EA-1/13 • EA's relationship with national accreditation bodies of countries that are not members of the EU or EFTA



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EA's relationship

with national accreditation bodies

of countries that are not

members of the EU or EFTA

PURPOSE

The purpose of this document is to describe EA's policy on its relationship with national accreditation bodies from countries that are not members of the EU or EFTA.

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The text may be translated into other languages as required. The English language version remains the definitive version.

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Further information

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1 INTRODUCTION

1.1 Context

The EA Articles of Association enable membership of national accreditation bodies (NABs) from countries that are members of the EU or EFTA, members of the Council of Europe, candidates for EU membership or from countries covered by the EU Neighbourhood Policy. According to Regulation (EC) No 765/2008, NABs from the European Economic Area (EEA) shall be members of EA and EA shall provide its members with peer evaluation services.

The EA peer evaluation process is open to all members unless they have already been peer evaluated by another recognized Regional Accreditation Group (RAG) or by ILAC/IAF.

Considering that EA has a prime role in defining, harmonising and building consistency in accreditation as a service to European trade, industry and society, with the aim of reducing barriers to trade and to contribute to protecting health and safety of people, there may be a need for those EA members, which have been peer evaluated by another RAG or ILAC/IAF, and other NABs from third countries, to demonstrate compliance with Regulation (EC) No 765/2008 and the capability to accredit conformity assessment bodies (CABs) for notification purposes and other EU regulatory schemes.

1.2 Current Agreements

EA's peer evaluation programme is aimed at developing and maintaining the EA Multilateral Agreement (MLA), whereby the signatories recognise and accepts:

- The equivalence of the accreditation systems operated by the signatories
- The reliability of conformity assessment results provided by CABs accredited by the signatories for the relevant scope.

In accordance with the Articles of Association, nationally recognised NABs established in countries that are part of the EU Neighbourhood Policy or potential candidates for EU membership or member states of the Council of Europe may become EA members. These members may sign the MLA with EA for the purpose of establishing mutual confidence in the respective accreditation systems and in conformity assessment results.

It is the policy of EA to rely on the ILAC Mutual Recognition Arrangement (ILAC MRA) and the IAF Multilateral Recognition Arrangement (IAF MLA) in relation to the global acceptance of reports and certificates issued by accredited CABs. Therefore, NABs joining the EA MLA shall be peer evaluated by EA and consequently not be peer evaluated by ILAC, IAF or another RAG.

2 POLICY

There are two scenarios that may apply to national accreditation bodies from non-EEA member countries that seek formal recognition through EA:

2.1 NABs from non-EEA countries, that qualify for EA membership

NABs from candidate countries to the EU, member states of the Council of Europe and countries covered in the EU Neighbourhood Policy are encouraged to join EA as members and hold the rights and obligations as defined in the EA Articles of Association. These NABs that have become EA members shall be encouraged to join the EA MLA.

In case the NAB is a member of EA, but also a member of another recognized RAG and peer evaluated by this RAG, the NAB can be additionally peer evaluated by EA for the purpose of demonstrating compliance with the requirements of Regulation (EC) No 765/2008 and its capability to accredit CABs for notification purposes and other EU regulatory schemes. Prerequisite for this peer evaluation is that the application to sign the COAMR for this specific purpose is supported by the European Commission.

2.2 NABs that are not an EA member

NABs, that are not an EA member, can sign a cooperation agreement (COA) and a cooperation agreement for mutual recognition (COAMR) with EA.

2.2.1 Signing a Cooperation Agreement (COA)

NABs from countries outside of Europe but within a RAG recognized by ILAC or IAF may apply to sign a COA with EA for the purpose of demonstrating their compliance with the additional requirements according to Regulation (EC) No 765/2008 and the corresponding EA provisions. A prerequisite for the application is that either:

- the European Commission declares to EA that it has reasonable interest in the establishment of mutual confidence and recognition in the respective accreditation systems and in conformity assessment activities in support of EU legislation and trade policy, e.g. by an Agreement on Conformity Assessment and Acceptance (ACAA) of Industrial Products or another similar agreement; or
- EA decides, for whatever reasons, that it has an interest in signing a COA with that NAB.

The provisions for signing the COA are:

- 1. Fulfilment of the requirements of ISO/IEC 17011 by being a signatory of an MLA established by a RAG which is recognized by ILAC or IAF.
- 2. Fulfilment of the applicable requirements in the Regulation (EC) No 765/2008.

The application for signing a COA shall be addressed to the Secretariat.

The COA signatory status will be decided by the Executive Board – based on the application review by the Secretariat and after consultation with the EA Advisory Board (EAAB).

2.2.2. Signing a Cooperation Agreement for Mutual Recognition (COAMR)

NABs from countries outside of Europe where a RAG recognized by ILAC or IAF is established may apply to sign a COAMR with EA for the purpose of demonstrating their capability to accredit conformity assessment bodies (CABs) for notification purposes and other EU regulatory schemes.

The provisions for signing the COAMR are:

- Being signatory of a COA, and
- Having support from the European Commission for signing a COAMR, and
- Successfully peer evaluated by EA for demonstrating competence to accredit CABs involved in conformity assessment activities based on EU legislations.

Detailed requirements for signing the COAMR are listed in Annex 1 clauses c) to o).

Application for signing the COAMR shall be addressed to the Secretariat. The Multilateral Agreement Council is responsible for the peer evaluation process, including decision-making on COAMR signatory status.

The COAMR signatory shall be re-evaluated every four years.

EA will invite NABs that have signed a COAMR to participate as observers in the meetings of the General Assembly as well as relevant Technical Committees and related working groups and task forces.

ANNEX 1

Requirements for signing the COA

Each NAB signatory of the COA agrees to abide by its terms and conditions and shall:

- a) Fulfil the requirements in ISO/IEC 17011.
- b) Fulfil the relevant requirements in the Regulation (EC) No 765/2008.

Requirements for signing the COAMR

Each NAB signatory of the COAMR agrees additionally to abide by its terms and conditions and shall:

- c) Fulfil supplementary requirements defined in EA mandatory documents.
- d) Have demonstrated experience in operating a NAB and have access to technical expertise regarding EU legislation.
- e) Ensure that all accredited CABs, performing conformity assessment activities regarding EU legislations, comply with the supplementary requirements defined in EU legislations and EA mandatory documents.
- f) Bring those supplementary requirements to the attention of accredited and applicant CABs.
- g) Inform accredited and applicant CABs that only conformity assessment results (e.g. reports or certificates) that refers to the relevant accreditation are considered to be under the EA MLA.
- h) Only subcontract assessment activities regarding EU legislations to NABs having signed the EA MLA for that particular scope and whose accreditation is recognised by the European Commission for the purposes of Regulation (EC) 765/2008.
- i) Cover the costs of the peer evaluations, including the daily rate specific to the peer evaluator's employers fee schedule, travel, accommodation and subsistence, and provide sufficient translators; unless compensated by other parties.
- j) Report any significant changes in its status and/or its operating practices without delay to the EA Secretariat. Significant changes are those that could

affect issues, stipulated in Regulation (EC) No 765/2008 and relevant for the accreditation of CABs according to EU legislations, such as competence, impartiality and operational ability and include, but are not limited to, those related to legal status, relationship with government, senior personnel, contact persons, accreditation criteria and procedures and office address. The NAB shall provide an impact analysis related to the reported changes.

- k) Accept accreditation systems operated by other signatories as equivalent to its own accreditation system.
- I) Declare, when requested, conformity assessment results (e.g. reports or certificates) issued by CABs accredited by NABs that are signatories for the relevant scope to the EA MLA, to the ILAC Mutual Recognition Arrangement (ILAC MRA) and to the IAF Multilateral Recognition Arrangement (IAF MLA) as reliable as those issued by CABs accredited by themselves.
- m) Make publicly accessible information about the level 4 Sector standards, sectorial schemes and activities based on EU Internal Market legislation (Directives, Regulations) included in the accreditation services offered by the NAB.
- n) Notify, in writing and not later than three months in advance, other EA MLA signatories of any voluntary withdrawal or reduction of the scope of recognition.
- o) Upon changes to requirements of this COAMR, ensure conformity with the new requirements within the period specified by the General Assembly.