EA REPORT TO IAF/ILAC AND REGIONS

STATUS JANUARY - JUNE 2023





TABLE OF CONTENTS

 I - STRUCTURAL STATUS AS AT JUNE 2023 1 - EA Membership 2 - Signatories to the EA MLA 3 - EA Recognised Stakeholders 	3 3 4
 II - EA MLA AND PEER-EVALUATION ISSUES New and remaining signatories to EA MLA scopes Latest developments relating to EA peer evaluations 	4 5 5 5 5 6
III - STATUS OF EA'S RECOGNITION IN IAF/ILAC	6
 IV - STATUS OF EA DOCUMENTS 1 - Documents published since January 2023 2 - Documents under revision 3 - New documents under development 4 - Documents withdrawn since January 2023 	7 7 8 8
V - ACTIVITIES TO PROMOTE THE IAF MLA AND ILAC MRA	8
VI - MAJOR OTHER ACTIVITIES/DEVELOPMENTS IN EA	8
VII - EA MEETINGS	10
VIII - EA REPRESENTATIVES IN IAF AND ILAC MEETINGS	10



I - Structural status as at June 2023

1 - EA Membership

In May 2023, the General Assembly approved that, according to Article 5 of the *EA Articles of Association*, San Marino Accreditation Service (SMAS), the National Accreditation Body of San Marino, becomes a Member of EA.

At the same meeting in May 2023, the General Assembly also noted that BSCA, the National Accreditation Body of Belarus, ceased to meet the requirements imposed for the membership in the *EA Articles of Association*, and terminated with immediate effect the EA Membership of BSCA.

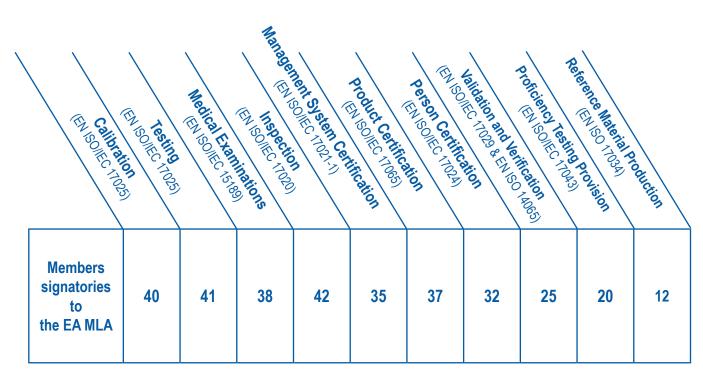
EA has a total of 49 Members.

The complete list of EA Members together with their details and their EA MLA status is available on the EA website at <u>https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signa-tories/</u>

2 - Signatories to the EA MLA

43 Members are signatories to the EA MLA.

The individual EA Multilateral and Bilateral Agreement Signatories are listed by EA MLA scope on EA-INF/03: *Signatories to the EA Multilateral and Bilateral Agreements.*



Recapitulative table of signatories by MLA scope



3 - EA Recognised Stakeholders

EA cooperates with more than 40 Recognised Stakeholders, whose complete list is available on the EA website at <u>https://european-accreditation.org/about-ea/ea-stakeholders/</u>

The General Assembly approved in May 2023 a Memorandum of Understanding between CEN, CE-NELEC, EURAMET, WELMEC and EA on the creation and implementation of the European Quality Infrastructure (QI) Network. The purpose of this MoU is to create the European QI Network as a partnership of regional quality infrastructure organisations that collaborate to strengthen the Quality Infrastructure in Europe.

II - EA MLA and peer-evaluation issues

1 - New and remaining signatories to EA MLA scopes

Upon decisions made by the MLA Council (MAC) at its 48th meeting held on 26-27 April 2023 in Belgrade, Serbia and through electronic ballots carried out in the first semester 2023:

• TUNAC, the Tunisian National Accreditation Body (NAB), became an EA MLA signatory in the fields of medical examinations (EN ISO 15189) and certification of products (EN ISO/IEC 17065);

TUNAC remained an EA MLA signatory in the fields of calibration (EN ISO/IEC 17025), testing (EN ISO/IEC 17025), inspection (EN ISO/IEC 17020), certification of management systems (EN ISO/ IEC 17021-1);

- CAI, the Czech NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing providers (EN ISO/IEC 17043), certification of management systems (EN ISO/IEC 17021-1), certification of products, certification of persons (EN ISO/IEC 17024), validation and verification (EN ISO 14065) and reference material producers (EN ISO 17034);
- CYS-CYSAB, the Cypriot NAB, remained an EA MLA signatory in the fields of certification of products and inspection;
- LATAK, the Latvian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, certification of management systems, certification of products, certification of persons, inspection, and validation and verification (EN ISO 14065);
- INAB, the Irish NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons and reference material producers;
- NAAU, the Ukrainian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of persons and certification of products;
- SA, the Slovenian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons, and validation and verification (EN ISO 14065);
- SNAS, the Slovakian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing providers, certification of management systems, certification of products, certification of persons, and validation and verification (EN ISO 14065 and EN ISO/IEC 17029).



2 - Latest developments relating to EA peer evaluations

2.1 - Peer evaluations in 2023

For 2023, the MAC scheduled 14 peer evaluations.

9 peer evaluations were carried out as follows by end of June 2023:

- 4 re-evaluations: ACCREDIA (Italy), ALGERAC (Algeria), ESYD (Greece) and MOLDAC (Republic of Moldova);
- 1 re-evaluation with extension to PTP and RMP: SAS (Switzerland);
- 1 re-evaluation with extension V&V: NAAU (Ukraine);
- 1 extension to RMP: NA (Norway);
- 1 witnessing for PTP: SWEDAC (Sweden);
- 1 extraordinary evaluation: CYS-CYSAB (Cyprus).

Since the membership of BSCA (Belarus) has been terminated in May 2023, the re-evaluation scheduled in December 2023 was ceased.

The remaining 4 peer evaluations to be performed in 2023 are related to CYS-CYSAB (Cyprus), HAA (Croatia), IPAC (Portugal) and OLAS (Luxembourg).

2.2 - Peer-evaluator trainings

Newcomer training sessions

Further to the couple of newcomer training sessions held in 2022 which have permitted EA to gain a total of 46 new peer evaluators, an additional newcomer training session should be organised in December 2023 before the one normally planned in 2024 in order to make up lost pandemic time.

Refresher training sessions

Three refresher training sessions are scheduled in 2023, all of which will be organised on-site to alternate with the remote sessions held in 2022.

The first session organised on 6-7 June 2023 in Paris, France, was dedicated to product certification and inspection.

The second session planned in November 2023 will focus on testing, medical examinations and proficiency testing provision (PTP). The last session in December 2023 will specially target Deputy Team Leaders and Team Leaders.

2.3 - Re-engineering of the peer-evaluation process

The MAC has completed the project for reengineering the peer-evaluation system, one of the key actions of the *EA Strategy 2025*, with the finalisation of two last documents related to the competence of evaluators and the mechanism to feedback any lessons learned during the peer evaluations.



3 - Development of the EA MLA

EA MLA signatory status for EN ISO/IEC 17029

Following the launching of the EA MLA on EN ISO/IEC 17029:2019 in October 2022, the MLA signatory status in the field of validation and verification was updated to EN ISO/IEC 17029 for 13 NABs by end of June 2023: AA (Austria), ACCREDIA (Italy), BAS (Bulgaria), BELAC (Belgium), DAkkS (Germany), EAK (Estonia), ENAC (Spain), NAH (Hungary), PCA (Poland), RvA (The Netherlands), SNAS (Slovakia), SWEDAC (Sweden) and TURKAK (Türkiye).

In May 2023, EA Members were informed of the extension by 6 months of the transition deadline for ISO/ IEC 17029 (level 3) + ISO 14065:2020 (level 4).

III - Status of EA's recognition in IAF/ILAC

The re-evaluation of EA by IAF/ILAC started in early September 2022 with the evaluation of the EA Secretariat, continued with the evaluation of the scopes of medical examinations, inspection, persons certification as well as validation and verification in 3 NABs, and terminated with the evaluation of the MAC decision-making process at the MAC meeting held in October 2022 in Turin, Italy. The final IAF/ ILAC decision on the re-evaluation of EA is expected by July 2023.

EA is getting ready for applying to IAF for recognition of IFS Food sub-scope under the MLA on product certification (ISO/IEC 17065) as follows:

- level 4 IFS Food Version 7, Part 1, Sections 2 & 3 and Part 4*
- level 5 IFS Food Version 7, Part 2*

* Note: This scope adds requirements at Level 1 - IFS Food Version 7, Part 3, Section 1.

For this purpose, EA Members have been invited to express their interest in being recognised for this specific sub-scope.





IV - Status of EA documents

1 - Documents published since January 2023

- EA-0/07 EA Procedure for Application for EA Membership or a Cooperation Agreement and Application Form
- EA-1/22 EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

2 - Documents under revision

- EA-0/06 Format & Layout of EA Documents
- EA-0/08 Procedure for EA Management Reviews
- EA-1/06 EA Multilateral Agreement. Criteria for Signing. Policy and Procedures for Development
- EA-1/13 EA's Relationship with Accreditation Bodies of Countries not being Members of the EU or EFTA
- EA-1/15 EA Policy for Relations with Stakeholders
- EA-1/17 EA Rules of Procedure
- EA-1/21 EA Internal Procedure for Liaison Activities
- EA-2/02 S4 Supplement 4 to EA-2/02: EA Procedure for the Evaluation of a National Accreditation Body. Procedure for the Management of the Peer Evaluations in case of Extraordinary Circumstances
- EA-2/15 EA Requirements for the Accreditation of Flexible Scopes
- EA-4/14 The Selection and Use of Reference Materials
- EA-5/02 Guidance on the Application of ISO/IEC 17020 in Vehicle Inspection
- EA-6/03 EA Document for Recognition of Verifiers under the EU ETS Directive
- EA-INF/04 Statement on Acceptance and Recognition of Activities under the EA MLA
- EA-INF/14 Communication with the European Commission and its DGs



3 - New documents under development

- EA-3/01 S1 Rules for Use of the EA MLA Mark Note: approved in October 2020; not to be published before the EA MLA mark is formally registered.
- EA-X/XX EA Code of Conduct
- EA-X/XX Guidelines for the Accreditation of Laboratories carrying out Genetic Testing using Next Generation Sequencing (NGS) / Whole Genome Sequencing (WGS) Techniques
- EA-X/XX Guidance Document on Transfers of Certificates under ISO/IEC 17024

4 - Documents withdrawn since January 2023

None.

V - Activities to promote the IAF MLA and ILAC MRA

The *EA MLA Report* 2022 released on 10 May 2023 highlights the outcome and actions achieved through the EA MLA during 2022, as well as EA's recognition in IAF and ILAC through their MLA and MRA – notably EA's application for updating its IAF MLA for validation and verification to ISO/IEC 17029. The report is coupled with an EA MLA 2022 Infographic stressing the main facts and figures in 2022.

EA celebrated and promoted the World Accreditation Day (WAD) 2023 entitled "*Supporting the Future of Global Trade*" on Twitter, as did several EA Members through their website as well. EA produced an infographic highlighting case studies in which accreditation provides businesses with access to a wider international marketplace whilst simultaneously improving the quality and safety of imports.

VI - Major other activities/developments in EA

New members in the Executive and Technical Management Boards

Further to their election at the General Assembly meeting in May 2022 for a two-year mandate starting on 1 January 2023, the Executive and Technical Management Boards welcomed the following five new members: Jesper Hoy (DANAK, Danish NAB) and Karine Vincent (COFRAC, French NAB) as Executive Members, Sergio Guzzi as Laboratory Committee (LC) Chair, Casper van Erp as Certification Committee (IC) Chair, and Marek Wilgos as Inspection Committee (IC) Chair.

New Manager of Peer Evaluations and Evaluators

Since March 2023, Ankica Barišić is part of the EA Secretariat's staff as Manager of Peer Evaluations and Evaluators.

Previously she worked for 15 years in different positions at the Croatian National Accreditation Body (HAA), mainly as Lead Assessor in several accreditation schemes, accreditation decision maker, Quality Manager and Acting Director General of HAA. She became an EA MAC member in 2013 and peer evaluator in 2018.

She will use all her valuable assets, knowledge and experience in her new position of Manager of EA Peer Evaluations and Evaluators, working together with Daniela Ionescu, the Secretary of the Multilateral Agreement Council, who is also responsible for managing peer evaluations.



New Communication Network

In May 2023, the General Assembly approved to disband the Communication and Publications Committee and to set up the Communication Network, with the effective date of the subsequent approval of the Terms of Reference by the General Assembly.

Finalisation of the EA MLA mark registration

According to *EA Strategy 2025*, EA has been establishing a MLA mark for the purpose of identifying EA MLA signatories and their accredited CABs. After EA Members selected their preferred option for the MLA mark at the General Assembly in November 2019, the previous Executive Committee has been mandated to proceed with the formal registration of the MLA mark as a collective mark of the European Union (EU) in a first stage, and then to extend registration to non-EU countries at the international level based on the Madrid Agreement.

The formal registration as a collective mark of the EU was completed in June 2022.

As agreed in November 2019, the EA MLA mark shall not be used until it is registered in the countries of all EA MLA signatories.

The process for registering the EU mark as an international mark is progressing for those 16 EA MLA signatories which are not EU Members: the mapping with all the relevant information about the registration rules in force in the concerned non-EU countries has been achieved at the end of the first quarter of 2023 and, in April 2023, EA has formally applied to the World Intellectual Property Organization (WIPO) to register the MLA mark as an international mark in the countries concerned.

The application of the EA MLA mark should remain voluntary for NABs signatories of the EA MLA, which will be entitled to use the MLA mark in combination with their logo. Conformity Assessment Bodies (CABs) accredited by a MLA-signatory NAB will have the right to use the MLA mark in combination with the NAB accreditation symbol. The basic principle is that the mark can only be used in a country where it has been properly registered. It means that the mark will be registered (at least) in all the countries of the EA MLA signatories.

EA trainings and events

The EA Laboratory Committee organised a training event to harmonise the understanding and use of the new version of the international standard ISO 15189:2022 *Medical Laboratories* — *Requirements for Quality and Competence*, focusing on those requirements in which relevant changes occurred or special focus was needed.





VII - EA meetings

Please visit the EA website https://european-accreditation.org/information-center/newsroom/events-2/

VIII - EA representatives in IAF and ILAC meetings

IAF Committee meetings

General Assembly (GA) Executive Committee (EX) Technical Committee (TC) MLA Committee (MLAC) MLA Management Committee (MLA MC)

Communications and Marketing Committee (CMC)

Development Support Committee (DSC) Database Management Committee (DMC)

ILAC Committee meetings

General Assembly (GA) Executive Committee (EX) Accreditation Committee (AIC) Marketing & Communications Committee (MCC) Arrangement Committee (ARC) Arrangement Management Committee (AMC)

Arrangement Council (AC) Inspection Committee (IC)

Joint IAF/ILAC Committee meetings

Joint Executive Committee (JEX) Joint Management Committee (JMC)

JWG Communications and Marketing (JCMC) JWG Developing Countries JWG A-series Andreas Steinhorst (EA Executive Secretary) Maureen Logghe (EA President) Casper van Erp (RvA, Netherlands) Maria Papatzikou (ESYD, Greece) Karine Vincent (COFRAC, France), Rolf Straub (SAS, Switzerland) Amandine Combe (EA Communications Manager) Andreas Steinhorst Herman Van den Langenbergh (BELAC, Belgium)

Andreas Steinhorst Andreas Steinhorst Sergio Guzzi (ACCREDIA, Italy) Amandine Combe Andreas Steinhorst Maria Papatzikou, Daniela Ionescu (MAC Secretary) Andreas Steinhorst Marek Wilgos (PCA, Poland)

Maureen Logghe, Andreas Steinhorst Maria Papatzikou, Daniela Ionescu Rolf Straub, Karine Vincent Amandine Combe Andreas Steinhorst Maria Papatzikou, Daniela Ionescu

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