PANEL SESSION: PROMOTING REGULATORY COOPERATION IN CONFORMITY ASSESSMENT

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The experience of the European Union

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OUTLINE

I. International cooperation on conformity assessment – Main tools

II. Regulatory Cooperation – Basic concepts

III. Regulatory Dialogues

IV. Free Trade Agreements

V. MRAs

V. ACAAs

VI. Conclusions

International cooperation on conformity assessment

Main tools:

- Support to WTO-TBT Agreement
  - ⇒ Triennial Reviews address conformity assessment policy issues
- Commitment to international standardisation
- Regulatory co-operation
- Bilateral Agreements - Government level
- Technical Assistance
- Promoting/encouraging international cooperation between accreditors (IAF-ILAC) and conformity assessment bodies (e.g. IECEE CB scheme or IECEx)

Regulatory Co-operation – Basics

Regulatory cooperation and dialogue with trading partners

- Voluntary and informal contacts between regulators
  - at bilateral or multilateral level
- Exchange of information about:
  - regulatory approaches (existing or prospective)
  - best practices
  - new initiatives (“early warning”)
- Long term process

Regulatory Co-operation – Basics

- **Regulatory cooperation can contribute to:**

- mutual confidence of regulators
- better understanding of regulatory choices
- greater convergence of regulatory approaches
  - avoidance of unnecessary regulatory differences
  - reduction of duplicative regulatory requirements and related burdens
  - promote better quality legislation
- facilitating trade by minimizing trade frictions
- promoting joint co-operation in relevant international bodies
- increased consumer confidence (esp. where product safety is an issue in bilateral relations)

- **Regulatory cooperation might result in a formal agreement**
- **Ultimately, the appropriate approach selected depends on policy context and objective**

Regulatory Dialogues

Examples of Bilateral Co-operation:

- EU – US (High-Level Regulatory Cooperation Forum plus numerous sectoral or policy dialogues (e.g. on risk assessment, good regulatory practices, standardisation and conformity assessment issues)
- EU – China (Regulatory Dialogue, Industrial Policy Dialogue)
- EU- Russia (Common Economic Space => Partnership for Modernisation:approximation of systems in the area of technical regulation, conformity assessment and standards)
- EU - Japan (Regulatory Reform Dialogue, Industrial Policy Dialogue, ongoing work on non-tariff measures in bilateral trade)
- EU – Canada (Voluntary Framework for Regulatory Cooperation)

Regulatory Co-operation

Examples of Multilateral Co-operation:

- Medical Devices – GHTF
- UN/ECE
- OECD - GLP
- EuroMed
- ASEM

NEGOTIATION OF FREE TRADE AGREEMENTS WITH TBT/REGULATORY COOPERATION COMPONENT

- Korea (signed, now pending ratification, also contains Annex on conformity assessment for electrical/electronic products)

- Colombia and Peru, Central America (negotiations technically closed, now text in legal scrubbing)

-Ukraine, India, Mercosur, ASEAN countries (Singapore, Malaysia, Vietnam, others may follow), Mercosur, Canada

- in preparation with Eastern Partnership Neighbours : Armenia, Moldavia, Georgia

Conclusions

- Regulatory Co-operation is often productive
- Can help to “converge” regulations and procedures
- But ….. not possible to have dialogues with all potential partners
- Prioritisation necessary

What MRAs are in place?

Country	Entry into force
Australia	1 January 1999
Canada	1 November 1998
Israel	1 May 2000
Japan	1 January 2002
New Zealand	1 January 1999
Switzerland	1 June 2002
United States	1 December 1998
United States (marine equipment)	1 July 2004

Types of MRA

- Traditional (without alignment of rules or standards) – US, Canada, Australia, NZ, Japan, Switzerland (in part)
- Based on *acquis* pre-accession: PECAs
- Based on *acquis* without foreseeing accession: ACAAs, Switzerland (in part)
- Based on international rules or standards: US marine equipment (based on IMO Conventions); Israel GLP (based on OECD)

Characteristics of a traditional-type MRA

- Recognition of results of *compulsory certification* required by a Party where the certificates are issued by conformity assessment bodies (CABs) in the territory of another Party

- Such an MRA *does not of itself* imply harmonisation of technical regulations or standards.

What does an MRA do?

Traditional MRA

- Enables certification to the other Party's rules by local CAB rather than by CAB located in other Party (that's all it does)

MRA based on common rules and standards

- Eliminates duplicate testing
- Improves market access for both sides

ACAA

- Recognises progress towards adoption of *European legislation*

Experiences

Some examples...

- Telecommunications – most active sector
- Marine Equipment – substantial activity – now mirrored by EFTA
- Canada EMC: rendered obsolete by move to supplier's declaration by both sides
- Electrical safety: No EU requirements for third party testing – so MRA has no effect on trade into Europe

Experiences

- Development of dialogue between MRA partners' regulatory authorities.
- MRAs in some sectors have not proved possible to implement – for example, owing to concerns of regulators
- Little or no trade observable under some MRA sectors.
- MRAs are ineffective if they do not cover *all* requirements for a product.

ACAAs

ACAA = Agreements on Conformity Assessment and Acceptance of industrial products.

Full alignment of the legislative system and infrastructure of the third country concerned with those of the European Community.

The conclusion of an ACAA is the end result of extensive dialogue and assistance in the fields of technical regulations and standards for industrial products.

ACAAs

- Pre-accession instrument (candidate countries for EU accession – ACAA will expire upon accession

- Privileged partnership with countries in the European neighbourhood with are not eligible for candidate country status (signature with Israël on GMP for pharmaceutical products; future negotiations with Mediterranean neighbours: Algeria, Tunisia, Egypt, Morocco, Jordan, Lebanon and Palestinian Authority; and with Ukraine)

OTHER INSTRUMENTS

Uptake of EU acquis by :

=> EFTA countries signatories to the Agreement Establishing the European Economic Area (Iceland, now candidate for accession, Norway and Liechtenstein)

=> EU-Turkey Customs Union Agreement

=> Accession negotiations (currently 4 candidate countries: Croatia, Former Yugoslav Republic of Macedonia, Iceland and Turkey; potential candidate countries: Albania, Serbia, Bosnia Erzegovina, Montenegro, Kosovo)

Some conclusions

Traditional-type MRAs are second best :

- Greatest savings need harmonisation of:
  - technical requirements
  - conformity assessment procedures
- Harmonisation is difficult
  - EU Internal Market a rare example
- Easier conformity assessment helps market access

Some conclusions

Tools to bring down trade barriers and facilitate trade:

- Compatibility of Approach (level of convergence or approximation may vary, culminating in equivalence or full alignment when justified by the economic and political context)
- Appropriate Level of Regulation and CA Procedure (apply Good Regulatory Principles in the choice of conformity assessment procedures)
- Commitment to international standardisation
- Compatibility of Market Surveillance
- Cooperation on tackling counterfeiting and IPR issues

Further information

Regulatory coperation:

http://ec.europa.eu/enterprise/policies/international/index_en.htm

WTO/TBT-MRAs-ACAAs:

http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/index_en.htm

http://ec.europa.eu/trade/creating-opportunities/trade-topics/european-competitiveness/non-tariff-barriers/