# *Steps in the Strengthening of the National Quality Infrastructure*
## *A Developing Country Perspective*

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# Outline

❑National Quality Policy

❑Regional Initiatives

❑Stakeholder engagement

# Considerations in the development of a National Quality Infrastructure

❑ <span style="color:red">Make linkages to the Multilateral System</span>

- The Republic of Trinidad and Tobago embarked on a national Aid for

Trade Strategy

❑ <span style="color:red">Participate in the International and Regional Initiatives</span> (if applicable)

- Coherence and integration is key

❑ <span style="color:red">Determine what is needed to effect the initiatives at the national level</span>

# National Quality System

❑ The system relies on an overarching policy to give it effect and an infrastructure to support the related initiatives

- it combines initiatives, institutions, organizations (public and private), activities and people

# Quality Policy

❑ The Quality Policy (QP) is the basic governing instrument for establishing, formalizing, and overseeing the development and performance of a Quality Infrastructure (QI)

- Developing and agreeing upon the QP requires wide stakeholder engagement

- An implementation plan and communication plan should accompany the policy

**Key:  Appropriateness for the specific context of a particular country (Gap Analysis)**

# Elements in Trinidad and Tobago's NQP Implementation Plan

- ❑ *Component 1*: Formation of Governance bodies
    - Quality Councils, Project oversite offices
- ❑ *Component 2*: Review of Legislation
    - To clearly define mandates, avoid overlaps and address gaps
- ❑ *Component 3*: Address institutional strengthening
    - Empowerment of institutions/ capacity building
- ❑ *Component 4*: Building a Quality conscious society
    - Effecting a Culture change

# A Quality Policy Supporting the Quality System and Infrastructure

❑ The QP provides a transparent  non-discriminatory framework to link and underpin other national policies

- it gives a definition of the QI institutions

  roles and responsibilities

- it gives authority for planned initiatives to be

  undertaken

- it harmonizes related national operational and

  legislative agendas

- it gives a clear direction for QI development in

  relation to national priorities

# Regional Initiatives

❑ CROSQ - CARICOM Regional Organization for Standards and Quality:

- Coordinated approach to the development of the quality infrastructure at the regional level – takes advantage of national competencies

- The development of National Quality Policies based on a Regional Quality Policy – promotes coherency

- Development of regional committees to treat with QI matters

- Capacity building

# Tangible Benefits Of Formal NQI

❑ **Economic Growth**:

   The NQI positively contributes to the SDGs, innovation and diversification

❑ **Social Development**:

   It promotes greater enforcement of regulations while ensuring the safety and well-being of persons

❑ **Environmental Protection**:

   the NQI to assists more effective use of natural resources, the environment and climate

# Stakeholder Engagement

❑ Have a National Launch of the (QP)

- ■ High level Participants
  - Persons aware of the QI gaps

- ■ Panel Discussions
  - legislative reform

- ■ Sectoral Break out Sessions
  - diversification

❑ Consider various forms of engagement

- ■ Prior and during implementation

# Summary – Key Learnings

❑ In the absence of a policy the infrastructure may be developed in an *ad hoc* manner and not relate to national development priorities
  - review other national related policies
  - legislative components may be needed to give mandatory status

❑ A robust gap analysis is needed:
  - if legislative roles are to be clearly defined
  - to avoid agenda overlap of responsibility
  - to establish a baseline for monitoring and evaluation

❑ Regional initiatives support buy-in at the national level

❑ Funding mechanisms should be identified for implementation

❑ Have the Government champion initiatives to foster buy- in
  - Engage stakeholders to relate NQP to their specific areas of interest

# Thank You for your attention

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# China's National Quality Infrastructure System

Yunsong WANG

State Administration for Market Regulation,China

November,2019

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## POLICIES

## LAWS & REGULATIONS

◆Quality Development Outline (2011-2020)

◆Guidance on Launching Quality Improvement Actions

◆Guidance on Strengthening the **Construction** of the Quality Certification System and Promoting Comprehensive Quality Management
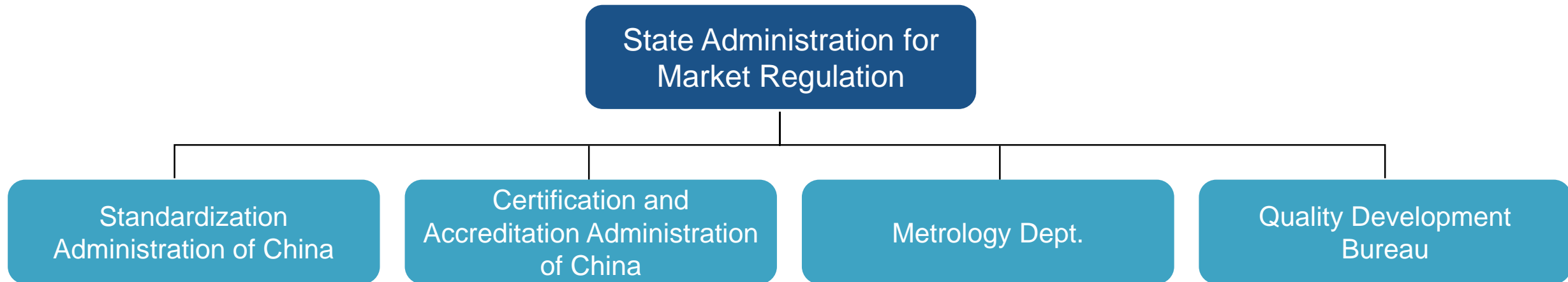
◆Product Quality Law

◆Standardization Law

◆Metrology Law

◆Regulations on Certification and Accreditation

# POLICIES SUPPORTING QUALITY DEVELOPMENT

## THE INSTITUTIONAL AND TECHNICAL SETTINGS

State Administration for Market Regulation

Standardization Administration of China

Certification and Accreditation Administration of China

Metrology Dept.

Quality Development Bureau

◆ The quality and technical institution at the national-level include the National Institute of Metrology (NIM), the China National Institute of Standardization (CNIS), the China National Accreditation Service for Conformity Assessment (CNAS), China Quality Certification Center (CQC).

◆ At the local level, the local governments have established metrology, standards, inspection and testing institutions to provide quality support for local economic and industrial development.

# QUALITY INFRASTRUCTURE

## STATUS QUO OF STANDARDS

◆ China has **over 37,000 national standards**.

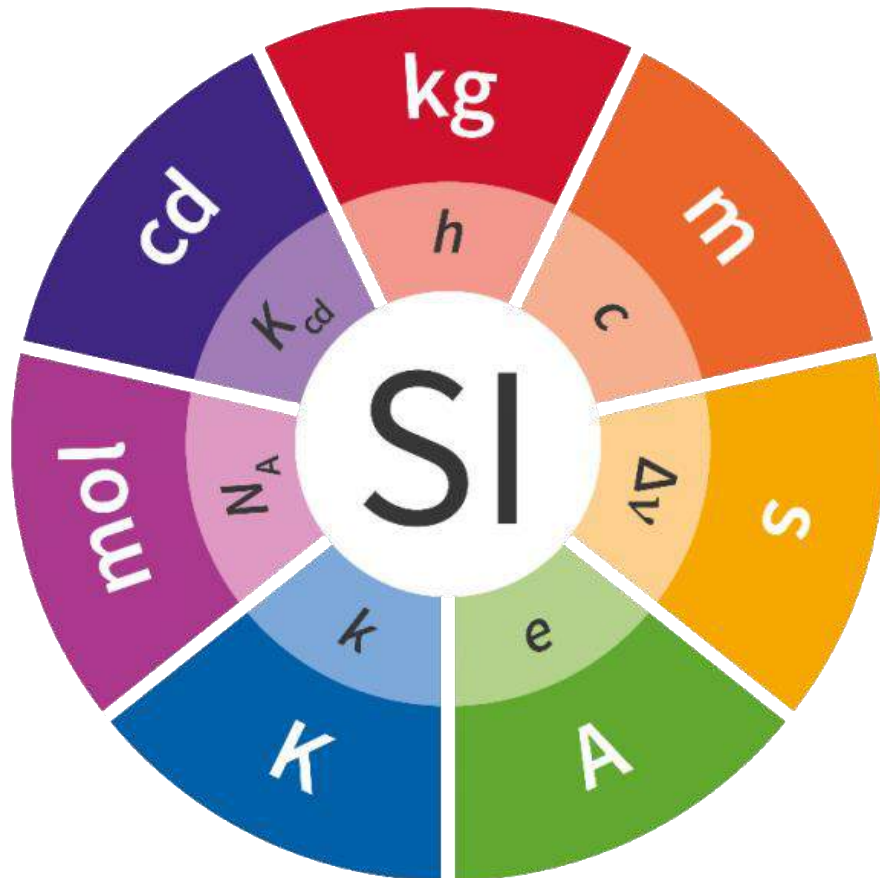**In the area of the primary, secondary and tertiary industries.**

The adoption rates of international standards in the light industry and textile industry have reached **86%** and **94%**, respectively.

**STATUS QUO OF METROLOGY**



China has established 182 national primary standards covering all disciplines, with more than 11,000 national reference materials, and 1576 internationally recognized CMCs.

# QUALITY INFRASTRUCTURE

**STATUS QUO OF CERTIFICATION AND ACCREDITATION**

China designated 558 certification bodies, issued 2 million valid certificates and 686,000 certified organizations.

China has launched "Million-Enterprise Certification Promotion Campaign", completed the ISO 9001 certification revision in 450,000 enterprises improved the quality management level of enterprises, especially in SMEs.

## STATUS QUO OF INSPECTION AND TESTING

The inspection and testing institutions in China had reached the revenue of 281 billion Chinese Yuan.

336 foreign-invested inspection and testing institutions are registered in China, with a revenue of 20 billion Yuan.
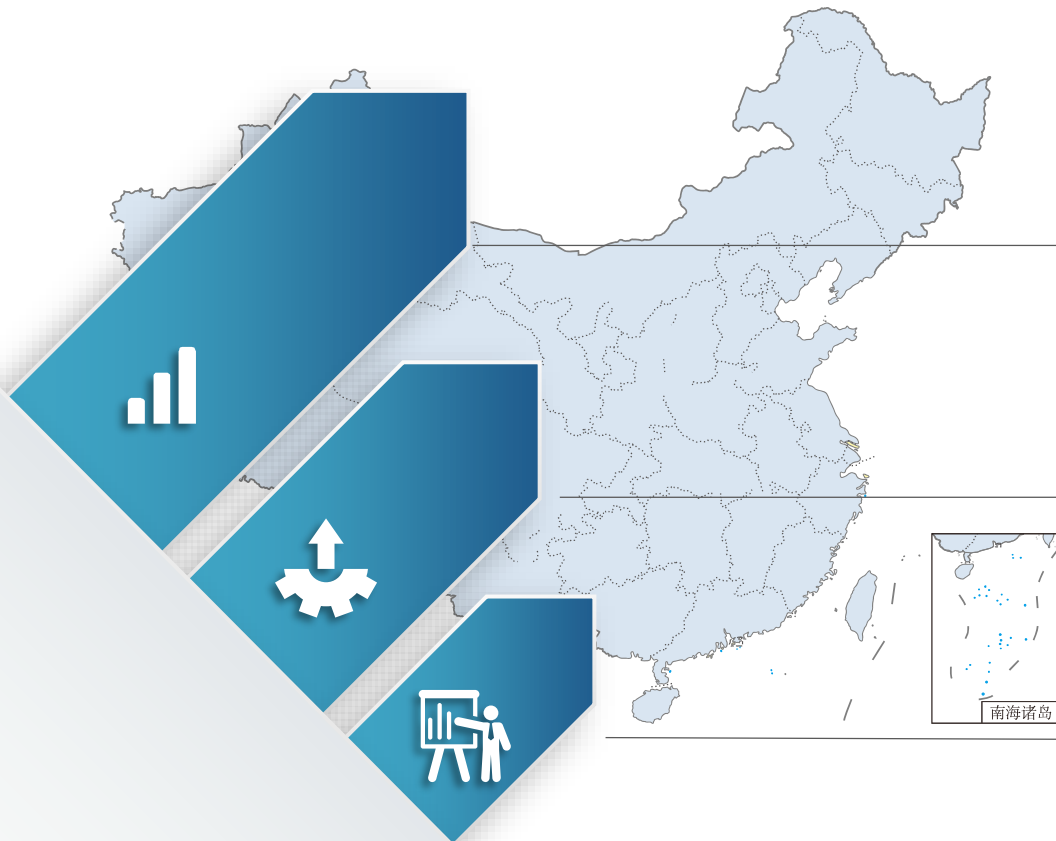
**THE BASIC IDEAS OF NQI REFORM**

The purpose of the reform is to streamline the organization, simplify procedures, improve operational efficiency, reduce enterprise burdens, improve the business environment, support trade development, promote industrial upgrading, and protect the public interest.

**IMPROVEMENT OF THE TOP-LEVEL DESIGN OF QUALITY POLICY**

➢ The Strategic Outline for revitalizing China through Quality development being formulated.

➢ The quality infrastructure was actively promoted to be integrated in China's next Five-Year Plan.

➢ The new joint inter-ministerial meeting mechanism for national quality work was established.

南海诸岛

**DEEPENING OF THE REFORM OF THE QUALITY INFRASTRUCTURE SYSTEM**

## METROLOGY

## STANDARDIZATION

◆ More than two-thirds of the measurement administrative review and approval items were cancelled.

◆ Fees such as compulsory verification of measurement were suspended.

◆ The catalog of measurement instruments was revised.

◆ The standard system is shifted from single government supply to government-organization-enterprise multi-supply.

◆ Strictly limits the scope of government-led standards, supports the development of social organization standard, etc,.

# REFORM AND APPLICATION

## DEEPENING OF THE REFORM OF THE QUALITY INFRASTRUCTURE SYSTEM

### COMPULSORY CERTIFICATION

### INSPECTION AND TESTING

◆ Dynamic catalog management was strictly implemented, and the CCC certification catalog was revised.

◆ The scope of implementation of the "self-declaration" evaluation method continued to expand.

◆ The market-oriented reform of inspection and testing institutions was promoted.

◆ The certification process was optimized and the time for administrative approval was reduced.

# REFORM AND APPLICATION

**ENHANCEMENT OF COOPERATIVE SERVICES FOR QUALITY INFRASTRUCTURE**

◆ The construction of a comprehensive information service platform for NQI was launched.

◆ Pilot projects  of "One-stop" service (comprehensive quality infrastructure service) were launched  in 10 cities.

# REFORM AND APPLICATION

**ADVANCEMENT OF REFORM AND INNOVATION OF MARKET REGULATION**

➡ ◆ **The reform of market supervision is deepened.**

➡ **The product safety recall management system is improved.**

◆ The recall of 72 million vehicles and 6187 million consumer goods is carried out.

◆ The product injury surveillance system was established.

◆ The establishment of a product safety accident mandatory reporting system is on schedule.

First, as the theory and concept of quality policy and quality infrastructure gradually form an international consensus, it is suggested that the WTO consider to establish relevant guidelines to clarify the concepts, components, basic principles, policy framework, status and role of quality infrastructure to strengthen the global understanding of the quality infrastructure.

Second, we have taken note of a series of efforts promoted by the WTO to promote international cooperation in QI. China is willing to actively participate in international exchanges and cooperation in the field of quality infrastructure.

Third, it is suggested to strengthen cooperation seminars in the field of law enforcement in TBT. It is suggested that the WTO members consider to conduct in-depth discussions on various TBT-related law enforcement measures to promote information exchanges and cooperation in the field of market surveillance.
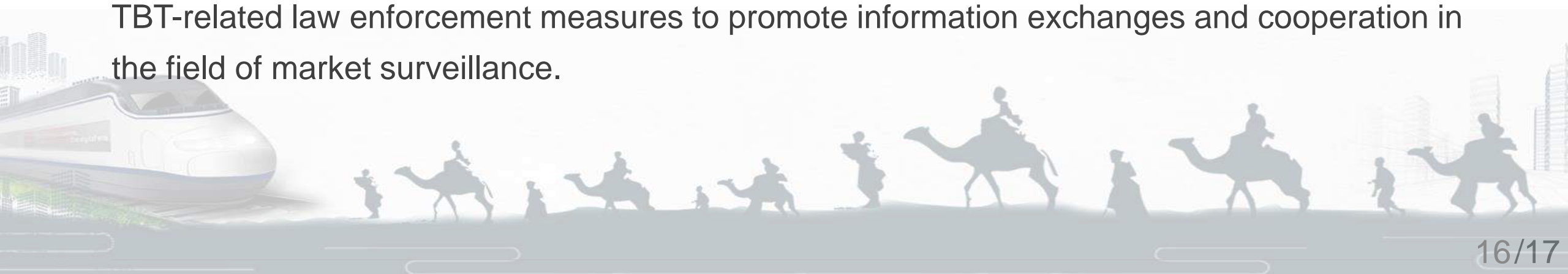
# THANK YOU FOR LISTENING!

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# LEGAL DIMENSION
# (LEGISLATION)

# LEGAL FRAMEWORK

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          ┌──────────────┬──────────────┬──────────────┐
          ↓              ↓              ↓              ↓
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| Customs Union **1/95** | **2/97** | **1/2006** | **2014** |

Articles 5 - 7.
Articles 8 - 11.

- The list of EU legislation to be harmonized
- The conditions and arrangements governing their implementation

Procedure for the Turkish notified bodies

Procedural guidelines
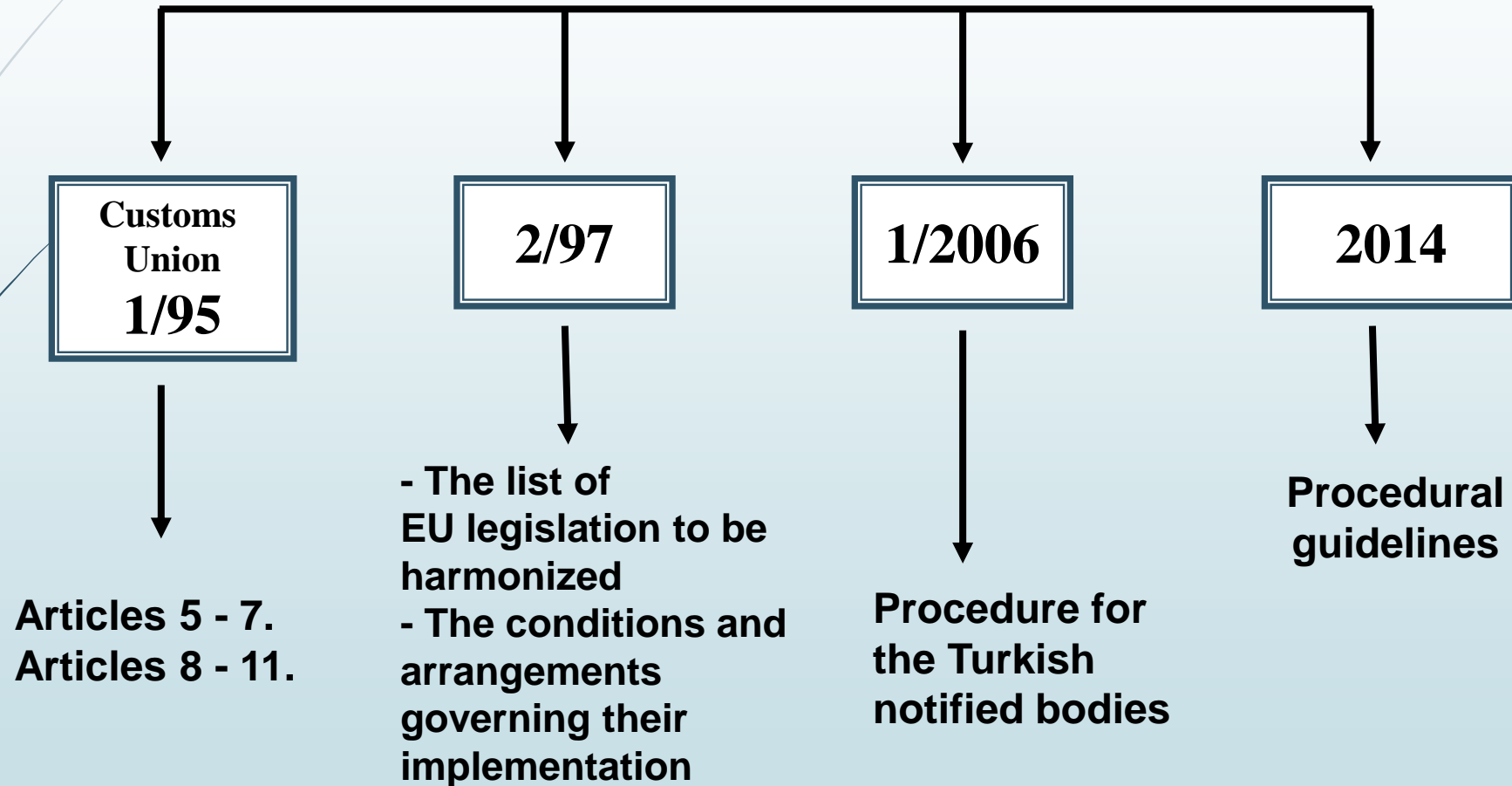
# 1/95 ASSOCIATION COUNCIL DECISION

- Turkey and the EU established a Customs Union (CU) in 1995 (Decision 1/95 of the EU-Turkey Association Council, 96/142/EC).

- The CU covers trade in manufactured products between Turkey and the EU.

- The CU covers both harmonised and non-harmonised area.

  - **Articles 5-7:** elimination of measures having an effect equivalent to quantitative restrictions (mirroring Articles 34-36 TFEU)

  - **Article 8:** incorporation of Community instruments into legal order

  - **Article 9:** trade between the Parties takes place in accordance with the conditions laid down by those instruments

# 1/95 ASSOCIATION COUNCIL DECISION

- In the non-harmonised area where there are no common EU rules, the rights and obligations of economic operators stem from CU meaning Turkish products are treated as Eu ones and the free movement is essential for Turkey.

  - Articles 5-7 (mirroring Articles 34-36 TFEU)

  - Interpretation in conformity with the relevant Judgments of the Court of Justice (Article 66)

- Commission's interpretative communication on 'facilitating the access of products to the markets of other Member States: the practical application of mutual recognition' (2003/C 265/02)

  «The Member State of destination of a product must allow the placing on its market of a product lawfully manufactured and/or marketed in another Member State or in Turkey.»

# 2/97 ASSOCIATION COUNCIL DECISION

- Annex I: the conditions and arrangements governing their implementation

- Annex II: the list of the Union's legal instruments

When Turkey adopts the legislation listed, the same rules and procedures would apply in the EU and Turkey.

- Need for an update of the list in Annex II - "2014 Procedural Guidelines"

    - Adopted by the Parties in January 2014

    - Rules for the update of the list, adoption of the legislation and exchange of opinions

# 1/2006 ASSOCIATION COUNCIL DECISION

- Designation of Turkish notified bodies (NBs)

- Recognition of the test reports and certificates issued by Turkish NBs

- Statements confirming Turkey's legislation is equivalent to that of the EU

  - 15 statements signed until now.

  - 46 NBs under 15 legislation

# NATIONAL TECHNICAL LEGISLATION

**Horizontal Technical Legislation
(General Rules)**

**The Law No. 4703 on the Preparation and Implementation of
Technical Legislation on Products**

**Regulation on Market Surveillance
of the Goods (2002-rev.2013-rev.2015)**

**Regulation on CE Marking (2002-rev.2012)**

**Regulation on Conformity Assessment Bodies
and Notified Bodies (2002-rev.2012)**

**Regulation on Mutual Recognition in the
Non-Harmonised Area (2012)**

**Regulation on the Exchange of Information on
Technical Legislation on Goods and Standards
between Turkey and the European Union**

**Regulation on Registration and Notification of
Market Surveillance Results and Measures (2013)**

**harmonized by the Ministry of Trade.**

**Vertical Technical Legislation
(Rules For Product Groups)**

| New Approach | Old Approach |
|---|---|
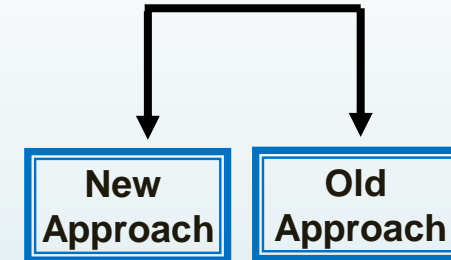
**Approximately 80% of the more than 300 technical regulations listed in the ACD No 2/97 have been harmonized by 9 different competent authorities.**

**The Ministry of Trade has a role of coordination between the Turkish competent authorities and The EU Commission.**

# The Law No. 4703

✓ The objective of this Law is to lay down the principles and the procedures for the placing on the market of the products, conformity assessment, market surveillance and inspection and the notifications relating to these arrangements.

✓ Covers;

- the conditions of placing on the market of the products,

- the obligations of the producers and the distributors,

- conformity assessment bodies and notified bodies,

- market surveillance and inspection,

- prohibition of the placing on the market of the products, withdrawal and destruction of the marketed products,

- the notifications relating to these arrangements.

# DRAFT LAW ON PRODUCT SAFETY AND TECHNICAL REGULATIONS

- A new draft "Law on Product Safety and Technical Regulations" has been prepared in the context of the revision of "Law No. 4703 on Preparation and Implementation of Technical Legislation for Products"

- Planned to be submitted to the Turkish Parliament

- The New Legislative Framework (NLF) Package, the General Product Safety Directive of the EU taken into consideration

- The purpose is to ensure that the products are safe and in compliance with the related technical regulations (whether produced in or imported to Turkey)

# DRAFT LAW ON PRODUCT SAFETY AND TECHNICAL REGULATIONS

MAIN IMPROVEMENTS:

- Economic operators defined in accordance with the current EU legislation
- Responsibilities of the economic operators clarified
- Recall
- E-commerce/E-Market Surveillance
- Product Liability
- Notification of Risks and Measures
- Administrative Fines in accordance with  the gravity of the non compliance
- Traceability

# HARMONISATION

✓Turkey transposes EU's harmonised legislation on products and quality infrastructure.

✓Up to now, Turkey has transposed into its legal order the rules of the EU on the CE marking, notified bodies, market surveillance and mutual recognition in the non-harmonised area as well as many EU sectoral legislation, including the acquis requiring the CE marking on products.

✓The CE marking is affixed on products that will be placed on the Turkish market

✓80% of EU's product legislation are already transposed. This work continues since it is a dynamic structure and revisions are taking place time to time in EU and thus Turkey.

✓Already published legislation includes 21 Turkish Regulations transposing the corresponding new approach directives of the EU such as toys, personal protective equipment, pressure equipment, lifts, etc. These have been confirmed by the Joint Statements signed by Turkey and the EU.

✓ 46 NBs under 15 legislation

✓ Test reports and certificates issued by NBs in Turkey are recognised in the EU

# TECHNICAL LEGISLATION

- Today, Turkish products are subject to <u>the same rules and procedures and have equal level of safety and quality with that of the EU where harmonisation is completed</u>.

- In order to be marketed, a Turkish product should complete all mandatory conformity assessment procedures required in the relevant technical regulation and should bear all conformity markings, particularly <u>CE marking</u>, and certificates, test reports and any other documents required by technical regulation.

- Turkey has notified 46 Turkish conformity assessment bodies in 15 Directives.

**IMPLEMENTATION DIMENSION**

**(QUALITY INFRASTRUCTURE OF TURKEY)**

# STANDARDISATION

Standardization is a key element to push up the capacities of export.
It is a necessary process for ensuring effectiveness in any product.

The international standards are strategic tools that reduce the costs by minimizing waste and errors.

➥ Turkish Standards Institute became a full member of CEN/CENELEC (2012).

➥ % 99,89 of EU standards are harmonized.

Turkey has become one of the decision-makers in the preparation of EU standards.

# STANDARDISATION

- Valid Turkish Standards — **42.839**
- ISO Standards adopted as Turkish Standards — **11.530**
- IEC Standards adopted as Turkish Standards — **1.570**
- European Standards adopted as Turkish Standards (CEN, CENELEC and ETSI) — **18.692**

TURKISH STANDARDS INSTITUTION

Standardization

Product Certification

Testing

Service Certification

Calibration

CE Marking

Conformity to Automotive Legislation

System Certification

Surveillance

Personnel Certification

Inspection

Training

TSE

# CONFORMITY ASSESSMENT

**Conformity Assessment Bodies:**

- Conformity assessment is a set of processes which show that the product complies with the requirements in the relevant technical legislation. Conformity assessment bodies assess and certify the products before they are placed on the market.

- Competency requirements for CABs are set under the relevant technical legislations or other regulatory actions.

- In Turkey, there are about 1782 accredited CABs.

- In 2006, UDDer, an umbrella organization for CA organizations in Turkey, is established. It gathers all parties in the field of CA.

**Notified Bodies;**

- According to 1/2006 ACD, Turkey designates NBs.

- Through NANDO, notifications are made to the Commission

- Recognition of the test reports and certificates issued by NBs in Turkey

- There are 46 Turkish NBs, 2 Technical Assessment Bodies and 1 Recognised Third Party Organization under the scope of 15 New Approach Directives. List is available on NANDO web site.

# ACCREDITATION AND METROLOGY

**Accreditation:**

- The Turkish Accreditation Agency (TURKAK) is a full member of International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF).

- TURKAK is also member of European co-operation for Accreditation (EA).

- TURKAK has signed multilateral agreements with the national accreditation bodies of the EU member states.

Certificates issued by Turkish CABs accredited by TURKAK are deemed equivalent to those issued by CABs established in the EU and accredited by EU National Accreditation Bodies.

**Metrology:**

- National Metrology Institute (UME) is the responsible authority in the field of scientific metrology, in the area of legal metrology, the responsible authority is Ministry of Science, Industry and Technology.

# QUALITY INFRASTRUCTURE IN TURKEY

| | 1995 | 2019 |
|---|---|---|
| **ACCREDITATION** | Turkey had no accreditation institute. | TÜRKAK is recognized for all fields of accreditation under ILAC, IAF, and EA. |
| **STANDARDIZATION** | Limited number of international standards were in force and TSE was not included in the European standardization system | TSE has harmonized 98% of EU standards and become full member of CEN/CENELEC. |
| **CONFORMITY ASSESSMENT** | The sector was backwards, CA was conducted as a public service No notified bodies (CE Marking) | CA sector is open to private testing, inspection and certification bodies. Turkey has designated 46 notified bodies, 2 technical assesment bodies, 1 recognized third party organization. |
| **METROLOGY** | Confusion about the roles of different institutions responsible for scientific, industrial and legal metrology. | Clear-cut division of labor between relevant institutions in accordance with the European Union. |

# INSPECTION DIMENSION

# Risk-Based Trade Control System (TAREKS)

- The import and export controls of various product groups are carried out by our Ministry through the "Risk-Based Trade Control System (TAREKS)"

  - ✓ 7/24 online applications are accepted within TAREKS and required documents should be uploaded during the application.

  - ✓ TAREKS is a risk-based software, which determine an inspection according to the criteria such as; "product", "origin country", "company", "trademark" and "model" analysis.

  - ✓ TAREKS is an award-winning software developed by our Ministry.

EIPA
EPSA
2013

# MARKET SURVEILLANCE

- Nine different public authorities carry out market surveillance in Turkey.
- Ministry of Trade coordinates these activities.
- The National MS Strategy for 2019-2021 has been adopted.
- It is the roadmap for the improvement of MS in Turkey for the following years.
- Annual reports on MS are prepared and made public.
- National Market Surveillance Information System was established in 2013.
- The system includes detailed data on unsafe and non-compliant products.
- Turkey's Annual MS Programmes are prepared and sent to the Commission every year.
- Turkey's National Market Surveillance Strategy is determined under the coordination of Ministry of Economy and adopted by "Market Surveillance and Product Safety Assessment Board", where MSAs are represented at the highest level.

- The data about the market surveillance activities are recorded by the market surveillance authorities in National Market Surveillance Database which was established by Ministry of Trade. The annual reports are made public via the web site of the Ministry of Trade. These data mainly contribute to the programming of future inspections.

# AWARENESS RAISING IN THE AREAS OF PRODUCT SAFETY, MARKET SURVEILLANCE AND CONFORMITY ASSESSMENT PROJECT

- **Awareness Raising in the Areas of Product Safety, Market Surveillance and Conformity Assessment Project** is a technical assistance project co-funded by Turkey and EU in which the MoT is identified as the Beneficiary, but also includes other stakeholders from public, private and civil society bodies. The Project duration is 24 months and has been commenced on 9th of October 2018.

- The overall objective of the project is to contribute to increased awareness in the areas of product safety, market surveillance and conformity assessment for better implementation of the EU technical legislation.

- To contribute to effective implementation of market surveillance and conformity assessment with bringing concepts such as transparency, accountability, citizen satisfaction and participation.

- **Directorate General for Product Safety and Inspection under the Ministry of Trade of Turkey is taking a crucial step towards increasing the awareness on product safety.** Within the scope of the Project, activities will be held for increasing the awareness on product safety among thousands of individuals from conformity assessment bodies to manufacturer and consumer associations, and more than 4000 consumer representatives and students across the country will be reached through conferences and seminars.

# TECHNICAL COOPERATION AGREEMENTS OF TURKEY

### Turkey-Azerbaijan
- Signing; Sept 11, 2012
- Entry into Force; May 16, 2013

### Turkey-Ukraine
- Signing; March 1, 2006
- Entry into Force; August 8, 2006

### Turkey-Lebanon
- Signing; April 21, 2009
- Entry into Force; Sept 17, 2009

### Turkey-China
- Signing; June 27, 2005
- Entry into Force; Sept 4, 2006

### Turkey-Israel
- Signing; March 7, 2007
- Entry into Force; August 31, 2008

### Turkey-Iran
- Signing; February 3, 2010
- Official Gazette; August 24, 2011

### Turkey- Kyrgyzstan
- Signing; Sempteber 1, 2018
- Entry into Force; February 7, 2019

### Turkey-Bulgaria
- Signing; April 15, 2009
- Official Gazette; Sept 10, 2009

**With the aim of removing technical barriers to trade and for an unhindered market access for our exporters, Ministry of Economy signs "Technical Cooperation Agreements" with the countries that plays an important role in Turkey's exports.**

**Thereby ,Turkey is seeking for:**

➢ **Promoting bilateral cooperation in fields of standardization, testing, certification, metrology or accreditation**

➢ **Eliminating technical barriers to trade in bilateral trade.**

# SCOPE OF TECHNICAL COOPERATION AGREEMENTS

➤ Framework agreements encompassing provisions of cooperation in technical regulations, standardization, conformity assessment, metrology and accreditation

➤ Establishment of mechanisms (Consultation and Cooperation Mechanism) for the removal of technical barriers to trade

➤ Contact Points as an "alert and notification system" for swift resolution of problems in relation to product safety and inspection

➤ Exchange of experience and information in outlined areas

➤ Enhanced cooperation at relevant international forums

➤ Room for enhanced cooperation in different areas of quality infrastructure

# CONCLUSION

- Having a functional quality infrastructure at international level is crucial for the elimination of technical barriers to trade.

- Turkey is ready to extend its efforts to realize cooperative activities with the aim of exchanging information and experience on technical legislation, facilitate the solution of technical barriers to trade, and provide a basis to develop technical cooperation between the parties' bodies responsible for standardization, accreditation and metrology.

# Thank you

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# CONTENT

# GEOPOLITICAL ADVANTAGE
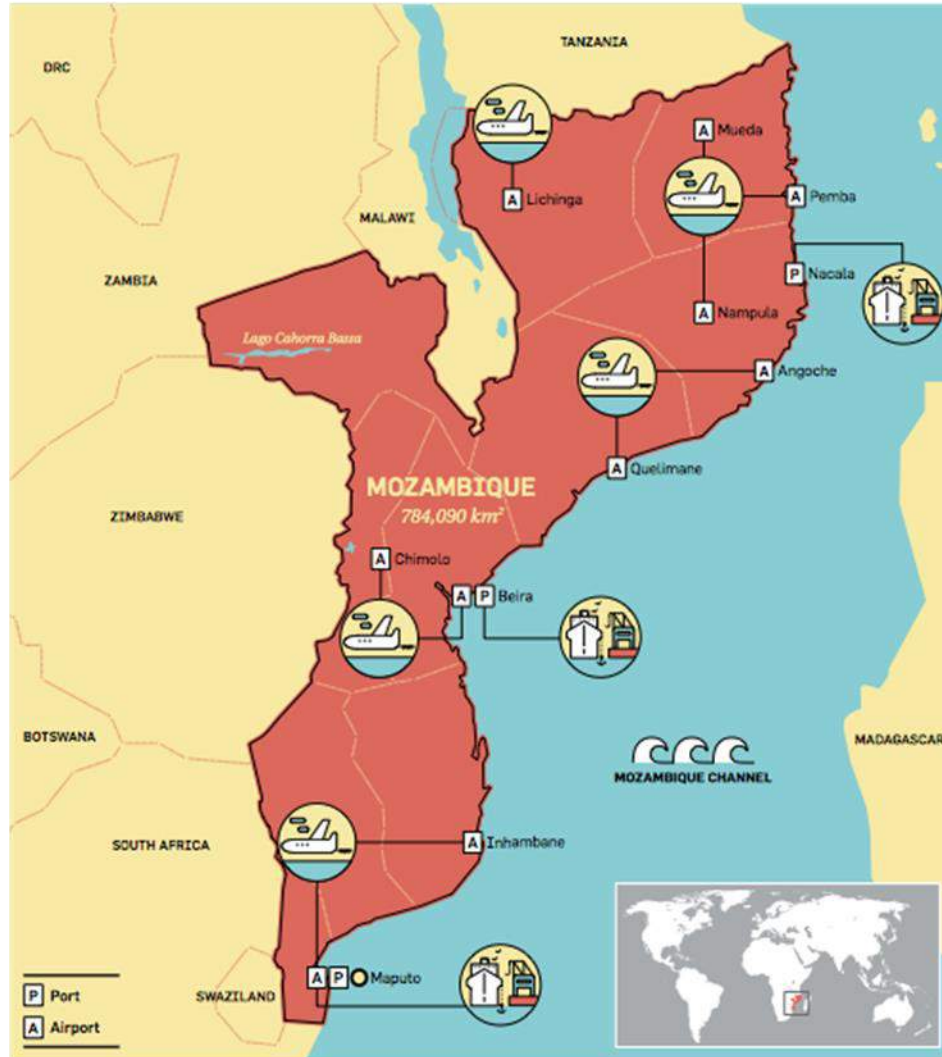


- Boardering Tanzania, Malawi, Zambia, Zimbabwe, South Africa and Swaziland.

- Serve as import/export hub for landlocked countries: Malawi, Zambia, Zimbabwe, Botswana and Swaziland.

- 3 International and 8 domestic airports.

- 3 Main seaports.

- Nacala is the deepest natural seaport in west coast of Africa, with a railway system reaching Zimbabwe through Malawi.

- Member of SADC or Southern African Development Community, 14 members include: Angola, Botswana, Democratic Republic of the Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe.

# INSTITUTO NACIONAL DE NORMALIZAÇÃO E QUALIDADE (INNOQ)

✓Public institution created in 1993, under the supervision of the Minister of Industry and Trade;

✓ Responsible for the implementation of Quality Policy through the activities of:

- Standardization;
- Metrology;
- Certification;
- Testing and Inspection;

That aim the development of the national economy.

# NATIONAL QUALITY SYSTEM ACT 17/2018

This Law establishes the National Quality System as well as the structural framework for the activities related to the development and demonstration of the quality of products and services, according to a set of national and internationally accepted management procedures.

The Law applies to natural and legal persons of public and private law who carry out activities related to Metrology, Standardization, Conformity Assessment, Accreditation, elaboration of Technical Regulations and Sanitary and Phytosanitary Measures in the national territory.

# NATIONAL QUALITY SYSTEM ACT 17/2018

# JUSTIFICATION FOR TECHNICAL ASSISTANCE

- Existance of a great potential of natural resources, such as petrol, gas and mineral coal, which exploration requires huge foreign investment

- Access to Preferred Markets (SADC, US, EU, China, India, Japan)

- Need for urgent implementation of National Quality System Act

- Need for national companies to seize opportunities by providing recognized quality products and services

- Need on the strengthening of technical capacity of INNOQ to satisfy the clients' demand by offering accredited services in Metrology, Certification, Testing and Inspection.

# TECHNICAL ASSISTANCE NEEDS FOR CERTIFICATION

- Training of 60 auditors on ISO:45001, 14001, 9001; FSSC, 22000, HACCP; 50001; 27000; in or out of country.

- Consultancy to design certification schemes for products such as Soja, Tea, Bananas, Sesame, Peanuts, Tobacco, Peas, Macadamia, Maize, Cassava, Beans, Cotton and related products, including "Global Good agricultural practices" (Global GAP) and organic certification.

- Accreditation consulting for management systems and products.

- Training of 20 technicians for testing and inspection.

- Equipment for testing (Chemical and Microbiology) and inspection Labs

- Accreditation consulting for testing and Inspection.

- Training of 38 technicians in diverse fields.

- Reference standards for verification of gas flow totalizers, Ovens, Digital readers, thermocouples, Calibrators of gas flow, temperature meters, digital thermometers, Climatic chamber, mass standards, standards for length, pressure, electrical, large volumes, strength, etc

- Accreditation consulting for calibration of measuring instruments in various fields

Obrigado

INNOQ
YOUR PARTNER FOR QUALITY

**INMETRO**

# The Brazilian National Quality Infrastructure: an overview and recent developments

**Léa Contier de Freitas**
Deputy Head for International Affairs
TBT National Notification Authority and Enquiry Point
National Institute of Metrology, Quality and Technology

13/11/2019

# Metrology, Standardisation and Industrial Quality, as from 1973

**SINMETRO – the system**
National System of Metrology, Standardisation and Industrial Quality

**CONMETRO – ministerial council**
National Council of Metrology, Standardisation and Industrial Quality

**INMETRO**
Secretariat of CONMETRO

**Technical Advisory Groups** *(under review)*

- **Metrology**
- **Standardisation**
- **Conformity Assessment**
- **Regulation**
- **Technical Barriers to Trade**
- **Codex Alimentarius**

# Standardisation

The **Brazilian Association of Technical Standards**, created in 1940, is the sole standardisation body in Brazil.

ABNT adopts the Code of Good Practice for the Preparation, Adoption and Application of Standards (Annex 3, TBT Agreement)

Total of 141 technical committees and study commissions, for 8,131 standards under macro sectors (2018):

| | |
|---|---|
| chemicals, manufacturing technology and materials | 28.3% |
| machinery, mechanical & transport equipment | 20.9% |
| energy, electrical electronics, ICT | 15.8% |
| health, safety & environment | 12.2% |
| building & infrastrucuture | 10.5% |
| others | 12.3% |

**Both**

**TBT National Notification Authority and Enquiry Point come under**  **INMETRO**

- **National Metrology Institute**

- **Legal Metrology Regulation Authority**

- **Product Safety Regulation Authority**

- **National Accreditation Body**

-  **TBT NNA & EP**

**The main regulators**

## Most TBT notifications for regulations are issued by:

- ANVISA – Brazilian Health Regulatory Agency

- MAPA – Ministry of Agriculture, Livestock and Food Supply

- INMETRO – Natl. Inst. of Metrology, Quality and Technology

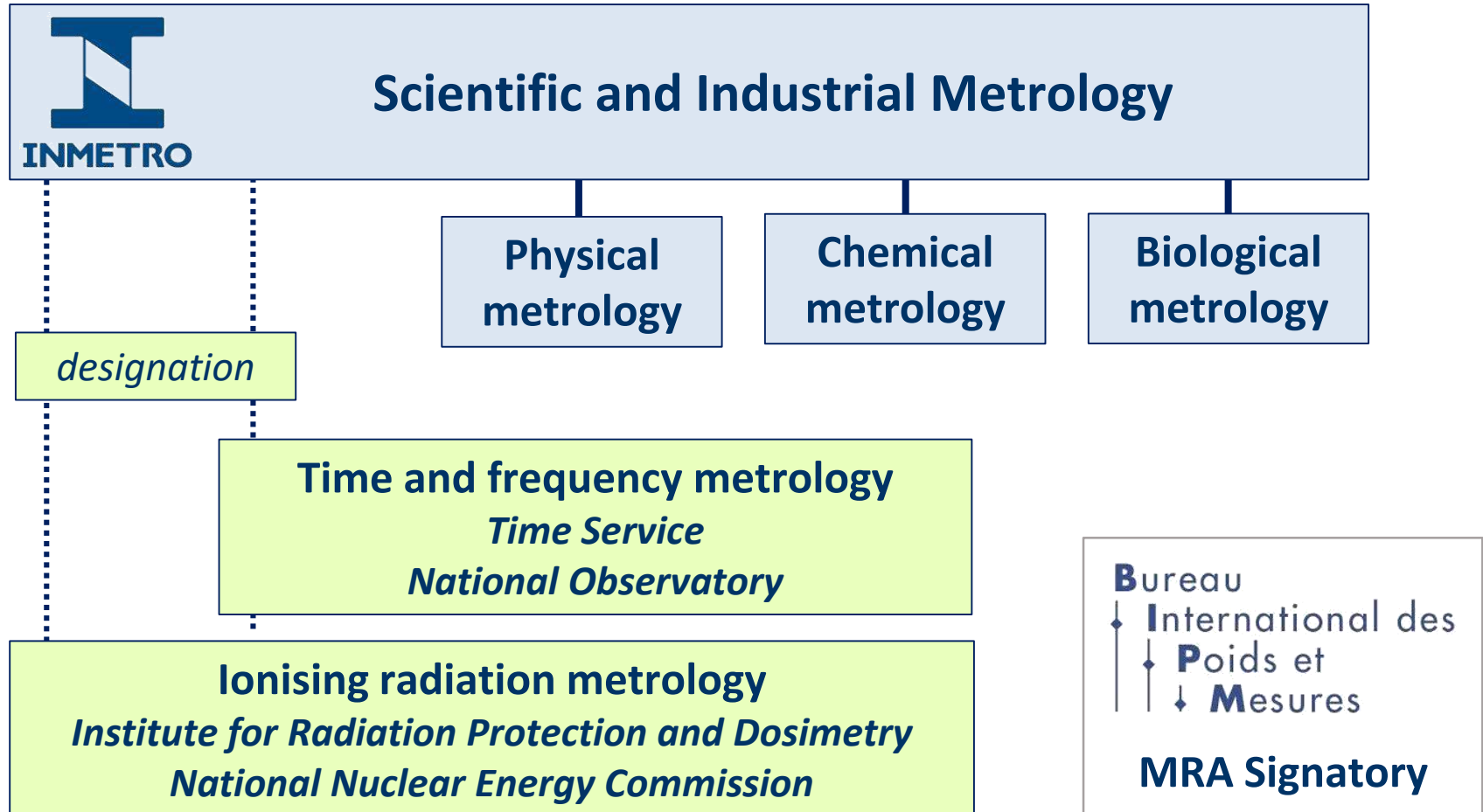**Around 160 TBT notifications per year:**

37% ANVISA

34% MAPA

23% INMETRO

6% other regulators

# Metrology: research; calibrations; tests; production of reference materials



**Scientific and Industrial Metrology**

**Physical metrology**

**Chemical metrology**

**Biological metrology**

*designation*

**Time and frequency metrology**
*Time Service*
*National Observatory*

**Ionising radiation metrology**
*Institute for Radiation Protection and Dosimetry*
*National Nuclear Energy Commission*

**B**ureau
**I**nternational des
**P**oids et
**M**esures

**MRA Signatory**

**They all provide traceability to accredited and non-accredited calibration and testing laboratories; research facilities and others**

**INMETRO**

**Innovation and Metrology Campus**
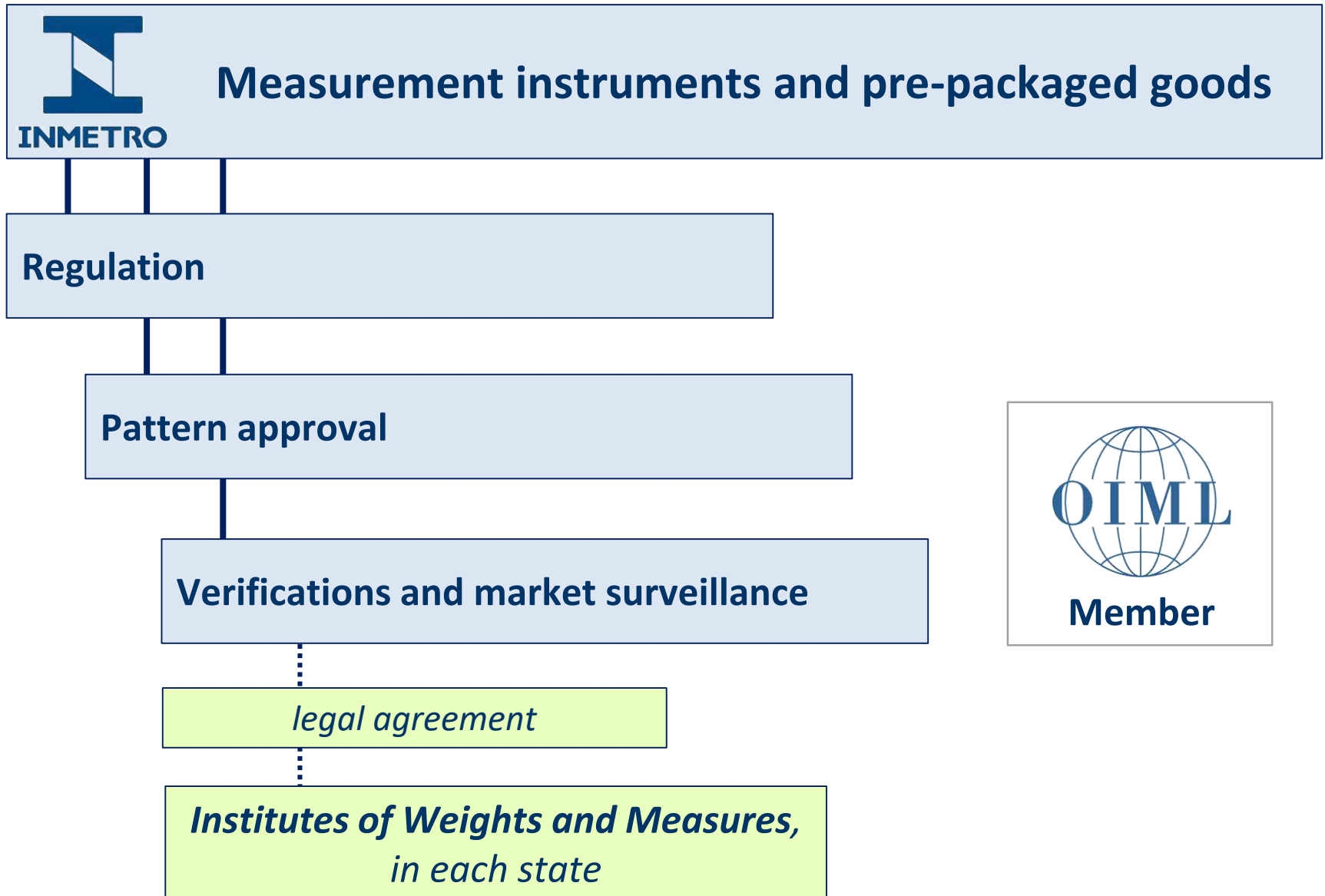
1.7 million m²; 52,700 m² built
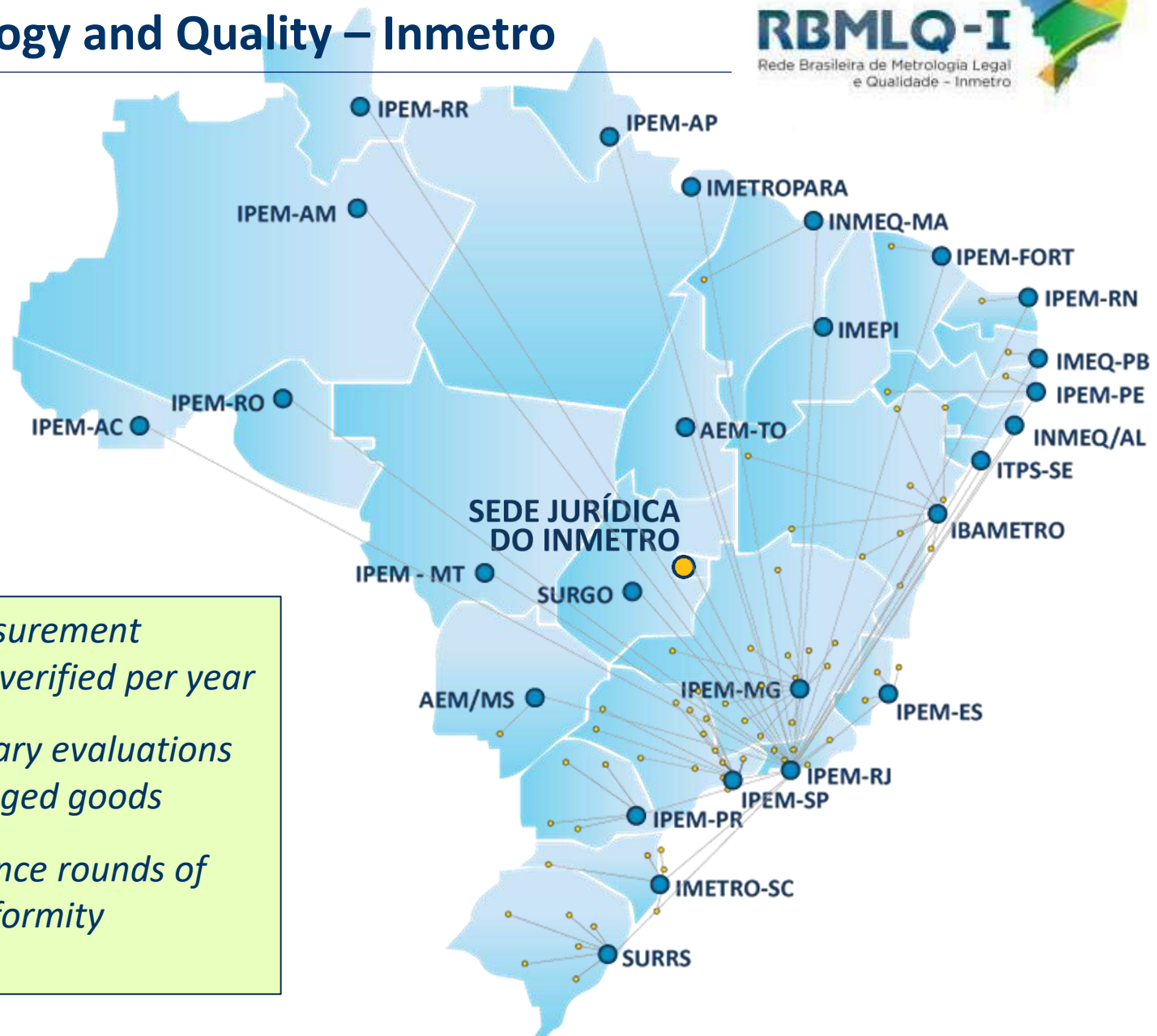
52 laboratories

55 buildings in the Campus

**Inmetro's system workforce**

6,620 profissionals, all over the country

# Legal Metrology

**Measurement instruments and pre-packaged goods**

**Regulation**

**Pattern approval**

**Verifications and market surveillance**

*legal agreement*

***Institutes of Weights and Measures,***
*in each state*

**OIML**

**Member**

# Brazilian Network for
# Legal Metrology and Quality – Inmetro



**28.6 million** *measurement instruments verified per year*

**626,000** *preliminary evaluations of pre-packaged goods*

**635,000** *surveillance rounds of product conformity assessment*

## Accreditation: CGCRE/Inmetro

**Calibration laboratories (ISO 17025): ~1,000**

**Testing laboratories (ISO 17025): ~1,000**

**Management system certification bodies: ~100**
*quality, environmental, social responsibility etc.*

**Product certification bodies: ~120**

**Inspection bodies: ~780**
*dangerous products, vehicle safety & emissions etc.*

**Reference material providers: 10**

**Proficiency test providers: 16**

**OECD—GLP recognised test facilities: 45**

**~ 2,700 accredited bodies**

**970 external assessors**

**4,000 assessments a year**

## Accreditation: CGCRE/Inmetro

**CGCRE is signatory to several MRA:**

**ILAC**          **International Laboratory Accreditation Cooperation**

**IAAC**          **Interamerican Accreditation Cooperation**

**IAF**           **International Accreditation Forum**

**AAQG**          **American Aerospace Quality Group**

**PEFC**          **Program for the Endorsement of Forest Certification Schemes**

**EPA**           **Environmental Protection Agency**

**Globalgap**  **The Global Partnership for Good Agricultural Practice**

**… and is the Brazilian Authority for Monitoring Compliance to the Principles of Good Laboratory Practices – GLP**

## Product safety regulation

**195**     **regulatory measures**

**612**     **ordinances (~ 9,000 pages)**

**684**     **product categories regulated**

**50**     **supplementary ordinances per year**

**US$ 220,000**     **for each new regulatory measure**

*7 years*     *to implement a new measure from scratch...*

**260,000**     **import licences issued per year for regulated products**

**57,000**     **registration applications per year**

**~ 2,000**     **import licences issued per year for measurement instruments**

**300**     **consumer accidents reported to the Inmetro's Monitoring System**

**... only 12% regulated scope covered**

## Product safety regulation

**Under the present regulatory model…**

- **only 1 in 10 products comes under regulation;**

- **regulation is individually applied for every product;**

- **rules are dense, detailed and prescriptive, hindering innovation and competitiveness;**

- **certification + registration + import control indistinctly applied as a general rule (regulatory burden);**

- **same treatment for good and bad manufacturers and importers;**

- **market surveillance is inefficient .**

# Product safety regulation

## Present regulatory model is very prescriptive...

**1** Low performance

**2** Adverse effects to the economy

**3** Not aligned with best international practices

**4** Not aligned with present governmental policy guidelines

INMETRO

# Product safety regulation: the new Inmetro model

**What if 100 % of the scope were regulated?**

**The new regulatory model for** products that come under the regulation scope of Inmetro
**aims at increasing performance and coverage.**

**It is assumed that:**

- suppliers are responsible for the product they offer on the market;

- suppliers must perform risk analysis and take actions to mitigate risks;

- certification bodies will have more freedom but greater responsibility;

- conformity assessment models will be applied according to need and risk;

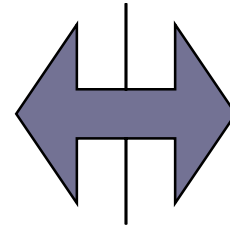- presumption of conformity to standards will be in place.
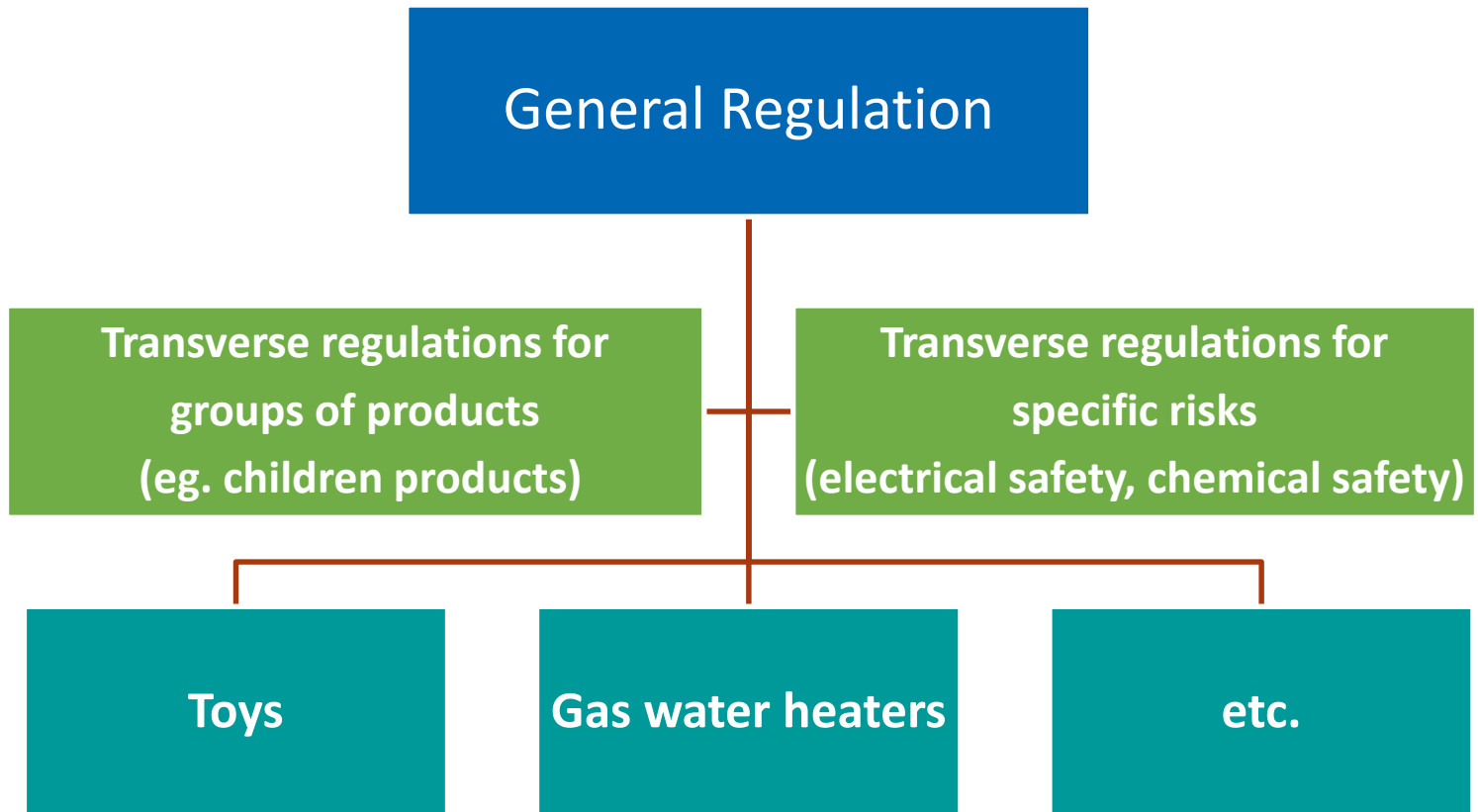
# Product safety regulation: the new Inmetro model

## Focus on problem solving

The basic idea, inspired by what other countries do, is developing a **monitoring strategy** capable of identifying problems related to inputs, products and services within Inmetro's legal competence.

Passive Monitoring

Active Monitoring

## Next steps

- **Simplification of import licensing procedures: 2019;**
- **Simplification of registration: 2019;**
- **Withdrawal of low impact regulation: 2019**
- **Development of the General Regulation: 2020**
- **Development of the second level regulations: 2020-2021**

# Product safety regulation: the new Inmetro model

**Public call for comments was notified. Links directed to a form with questions and to document containing detailed study.**

## Notification summary: G/TBT/N/BRA/890

| | |
|---|---|
| Notifying Member(s) | Brazil |
| Symbol, title and description of content | Ordinance 322, 03 July 2019.<br><br>G/TBT/N/BRA/890 The National Institute of Metrology, Quality and Technology (INMETRO) has initiated the process to elaborate the General Regulation of Products and Services under the regulatory scope of Inmetro. Therefore, it is launching a public enquiry to promote social participation in such process. |
| Distribution date | 12/07/19 |
| Products | Product name(s):<br>Public Call for Comments<br><br>; |
| Objectives | Protection of Human health or Safety |

| | |
|---|---|
| Link(s) to full text | http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002584.pdf<br><br>http://www4.inmetro.gov.br/tomadadesubsidios/regulamento-geral-do-inmetro |

# Thank you

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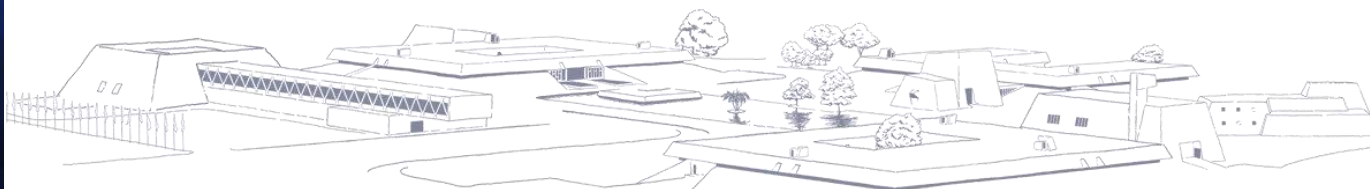
**INMETRO's mission**

The **right measure** to foster  trust for society and competitiveness for the productive sector

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