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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, defines the activities which are covered by the agreement, and describes the expansion of the agreement to new scopes.

Authorship

This document has been prepared by the 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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Further information

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1 INTRODUCTION

The European co-operation for Accreditation (EA) is the association of National Accreditation Bodies (NABs)¹, as defined in the Articles of Association (AoA). The mission of EA is ensuring confidence in accredited conformity assessments results through harmonized operations of accreditation activities in support of European and global economies. To fulfil this mission, EA has established a Multilateral Agreement (EA MLA), under which the signatories recognise the equivalence of each other's accreditation system.

The objectives of the EA are defined in the AoA one of which is to consolidate and strengthen the multilateral agreement based on the peer evaluation activities on mutual recognition of the accreditation activities operated by Members and to promote the international acceptance of this agreement.

EA is also the body recognised by the European Commission pursuant to Article 14 of the Regulation (EC) No 765/2008 as the "European Accreditation Infrastructure".

The principal elements 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;
- Cooperation in efforts to set up assessment teams and in the exchange of persons to participate in assessments of accredited Conformity Assessment Bodies (CABs);
- Cooperation with parties interested in the European accreditation system including the European Commission, stakeholders and international organisations like IAF and ILAC.

2 SCOPE AND DEFINITIONS

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:** Accreditation fields endorsed by the EA GA;

¹ A National Accreditation Body is the sole accreditation body of a country appointed by its government according to the national legislation and, for EU/EFTA member states, declared to the EC pursuant to article 12.2 of the Regulation (EC) No 765/2008

- **Scope of Recognition** (of an EA MLA signatory): The current Accreditation Field(s) of a NAB which have been approved by the EA MAC.

3 THE EA MLA

The EA Multilateral Agreement (EA MLA) is a multilateral arrangement between EA members² 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.

4 PURPOSE OF THE EA MLA

The main purpose of the EA MLA 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 with the aim of facilitating the acceptance in the marketplace of conformity assessment results provided by CABs accredited by EA MLA signatories

Such acceptance has a major importance for the development of industry and business opportunities by removing the need to repeat the accredited conformity assessment in different countries. Therefore, the EA MLA contributes to increasing the competitiveness of European products and services eliminating technical barriers to trade, reducing costs and adding value to businesses and consumers.

The EA MLA is binding on the signatory NABs only, as described in section 3. Authorities or other parties may quote the EA MLA for legal or binding effects, including recognition and acceptance, as they see appropriate

Note: For EA NABs declared to the EC pursuant to article 12.2 of the Regulation (EC) No 765/2008, being signatory the EA MLA is the demonstration of having successfully undergone the peer evaluation under article 10 in Regulation (EC) No 765/2008

5 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 Procedure for the evaluation of a National Accreditation Body) and considering the requirements described in clause 6 of this 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.

² Admission to the EA MLA is restricted to EA members. NABs that are not eligible to be an EA 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 (COA) may be extended into cooperation agreements for mutual recognition (COAMR).

The acceptance of signatories is associated to a Scope of Recognition. A NAB can be signatory to a limited number or to all the accreditation fields included in the scope of the EA MLA (see EA MLA Signature Template – Appendix 1). The scope and structure of the EA MLA is detailed in clause 8 of this document.

A list of signatories to the EA MLA, 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 (Signatories to the EA Multilateral Agreement) also available on the EA website.

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

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

6 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 AoA , the obligations defined in the Rules of Procedure (EA-1/17) and with the specific membership criteria defined in EA-1/17-S1; which includes relevant requirements from the Regulation (EC) No. 765/2008;
- (b) Fulfil the requirements in EN ISO/IEC 17011;
- (c) Fulfil supplementary requirements defined in EA mandatory documents;
- (d) 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 8.1) for which it signed or applied;
- (e) Ensure that all accredited CABs comply with the relevant standard defining requirements for CABs (Level 3 and, where applicable, Level 4,) the supplementary requirements defined in EA mandatory documents and in IAF and/or ILAC documents approved by EA as mandatory; and, when relevant, in European legal provisions.
- (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 refer to the relevant accreditation are considered to be under the EA MLA;
- (h) Only subcontract assessment activities to accreditation bodies that are signatory to the relevant scope(s) of the EA MLA, or the IAF MLA, or the ILAC MRA;
- (i) Cover the costs of the peer evaluations including travel, accommodation and expenses of the evaluation teams and provide sufficient translators;
- (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 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,

and office addresses. The NAB shall provide an impact analysis related to the reported changes;

- (k) Accept accreditation systems operated by other EA MLA signatories as **equivalent** to its own accreditation system;
- (l) 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);
- (m) Declare, when requested and applicable, conformity assessment results (e.g. reports or certificates) issued by CABs accredited by accreditation bodies that are signatories to the relevant scope of 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 themselves³;
- (n) Promote the EA, ILAC and IAF arrangements to stakeholders;
- (o) Make publicly accessible information about the Level 4 Sector standards and sectorial schemes included in the accreditation services offered by the NAB;
- (p) Notify, in writing and not later than three months in advance, the MAC Secretariat of any voluntary withdrawal or reduction of the scope of recognition;
- (q) Upon changes to EA MLA requirements as detailed in this document, ensure conformity with the new requirements within the period specified by EA.

7 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 as stipulated in EA-3/01.

8 SCOPE AND STRUCTURE OF THE EA MLA

8.1 General

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

Table 1 presents the hierarchy of conformity assessment activities, standards and schemes with possible combinations.

³ The activity is only deemed to be accredited if the corresponding certificate or report refers to the relevant accreditation.

Table 1 – EA MLA Structure

EA MLA LEVEL		STANDARDS, ACTIVITIES AND EXPLANATIONS
LEVEL	DEFINITION	
1	Requirements for accreditation bodies	The requirements in EN ISO/IEC 17011, and, the supplementary requirements defined by EA in EA 1/17-S1
2	Conformity assessment activities of conformity assessment bodies to which accreditation bodies grant accreditation against standards included in Level 3 (hereafter conformity assessment fields)	(a) Calibration (b) Testing (including Medical examinations) (c) Inspection (d) Product certification (e) Management system certification (f) Certification of persons (g) Validation and Verification (h) Proficiency testing providers (i) Reference material producers (j) Biobanking
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 17021-1 (f) EN ISO/IEC 17024 (g) EN ISO/IEC 17029 (h) EN ISO/IEC 17043 (i) EN ISO 17034 (j) EN ISO 20387
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) No 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); ; ISO 22003-1 (e); ISO/IEC 27006 (e); ISO 14065 (g) - Examples of Sectoral schemes: GLOBALGAP General regulations (d); WADA International Standard for Laboratories (ISL) (b1)
5	Scope of accreditation: standards or other normative documents used by the accredited conformity assessment body to deliver an accredited conformity assessment field.	Note: - Can include both specific methods to perform a conformity assessment (e.g. testing methods) or requirements to be met by the clients of the accredited CAB and whose conformity is to be confirmed.) (e.g.: ISO 9001, or product requirements).

8.2 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 according to EA-3/01.

8.3 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 8.3.1 and 8.3.2;
- ii. A new conformity assessment standard (Level 3) – see 8.3.1 and 8.3.2; and
- iii. New sector standards and schemes (Level 4) – see 8.3.3.

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.

8.3.1 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 fields 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.

8.3.2 Procedure: Level 2 and Level 3

Whenever a new conformity assessment standard to be used for accreditation of CABs is published, the EA HHC is requested 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 8.3.1;
- (b) The compatibility with the requirements in EN ISO/IEC 17011 and in the Regulation (EC) No 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 HHC shall prepare a proposal to the EA GA. The EA HHC 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 HHC, 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.

8.3.3 Specific procedure: Level 4

- (a) Sector standards (e.g. ISO/22003-1, ISO/IEC 27006,): The application of sector standards 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.

Note: These Level 4 standards are published in EA-INF/01.

- (b) EU legislations: The application of sector schemes, included in EU legislations, do not need endorsement by EA (e.g. Implementing Regulation (EU) 2018/2067.
- (c) The application of other EU regulatory sector schemes, which are not published as EU legislation, but in another type of (non-legal) document, need approval by EA
- (d) Sector schemes included in the IAF MLA or ILAC MRA scopes do not need endorsement by EA.
- (e) Schemes: EA has developed a specific procedure for evaluation of schemes by EA members (EA-1/22). Sector schemes that have been satisfactorily evaluated according to EA-1/22 do not need further endorsement by EA.

9 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 the EA website (www.european-accreditation.org).

NATIONAL ACCREDITATION BODY COUNTRY

SCOPE OF RECOGNITION		
ACCREDITATION FIELD		EA MLA Council decision date
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 17021-1	
Certification of persons	EN ISO/IEC 17024	
Validation and Verification	EN ISO /IEC 17029	
Proficiency testing providers	EN ISO/IEC 17043	
Reference material producers	EN ISO 17034	
Biobanking	EN ISO 20387	

Issue date

Name

Position

Authorised signature on behalf of
above National Accreditation Body

Name

Chair of EA MLA Council
Authorised signature on behalf
of EA MLA Signatories