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ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach

NOTE TO THE SENIOR OFFICIALS GROUP FOR STANDARDISATION AND CONFORMITY ASSESSMENT POLICY

Title:	**CERTIF 2008-03 Impact of the EU accreditation framework at international level**		
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Abstract:

This document is intended to outline the impact of the new European accreditation framework at international level. It describes the specific principles of this framework, its effects on the international cooperation between accreditation bodies and its impact on the Community's external trade policy in the field of conformity assessment.

Keywords:	**Accreditation, Accreditation bodies, International accreditation Forum (IAF), International Laboratory Accreditation Cooperation (ILAC), European Co-operation for accreditation (EA), conformity assessment attestations**
References:	**Regulation (EC) N° 765/2008 of the European Parliament and of the Council setting out requirements for accreditation and market surveillance relating to the marketing of products;**

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Subject: Impact of the EU accreditation framework at international level

The new Regulation (EC) No 765/2008[1] embodies the European accreditation policy in relation to conformity assessment. It introduces for the first time a common legal base for accreditation by providing for a horizontal framework for accreditation which lays down at European level the principles for its operation and organisation. This framework covers accreditation linked to conformity assessment independently whether the conformity assessment is performed in the mandatory or voluntary sphere. Moreover it applies beyond the New Approach legislation covering conformity assessment activities carried out in industrial sectors not covered by the New Approach as well as in other areas such as environment, health and agriculture.

This documents attempts to explain the impact of the new accreditation framework at international level. This includes outlining the main features and specific principles of the European accreditation policy, the effects on the international cooperation between accreditation bodies and its significance for the Community's external trade policy in the field of conformity assessment.

1. BACKGROUND

Accreditation as an impartial means of assessing and conveying formal demonstration of the technical competence, impartiality and professional integrity of conformity assessment bodies is an effective quality infrastructure tool used worldwide.

At international level, cooperation between accreditation bodies takes place within two organizations: namely within the International Accreditation Forum (IAF) between accreditation bodies accrediting certification and inspection bodies and within the International Laboratory Accreditation Cooperation (ILAC) between accreditation bodies accrediting laboratories and inspection bodies. Both entities provide for multilateral mutual recognition arrangements between its accreditation body members. IAF manages a Multilateral Recognition Arrangement (MLA), while ILAC operates a Mutual Recognition Arrangement (MRA). Although the names of the arrangements changes, both

[1] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

organizations have the aim through these arrangements to establish confidence concerning the equivalence of the operation of the signatories to the agreement and that the results of accredited conformity assessment bodies issued under accreditation of the signatories are equally reliable. These multilateral mutual recognition arrangements/agreements of competence at technical level between accreditation bodies have the ultimate aim to allow products and services accompanied by accredited conformity attestations to enter foreign markets without a re-testing or re-certification in the import country. The objective of such recognition arrangement/agreements between accreditation bodies is therefore to contribute to reinforce the acceptance of conformity assessment certificates.

At the regional level, cooperation organizations between accreditation bodies have been established in[2]:

- Europe: European co-operation for accreditation (EA)
- America: Inter America Accreditation Cooperation (IAAC)
- Asia – Pacific: Asia Pacific Laboratory Accreditation Cooperation (APLAC) and Pacific Accreditation Cooperation (PAC)
- Africa: Southern African Development Community Accreditation (SADCA)

Except for SADCA which is currently developing its regional mutual recognition arrangement, the above listed cooperation organisations have agreements/arrangements in place within their region on which the ILAC/IAF arrangements build upon. By granting special recognition IAF accepts the mutual recognition arrangements established within EA and PAC: accreditation bodies being member of IAF and signatories to the EA Multilateral agreement (EA MLA) or the PAC Multilateral Recognition Arrangement (PAC MLA) are automatically accepted into the IAF MLA[3]. ILAC accepts the mutual recognition arrangements and underlying evaluation procedures of EA, APLAC, and IAAC. Accreditation bodies which are not affiliated to any recognised regional cooperation entity may apply directly to ILAC and/or IAF for evaluation and recognition.[4]

2. THE NEW LEGAL ENVIRONMENT

Regulation (EC) No 765/2008 provides for a comprehensive horizontal legal framework for the operation and organisation of accreditation in the European Economic Area (EEA)[5] applicable as from 1 January 2010. It imposes obligations and requirements on

[2] Only the main accreditation cooperation organisations at regional level are listed.

[3] While the special recognition by IAF granted to EA and PAC covers the IAF Product MLA, the IAF Quality Management System MLA and the IAF Environmental Management Systems MLA, special recognition granted to IAAC is limited to the IAF Quality Management Systems MLA. http://www.iaf.nu/

[4] For more detailed information on the IAF MLA and the ILAC MRA and their signatories: http://www.iaf.nu/ and http://www.ilac.org/ilacarrangement.html

[5] The Agreement creating the European Economic Area which came into force 1 January 1994 extends the Single Market to the EEA EFTA States (Norway, Iceland, Liechtenstein) therefore covering, among others, all the *acquis* relevant to the free circulation of products.

European national accreditation bodies, Member States and the European Commission and sets out the respective responsibilities as well as the co-ordinating role of the European co-operation for Accreditation (EA). Under Regulation (EC) No 765/2008 EA is recognised as the official European infrastructure for cooperation in the field of accreditation responsible for the management of the European peer evaluation which ascertain the competence of the European accreditation bodies[6].

The stabilization of accreditation as authoritative and therefore last level of control of conformity assessment activities from a technical competence point of view is at the core of the European accreditation policy. In this respect Regulation (EC) No. 765/2008 formalizes a set of requirements in particular for accreditation bodies. These requirements are in line with the globally accepted requirements laid down in the relevant ISO/IEC international standards, although some of them can be perceived as being more rigorous, going beyond the requirements set out in the applicable standards. In particular

- Accreditation is carried out by one single national accreditation body appointed by its Member State (Art 4.1)

- Accreditation is performed as a public authority activity (Art 4.5)

- National accreditation bodies operates free from commercial motivations (Art 8.1) and on a not-for- profit basis (Art 4.7)

- National accreditation bodies do not compete with conformity assessment bodies and among each other (Art 6.1 and Art 6.2)

- Cross frontier accreditation is carried out only under certain limited circumstances (Art 7): European conformity assessment bodies are required to request accreditation by the national accreditation body of the Member State in which they are established. The possibility of a conformity assessment body to request accreditation in another Member States is limited to the cases where in its Member State there is no national accreditation body, where the national accreditation body does not offer the requested accreditation service or where the national accreditation body has not received a positive result in the peer evaluation in relation to the conformity assessment activity for which accreditation is requested

By laying down these specific "supplemental" requirements, Regulation (EC) No 765/2008 protects accreditation in Europe against the risk to become an additional layer of commercial certification which would jeopardize its reliability, neutrality and credibility. Accreditation would in this case not only entail added and unjustified cost without added value but would also be unable to provide the necessary confidence to the market creating the need for an extra layer for supervision.

[6] The peer evaluation managed by EA forms the basis for the EA multilateral agreement (EA MLA), underpinning the ILAC MRA and IAF MRA.

3. THE IMPACT ON THE RELATION BETWEEN EA AND ILAC AND IAF

According to Regulation (EC) No 765/2008 European national accreditation bodies fulfilling the requirements of the Regulation are member of EA (Art. 4.10). Different from European national accreditation bodies, accreditation bodies not members of EA may not necessarily meet all the above outlined EU requirements as these do not apply outside the EEA and are not addressed to third country accreditation bodies. Although Regulation (EC) No 765/2008 does not provide for rules regarding the relationship between EA and international co operations between accreditation bodies, the question arises on the impact for the co-operation between European and third countries accreditors at international level taking place within ILAC and IAF and within their respective global Mutual Recognition Arrangement and Multilateral Agreement to which EA belongs as a Region. If EA would recognise the equivalence among accreditation bodies and the equal reliability of accredited conformity assessment bodies' only by accreditation bodies meeting the same requirements, EA would undermine the international multilateral mutual recognition arrangement/agreements and isolate itself. As this is in no way the intention of Regulation (EC) No 765/2008, EA recognizes that attestations of conformity issued in accordance with the requirements of ISO/IEC 17011 under accreditation bodies signatories to the ILAC MRA and IAF MLA but not signatories to the EA MLA or BLAs[7] and not complying with all the requirements of the EU regulation are considered to be equally reliable from a technical point of view to those issued within the EA MLA and BLAs.[8]

4. THE IMPACT ON TRADE RELATIONS IN THE FIELD OF CONFORMITY ASSESSMENT BETWEEN THE EU AND THIRD COUNTRIES

The international mutual recognition between accreditation bodies allow certificates and reports accompanying exported goods and services to be more readily accepted on the international and the European market, but the ultimate acceptance in the EU of conformity assessment attestations issued under accreditation by non European bodies not necessarily complying with the new European requirements does not depend on the cooperation and mutual recognition of accreditation bodies. The ultimate acceptance of conformity assessment attestations is decided by the public authorities and, from an economic point of view, by industry users and consumers. The voluntary multilateral mutual recognition agreements between accreditation bodies taking place at technical level support, further develop and enhance intergovernmental trade agreements.

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[7] Nationally recognized accreditation bodies not established in one of the EU Member States or EFTA or a candidate country to the EU, which according to the current Articles of Association of EA may not become EA "full members", may enter into a contract of cooperation with EA. An accreditation body that has signed a contract of cooperation with EA may apply to be a signatory of a Bilateral Agreement (BLA). The BLA conveys the same benefits in relation to mutual recognition as the MLA: recognition of the equivalence of the operation of the Bilateral Signatory accreditation body to those of EA MLA signatories and equal reliability of conformity assessment attestations issued by organizations accredited by the Bilateral Signatory accreditation body. For more detailed information: http://www.european-accreditation.org/content/mla/what.htm

[8] Such a statement has been formally endorsed by the EA General Assembly the 19 November 2008.

The requirements set out above affect the acceptance of non European certificates and test results accredited by non European Accreditation bodies not complying with the new EU requirements but signatories to the ILAC/IAF MRA/MLA in the following way:

a) Conformity assessment delivered in the voluntary sphere

It will be up to the non European conformity assessment body operating on the European market to decide if and where to get accredited. In order to boost the acceptance of its conformity assessment attestations by the European market (industry as purchasers of conformity assessment attestations and ultimately consumers) the Non European conformity assessment body opting for accreditation may choose whether to resort to the service of a third country accreditation body not necessarily conforming to the new European requirements but signatory to the ILAC/IAF MRA/MLA or rather to that of a European accreditation body. Unchanged compared to the present situation, non European Conformity assessment attestations issued under accreditation by non European Accreditation bodies not fulfilling the new European requirements, can continue to be used on the European Market.

b) Conformity assessment delivered in the mandatory sphere

Where conformity assessment is legally regulated, national authorities of European Member States may refuse to accept attestations of conformity issued under accreditation by non European accreditation bodies not complying with the new European requirements but signatories to the ILAC/IAF MRA/MLA. However this refusal can not be based on the sole argument of the non fulfilment by the third country accreditation body as such. The conformance to the EU requirements by the third country accreditation body is not a condition for recognition, but non conformance could reinforce doubt as to the quality and value of the accreditation and therefore as to the quality and confidence in the accredited certificates or reports.

However, where government-to-government Mutual recognition agreements (MRAs) between the Community and a third country in relation to conformity assessment are in place[9], national authorities of European Member States will accept the test reports and certificates issued by bodies that the foreign party has designated under the MRA for assessing conformity in the categories of products or sectors covered by the MRA. The products accompanied by such conformity attestations can be exported and placed on the other party's market without undergoing additional conformity assessment procedures. Each importing party agrees, by the terms of the MRA, to recognize the conformity assessment attestations issued by agreed conformity assessment bodies of the exporting party, independently of whether accreditation has been used to back up the designation process of the conformity assessment bodies under the MRA or not, and independently of, in case accreditation is used by the non European Party, the fulfillment by the third Party accreditation body of the EU requirements.

[9] Currently MRAs between the European Union and the following countries are in place: Australia, Canada, Israel, Japan, New Zeeland, Switzerland, United States

Accreditation contributes to a quality driven and reliable conformity assessment infrastructure. It provides for confidence which is of great importance for Regulators, purchasers of conformity assessment services and consumers and facilitates cross-border trade of goods and services. By providing mutual confidence in the competence of CABs and attestation issued by them, accreditation technically underpins trade by promoting mutual recognition and the global acceptance of conformity assessment results within the Internal Market and in relation to third countries. The "additional" requirements for accreditation bodies set out in Regulation 765/2008 designed to consolidate the added value of accreditation do not create a technical barrier impeding trade. The level of acceptance of conformity attestations issued under accreditation of accreditation bodies not meeting the EU requirements in the European Union will continue to be accepted or refused in the same way as they are today.