

EA REPORT TO IAF/ILAC AND REGIONS



STATUS JULY - DECEMBER 2022



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I - Structural status as at December 2022

1 - EA Membership

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 https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/

2 - Signatories to the EA MLA

44 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

\	EM BOILE TOPS	Testing TOS	Medical Example (5/05)	Manager (EN SOME TODO)	ment Systems Celt	products Certification	Persons Certification	Validation and Very Sol	Proficiency Testing (10/3)	terence Material Provision	Toduction
	Members signatories to the EA MLA	41	42	38	43	36	37	33	25	20	12



3 - EA Recognised Stakeholders

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

In accordance with EA-1/15: *EA Policy for Relation with Stakeholders* providing for a formal review every five years, the Recognised Stakeholder agreements with FSSC 22000 (Food Safety System Certification) and UILI (International Union of Independent Laboratories) have been renewed in November 2022 for the coming five years.

Moreover three organisation and groups were granted the EA Recognised Stakeholder status in November 2022, i.e.:

- the Comité Européen des Constructeurs d'Instruments de Pesage (CECIP), the European weighing industry association;
- the Recreational Craft Sectoral Group (RSG), a Notified Body Coordination Group pursuant to Article 42 of Recreational Craft Directive (RCD) 2013/53/EU;
- the EU FPR Notified Body Coordination Group pursuant to Article 36 of the Fertilising Products Regulation (FPR) 2019/1009/EU.

II - EA MLA and peer-evaluation issues

1 - New and remaining signatories to the EA MLA scopes

Upon decisions made by the MLA Council (MAC) at its 47th meeting held on 4-5 October 2022 in Turin, Italy and through electronic ballots carried out in the second semester 2022:

- ATS, the Serbian NAB, became an EA MLA signatory in the field of proficiency testing providers (EN ISO/IEC 17043);
- ATS also remained an EA MLA signatory in the fields of calibration (EN ISO/IEC 17025), testing (EN ISO/IEC 17025) including medical examinations (EN ISO 15189), inspection (EN ISO/IEC 17020), certification of management systems (EN ISO/IEC 17021-1), certification of products (EN ISO/IEC 17065) and certification of persons (EN ISO/IEC 17024);
- ISAC, the Icelandic National Accreditation Body (NAB), became an EA MLA signatory in the field of inspection;
- BAS, the Bulgarian 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);
- CYS-CYSAB, the Cypriot NAB, remained an EA MLA signatory in the field of calibration and testing including medical examinations;
- IARNM, the North Macedonian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems and certification of products;
- SWEDAC, the Swedish NAB, remained an EA MLA signatory in the field of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons, validation and verification, and proficiency testing providers.



2 - Latest developments relating to the EA peer evaluations

2.1 - Peer evaluations in 2022

For 2022, the MAC scheduled 14 peer evaluations. 8 of those peer evaluations were performed by end of June 2022.

5 peer evaluations were carried out as follows by end of December 2022:

- 4 re-evaluations: BELAC (Belgium), DAkkS (Germany), ENAC (Spain) and GAC (Georgia);
- 1 initial evaluation: ATCG (Montenegro).

At its meeting in October 2022, the MAC reconfirmed the EA MLA signatory status of NAAU, the Ukrainian NAB, whose full re-evaluation, anticipated in 2022, will finally be carried out in May 2023 as originally planned.

Since the pandemic has become alleviated and NABs in most European countries have decided to restart performing on-site assessments again, the MAC restarted on-site peer evaluations in 2022, with notably the re-evaluations of BELAC, DAkkS, ENAC and GAC and the initial evaluation of ATCG during the second half of 2022. Due to the lifting of COVID-19 pandemic restrictions, the EA MAC has decided that all peer evaluations will be carried out on site as from 1 January 2023. In case of extraordinary circumstances preventing the peer-evaluation team from going on-site, the MAC Management Group will consider the specific situation and decide accordingly.

2.2 - Peer-evaluator trainings

Newcomer training sessions

In addition to the newcomer training session held in March 2022, a second newcomer training session for EA evaluators took place face-to-face on 18-20 October 2022 in Brussels, Belgium, in order to make up lost pandemic time.

Launching of the EA MLA for EN ISO/IEC 17029

EA adopted in November 2021 the IAF Resolution 2021-22 related to the transition to a single Validation & Verification MLA under ISO/IEC 17029:2019 Conformity assessment — General principles and requirements for validation and verification bodies besides the EN ISO 14065:2013 Greenhouse gases — Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition.

For this purpose, the MAC approved in April 2022 the roadmap towards an EA MLA according to EN ISO/IEC 17029 and the transition plan to EN ISO/IEC 17029:2019 + EN ISO 14065:2020. The actions foreseen in the transition plan, including the training of peer evaluators and decision-makers, have been completed.

At its meeting in October 2022, the MAC decided that the peer evaluations in the field of validation and verification against EN ISO/IEC 17029 will start on 5 October 2022.

Furthermore the MAC decided to launch the EA MLA for validation and verification bodies (EN ISO/IEC 17029) based on at least one successful transition to EN ISO/IEC 17029 (level 3) and EN ISO 14065:2020 (level 4), declared by a NAB, or at least one successful peer evaluation of a NAB against EN ISO/IEC 17029.

The first signatories are ENAC, the Spanish NAB, and TURKAK, the Turkish NAB.



Refresher training sessions

Three refresher training sessions were scheduled remotely in 2022, starting with a first one dedicated to calibration and reference material production (RMP) held in June 2022.

The second training session organised on 15-16 November 2022 was targeted to peer evaluators in testing, medical examinations and proficiency testing provision (PTP).

The last refresher training session on 28-30 November 2022 was dedicated to management systems certification, persons certification and validation and verification.

2.3 - Re-engineering of the peer-evaluation process

The elaboration of the last supplement to EA-2/02 *EA Procedure for the evaluation of a National Accreditation Body*, EA-2/02 S3 *Risk-Based Approach for the Planning of a Peer Evaluation of a National Accreditation Body*, has been recently finalised by the MAC and adopted within EA; it was published on 1 December 2022. The MAC agreed on its implementation as from 1 January 2023 for the peer evaluations planned in 2024. The Team Leaders (TLs) are being trained on the application of the document, and the MAC Management Group will be involved in the review of the outcome of the risk-based approach performed by the TLs for all the peer evaluations planned for 2024 to have a harmonised approach in the implementation of the document. A first training of the TLs took place on 16 December 2022; two more trainings should take place in 2023.

Finally, at its meeting in October 2022, the MAC decided to revise EA-2/02 S4 *Procedure for remote peer evaluations during the COVID-19 pandemic* in order to make it applicable to other extraordinary circumstances than the COVID pandemic.

3 - Development of the EA MLA

Extension of the EA MLA to biobanking

EA has completed the process of extending its MLA to include biobanking.

On 23 November 2022, the EA General Assembly has decided to expand with immediate effect the EA MLA for biobanking as a level 2 conformity assessment activity using EN ISO 20387 *Biotechnology* — *Biobanking* — *General Requirements for Biobanking* as a new level 3 normative document.

A last decision has still to be made by the MAC in April 2023 to define the prerequisites for the launch of the MLA on biobanking. In the meantime, the MAC has made those arrangements needed to start with the peer evaluations of EA NABs, including the training of the MAC members, who are the decision-makers.

Besides a training course on biobanking was held remotely on 13 and 25 October 2022 under the auspices of the EA Laboratory Committee.

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, and continued with the evaluation of the scopes of medical examinations, inspection, persons certification as well as validation and verification in 3 NABs.

Furthermore IAF/ILAC evaluated the MAC decision-making process when they participated remotely in the MAC meeting held on 4-5 October in Turin, Italy.

The final IAF/ILAC decision on the re-evaluation of EA is awaited in 2023.



IV - Status of EA documents

1 - Documents published since July 2022

EA-1/13 EA's Relationship with Accreditation Bodies of Countries not being Members of the EU or EFTA

EA-2/02 S3 Supplement 3 to EA-2/02: EA Procedure for the Evaluation of a National Accreditation Body. Risk-Based Approach for the Planning of a Peer Evaluation.

EA-2/21 Guidance on Remote Assessments

2 - Documents under revision

EA-0/06 Format & Layout of EA Documents

EA-1/06 EA Multilateral Agreement. Criteria for Signing. Policy and Procedures for Development

EA-1/22 EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

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-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

FA-3/01 S1 Rules for Use of the FA MI A 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 July 2022

None.



V - Activities to promote the IAF MLA and ILAC MRA

EA published a great number of information on the EA Twitter account about the IAF MLA and ILAC MRA, as well as about IAF and ILAC major activities such as meetings and impact of accreditation during the second half of 2022.

EA also contributed to the ILAC and IAF newsletters published in November and December 2022 with several articles on the latest developments in EA relating to, notably, the evolvement of the EA MLA, the webinar and renewed partnership with the Standards Council of Canada, certification of carbon removals to help reach net zero emissions, the EA document on accreditation for notification purposes (EA-2/17) and accreditation of notified bodies, a key component for the functioning of the EU single market for goods, etc.

Besides the meeting of the EA Communications and Publications Committee (CPC) held on 12-13 October 2022 in Rome, Italy, welcomed Brahim Houla, the IAF Communications and Marketing Committee (CMC) Chair, and Aparna Dhawan, the APAC CPC Chair, in order to exchange views and feedback on the communication in ILAC, IAF and APAC.

VI - Major other activities/developments in EA

Framework Partnership Agreement 2023-26 with the EC and EFTA

On 30 August 2022, EA signed the 4th Framework Partnership Agreement (FPA) for a new four-year period with the European Commission (EC); a similar agreement was signed with the European Free Trade Association (EFTA) on 16 November 2022.

Since 2010, the FPA widens and strengthens the cooperation between the EC, EFTA and EA to support the development of EU policy and legislation for open and fair trade in the European market. The objective of this new FPA is to help the realisation of the EA Action Plan 2023-2026.

Renewal of partnership with Standards Council of Canada in support of CETA

The Comprehensive Economic and Trade Agreement (CETA) is designed to strengthen economic relations and business development between the European Union and Canada. CETA includes a chapter on technical barriers to trade that encourages cooperation in the areas of accreditation and conformity assessment in order to facilitate the free movement of goods between the EU and Canada. Accordingly, CETA includes a Protocol on the Mutual Acceptance of the Results of Conformity Assessment (the CA Protocol) which establishes mutual recognition of European and Canadian NABs and conformity assessment bodies to accept the results of each other's conformity assessment.

To facilitate this mutual recognition, EA and the <u>Standards Council of Canada (SCC)</u> signed a Bilateral Cooperation Agreement (BCA). The agreement establishes the conditions and procedures for cooperation between EA and SCC for technical support of activities aimed at mutual recognition of NABs and accredited conformity assessment bodies operating in the EU and Canada. To get detailed information on the bilateral cooperation agreement signed between EA and the SCC, please read the brochure "<u>CETA Agreement and Conformity Assessment Accreditation: a tool to enhance trade between the European Union and Canada</u>".



In 2022, the 5th and 6th anniversaries of the CETA Agreement and Protocol, respectively, offered relevant opportunities for increasing promotion of the agreement among European accredited conformity assessment bodies.

On 29 September 2022, the SCC and EA renewed their partnership agreement to strengthen the implementation of the Protocol, notably in order to extend it to additional product sectors.

Death of Daniel Pierre, former EA Chair

Daniel Pierre passed away on 4 November 2022.

Daniel served as the EA Chair from 2000 to 2006, and the EA Vice-Chair from 2010 to 2013 when he stopped his professional activities. He was the first chairman of the newly established EA in 2000 and supported the setting-up of the EA Secretariat in Paris in 2010.

He was vigorously committed to the values of accreditation, and fully devoted to continuously reinforcing and promoting the European accreditation model, notably in ILAC which he vice-chaired between 2001 and 2004, and chaired from 2005 to 2010.

Daniel was an exceptional professional. He was the image of energy, a solicitous and humane man, and despite all his achievements, always remained humble.

Leaving members from the Executive and Technical Management Boards

The General Assembly at its meeting on 23 November 2022 paid tribute to a couple of leaving members of the EA Executive Board, i.e. Adrienne Duff (INAB, the Irish NAB) and Emanuele Riva (ACCREDIA, the Italian NAB).

The General Assembly also paid tribute to several leaving members of the EA Technical Management Board:

- Lucyna Olborska (PCA, the Polish NAB) who chaired the Communications & Publications Committee;
- Laurent Vinson (COFRAC, the French NAB) who chaired the Laboratory Committee;
- Kevin Belson (UKAS, the UK NAB) who chaired the Certification Committee;
- Orbay Evrensevdi (TURKAK, the Turkish NAB) who chaired the Inspection Committee.

The management of EA had been renewed at the General Assembly meeting held in May 2022, when the leaving members had made way for these newly elected persons for a two-year mandate starting on 1 January 2023: Jesper Hoy (DANAK, the Danish NAB) and Karine Vincent (COFRAC) at the Executive Board, Sergio Guzzi (ACCREDIA) as Laboratory Committee Chair, Casper van Erp (RvA) as Certification Committee Chair, and Marek Wilgos (PCA) as Inspection Committee Chair.

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. 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 General Assembly on 23 November 2022 reconfirmed that, 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 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.

Guidance on remote assessments

Due to the COVID-19 outbreak in early 2020 which limited the possibility of on-site assessments of conformity assessment bodies, national accreditation bodies had to quickly adapt their practices by developing remote assessment techniques in order to maintain confidence in accredited conformity assessment activities. Since then, NABs have been noting the benefits and the limitations of remote assessment techniques.

EA published a general framework to provide guidance and improve harmonisation among EA Members. <u>EA-2/21: Guidance on Remote Assessments</u> includes the basic requirements, elements for the preparation and the conduction of the remote assessment, the reporting, and circumstances where remote assessment may not be appropriate.

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)

Manager)

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 Communication

Andreas Steinhorst

Maarten Aerts (NA, Norway)

Andreas Steinhorst Andreas Steinhorst

Sergio Guzzi (ACCREDIA, Italy)

Amandine Combe Andreas Steinhorst

Maria Papatzikou, Andreas Steinhorst

Andreas Steinhorst

Marek Wilgos (PCA, Poland)

Maureen Logghe, Andreas Steinhorst Maria Papatzikou, Andreas Steinhorst,

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