

EAAB position on cross-border accreditation

Introduction

During its meeting of 15 April 2010, the EAAB agreed to issue a position paper on European cross-border accreditation, which sets out a number of proposals and recommendations aimed at contributing to the clarification of the issues raised by the application of Regulation 765/2008/EC, and in particular its Articles 6 and 7.

The position paper is based on the report prepared by the Task Force Group (TFG) that was set up by the EAAB with a view to “putting together relevant scenarios and evidence of practical issues, carrying out an analysis of current practices and presenting available options, and ultimately making recommendations for harmonised solutions by taking into account the comments made by all interested parties represented on the Board”.

The rationale behind the proposals made in this paper can be found in the EAAB Background document EAAB(10)16.

Proposals and recommendations for solutions

There is consensus among all interested parties that while respecting fully the regime for cross-border accreditation as laid down in the Regulation, its implementation should also take into account the business needs of European Conformity Assessment Bodies and of their customers and the economic realities in a globalised market place.

Some of the proposals and recommendations made can be immediately implemented, in particular those relating to the multi-site issue. For others, such as those relating to the multiple accreditation and flexible scope issues, further consideration will be necessary.

A. The multi-site issue

The following recommendations are made by the EAAB:

General terms:

1. A CAB shall be a legal entity.
2. This legal entity can have other activities or have other departments with other activities to the extent allowed by the relevant CAB standards.
3. An accreditation certificate (including the annexes) issued by a National Accreditation Body shall only name one legal entity and it is this legal entity that holds the accreditation and is legally responsible for the accredited activities of the CAB.
4. If the accredited CAB has site offices (e.g. branch offices, regional offices, subsidiaries, etc) such that the legal responsibility for the activities of the site offices are undertaken by the accredited CAB then these can be included in the same accreditation granted by the National Accreditation Body in the country where the accredited CAB has its legal entity registered or in other ways established. If these site offices are in other countries (Member States), they may have to be registered in these countries for administrative and/or regulatory or other purposes, but it would still be the accredited CAB that maintains the legal responsibility for

any activities performed by the site offices that form part of the scope of accreditation. Where these site offices are considered to be locations where key activities (as defined in EN ISO/IEC 17011) take place then the Annexes of the accreditation certificate shall clearly identify the address of these site offices. However, the rules of the EA Cross Frontier Policy shall always apply for assessment, monitoring, surveillance, etc. of the site offices in these other countries.

5. Accredited certificates or reports can be granted or issued by the site offices if and only if the accredited CAB, within the legal framework in which it works, takes legal responsibility for the certificates and reports issued by the site offices for the work covered by accreditation. The certificates or reports granted or issued by the site offices shall clearly reflect that those certificates have been granted or issued by the site offices on behalf of the accredited CAB. This means that certificates and reports are issued under the accreditation, name and address of the central office, and not with the logo of the site office.

These terms should apply to all types of sites (e.g. branch offices, regional offices, subsidiaries) and all types of conformity assessment bodies (e.g. certification bodies, inspection bodies, laboratories).

All necessary safeguards and conditions must be put in place to guarantee the credibility of the system and to avoid possible misuse. In particular, the accredited CAB must **maintain full legal responsibility for the activities performed by sites**:

1. This legal responsibility shall be demonstrated on the basis of the contractual relationships between the central office and the foreign site and the internal regulations that further specify these relationships in terms of management and responsibilities;
2. The central office shall be allowed to substantially influence the activities of the site;
3. There is a common management system covering the sites;
4. The responsibility taken by the central office shall imply its full responsibility externally for the foreign site's activities and that it can be sued for these activities in court;
5. The legally responsible organisation (i.e. the "central" site) shall be clearly identified on the CABs CA reports and certificates.

In giving its support to these general terms, the EAAB would like to underline the need for **correct and consistent implementation of the EA cross-frontier policy** for cooperation between EA members (EA 2/13). The EA cross frontier policy for cooperation between EA members will guarantee the involvement of the local national accreditation bodies in the surveillance plan and witnessing (provided they comply with the relevant requirements)

Furthermore, this solution is meant for use only by companies within the same corporation where there is the formal, legal possibility of the mother organisation having the legal responsibility for the activities of the local offices. **It is not meant to be used by companies which have no other legal affiliation than a contractual relationship.**

B. The multiple accreditation issue

The following recommendations are made by the EAAB:

1. EA and the signatories to the EA MLA should be formally required 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.

2. 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.”*
3. It is also suggested to support 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 attestations issued by them. This is a medium/long term measure whose efficiency may not be guaranteed taking into account the reluctance of some actors and the limited success of the IAF and ILAC accreditation symbols. The Board noted the current EA activities relating to the desirability of an EA accreditation symbol and supported the idea and the action programme. It also underlined the need for the symbol to reflect the robustness and credibility of the peer evaluation system, to be guaranteed by EA.
4. On a general basis, the new regime and the effects of the EA MLA should be made known through **efficient promotion campaigns** addressed to CABs who can then pass the information on to their customers.
5. Another element to facilitate the acceptance of equivalence in the market place would be to require the EA MLA signatories to closely cooperate on 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, also it is also recommended 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.
6. Furthermore, it is also suggested that the accreditation certificates issued by the various accreditation bodies 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.

At this stage, the EAAB is not supportive of the idea to allow multiple accreditations. There is today no evidence that the solutions proposed above are not sufficient.

The EAAB recommends that the situation of purely national accreditation schemes should be clarified: can they be covered by a statement of equivalence and can the EA symbol be used?

C. The competition issue

In the same way as the multiple accreditation issue, the competition issue needs to be addressed by promoting actively the visibility of the EA MLA and its perception in the international market place. Therefore, the recommendations under point B also apply to this point.

However, in addition to the above recommendations, the EAAB also recommends that::

whenever approached by a third-country CAB/customer with a request for accreditation, EA MLA signatories should be required to investigate whether the applicant CAB/customer is already in possession of an accreditation certificate issued by another EA MLA signatory for the same scope and, if so, should reject the application in order not to undermine the value of the MLA and to ensure equal treatment of both European and third-country CABs.

It has been highlighted that this recommendation is not in contradiction with the WTO TBT Agreement as the TBT Agreement forbids discriminatory treatment. As a matter of fact, the proposal aims to ensure equal treatment for all CABs operating on the European market.

D. The flexible scope issue

Since it is very difficult, at this stage, to clearly define what a flexible scope is, the EAAB does not consider it appropriate to make recommendations strictly in relation with the application of flexible scopes. It was emphasised that a "broad scope" can, in some cases, be more adequate than a "flexible scope".

However, the two significant activities for which the question has to be raised and needs to be further discussed are

1. The notified bodies

As a first step, there is consensus at EAAB level on the recommendations hereafter

Basic principles

- a) The relation between the scope of accreditation and the scope of notification should be unambiguous. The notifying authorities should not have to guess which modules and which products are covered by the accreditation
- b) The direct reference to harmonised product standards in the accreditation scope may be possible for some directives (there are only 9 harmonised standards for the toys directive) but is highly hypothetical when it goes about directives supported by 1, 2, 3 or 6 hundred standards
- c) The identification of categories of products covered is sometimes possible and useful (Construction products, machinery, Personal protective equipment, etc.) sometimes irrelevant (Pressure equipment directive, etc.)
- d) Since none of the accreditation standards is perfectly fit for any module, several combinations are possible for the same purpose. The important issue is principle A.

Practical consequences, content of the scope of accreditation for notified bodies

- a) Reference to the European (and possibly national) regulatory acts
- b) Reference to the applicable modules. Depending on the policy of the accreditation bodies/notifying authorities, different accreditation standards may be taken into consideration to support an accreditation related to a specific module.
- c) Reference (when applicable) to the categories of product covered. Use of the wording of the directive to define the category.
- d) Reference to harmonised standards if and when it is formally necessary, for instance the construction products directive.

2. The laboratories whose activities are connected to regulatory purposes (food safety, construction products, medical/pharmaceutical laboratories, etc.)

In both cases, the issue is that the public authorities have to ensure that the relevant conformity assessment activities are fully covered by accreditation. On the other hand, EA member accreditation bodies need to ensure that the relevant competencies within the accreditation bodies are properly assessed during the peer evaluation.