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EA Multilateral Agreement

Criteria for signing.

**Policy and procedures for
development**

PURPOSE

This document sets out the terms of the EA Multilateral Agreement, under which the signatories recognise the equivalence of each other's accreditation systems, and defines the activities which are covered by the agreement.

Authorship

This document has been prepared by the EA Horizontal Harmonization Committee.

Official language

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

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1 INTRODUCTION

The European co-operation for Accreditation (EA) is the association of National Accreditation Bodies (NABs), which conduct and administer accreditation of Conformity Assessment Bodies (CABs).

The role of EA and the individual accreditation bodies of the EU member states are defined in the Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. In the European accreditation system EA has been assigned the prime role for defining, harmonising and building consistency in accreditation as a service to European trade, industry and society.

EA has established a Multilateral Agreement (EA MLA), under which the signatories recognise the equivalence of each other's accreditation system.

An on-going programme of cooperation has been set up which is aimed at developing and maintaining the EA MLA.

The principal elements of the programme to establish mutual confidence are:

- Participation in the EA peer evaluation program;
- Exchange of information on the development and operation of accreditation systems;
- Participation in the work and decision making of the EA General Assembly (EA GA), Committees, EA MLA Council (EA MAC) and working groups, where applicable;
- Cooperate in efforts to set up assessment teams and in the exchange of persons to participate in assessment, re-assessment or surveillance visits to accredited CABs;
- Participation in regional and international proficiency testing activities and other interlaboratory comparisons;
- Cooperation with parties interested in European accreditation system including the European Commission, stakeholders and international organisations like IAF and ILAC.

This document sets out the terms of the EA MLA, defining:

- The EA MLA, its purpose and consequences;
- The criteria to sign the EA MLA and the rights of signatories; and
- The structure and scope of the EA MLA, including the procedures to expand its scope.

For the purpose of this document the following definitions apply:

- **Accreditation Field:** The unique combination of a conformity assessment field (EA MLA Level 2) and a standard containing requirements for CABs performing that activity (EA MLA Level 3), e.g.: Testing / EN ISO/IEC 17025;
- **Scope of the EA MLA:** All the Accreditation Activities endorsed by the EA GA;
- **Scope of Recognition** (of an EA MLA signatory): Accreditation Field(s) of a NAB for which the EA MAC decided positively the signatory status.

2 THE EA MLA

The EA Multilateral Agreement (EA MLA) is a multilateral arrangement between EA Full members¹ whereby the signatories recognise and accept:

- (a) The **equivalence** of the accreditation systems operated by the signatories;
- (b) The **reliability** of the conformity assessment results (e.g. a report or certificate) provided by CABs accredited by the signatories for the relevant scope.

EA is the body designated by the European Commission pursuant to Article 14 in the Regulation (EC) 765/2008 to operate the peer evaluation of NABs in the Member States. Thus, a NAB being a signatory to the EA MLA means that the NAB had successfully undergone a peer evaluation as referred by Articles 10 and 11 of the Regulation.

A Bilateral Agreement (BLA) between an EA Associate member (or a NAB with a contract of cooperation with EA) and EA has the same purpose as the EA MLA. Further references in this document to the EA MLA and EA MLA signatories are also applicable to any EA BLA except when noted.

3 PURPOSE OF THE EA MLA

The EA MLA main purpose is to provide confidence to all interested parties in conformity assessment results (e.g. reports and certificates) provided by CABs accredited by EA MLA signatories.

Acceptance in the marketplace of the EA MLA and thereby of conformity assessment results provided by CABs accredited by EA MLA signatories is of major importance for the development of the internal market in Europe in facilitating cross border trade as well as in demonstration of compliance with the European legislation for products and services contributing to protect the health, safety and environment.

NABs are expected to apply for every MLA Accreditation Field where they are active.

4 OPERATION AND MANAGEMENT OF THE EA MLA

The EA MLA is managed by the EA MAC, which is responsible for conducting peer evaluations of NABs according to the procedures defined in EA-2/02 (EA Policy and Procedures for the Multilateral Agreement) and considering the requirements described in clause 5 of the present document.

The outcomes of peer evaluations are the basis for the decision-making process of the EA MAC and the acceptance of signatories to the EA MLA.

The acceptance of signatories is associated to a Scope of Recognition. A NAB can be signatory to a part or to all the Accreditation Activities included in the Scope of the EA MLA

¹ Admission to the EA MLA is restricted to EA Full members. EA Associate members are eligible to enter into an EA Bilateral Agreement. NABs that are not eligible to be an EA Full or Associate member, as defined in the EA Articles of Association may, under certain circumstances, be invited to enter into a cooperation agreement with EA. Some of these cooperation agreements may be extended into Bilateral Agreements with EA.

(see EA MLA Signature Template – Appendix 1). The Scope and structure of the EA MLA is detailed in clause 7 of this document.

A list of signatories, identifying the Scope of Recognition for each one, of the EA MLA is maintained on the EA website as well as in document EA-INF/03 (EA Multilateral and Bilateral Agreements, and signatory Lists).

EA-2/02 also defines procedures to deal with EA MAC decisions on suspensions and withdrawals of signatory status.

5 REQUIREMENTS FOR SIGNING THE EA MLA

Each NAB signatory or applicant to the EA MLA agrees to abide by its terms and conditions and shall:

- (a) Maintain conformity with the relevant requirements defined in the Articles of Association, the obligations defined in the Rules of Procedure (EA-1/17) and with the membership specific criteria defined in EA-1/17-S1;
- (b) Fulfil the requirements in EN ISO/IEC 17011;
- (c) Fulfil the relevant requirements in the Regulation (EC) 765/2008;
- (d) Fulfil supplementary requirements defined in EA mandatory documents and in IAF and ILAC documents endorsed by EA as mandatory;
- (e) Be fully operational, having demonstrated experience in operating an accreditation body, access to technical expertise in all aspects of its accreditation activities, and granted at least one accreditation that is valid at the time of the peer evaluation in each scope of recognition (see 7.1) for which it signed or applied;
- (f) Ensure that all accredited CABs comply with the relevant standard defining requirements for CABs (Level 3 and Level 4, where applicable) and the supplementary requirements defined in European legal provisions, EA mandatory documents and in IAF and/or ILAC documents endorsed by EA as mandatory;
- (g) Bring those supplementary requirements to the attention of accredited and applicant CABs;
- (h) 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;
- (i) Have a policy and procedure on the participation of laboratories in regional and international inter-laboratory comparisons used by EA in order to monitor the effectiveness of the EA MLA;
- (j) Only subcontract assessment activities to accreditation bodies having signed the EA MLA, or the IAF MLA, or the ILAC MRA for that particular scope;
- (k) Cover the costs of the peer-evaluations including travel, accommodation and expenses of the evaluation teams and provide sufficient translators;
- (l) 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 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 offices addresses. The NAB shall provide an impact analysis related to the reported changes;

- (m) Accept accreditation systems operated by other signatories as **equivalent** to its own accreditation system;
- (n) Promote the international acceptance of the conformity assessment results (e.g. reports or certificates) issued by CABs accredited by accreditation bodies that are signatories to the EA MLA, to the ILAC Mutual Recognition Arrangement (ILAC MRA) and to the IAF Multilateral Recognition Arrangement (IAF MLA);
- (o) Declare, when requested, conformity assessment results (e.g. reports or certificates) issued by CABs accredited by accreditation bodies 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 themselves²;
- (p) Promote the EA, ILAC and IAF arrangements to stakeholders;
- (q) 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;
- (r) 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;
- (s) Upon changes to requirements of this Agreement, ensure conformity with the new requirements within the period specified by the EA General Assembly (EA GA).

6 RIGHTS OF EA MLA SIGNATORIES

An EA MLA signatory may refer at any time to its status as a signatory to the EA MLA, according to EA rules (EA-3/01: EA Conditions for the use of accreditation symbols, text reference to accreditation and MLA signatory status).

7 SCOPE AND STRUCTURE OF THE EA MLA

7.1 General

The scope of the EA MLA is described in a five level structure, according to Table 1, two of which (Levels 2 and 3) are used to define the Scope of Recognition of the signatories.

For information, Appendix 2 presents the hierarchy of conformity assessment activities, standards and schemes with possible combinations.

² The activity is only deemed to be accredited if the corresponding certificate or report refers to the relevant accreditation.

EA MLA LEVEL		STANDARDS, ACTIVITIES AND EXPLANATIONS
LEVEL	DEFINITION	
1	Requirements for accreditation bodies	The requirements in EN ISO/IEC 17011, in Regulation (EC) 765/2008 and, when applicable, the supplementary requirements defined in EA mandatory documents and in IAF and/or ILAC documents endorsed by EA as mandatory
2	Conformity assessment activities of conformity assessment bodies to which accreditation bodies grants accreditation against standards included in Level 3 (hereafter conformity assessment activities)	(a) Calibration (b) Testing (including Medical examinations) (c) Inspection (d) Product certification (e) Management system certification (f) Certification of persons (g) Verification (h) Proficiency testing providers
3	Harmonized Standards (or other normative documents) containing general requirements for conformity assessment bodies performing conformity assessment activities included in Level 2 (hereafter conformity assessment standards)	(a) EN ISO/IEC 17025 (b)1 EN ISO/IEC 17025 (b)2 EN ISO 15189 (c) EN ISO/IEC 17020 (d) EN ISO/IEC 17065 (e) EN ISO/IEC 17021 (f) EN ISO/IEC 17024 (g) EN ISO 14065 (h) EN ISO 17043
4	Documents containing criteria supplementary to those contained in Level 3 standards. Such documents are: (i) Sector specific standards or other recognisable normative documents (hereafter Sector standards); (ii) Sectoral schemes as specified in Regulation (EC) 765/2008 Articles 2(10) and 13; (iii) Conformity assessment schemes according to EA-1/22 (hereafter Schemes) Note: Level 4 is only applicable where documents supplementing Level 3 standards exist (meaning that a Level 5 is often directly connected to a Level 3 standard).	- Examples of Sector standards: ISO 15195 (a); CEN/TS 15675 (b)1; ISO 22870 (b)2; ISO/TS 22003 (e); ISO/IEC 27006 (e). - Examples of Sectoral schemes: Regulation 600/2012 EU.
5	Scope of accreditation: standards or other normative documents used by the accredited conformity assessment body to deliver an accredited conformity assessment field.	Notes: - Can include, for example, specific testing methods and specific management system requirements (e.g.: ISO 9001 and ISO 14001).

Table 1 – EA MLA Structure

7.2 Coverage of the EA MLA

All conformity assessment results (e.g. reports and certificates) provided by CABs accredited by a NAB signatory to an EA MLA Accreditation Field are considered to be under the EA MLA

provided that the conformity assessment results issued by the CAB contain a reference to the relevant accreditation.

7.3 Expansion of the scope of the EA MLA

This procedure shall apply when considering the inclusion of:

- i. A new conformity assessment field (Level 2) – see 7.3.1 and 7.3.2;
- ii. A new conformity assessment standard (Level 3) – see 7.3.1 and 7.3.2; and
- iii. New sector standards and schemes (Level 4) – see 7.3.3.

The procedure to be followed includes evaluating some general criteria and performing a technical analysis and examination of the activity in the field, standard or scheme in question which is normally carried out by the relevant EA technical committee.

Furthermore, analysis of the impact on the EA peer evaluation program and the need for an EA mandatory document to ensure a harmonised application of the criteria by the NABs should be carried out by the EA Horizontal Harmonization Committee (EA HHC) and EA MAC.

7.3.1 General policy

Whenever a new conformity assessment standard for CABs (Level 3) performing a conformity assessment field (Level 2) used for accreditation is introduced to the market, and a need for it in the European market place can be clearly established, a proposal on its inclusion in the EA MLA and by what mechanism shall be put to the EA GA for decision.

The EA GA will decide if the new conformity assessment standard shall be included in combination with a new conformity assessment field or under an already endorsed conformity assessment field (i.e. defining a new Level 2 and a new Level 3 in combination or just a new Level 3). All conformity assessment activities and conformity assessment standards have to be endorsed by the EA GA before being included in the EA MLA.

The general criteria for evaluating the suitability of a conformity assessment field, conformity assessment standard, sector standard or scheme for inclusion under the EA MLA Levels 2, 3 or 4 are:

- i. Significant relevance to the accreditation of CABs under the scope of the EA MLA accreditation activities;
- ii. Sufficient substance to contribute to the recognition of competence of CABs and/or conformity assessment activities done by CABs;
- iii. Fulfils appropriate and clearly established needs in the European market;
- iv. Lack of inclusion poses threats to the European accreditation infrastructure as serving the public interest;
- v. Complementary to or supportive of any other standards currently being used;
- vi. Does not contradict, dilute the substance or have a negative impact on the outcome of any existing Level 2 / Level 3 combination under the EA MLA; and
- vii. Conformity assessment standards, sector standards and schemes must be produced by a recognizable consensus process with involvement of relevant interested parties.

A precondition for EA expanding the EA MLA for a new conformity assessment field (Level 2) shall be that a European or International conformity assessment standard for competence of

CABs contains requirements applicable to types of conformity assessment activities other than those covered by the existing EA MLA.

If the new standard describes competence criteria different to those included in the standards already included in the EA MLA for the performance of activities being under the EA MLA and it may be used as a stand-alone document i.e. contains all criteria for accreditation of a CAB to the standard, then the standard shall be classified as conformity assessment standard (Level 3) in the EA MLA under the relevant activity (Level 2).

If the standard can only be used in combination with a conformity assessment standard already included at Level 3 of the EA MLA, the new standard shall be considered as a Level 4 document (sector standard).

Whenever a new standard is introduced in the EA MLA as a Level 3 standard, it must be further analysed to ascertain if it can be included as one of the activities already endorsed at Level 2 of the EA MLA. If the new standard does not fit into one of the activities defined at Level 2, a new conformity assessment field shall be introduced.

7.3.2 Procedure: Level 2 and Level 3

Whenever a new conformity assessment standard to be used for accreditation of CABs is published, the EA Executive Committee (EA EXE) shall request the EA HHC in close collaboration with the relevant technical committee - EA Laboratory Committee (EA LC), EA Certification Committee (EA CC) or EA Inspection Committee (EA IC) - to prepare an evaluation of the standard against:

- (a) The criteria under clause 7.3.1;
- (b) The compatibility with the requirements in EN ISO/IEC 17011 and in the Regulation 765/2008.

The analyses prepared by the EA HHC shall make a recommendation on:

- (a) The suitability of the standard for the accreditation of CABs;
- (b) The necessity to develop additional criteria to ensure a harmonised application of the standard by NABs;
- (c) The need to introduce, with justification, an additional conformity assessment field on the EA MLA Level 2.

Based on the recommendation received, the EA EXE shall prepare a proposal to the EA GA. The EA EXE shall advise the EA GA, as appropriate, of the need to develop an EA application document and the applicable timeframe for completion.

The EA GA following a recommendation from the EA EXE, shall decide if the conformity assessment standard shall be included under the EA MLA and any additional requirements needed for inclusion of the standard under the EA MLA.

Following a decision by the EA GA to include a new conformity assessment standard under the EA MLA the relevant EA Committee shall draft application document(s), as appropriate, and the EA MAC shall analyse and decide on the need to develop additional procedures for the peer evaluation process.

When the conditions, as decided by the EA GA for expansion of the scope of the EA MLA, have been fulfilled including the adoption of peer evaluation procedures as proposed by the EA MAC, EA shall inform members that a new standard has been included under the EA MLA and that EA members can apply to the EA MAC to join the EA MLA for the extended scope.

The procedure proposed by the EA MAC for inclusion of a new standard under the EA MLA may include a peer review activity e.g. peer evaluation of the NAB's accreditation field or document review of NAB accreditation procedures, competence, etc. This peer evaluation or review activity shall be completed and an EA MAC decision on compliance with the applicable requirements shall be taken before signatories to the EA MLA may claim the activity is under the EA MLA.

7.3.3 Specific procedure: Level 4

- (a) Sector standards (e.g. ISO/TS 22003, ISO/IEC 27006, ISO 22870 and CEN/TS 15675):
Need approval by the EA GA after recommendation from the relevant technical committee (EA LC, EA CC or EA IC). The full application of those Sector standards is required for the related conformity assessment activities to be considered under the EA MLA;
- (b) Schemes: EA has developed a specific procedure for evaluation of schemes by EA members (EA-1/22).

8 APPENDIX 1 – EA MLA SIGNATURE TEMPLATE**MULTILATERAL AGREEMENT**

The National Accreditation Body signatory to EA MLA commits itself to comply with the requirements and obligations applicable notably those defined in document EA-1/06. The signatory status of any National Accreditation Body is subject to changes (extension, suspension and withdrawal) and can be checked on EA website (www.european-accreditation.org).

**13 ACCREDITATION BODY
COUNTRY**

SCOPE OF RECOGNITION	
ACCREDITATION FIELD	
EA MLA Level 2: Field of activity	EA MLA Level 3: Standard
Calibration	EN ISO/IEC 17025
Testing (including Medical examinations)	EN ISO/IEC 17025
	EN ISO 15189
Inspection	EN ISO/IEC 17020
Product certification	EN ISO/IEC 17065
Management system certification	EN ISO/IEC 17021
Certification of persons	EN ISO/IEC 17024
Verification	EN ISO 14065
Proficiency testing providers	EN ISO 17043
EA MLA Council decision date: YYYY-MM-DD	

(VI) **Name**
(VII) **Position**
*Authorised signature on behalf of
above Accreditation Body*

Name
Chairman of EA MLA Council
*Authorised signature on behalf
of EA MLA Signatories*

9 APPENDIX 2 – THE EA MLA



