World Trade Organization Agreement on Technical Barriers to Trade and What It Means for Health Regulatory Authorities

Kristan Callahan, JD
Office of Global Policy and Strategy (OGPS),
Office of Trade and Global Partnerships (OTGP)

November 2023

Objectives

- Understand the WTO Agreement related to Technical Barriers to Trade
- Identify regulations that may have trade obligations
- Understand and model good regulatory practices to make better regulations

World Trade Organization

- International organization that provides a legal and institutional framework for the implementation and monitoring of trade commitments made by WTO Member States
  - Provides a forum for members to negotiate trade agreements
  - Serves as a forum to resolve the trade disputes
  - Monitors how the agreements are being implemented

World Trade Organization

Agreements Particularly Relevant to USFDA

Relevant Agreements

- General Agreement on Tariffs and Trade (GATT)
  - **Agreement on Technical Barrier to Trade (TBT Agreement)**
  - Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
  - Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)

World Trade Organization

Agreement on Technical Barriers to Trade (TBT)

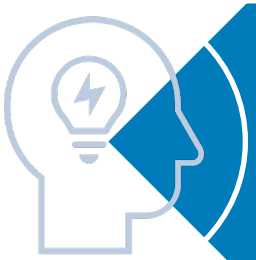
TBT Agreement

- Aims to ensure that technical regulations, standards, and conformity assessment procedures are:
  - Non-discriminatory
  - Do not create unnecessary obstacles to trade

AfCFTA

- Reaffirms TBT Agreement
- Objectives:
  - Reinforces international best practices in regulation and standards setting;
  - Promotes the use of relevant international standards as a basis for technical regulations; and
  - Identify and assess instruments for trade facilitation such as harmonization of standards, equivalence of technical regulations, metrology, accreditation and conformity assessment.

Terms and Definitions



Technical Regulations

- Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which **compliance is mandatory**.

Standards

- Document **approved by a recognized body**, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which **compliance is not mandatory**.

Conformity Assessment Procedures

- Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled

Key TBT Principles

- Use of International Standards
- Transparency
- Not More Trade-Restrictive Than Necessary
- Non-Discrimination

Non-Discrimination Principles

Most Favored Nation (MFN)

- Countries should treat all their trade partners equally
- No country should be “more favored” in terms of their imports.

National Treatment

- Eliminate “hidden” domestic barriers by according imported products treatment no less favorable than that accorded to products of national origin.

MFN and National Treatment

Article 2.1

Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment **no less favorable** than that accorded to **like products of national origin** and to **like products originating in any other country**

Article 5.1.1

Conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions **no less favorable** than those accorded to suppliers of **like products of national origin** or **originating in any other country**

Trade Restrictiveness

Article 2.2

- Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, **technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective**, taking account of the risks non-fulfilment would create.

Article 5.1.2

- Conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, inter alia, that **conformity assessment procedures shall not be more strict or be applied more strictly than is necessary** to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.

Trade-Restrictiveness and Legitimate Objectives

Legitimate Objectives

- Protection of human health or safety
- The protection of animal or plant life or health
- The protection of the environment
- National security interests
- Prevention of deceptive practices
- Etc.

Elements of Consideration

- Scientific and technical information
- Related processing technology
- Intended end-uses of products
- Etc.

USE OF INTERNATIONAL STANDARDS

Use of International Standards

Article 2.4

Where technical regulations are required and **relevant international standards** exist or their completion is imminent, **Members shall use them, or the relevant parts of them**, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

Article 5.4

In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by **international standardizing bodies** exist or their completion is imminent, **Members shall ensure that central government bodies use them, or the relevant parts of them**, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate…

FDA and International Standards

1995 Federal Register Notice, announcing Policy on Standards:

A. Participation in standards development activities
B. FDA is not bound by standards developed with FDA participation
C. The way in which FDA will include standards (or relevant parts of them)
D. The use of a standard in the regulatory programs of FDA is dependent upon factors, like standard stresses product safety and effectiveness
E. FDA employees will comply with agency regulations (Sec. 10.95) covering participation in standard setting activities outside the agency.

FDA and International Standards

- Participation in Standard-Setting Bodies:
  - ISO
  - IEC
  - ANSI
  - ASTM
  - Codex
- Multilateral Organizations:
  - OECD
  - WHO

- Example:
  - ISO 13485 and
  - 21 CFR Parts 4 and 820

IMPLEMENTING TRANSPARENCY

Process for Notification to the WTO of FDA Regulatory Actions

Obligation to Implement Transparency

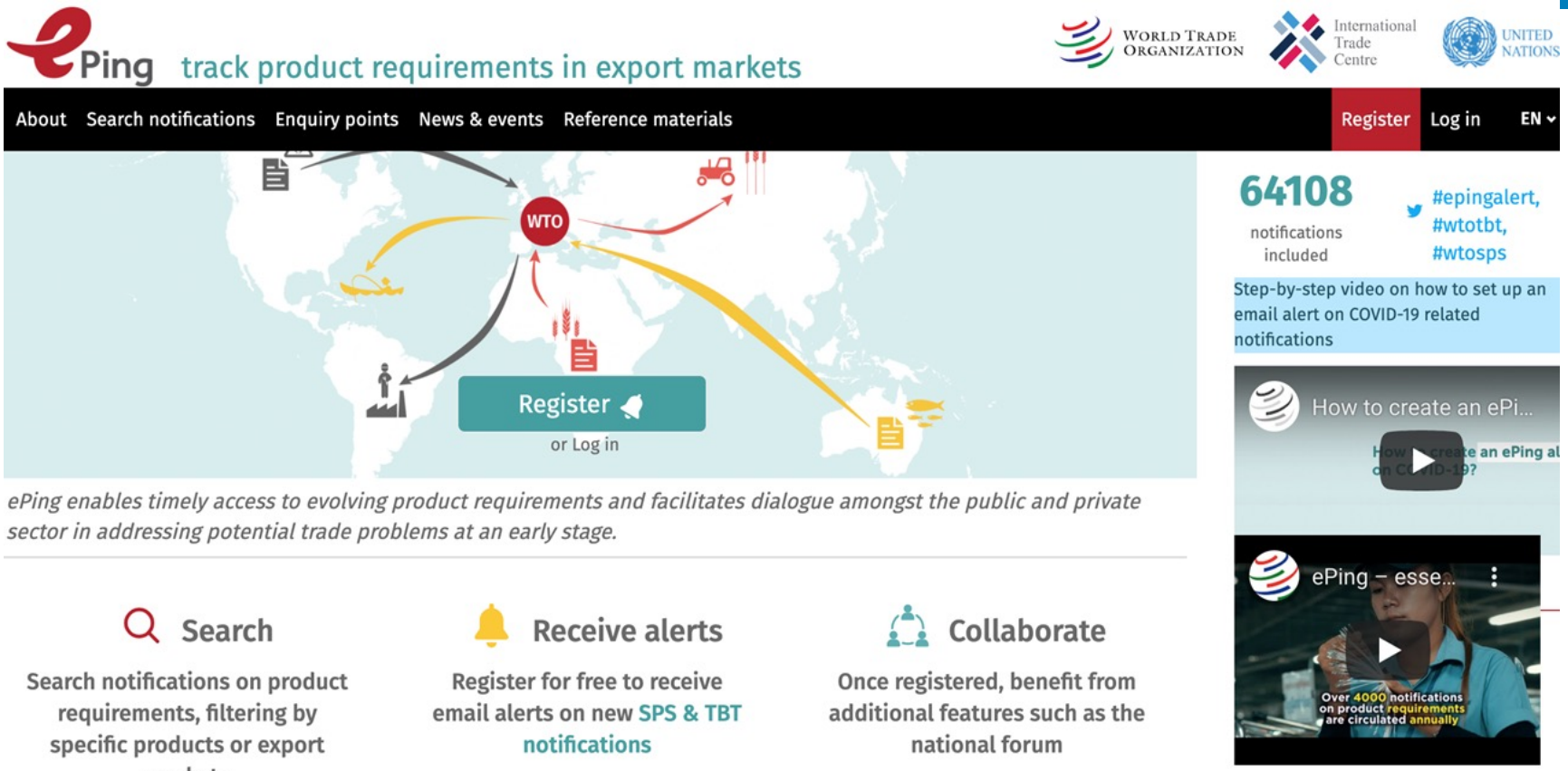
Establish and maintain	Establish and maintain a national enquiry point;
Publish	Publish draft regulations (technical regulations, or TRs) and conformity assessment procedures (CAPs) at an early appropriate stage;
Notify	Notify draft regulations/amendments to the World Trade Organization (WTO);
Allow	Allow for reasonable time for comments while amendments can still be introduced (60 days minimum, longer if possible);
Provide	Provide copies of relevant documents (upon request);
Take	Take written comments/discussions into account when developing the final regulation;
Allow	Allow a reasonable interval between publication and entry into force of the final TR or CAP so producers may adapt (6 months minimum, longer if possible).

e-Ping

ePing is an SPS & TBT notification alert system is a publicly available and self-subscribing service, whereby subscribers are able to receive email alerts regarding SPS and TBT notifications covering particular products and/or markets of interest to them.

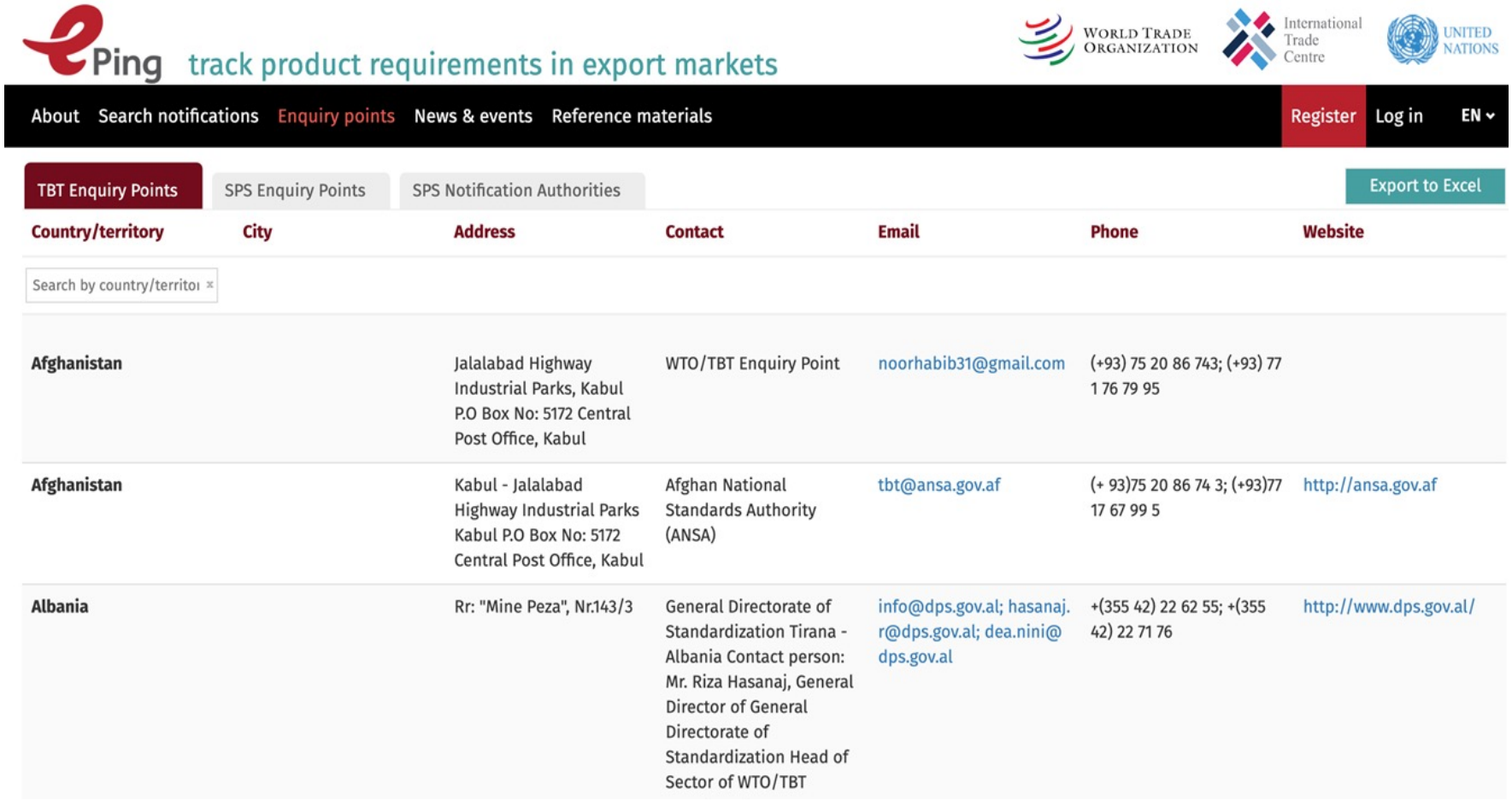
In addition, users can search notifications, share notifications, upload additional information and participate in discussions.

ePing also offers an Enquiry Point Management Tool to facilitate domestic as well as international information sharing and discussion.


ePing track product requirements in export markets
World Trade Organization
International Trade Centre
United Nations
About
Search notifications
Enquiry points
News & events
Reference materials
Register
Log in
EN
WTO
Register
or Log in
64108
notifications included
#epingalert, #wtotbt, #wtosps
Step-by-step video on how to set up an email alert on COVID-19 related notifications
How to create an ePi...
ePing – esse...
Over 4000 notifications on product requirements are circulated annually
ePing enables timely access to evolving product requirements and facilitates dialogue amongst the public and private sector in addressing potential trade problems at an early stage.
Search
Search notifications on product requirements, filtering by specific products or export markets
Receive alerts
Register for free to receive email alerts on new SPS & TBT notifications
Collaborate
Once registered, benefit from additional features such as the national forum

e-Ping

TBT Enquiry Contacts



ePing track product requirements in export markets

World Trade Organization · International Trade Centre · United Nations

About | Search notifications | Enquiry points | News & events | Reference materials | Register | Log in | EN

TBT Enquiry Points | SPS Enquiry Points | SPS Notification Authorities | Export to Excel

Country/territory	City	Address	Contact	Email	Phone	Website
Search by country/territor						
Afghanistan		Jalalabad Highway Industrial Parks, Kabul P.O Box No: 5172 Central Post Office, Kabul	WTO/TBT Enquiry Point	noorhabib31@gmail.com	(+93) 75 20 86 743; (+93) 77 1 76 79 95	
Afghanistan		Kabul - Jalalabad Highway Industrial Parks Kabul P.O Box No: 5172 Central Post Office, Kabul	Afghan National Standards Authority (ANSA)	tbt@ansa.gov.af	(+ 93)75 20 86 74 3; (+93)77 17 67 99 5	http://ansa.gov.af
Albania		Rr: "Mine Peza", Nr.143/3	General Directorate of Standardization Tirana - Albania Contact person: Mr. Riza Hasanaj, General Director of General Directorate of Standardization Head of Sector of WTO/TBT	info@dps.gov.al; hasanaj.r@dps.gov.al; dea.nini@dps.gov.al	+(355 42) 22 62 55; +(355 42) 22 71 76	http://www.dps.gov.al/

Regulator Perspective

- Implementation:
  - Inter- and intra- agency coordination
  - Be a part of the broader conversation
    - E.g., Thematic sessions
  - ePing is a tool for anyone, including regulators

Benefits – E.g, International Standards

Standards play a significant role in the design, production, post-production and regulation of medical devices throughout their lifecycle.

Consistency + **Predictability** + **Credibility**

= Science Based Decisions


FDA
U.S. FOOD & DRUG
ADMINISTRATION