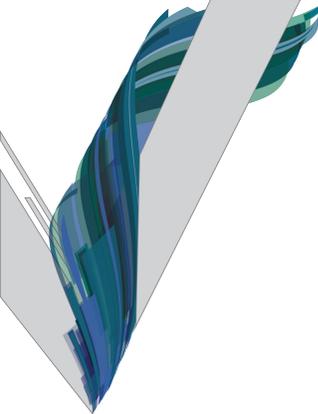
Public Comment Process

- Regulation vs. legislation
- Advance Notice of Proposed Rulemaking: U.S. only
- Colombia, Costa Rica, and Mexico may – and often do – consult with interested stakeholders in the regulatory development process (i.e., before publishing a draft regulation for comment), including by establishing working groups)
- In many cases, there are different requirements for RTs and non-RTs, with one exception (USA)
 - Development process
 - Costa Rica maintains two separate processes, run by two different entities
 - Question of whether to notify to the WTO is part of the development process, because there are often different requirements for RTs



Public Comment Process (continued)

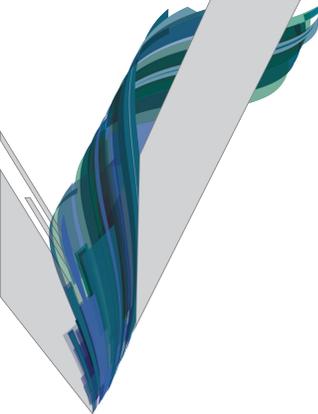
- Comment periods
 - Comment periods for RTs tend to be much longer than for other regulations (10-30 days for non-RTs vs. 60-90 days for RTs)
 - **Mexico:** there is no required minimum comment period for general administrative acts
- Taking comments into account
 - This is required for RTs, but not always for other regulations (**Costa Rica, Peru**)
 - **Costa Rica:** for RTs, a regulator is required to develop a matrix of public comments and their responses; must be done for both domestic and international comment periods and posted on ReglaTec
- Posting of comments



Public Comment Process (continued)

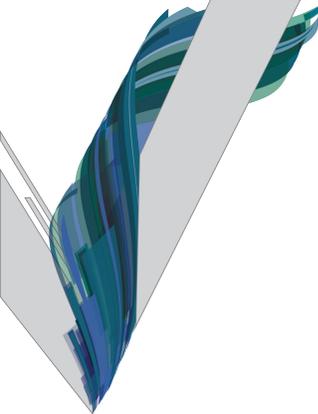
- USA is the exception

- The internal rules governing the regulatory review process do not differentiate between RTs and non-RTs
- Periodic reminders are given through guidance, but compliance is driven by stakeholders raising issues, which activates USTR
- NIST reviews the Federal Register and notifies the WTO if a proposed regulation is an RT (domestic and international comment is solicited at around the same time)



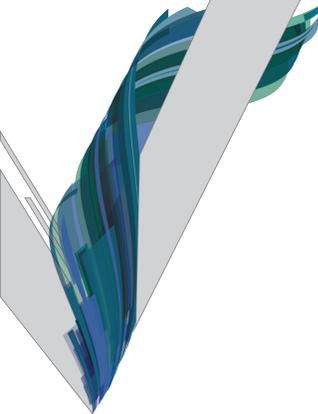
Public Comment Process (continued)

- U.S. system is a product of the Administrative Procedure Act and the requirement that interested parties be allowed to participate in regulatory process (notice and comment)
 - Comment period should be at least 60 days (Executive Order 12866), but often 30 days
 - Could be longer for complex rulemakings
 - Discussion of legal authority, summary of provisions, description of potential alternatives must be discussed in preamble of proposed regulation (which contains draft regulatory text)
 - Comments must be taken into account; responses to comments and discussion of changes made/not made (with justification) provided in preamble of final regulation
 - Final regulation must be a logical outgrowth of the proposed regulation and administrative record and not arbitrary and capricious
 - References to standards in regulation must be static (cannot include later versions of the standard)
 - Administrative record (available online) must contain all and only documents relied upon by the regulator (e.g., comments, RIA and other analysis, supporting data, studies, notes from public hearings and meetings with outside parties)



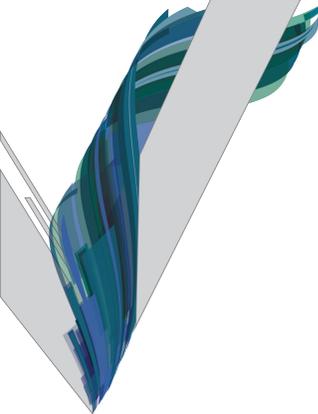
Regulatory Analysis

- Sources of authority to regulate
 - Legislative mandate
 - Regulator self-initiation under its general authority
- Regulatory Impact Assessment (RIA) is conducted for many measures in Costa Rica, Mexico, USA
 - **Costa Rica:** regulations that would add or modify an administrative burden
 - **Mexico:** regulations that would impose costs on citizens
 - **USA:** economically significant regulations
- RIA system still under development in other systems
 - **Peru:** required as part of Description of Motivation but only done sporadically
 - **Colombia:** required for RTs as of January 2018; Decree to cover other regulations is planned



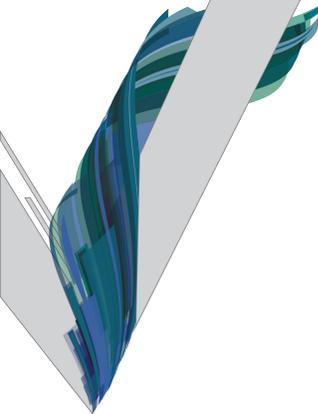
Regulatory Analysis (continued)

- Mexico: RIA calculator
 - Regulators use series of online tools that determine type of RIA to perform and submit results to CONAMER
 - Regulatory Impact Calculator (determines level of impact)
 - Competition Impact Checklist
 - Risk Impact Checklist
 - Foreign Trade Impact Checklist
 - Results indicate which analyses regulator must conduct
 - RIA Manual sets out different types and specific elements of each
 - CONAMER can require high-impact RIA even if results of calculator do not show that an RIA is needed
 - Test: benefits must exceed costs



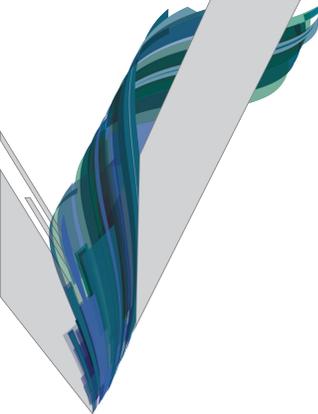
Regulatory Analysis (continued)

- USA: EO 12866 and OMB Circular A-4
 - Principle: maximize net benefits to society or at least ensure that benefits justify costs
 - RIA must contain:
 - Statement of need
 - Benefits of proposed action
 - Costs of proposed action
 - Benefits and costs of alternatives and explanation for selected alternative
 - Regulatory Flexibility Act
 - Consider impact on small entities and conduct a regulatory flexibility analysis



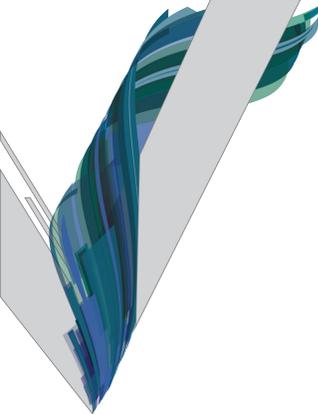
Regulatory Analysis (continued)

- Publication of RIAs
 - **Colombia:** Explanatory Report is published on agency website; docket (including RIA) will be published on SUCOP when operational
 - **Costa Rica:** published on SICOPRE
 - **Mexico:** published on SYRIA
 - **Peru:** Description of Motivation is published on agency website
 - **USA:** published in docket on regulations.gov
- Other noteworthy elements of regulatory analysis
 - **Colombia:** in cases where a regulation would add or modify an administrative burden, regulator must prepare written justification, include information on costs to regulated entities, budget/staff needed to implement, and flow chart containing description of burden, including steps and timing
 - **Costa Rica:** regulator needs to explain how it will evaluate effectiveness of regulation in achieving its objectives



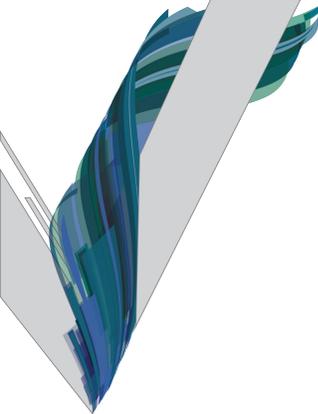
Regulatory Analysis (continued)

- Risk analysis and use of sound science/valid and reliable data
 - **Mexico:** regulator must perform a risk analysis when indicated by the RIA calculator, including any high-impact RIA; the RIA Manual also encourages a regulator to include in its analysis the data supporting its assertions and sources
 - **USA:** pursuant to EOs and guidance, regulators should base regulations on the best reasonably obtainable scientific information (and make supporting documentation publicly available); consider how a regulation would reduce risks to health, safety, and environment; ensure objectivity of scientific information and processes used to support regulations; perform risk assessments for significant draft regulations; and rely on peer-reviewed information and risk assessments
 - Some country policies are at an early stage, focused on RTs
 - **Colombia:** agencies need to prepare an RIA that includes a risk analysis for all RTs (as of January 2018)
 - **Costa Rica:** agencies are encouraged to conduct a risk analysis when analyzing the impact of a draft RT and to consider data quality; international standards and standards developed by recognized agencies are presumed to have solid scientific support
 - **Peru:** measures that may affect plant or animal health need to be based on technical and scientific analysis



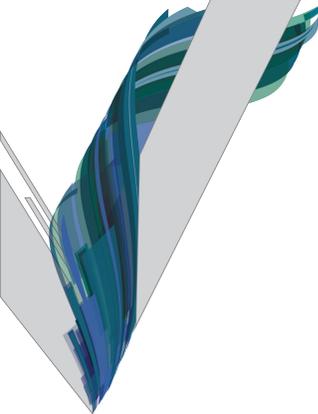
Regulatory Analysis (continued)

- Pro-competitive Analysis
 - **USA:** yes, for significant regulations
 - **Colombia:** yes, when the results of Preliminary Studies indicate that a draft regulation will cause an economic impact
 - SIC (Colombia's National Competition Authority) also reviews and issues a non-binding opinion, which the regulator can disregard, but it will need to explain its reasoning; SIC's opinion will be part of the package that the Office of the President reviews before signature
 - **Mexico:** yes, when the RIA calculator determines that a regulator needs to perform a Competition Impact Analysis
 - CONAMER informs COFECE (Mexico's competition commission) of any draft regulations with a Competition Impact Analysis so that COFECE can review them and offer views and recommendations
 - COFECE may also require such an analysis if the calculator failed to detect a potential impact on competition
 - **Costa Rica:** no, but DMR sends measures to MEIC's competition office for its analysis and issuance of a non-binding opinion
 - **Peru:** no, but MEF may examine competition issues when it reviews a measure



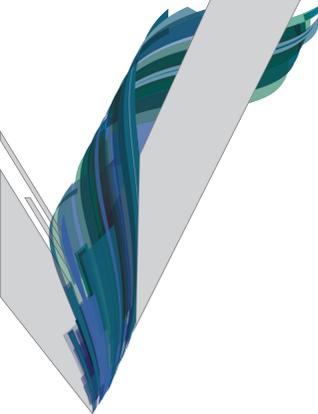
Regulatory Analysis (continued)

- Assessment of International Impact
 - **Colombia:** yes, when a draft regulation could have an international impact or is a technical regulation
 - **Mexico:** yes, when the RIA calculator determines that a regulator needs to perform a Foreign Trade Impact Analysis
 - **Costa Rica:** no, but ORT reviews for potential international commitments during the regulatory process
 - **Peru and USA:** no, but trade ministries can weigh in during the regulatory process where a draft regulation has international trade implications
 - USA: agencies need to publicly identify any significant regulations that have significant international impacts



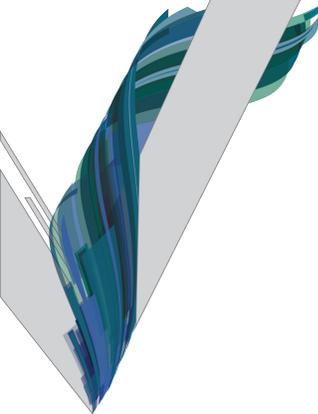
Standards

- Policy on use of international standards in regulation
 - **USA:** any standard developed in accordance with the WTO TBT Committee Decision
 - **Mexico:** Committee Decision is official policy, but emphasis is on ISO and IEC and use depends on agency
 - **Costa Rica and Peru:** hierarchy of standards:
 - International standards: ISO, IEC, Codex, etc.
 - Regional standards: CEN, CENELEC, COPANT, Andean, etc.
 - National standards: BSI, DIN, AFNOR, INTEC, etc.
 - Association standards
 - **Colombia:** international standards that have been adopted by international organizations; no hierarchy but terms undefined



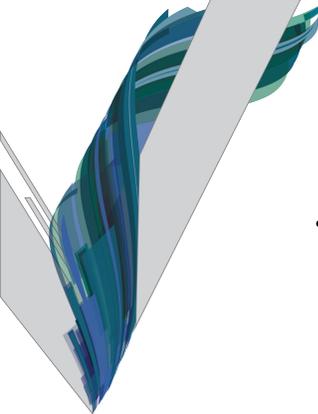
Standards (continued)

- Other policies of note:
 - **USA:** OMB Circular A-119 sets out guidance for agencies on how to: participate in standards development; select the appropriate standard and conformity assessment procedure; reference standards; report on their use of standards; comply with international standards-related obligations; and implement the Circular through their Standards Executives
 - **Mexico:** DGN recognizes ten Mexican bodies (each with a specific scope) to develop NMXs, which can be referenced in regulation
 - **Costa Rica:** for any draft RT, regulator must prepare a study to determine whether the relevant international standard should be adopted (in whole or in part)



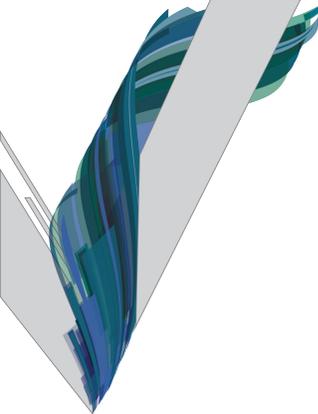
Entry into Force

- In general, the transition period provided for technical regulations is longer than for other types of regulations
 - Non-RTs: no requirement to provide a transition period in Costa Rica, Colombia, or Mexico; in Peru, it's at least 30 days
 - RTs:
 - Colombia (at least 90 days after WTO notification);
 - Peru (at least 180 days after WTO notification);
 - Costa Rica (administrative customs to allow 180 days);
 - Mexico (at least 60 days for NOMs, but could be 180 days if required by international commitments)
 - USA: no distinction between RTs and non-RTs
 - at least 30 days are required, but guidance notes that a “reasonable interval” should be provided, consistent with law and international obligations



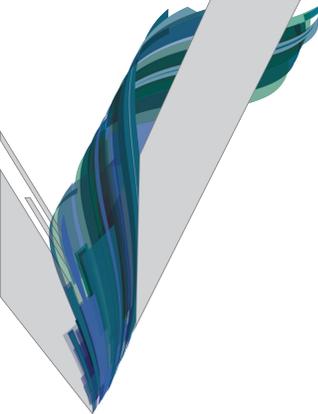
Judicial Review

- Colombia, Costa Rica, and the USA: yes
 - Costa Rica also provides a mechanism for challenging a regulation with the head of the issuing agency
- Mexico: not explicitly provided for, but regulations are regularly challenged in court
- Peru: no judicial review
 - INDECOPI maintains a bureaucratic barrier elimination process that private parties can use to challenge a specific measure



Ex Post Review

- Costa Rica: yes, but no set time period
- USA: yes, but emphasis tends to be intermittent and varies by administration
 - Initiatives have been across-the-board or have focused on a specific type of measure, such as paperwork or a particular sector
- Colombia and Peru: ex post review is required only for RTs (but Colombia plans to extend it to all rules)
 - Peru: required every three years (first reports due at end of 2018)
 - Colombia: required every five years; if an RT is not reviewed by the deadline, it expires (first deadline is 1/1/19)
- Mexico: ex post review is required only for NOMs with a high-impact RIA (every five years)



Things to Watch

- Rollout of Mexico's General Law on Regulatory Improvement
- Implementation of Regulatory Budgeting: USA and Mexico
- Implementation of Ex Post Review: USA, Colombia, Peru
- Growth of International Regulatory Cooperation?
- Costa Rica's OECD accession process
- Areas for improvement: analysis, science/risk, standards
- Colombia's evolution on regulatory coherence
 - E.g., SUCOP, role of OMR, ex post assessments on RTs

Questions?



Jeffrey G. Weiss
Partner

Venable LLP

jweiss@venable.com

+1 (202) 344-4377