

EA REPORT TO IAF/ILAC AND REGIONS



STATUS JANUARY - JUNE 2022



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I - Structural status as at June 2022

1 - EA Membership

EA has a total of 49 Members.

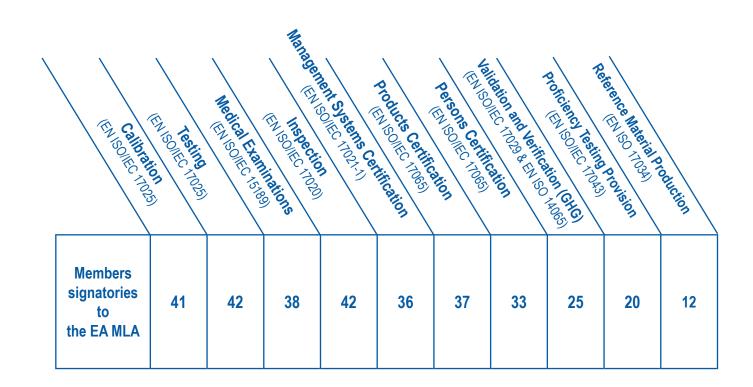
The complete list of EA Members together with their details and their EA MLA status is available on the EA website at <u>https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signa-tories/</u>

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 <u>EA-INF/03</u>: *Signatories to the EA Multilateral and Bilateral Agreements*.

Recapitulative table of signatories by MLA scope





3 - EA Recognised Stakeholders

EA cooperates with about 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 E3S (European Sensory Science Society) and GLOBALG.A.P. (Trademark and Set of Standards for Good Agricultural Practices) have been reviewed by the Executive Board and renewed in May 2022 for the coming five years.

As also set out in EA-1/15, FAMI-QS, the worldwide Quality and Feed Safety Management System for the sector of Specialty Feed Ingredients, informed EA of their decision to terminate their Recognised Stakeholder agreement with EA.

No new organisation was granted the EA Recognised Stakeholder status by June 2022.

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 46th meeting held remotely on 6-7 April 2022 and through electronic ballots in the first semester 2022:

- BATA, the Bosnia and Herzegovina 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);
- BATA remained an EA MLA signatory in the fields of calibration (EN ISO/IEC 17025), testing (EN ISO/IEC 17025) and inspection (EN ISO/IEC 17020);
- EGAC, the Egyptian NAB, remained an EA MLA signatory in the field of proficiency testing provision (EN ISO/IEC 17043);
- ISRAC, the Israelian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, and inspection;
- NAAU, the Ukrainian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of persons (EN ISO/IEC 17024), certification of products and certification of management systems (EN ISO/IEC 17021-1);
- NAB-MALTA, the Maltese NAB, remained an EA MLA signatory in the fields of calibration, testing and inspection;
- RENAR, the Romanian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing provision, certification of management systems, certification of products, certification of persons, and validation and verification (EN ISO 14065);



- RvA, the Dutch NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing provision, reference material production, certification of management systems, certification of products, certification of persons, and validation and verification;
- UKAS, the United Kingdom NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing provision, certification of management systems, certification of products, certification of persons, validation and verification, and reference material production (EN ISO 17034).

2 - Latest developments relating to the EA peer evaluations

2.1 - Peer evaluations in 2022

For 2022, the MAC has scheduled 14 peer evaluations, including the initial peer evaluations of:

- ISAC, the Islandic NAB, rescheduled in 2022;
- ATCG, the Montenegrin NAB.

8 peer evaluations were carried out as follows by end of June 2022:

- 6 re-evaluations: CAI (Czech Republic), INAB (Ireland), ISRAC (Israel), NAH (Hungary), SNAS (Slovakia) and SA (Slovenia);
- 1 re-evaluation with extension for medical examinations and products certification: TUNAC (Tunisia);
- 1 initial evaluation: ISAC (Iceland).

Since the pandemic is becoming alleviated and NABs in most European countries have been performing on-site assessments again, the MAC decided to restart on-site peer evaluations in 2022 with the re-evaluations of CAI, INAB, NAH and TUNAC.

Following the war situation in Ukraine, the MAC decided that the peer evaluation of NAAU, initially planned in September 2022 is on-hold. The MAC will consider the evolution of the situation in Ukraine during the next MAC meeting on 4-5 October 2022 at the latest.

2.2 - Peer-evaluator trainings

Newcomer training sessions

The newcomer training session for EA evaluators took place from 1 to 3 March 2022 and gathered 25 participants from 20 NABs. Trainers were Nicole Van Laethem (BELAC, Belgian NAB), Tuija Sinervo (FINAS, Finnish NAB) and Kevin Belson (UKAS, UK NAB).

To make up lost pandemic time, a second newcomer training session will be held face-to-face on 18-20 October 2022 in Brussels, Belgium.



Refresher training sessions

Three refresher training sessions are planned in 2022.

The first session held on 28-29 June 2022 was dedicated to calibration and reference material production (RMP). 27 Team Members from 17 NABs took part in the program covering first procedural aspects related to the peer-evaluation process, and then focusing on the more technical aspects directly related to the specific fields and applicable standards, namely EN ISO/IEC 17025 and 17034. The trainers were Jeff Ruddle (UKAS) for the RMP group, Zacharias Ioannidis (ESYD, Greek NAB) for the calibration group and Daniela Ionescu, EA MAC Secretary, for the general aspects related to the peer-evaluation process.

Two other refresher training sessions are scheduled on 15-16 and 28-30 November 2022, respectively targeted to peer evaluators in testing, medical examinations and proficiency testing production, and management systems certification, persons certification and validation and verification.

2.3 - Re-engineering of the peer-evaluation process

The MAC project to re-engineer the peer-evaluation system, one of the key actions of the *EA Strategy* 2025, is nearing its final completion.

The MAC finalised the revision of EA-2/02: *EA Procedure for the Evaluation of a National Accreditation Body*, as well as the revision of the MAC Terms of Reference in order to include the role and responsibilities of the Secretariat and to clarify the Task Force Group's and the Secretariat's roles, the rules on the performance of witnessing in advance of the peer-evaluation visit, and the rules on assignment of Team Leaders and Team Members to peer evaluations. Both documents have been approved and published on the EA website.

The MAC also finalised the following four supplements to EA-2/02 which have all been adopted and published:

- EA-2/02 S1 Description of Competence Criteria of the EA Secretariat Personnel Involved in the Management of the Peer-Evaluation Process;
- EA-2/02 S2 Circumstances and Process of Involving EA Technical Committees in Peer-Evaluation Issues;
- EA-2/02 S4 Procedure for Remote Peer Evaluations during the COVID-19 Pandemic;
- EA-2/02 S5 Procedure for Remote Decision-Making.

The last supplement, EA-2/02 S3 *Risk-Based Approach for the Planning of a Peer Evaluation of a National Accreditation Body*, should be available by end of 2022.



3 - Development of the EA MLA

Extension of the EA MLA to biobanking

The international standard ISO 20387: *General requirements for biobanking* has been published in 2018. This standard specifies general requirements for the competence, impartiality and consistent operation of biobanks, including quality control requirements to ensure biological material and data collections of appropriate quality. Many EA NABs are offering accreditation to biobanking facilities since accreditation is the best means to demonstrate the competence of biobanks.

EA is currently in the process of extending its MLA to include biobanking. EA has approved the roadmap towards the EA MLA for biobanking, which identifies the actions to be undertaken such as the revision of EA documents to include the activity and the harmonised standard into the EA MLA and training of peer evaluators.

A workshop on biobanking should also be carried out in September 2022 by the EA Laboratory Committee.

Roadmap towards a single EA MLA for validation and verification according to EN ISO/IEC 17029

EA decided in November 2019 to extend the EA MLA under "Validation and Verification" to include EN 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, since EN ISO/IEC 17029:2019 expands the scope of EN ISO/IEC 14065 which only covers the accreditation of Greenhouse Gas Verification Bodies.

In order to reach this objective, the MAC has approved at its meeting 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, which are describing the actions to be taken such as training of peer evaluators and decision-makers and the steps to be taken for the transition process.

The MAC already organised a training workshop on EN ISO/IEC 17029 for its members in order to ensure sound decisions on the MLA signatory status in relation to this standard in future. The workshop was led by Nathalie Saveant (COFRAC, French NAB).

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

The next re-evaluation of EA by IAF/ILAC should begin in early September 2022.



IV - Status of EA documents

1 - Documents published since January 2022

- EA-1/06 EA Multilateral Agreement. Criteria for Signing. Policy and Procedures for Development Note: being further revised after publication.
- EA-1/14 Procedure for Development and Approval of EA Documents and Adoption of ILAC/IAF Documents
- EA-1/17 EA Rules of Procedure
- EA-1/17 S1 Criteria for Membership
- EA-1/17 S3 EA Procedure for the Investigation and Resolution of EA Complaints and Appeals
- EA-1/17 S4 Proxy Procedure
- EA-1/17 S5 Levying of Membership Fees
- EA-1/19 Rules for Use of the EA logo
- EA-1/20 Procedure for the Control of Expenditures and Preparation of Budgets
- EA-1/20 S1 Terms and Conditions for Financial Compensation from the Operating Grant to an EA Member Accreditation Body
- EA-1/21 EA Internal Procedure for Liaison Activities
- EA-2/02 Procedure for the Evaluation of a National Accreditation Body
- EA-2/02 S1 Description of Competence Criteria of the EA Secretariat Personnel Involved in the Management of the Peer-Evaluation Process
- EA-2/02 S2 Circumstances and Process of Involving EA Technical Committees in Peer-Evaluation Issues
- EA-2/02 S4 Procedure for Remote Peer Evaluations during the COVID-19 Pandemic
- EA-2/02 S5 Multilateral Agreement Council Procedure for Making the EA MLA Decisions by Online Ballot, In-Between Meetings
- EA-3/02 EA Policy for the Accreditation of Certification Activities under Protected Designations of Origin, Protected Geographical Indications and Traditional Specialities Guaranteed
- EA-3/12 EA Policy for the Accreditation of Organic Production Certification
- EA-4/09 Accreditation for Sensory Testing Laboratories
- EA-4/17 EA Position Paper on the Description of Scopes of Accreditation of Medical Laboratories



- EA-6/02 EA Guidelines on the Use of ISO/IEC 17065 and ISO/IEC 17021-1 for Certification to EN ISO 3834
- EA-6/03 EA Document for Recognition of Verifiers under the EU ETS Directive
- EA-INF/17 Register of EA resolutions for use by National Accreditation Bodies and EA Evaluators

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-1/13 EA's Relationship with Accreditation Bodies of Countries not being Members of the EU or EFTA
EA-1/22 EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members
EA-4/14 The Selection and Use of Reference Materials
EA-INF/14 Communication with the European Commission and its DGs

3 - New documents under development

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

HHC guidance document on remote assessment.

LC guidelines for the Accreditation of Laboratories carrying out Genetic Testing using Next Generation Sequencing (NGS) / Whole Genome Sequencing (WGS) Techniques.

4 - Documents withdrawn since January 2022

- EA-2/18 Guidelines on the Contents of the Scopes of Accreditation for PTP
- EA-6/04 EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites



V - Activities to promote the IAF MLA and ILAC MRA

The *EA MLA Report 2021* released on 11 April 2022 highlights the outcome and actions achieved through the EA MLA during 2021, as well as EA's recognition in IAF and ILAC through their MLA and MRA — notably EA's recognition for the IAF MLA Level 4 Food Safety System Certification (FSSC) 22000 subscope. The report is coupled with an EA MLA 2021 Infographic stressing the main facts and figures in 2021.

EA celebrated the World Accreditation Day (WAD) 2022 entitled "Sustainability in Economic Growth and the Environment":

- an EA Homepage news, available at https://european-accreditation.org/world-accreditation.tem https://european-accreditation.org/world-accreditation.tem https://european-accreditation.org/world-accreditation.tem
- dedicated electronic newsletters were circulated by EA Members on 9 June among the whole EA community;
- WAD 2022 was promoted on Twitter;
- several EA Members promoted the WAD through Twitter and their website.

VI - Major other activities/developments in EA

Renewal of the management of EA

At the General Assembly meeting held on 18-19 May 2022, the members of the EA management structure implemented since 1 January 2021 have been elected or re-elected for a two-year mandate starting on 1 January 2023:

Members of the Executive Board, responsible for implementing EA governance and financial policies, as well as managing the organisation between the General Assembly meetings and as directed by the General Assembly:

President: Maureen Logghe, BELAC, Belgium Vice-President: Cecilie Laake, NA, Norway Leopoldo Cortez, IPAC, Portugal Jesper Hoy, DANAK, Denmark Roeland Nieuweboer, RvA, The Netherlands Karine Vincent, COFRAC, France



Members of the EA Technical Management Board in charge of coordinating the technical activities of EA, and chaired by the Vice-President:

Vice-President: Cecilie Laake, NA, Norway Multilateral Agreement Council Chair: Maria Papatzikou, ESYD, Greece Horizontal Harmonization Committee Chair: Gabriel Zrenner, DAkkS, Germany Laboratory Committee Chair: Sergio Guzzi, ACCREDIA, Italy Certification Committee Chair: Casper van Erp, RvA, The Netherlands Inspection Committee Chair: Marek Wilgos, PCA, Poland

EA in the face of the war in Ukraine

On 7 March 2022, an EA statement on the war in Ukraine was published on the EA Homepage, stating that EA and its members stand for democracy, transparency and partnership. EA strongly condemns the invasion of Ukraine by Russia: this is a clear violation of the international law, and poses a real threat to peace and security in Ukraine, Europe and beyond. In solidarity with Ukraine, EA supports the strong measures of the European Union and its European and International partners to defend international rules and to support Ukraine and its people. EA's thoughts are with Ukrainian colleagues and friends from NAAU, the National Accreditation Body of Ukraine, and with all Ukrainian people.

Moreover, in accordance with the European Commission's formal recommendation to EA in the context of the situation in Ukraine received in early May 2022, the EA General Assembly has adopted the following specific resolution EA Resolution 2022 (51) 04 on 18-19 May 2022:

The General Assembly, acting upon the recommendation from the Executive Board, agrees that EA considers it contrary to reasonableness and fairness if any EA member does not also comply with the EU sanction regulations. EA Members cannot offer accreditation services to Conformity Assessment Bodies in particular established in Russia and Belarus if these bodies are listed in the EU sanctions list. Compliance with EU sanction regulations shall be deemed as an obligation according to paragraph 5 of EA-1/17 *EA Rules of Procedure*. The Executive Board may suspend a member if it does not fulfil its obligations to EA.

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 started in May 2021 and, after some editorial improvements, has just been completed in June 2022. The process for registering the EU mark as an international mark can now start for those 16 EA MLA signatories which are not EU Members.

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.



Two major international issues considered in EA

A couple of major issues regarding the IAF CertSearch database and the future single international accreditation organisation is currently examined in EA. In addition to lively discussions at the last General Assemblies in November 2021 and May 2022, both issues have been subject to an Extraordinary General Assembly on 10 September 2021 and a dedicated EA meeting on 17 December 2021, which gathered all Chief Executive Officers (CEOs) or heads of EA NABs.

The IAF CertSearch online database, managed by an IAF Database Management Committee (DMC), includes accredited management system certificates issued by certification bodies (CBs) with the purpose to check whether any certificate is delivered under accreditation or not. It is mandatory for NABs to feed the accreditations they issue to a database, but so far CBs have to put their data down in a database only on a voluntary basis. Owing to financial issues, IAF is proposing an option to run the CertSearch database which would make it mandatory for all accredited CBs.

Since the IAF consultation process started in 2021, EA has been quite reluctant to this option because CBs cannot be obliged to put their data in a database. EA NABs have put forward such comments to the IAF DMC during the consultation period.

Acknowledging the importance of this issue for EA, the EA Advisory Board (EAAB) dedicated large discussions to the proposals for development of the IAF database during its meeting in November 2021, and held an extraordinary EAAB meeting on 19 January 2022. The EAAB Colleges have sent EA and EA NABs a position paper which demonstrates their points of concern and their objections to the new principles of the CertSearch database.

The final ballot on the IAF CertSearch online database is expected in July 2022.

Since it was agreed to build up a single international accreditation organisation, an ILAC/IAF Steering Committee was set up and a questionnaire was sent out through the Steering Committee to define the most appropriate new entity. A Task Force Group composed of NABs' CEOs has been created in EA in order to follow up and progress the issue.

EA is supporting applying the EA model with the EAAB to the new international organisation: EA is advocating for having an association of accreditation bodies, while actively involving stakeholders which do not have voting rights. The EA position and NABs' views have been shared and commented at the dedicated meeting on 17 December 2021, before EA NABs commented back to ILAC and IAF in January 2022.



EA trainings and events

The Horizontal Harmonisation Committee (HHC) organised a workshop on EA-2/17 M:2020 *EA Document on Accreditation for Notification Purposes* on 14 March 2022. About 80 representatives from 39 EA NABs and 7 Recognised Stakeholders attended this large virtual workshop, whose trainers were Maureen Logghe (BELAC, Belgian NAB), Gabriel Zrenner (DAkkS, German NAB), the HHC Chair, Leopoldo Cortez (IPAC, Portuguese NAB) and Hélène Tagzout (COFRAC, French NAB).

On 28 April 2022, an EA webinar was also organised together with the European Commission (EC) Joint Research Centre (JRC) to give EA Members an update on *"Accreditation under the European Commission Initiative on Breast Cancer (ECIBC)"*.

The ECIBC is a patient-centred initiative aiming to improve and harmonise breast cancer care in Europe with the aim of contributing to reduce the burden of cancer and decreasing the avoidable differences in breast cancer incidence, prevalence, mortality and survival. EA has signed an agreement with the EC represented by the JRC, which is currently developing a European quality assurance scheme for breast cancer services underpinned by accreditation.

This webinar was attended by 63 representatives from 26 EA NABs, including members of the EA Working Group on Breast Cancer Services (BCS) chaired by Tuija Sinervo, FINAS (Finland, Finnish NAB). After a presentation of the EC initiative made by a member of the EC Joint Research Centre, the participants were provided with exhaustive information on the European quality assurance scheme for BCS, the European breast cancer guidelines on screening and diagnosis, and finally the requirements for the accreditation under the BCS scheme.

The EA Laboratory Committee (LC) organised a remote workshop dedicated to sampling on 23 June 2022. The workshop program was based on the results of a survey ran among LC Members earlier in 2022 to identify any unharmonised approach regarding sampling accreditation under EN ISO/IEC 17025. The facilitators of this workshop, which enabled 76 participants to discuss the difficulties met by EA NABs in light of five case studies developed in different fields, were LC Management Group Members, i.e. Laurent Vinson (COFRAC), Sergio Guzzi (ACCREDIA, Italian NAB), Maarten Aerts (NA, Norwegian NAB), Ioannis Sitaras and Kondylia Sotiriou (ESYD).



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 Communication Manager) Andreas Steinhorst Adrienne Duff (INAB, Ireland)

Andreas Steinhorst Andreas Steinhorst Laurent Vinson (COFRAC, France) Amandine Combe Andreas Steinhorst Maria Papatzikou, Andreas Steinhorst Andreas Steinhorst Orbay Evrensevdi (TURKAK, Turkey)

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





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