

Project
funded by the EU

Development of Quality Infrastructure
and Metrology - Montenegro

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Assistance Technique France

A project implemented by ADETEF in
consortium with LNE and SMU

Workshop on WTO/TBT notification procedures

Speaker: Christer Arvius, expert at the project

“Development of Quality Infrastructure and Metrology in Montenegro”

Bureau of Metrology: Podgorica, 17.10.2013

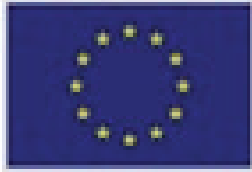
EU internal market and EU external trade policy



**EU - external trade
policy for elimination of TBTs**

**EU -
internal market
- various principles
and techniques
for elimination
of TBTs**





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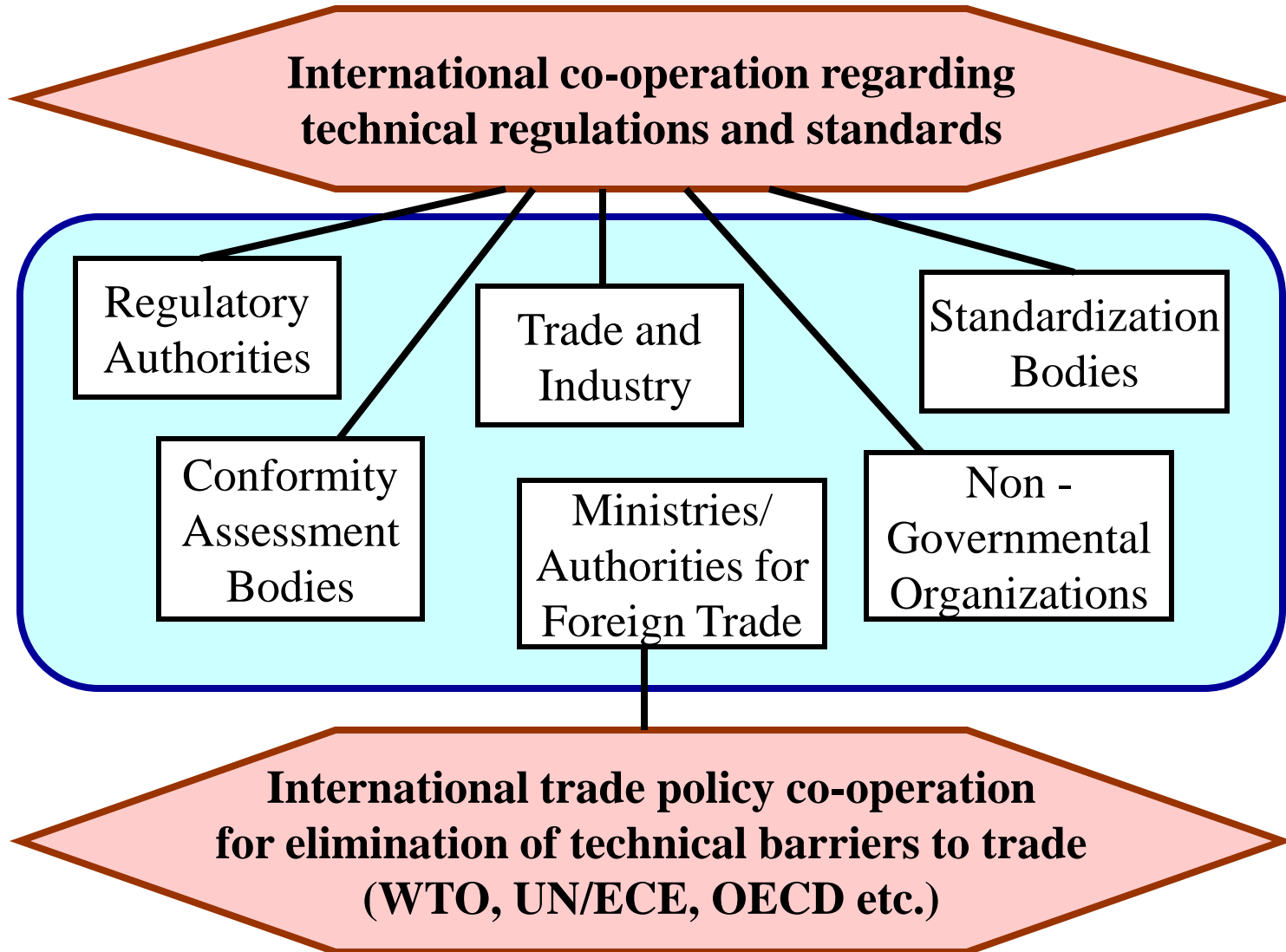
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National Quality Infrastructure

National Quality Infrastructure



Products on the EU Market – proportions?

**Products subject
to national
legislation**

**Products
subject to EU
legislation**

**Products not subject
to legislation**

Notification history on European and International level



1964...



1980...

(First TBT-Agreement)



1983...



1995...

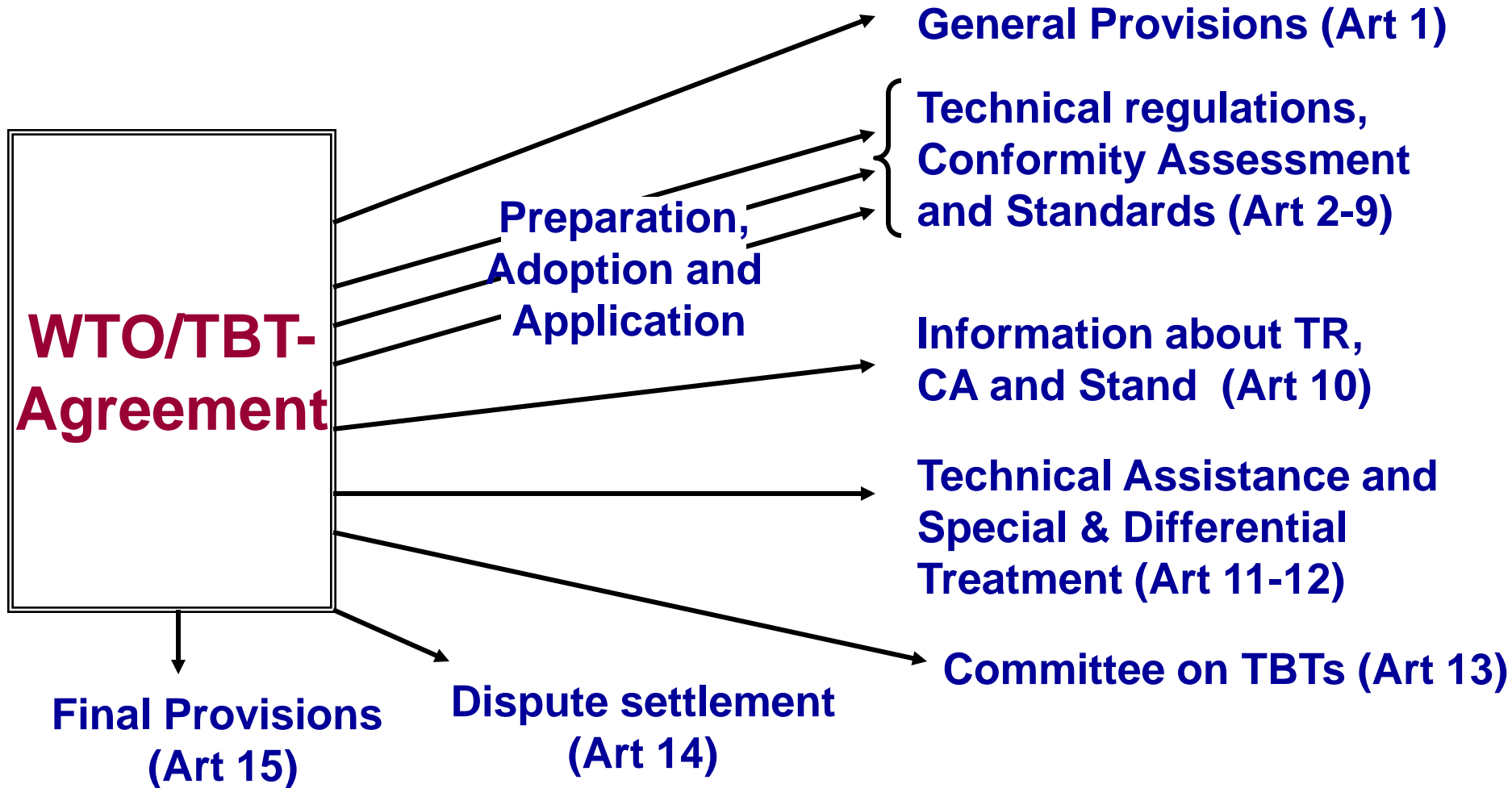
(Existing TBT-Agreement)



WTO Agreement on Technical Barriers to Trade

**Provisions on Technical regulations and
conformity assessment procedures
- especially transparency/notification provisions**

WTO/TBT - Agreement; A General Survey



WTO/TBT Agreement



- in the TBT Committee

WTO/TBT Agreement

- Transparency provisions

- ⇒ Notification of technical regulations/conformity assessment procedures [[Articles 2.9, 2.10, 3.2, 5.6, 5.7 and 7.2](#)]
- ⇒ Notification of Bilateral or Multilateral Arrangements [[Article 10.7](#)]
- ⇒ Designation of a Government Authority for implementation of notification obligations [[Articles 10.10 and 10.11](#)]
- ⇒ Enquiry Points [[Articles 10.1 and 10.2](#)]
- ⇒ Notification of Acceptance or Withdrawal from Code of Good Practice and of the existence of Work Programmes [[Paragraphs C and J of Annex 3](#)]
- ⇒ Statement on the Implementation and Administration of the Agreement [[Article 15.2](#)]

WTO TBT Agreement - Notification procedures and Enquiry Point functions

**Enquiry Point
functions**

Notification procedures

**New, proposed, technical
regulations, conformity
assessment procedures etc.**

**National technical regulations,
conformity assessment procedures,
standards etc.
(adopted or proposed)**

The diagram features a horizontal line representing the WTO TBT Agreement. Below this line is an irregularly shaped area representing national technical regulations, conformity assessment procedures, and standards. An arrow labeled 'Enquiry Point functions' points from the left towards the national regulations area. Another arrow labeled 'Notification procedures' points from the national regulations area towards the right, specifically towards the text 'New, proposed, technical regulations, conformity assessment procedures etc.'.

Technical regulation

“Regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice”
(ISO/IEC Guide 2:2004)

“Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packing, marking or labelling requirements as they apply to a product, process or production method” *(WTO/TBT Agreement, Annex 1)*

The WTO/TBT Agreement prescribes that:

- A proposed technical regulation shall be notified when (Article 2.9)
 - the proposal is not in accordance with existing relevant international standards, and
 - if the technical regulation may have a significant effect on trade of other Members

(Similar notification provisions are prescribed for proposed Conformity Assessment Procedures in Article 5.6)

**SIXTH TRIENNIAL REVIEW OF THE OPERATION AND IMPLEMENTATION
OF THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE
under Article 15.4**

(i) "Significant effect on trade of other Members"

It is recalled that both Articles 2.9 and 5.6 of the TBT Agreement refer to the concept of "significant effect on trade of other Members". With a view to enhancing the practical application of this concept while keeping in mind the criteria established by the Committee in 1995, the Committee agrees:

to *encourage* Members, for the purpose of enhancing predictability and transparency in situations where it is difficult to establish or foresee whether a draft technical regulation or conformity assessment procedure may have a "significant effect on trade of other Members", to notify such measures.

EU (Directive 98/34) and WTO/TBT (Articles 2.9, 2.10, 3.2, 5.6, 5.7 and 7.2) - notification procedures

Other interested parties (Trade and Industry, conformity assessment bodies, standardization bodies, NGOs etc.)

Regulatory Ministries/Authorities

Sending info
Receiving info

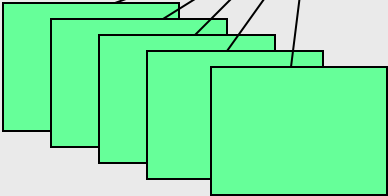


Notification Authority

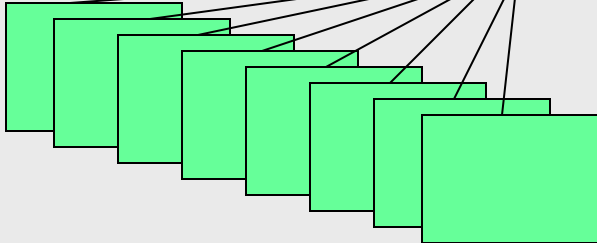


EU Commission

WTO Secretariat

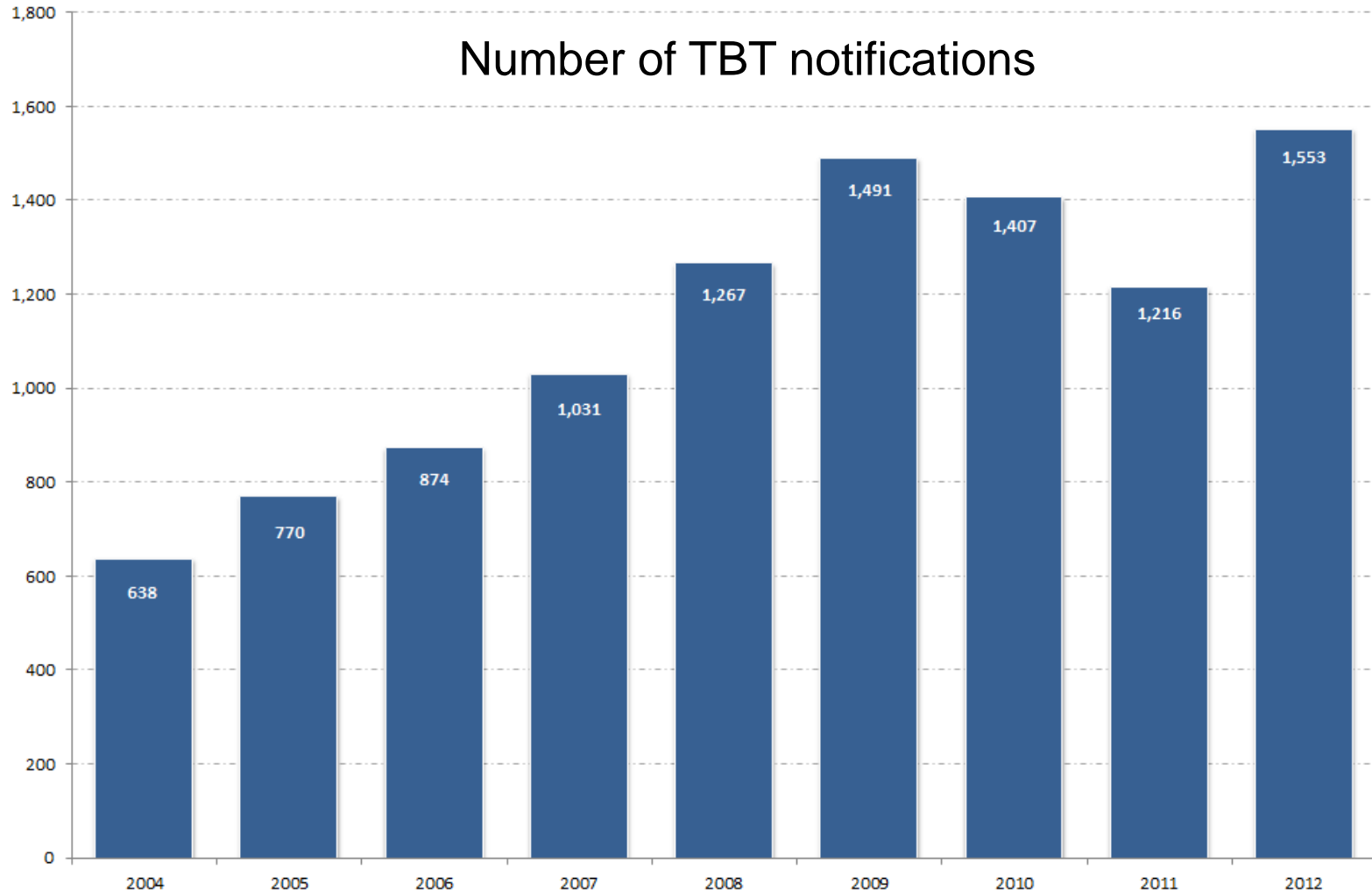


28 Member States



159 Member States

Some statistics...



WORLD TRADE ORGANIZATION

G/TBT/N/BRA/328
18 May 2009

(09-2412)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Member to Agreement notifying: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: Brazilian Sanitary Surveillance Agency – ANVISA Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: National Institute of Metrology, Standardization and Industrial Quality-INMETRO Tel:+(55) 21 2563 2821 Fax: +(55) 21 2502 6542 Email: barreirastecnicas@inmetro.gov.br Website: http://www.inmetro.gov.br/barreirastecnicas/
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Health products.
5.	Title, number of pages and language(s) of the notified document: Draft Resolution nº11, 24 March 2009 – Health Products (2 pages, in Portuguese).
6.	Description of content: This technical regulation establishes the moment to submit the Certificate of Good Manufacturing Practice for registration of health products. It determines that the Certificate must be submitted at the moment of the submission of the registration petition of health products at ANVISA. It also establishes the health products and medical devices that have to follow this requirement. The technical regulation will be in force 365 days after its adoption.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health and prevention of deceptive practices

8.	<p>Relevant documents: Brazilian Official Journal (Diário Oficial da União), March 24th 2009; Section 1. Draft Resolution (Consulta Pública) number 11, 23 March 2009, issued by Brazilian Sanitary Surveillance Agency – Anvisa; When adopted, it will be published in the Brazilian Official Journal. Available in Portuguese.</p>
9.	<p>Proposed date of adoption: To be determined after the end of the consultation period.</p> <p>Proposed date of entry into force: 365 days after the date of adoption.</p>
10.	<p>Final date for comments: Not applicable.</p>
11.	<p>Text available from: National enquiry point [X], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</p> <p>National enquiry point Agency responsible Brazilian Sanitary Surveillance Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Tel: 55 61 3462 5402 E-mail: rel@anvisa.gov.br Website: http://www.anvisa.gov.br/ http://www4.anvisa.gov.br/base/visadoc/CP/CP[25166-1-0].PDF</p>

The Brazilian notification caused:

- **Dialogue** within the TBT notification procedure
 - Comments by EU 2 July 2009
 - Answer by Brazil 9 July 2009
 - Reaction by EU 19 Oct 2009
 - Reaction by EU 25 March 2010
 - Answer by Brazil 14 June 2010

- Further discussion at **TBT Committee** meetings
 - Latest discussion in TBT meeting 17-19 June 2013

(EXTRACT FROM THE MINUTES OF THE WTO/TBT COMMITTEE MEETING OF 17-19 JUNE 2013)

Brazil - Health Products Good Manufacturing Practices (GMP) Requirements for Health Products (G/TBT/N/BRA/328) (IMS ID 233)

1.1. The representative of the European Union recalled Brazil's information at the last TBT Committee meeting that it had adopted several measures to improve the National Health Surveillance Agency's (ANVISA) inspection capacity. Such measures included the augmentation in the number of Good Manufacturing Practices (GMP) inspectors, and the publication of a draft resolution aimed at, *inter alia*, optimising conditions for the concession of GMP certificates. The EU understood that several hundred medical devices were still awaiting GMP inspections, thus pending authorization to be placed on the Brazilian market. The EU welcomed efforts taken by Brazilian authorities to accelerate inspections, but stressed that it would take a long time before the situation was regularized. Therefore, the EU called on Brazil to consider interim steps, such as temporary authorization of foreign GMP certificates. She suggested that ANVISA could continue issuing GMP certificates, however on the basis of inspection reports carried out by bodies established outside the Brazilian territory and shared on a confidentiality basis. This would allow Brazil to safeguard consumer health and safety, optimise resources, and guarantee inspections being carried out within three months after filing of a request. The EU enquired if Brazil was considering these suggestions and asked for an update on the situation and steps to be taken.

1.2. The representative of the United States supported the EU's intervention and recalled previously raised concerns on this issue.

The representative of Brazil referred to the minutes of previous meetings containing explanations on this subject. With regard to the Brazilian authorities' work to improve ANVISA's inspection capacities, he informed that improvements had been taken in the certification process due to the relocation of experts from other areas. Further measures under consideration included an increase in the number of GMP inspectors by opening a new public selection process, and a new regulation allowing for the mutual recognition and acceptance of GMP certificates issued by foreign authorities. He said that Brazil remained open to alternative approaches, such as confidentiality agreements between health agencies in Brazil and other Members to exchange inspection reports, and recalled that Brazil had joined the International Medical Device Regulators Forum (IMDRF).

The Brazilian notification caused:

- even further discussions **bilaterally**
 - The issue is on the Agenda for the forthcoming EU – Brazil Joint Committee meeting
11 November 2013

The EU-TBT website

<http://ec.europa.eu/enterprise/tbt/>

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ENTERPRISE AND INDUSTRY

Technical Barriers to Trade

European Commission > Enterprise and Industry > TBT

≡ **The notification procedure created by the Agreement on Technical Barriers to Trade : an instrument of market openness.**

Enterprises are the driving forces in international trade. So that they can fully benefit from the growth in international trade, the tariff liberalisation undertaken must be accompanied by the removal of unjustified technical barriers. Differences between the technical regulations and conformity assessment procedures adopted by various countries can result in the creation of obstacles to international trade. The Agreement on Technical Barriers to Trade (**TBT Agreement**) is the main international instrument adopted to date in the field of technical regulations. The Agreement aims to ensure that regulations, standards and testing and certification procedures do not create unnecessary obstacles to international trade.

≡ **PRESENTATION OF THE TBT AGREEMENT**

[Presentation](#) | [The notification procedure](#) | [Management at community level](#) | [Comparison 98/34 vs TBT](#)



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WTO Agreement on Technical Barriers to Trade

Standards

National and Regional Standards in the WTO TBT Agreement

Provisions on national and regional standards are contained in:

- **Article 4**
- **Annex 3 (“The Standards Code”)**

cont.

Standards Code (Annex 3 of TBT-Agreement)

Up to Mid February 2013:

162 standardizing bodies (159 national and 3 regional) from 122 Members have accepted the Code of Good Practice

(among them, 87 central governmental standardizing bodies)

(in certain countries several standardizing bodies have accepted the Code: e.g. 6 from Australia; 5 from Hong Kong, China; 10 from Japan; 10 from Mexico)



MEASURES NEEDED FOR AN
EFFECTIVE IMPLEMENTATION
AND ADMINISTRATION OF
THE WTO/TBT AND WTO/SPS
AGREEMENTS



Measures for an effective implementation and administration in Montenegro of the WTO/TBT Agreement and its transparency provisions

- “Decree on notification of technical regulations, standards, regulations on services by the information society and procedure of compliance assessment”; 10 January 2013
(Articles 1-3 and 28-36 related to the WTO/TBT Agreement)
(Articles 4-27 related to Directives 98/34 and 98/48)
- To implement and apply the Decree on notification in an efficient manner in cooperation with relevant parties in the Montenegrin administration and business concerning regulatory and standardisation matter in the WTO/TBT Agreement;



WTO/TBT vs. WTO/SPS AGREEMENTS

TBT

Type of measures

SPS

Objectives

Technical regulations

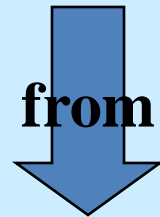
Standards

Conformity assessment procedures

Other measures

**Protection of
animal, plant,
or human
health or life**

from



**Food born risks
and animal
and plant
carried
diseases**

TBT =



SPS =



Electrical Safety	
Pressure Equipment	
Personal Protective Equipment	
Constructions	
Chemicals	
Pharmaceuticals	
Foodstuff	safety and health aspects
Feedingstuff	
Plant	
Motor Vehicle	
Radio and Teleterminal Equipment	
Ships Equipment	
etc.....	

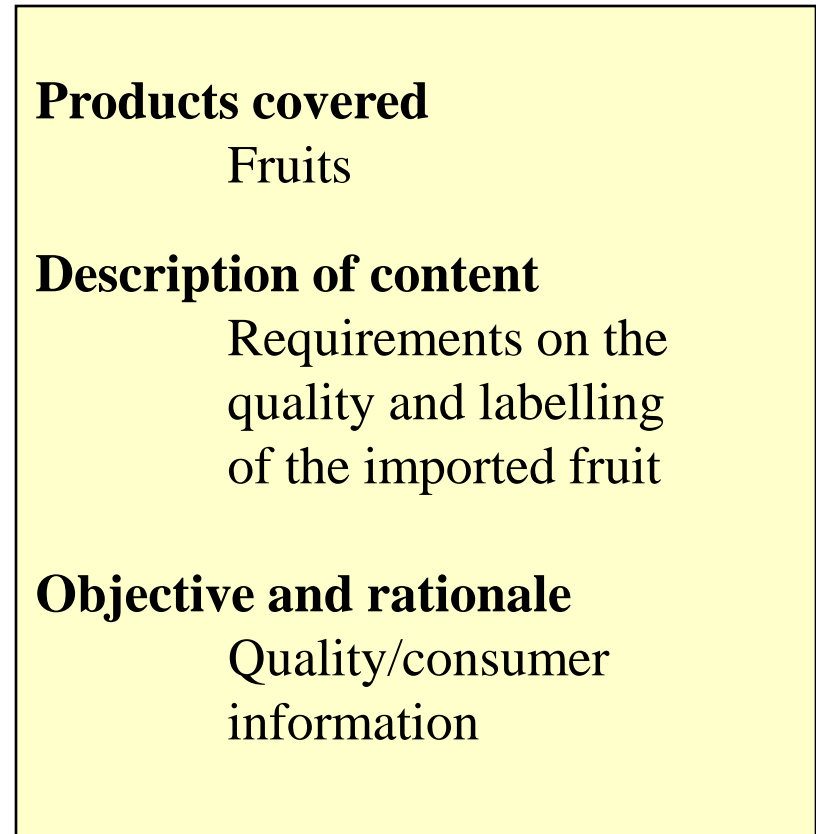
WTO - TBT - SPS

Example 1



SPS

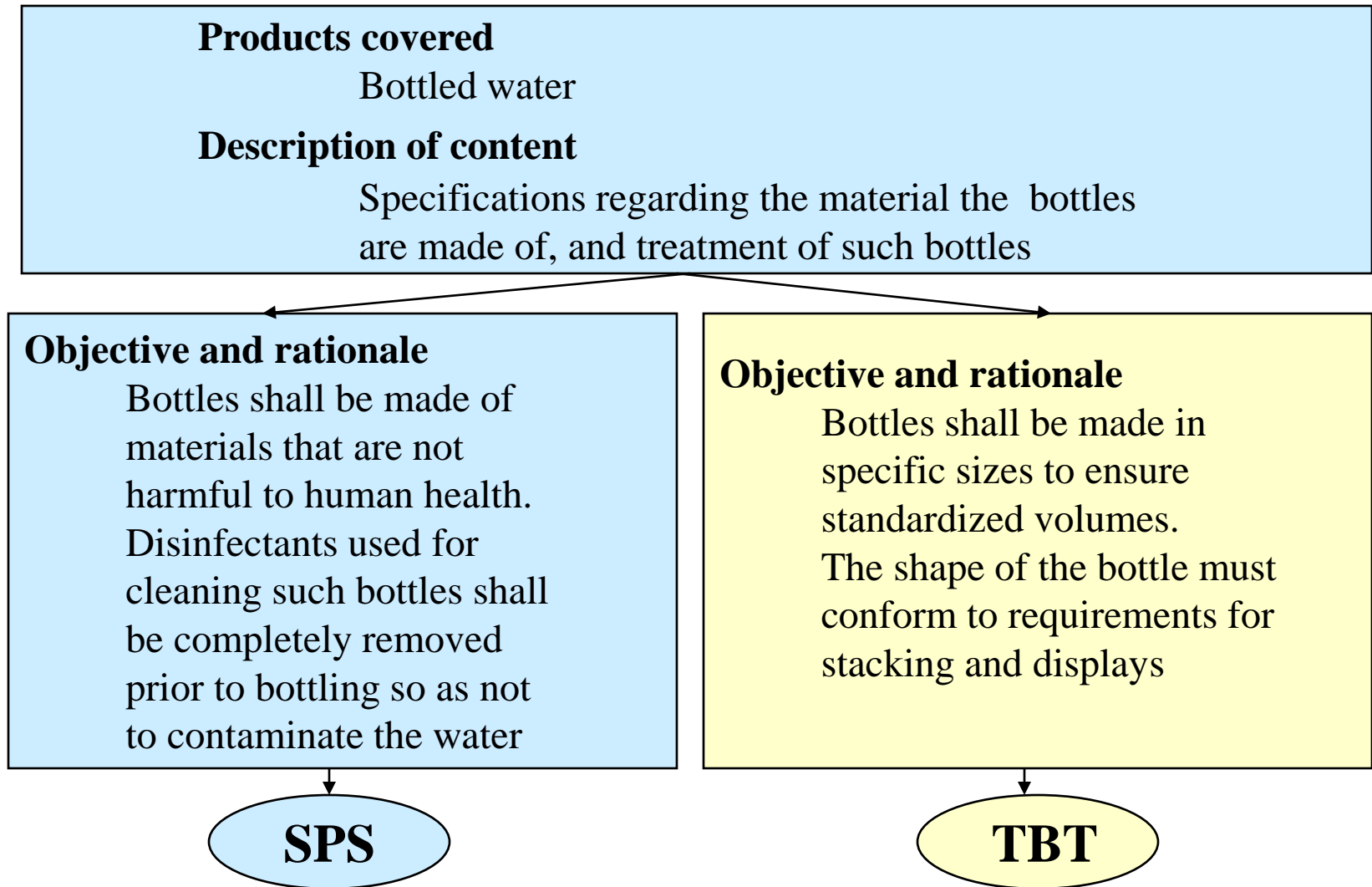
Example 2



TBT

WTO - TBT - SPS

Example 3



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Member to Agreement notifying: <u>EUROPEAN COMMUNITIES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission, EC-TBT Enquiry Point, Fax: 0032 2 299 57 25, E-mail: ec-tbt@cec.eu.int
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Natural Mineral Waters, as per Directive 80/777/EEC, last modified by Directive 96/70/CE, and spring waters, as per Directive 80/778/EEC.
5. Title, number of pages and language(s) of the notified document: Commission Directive establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters – 9 pages, English
6. Description of content: Measures on the admissible limits of mineral waters' constituents and the corresponding labelling requirements as well as on the conditions for using ozone-enriched air for separating certain compounds from natural mineral waters or spring waters, and the corresponding labelling requirements.

(Cont. Notif EEC-26)

7. Objective and rationale, including the nature of urgent problems where applicable:

Constituents naturally present in certain natural mineral waters may, above a certain concentration, present a risk to public health. In 1996, the European Union Scientific Committee for Food issued an opinion on concentration limits and, in several instances, validated the WHO recommended limits for drinking water. Additional guidance was provided by the 1997 revised Codex standard for natural mineral waters, which is based on the most up-to-date international scientific evidence and on public health considerations.

Framework Directive 80/777/EEC provides for the separation of iron, manganese, sulphur and arsenic from certain mineral waters using ozone-enriched air treatment, subject to an assessment by the Scientific Committee for Food and approval of the conditions for use of this treatment by the Standing Committee on the Food Chain and Animal Health. The Scientific Committee issued its advice in the previously recalled 1996 opinion. The Standing Committee's opinion is expected by the end of 2002.

The rationale of these measures focuses on guaranteeing to consumers the high quality and the absence of harmful substances in natural mineral waters. Moreover, the same quality guarantees are laid down for spring waters – which, at the EU level, undergo the same requirements as drinking water – as regards ozone-enriched air treatment, geared to separation of iron, manganese, sulphur and arsenic.

→ This draft has also been notified to the WTO Secretariat under the Agreement on SPS measures.

8. Relevant documents: Draft Directive

9. Proposed date of adoption: End of February-March 2003

Proposed date of entry into force: Implementation by the EU Member States: 1 January 2004 at the latest.

10. Final date for comments: 60 days from date of notification

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

European Commission,
EC-TBT Enquiry Point,
Fax: 0032 2 299 57 25,
E-mail: ec-tbt@cec.eu.int



...what will be the way forward ...

ROAD MAP

for establishing Notification and Enquiry Point systems according to WTO/TBT in Montenegro

7 main tasks for MoE-DQI to be accomplished together with competent regulatory authorities and stakeholders in MN as appropriate by end of March 2014:

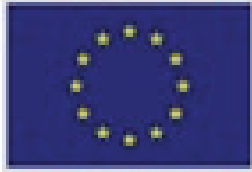
- ⇒ Identify and list all regulatory authorities (line ministries and other institutions), with names, addresses etc.
- ⇒ Clarify how to handle notification of MN draft technical regulations/conformity assessment procedures between MoE-DQI (“Notifying Authority”) and regulatory authorities (see MN Decree on Notification procedures etc., Articles 29-32 and annexed Form on Notification)
- ⇒ Clarify how to handle notifications from other WTO/TBT countries (MoE-DQI to disseminate notifications and gather reactions on notifications from relevant stakeholders in MN)

(cont 1.)

- ⇒ Clarify how to handle Enquiry point functions by MoE-DQI with regard to:
- requests for information from other WTO/TBT countries (cf. need for MN Register on Technical regulations etc.)
 - requests from interested parties in MN for information from Enquiry Points in other WTO/TBT countries (see document G/TBT/ENQ/38/Rev.1)
- ⇒ Identify and list (with names, addresses etc.) major stakeholders in MN for issues related to technical regulations, standards and conformity assessment procedures

(cont 2.)

- ⇒ ISME to notify its acceptance of the “Standards Code” (with regard to procedures to be followed, see Article C of the Code)
- ⇒ MN to make a supplementary statement on the implementation and administration of the WTO/TBT Agreement according to Article 15.2 (with regard to procedures to be followed see page 16-18 of document G/TBT/1/Rev.10)



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**Thank you very much
for your attention!**

(christer.arvius@comhem.se)



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