EUROPEAN ACCREDITATION

EA REPORT
to IAF/ILAC
and REGIONS

STATUS
JANUARY - JUNE 2020

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I - Compositional state of play in June 2020

1 - EA Membership

EA has 36 Full Members and 14 Associate Members.

The EA associate membership status of SEMAC, the Moroccan Accreditation Service, has been suspended in June 2020 according to clause 4.1 in EA-17 S5: *Supplement 5 to EA-1/17 - EA Rules of Procedure - Levying of Membership Fees*.

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

	Calibration	Testing	Medical Examinations	Inspection	Management Systems	Products	Persons	Validation and Verification (GHG)	Proficiency Testing Providers	Reference Material Producers
EA Members signatories to the EA MLA	41	42	36	42	36	36	32	25	20	8

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/

So far no new organisation was granted the EA Recognised Stakeholder status in 2020.

The cooperation agreement between EA, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), concluded in 2016, has been reviewed and reconducted for a further 3-year period. The agreement is being signed in July 2020.

I - 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) through electronic ballots in May and June 2020 due to the cancellation of the 43rd meeting in April resulting from the Covid-19 pandemic:

- CYS-CYSAB, the Cyprus national accreditation body (NAB), became an EA MLA signatory in the field of certification of products according to ISO/IEC 17065.

- DPA, the Albanian NAB, became an EA MLA signatory in the field of certification of persons according to ISO/IEC 17024.

- BSCA, the Belarusian NAB, became an EA BLA signatory in the fields of medical examinations (ISO 15189), inspection (ISO/IEC 17020) and proficiency testing providers (ISO/IEC 17043).

  Furthermore, BSCA remained an EA BLA signatory in the fields of calibration (ISO/IEC 17025), testing (ISO/IEC 17025), certification of management systems (ISO/IEC 17021-1), certification of products and certification of persons.

- ESYD, the Greek 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 according to ISO 14065.

- NAH, the Hungarian NAB, remained an EA MLA signatory in the field of certification of products.

- SAS, the Swiss NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products and certification of persons.

2 - Latest developments relating to the EA peer evaluations

2.1 - Peer evaluations in 2020

For 2020, the EA MAC had scheduled:

- 8 re-evaluations: COFRAC (France), DANAK (Denmark), EGAC (Egypt), NA (Norway), PCA (Poland), SWEDAC (Sweden), TURKAK (Turkey) and UKAS (UK);

- 3 second and third stage evaluations: HAA (Croatia), IPAC (Portugal) and OLAS (Luxembourg);

- 1 extension evaluation: INAB (Ireland).

Due to Covid-19 outbreak, only few of the scheduled evaluations were finalized (TURKAK re-evaluation, HAA and OLAS second stage evaluations). Therefore the EA MAC Management Group intensified their work and played a key role by proposing solutions to maintain the peer-evaluation system operational during this period and to enable decisions to be made without delay. Everything was made in compliance with the rules and procedures to avoid stopping the peer-evaluation system and undermining both accreditation and accredited conformity assessment activities.

The EA MAC agreed with the contingency plan proposed by the EA MAC Management Group and, as a result:

- IPAC second stage evaluation, OLAS third stage evaluation and DANAK re-evaluation were rescheduled for the second half of 2020;

- 5 re-evaluations (COFRAC, EGAC, NA, PCA, UKAS) and 1 extension evaluation (INAB) were postponed to 2021.

Even though the postponements from 2020 to 2021 have a major impact on the programme of peer evaluations for 2021, no postponements from 2021 to 2022 have been made so far.

Further dispositions will be developed by the EA MAC Management Group to consider a combination of alternative approaches that, while not dispensing an on-site visit, will assist in keeping the confidence in the accreditation infrastructure by the interested parties.

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 June 2020, the EA MAC confirmed that the following 35 NABs successfully made the transition from ISO/IEC 17011:2004 to ISO/IEC 17011:2017:

- ACCREDIA, the Italian NAB;
- ALGERAC, the Algerian NAB;
- ATS, the Serbian NAB;
- BAS, the Bulgarian NAB;
- BATA, the Bosnia and Herzegovina's NAB;
- BELAC, the Belgian NAB;
- BSCA, the Belarusian NAB;
- CAI, the Czech NAB;
- COFRAC, the French NAB;
- CYS-CYSAB, the Cyprus NAB;
- DANAK, the Danish NAB;
- DPA, the Albanian NAB;
- EAK, the Estonian NAB;
- EGAC, the Egyptian NAB;
- ENAC, the Spanish NAB;
- ESYD, the Greek NAB;
- GAC, the Georgian NAB;

- IARNM, the Republic of North Macedonia's NAB;
- INAB, the Irish NAB;
- ISRAC, the Israeli NAB;
- LA, the Lithuanian NAB;
- MOLDAC, the Moldavian NAB;
- NA, the Norwegian NAB;
- NAB-MALTA, the Maltese NAB;
- NAH, the Hungarian NAB;
- PCA, the Polish NAB;
- RENAR, the Romanian NAB;
- RvA, the Dutch NAB;
- SA, the Slovenian NAB;
- SAS, the Swiss NAB;
- SNAS, the Slovakian NAB;
- SWEDAC, the Swedish NAB;
- TUNAC, the Tunisian NAB;
- TURKAK, the Turkish NAB;
- UKAS, the UK NAB.

The decisions concerning the last 8 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

Two refresher training sessions will be organised in 2020: the first one, on 17-18 November, will be dedicated to testing and calibration; the second one, on 15-16 December, will focus on inspection and/or certification of products. Because of the uncertainties in logistics resulting from the health and travel conditions related to the Covid-19 pandemic, it has been decided to hold both trainings remotely.

One newcomer training session is also planned on 9-11 December 2020. Whether to hold it remotely or to postpone it has still to be agreed.

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.

After a commenting period at the EA MAC level, the papers related to the necessary competences of the EA MAC Secretariat to undertake more responsibilities for the operational management, the criteria for EA MAC Members, the tasks of the EA MAC Task Force Group (TFG) assigned to review the evaluation reports and the conditions to perform the witnessing in advance of the Head Office visit, are being finalized and the EA MAC will decide in its autumn meeting the steps to be taken further.

Regarding the elaboration of the guidance on peer-evaluation effort, taking into account a risk-based approach, a TFG was created, composed of Team Leaders, Team Members, representatives of NABs and the MAC Secretary. The paper prepared by the TFG was discussed in the EA MAC Management Group web-meeting in May and will be further discussed with the EA MAC Members at the autumn meeting.

Another paper prepared by the EA MAC Management Group will be submitted to MAC discussions during the autumn meeting, such as the paper related to the process to deal with technical issues raised during an evaluation.

Further papers are under development related to:
- the principles to be considered in order to decide for a split evaluation;
- the change of the peer-evaluation report template into a package of different elements;
- the introduction of an online decision-making process for cases where there are no open or contentious/difficult issues;
- the introduction of an electronic ballot system to be used in MAC meetings in order to enable anonymous voting;
- 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.

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

Further to the approval of its application by IAF, EA has been recognised for the IAF MLA scope extension to ISO/IEC TS 17021-10 and ISO 45001, setting out the requirements with guidance for use for occupational health and safety (OH&S) management systems, as of 5 February 2020.

In April 2020, the ILAC Arrangement Council have endorsed the recommendation of the ILAC Arrangement Management Committee (AMC) to recognise the EA MLA for the accreditation of reference material producers (RMP) using ISO 17034, as a result of EA's full re-evaluation including this extension carried out during 2018 and 2019. EA has become the first regional cooperation body member of the ILAC MRA for accreditation of RMP.

In addition, the recognition of the EA MLA to the ILAC MRA for the accreditation of calibration and testing (including medical) laboratories, inspection bodies and proficiency testing providers has been continued.

The next re-evaluation of EA by ILAC is scheduled to begin not later than July 2022.

IV - Status of EA documents

1 - Documents published since January 2020

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-2/19   *List of Risks for Accreditation Processes and Operation of National Accreditation Bodies*

EA-2/20   *Consultancy, and the Independence of Conformity Assessment Bodies*

EA-3/12   *EA Policy for the Accreditation of Organic Production Certification*

EA-INF/05   *Directory of European Legislations and EU Schemes with Provisions to Accreditation and/or Conformity Assessment*

EA-INF/07   *National Accreditation Body Communication with National Regulators – Best Practice Guide*

EA-INF/17   *Register of EA Resolutions for Use by EA, 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-1/17 S3   *EA Procedure for the investigation and resolution of Complaints and Appeals*

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-4/02   *Evaluation of the Uncertainty of Measurement in Calibration*

EA-4/09   *Accreditation for Sensory Testing Laboratories*

EA-4/14   *The Selection and Use of Reference Materials*

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-5/02	*EA Guidance on the Application of ISO/IEC 17020 in Periodic Inspection of the Roadworthiness of Motor Vehicles and their Trailers*
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*
EA-INF/04	*Statement on Acceptance and Recognition of Activities under the EA MLA*

3 - New documents under development

• EA policy for the Accreditation of Certification Activities under (EU Regulation 1151/2012) PDO/ PGI/TSG; (EU Regulations 606/2009, 607/2009 and 1308/2013) Wine Products; (EU regulation 110/2008) Spirits and (EU Regulation 251/2014) Aromatised Wine Products

• Guidance on Anti-Bribery Management Systems (ABMS)

4 - Documents withdrawn since January 2020

None.

V - Activities to promote the IAF MLA and ILAC MRA

The *EA MLA Report 2019* released on 14 April 2020 highlights the outcome and actions achieved through the EA MLA during 2019, as well as EA's recognition in IAF and ILAC though their MLA and MRA.

Likewise, the *EA Annual Report 2019* just published on 6 July 2020 includes a specific section dedicated to *EA's cooperation with IAF and ILAC*, stressing:

- IAF/ILAC full re-evaluation of EA;

- EA's appropriate contribution to the IAF/ILAC peer-evaluation system;

- EA's strengthened process for ensuring continuing compliance with the MLA requirements on transitions to publications and standards.

Both reports, which were promoted through the EA Homepage, an electronic news sent to the whole EA community and on Twitter, are available on the EA website at: https://european-accreditation.org/information-center/newsroom/promotional-materials-2/

Two EA Homepage news were also published in March and April to promote EA's recognition:

- for the IAF MLA scope extension to ISO/IEC TS 17021-10 and ISO 45001 setting out the requirements with guidance for use for occupational health and safety management systems;

- for the ILAC MRA for accreditation of Reference Material Producers (RMP) using ISO 17034.

EA celebrated the World Accreditation Day (WAD) 2020 entitled "*Accreditation: Improving Food Safety*":

- an EA Homepage news, available at https://european-accreditation.org/world-accreditation-day-2020-accreditation-improving-food-safety/, was published on 2 June 2020 to present the key issues of the WAD 2020 together with the IAF/ILAC video and a link towards the promotional materials on the WAD 2020 jointly prepared by IAF and ILAC;

- a dedicated electronic newsletter was also sent on 9 June to the whole EA community;

- WAD 2020 was promoted on Twitter during the weeks before and after 9 June;

- several EA Members promoted the WAD through Twitter and their website.

The EA Communication Manager, Amandine Combe, is participating in a task force group of the IAF Communications and Marketing Committee (CMC) and ILAC Marketing & Communications Committee (MCC) dedicated to the promotion of medical devices accredited certification amid Covid-19 crisis.

VI - Major other activities/developments in EA

Upsurge of EA online events

As a consequence of the Covid-19 outbreak, the EA committees' and the General Assembly meetings planned from March to May 2020 should be cancelled as physical meetings and held remotely.

Likewise, due to the uncertainties in health and travel conditions related to the Covid-19 pandemic, the EA Executive Committee has decided in early June to cancel the in-person set of next autumn's meetings including EA trainings and to hold them instead as a series of virtual meetings. Committee chairs and working group conveners have been encouraged to continue to progress and complete their work activities electronically.

The success of the EA General Assembly (GA) meeting held online on 14 May 2020, resulting from the active contribution from EA Members, is much encouraging EA to build up a strategy for the future EA meetings. EA has been working for the past year on a plan to reduce its environmental impact and the current pandemic has only emphasised the growing need for such a strategy. EA is developing a concrete plan for future EA travels taking into account climate change, which will be discussed at the next online EA GA meeting in November 2020.

The impact of Brexit on UKAS

In May 2020, the EA General Assembly acknowledged that the United Kingdom (UK) left the European Union (EU) and noted accordingly that UKAS, the UK NAB, did not meet anymore the EA membership criteria as set out in Article 5 paragraph 1 of the *EA Articles of Association*.

The General Assembly has implemented the Article 6 paragraph 7 of the *Articles of Association* and has accepted to maintain UKAS as an EA Full Member until 31 January 2022. UKAS and EA will work together during this transition period to determine the future role of UKAS within EA, taking into consideration the outcome of the EU-UK trade negotiations. EA and UKAS are both keen to keep an active cooperation for the sake of the European market and in appreciation of their long-term collaboration.

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. EA Members finally selected their preferred option for the EA MLA mark at the EA General Assembly in November 2019.

The EA Executive Committee is mandated to proceed with the formal registration of the EA MLA mark, whereas the Horizontal Harmonisation Committee (HHC) is finalising 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.*

The EA MLA mark should be in place in 2021.

EA trainings

Before the Covid-19 outbreak, the second session (first session in December 2019) of a train-the-trainer workshop on ISO/IEC 17029: *Conformity Assessment -- General requirements for bodies performing validation and verification activities* was hosted on 29 January 2020 near Paris by the EA Secretariat. 13 representatives from EA NABs participated in this additional workshop, whose trainers were Nathalie Savéant (COFRAC, France) and Stefanie Vehring (VdTÜV, Germany).

Another train-the-trainer workshop jointly organised on 7 October 2020 by the EA Harmonisation (HHC) and Certification (CC) Committees will be dedicated to the evaluation of schemes based on revised EA-1/22: *Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members* and a document developed by the EA CC on selection of standards between 17021-1 and 17065. The detailed programme is being elaborated by the trainers who will be Gabriel Zrenner (HHC Chair), Sjaak Hendriks (HHC Vice-Chair), Kevin Belson (CC Chair) and Casper van Erp (RVA, CC WG Environment convener). Due to the health and travel uncertainties still related to the Covid-19 pandemic, this training targeted at NABs' staff in charge of sector schemes will be held remotely.

Another remote training on revised EA-2/17: *EA Document on Accreditation for Notification Purposes* will be organised by the HHC on 3 December 2020.

EA Strategy 2025

The full text of *EA Strategy 2025 – From Good to Great* is available on the EA website at http://www.european-accreditation.org/brochure/ea-strategy-2025-full-document-v2

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 should come into force in January 2021.

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.

With respect to the *EA Strategy 2025* Implementation Plan, the Secretariat launched in late 2019 a survey on EA future training activities, which has demonstrated that EA should develop e-trainings, especially regarding standards, legislations and EA documents. The Covid-19 outbreak reveals also the need and benefit of e-trainings. Accordingly, EA is preparing the first e-learning/training sessions, for instance regarding the following sectors/standards:

- ISO/IEC 17025:2017 Requirements for laboratories;

- ISO/IEC 17029:2019 Requirements for validation & verification bodies;

- ISO 20387:2018 Biobanking;

- EU-ETS Regulation (EU) 2018/2067;

- Maritime transport regulation (EU Regulations 2015/757 and 2016/2072);

- Regulation (EU) No 305/2011 on construction products (CPR).

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.

Cooperation with the European Union Agency for Cybersecurity (ENISA)

EA is a permanent member of the Stakeholder Cybersecurity Certification Group (SCCG), composed of 40 members. The SCCG's role, defined in the EU Cybersecurity Act published on 17 April 2019, is to advise on strategic issues regarding cybersecurity certification. The SCCG's kick-off meeting, mainly dedicated to procedural issues, was held on 24 June 2020. The most important issue is the preparation of the Union Rolling Work Programme (URWP) for European Cybersecurity Certification.

Further information is available on ENISA's website: https://www.enisa.europa.eu/

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)	Andreas Steinhorst (EA Executive Secretary)
Executive Committee (EX)	Cecilie Laake (NA, Norway)
Technical Committee (TC)	Kevin Belson (UKAS, UK)
MLA Committee (MLAC)	Paulo Tavares (IPAC, Portugal)
MLA Management Committee (MLA MC)	Paulo Tavares, Andreas Steinhorst, Gokhan Birbil (TURKAK, Turkey), Cecilie Laake (NA, Norway), Rolf Straub (SAS, Switzerland), Karine Vincent (COFRAC, France)
Communications and Marketing Committee (CMC)	Amandine Combe (EA Communication Manager)
Development Support Committee (DSC)	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)	Cecilie Laake, Andreas Steinhorst
Joint Management Committee (JMC)	Paulo Tavares, Andreas Steinhorst, Gokhan Birbil, Cecilie 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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