EA REPORT to IAF/ILAC and REGIONS

STATUS
JULY - DECEMBER 2019
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I - Compositional state of play in December 2019

1 - EA Membership

EA has 36 Full Members and 14 Associate 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

34 Full Members and 9 Associate 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 EA MLA scope

<table>
<thead>
<tr>
<th>Calibration</th>
<th>Testing</th>
<th>Medical Examinations</th>
<th>Inspection</th>
<th>Management Systems</th>
<th>Products</th>
<th>Persons</th>
<th>Proficiency Testing Providers</th>
<th>Reference Material Producers</th>
</tr>
</thead>
<tbody>
<tr>
<td>EA Members signatories to the EA MLA</td>
<td>41</td>
<td>42</td>
<td>35</td>
<td>41</td>
<td>36</td>
<td>35</td>
<td>31</td>
<td>25</td>
</tr>
</tbody>
</table>
3 - EA Recognised Stakeholders

EA cooperates with about 40 Recognised Stakeholders.

The EA General Assembly in November 2019 decided to grant the EA Recognised Stakeholder status to a couple of organisations:

• TIC (Testing, Inspection and Certification) Council, into which have merged CEOC International and IFIA, the International Federation of Inspection Agencies. As a result, the EA cooperation agreements with CEOC and IFIA have been terminated.

• NB-Rail Association, an international non-profit organisation of the notified bodies for interoperability in the railway sector.

Because AEBIOM, the European Biomass Association, changed its name in 2019 into Bioenergy Europe, the EA Recognised Agreement with AEBIOM concluded last year was identically replaced in October 2019 by an agreement with Bioenergy Europe.

In accordance with EA-1/15: *EA Policy for Relation with Stakeholders* providing for their formal review every five years, the EA Recognised Agreement of IQNet (The International Certification Network) has been reviewed and renewed for the coming five years.

II - EA MLA and peer-evaluation issues

1 - Latest developments relating to the EA MLA

New and remaining signatories to the EA MLA scopes

Upon decisions made by the EA Multilateral Agreement Council (MAC) at its 42nd meeting on 2-3 October 2019 in Vilnius, Lithuania:

• DAkkS, the German national accreditation body (NAB), became an EA MLA signatory in the field of reference material producers according to ISO 17034.

  Furthermore, DAkkS remained an EA MLA signatory in the fields of calibration (ISO/IEC 17025), testing (ISO/IEC 17025) including medical examinations (ISO 15189), inspection (ISO/IEC 17020), proficiency testing providers (ISO/IEC 17043), certification of persons (ISO/IEC 17024), certification of products (ISO/IEC 17065), certification of management systems (ISO/IEC 17021-1) and GHG validation and verification (ISO 14065).
• GAC, the Georgian NAB, became an EA BLA signatory in the field of medical examinations according to ISO 15189.

Furthermore, GAC remained an EA BLA signatory in the fields of calibration, testing, inspection certification of persons and certification of products.

• ALGERAC, the Algerian NAB, remained an EA BLA signatory in the fields of calibration, testing and inspection.

• MOLDAC, the Moldavian NAB, remained an EA BLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of products and certification of management systems.

Extension of the EA MLA to ISO/IEC 17029

Following the IAF Resolution 2019-25, the General Assembly in November 2019 endorsed the extension of the EA MLA under the Level 2 Validation and Verification to ISO/IEC 17029 as new EA MLA Level 3 standard in accordance with EA-1/06: EA Multilateral Agreement. Criteria for signing. Policy and procedures for development.

2 - Latest developments relating to the EA peer evaluations

2.1 - Peer evaluations in 2019

2019 totalized 16 peer evaluations. In addition to those 8 peer evaluations that had already been completed by end of June, 8 other peer evaluations were performed in 2019 as follows:

• 1 re-evaluation with scope extension to inspection, PTP and medical examinations: BSCA (Belarus);
• 4 re-evaluations: HAA (Croatia), FINAS (Finland), IPAC (Portugal), OLAS (Luxembourg);
• 3 follow-up evaluations: DPA (Albania), CYS-CYSAB (Cyprus), NAH (Hungary).

By end of December 2019, the MAC Secretariat can rely on a total of 177 active evaluators (24 Team Leaders, 28 Deputy Team Leaders, 95 Team Members and 30 Trainee Team Members) to carry out the peer evaluations on behalf of EA.

Implementation and monitoring of ISO/IEC 17011 transition period

The revised internationally-accepted standard ISO/IEC 17011:2017 Conformity Assessment - Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies has been published in November 2017. The peer evaluations done as from 1 July 2018 are performed according to the new standard.
By the end of December 2019, the EA MAC confirmed that the following 13 NABs successfully made the transition from ISO/IEC 17011:2004 to ISO/IEC 17011:2017:

- ACCREDIA, the Italian NAB;
- ALGERAC, the Algerian NAB;
- BELAC, the Belgian NAB;
- CAI, the Czech NAB;
- ENAC, the Spanish NAB;
- GAC, the Georgian NAB;
- INAB, the Irish NAB;
- ISRAC, the Israeli NAB;
- MOLDAC, the Moldavian NAB;
- SNAS, the Slovakian NAB;
- TUNAC, the Tunisian NAB;
- TURKAK, the Turkish NAB;
- UKAS, the UK NAB.

The decisions concerning the other 30 EA MLA signatories for demonstrating compliance with the requirements of the new ISO/IEC 17011 (either by peer evaluation or document review) are to be made prior to November 2020.

### 2.2 - Peer-evaluator (PE) trainings

Further to a first session held in June 2019, a second refresher training session mainly dedicated to proficiency testing providers and person certification took place on 12-13 December 2019 near Paris. About 30 participants attended this session, which also focused on general issues related to other scopes (testing, inspection, e.g.) in order to allow a number of deputy team leaders and team members to boost their experience with peer evaluation issues. The trainers were Anna Stefanidou (ESYD, Greece), Tuija Sinervo (FINAS, Finland), Ian Ronksley (UKAS, UK) and Daniela Ionescu, the EA MAC Secretary.

### 2.3 - Re-engineering of the peer-evaluation process

The MAC project to reengineer the peer-evaluation system, one of the key actions of the *EA Strategy 2025*, is nearing its goal. The MAC Management Group prepared a few papers defining the competences for carrying out peer evaluation and the head office’s preliminary observation, the criteria for MAC members, as well as the respective tasks of the MAC Secretariat and the MAC Task Force Group (TFG) assigned to review the evaluation reports.
Further to a commenting period, decision papers will be elaborated on for the MAC meeting in April 2020 concerning:

- the implementation of a mechanism to collect feedback and previously learned lessons to keep peer evaluators and MAC members updated on issues raised, and their resolution to prevent issues reoccurring;
- the introduction of an online decision-making process for cases where there are no open or contentious/difficult issues.

Regarding the development of the guidance on peer-evaluation effort, taking into account a risk-based approach, a new TFG was created, composed of team leaders, team members, representatives of NABs and the MAC Secretary.

2.4 - Peer evaluations in countries with security problems

The revised EA-2/02: *EA Procedure for the Evaluation of a National Accreditation Body* that includes provisions related to the respective responsibilities of EA and NABs for the peer evaluators carrying out peer evaluations in (third) countries with security problems, was published in July 2019.

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

EA’s application to ILAC for extending the signatory status of EA as a recognized region for the scope “Reference Material Producers – ISO 17034”, as agreed at the EA General Assembly in May 2017, was accepted by the ILAC Arrangement Management Committee (AMC) in January 2018.

The RMP scope extension has been covered by ILAC during EA’s full re-evaluation in 2018 and 2019, when the decision-making process of the EA MLA Council was finally evaluated during its meeting in May 2019.

The outcome of EA’s IAF/ILAC re-evaluation is fine: there was no non-conformity, and only one concern that has been closed. The report on the re-evaluation of EA is still being reviewed at IAF/ILAC level.
IV - Status of EA documents

1 - Documents published since July 2019

- EA-2/02  Procedure for the Evaluation of a National Accreditation Body
- EA-3/01  EA Conditions for the use of Accreditation Symbols, Logos and other claims of accreditation and reference to the EA MLA Signatory status
- EA-4/23  The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017
- EA-INF/17  Register of EA Resolutions for Use by National Accreditation Bodies and EA Evaluators

2 - Documents under revision

- EA Articles of Association (AoA)
  - EA-1/06  EA Multilateral Agreement. Criteria for signing. Policy and procedures for development
  - 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-1/22  Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members
  - EA-2/17  Document on Accreditation for Notification Purposes
  - EA-3/12  EA Policy for the Accreditation of Organic Production Certification
  - EA-4/02  Evaluation of the Uncertainty of Measurement in Calibration
  - 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-4/18  Guidance on the Level and Frequency of Proficiency Testing Participation
  - EA-4/20  Guidance for the Assessment of Laboratories against EN ISO 15189 and EN ISO 22870 Point-of-Care Testing (POCT)
  - EA-6/02  Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834
  - EA-6/03  EA Document for Recognition of Verifiers under the EU ETS Directive
  - EA-6/04  EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites
3 - New documents under development

- List of possible risks related to operation of conformity assessment bodies
- Guidance on consultancy and independence of conformity assessment bodies in order to address concerns of stakeholders in regard to EA GA Resolution 2017 (40) 13
- Guidance on Anti-Bribery Management Systems (ABMS)

4 - Documents withdrawn since July 2019

None.
V - Activities to promote the IAF MLA and ILAC MRA

The EA Communication Manager, Amandine Combe, participated in the IAF Communications and Marketing Committee (CMC) and ILAC Marketing & Communications Committee (MCC) held in October 2019 in Frankfurt am Main, Germany.

EA published a news item on the IAF/ILAC Frankfurt Annual Meetings which took place on 21-30 October 2019, highlighting the decision made by the Joint General Assembly to endorse the recommendation of the Joint Executive Committee to establish a single international organisation for accreditation.

VI - Major other developments in EA

Finalisation of the EA MLA mark

EA has been working on having an EA MLA mark for the purpose of identifying EA MLA signatories and their accredited CABs. Different options of the mark itself were fine-tuned by the Secretariat and the Communications and Publications Committee (CPC) which, together with the EA Executive Committee, elaborated on the message to be conveyed by the EA MLA mark. Four agreed options of the EA MLA mark were finally submitted to the EA General Assembly in November 2019, when EA members selected their preferred EA MLA mark.

The EA Executive Committee is mandated to proceed with the formal registration of the EA MLA mark, whereas the Horizontal Harmonisation Committee (HHC) is defining the rules for use of the EA MLA mark, which will be annexed to EA-3/01: EA Conditions for the use of Accreditation Symbols, Logos and other claims of accreditation and reference to the EA MLA Signatory status.

Leaving members of the EA Executive Committee

Further to the elections held at the EA General Assembly in May 2019 when a new EA Vice-Chair (Cecilie Laake from NA, Norway) and Inspection Committee Chair (Orbay Evrensevdi from TURKAK, Turkey) were elected for the 2020-2022 term, the last EA General Assembly in November 2019 paid a glowing tribute to Maria Papatzikou (ESYD) who has been vice-chairing EA since 16 May 2018, and to Rolf Straub (SAS) who has been chairing the Inspection Committee since January 2012.

European private scheme owners seating in the EAAB

The EA Advisory Board (EAAB) gives continuous support to EA work and provides advice to EA on a broad range of issues relating to harmonisation and policy on accreditation. The Board’s composition constitutes a well-balanced representation of the parties which rely on and contribute to the European accreditation system. It is composed of representatives from:

- the conformity assessment community;
- the industry, services and trade;
- the EU Member States' national authorities;
• European private scheme owners;
• the consumer associations;
• the European metrological institutions;
• the European standardisation organisations;
• the European Commission; and
• the European Free Trade Association (EFTA).

Because Emmanuel Geneiatakis from FAMI-QS (the Quality and Safety System for Speciality Feed Ingredients asbl) resigned from the Board in early 2019, the seat allocated to those European private scheme owners that are also EA Recognised Stakeholders had remained vacant. Further to an invitation sent by the EA Secretariat to the relevant scheme owners, the European Organisation for Quality (EOQ) appointed Anni Koubek from Quality Austria (QA) as a member of the Board to represent European private scheme owners, with the ensuing obligation to coordinate and express stakeholders’ views on political and strategic issues discussed in the Board.

EA trainings

In addition to the refresher training session in December 2019, two other trainings were hosted near Paris by the EA Secretariat in the second half of 2019. The first one, held on 13-14 November 2019, was a training organised by the EA Laboratory Committee on accreditation of reference material producers against ISO 17034. 22 participants attended the event whose trainers were Jeff Ruddle (UKAS, UK) and Henk Deckers (RvA, The Netherlands).

The second event was a train-the-trainer workshop on ISO/IEC 17029: Conformity Assessment -- General requirements for bodies performing validation and verification activities. 40 representatives from EA NABs participated in the training which took place on 28 November 2019. The trainers were Nathalie Savéant (COFRAC, France) and Stefanie Vehring (VdTUV, Germany). A second session will take place on 29 January 2020.

EA Strategy 2025


First of all, the Strategy’s implementation includes the building up of the most efficient management structure to achieve efficient governance in EA. Adopted by the EA General Assembly in November 2018, the new structure consists in the setting up of two new bodies aimed to replace the current Executive Committee, i.e. the Executive Board and the Technical Management Board. A substantial revision of the EA Articles of Association is being made to reflect the change in the EA management structure, which should also be introduced into EA-1/17: EA Rules of Procedure. The new structure shall be in place in 2020.

Furthermore the EA Strategy’s implementation includes the establishment of a system to enforce and monitor EA decisions. The EA system ensures through the peer evaluation system that the implementation of these decisions/requirements is monitored. But there was a risk that decisions/requirements covered
in single EA resolutions, which are not transferred into an EA document, would not be implemented by EA members and would not be covered in the monitoring system. In order to ensure that all EA decisions/requirements are implemented by EA members and covered in the peer evaluation system, the EA General Assembly in November 2019 endorsed that the Secretariat should establish and maintain a separate directory of all relevant EA resolutions which are not covered in published EA documents, with support by the relevant committee(s)/council/boards. This directory is now published in EA-INF/17: Register of EA Resolutions for Use by EA, National Accreditation Bodies and EA Evaluators.

One of the actions of the EA Strategy is to promote more active cooperation among members and develop efficient tools to enhance harmonisation and coordination, both at operational and technical levels, to give common answers to global needs. A service concept, the “EA Academy”, is being developed for training and benchmarking in order to disseminate knowledge and experience between members. The main target of EA training activities should be NABs’ members; occasionally, for specific issues only, stakeholders and other observers may be invited to EA trainings. These trainings should cover peer-evaluator trainings, harmonisation trainings (NAB assessor training and train-the-trainer activities) and experience sharing. The EA Academy should be managed by the EA Secretariat which should be responsible for preparing the budget, designing the programme, selecting the participants and trainers (in cooperation with the relevant Committee Chairs), making logistical arrangements, managing the documentation, communicating and reporting on the training activities, and providing necessary IT support for web based and IT training tools.

The improvement of the peer-evaluation process, cooperation with stakeholders and the process for EA to input to international discussions are other issues that are being elaborated on by the TFGs in charge of the Strategy’s implementation.

Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada

EA and the Standards Council of Canada (SCC) signed a bilateral cooperation agreement in 2016, which will enable the implementation of the Conformity Assessment (CA) Protocol provided for in the CETA agreement, allowing for the mutual acceptance by Canada and the EU of conformity assessment results delivered by each other’s recognized accredited conformity assessment bodies. This will help facilitate trade and open doors for EU and Canadian companies.

EA and SCC renewed the bilateral cooperation agreement in June 2019.

To get detailed information on the bilateral cooperation agreement signed between EA and SCC, please read the brochure “CETA Agreement and Conformity Assessment Accreditation: a tool to enhance trade between the European Union and Canada”. Further information is also available in the Comprehensive Economic and Trade Agreement (CETA).
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)

IAF Committee meetings

- General Assembly (GA)    Andreas Steinhorst (EA Executive Secretary)
- Executive Committee (EX) Cecilie Laake (NA, Norway)
- Accreditation Committee (AIC)    Kevin Belson (UKAS, UK)
- Marketing & Communications Committee (MCC) Paulo Tavares (IPAC, Portugal)
- Arrangement Committee (ARC) Paulo Tavares, Andreas Steinhorst, Gokhan Birbil (TURKAK, Turkey), Cecilie Laake (NA, Norway), Rolf Straub (SAS, Switzerland), Karine Vincent (COFRAC, France)
- Arrangement Management Committee (AMC) Amandine Combe (EA Communication Manager)
- Arrangement Council (AC) Andreas Steinhorst
- Inspection Committee (IC) Andreas Steinhorst

ILAC Committee meetings

- General Assembly (GA)    Andreas Steinhorst
- Executive Committee (EX) Andreas Steinhorst
- Accreditation Committee (AIC) Laurent Vinson (COFRAC, France)
- Marketing & Communications Committee (MCC) Amandine Combe
- Arrangement Committee (ARC) Andreas Steinhorst
- Arrangement Management Committee (AMC) Paulo Tavares
- Arrangement Council (AC) Andreas Steinhorst
- Inspection Committee (IC) Orbay Evrensevdi

Joint IAF/ILAC Committee meetings

- Joint Executive Committee (JEX) Cecilia Laake, Andreas Steinhorst
- Joint Management Committee (JMC) Paulo Tavares, Andreas Steinhorst, Gokhan Birbil, Cecile Laake, Rolf Straub, Karine Vincent
- JWG Communications and Marketing (JCMC) Amandine Combe
- JWG Developing Countries Andreas Steinhorst
- JWG A-series Paulo Tavares, Andreas Steinhorst
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