ORGALIME

Position Paper

Brussels, 26 November 2009

Cross border European accreditation in practice[1]

Introduction

EC Regulation n°765/2008 of 9 July 2008 sets out the general framework and requirements for European accreditation. One of the main principles under the new framework is non-competition. Therefore a stringent regime for cross-border accreditation has been set up (cf. article 7). The Regulation applies to accreditation used to support both compulsory and voluntary conformity assessment.

While strongly supporting the fundamental principles of non-competition and mutual recognition between accreditation bodies in order to reduce the need for multiple accreditations, Orgalime draws attention to the special challenges that arise due to the very stringent cross-border provisions.

According to these provisions a conformity assessment body (CAB)[2], whether third-party or first-party/in-house, is in principle only allowed to apply for accreditation by another Member State's national accreditation body if the accreditation which is sought is not provided for in its Member State of establishment (see details in art. 7).

Issues to be addressed

The cross-border accreditation regime implies that:

1) A CAB or other customer from a third country asking for European accreditation may have a competitive advantage compared to a European CAB/customer, as the Regulation does not apply to organisations established outside the EU and therefore third-country CABs/customers are free to contact a European accreditation body of their own choice.
2) In those cases where, in a commercial relationship, a customer requires an accreditation certificate issued by his local accreditation body and cannot be convinced of the equivalence of the accreditation issued by a foreign accreditation body signatory to the EA MLA (European co-operation for Accreditation's multi-lateral agreement), CABs and manufacturers with accredited in-house bodies established in another Member State may

[1] This position is an update, which complete our previous position of 20 February 2009.

[2] Defined as a body that performs conformity assessment activities including calibration, testing, certification and inspection.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

be put at a competitive disadvantage, e.g. in a bidding/tendering process for a contract. This would result in hampering the functioning of the Internal Market rather than supporting its efficiency, which is one of the major objectives of the Regulation.

3) In cases where CABs (including manufacturers with accredited in-house bodies) are cross-frontier organisations with sites/subsidiaries in more than one Member State, they might be forced to take out several accreditations, even for the same kind of laboratories.

The above situations must be addressed in order to avoid the creation of new technical barriers and an uneven playing field for CABs and manufacturers with accredited in-house laboratories.

Orgalime Recommendations

The overall objective is clear: that all accreditations issued under the EA MLA are considered equivalent by both the public authorities and the market place. However, it may take some time until this is understood and functions in practice. Experience from the certification field shows that national preferences are difficult to influence, even at the level of public authorities. Therefore it will be all the more challenging to make private customers understand and accept the new requirements in the voluntary field. It should also be stressed that accreditation (for example of measuring instruments) might be used in court cases.

Orgalime recommends that pragmatic and harmonised solutions should be found to address the above challenges, and that these solutions should also be reflected in the Commission guidelines to be drawn up under Article 38 of the Regulation.

Orgalime would like to offer the following elements for such pragmatic solutions:

- One way to address the challenge mentioned under points 1) and 2) above would be to formally require EA and the signatories to the EA MLA to issue a **statement which attests to the equivalence** of the accreditations performed by all signatories to the EA MLA or, more specifically, of their local accreditation with any other accreditation issued under the EA MLA, whenever such a statement is requested by a customer.

- We also suggest that on each accreditation certificate issued by a signatory to the EA MLA a **statement should be systematically inserted** to say:

  "*This accreditation has been issued under the EA MLA and is therefore equivalent to all other accreditations issued under the EA MLA within the same accreditation scope.*"

- Orgalime further recommends the creation of a **single European accreditation symbol** for use by the EA MLA signatories on the accreditation certificates issued by them, as well as by the accredited organisations on the conformity assessment results issued by them. We believe that such a symbol would help increase awareness of the EA MLA and promote its perception in the market place. Such a symbol would also be fully in line with the objectives of the Goods Package/NLF and of Regulation 765/2008 to create a unified European accreditation system, which would be undermined by the continued use of 27 different national accreditation marks. Moreover, such a symbol would also introduce greater transparency in accredited conformity assessment as it would be much easier for customers to identify whether a CAB has been accredited by a competent accreditor.

- Furthermore, on a general basis the new regime and the effects of the EA MLA must be made known through efficient promotion campaigns addressed to CABs who can then pass the information on to their customers.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

- As for the challenge mentioned under point 3) above, such **organisations with sites or subsidiaries in more than one Member State should be considered as *one* organisation for the purpose of accreditation.** This means that the organisation concerned should be allowed to request *only one* accreditation, which should cover its entire structure and under which the audits/assessments of all sites and subsidiaries, carried out by auditors/assessors of the respective national accreditation body of the Member State where the site/subsidiary is established, should be coordinated and consolidated. Based on overall mutual recognition of all assessments, any duplication of assessments of organisational aspects or requirements should be strictly avoided.

- Another important element to facilitate the acceptance of equivalence in the market place would be to require the EA MLA signatories to closely cooperate for the exchange of specific technical expertise and, in particular, to **provide technical experts in specific fields of technology to other EA MLA signatories whenever this is requested by a foreign customer** (within the limits of the accreditation body's own needs and capacities). More generally, we also recommend that EA should consider the **creation of a pool of experts** for the various fields of technology serviced by its members, which the MLA signatories could draw on e.g. in those cases where specific services are not offered at national level due to either lack of local expertise or insufficient demand.

- Furthermore, Orgalime suggests that the accreditation certificates issued by the various Accreditation Body signatories to the EA MLA should all have the same shape and layout. This would also signal to the market place that all accreditations issued under the EA MLA are equivalent.

___ - _ - _ - ___

Adviser in charge: Philippe Portalier (Philippe.Portalier@Orgalime.org)