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Multilateral TAIEX seminar on accreditation and conformity assessment for the Mediterranean neighbour countries in the framework of the ACAA preparations

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The ACAA preparations:
List of requirements to fulfil before launching and concluding negotiations and
Where are we with the Mediterranean partners?

The ACAA preparations

Our Mediterranean partners are stakeholders in the European neighbourhood policy and the Union for the Mediterranean.

This includes negotiating Agreements on Conformity Assessment and Acceptance of industrial products (ACAA) to facilitate access to the market for industrial products.

The challenge before us is to find a way to extend the benefits of the EU's internal market to our neighbouring countries which are not candidates to accession. Adopting common regulatory structures will, in time, help to facilitate the creation of an EU/Mediterranean free trade area for industrial products.

Specifically, the conclusion of a bilateral agreement for certain industries will make it easier for industrial products to gain access to the EU market. The products covered by the agreement will be able to enter the EU without further testing or certification and move freely in the 27 Member States and vice versa.

The ACAA is an ambitious instrument: it removes technical barriers to trade in specific sectors first, and then could gradually be extended to cover all sectors where the legislation is harmonised at European level. It could therefore lead to a real enlargement of the European internal market for products including Mediterranean partners.

As part of the preparations for negotiating such an agreement, the partner countries need to overhaul their quality systems for industrial products. This includes a gradual approximation of technical regulations, standards and procedures for conformity

assessment in the priority sectors and the upgrading of infrastructure for standardisation, accreditation, conformity assessment, metrology and market surveillance.

Pre-conditions for the ACAA negotiations:

(1) The existence of an official agreement between the EU and the partner country defining their relationship (Association Agreement / Free Trade Agreement);

(2) Regulatory cooperation with the partner country;

(3) Alignment (adoption and maintenance) with the corresponding part of the *acquis* (horizontal and sectoral) by the partner country;

(4) A suitable level of standardisation, accreditation, conformity assessment, metrology and market surveillance infrastructure in the partner country;

(5) Adoption of relevant harmonised European standards and withdrawal of conflicting ones;

(6) Assessment by the EU of partner country's corresponding legislation, implementing infrastructure and standards.

1. NEED OF A BASIC ACT

The countries potentially concerned must have concluded a general agreement with the EU (association, partnership and/or free trade agreement) which includes provisions to promote the application of EU technical rules and standards for industrial products and certification procedures.

These agreements also provide an institutional framework which can be used or adapted for the management of ACAAs. The purpose is to create a flexible mechanism to facilitate their operation, without creating an extra administrative burden.

The ACAA comprising a framework agreement and specific annexes related to the priority sectors and the lists of horizontal and sectoral legislation, will be a protocol to the basic act.

2. Regulatory cooperation with the partner country

In view of the fulfilment of the pre-conditions, there should be an enhanced regulatory cooperation between the EU and the partner countries.

Full clarity about the responsibility of the coordinator and the different stakeholders having a role to play in the ACAA preparations in the partner country should be ensured.

A timetable listing the tasks and deadlines within which each preparatory activity should be finalised will be annexed to the basic act. The release of the necessary technical assistance will be linked to the progress in performing the tasks listed in the timetable.

Technical assistance should be designed in function of the choice of sectors.

Commission services will regularly organise seminars financed by TAIEX as a training in support of the infrastructure upgrading and on the new ACAA related EU legislation.

After the entry into force of the agreement, partner countries should participate in Committees managing EU Directives related to the ACAA sectoral annexes and market surveillance committees.

The training of manufacturers should be foreseen at the final stage of the preparations.

3. ADOPTION OF THE CORRESPONDING PART OF THE SECTORAL ACQUIS BY THE PARTNER COUNTRY

One of the basic requirements of an ACAA is the legislative horizontal and sectoral alignment. Non-harmonised areas are not suitable for an ACAA.

The Adoption and maintenance of the legislative alignment is mentioned in the ACAA text.

A timetable for the adoption of the identified legislation will be annexed to the basic act. This annex may also be subject to changes over time.

4. SUITABLE INFRASTRUCTURE IN THE PARTNER COUNTRY

Suitable standardisation, accreditation, conformity assessment, metrology and market surveillance infrastructure must be created in the partner country before the entry into force of an ACAA. An important element is the participation of the partner country in European standardisation and accreditation work.

More specifically, the following requirements must be met in the 'new approach' sectors:

- all the relevant harmonised European standards must be transposed, and conflicting standards withdrawn;
- if the partner country decides to set up a future Notified Body, its competence will have to be demonstrated;
- a functioning market surveillance system and appropriate safeguards must be applied. Moreover, any incompatible national procedures, e.g. authorisation systems prior to placing on the market, must be abolished.

At institutional level, a clear and complete hierarchical separation between the regulatory, standardisation, accreditation and certification functions is necessary for an ACAA to be properly implemented. The public authorities should keep for themselves just the legislative and enforcement roles (including market surveillance) and ensure that the system of third-party certification of compliance with the regulatory provisions is of sufficient technical quality and independence.

Accreditation must be used to ensure the competence of the notified bodies for conformity assessment in the countries which have concluded an ACAA so as to meet the requirement of Member States that only safe products be allowed to enter the EU's internal market. The application of the harmonised European standards is also important. Consequently, the basic requirement would be that 100 % of these standards have been transposed in the sectors covered by the ACAA. The countries concerned must abolish any contradicting national standards.

For metrology, partner countries should have signed a CIPM/BIPM (International Convention of Weights and Measures) for units of measurement, be affiliated to WELMEC and OIML for legal metrology and to EURAMET for scientific metrology.

Assessment missions in partner countries will take place at the end of the preparations to confirm the adequacy of the implementing infrastructure.

4.1. Standardisation

As European standards are an important part of any ACAA, the countries concerned must be able to participate in the work of the European standardisation bodies (CEN, CENELEC and ETSI). Under the current rules, the status of affiliate is open to the EU's neighbouring countries, allowing them to take part in the work of CEN and CENELEC but without voting rights. Full membership of CEN and CENELEC is available only to the standardisation bodies of EEA countries or EU candidate countries.

4.2. Accreditation

The participation of ACAA signatory countries in the ongoing work of the European accreditation organisation is equally important. Countries which are not in the EEA or are not EU candidate countries can conclude bilateral agreements with European Cooperation for Accreditation (EA) which have the same content as the multilateral agreements for EA members. These agreements relate to:

- testing and calibration for the accreditation of laboratories;
- certification for the accreditation of certification bodies, products, persons and management systems;
- inspection for the accreditation of inspection bodies.

The scope of the agreements to be signed by the partner countries will depend on the conformity assessment modules contained in the European directives to be transposed in the chosen sector.

Even though the application of harmonised standards and accreditation are part of the preparation process, it is for the competent European bodies – not the Commission – to define their position with regard to participation and membership. The Commission can, however, provide advice for the establishment of appropriate cooperation mechanisms.

4.3. Market surveillance:

- The Regulation 765/2008 should be fully implemented;
- The partner countries should apply the risk assessment methodology of RAPEX;

Guidelines:

http://ec.europa.eu/consumers/safety/rapex/docs/rapex_guid_26012010_en.pdf

and web page:

http://ec.europa.eu/consumers/safety/rapex/guidelines_states_en.htm

- The partner countries should create a national database to collect information about the cases of non-safe products;
- We recommend the creation of an electronic portal to inform potential users (other public administrations, the economic operators and the public) about the existence of market surveillance authority(ies) and providing the opportunity for the stakeholders to send complaints, signals about non-safe products;
- We also recommend to develop further cooperation between market surveillance authorities and external border control authorities including the exchange information on products representing a risk.

5. ADOPTION OF RELEVANT HARMONISED EUROPEAN STANDARDS AND WITHDRAWAL OF CONFLICTING ONES

This refers to the standards as being referenced in horizontal and sectoral legislation.

A transitional period could be granted for the withdrawal of conflicting national standards according to the rules of CEN/CENELEC, i.e. not exceeding 12 months.

The CE marking cannot be affixed on the product during the transitional period.

6. ASSESSMENT BY THE EU OF PARTNER COUNTRY'S CORRESPONDING LEGISLATION (HORIZONTAL AND SECTORAL) IMPLEMENTING INFRASTRUCTURE AND STANDARDS

Prior to the time of negotiations, there should be a screening of horizontal and vertical legislation performed Commission services.

Throughout the preparatory phase, technical assistance projects could also provide support for drafting or assessment of legislative drafts.

Where are we in terms of preparations with the Mediterranean partners?

The ACAA on pharmaceuticals with **Israel** entered into force on 19 January 2013. Preparations are in progress to add the pressure equipment sector to the existing ACAA.

Morocco and **Jordan** are making good progress in their preparations, in particular with regard to the legislative alignment. The infrastructure upgrading is continuing with the help of technical assistance.

The preparations are ongoing in **Tunisia** and **Egypt** at a slow pace.

Lebanon, **Algeria** and **the Palestinian Authority** are currently benefiting from technical assistance as a support to restructure their quality infrastructure.

Forthcoming TAIEX workshops in Member States in the context of ACAA preparations:

- Market surveillance before the end of the year, and
- Metrology, with the participation of Euramet and Welmec, early next year.