



Latest developments in the EU with respect to cooperation in the field of technical regulations and conformity assessment

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Objectives

- Minimize unnecessary regulatory divergences
- Facilitate trade
- Promote better quality regulations
- Reduce unnecessary regulatory burdens
- Increase consumer confidence

Geographical coverage

- Enlargement
- European Neighborhood – East and South
- Mutual Recognition Agreements – traditional and enhanced
- Free trade agreements – Technical barriers to trade chapters
- Regulatory dialogues

Regulatory dialogues of DG GROW – in 2017

- **Japan** – Working group on conformity assessment and standardisation, January 2017
- **China** – Working group on conformity assessment, November 2017



Comprehensive Economic and Trade Partnership between EU and Canada

- Provisional application as of 21 September 2017
- Regulatory Cooperation Chapter
- Protocol on Conformity Assessment (hereinafter: CETA protocol)

Regulatory Cooperation Chapter - Objectives

- Article 21.3:
 - Protection of human life, health or safety, environment
 - Trade and investment
 - Competitiveness of industry
 - Trust and mutual understanding of regulatory governance
- Important to note (joint interpretative statement):
 - Fully preserving the right to regulate
 - Voluntary nature of cooperation

Regulatory Cooperation Chapter – Possible activities

- Discussions and information exchanges
 - Regulatory governance
 - Contemplated regulatory actions
 - Administration, implementation and enforcement of regulations
- Look for solutions to minimise unnecessary divergences in regulation
- Cooperation
 - International standards
 - Data collection
 - Research agendas

Regulatory Cooperation Chapter - Next steps

- Within one year (unless agreed otherwise) meeting of the Regulatory Cooperation Forum
 - Terms of reference, procedures and work-plan
- Very early stages – possible steps:
 - Deepen knowledge of horizontal regulatory systems
 - Identification of specific sectors of mutual interest



CETA Protocol on **Conformity**

Assessment - Traditional-type MRA (but with innovative features!)

- **The requirements of the importing party apply** (CAN products must comply with EU requirements and vice-versa)– No equivalence of EU and CAN regulatory requirements
- **Mutual acceptance of conformity assessment results:** conformity assessment bodies (CABs) established in the EU allowed to certify according to CAN requirements and vice-versa (i.e. equal validity of certificates issued by EU or CAN recognized CABs)
- It **replaces the existing 1998 EU-CAN MRA** (to avoid disruption, CABs operating under the MRA will be carried over, unless re-designation is necessary for other reasons, e.g. important changes in EU or CAN regulations)

CETA Protocol on Conformity Assessment – Key features

- Canada undertakes same role and responsibilities as EU Member States for the CABs it designates
 - Initial assessment backed by accreditation
 - Notification (like for EU Member States – but 30 days)
 - Monitoring and Supervision
 - Cooperation with EU side on **market surveillance** of products assessed under the Protocol
 - Cooperation with EU side on **investigating** complaints and challenges to competence of **CABs or accreditation bodies (ABs)** recognized under the Protocol

CETA Protocol on Conformity Assessment – Accreditation

- Anchorage in the international accreditation system
- Role of accreditation as the tool to create mutual confidence in the CABs' competence
 - **Recognition of CABs based on their adequate accreditation**
– no other methods of assessment allowed under the Protocol
 - **Equivalent accreditation systems** - CAN operates a public-authority, not-for profit accreditation system through a **single body: Standards Council of Canada (SCC)**
 - **Close cooperation between CAN and EU accreditation systems** to ensure uniformity in CAB assessment
 - => **EA-SCC cooperation agreement to be signed on 10 June 2016**

CETA Protocol on Conformity Assessment – 2 levels of recognition

- **Recognition of ABs** as competent to accredit according to the requirements of the other Party
 - (e.g. SCC recognised as competent to accredit under the EU Machinery Directive)
- **Recognition of CABs** established in the territory of the other Party on the basis of accreditation delivered by a recognised AB
- Recognition always for **specific scopes**
- If no AB in the territory of a Party is recognised ("Phase 2"), a CAB established in that Party can seek accreditation from a recognised AB in the other Party ("Phase 1")

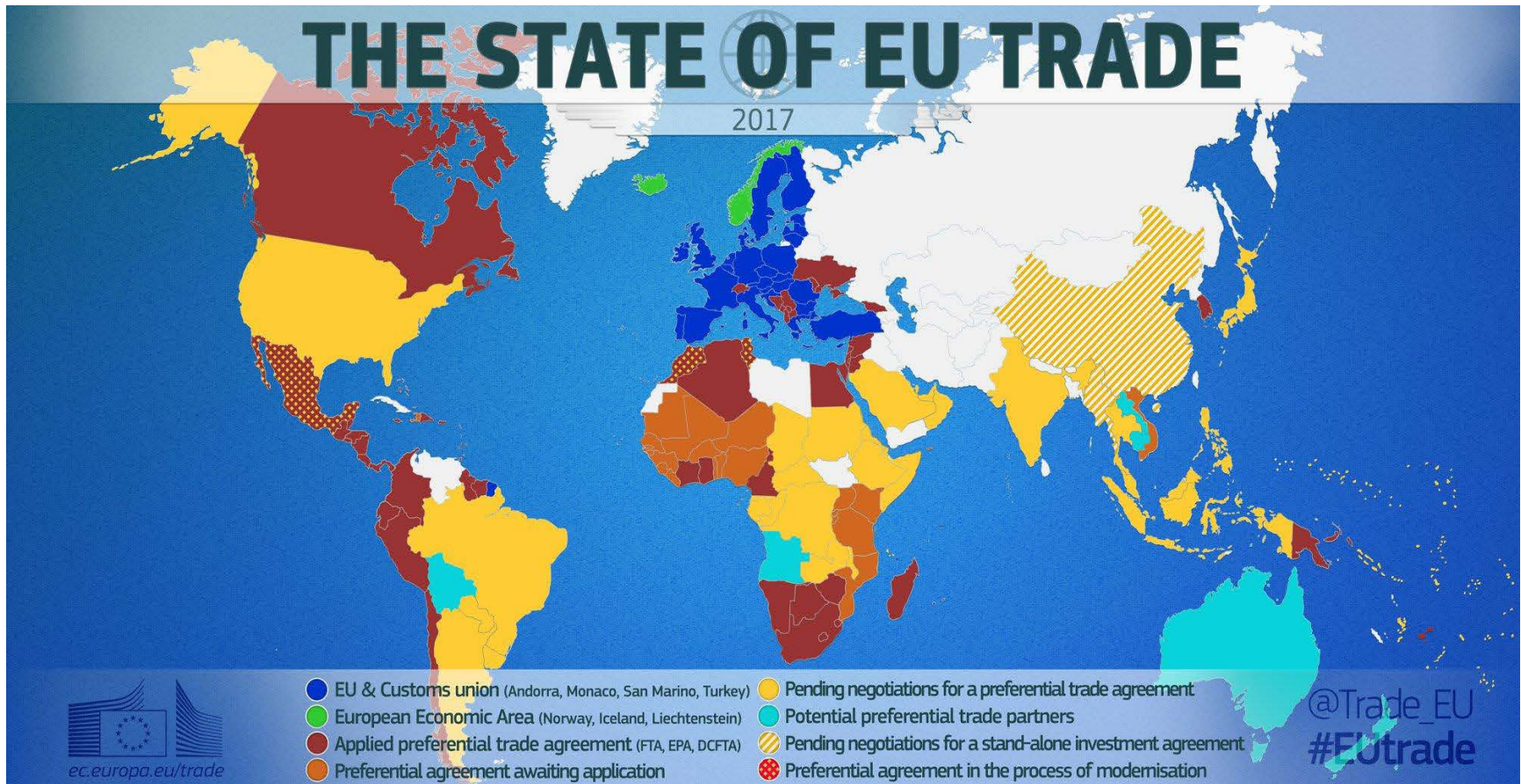
CETA Protocol on Conformity Assessment – Product scope

- **Building blocks approach**
 - **Annex 1: sectors for immediate coverage**, building on sectoral scope of existing MRA (in *italics*)
 - ❖ *electrical equipment, radio equipment, EMC, recreational craft, machinery, ATEX, noise emissions for outdoor machinery, measuring instruments, toys, construction products, hot-water boilers*
 - **Annex 2 – priority sectors for consideration for inclusion after 3 years (list is not exclusive)**
 - ❖ Medical devices, pressure equipment, gas appliances, personal protective equipment, rail systems, equipment placed on board of a ship

CETA Protocol on Conformity Assessment – Expected benefits

- Streamlined CAB designation process relying on accreditation
- Avoid the trap of the ex-post confidence-building phase
- Rigorous process for the assessment of CABs through accreditation
- The Protocol should be a more attractive and business-friendly tool for business
- Substantial reduction of administrative "maintenance" burdens

Free Trade Agreements





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THANK YOU!