



VENABLE

Regional Trends in Good Regulatory Practices and the Road to Competitiveness

October 19, 2018

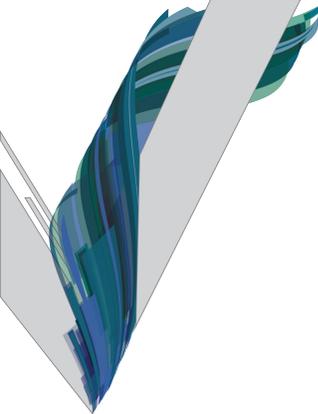
Jeff Weiss

Partner, International Trade & Logistics

Venable LLP

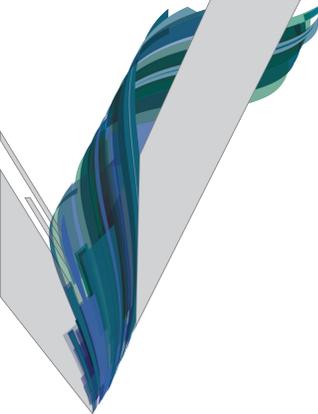
JWeiss@Venable.com

+1.202.344.4377



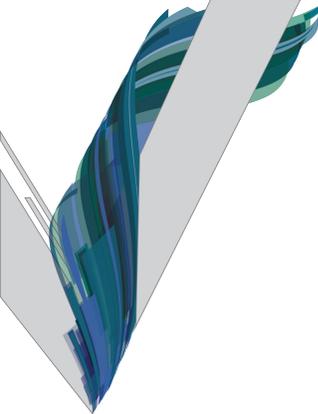
Agenda

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



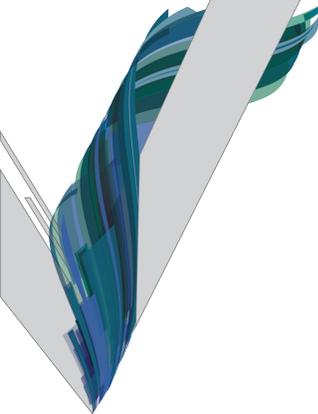
Project Overview

- 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



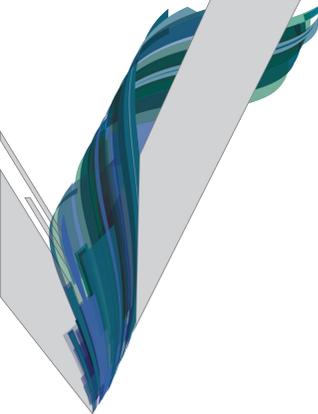
Overview of Regulatory Coherence

- 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



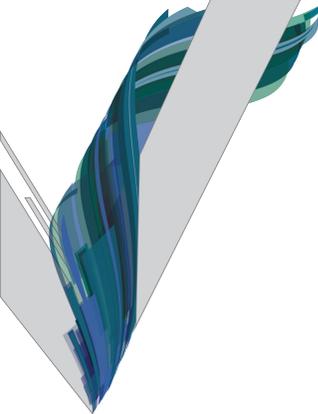
Key Influencers and Drivers of Regulatory Coherence

- 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)
 - OECD accession
 - Major influencers
 - USA
 - United Kingdom
 - Mexico



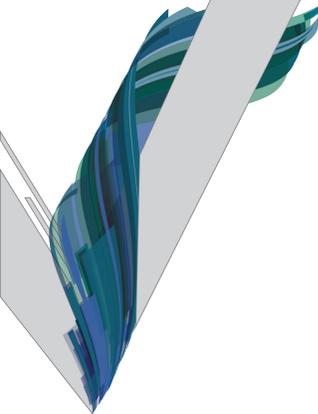
Central Coordination

- 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



Central Coordination in Colombia

- National Planning Department (Departamento Nacional de Planeación or “DNP”)
 - Regulatory Improvement Group (Grupo de Mejora Regulatoria or “OMR”)
- Función Pública
- Ministry of Commerce, Industry, and Tourism (MINCIT)
- Industry and Commerce Superintendencia (SIC)
- Legal Department for the Office of the President



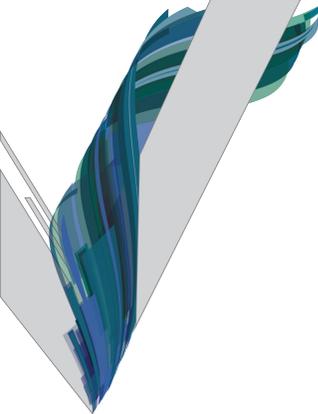
Central Coordination (continued)

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

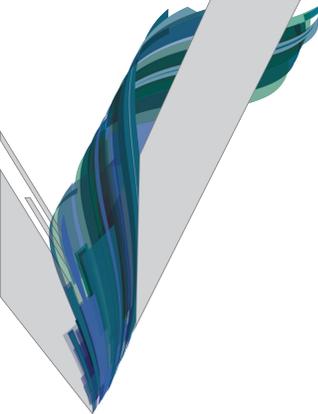
Regulatory Budgeting

- Only in the USA (through executive order) and Mexico (by law)



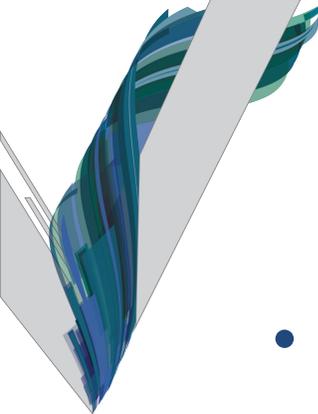
Central Coordination (continued)

- 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



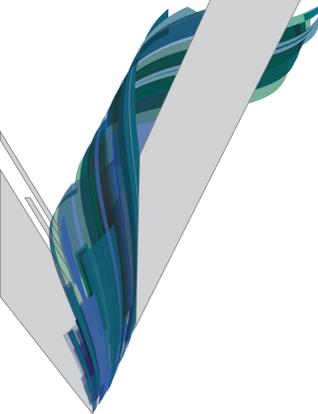
Central Coordination (continued)

- 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



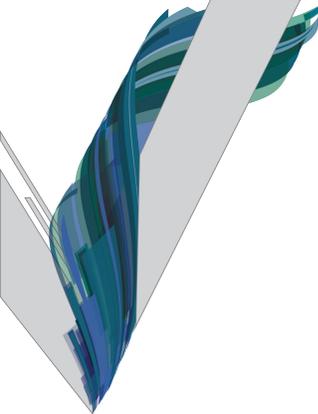
Regulatory Forecasting

- 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



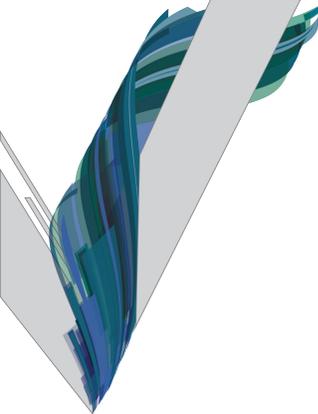
National Regulatory Register

- 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)



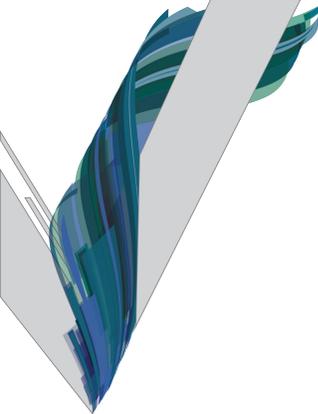
Public Comment Process

- 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



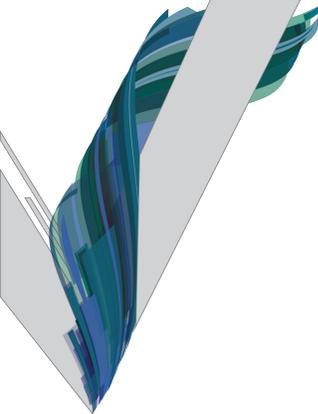
Public Comment Process (continued)

- 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



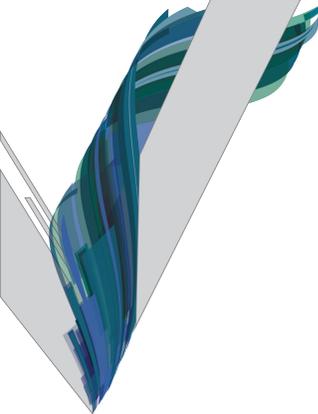
Regulatory Analysis

- 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 (calculator)
 - **USA:** economically significant regulations (EO 12866 and A-4)
- 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



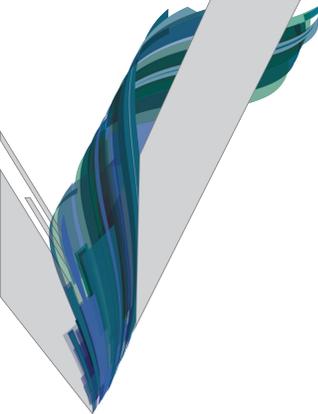
Regulatory Analysis (continued)

- 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



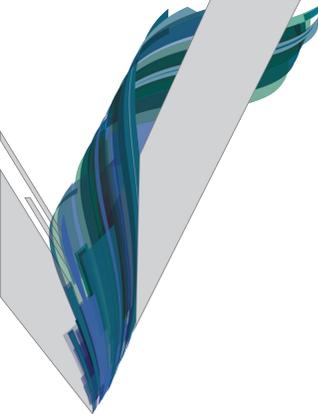
Regulatory Analysis (continued)

- 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



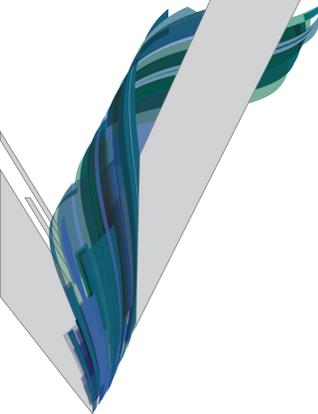
Regulatory Analysis in Colombia

- Regulatory Impact Assessment (RIA)
 - In its infancy
 - Currently required just for RTs
- Scientific analysis
 - No policy on use of valid and reliable data and sound science
 - No requirement to use a risk-based approach
 - For RTs, the RIA includes a risk analysis and an agency must identify and categorize the level of risk



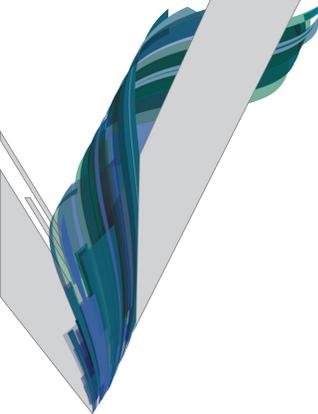
Regulatory Analysis (continued)

- 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



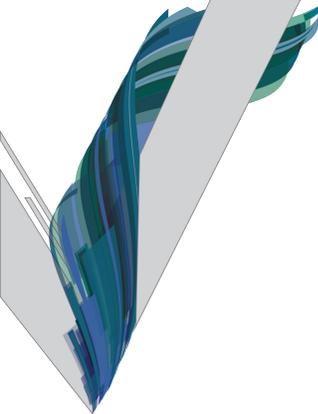
Regulatory Analysis (continued)

- 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



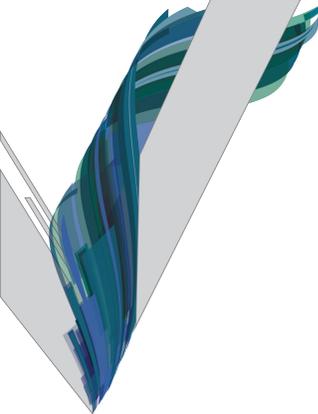
Standards

- 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



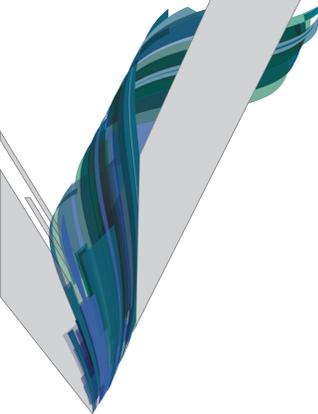
Standards (continued)

- 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)



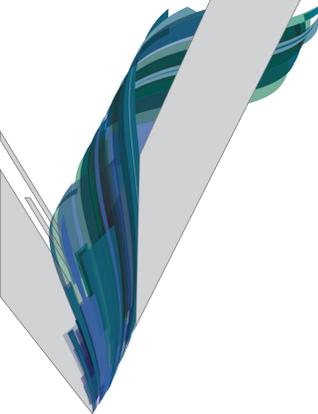
Entry into Force

- 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



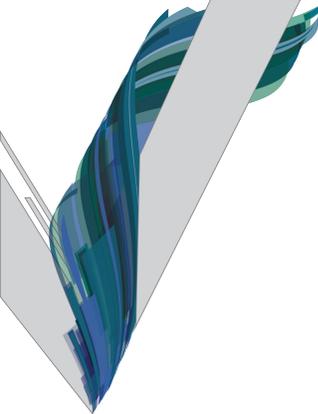
Ex Post Review

- 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)



Ex Post Assessment in Colombia

- Retrospective review is not required for regulations of general applicability
- But it is required for RTs
 - Timing
 - Objective
 - Consequences of non-performance
 - Effective date
- Different requirements for Regulatory Commissions



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, RIA and ex post assessments on RTs, RIA for other types of regulations, Pacific Alliance

Questions?



Jeff Weiss
Partner
Venable LLP
jweiss@venable.com
+1 (202) 344-4377