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Policy Brief

OVERVIEW OF THE AGREEMENT ON CONFORMITY ASSESSMENT AND ACCEPTANCE OF INDUSTRIAL PRODUCTS (ACAA)

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The EU and Lebanon have not yet concluded an Agreement on Conformity Assessment and Acceptance of Industrial Products, but negotiations are underway.

Conformity assessment for goods manufactured in the EU

The WTO TBT Agreement tries to ensure that national trade regulations, standards, testing and certification procedures do not create unreasonable obstacles to trade. On the other hand, the WTO TBT Agreement recognizes members' rights to adopt and implement measures to achieve legitimate policy objectives, as could be the protection of human life and safety, the protection of plant life, the protection of the environment, etc.

Conformity Assessment is a mandatory step for the manufacturer within the EU in his process to market products complying with specific product legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages of the production process, in order to facilitate acceptance of the industrial product by the consumer. Conformity assessment includes activities such as testing, inspection and certification. Manufacturers can choose between self-certification, type examination, production quality systems and full quality assurance systems. Conformity Assessment Bodies (CABs) exist in all Member States.

In any case, conformity assessment procedures serve the purpose to demonstrate that a product, before it is placed on the market, conforms to the essential requirements in the legislations applicable to it. As a general rule, a product should be covered by conformity assessment during both the design and the production phase.

The consumer usually is aware of the CE marking that is required for many products (not all!). The CE marking informs the consumer that the product is assessed before being placed on the market and meets EU safety, health and environmental protection requirements. CE marking must be obtained before marketing the product in the Single Market and not only for products originating in the EU, but also for many products originating in third countries (certain electrical equipments, civil

explosives, toys, medical devices, etc). Manufacturers, importers and distributors are thus equally concerned with obtaining the CE marking.

Conformity assessment for goods manufactured in third countries in the absence of a MRA

For marketing products from third countries within the EU, importers and distributors need a specific Product Certification, the CE marking, whenever their product is covered by specific product legislation. Manufacturers may choose among a series of options to obtain the final Product Certification under the New Approach Directives. It is the importers and distributors responsibility to find out whether the specific technical requirements are obligatory for their products. In principle, this information is available from the EU Export Help-Desk. Each Directive covering the product specifies whether an independent conformity assessment is required from a Notified Body. Testing the products and risk assessments are also required.

Technical standards are set by the standards organizations CEN, CENELEC and ETSI. At the end of the procedure, manufacturers issue a declaration of conformity and market their products with the EU sign.

Independent Certification Bodies, or Notified Bodies, obtain official accreditation to test and certify EU technical requirements.

Conformity assessment for goods manufactured in third countries with a MRA

Mutual Recognition Agreements (MRAs) provide for testing performed by Notified Bodies established in third countries and for the recognition of their certifications by EU authorities. MRAs include relevant lists of designated laboratories, inspection bodies and conformity assessment bodies in both the EU and the third country.

The EU has entered so far into MRAs with the USA, Switzerland, Japan, Canada, Australia and New Zealand.

Market surveillance

Market surveillance consists of controls performed after the product has been placed in the market. Member States authorities perform market surveillance for all products that are offered in their national markets. It is one of the mechanisms available to protect the final consumer efficiently.

In February 2013, the EU Commission proposed to improve product safety in the EU by strengthening market surveillance in the Member States. At that time, inequalities in the level of market surveillance could be identified in certain Member States and/or regions. The EU Commission pursues with this initiative a double objective. On the one hand, it intends to protect consumers from “unsafe” products. On the other hand, it plans to avoid unfair trade practices to the detriment of industry and commerce. The EU Commission has spelt out that its decision is linked to a risk that derives directly from products entering the Single Market from third countries. The

EU Commission confirms that effective market surveillance must be comparable along all the length of the EU's external borders. The swift cooperation among national market surveillance authorities will certainly contribute to the creation of a level playing field in terms of product safety as viewed from the perspective of the consumer.

The package for the implementation of the new market surveillance mechanisms is a matter that is closely related to the free trade area according to the Association Agreement. As a matter of fact, the generous market access provisions for Lebanese products (and of other MEDA countries with AAs) support the improvement of the current market surveillance systems within the Single Market.

International dimension of EU industrial policy

The European Union has been always in the forefront of support for international cooperation regarding the areas of technical regulations, standards, conformity assessment and the elimination of technical barriers to trade for products. The EU Commission has made clear its intention to intensify cooperation with its Eastern and Southern neighbours in the areas of trade, market access and regulatory structure, within the framework of the European Neighbourhood Policy (ENP).

The use of the EU system of standardisation and conformity assessment by third countries is designed to facilitate trade and market access in both directions.

Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs)

ACAAs have been designed for their adoption between the EU and third countries eligible for ENP measures. ACAAs are a type of MRAs based on the alignment of the legislative system of the third country concerned with those of the EU.

ACAAs (and MRAs) have the objective of promoting trade in goods between the European Union and third countries by facilitating market access. This objective is achieved by means of getting an easier access to conformity assessment procedures and decisions.

MRAs and ACAAs lay down the conditions under which the EU and the third country concerned will accept test reports, certificates and marks of conformity issued by the CABs of the other party to the Agreement, in conformity with the legislation of the first party. At present, the only ACAA entered into by the EU in Mediterranean countries is the Agreement between the EU and Israel on conformity assessment and acceptance of industrial products, signed in Brussels on 6 May 2010, which entered into force on 19 January 2013. This ACAA has similarities with MRAs entered by the EU with other third countries. It deals with good manufacturing practices (GMPs) for pharmaceutical products.

GMPs are the practices required in order to conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food,

drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

The parties to the ACAA have the following obligations:

- Each party to the Agreement shall recognise the conclusions of inspections of compliance of manufacturers and importers with the principles and guidelines of EU GMPs and equivalent GMPs from the third country. GMP certificates issued by either party are mutually recognised. This applies also to inspections conducted outside the territory of the parties.
- Each party shall recognise the relevant manufacturing and import authorisations confirming compliance with legislation of manufacture and importation and the principles and guidelines on EU GMP and equivalent GMPs from the third country.
- Certification of the conformity of each batch to its specifications by either the manufacturer established in one of the parties, or the importer, shall be recognised by the other party without re-control at import from one party to the other. The batch certificate should follow the internationally harmonised template published in EUDRALEX, vol. 4, Part III (http://ec.europa.eu/health/files/eudralex/vol-4/mra_batch-certificate_05-2011.pdf). EUDRALEX is the body of EU legislation in the pharmaceutical sector.

These provisions do not apply to products imported from a third country (=not a party to the ACAA) that have exclusively tested in and inspected by a competent authority of that, or another third country.

ACAAs provide typically for two mechanisms:

- Recognition of equivalence in technical regulations, standardization and conformity assessment for industrial products subject to equivalent regulations in EU law and the national law of the partner country. Mutual recognition of products operates on the basis of the acquis communautaire that has been transposed by the partner country, in the same way as it would apply to products placed on the market of a Member State. No duplication in the approval procedures is required. The partner country takes over the Community technical legislation and participates in the EU organisations
- Mutual acceptance of industrial products that fulfil the requirements to be lawfully placed on the market in one of the Parties

<u>An outlook over the future EU-Lebanon ACAA</u>

The Euro-Mediterranean Agreement establishing an Association between the European Community and its Member States, of the one part, and the Republic of Lebanon (AA), of the other part, signed on 17 June 2002, which entered into force on

1st April 2006, calls for the reduction of divergences in standardisation, metrology, quality control and conformity assessment. More importantly, it also refers to negotiating MRAs “as soon as the conditions for them are met”.

The European Union provided funding through the European Neighbourhood Instrument (ENPI) to support the Lebanese Quality Programme, QUALEB. The overall objective of the Twinning Project was to support private sector competitiveness in Lebanon by improving the national technical and quality between the end of 2012 and September 2014 (budget: 1,4 million EUR). It is expected that the Twinning Project will add to the preparation for the ACAA negotiations and help to increase Lebanese exports to the EU.

The raison d’être of the ACAA is to effectively remove technical barriers to trade in specific sectors first; this could then be gradually extended to cover other, even all sectors where the legislation is harmonized with the acquis communautaire.

Negotiations are now ongoing between EU and Lebanese authorities.

The negotiating parties consider that the conclusion of a bilateral agreement for certain industries will make it easier for industrial products to gain access to the EU and to the Lebanese markets. The products covered will be able to enter the EU without further testing or certification and move freely in the 27 Member States and vice versa.