

Training on Good Regulatory Practices and their Implementation in the Medical Device Sector



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Comercio Exterior
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October 27th, 2021

Fulfillment of International Trade Obligations

1989 – Economic Deregulation Unit (SE)
1994 – Publication of the Federal Law on Administrative Procedure
2000 – Creation of the Federal Commission of Regulatory Improvement (COFEMER)

Good regulatory practices Mexico

Political Constitution of the United Mexican States

(02/05/2017)

Article 25, paragraph 10: "In order to contribute to the fulfillment of the objectives indicated in paragraphs 1, 6 and 9 of this article, the authorities of all levels of government, within the scope of their jurisdiction, shall implement public policies for regulatory improvement for the simplification of regulations, procedures, services and other objectives established by the general law on the matter.

General Law of Regulatory Improvement (GLRI)

(05/18/2018)

Creation of the National Commission of Regulatory Improvement
(CONAMER)*

*As per its acronym in Spanish

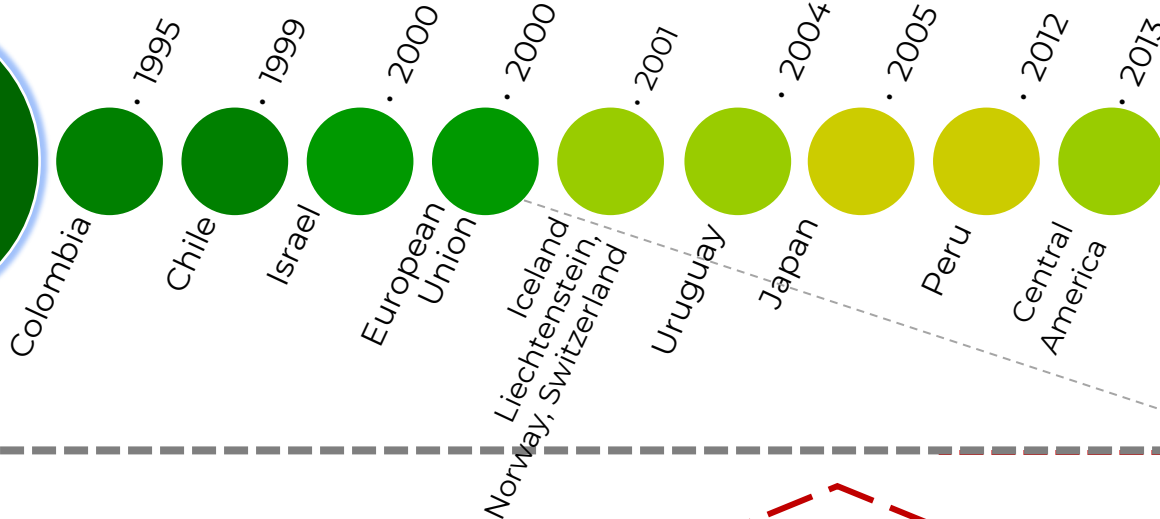
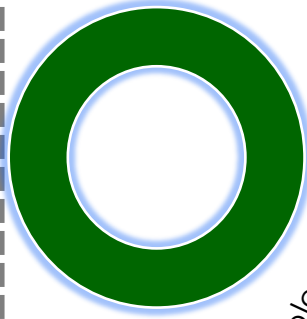
Quality Infrastructure Law(QIL)

(07/01/2020)

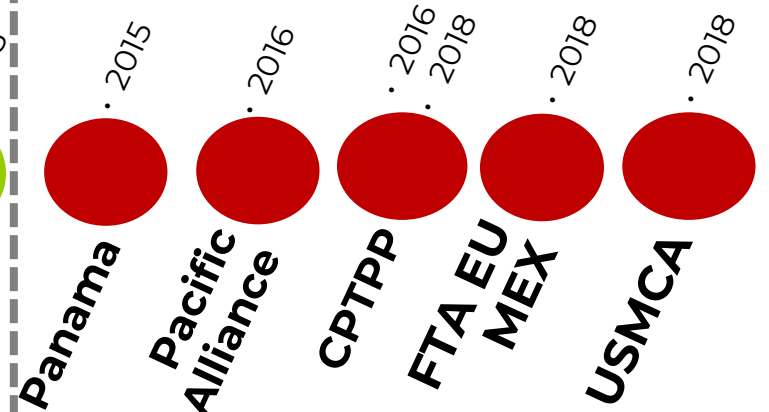
Chapters on TBT and SPS

Chapters on TBT, SPS, GRP, and Regulatory Cooperation

**NAFTA
1994**



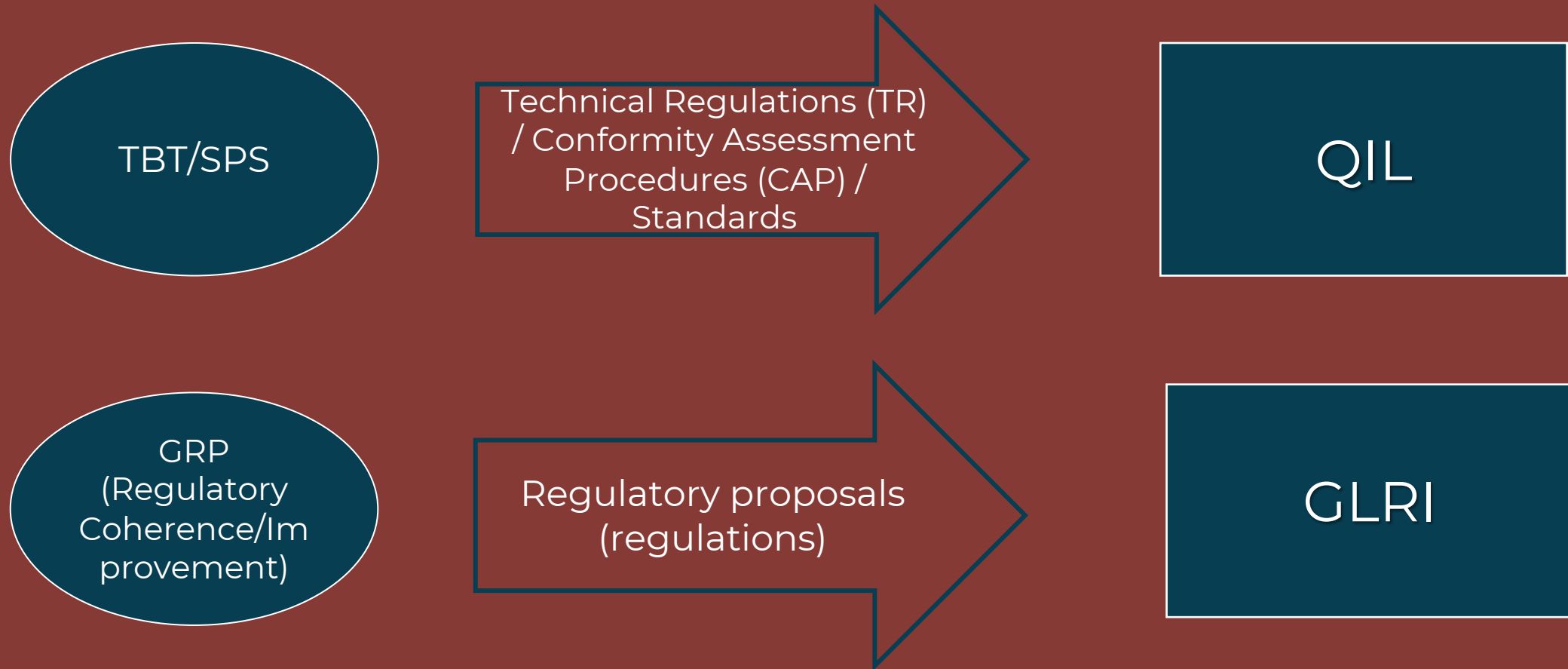
New Generation FTAs



Agreement on Technical Barriers to Trade (TBT)
 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)



Good regulatory practices Mexican Legal Framework



Regional and Bilateral Trade Agreements: GRP on TBT

Pacific Alliance (Chapter 7)

- International standards (7.4)
- Cooperation and trade facilitation (7.5)
- Regulatory Cooperation TR and Conformity Assessment (CA) (7.6 and 7.7)
- Transparency (7.8)
- Implementation Annexes (7.11)

CPTPP (Chapter 8)

- International standards, guides and recommendations (8.5)
- Cooperation and trade facilitation (8.9)
- CA Regulatory Cooperation (8.6)
- Transparency and *vacatio legis* (8.7 and 8.8)
- Annexes (8.13)

USMCA (Chapter 11)

- International standards, guides and recommendations (11.4)
- Cooperation and trade facilitation (11.9)
- CA Regulatory Cooperation (11.6)
- Transparency and *vacatio legis* (11.7 and 11.8)
- Sectoral Annexes (Chapter 12 and Annex #-C)
- Good regulatory practices for TR and CA (11.5)

Regional and Bilateral Trade Agreements:

GRP on TBT

GRPs (11.5)

- Preparation and review
 - ❖ Evaluation of TR (RIA) alternatives
 - ❖ Periodic review TR and CA
- Use of international standards in TR and CAP.
- TR and CA information exchange.
- Labeling.

RC/CA (8.6 and 11.6)

- National treatment for bodies
- No local presence
- Providing status information
- Outsourcing of testing laboratories
- Location and nature of accreditation bodies
- Mutual recognition agreements
- Tariffs

Regional and Bilateral Trade Agreements:

GRP on TBT (Cont.)

RC
(7.5, 8.9
and 11.9)

- ❑ Conformity assessment:
 - ✓ Mutual recognition of CA results.
 - ✓ Recognition of regional and international mutual recognition arrangements
 - ✓ Accreditation
 - ✓ Designation of CA bodies or recognition of the designation of CA bodies by another Party.
 - ✓ Unilateral recognition of CA results.
 - ✓ Supplier's Declaration of Conformity.
- ❑ Harmonization, compatibility and equivalence:
 - ✓ Regulatory dialogue
 - ✓ Alignment with international standards
 - ✓ Use of international standards as a basis for TR and CA
 - ✓ Equivalence

**Regional and
Bilateral
Trade
Agreements**

Chapter 15 Bis – Regulatory Improvement
Additional Protocol to the Framework Agreement of the
Pacific Alliance
(PA)

GRP Chapters

Chapter 25 – Regulatory Coherence
Comprehensive and Progressive Agreement for Trans-
Pacific Partnership
(CPTPP)

Chapter 28 – Good Regulatory Practices*
United States, Mexico and Canada Agreement (USMCA)

Good regulatory practices Mexican Legal Framework

- **Representativity (QIL)**
- **Consensus (QIL)**
- **Transparency (GLRI/QIL)**
- **Proportionality: regulatory impact analysis (GLRI/QIL)**
- **Harmonization (GLRI/QIL)**
- **Ex Post Review (QIL)**
- **Coordination between competent authorities (QIL)**
- **Alternative procedures (QIL)**
- **Acceptance Supplier Declaration of Conformity (QIL)**
- **Regulatory Cooperation: Mutual Recognition and Equivalence Agreements and Arrangements (GLRI/QIL)**

Is it necessary for the provisions of international trade agreements to be incorporated into the ordinary legislation of Mexico?

Strictly NO, but...

- The alleged superior hierarchy of international treaties is not in the constitutional text.
- Jurisprudence and judicial thesis are only mandatory for the courts.
- In the event of a contradiction, the administrative authorities will only apply domestic Law.
- Mexican nationals also have the right to claim the rights contained in the treaties.
- There are rules of the treaties that are simply not applicable if their content is not detailed.
- Legal certainty is generated, and the legal framework is improved and updated if the provisions of the Treaties are implemented in domestic Law.

However...

- It is complex to implement without exceeding or breaching the text of the treaty.
- Concessions may be extended to countries with which there are no treaties without reciprocity (free riding).



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