

# COVID-19 Medical Device Regulatory Convergence Project (MDRC)

9<sup>th</sup> Summit of the Americas

*Workshop : Advancing the  
Implementation of Cross-Sectoral,  
Foundational GRP and Regional  
Cooperation in Latin America*

*8 June 2022 | Los Angeles , California*



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# General Information

- **Virtual guests:**

- Please keep yourself muted throughout the duration of the session.
- Use the chat box for any questions or comments.
- The morning programming for this workshop is open. After the lunch break, the workshop will continue in a closed session. If you have been invited to join, please use the unique link to connect to our afternoon. This link is different than the link to join this morning session.
- *If you have any technical difficulties accessing the meetings during the day of the event, please contact: [hugo@perlitteras.com](mailto:hugo@perlitteras.com); [ablasi@crowell.com](mailto:ablasi@crowell.com)*

- **In-person guests:**

- Masks are available upon request, please let a team member know.
- Simultaneous translation is offered for all hybrid Coalition activities. Please connect your device to the meeting Zoom (such as a cell phone or laptop) along with headphones. *Please keep your mic muted once connected.*
- Restrooms
- Guest Wifi Network: *Pipeline*
  - Username: *guest@crowell.com*
  - Password: *Pochard*



# Opening Welcome Remarks



*Paul Fekete*

*Team Leader, Acting Head for the Center for Economics  
and Market Development, Bureau for Development,  
Democracy, and Innovation, U.S. Agency for  
International Development (virtual)*



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# GRP Implementation and Project Country Initiatives (External Session)



*GeanLuca Lorenzon*

*Secretary for Competition  
Advocacy and Competitiveness,  
Secretariat for Competition  
Advocacy and Competitiveness,  
Brazil*



*Lina Valencia*

*Director of Governance, Human Rights  
and Peace, Colombia National  
Planning Department (DNP),  
Colombia*



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# Brazil's Regulatory Policy

**Secretariat for Economic Monitoring,  
Competition Advocacy and Competitiveness  
(SEAE)**

**Special Secretary of Productivity and  
Competitiveness (SEPEC)**

Ministry of Economy

Jun/2022

- ① **SEAE**
- ② Brazilian context
- ③ Implementation process
- ④ Dissemination
- ⑤ Challenges

# 1 Secretariat for Economic Monitoring, Competition Advocacy and Competitiveness

## Who are we and what do we do?



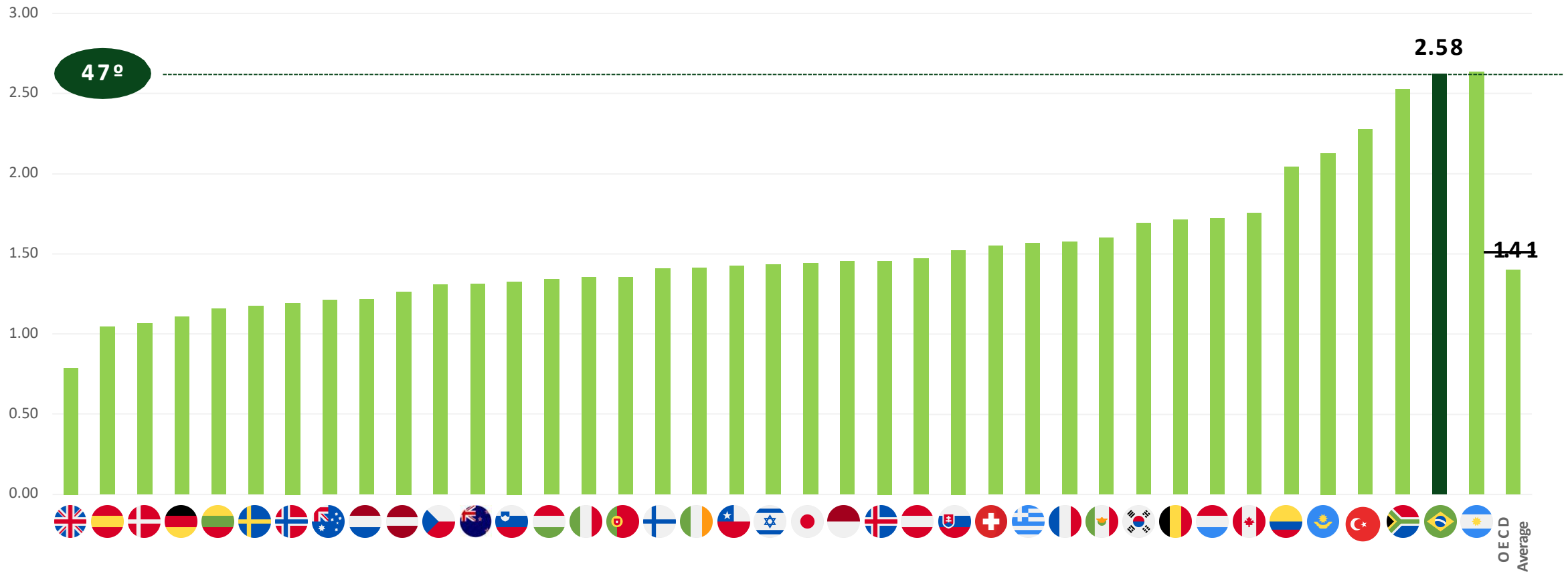
- ① SEAE
- ② **Brazilian context**
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# 2

## Brazil's performance on OECD PMR Index is considerably disappointing

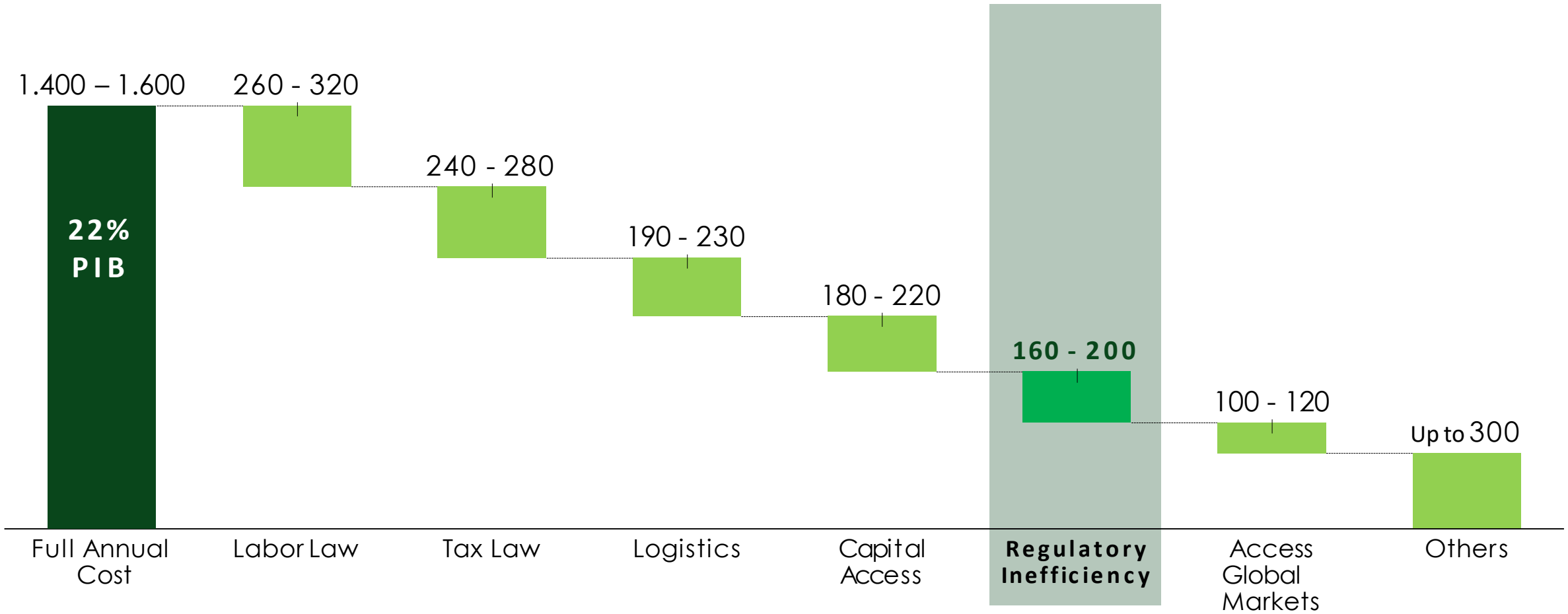
**Product Market Regulation Ranking**  
2019



Source: Ministério da Economia

# 2 The "Brazilian Cost" (Custo Brasil)

Annual estimated cost of doing business in Brazil vs avg. OECD country  
BRL Bn - 2019



Source: Ministério da Economia

# 2 What's been done?

2007

## Pró-Reg

Exchange of experiences with international regulators and training



2019

## Regulatory Agencies Law

A topic under discussion since 2003, the bill was converted into Law on June 25, 2019. It establishes good practices for agencies.



2018

## Directives and RIA Guide

Guidelines and the RIA Guide. Recommendation for RIA practice. RIA pilots with some bodies and agencies.



2019

## Economic Freedom Act

Extends RIA's obligation to the entire public administration. It also limits the government's power over entrepreneurs and citizens



## 2

# What's been done? - Regulation of Economic Freedom Act

The Economic Freedom Act established limits for the state's power. Several Decrees were edited to comply with its premises:



**Economic Freedom Act**

**2019**



### **2019 – Full Federal Regulatory Review**

Establishes a **review of all existing regulations**. Over 74.000 normatives analyzed and more than 31.000 revoked.



### **2019 – Federal Licensing Review**

Decree n° 10.178/2019. Establishes a **review of all existing required licenses** aiming to extinguish all but those associated with risk.



### **2020 – International Standardization**

Decree n° 10.229/2020. Establishes the **adoption of international technical regulations** over outdated federal rules

**A**



### **2020 – RIA Decree**

Decree n° 10.411/2020. **RIA is mandatory** before enacting regulations for all regulators.

**B**

# A Decree n° 10.229/2020 – International Standardization



## Decree Published in Feb/2020

- ✓ It is the **right** of every person, to **develop, execute, operate** or **commercialize** new types of products and services when the infra-legal rules become outdated due to internationally consolidated technological development
- ✓ After the request, the regulator can take **no longer than six months to rule on it**
- ✓ Unless opposed after the request, the applicant can choose to follow the international norm over the domestic ones as long as he accepts full responsibility for compliance and liability for any damages due to its exercise

## Allowed International Standards



International Organization for Standardization



International Organization of Legal Metrology



International Telecommunication Union

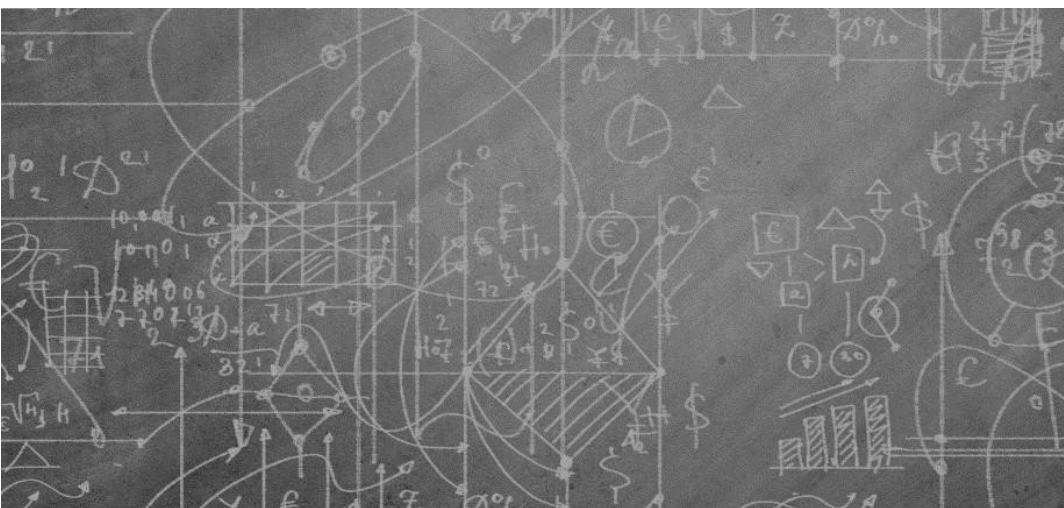


Codex Alimentarius



International Electrotechnical Commission

# B Decree nº 10.411/2020 – Regulatory Impact Analysis



## The RIA Decree



RIA is **mandatory** before enacting regulations



**For all bodies** of Brazilian Federal Administration, including collegiate body



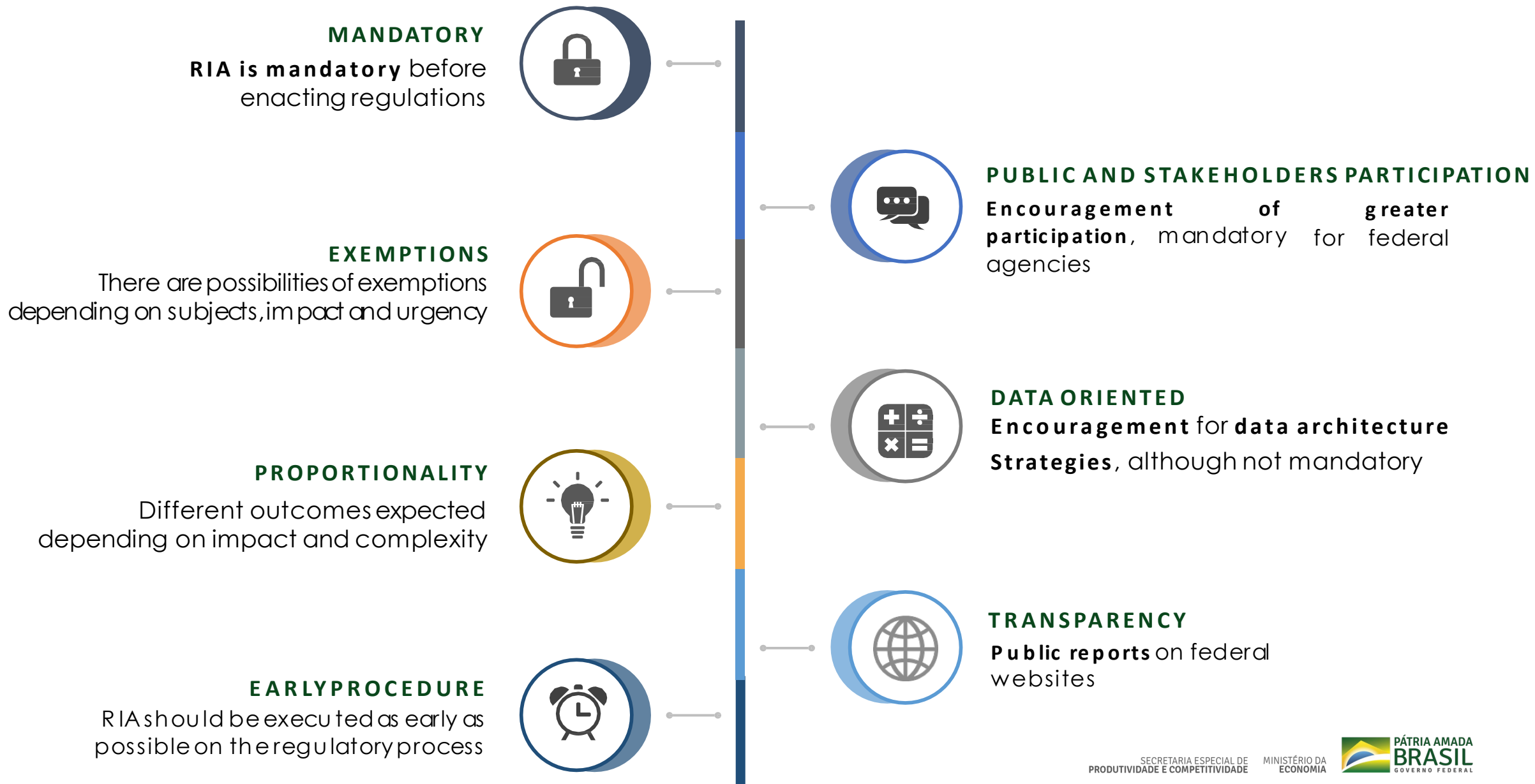
**Published in June/2020**

Starting effects on:

April/2021 - Ministry of Economy and Inmetro

October/2021 - Other Public Administration bodies

# B Decree nº 10.411/2020 – Regulatory Impact Analysis



# 2 What's been done? – US-Brazil Protocol – Good Regulatory Practices

2020



## United States-Brazil Protocol

Annex II of the US-Brazil Protocol on Trade Rules and Transparency brought a series of **innovations and concrete commitments** for **regulatory improvement** that will bring several benefits to the Brazilian regulatory environment.

Brazil has made **concrete commitments** for Regulatory Improvement





- ① SEAE
- ② Brazilian context
- ③ **Implementation process**
- ④ Dissemination
- ⑤ Challenges

# 3 Actions took for implementing decrees



## New Courses

- ✓ New courses available for the entire public administration
- ✓ Ministered by National School of Public Administration - ENAP



## Pilot Projects

- ✓ Since the second half of 2020, the Ministry of Economy has implemented **pilot projects with its bodies** to disseminate RIA.
- ✓ The project has **consultants specialized in impact analysis**



## Guides and Presentations

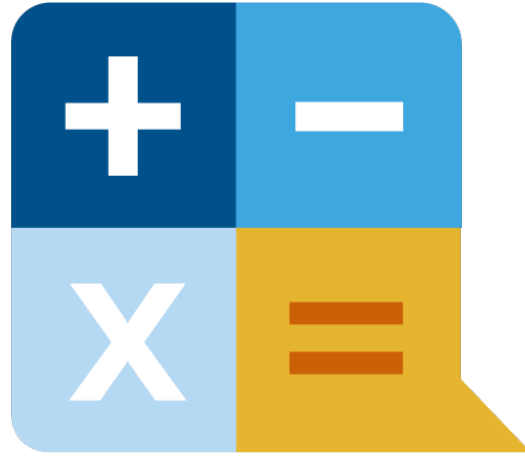
- ✓ SEAE held **presentations and meetings** to disseminate the new decrees
- ✓ **New RIA Guide published**



## Tools

- ✓ **CalReg**: a tool for calculating regulatory costs (*detail below*)
- ✓ **Gov.br/Reg**: information hub (*detail below*)

# 3 Calculator of Regulatory Burden



CalReg  
S E A E  
beta

## What is it?

Tool for calculating regulatory costs, borne by companies, individuals and the public administration. Its scope covers direct and administrative costs, without incorporating indirect costs.

## Objectives

- ✓ **Assist Public Administration bodies in their RIAs:** not all public administration bodies have the necessary expertise for this type of analysis.
- ✓ **Disseminate the culture of calculating the regulatory cost:** currently, only 8% of the RIAs use quantitative methodologies in their analyses. Most of the regulations issued by the federal government do not have the associated regulatory cost measurement.

### 3 Information hub: Gov.br/Reg



**Gov.br/Reg: regulation portal – beta version is online!**

- ✓ Development of a single portal
- ✓ **Information hub**, including normative acts, public consultations, regulatory agendas, etc.

- ① SEAE
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# 4

## Dissemination: SEAE has published two guides about regulatory impact analysis and regulatory improvement



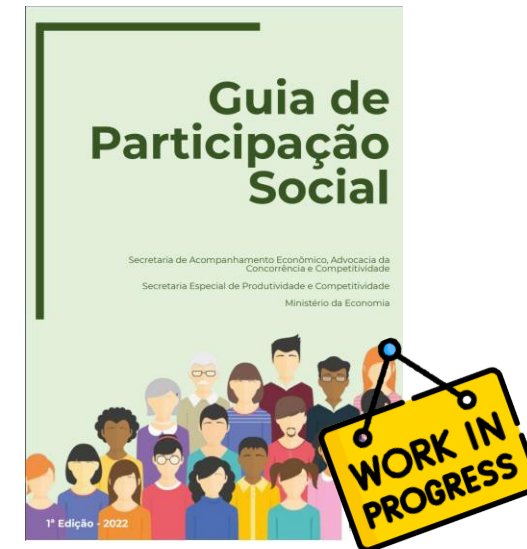
### New RIA Guide - Apr/2021

- ✓ Updated by Decree n° 10.411/2020
- ✓ **RIA on the Deregulation scenario**
- ✓ **Focus on maintenance/ promotion of competition**
- ✓ Regulation that feeds the cycle of innovative solutions



### Deregulation Guide - Dec/2020

- ✓ **Framework for deregulation**
- ✓ **Benchmark** on deregulation practices
- ✓ **General recommendations** for regulatory environment improvement



### Stakeholder Engagement Guidance

- ✓ Guide that will facilitate **understanding of how citizens can actively contribute to public consultations**
- ✓ Work in progress, expected to be released in late June 2022

## Meeting of Federal Regulators

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- ✓ Series of periodic events with regulatory bodies and entities
- ✓ Objective: **dissemination of good regulatory practices, sharing of successful experiences and dissemination of results**
- ✓ **International attendance:** OECD, Federal Ministry of Economics and Technology (Germany) - BMWi and BNetzA



# Encontro de Reguladores Federais

*Disseminando boas práticas regulatórias*

# semana da AIR (Análise de Impacto Regulatório)

Com a apresentação pela OCDE do *Peer Review* da Reforma Regulatória do Brasil.

21 a 24  
de junho



Auditório Sede  
do TCU  
Brasília/DF

Organização:

SECRETARIA DE ACOMPANHAMENTO ECONÔMICO  
ADVOCACIA DA CONCORRÊNCIA E COMPETITIVIDADE

SECRETARIA ESPECIAL DE  
PRODUTIVIDADE E COMPETITIVIDADE

MINISTÉRIO DA  
ECONOMIA



Participação:



4 days of debates

OECD Participation

7 Thematic Panels:

- *Regulatory Reform of Brazil*
- Regulatory Impact Analysis (AIR)
- Engagement and Social Participation
- Regulatory Result Analysis (ARR)
- Quantitative Analysis
- Regulatory Policy in Subnational Entities
- Impact Analysis in Direct Administration



- ① SEAE
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# Challenges



## Institutionalization

Institutionalize good regulatory practices adoption, ensuring its continuous evolution within each organization's governance



## Cultural Change

**Regulatory mindset** must go through a profound transformation in order to adapt to the new scenario



## Public Participation

Integrating the regulatory procedures with public participation while expanding different tools in order to ensure effectiveness.



## Transparency

Implementing overall digital availability of reports, results, research and others.

# Challenges



## Data

Development of data strategy (collection and analysis)



## Ex-post

Expand ex post assessment, specially over regulations enacted without RIA



## Quantitative methodologies

Adoption of quantitative methodologies such as **Cost-Benefit Analysis**



## Qualitative adaptation

Ensure RIA has the suitable complexity and does not become a bureaucratic report over time.

**GEANLUCA LORENZON**  
SECRETARY FOR ECONOMIC MONITORING, COMPETITION  
ADVOCACY AND COMPETITIVENESS

SECRETARIA ESPECIAL DE  
**PRODUTIVIDADE E COMPETITIVIDADE**

MINISTÉRIO DA  
**ECONOMIA**



# GRP Implementation and Project Country Initiatives (External Session)



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# Mejora Regulatoria: *Buenas prácticas en regulación*

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Lina María Valencia O.

*Directora de Gobierno, DDHH y Paz*

Departamento Nacional de Planeación

*Advancing the Implementation of Cross-Sectoral, Foundational GRP and  
Regional Cooperation in Latin America*

*Los Ángeles, California*

*8 junio de 2022*

# ¿Cómo ha tomado forma la política regulatoria en el país?

Visión de la producción regulatoria: ciclo de gobernanza de la OCDE

Se trata de un ciclo y no de un **proceso lineal**

Aporta a la **eficiencia** del Estado pero también a **confianza** en instituciones

Avances específicos en cada etapa: **normas, políticas, herramientas, guías**



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# Etapa 1: Planeación



**Planeación normativa:** Identificación de la necesidad de acción gubernamental a través de regulación

**Transparencia:** Comunicar y dar a conocer a los grupos de interés las posibles acciones del Estado.

**Agenda regulatoria como principal herramienta de los ministerios y departamentos administrativos**

*Consulta – 31 de octubre*

*Ajuste y publicación – 31 de diciembre*

*Definitivo a Presidencia – 5 días hábiles de enero*



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# Etapa 2: Diseño

**Diseño de la regulación:** Justificar la necesidad de intervenir y cómo hacerlo de forma eficiente.

El **AIN** es una herramienta que permite evaluar conveniencia, potenciales impactos y alternativas de solución

## ¿Qué hemos logrado?

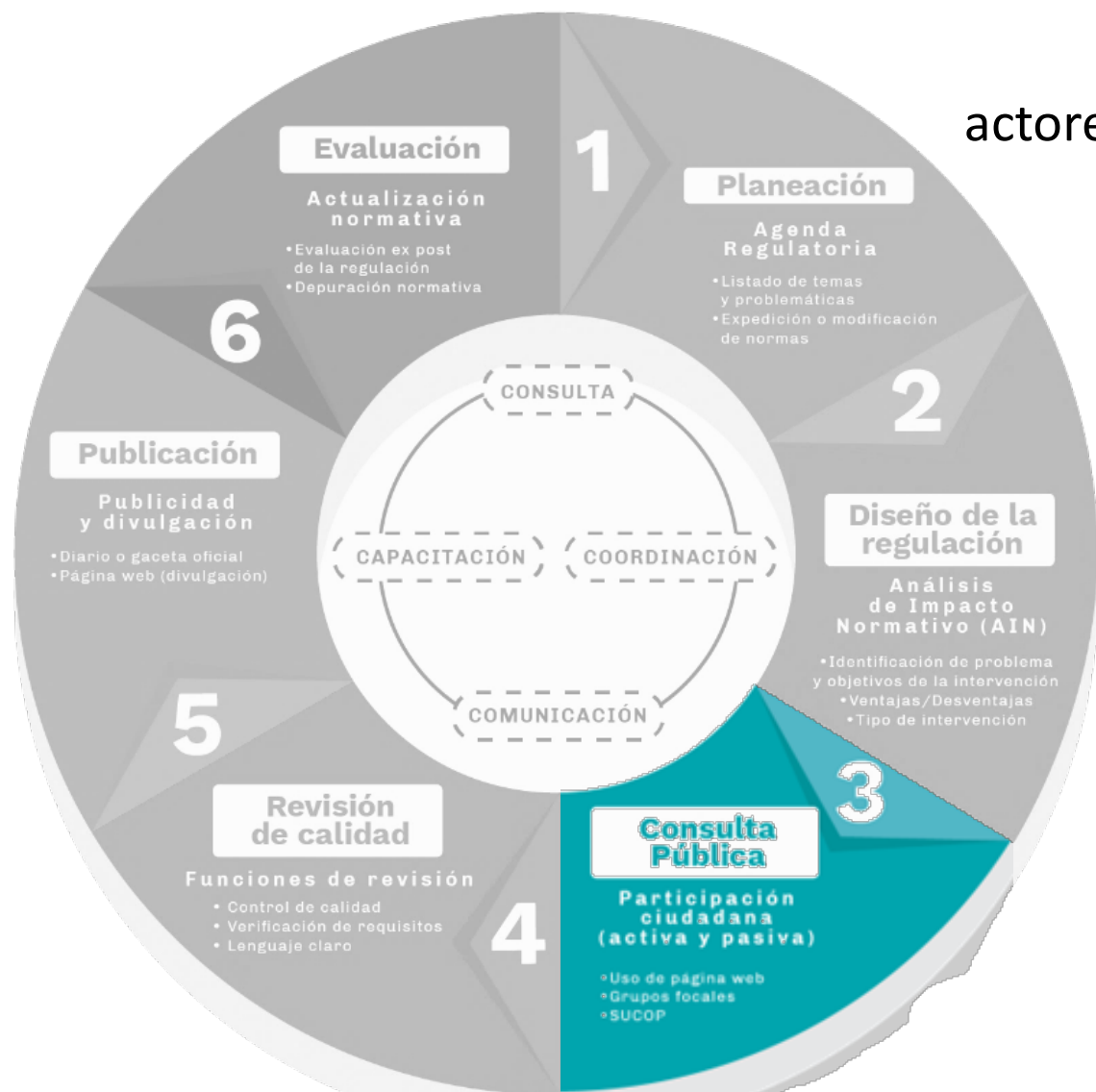
- ✓ Reglamentar el uso del AIN en la **emisión** o **modificación** de reglamentos técnicos.
- ✓ Adoptar **dos tipologías de AIN** proporcionales a la intervención (simple y completo).
- ✓ Ofertar un **curso virtual de AIN** (inglés/español): **679** personas matriculadas.
- ✓ Diseñar y divulgar distintas **herramientas** para facilitar la implementación de la metodología: guía metodológica, rúbricas, plantillas, infografías.
- ✓ Implementar un punto de revisión sobre la **calidad de AIN**: Concepto técnico del DNP sobre aplicación de AIN en reglamentos técnicos.



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# Etapa 3: Consulta pública



**Consulta pública:** Garantiza la participación de los actores interesados, el cumplimiento de los principios de Estado abierto y es transversal a todo el ciclo.

¡Es **obligatoria** en el país!

¿Qué conseguimos?

Publicar y divulgar una **Guía de Consulta Pública** (en proceso de actualización con nuevas recomendaciones y prácticas internacionales).

Desarrollo del **SUCOP**:

23 entidades vinculadas  
112 consultas realizadas  
12.761 usuarios han interactuado

Documentos CONPES, AIN, evaluaciones, agendas y proyectos normativos, etc.



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# Etapa 6: Evaluación ex post

**Evaluaciones ex post:** Revisión periódica y sistemática de las regulaciones y el entorno en el que se implementan - ¿Se han cumplido los objetivos de la intervención?

Generación de **evidencia**.

## ¿Qué tenemos?

- ✓ Obligatoriedad de **evaluar periódicamente** los reglamentos técnicos: **Mínimo una vez cada cinco (5) años**.
- ✓ Cronograma de **evaluaciones** para los años **2022–2024**:
  - **2022:** Reglamentos técnicos anteriores a 2005.
  - **2023:** Reglamentos técnicos entre 2005 y 2010.
  - **2024:** Reglamentos técnicos entre 2010 y 2015
- ✓ Herramientas como la **guía metodológica**, **curso virtual** e **infografías**.
- ✓ Acompañamientos en evaluaciones a regulaciones:
  - **6** regulaciones evaluadas entre 2020 y 2021 (Banco Mundial).
  - **2** regulaciones en proceso de evaluación (**proyecto MDRC**).



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# Otras herramientas...

## Institucionalización del Ciclo de gobernanza regulatoria

- Proyecto MDRC
- Construcción de procedimientos
- Instrucciones para implementar BPR en todas las etapas del ciclo.
- Aplicación en sector salud, con potencial a otros sectores.

1

## SUCOP

- Herramienta para centralizar las consultas públicas.
- Fácil participación.
- 23 entidades vinculadas a mayo de 2022.
- 112 consultas adelantadas.
- 12.761 usuarios participando.
- Consulta de AIN, evaluaciones, CONPES, agendas, entre otros.

3

## Calculadora de AIN

- Instrumento para clasificar los niveles de impacto de las regulaciones.
- Genera recomendaciones específicas para implementar la metodología de AIN.

5

## Generación de capacidades

- Socializaciones virtuales sobre las etapas del ciclo y sus herramientas.
- Tres ciclos: 2021-I (73 entidades), 2021-II (224 entidades) y 2022-I (en curso).

2

## Observatorio de Mejora Normativa

- Seguimiento sobre la producción normativa con datos del Diario Oficial.
  - Desde 2000 y a 2021 se han expedido y publicado 120.300 normas, por 168 entidades (nación y territorios).
  - 62% de estas normas son de carácter sustancial.
  - En 2021 se publicaron aproximadamente 9,4 normas sustanciales por día, en su mayoría por Ministerio públicos.

4



# Aplicación de BPR...

## Comité de Mejora Normativa

- Desde 2018 participan entidades que promueven acciones para fortalecer las prácticas regulatorias.
- Instancia de coordinación entre actores públicos y privados.
- Identificación y gestión de barreras u obstáculos en la actividad empresarial y el comercio.

## Comunidad de BPR

- Espacio conjunto de generación de conocimiento.
- Identificar y socializar lecciones aprendidas en la implementación de BPR.
- Facilitar la implementación de BPR a los interesados.

## Concurso de BPR

- Estrategia para identificar iniciativas que evidencien el uso de BPR.
- Recompensar e incentivar el uso de BPR.
- En 2022 se llevará a cabo la segunda versión del concurso.
- Acción promovida por la CAF y el DNP.

## Notas de política en Mejora Regulatoria

- Socializar los avances en la implementación de la Política de Mejora Normativa.
- Generar evidencia sobre la implementación de la - política.
- Analizar los retos



# ¿Qué retos nos quedan?

## Generación de capacidades

Fortalecer las capacidades de entidades para usar las herramientas y las BPR.

## Adaptación del uso de AIN

Extender el uso del AIN a otro tipo de normas. Para esto, es necesario diseñar variantes que permitan adaptar la metodología a las necesidades económicas, sociales y ambientales.

## Generación de datos y evidencia

Incentivar la cultura de los datos y producción de información a lo largo del Ciclo de Gobernanza Regulatoria, para fortalecer el proceso de toma de decisiones basadas en evidencia.

## Fortalecimiento institucional

Posicionar la Política de Mejora Normativa y las BPR en la agenda pública.



# ¡Gracias!



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[www.dnp.gov.co](http://www.dnp.gov.co)



# Coffee and Networking Break



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# GRP Implementation and Project Country Initiatives

## *(External Session)*

- *Presentations by National Standards Bodies*

- Jessica Roop, Senior Manager, International Development, American National Standards Institute, United States
- Jorge Emanuel Reis Cajazeira, Head of International Standardization, Brazil Association of Technical Standards (ABNT), Brazil
- Monica Vivas, Standardization Director, ICONTEC, Colombia
- Daniel Trillos, Subdirector de Normalization, ICONTEC, Colombia
- Raul Romero Anaya, Quality Infrastructure Coordinator, General Directorate of Standards, Mexico

- *Presentation by INMETRO*

- Marcos Aurélio Lima de Oliveira, Coordinator of the National Quality Infrastructure Policy WG, Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO), Brazil



# American National Standards Institute

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*The Code of Good Practice and*

*ANSI's Role in the United States*

*Standards System*



June 8, 2022

MDRC GRP workshop, Los Angeles, CA

# Presentation Objectives

- Recap of the key aspects of the Code of Good Practice for the Preparation, Adoption and Application of Standards
- Overview of ANSI
- Overview of the U.S. system for standards and conformity assessment
- Key ways in which ANSI implements the Code of Good Practice

# WTO TBT Annex 3: Code of Good Practice for the Preparation, Adoption, and Application of Standards

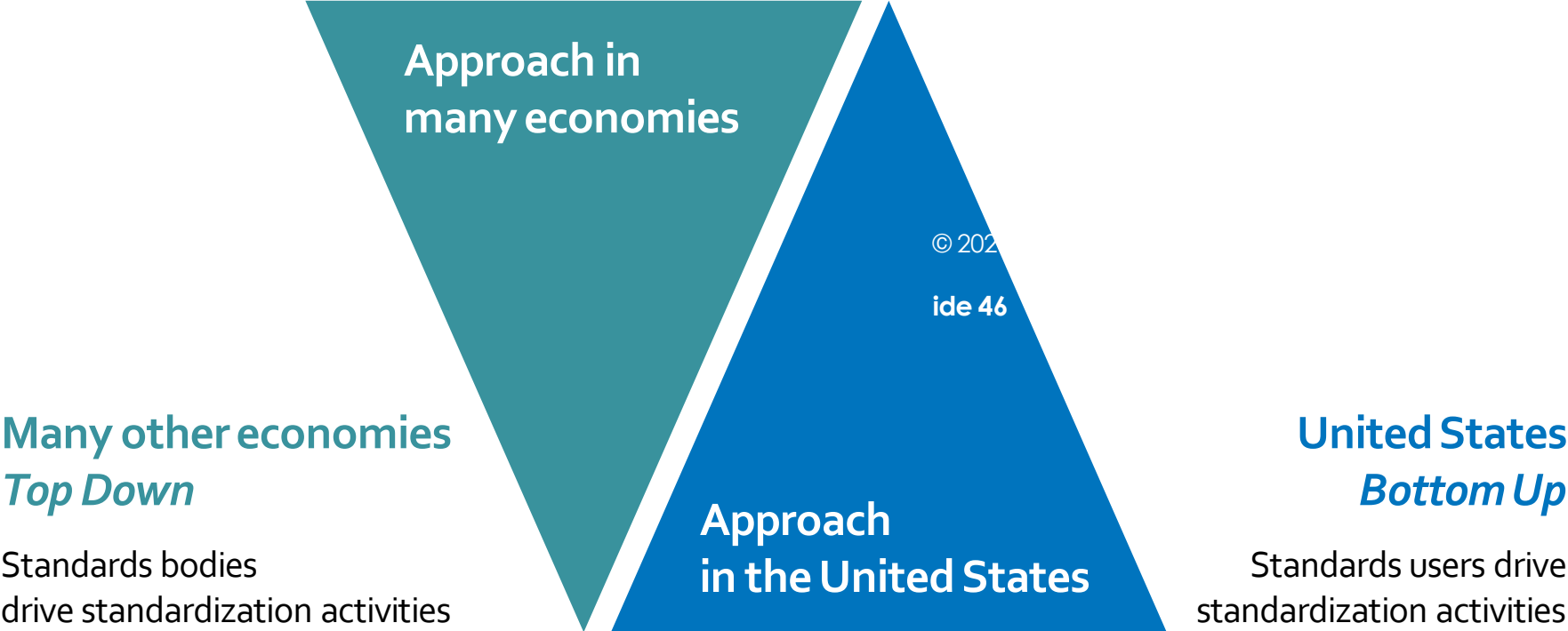
- ◆ Key provisions:
  - Standards should not act as technical barriers to trade
  - Preference for international standards
  - Avoid duplication and overlap, strive for consensus
  - Publish a work program
  - Allow for a 60-day comment period
  - Take comments into account
- ◆ ANSI has accepted the CGP on behalf of its accredited SDOs.

# Code of Good Practice: Substantive Provisions

Clause	Summary
F	Use international standards as a basis, except where inappropriate or ineffective
G	Play a full part in standards development of relevant international standardizing bodies
H	Make every effort to avoid duplication of work of other standardizing bodies (national or international)
I	Preference of performance-based product requirements over design-based or descriptive characteristics
J/K (P)	Publication of a work programme every 6 months
L/M/N	Allow public comment period of at least 60 days for draft standards; provide copy of draft standard upon request; take comments into account and reply promptly to other signatories to the Code
O	Promptly publish standards once adopted
Q	Afford opportunity for consultation on the operation of the Code

# U.S. Standardization System

comparison with many other economies



# U.S. Standards System

## guiding principles

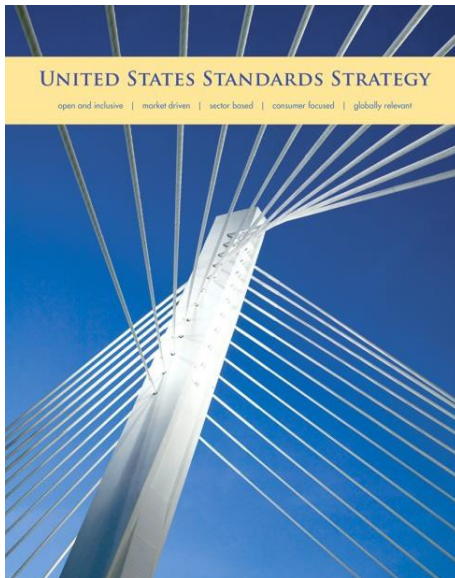
- ◆ Standards should meet societal and market needs and should not be developed to act as barriers to trade
  
- ◆ The U.S. endorses the globally accepted standardization principles of the World Trade Organization Technical Barriers to Trade Agreement
  - Transparency
  - Openness
  - Impartiality
  - Effectiveness and relevance
  - Consensus
  - Performance-based
  - Coherence
  - Due process
  - Technical Assistance
  - Flexible
  - Timely
  - Balanced



# U.S. Standards and Conformity Assessment System

reliable – flexible – responsive

- ◆ Market driven
- ◆ Flexible and sector-based
- ◆ Industry-led and government-supported



This system is designed to . . .

- ◆ Support a broad range of stakeholder engagement
- ◆ Address emerging priorities and new technologies
- ◆ Allow stakeholders to find the solutions that best fit their respective needs

As defined in the *United States Standards Strategy*

[www.us-standards-strategy.org](http://www.us-standards-strategy.org)



# U.S. Standards & Conformity Assessment System

## the public-private partnership

- ◆ No single government agency has control over standards
  - Each agency determines which standards meet its needs
- ◆ **National Technology Transfer and Advancement Act (NTTAA)** — Public Law 104-113
  - Encourages each government agency to seek existing private-sector standards that are appropriate for its purpose and mission



# ANSI GRP document in Support of Reducing TBTs through

## Appendix

### Elements of Good Regulatory Practices from APEC<sup>4</sup> and USMCA<sup>5</sup> texts:

1. Ensuring transparency and stakeholder involvement in the development of standards, technical regulations and conformity assessment procedures:
  - a) Producing regulatory forecasts.
  - b) Maintaining a National Register of existing regulations.
  - c) Publishing a proposed regulation for public comment.
  - d) Publishing evidence or regulatory analysis that supports a proposed regulation.
  - e) Providing a reasonable time period for public comment on a proposed regulation and making such comments publicly available.
  - f) Taking into account and responding to public comment on a proposed regulation.
  - g) Publishing final regulations and ensuring a reasonable period for the entry into force of regulations.
  - h) Allowing for any interested person to submit to a regulatory authority written suggestions for the issuance, modification, or repeal of a regulation.
2. Maintaining internal processes or mechanisms that provide for consultation, coordination, and review among domestic authorities in the development of regulations, including for the purposes of ensuring consistency with international trade agreements and avoiding unnecessary burdens and duplication.
3. Using evidence-based decision-making and regulatory analysis:
  - a) Relying on valid, reliable data and sound science.
  - b) Placing risk assessment and risk management at the core of regulatory decision-making.
  - c) Using evidence-based decision-making.
  - d) Assessing the impact of regulations, including conducting Regulatory Impact Assessments (RIAs).
    - i. Considering benefits and costs of the selected and other feasible alternatives, including the relevant impacts (such as economic, social, environmental, public health, and safety effects) as well as risks and distributional effects over time, recognizing that some costs and benefits are difficult to quantify or monetize;
4. Using international standards (as defined in the WTO/TBT Committee Decision) as the basis for regulations.
5. Leveraging international conformity assessment mechanisms.
6. Providing for independent judicial review of regulation.
7. Undertaking retrospective review of regulations for possible modification or repeal.

# ANSI's Web-Based Information Tools



- ◆ ANSI Essential Requirements: [www.ansi.org/essentialrequirements](http://www.ansi.org/essentialrequirements)
- ◆ Summary of ANS process steps: [www.ansi.org/anskeysteps](http://www.ansi.org/anskeysteps)
- ◆ Lists of proposed and approved American National Standards: [www.ansi.org/asd](http://www.ansi.org/asd)
- ◆ ANS Value Brochure: [www.ansi.org/ansvalue](http://www.ansi.org/ansvalue)
- ◆ ANSI Standards Action (weekly information about proposed and approved ANS): [www.ansi.org/standardsaction](http://www.ansi.org/standardsaction)
- ◆ Online and in-person training options: [www.standardslearn.org](http://www.standardslearn.org)
- ◆ **ANSI Good Regulatory Practices Document in Support of Reducing Technical Barriers to Trade through International Standardization: [ANSI GRPs document 2019 JUNE.pdf](#)**

For More Information

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# GRP Implementation and Project Country Initiatives

## *(External Session)*

- *Presentations by National Standards Bodies*

- Jessica Roop, Senior Manager, International Development, American National Standards Institute, United States
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INMETRO

# GRP Implementation and Project Country Initiatives: a view from the Standardization.

JORGE CAJAZEIRA, Ph.D.



**USAID**  
FROM THE AMERICAN PEOPLE



American National Standards Institute



**AdvaMed**  
Advanced Medical Technology Association

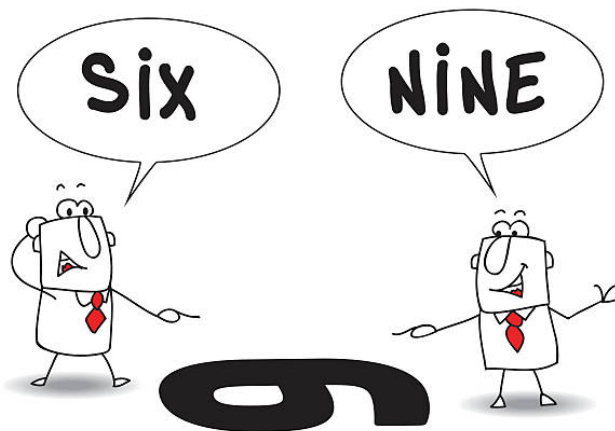


COALICIÓN INTERAMERICANA PARA LA  
**CONVERGENCIA  
REGULATORIA**  
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA  
**CONVERGÊNCIA  
REGULATÓRIA**  
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR  
**REGULATORY  
CONVERGENCE**  
MEDICAL TECHNOLOGY SECTOR

# How the world sees us



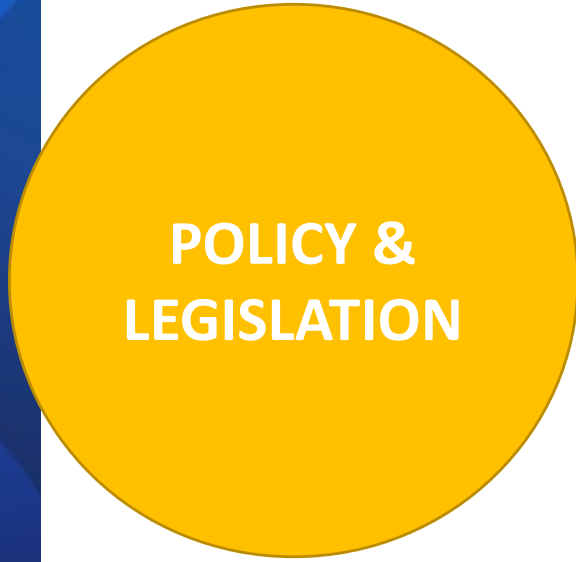
Agro Brazilian feeds 1 billion people, taking into account only the production of soy, corn, wheat, barley and rice

**BRAZILIAN AGRIBUSINESS**  
**FEEDING THE WORLD.**  
**RESPECTING THE PLANET**

**How we would like to be seen**



**Forest Area::**  
**Brazil 56.1%**  
**Russia 49,4%**  
**Canada 49.2 %**  
**USA 33,8%**  
**China 21.8%**



create the **policy framework** and set legal requirements, e.g. for product safety, occupational health and safety, and environmental protection



bring together stakeholders to specify the details that enable industry to meet the **essential requirements**



# ABOUT ABNT

- Founded in 1940;
- Private, non-profit and public utility organization;
- **National Forum for Standardization (unique);**
- Representative of Brazil at ISO, IEC, COPANT and AMN (International and regional standardization bodies);
- Responsible for the elaboration of Brazilian National Standards (ABNT NBR);
- Certification body for products, services, systems and environmental labeling;
- Signatory to the Code of Good Practices in Standardization of the World Trade Organization (OMC).

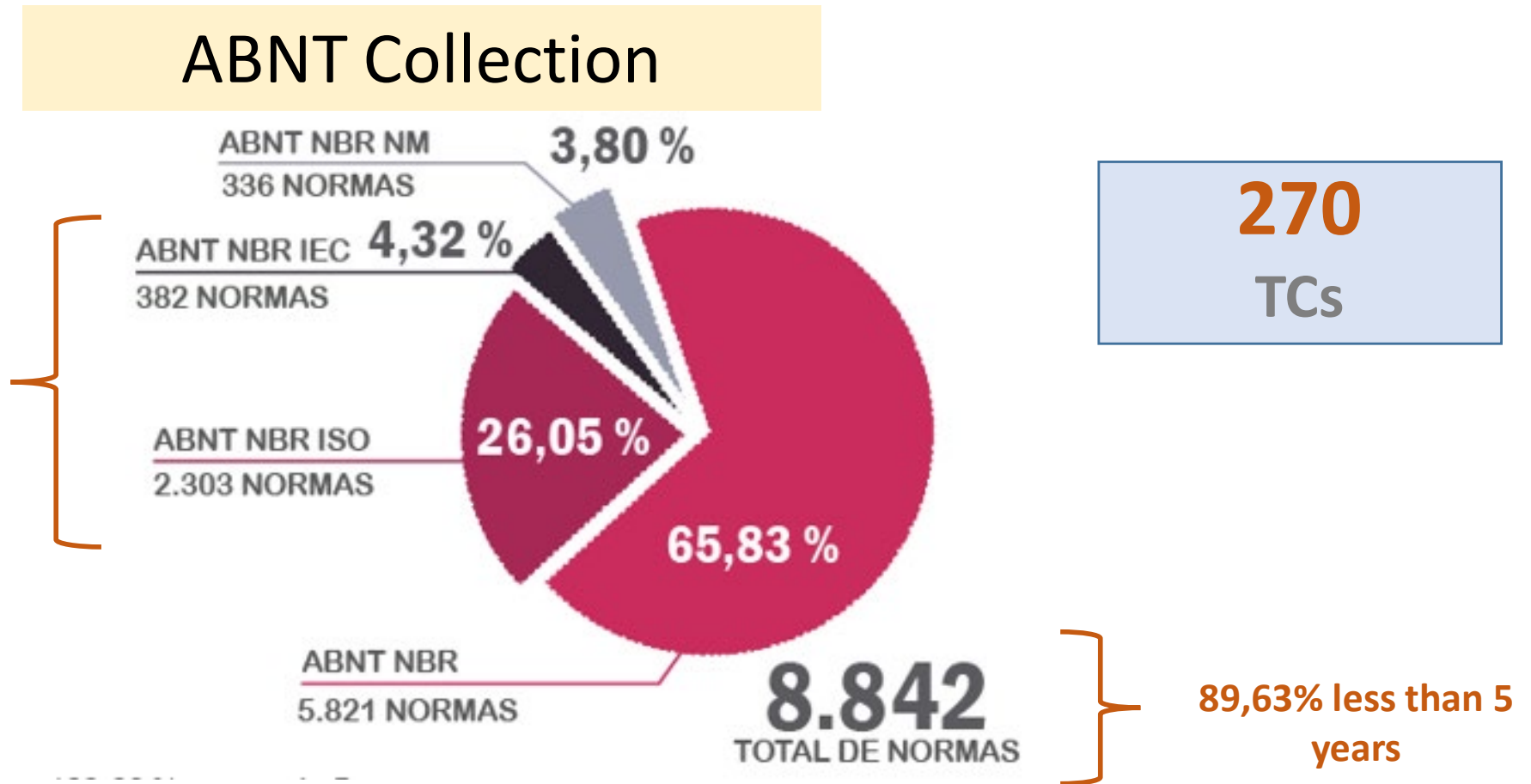


# ABNT's COLLECTION OF STANDARDS



## Numbers

30,37%  
International  
Standards



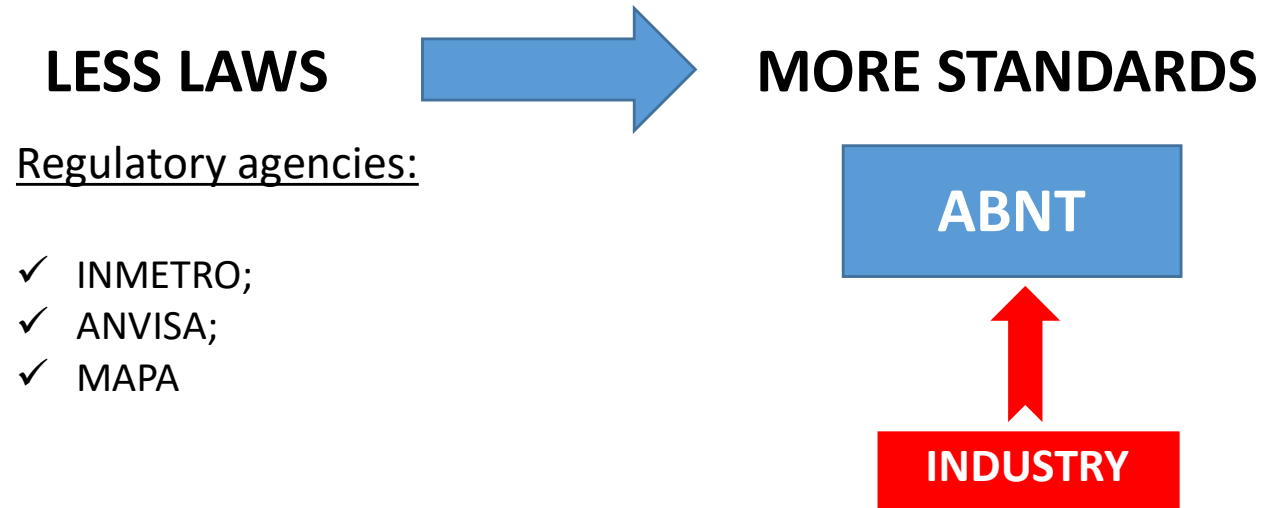
# BRAZILIAN INTERNATIONAL STANDARDIZATION STRATEGY



# CURRENT CHALLENGE

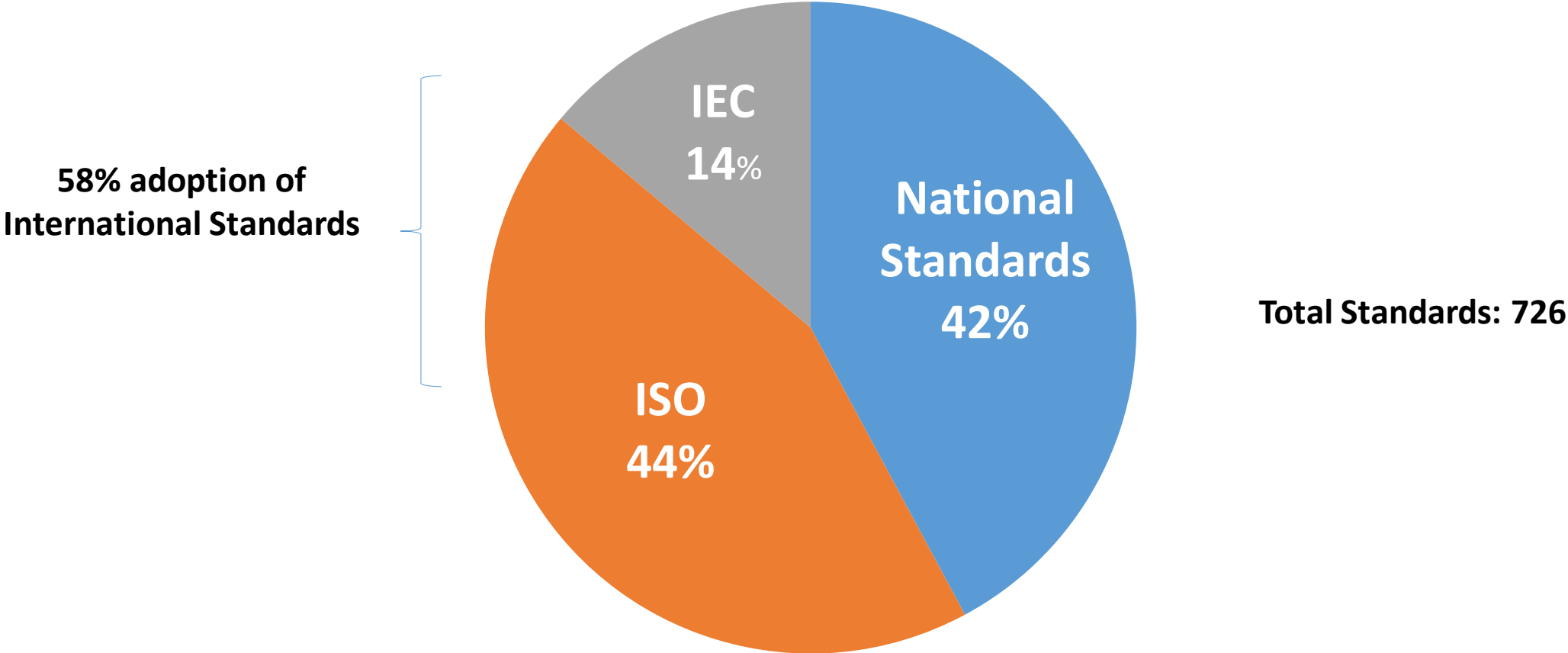
## ➤ Law 13.874 – Economic Freedom

- Decree 10.229:2020
- It establishes the conditions for citizens to develop products and services when infra-legal standards are outdated in relation to internationally consolidated technological knowledge, as long as it is not restricted by law;
- Decreased State intervention and presence in private activities;
- Clearer rules to increase competitiveness;
- Organizations accepted as international standards: ISO, IEC, ITU, Codex Alimentarius, OIML - International Organizations of Legal Metrology.



# TECHNICAL COMMITTEE DENTAL-MEDICAL-HOSPITAL

## STANDARDS



# REGULATORY MODEL

- 📣 The regulatory model has rules in line with the **best international regulatory** and inspection practices, compatible with the **Economic Freedom Act**.
- 📣 In this model, among its provisions, the **need for risk analysis** stands out to support the decision on which document should be prepared.

If it assesses medium or low risk, it is up to ABNT to prepare a technical standard.



If the analysis points to a high risk, a technical regulation issued by the Brazilian government is applicable, which is mandatory.

# REGULATORY MODEL

## THE ROLE OF TECHNICAL STANDARDS

- Self-regulation of society by society itself
- Alignment with the government's new economic freedom policy
- Technological innovation and speed in economic development
- Interaction between technical standards and technical regulations
- Agility in having normative references aligned with the state of the art
- Participation in the development of international standards
- Speed in publishing and revising standards

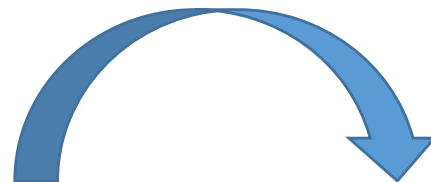


With the aim of collaborating with the global fight against the Coronavirus pandemic, ABNT made available, free of charge and unrestricted, the seven standards mentioned in Resolution RDC 356/2020, of the National Health Surveillance Agency (Anvisa), related to the manufacture, import and acquisition of medical devices identified as priorities for use in health services.

# IMPORTANCE OF STANDARDIZATION

Standardization, as an activity of natural selection, which aims to simplify an activity, which would otherwise become more complex, allows, among others:

- Determine the appropriate level of quality, safety, compatibility, performance, environmental impact for products, services, methods and processes;
- Create national and international standards that specify how things should be done;
- Provide competitive basis for market leveling;
- Disseminate and improve business practices;
- Access to the market and international trade;



**ABNT PR  
1002**

Baseada no Documento  
AFNOR SPEC S76-001



**Máscaras de proteção  
respiratória de uso  
não profissional**

**Guia de requisitos básicos  
para métodos de ensaio,  
fabricação e uso**



- ☺ From Brazil's point of view, it is not difficult to achieve **regulatory convergence from a standardization point** of view because **58% of the standards are already international adoptions.**
- ☺ We are members of these entities (ISC IEC) and our policy is to **adopt international standards** as set out in the Economic Freedom Act.
- ☺ National Forum for Standardization **(single).**



# Thank you!

Jorge Cajazeira

Head of international Affairs

[cajazeira@abnt.org.br](mailto:cajazeira@abnt.org.br)

- ✓ **One Standard**
- ✓ **One Test**
- ✓ **Accepted everywhere**



Facebook

ABNT Normas Técnicas



Twitter

@abntoficial



LinkedIn

ABNT



Youtube

abntweb



Instagram

ABNT\_oficial

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**Implementación de  
MDRC**

**Experiencia de  
ICONTEC**



# ¿Quiénes somos?



# ¿Quiénes somos?

Consejo Directivo

Sector  
Privado

## GOBIERNO MIXTO

**10 miembros**

Organizaciones

Sector  
Público

**5 miembros**

Representantes de los ministerios:

- ✓ Comercio, Industria y Turismo
- ✓ Agricultura
- ✓ Minas y Energía
- ✓ Transporte
- ✓ Salud y Protección Social

Aporte  
económico

**Sector Privado**

# ¿Quiénes somos?

## Unidades Técnicas



**Normalización**



**Educación**



**Evaluación de la Conformidad**

- ✓ Certificación Sistemas de Gestión
- ✓ Certificación PPS
- ✓ Inspección
- ✓ Validación y Verificación
- ✓ Acreditación Salud



**Laboratorios de Metrología**



**Cooperación y Proyectos Especiales**

# Rol como Asesores del Gobierno Nacional (Decreto 1595/2015)

**Acompañamiento  
Reguladores,  
elaboración RT y  
Legislación relacionada**



**Gestión Comisiones  
Intersectorial de la  
Calidad y de  
Reglamentación  
Técnica**

**Soporte en  
compromisos del  
país en Acuerdos  
Comerciales sobre  
Obstáculos  
Técnicos al  
Comercio OTC**



# Algunas de nuestras cifras

6.835 Normas vigentes  
276 Comités Técnicos de normalización

## 421 Proyectos en proceso

Sector	Cantidad
01 - Agro y Alimentos	54
02-1 - Industria (Otros)	32
02-2 - Industria (Químico)	53
02-3 - Industria (Metalurgia)	1
02.4 - Industria (Maquinaria y equipos)	50
03 - Minería, Petróleo y Gas	4
04 - Energético	7
05 - Construcción e ingeniería	89
06 - Educación	1
07 - Logística y transporte	13
08 - Turismo y gastronomía	3
09 - Administración organizacional y pública	14
10 - Salud	39
11 - Transformación digital	23
12 - Sostenibilidad	27
13 - Ciencia y tecnología e innovación	11
<b>Total</b>	<b>421</b>

## 441 NCE (Nuevos casos de estudio)

Sector	Cantidad
01 - Agro y Alimentos	48
02-1 - Industria (Otros)	29
02-2 - Industria (Químico)	25
02-3 - Industria (Metalurgia)	24
02.4 - Industria (Maquinaria y equipos)	63
03 - Minería, Petróleo y Gas	11
04 - Energético	19
05 - Construcción e ingeniería	123
06 - Educación	6
07 - Logística y transporte	16
08 - Turismo y gastronomía	0
09 - Administración organizacional y pública	16
10 - Salud	9
11 - Transformación digital	22
12 - Sostenibilidad	29
13 - Ciencia y tecnología e innovación	1
<b>Total</b>	<b>441</b>



# Estrategia de normalización (Metodología ISO)

Relacionamiento  
con la sociedad

Descripción : Estrategia Normalización Anual 2021 - ICONTEC

Año : 2021

Sector/Producto	Impacto PIB	Impacto Exportaciones	Impacto Importaciones	Planes de Desarrollo	Importancia no económica	Promedio Parcial	Evaluación Stakeholders	Promedio Final
02-2.05 Plástico	2	2	2	1	1	1,00	2,00	1,50
02-2.05.01 Envases, empaques y embalajes	2	2	2	1	2	1,00	2,00	1,50
02-2.05.02 Aspectos ambientales de plásticos	5	5	5	1	1	1,00	2,00	1,50
02-2.05.03 Materias primas	3	4	3	1	2	1,00	2,00	1,50
02-2.05.04 Productos de plástico	3	3	3	1	2	1,00	2,00	1,50
02-2.05.05 Otros aspectos relacionados con plásticos	4	3	3	1	2	1,00	2,00	1,50
02-2.06 Pinturas y productos afines	2	4	4	1	4	1,00	2,00	1,50
02-2.06.01 Pinturas y productos afines de uso arquitectónico	2	4	4	1	3	1,00	2,00	1,50
02-2.06.02 Pinturas y productos afines de uso industrial	2	4	4	1	3	1,00	2,00	1,50
02-2.06.03 Pinturas y productos afines para otros usos	2	4	4	1	3	1,00	2,00	1,50
02-2.07 Productos de caucho	5	4	3	5	3	1,00	2,00	1,50

Bienvenido a ICONTEC e-conecta

Buscar

INFORMACIÓN GENERAL ESTRATEGIA SOLICITUD DE ESTUDIO COMITÉS MI REGISTRO CALENDARIO SALIR

INICIO > ESTRATEGIA

**!** Su aporte es muy importante para la definición de los temas estratégicos en los que se debería enfocar la normalización en el país, por favor califique los sectores y subsectores de su interés. El resultado de esta calificación ayudará a definir los temas a normalizar en nuestros comités técnicos.

Para evaluar un tema de clic en la flecha que se encuentra a la izquierda de los sectores, se mostrarán los subsectores y temáticas que lo componen, seleccione aquellos que son de interés para su organización, de clic en continuar y realice la evaluación de los temas seleccionados. Si selecciona un sector de segundo nivel, esta calificación se asumirá para los de tercer nivel que le correspondan. Si quiere evaluar un sector de tercer nivel en particular deberá seleccionarlo.

13.01 - Ciencia y Tecnología

Relevancia

No calificar Ninguna Baja Media Alta Muy alta

13.02.01 - Gestión de la innovación

Relevancia

No calificar Ninguna Baja Media Alta Muy alta

13.02.02 - Economía colaborativa

Relevancia

No calificar Ninguna Baja Media Alta Muy alta

13.02.03 - Innovación tecnológica

Relevancia

# Sectores

Relacionamiento  
con la sociedad

01 - AGRO Y ALIMENTOS



02.1 - INDUSTRIA (OTROS)



02.2 - INDUSTRIA (QUÍMICO)



02.3 - INDUSTRIA (METALURGIA)



02.4 - INDUSTRIA (MAQUINARIA Y EQUIPOS)



03 - MINERÍA, PETRÓLEO Y GAS



04 - ENERGÉTICO



05 - CONSTRUCCIÓN E INGENIERÍA



06 - EDUCACIÓN



07 - LOGÍSTICA Y TRANSPORTE



08 - TURISMO Y GASTRONOMÍA



09 - ADMÓN ORGANIZACIONAL Y PÚBLICA



10 - SALUD



11 - TRANSFORMACIÓN DIGITAL



12 - SOSTENIBILIDAD



13 - CIENCIA Y TECNOLOGÍA E INNOVACIÓN



# e-conecta



## La Normalización a un clic



e-conecta



Participar en la normalización nacional aporta al crecimiento del País y ahora lo puedes hacer de manera **mas activa** por medio de la plataforma **e-conecta**.



Te invitamos a realizar tu registro para poder:

Participar en la gestión de los **proyectos de normalización** y las **consultas públicas** de tu interés

Participar en la **definición de la estrategia** nacional de normalización

Tener un **manejo colaborativo** de información de los comités

Solicitar nuevos **temas para estudio**

**HAZ CLIC AQUÍ Y REGÍSTRATE**

Una normalización mas ágil y colaborativa



EL DESARROLLO DE E-CONECTA CONTÓ CON EL APOYO DEL PROYECTO



# PAGINA PRINCIPAL

<https://econecta.icontec.org>

**Aquí encontrará los documentos en consulta pública, agrupados por sector, comité, ICS.**

The screenshot shows the main page of the ICONTEC e-conecta website. At the top left is the logo for 'e-conecta' and 'icontec'. To the right, it says 'Bienvenido a ICONTEC e-conecta'. There is a search bar with the text 'Buscar' and a magnifying glass icon. Below this is a blue navigation bar with the following items: a home icon, 'INFORMACIÓN GENERAL', 'ESTRATEGIA', 'SOLICITUD DE ESTUDIO', 'COMITÉS', 'MI REGISTRO', 'CALENDARIO', 'INGRESAR' (with a right arrow), and a help icon (question mark). The main content area has a blue header for 'PROYECTOS EN CONSULTA'. Below this, there is a paragraph: 'Aquí encontrará los documentos que se encuentran en estudio para que opine sobre ellos. Con su opinión aporta al desarrollo de la normalización y a la competitividad del país.' There are three tabs: 'Macro-Sectores' (selected), 'Comités Técnicos', and 'ICS'. Under 'Macro-Sectores', there is a list of items with checkboxes on the right: '01 Agro y alimentos - (12 Consulta(s))', '02-2 Industria (Químico) - (7 Consulta(s))', '02-4 Industria (Maquinaria y equipos) - (15 Consulta(s))', '03 Minería, Petróleo y Gas - (3 Consulta(s))', '04 Energético - (1 Consulta(s))', '05 Construcción e ingeniería - (14 Consulta(s))', and '06 Educación - (1 Consulta(s))'. To the right of this list is a large image of a target with several arrows hitting the bullseye. Below the image is the heading 'Estrategia' and a paragraph: 'La estrategia de normalización guía el rumbo del país en esta materia. Lo invitamos para que con su opinión contribuya a la definición de este importante documento.'

# Adopción de normas internacionales

La adopción de normas internacionales responde a una estrategia País para ser mas competitivos y facilitar el comercio (Decreto 1595/2015)

Somos miembros de ISO, IEC, y tenemos acuerdos con Organismos de Normalización como:  
ASTM, SAE, UL, NEMA, AATCC, ICC, INTECO, NYCE, UNE, SAC, INN,

# Adopción de normas internacionales

## BENEFICIOS

Se facilita el comercio y se considera como un mecanismo importante para apoyar la eliminación de barreras innecesarias al comercio.

Mejora de la competitividad de los sectores y la eficiencia económica

Facilita el acceso a los mercados (mediante la armonización de los requisitos y las prácticas de evaluación de la conformidad) y el establecimiento y funcionamiento de redes de la cadena de suministro

Inserción del país en mercados regionales e internacionales

Optimización de costos para los reguladores

Facilita a los reguladores el cumplimiento de las Buenas Prácticas Regulatorias

Permite cumplir las obligaciones del acuerdo de OTC

Permite acceder a información sobre mejores prácticas y sobre nuevas tecnologías y su adopción y contribuye a la evolución técnica de los sectores

Permiten conocer prácticas que ya han sido probadas y aplicadas en el mundo

Optimización de costos y tiempos en el proceso de normalización



# Adopción de normas internacionales

## CONTRAS

Al tener dificultad de participar en los procesos de normalización internacional no se logra que se consideren las necesidades propias del país

Cuando la norma internacional no ha considerado lo aplicable al país, conlleva resistencia por parte de los fabricantes nacionales quienes pueden quedar fuera del mercado o incluso no ingresar

Desbalance entre el desarrollo tecnológico del país y el nivel incluido en la Norma internacional

Costos altos de los derechos de autor de algunos Organismos de Normalización para poder adoptar sus normas como normas nacionales

Imposibilidad de usar algunas normas internacionales para adoptarlas como normas nacionales o imposibilidad de incluir consideraciones particulares del país ya que se exige que se use la norma internacional directamente. Se genera una ventaja competitiva y puede conllevar a crear OTC

Normas internacionales que tienen en cuenta consideraciones particulares de solo algunas regiones (antropomórficas, clima y ubicación geográficas)

## Iniciativas para fomentar la participación y difusión de las normas



**Facilidad de participación en la proposición de temas y su priorización, y en el proceso de normalización mediante herramientas tecnológicas (e-conecta)**

**Relacionamiento con entidades públicas y privadas para detectar necesidades de normalización y de apoyo a la implementación de políticas públicas y de medidas de regulación**

**Plan de Normalización**

**Facilidad de acceso para la consulta y compra de Normas:**  
Sala de consulta Virtual  
Plataforma de consulta en cada entidad 7/24 (e-collection)  
Normas en formato digital (e-book)  
Plataforma de e-commerce

## Iniciativas para fomentar la participación y difusión de las normas



**Campañas de marketing en redes sociales sobre las normas aplicables a un sector o temas transversales**

**Desarrollo y participación en foros, charlas y eventos ( presenciales y virtuales)**

**Desarrollo de material como videos y folletos para promocionar normas en particular**

**Proyectos conjuntos con entidades para el desarrollo y aplicación de las normas en procesos de evaluación de la conformidad o de mejora de un sector (ej. Ganadería sostenible, embarcaciones, continuidad de negocio)**

## Iniciativas para fomentar la participación y difusión de las normas



Explorar y desarrollar nuevas herramientas tecnológicas para facilitar el desarrollo de las normas ( hacer normas on-line)

Inclusión de las normas en nuevas plataformas:  
Redes de bibliotecas  
Comercio electrónico

Normas vs. Servicio de Normas: Normas para responder a una necesidad

Acuerdos con otros organismos y entidades para promocionar la consulta y uso de las normas

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# Promoting the Implementation of Good Regulatory Practices at the cross-sectoral level and Regional Cooperation in Latin America

General Bureau of Technical Regulations And Standards (DGN)

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**ECONOMÍA**  
SECRETARÍA DE ECONOMÍA

**DGN**  
DIRECCIÓN GENERAL  
DE NORMAS

Los Angeles, California  
June 8th, 2022



**2022** *Ricardo Flores*  
*Año de Magón*  
PRECURSOR DE LA REVOLUCIÓN MEXICANA

# Context of the new legislation on Quality Infrastructure in México

## Evolution

### ✓ First Stage **1905-1928**

The Law of Weights and Measures did not regulate standardization, however, a National System of Measurement Units was formally adopted.

### ✓ Second Stage **1941-1961**

First with the Law of Industrial Standards and later with the General Law of Standards, Weights and Measures, powers were granted to the Secretariat of Industry and Commerce to develop a standardization system for the first time in Mexico. This precarious model was addressed exclusively to aspects of the Industry, establishing Nomenclature, Quality and Operation Standards.

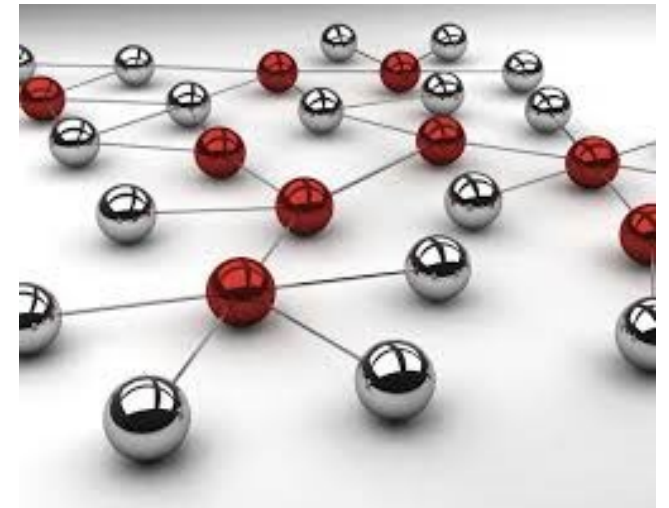
### ✓ Third Stage **1988-1997**

With the Federal Law on Metrology and Standardization, Mexico faced the transition from a closed economy scheme to a policy of economic liberation, which affected the construction of the model.



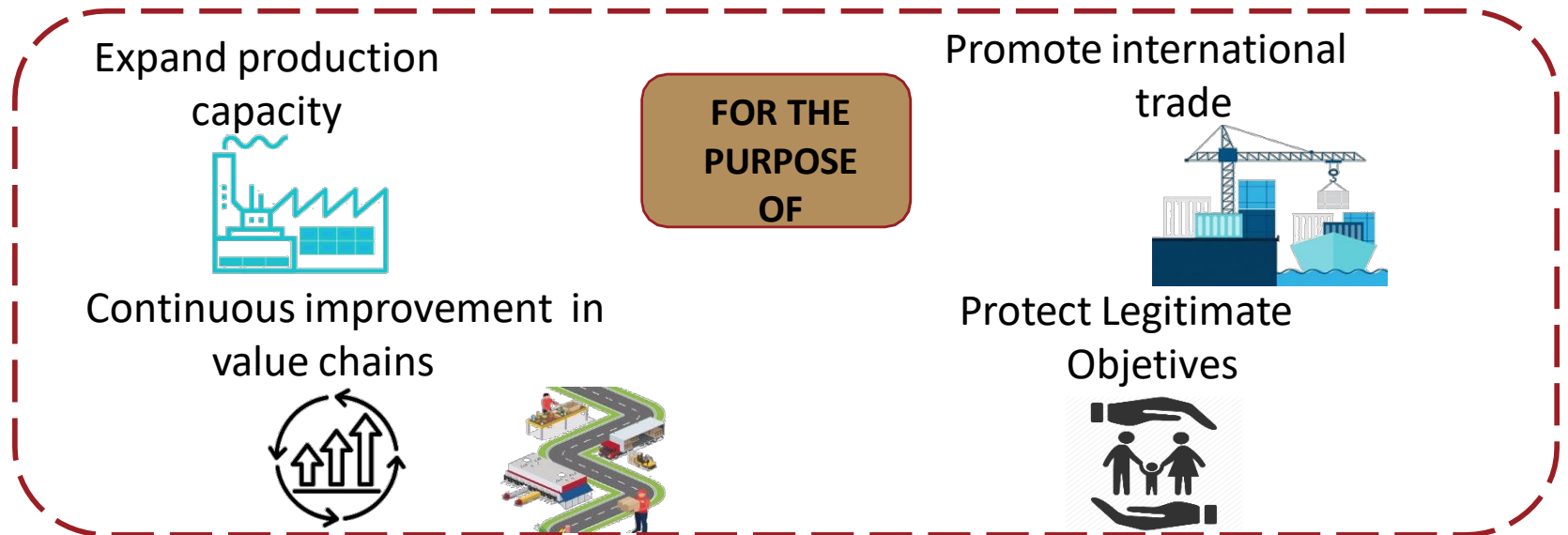
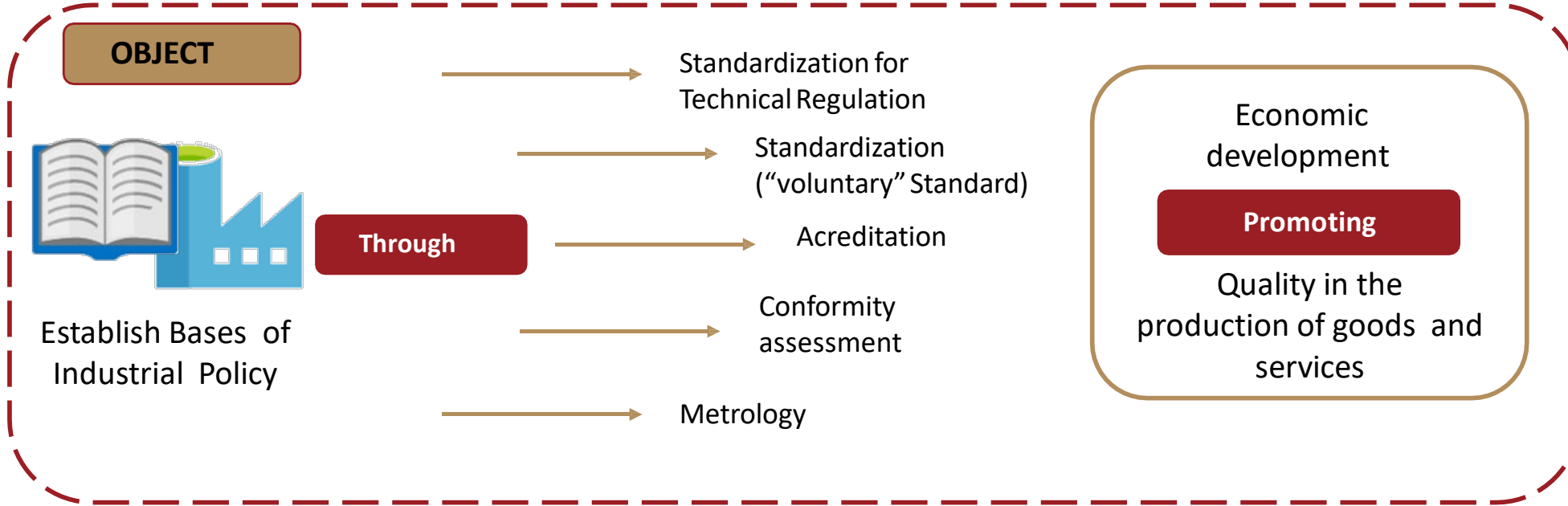
# Quality Infrastructure Law

- Published on July 1st, 2020;
- Establish the basis for Industrial Policy;
- Promote the concurrence of all sectors in standardization activities;
- Promote the quality of goods and services;
- Mitigate the risk of affecting Legitimate Objectives of Public Interest;
- Promote International Trade;
- Create physical and digital Infrastructure for conformity assessment; and
- Establish the coordination and collaboration mechanisms between the members of the system.
- Establishes market surveillance procedures as a new concept in the legal framework





# Quality Infrastructure Law



# System rules, policies and principles



- Ley sobre Pesas y Medidas (1905)
- Ley de Normas Industriales (1945)
- Ley General de Normas y de Pesas y Medidas (1961)
- Ley Federal sobre Metrología y Normalización (1992)
- Ley de Infraestructura de la Calidad (2020)



- Ley de Planeación
- Plan Nacional de Desarrollo
- Programas Sectoriales de Economía
- Programa Nacional de Infraestructura de la Calidad (antes de Normalización)



- Tratados Internacionales (T-MEC, TIPAT, TLCUEM)
- Acuerdo sobre Obstáculos Técnicos al Comercio (OMC)
- Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias
- Normas Internacionales (ISO, entre otros)

# General principles of the System

Planning	Efficiency	Quality
Transparency	Agility	Coherence
Integrity	Maximum publicity	Sustainability
Certainty	International best practices	Inclusion
	Measurement traceability	

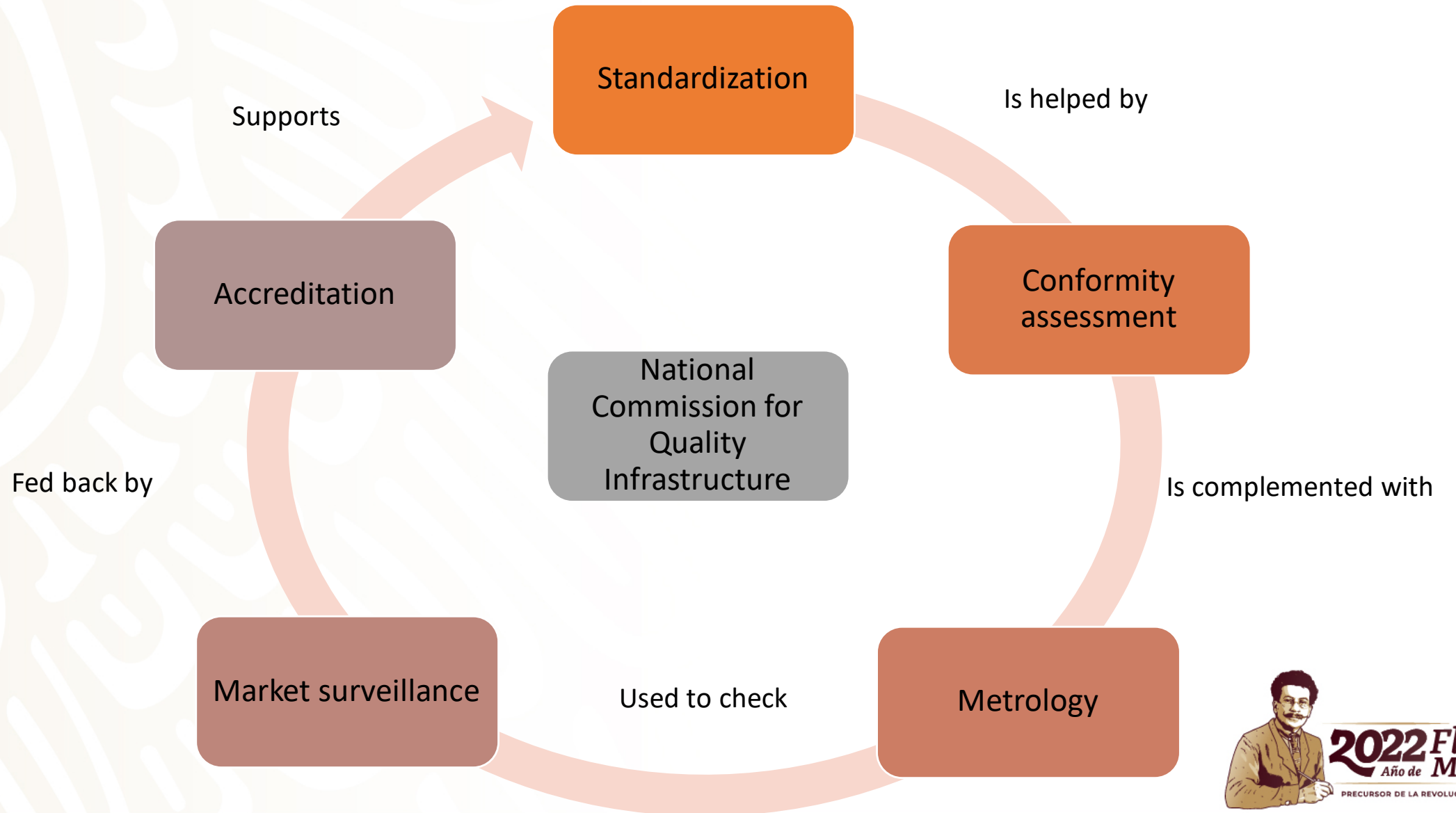


# Legitimate Objectives of Public Interest

- ✓ Protection and **promotion of health**
- ✓ Protection of physical integrity, health, and **life of workers in the workplace;**
- ✓ **Protection of organic production**, of genetically modified organisms, health and food safety, aquaculture, fisheries, animals and plants;
- ✓ **Food safety;**
- ✓ **Education and culture;**
- ✓ **Touris services;**
- ✓ **National security;**
- ✓ Protection of the environment and **climate change;**
- ✓ Use and exploitation of **natural resources;**
- ✓ **Healthy rural and urban development;**
- ✓ **Public works and services;**
- ✓ **Road safety;**
- ✓ Protection of the **right to information;**
- ✓ Protection of **denomination of origin**, and
- ✓ **Any other public need**, in terms of the applicable legal provisions.



# Pillars of Quality Infrastructure



# Change of model

## Previous model:

- Sparse system
- Slow and complex processes
- Lack of governing body
- Mix of objectives and attributions

- 1992

2020 +

## Current model:

- The State as rector
- Planning and programming
- Concurrence and coordination with the sectors
- Information Technology Support
- Market Surveillance

# General Bureau of Technical Regulations And Standards (DGN)

- Design, promote and disseminate public policies and strategies in the areas of technical regulations, standardization, accreditation, conformity assessment, market surveillance and metrology, both nationally and internationally.
- To carry out actions and programs to promote the quality of products and services for the promotion and disclosure of standardization and to coordinate the work carried out by National Standardization Bodies, among others.
- Operate as Mexico's enquiry point for standardization.

**DGN**  
DIRECCIÓN GENERAL  
DE NORMAS



# Federal Standardizing Authorities

## ECONOMÍA

SECRETARÍA DE ECONOMÍA

## SADER

SECRETARÍA DE AGRICULTURA  
Y DESARROLLO RURAL

## SALUD

SECRETARÍA DE SALUD

## SEMARNAT

SECRETARÍA DEL MEDIO AMBIENTE Y  
RECURSOS NATURALES



## SEDATU

SECRETARÍA DE DESARROLLO  
AGRARIO, TERRITORIAL Y URBANO

## TURISMO

SECRETARÍA DE TURISMO

## STPS

SECRETARÍA DE TRABAJO  
Y PREVISIÓN SOCIAL



## SENER

SECRETARÍA DE ENERGÍA

## PROFECO

PROCURADURÍA FEDERAL  
DEL CONSUMIDOR



## AFAC

AGENCIA FEDERAL  
DE AVIACIÓN CIVIL



## ARTF

AGENCIA REGULADORA  
DEL TRANSPORTE  
FERROVIARIO



## ASEA

AGENCIA DE SEGURIDAD,  
ENERGÍA Y AMBIENTE

## CONUEE

COMISIÓN NACIONAL PARA EL  
USO EFICIENTE DE LA ENERGÍA

## PROFEPA

PROCURADURÍA FEDERAL DE  
PROTECCIÓN AL AMBIENTE



2022 *Ricardo Flores*  
Año de *Magón*

PRECURSOR DE LA REVOLUCIÓN MEXICANA



# National Standardization System

## DGN

DIRECCIÓN GENERAL  
DE NORMAS



ASOCIACIÓN DE NORMALIZACIÓN  
Y CERTIFICACIÓN, A.C.



# NOM Development



# NOM Development

Revisión de comentarios y elaboración del documento definitivo



Aprobación de la NOM



Dictamen final CONAMER



Información pública



CONCLUSIÓN

Aplicación e implementación



Entrada en vigor NOM



# National Commission for Quality Infrastructure

Governing Body of the **National Quality Infrastructure System**

As of January 1, 2021, the SE is responsible for directing and coordinating the activities of the **CNIC**

**CNIC**

Its integration must be adjusted in accordance with what is indicated in article 16 of the LIC

Endowed with essential responsibilities to harmonize the System in order to achieve its supreme goals: development and quality

# National Commission for Quality Infrastructure

## President:

Maximum Body of the National Quality Infrastructure System.

He permanently chairs the Ministry of Economy.

## Technical advice:

Auxiliary body of an advisory nature.

## Executive Secretary:

Coordinates and executes determinations of the CNIC.

The position falls to the General Director of Standards.

## FEDERAL ENTITIES (Undersecretaries)

- SEGOB, SSPC, SHCP, Bienestar, SEMARNAT, SENER, SCT, SADER, SEP, SSA, STPS, SE, SEDATU, SECTUR, SEMAR.

## OTHER GOVERNMENT BODIES

- CRE, CNH, ASEA, COFEPRIS, PROFEPA, CONAGUA, AFAC, ARTF, CNSNS, CONUEE, SE-SNSP, CONOCER, SENASICA, PROFECO.

## SCIENTIFIC SECTOR

- CONACYT, CENAM, Designated Institutes of Metrology.

## PRIVATE SECTOR

- Chambers, Confederations, Industrial and Commercial Associations.

## OTHER INSTITUTIONS

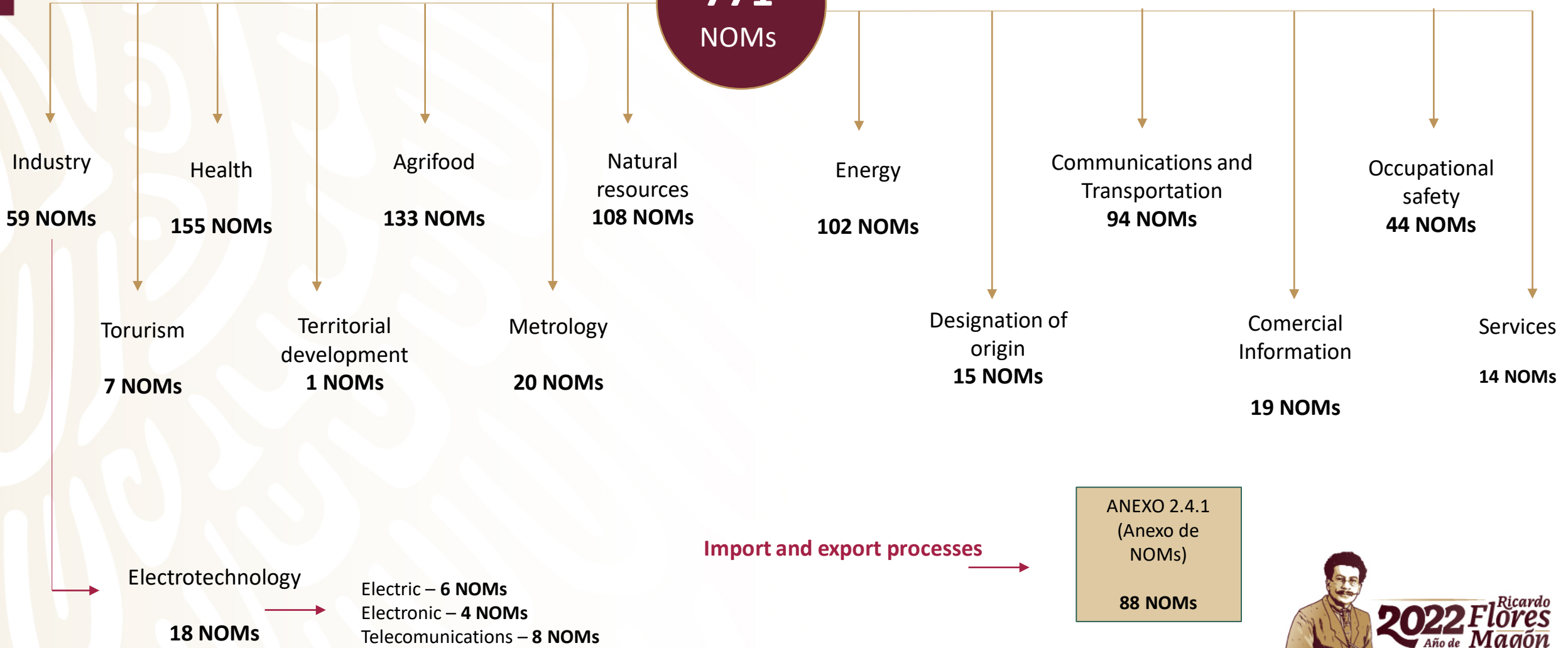
- Public and Private Academy, specialists.

## OTHER ORGANISMS

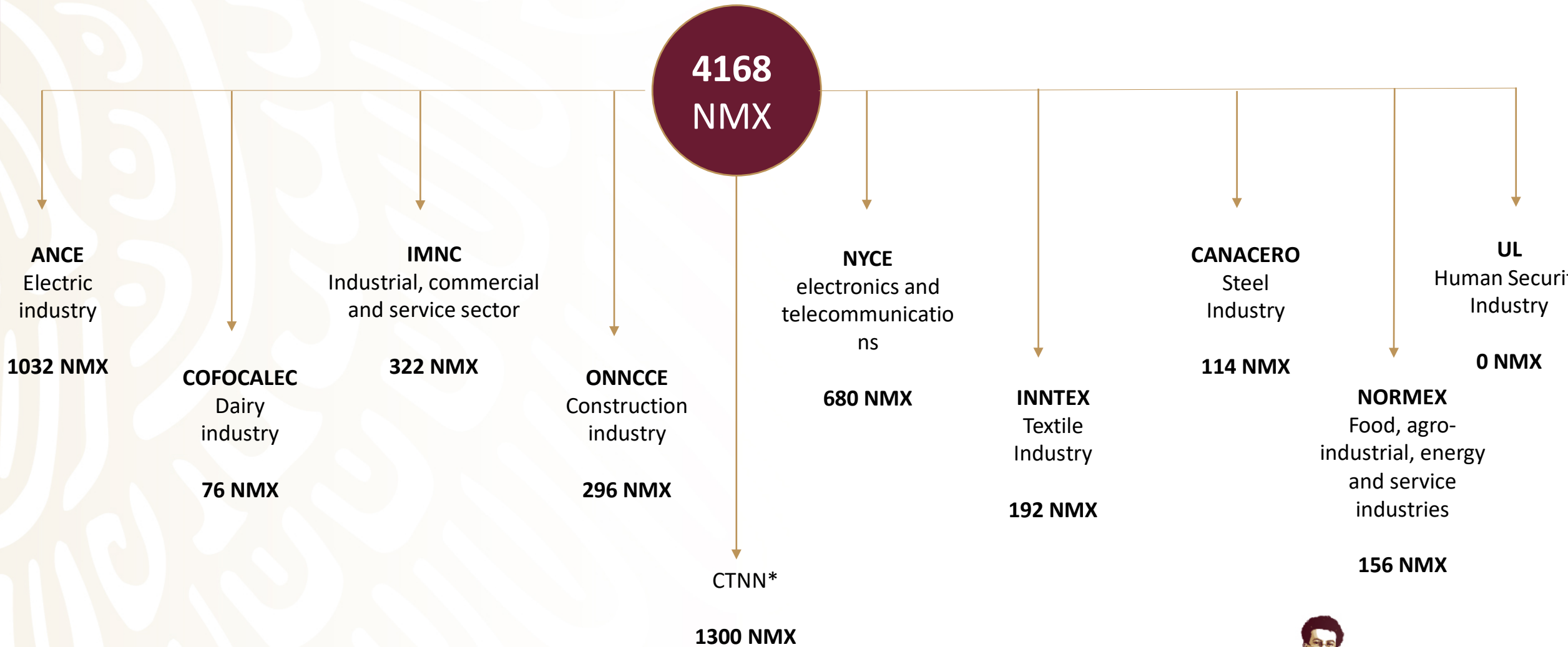
- Accreditation Entities and National Standardization Organizations.

# Mexican catalog of Technical Regulations

**771**  
NOMs



# Mexican catalog of Standards



\*CTNN: Technical Committee for National Standardization

# Infraestructura para la Evaluación de la Conformidad

## ACREDITACIONES\*

Organismos de Evaluación de la Conformidad	Enero a diciembre de 2016	Enero a diciembre de 2017	Enero a diciembre de 2018	Enero a diciembre de 2019	Enero a diciembre de 2020	Enero a diciembre de 2021	Al 30 de abril 2022	Incremento %
								2016-2022
Organismos de Certificación	90	104	242	293	365	438	456	406.67%
Unidades de Inspección	2016	2157	2573	2886	2969	3166	3215	59.47%
Laboratorios de Prueba (Ensayo)	1644	1753	1920	2053	1991	2138	2183	32.79%
Laboratorios de Calibración	673	723	793	885	993	1068	1096	62.85%
<b>Total</b>	<b>4,423</b>	<b>4,737</b>	<b>5,528</b>	<b>6,117</b>	<b>6,318</b>	<b>6,810</b>	<b>6,950</b>	<b>57.13%</b>

\* Las cifras representan al total de personas morales acreditadas como Organismos de Evaluación de la Conformidad en todas las áreas metrológicas, ramas, materias, sistemas de gestión y de producto.

Fuente: ema, al 30 de abril de 2022.





# International Cooperation

- International Electrotechnical Commission (IEC);
- International Organization for Standardization (ISO);
- Mexican-German Dialogue on Quality Infrastructure;
- Pan-American Commission for Technical Standards (COPANT); and
- Memorandums of Understanding:
  - ASTM International;
  - Underwriters Laboratories (UL);
  - National Quality Institute of Peru (INACAL);
  - Among others.



International  
Electrotechnical  
Commission



International  
Organization for  
Standardization



GLOBAL PROJECT  
Quality Infrastructure  
giz  
Deutsche Gesellschaft  
für Internationale  
Zusammenarbeit (GIZ) GmbH



COPANT



# Adapting International Standards in Mexico

## PROS

- Promotes the inclusion of Mexican experts in the development of adaptation of the International Standards
- Considers directly the domestic market according to needs of Mexico
- Facilitates application of the Standard and use of terms
- Attends specific issues identified by Mexico

## CONS

- Affects the participation for exporters by incompatibility in the requirements between national and international stages
- Sometimes may generate extra or different requirements
- Constraints the international market for importers
- Increases the implementation time in the National Quality Infrastructure System.
- Duplication of resources (national and international)



# Adopting International Standards in Mexico

## PROS

- Elimination of unnecessary technical barriers to international trade
- Facilitates comparison of the Mexican market
- Increased quantity and improved quality of information
- Harmonize with the International Quality Infrastructure Systems

## CONS

- Mexico may not have the required infrastructure
- Mexico could not be able to comply with adoptions
  - Shortage of resources
- Limitation to attend face-to-face meetings

# Challenges

- Attention and active participation in International Standardization Organizations;
- Improve communication among National Standardization Bodies to avoid duplication of work;
- Improve the implementation of regional MoUs on equivalence, mutual recognition and conformity assessment to facilitate international trade.
- Encourage meetings & materialize cooperation instruments that give concrete and measurable results;
- Implementar PLATIICA y sistematizar la información para la toma de decisiones



# Next steps

- Incorporate Mexico's needs in the work of International Standardization Bodies;
- Inclusion of SMEs, Academia and Research Institutions in the Standardization processes;
- Reducing the adaptation and adoption time of International Standards;
- Efficient use of Mexico's material and human resources;
- Strengthening Mexico's infrastructure for conformity assessment activities; and
- Encourage the participation of importers, exporters and other interested parties.



# Good Regulatory Practices adopted

- ✓ The OECD, through the 2012 Recommendation of the Council on Regulatory Policy and Governance, recognized the need for nations to work systematically to benefit from experiences, contributions to scarce resources and the alignment of the different approaches.
- ✓ Principle 12 of the Recommendation calls for “Take into account, when developing regulatory measures, all relevant international cooperation standards and frameworks in the same area and, when appropriate, the likely effects they have on third parties outside their jurisdiction”.
- ✓ Regulatory management tools (Regulatory Impact Statement, stakeholder engagement, and ex post reviews of regulation) are important entry points in the rulemaking process to take into account the international environment in the development and review of regulations.
- ✓ The main provisions related to good regulatory practices are related to planning, design, issuance, implementation and review of regulations.



# Good Regulatory Practices adopted

- ✓ Also contemplate commitments such as the publication of an annual regulation plan (**PNIC**), the importance of the central regulatory coordination bodies, transparency for interested parties through minimum periods of public consultation, conducting regulatory impact assessments, publication of regulations in official media and general access.
- ✓ The legal framework for regulatory improvement was institutionalized in the year 2000 through the reform of the Federal Law of Administrative Procedure with which the Federal Commission for Regulatory Improvement was created. With the General Law on Regulatory Improvement, in force since 2018, the National Commission for Regulatory Improvement, the entity in charge of coordinating the matter at all three levels of government, was modified.
- ✓ In this new system, a series of highly relevant elements are adopted that allow integrating the OECD recommendations, the commitments of chapter 28 of the **T-MEC** and are manifested in the processes of elaboration of regulations, the evaluation or analysis of regulatory impact, conformity assessment, verification and market surveillance.

# Good Regulatory Practices adopted

- ✓ The application of the risk-based approach starts from the Regulatory Impact Analysis since, through this tool, different impacts that the regulations could have are analyzed and the ways in which the eventual risks could be mitigated or prevented are contemplated. **Frequency-Severity Matrix. Risk analysis**
- ✓ In the Mexican Ministry of Economy, systematic ex ante evaluations are carried out through Regulatory Impact Analysis that mainly contemplate the definition of the objectives pursued by technical regulations in matters of public policy, a substantiation of the problems that concern to the legitimate objectives of public interest (through the use of quantitative, empirical, scientific and behavioral evidence) associated with inefficient or asymmetric markets, health or safety of people, the consumer, analysis of different public policy alternatives, evaluation of possible impacts on competition and foreign trade, as well as a detailed analysis of the costs and benefits that the regulations imply, in order to find the best alternative based on multi-criteria analysis, cost-effectiveness, cost-benefit, considering, in addition, qualitative elements that allow dimension properly address problems.





# Prospective of the National Quality Infrastructure System



ODS 9



Construir infraestructuras resilientes, promover la industrialización inclusiva y sostenible y fomentar la innovación



Thank you  
Raúl Romero Anaya  
Quality Infrastructure Coordinator  
[raul.romero@economia.gob.mx](mailto:raul.romero@economia.gob.mx)

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**ECONOMÍA**

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DE NORMAS



**2022** *Ricardo Flores*  
Año de *Magón*

PRECURSOR DE LA REVOLUCIÓN MEXICANA

# GRP Implementation and Project Country Initiatives (*External Session*)

- *Presentations by National Standards Bodies*

- Jessica Roop, Senior Manager, International Development, American National Standards Institute, United States
- Jorge Emanuel Reis Cajazeira, Head of International Standardization, Brazil Association of Technical Standards (ABNT), Brazil
- Monica Vivas, Standardization Director, ICONTEC, Colombia
- Daniel Trillos, Subdirector de Normalization, ICONTEC, Colombia
- Raul Romero Anaya, Quality Infrastructure Coordinator, General Directorate of Standards, Mexico

- *Presentation by INMETRO*

- Marcos Aurélio Lima de Oliveira, Coordinator of the National Quality Infrastructure Policy WG, Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO), Brazil

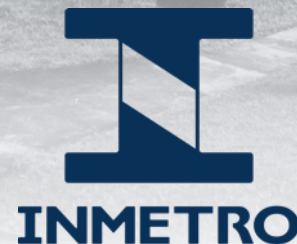


*Workshop Agenda: Advancing the Implementation of Cross-Sectoral,  
Foundational GRP and Regional Cooperation in Latin America*

**GRP Implementation and Project Country Initiatives**

**Transformation of the Quality Infrastructure in Brazil**

**Marcos Aurélio Lima de Oliveira**  
Advisor to the President



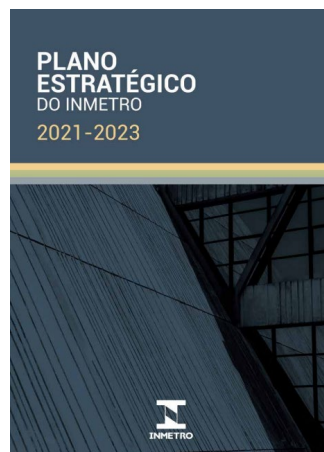


INMETRO



**Approved by  
Conmetro on  
12/05/2007**

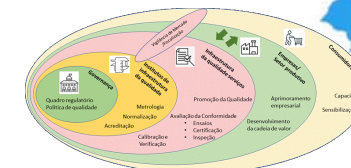
# How Inmetro is planning to strengthen its regulatory and quality infrastructure framework ?



Strategic Plan  
Inmetro 2021 - 2023



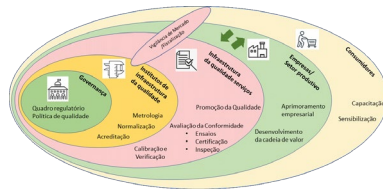
Inmetro's Regulatory Framework - Principles and Guidelines



National Quality Infrastructure Policy

# Some of Inmetro's Challenges

## National Quality Infrastructure Policy



Jan 2022 – August 2022



Jan 2022 – July 2022

## Inmetro's Strategic Planning



Apr 2020 – Mar 2021

### STAGE 2 – IMPLEMENTATION:

- Governance process framework
- Procedure for risk assessment and management;
- establishment of Essential Requirements;
- identification and selection of technical standards that give presumption of conformity;
- identification of regulatory issues and objectives;
- suppliers' responsibilities in the regulatory process
- To identify the possible need to adapt the legal framework

Jun 2020 – Feb 2022



**STAGE 1 – INMETRO'S REGULATION MODEL APPROVAL -**  
 Vision, Objectives, Principles and Guidelines

# Inmetro's Strategic Planning (2021-23)

---

## Strategic Objectives

- To offer technological solutions of quality infrastructure to the productive sector, with emphasis on the demands of the 4.0 economy
- To increase regulatory efficiency in alignment with the principles of Economic Freedom
- To increase the effectiveness of market surveillance actions
- To consolidate the activity of conformity assessment in Brazil
- To increase support for overcoming technical barriers to trade
- To resignify the understanding between society and Inmetro





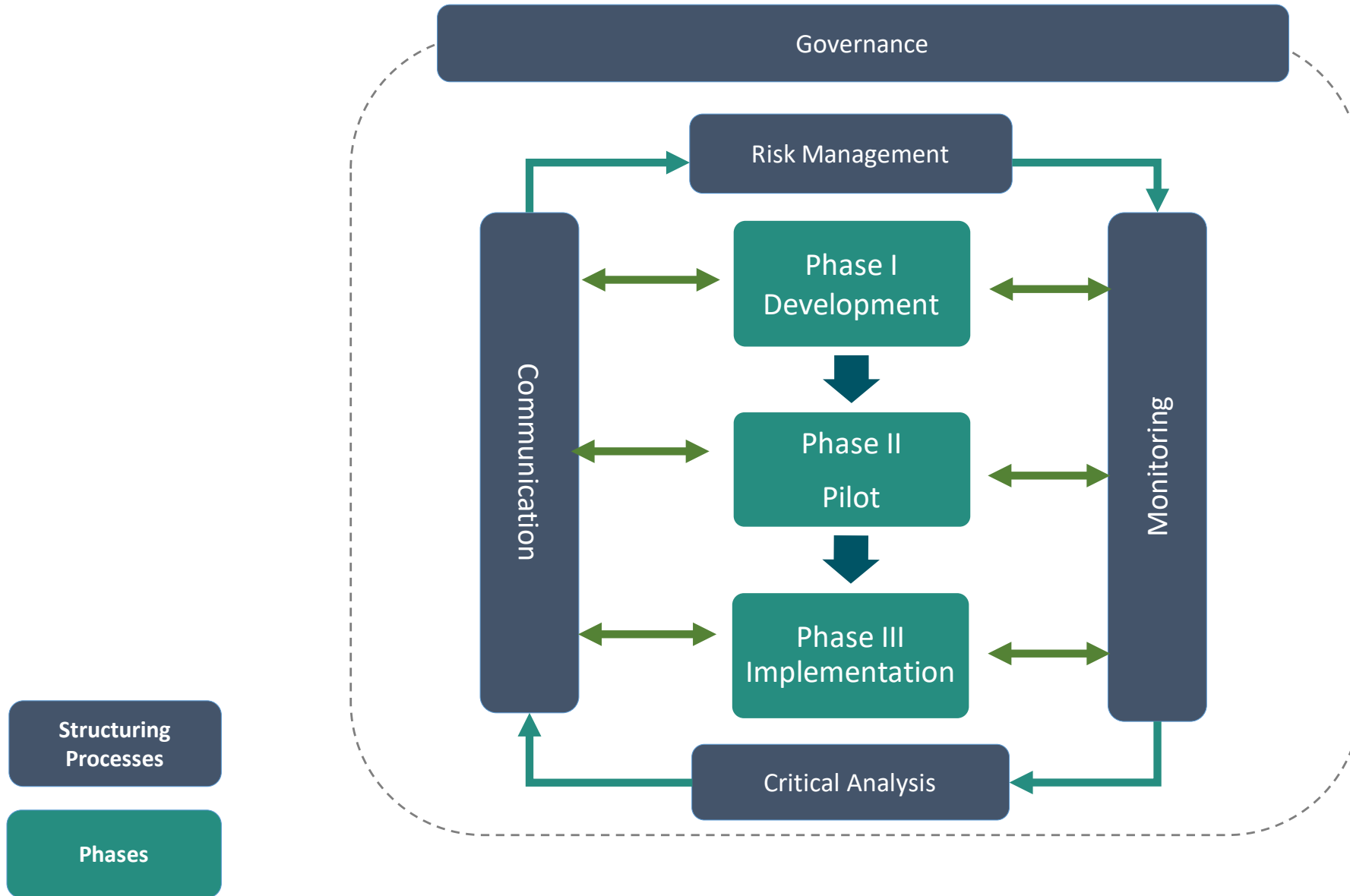
# Inmetro Regulatory Framework

# Inmetro Regulatory Framework

- Launched on 02/25/22, Ordinance No. 30
- **Principles and guidelines** aligned with the best practices of international regulation and inspection, compatible with the Economic Freedom Act and the new global economic order of Industry 4.0
- It aims to **reduce additional costs** to the productive sector, to **minimize bureaucracy**, to **facilitate the growth** of small and medium-sized companies and to **encourage innovation**
- Nearly two years of development, with **more than 1,200 contributions in the public consultation**
- **Period of 5 (five) years** for the implementation of the model to take place gradually, safely and effectively
- **Creation of a Governance Committee**, with representation of the State and civil society, which will provide guidelines and monitor the work
- **The impacts will depend on the productive sectors itself**

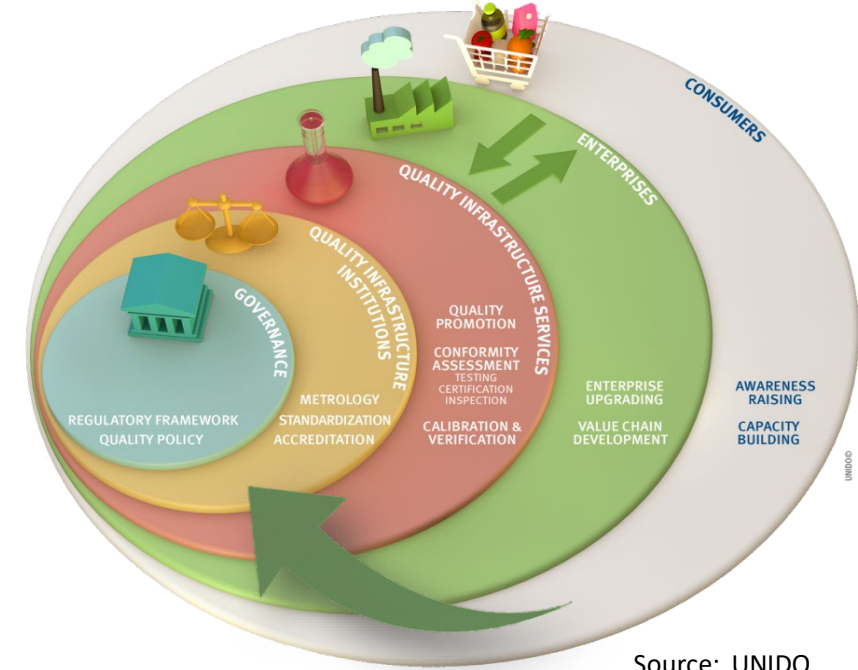


# Roadmap for implementing the Inmetro Regulatory Framework - MRI



# Quality Infrastructure

A Quality Infrastructure is a system contributing to governmental policy objectives in areas including industrial development, trade competitiveness in global markets, efficient use of natural and human resources, food safety, health, the environment and climate change.



Source: UNIDO

## Quality infrastructure services

A Quality Infrastructure System (QIS) is a combination of initiatives, institutions, organizations, activities and people.



1. QUALITY PROMOTION
2. CONFORMITY ASSESSMENT
  - Testing
  - Inspection
  - Certification
3. CALIBRATION & VERIFICATION

The key institutional components in the Quality Infrastructure are made up of the high-level institutions responsible for:

Metrology

Standardization

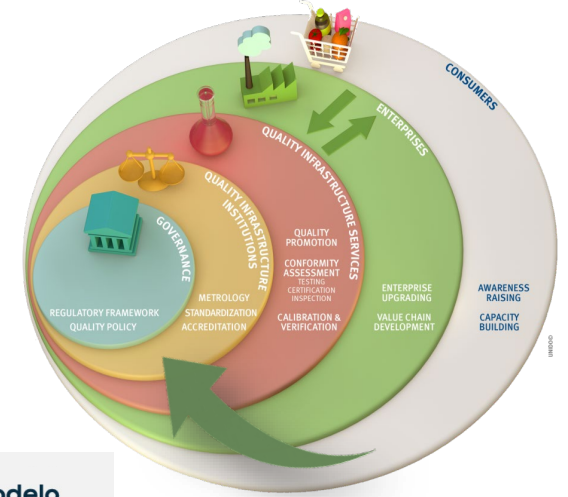
Accreditation



National Quality Policy

# Quality Infrastructure - key institutional components

The key institutional components in the QI are made up of the high-level institutions responsible for



Source: UNIDO

## Metrology



## Standardization



## Accreditation



## Regulatory Framework



Ministry of Economy



Industry and consumer



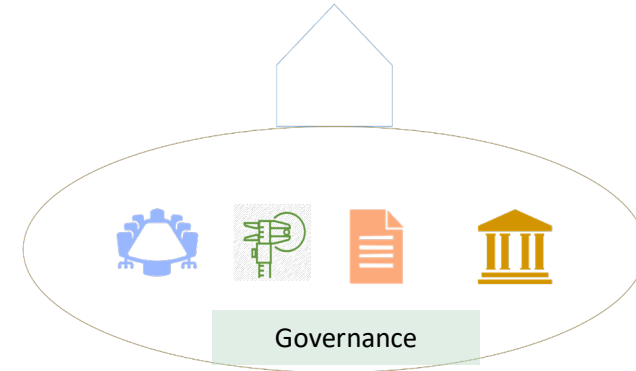
## National Quality Policy



Ministry of Economy



# The importance of the Quality Infrastructure concept



## Quality Infrastructure

- The importance of each of the pillars was clearly established
- Coordination was not effective and systematic (often non-existent)
- For this reason, the concept, in the early years of the century, of the importance of an interconnected, shared and effective vision



# National Quality Infrastructure Policy – it is about...

---

What is it about?

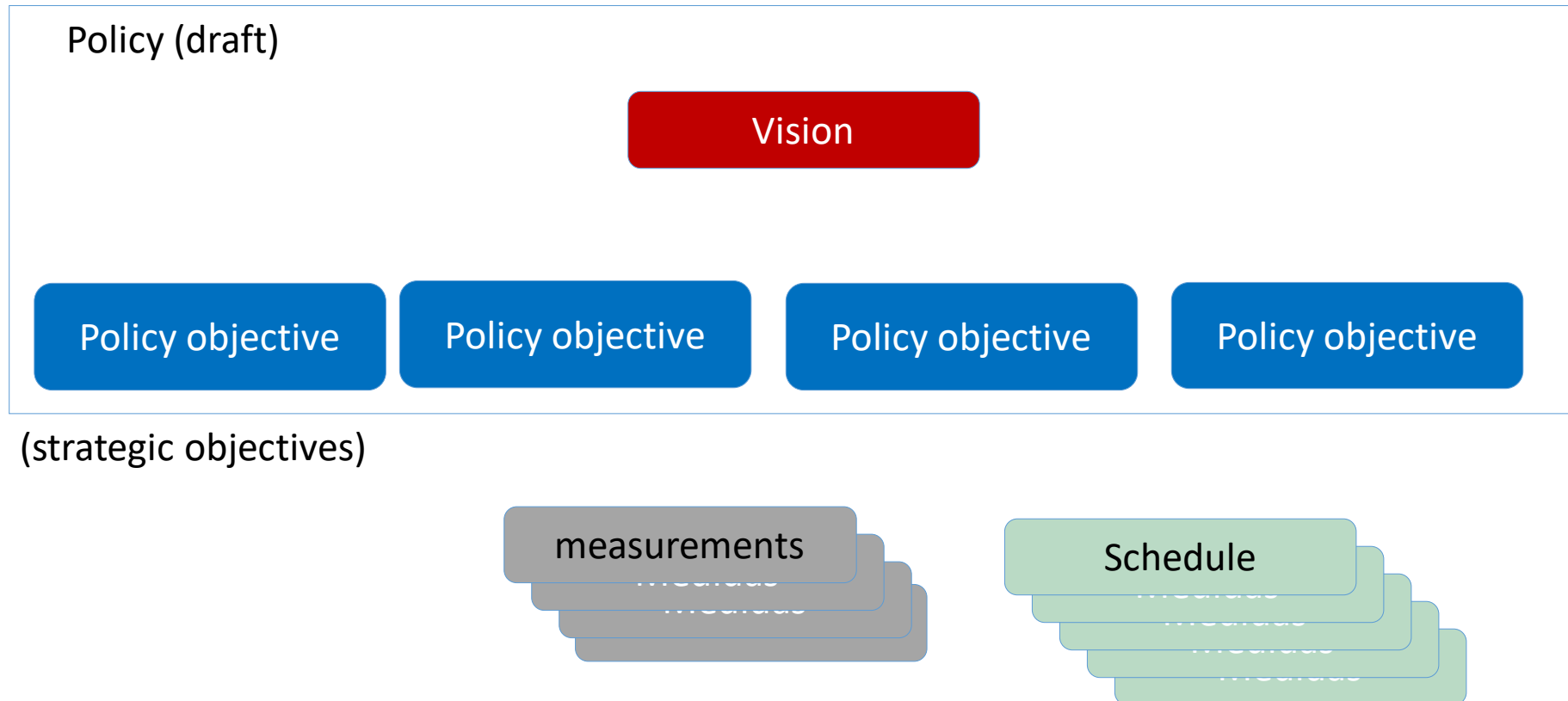
The national outlines, ambitions and objectives in terms of:

- Technical Regulation
- Standardization
- Accreditation
- Metrology
- Conformity assessment
- Market surveillance

Technical results that  
society can trust and  
use to make decisions

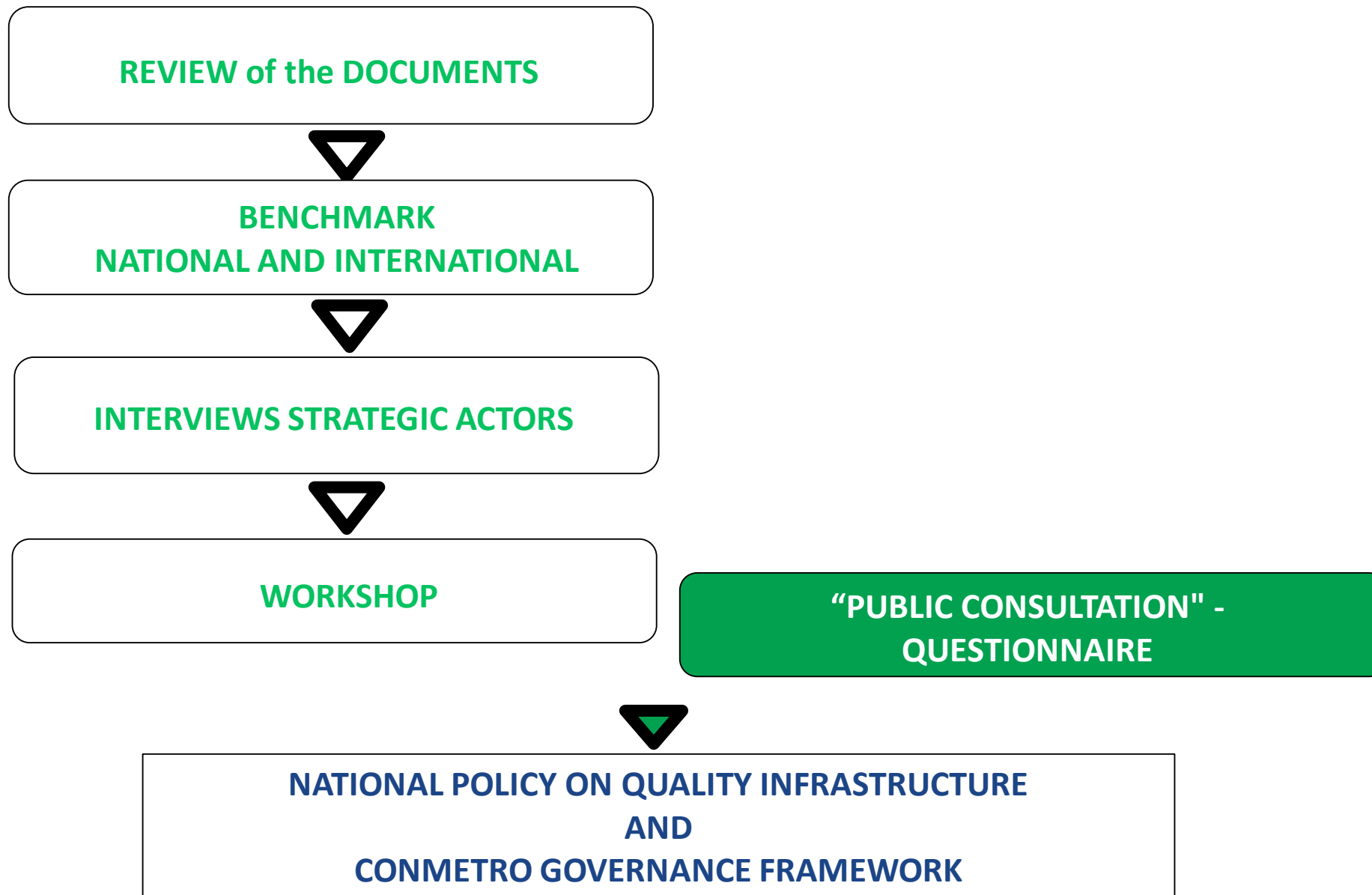
# National Quality Infrastructure Policy – consists of...

- What does it consist of?



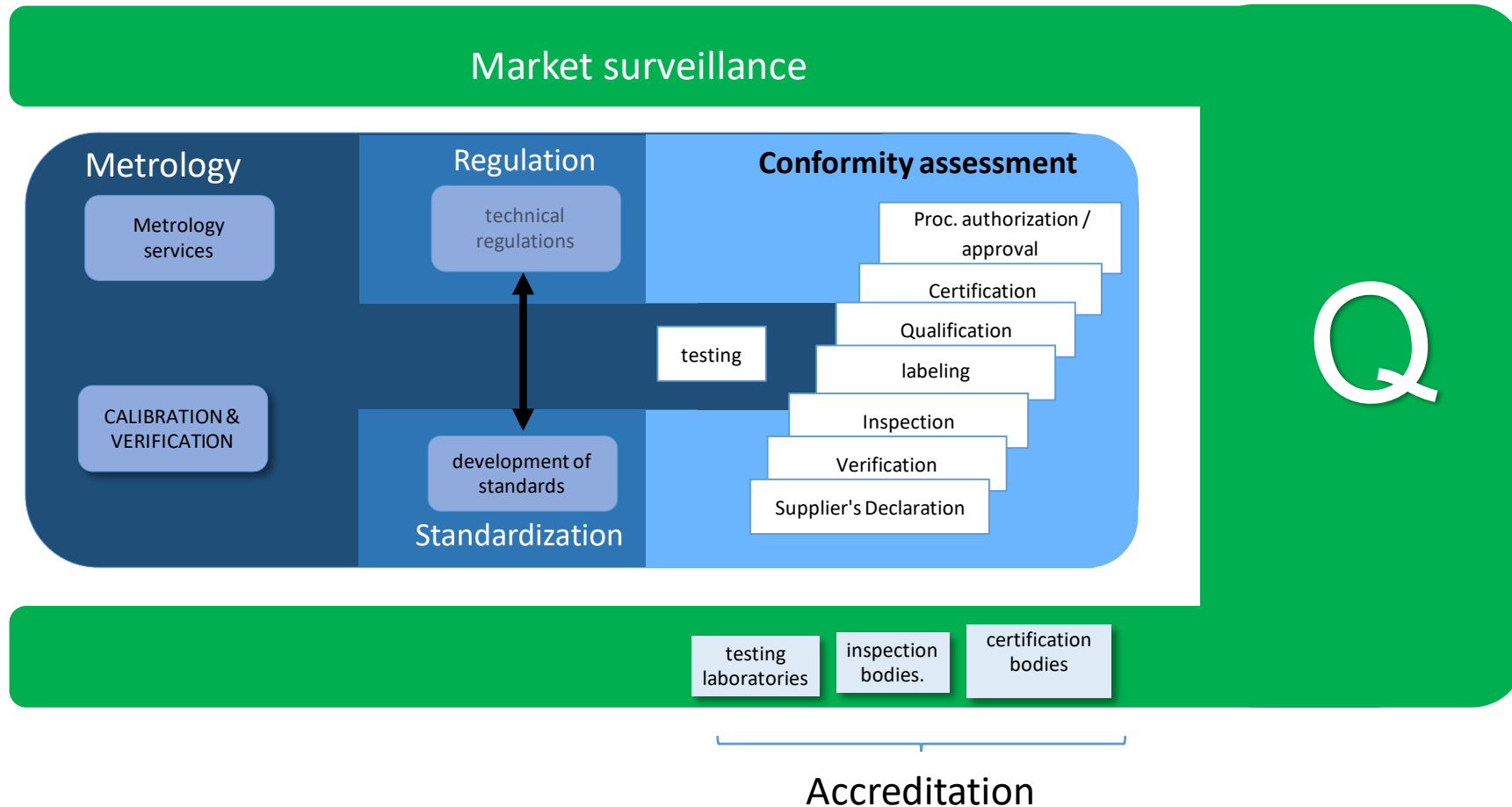


# Work Methodology



# The importance of the Quality Infrastructure concept

## Coordination of elements



# Mutual or multilateral recognition



How:

- Coordinate?
- Integrate?
- Line UP?

- Various scopes
- Several instances
- Public and private

- Connect
- Cooperate
- Costs and investments
- Protagonism
- Culture

- Participate
- Collaborate
- Engage
- Influence
- Lead

# The Highlights of the Quality Infrastructure in Brazil

- Pioneer vision of the concept and role of Quality Infrastructure
- Coordination and governance body – Conmetro
- Single national accreditation body
- Single National Standardization Body, private, economically self-sustainable
- Single National Metrology Institute (NMI), which also acts as coordinator of legal metrology
- Expressive number of accredited certification bodies, testing laboratories and inspection bodies.
- Significant number of certified products, processes, services and systems
- Active participation in international and Quality Infrastructure issues
- Alignment with international standards and good practices
- Quality Infrastructure still little promoted and recognized by various instances in Brazil Market surveillance varies widely from agency to agency
- Little use of Quality Infrastructure in market surveillance



## OUR MISSION

*To enable quality infrastructure solutions that add confidence, quality and competitiveness to the products and services provided by Brazilian organizations, in favor of economic prosperity and well-being in our society.*

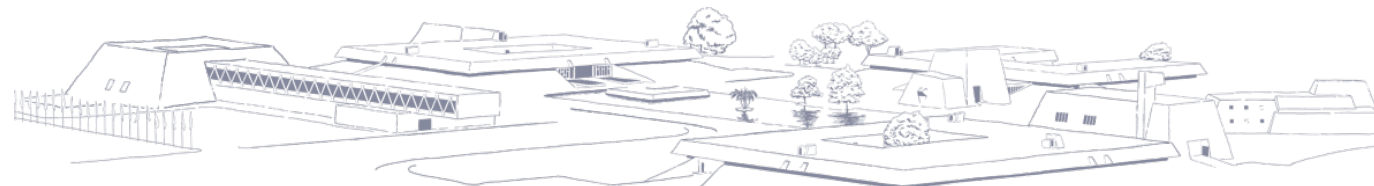


MINISTÉRIO DA  
ECONOMIA



-  Ouvidoria: 0800 285 1818
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-  [flickr.com/inmetro](https://flickr.com/inmetro)

# Thank you very much!





# Workshop Lunch



**USAID**  
FROM THE AMERICAN PEOPLE



# MDRC and Project Country GRP Implementation Roundtable *(Internal Session)*

- **Regulatory Bodies**
  - GeanLuca Lorenzon, Secretary for Competition Advocacy and Competitiveness, Secretariat for Competition Advocacy and Competitiveness, Brazil
  - Lina Valencia, Director of Governance, Human Rights and Peace, Colombia National Planning Department (DNP), Colombia
  - Hernán Zuñiga, Coordinator of the Technical Regulations Group and SICAL, Ministry of Commerce, Industry and Tourism, Colombia *(virtual)*
- **National Standardization and Conformity Assessment Bodies**
  - Marcos Aurélio Lima de Oliveira, Coordinator of the National Quality Infrastructure Policy WG, Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO), Brazil
  - Eduardo Montemayor Treviño, General Director, General Directorate of Standards, Mexico
  - Jorge Emanuel Reis Cajazeira, Head of International Standardization, Brazil Association of Technical Standards (ABNT), Brazil
  - Monica Vivas, Standardization Director, ICONTEC, Colombia
  - Daniel Trillos, Subdirector de Normalization, ICONTEC, Colombia
  - Jessica Roop, Senior Manager, International Development, American National Standards Institute, United States
- **COVID-19 Medical Device Regulatory Convergence Project**
  - Renata Amaral, Technical Secretariat, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (GRP Lead)
- **Moderator:** Renee Hancher, GRP Lead, Office of the U.S. Trade Representative (USTR)



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# Closing Remarks

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*Steven Bipes*

*Vice President – Global Strategy & Analysis – Advanced  
Medical Technology Association (AdvaMed)*





# MDRC and Project Country GRP Implementation Roundtable *(Internal Session)*

- *Tier 1 – National*
  - Ministries of Trade (MoTs)
  - Central Regulatory Coordination Bodies (CRCBs)
  - National Standards Bodies (NSBs)
  - Industry (multi-sectoral - ABD Members)
- *Tier 1 – Regional*
  - Inter-American Development Bank (IDB)
    - Trade Team
    - Modernization of State Team
    - Ibero-American Regulatory Improvement Ntwk
  - Pan-American Standards Institute (COPANT)
  - Industry (multi-sector – Americas Business Dialogue)
  - Regional Summit Outputs, Trade Recs & Commitments
- *Tier 2 – National*
  - Ministries of Health (MOHs)
  - National Regulatory Authorities (NRAs)
  - Standards Developing Organizations (SDOs) & NSB Technical Committees (TCs/SCs)
  - Industry (MedTech)
  - Conformity Assessment Bodies (CABs)
- *Tier 2 – Regional*
  - Inter-American Development Bank (IDB)
    - Health Team
  - Pan American Health Organization (PAHO)
  - Industry (MedTech Sector – IACRC-MTS)
  - Regional Trade Recs & Commitments



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