







EA REPORT to IAF/ILAC and REGIONS

STATUS
JULY - DECEMBER 2018











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I - Compositional state of play in December 2018

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 8 Associate Members – the last of which was BSCA, the national accreditation body of Belarus, becoming an EA BLA signatory in October 2018 – are signatories to the EA MLA.

Recapitulative table of signatories by EA MLA scope

	Full Member signatories to the EA MLA	Associate Member signatories to the EA MLA	Total signatories
Calibration	33	8	41
Testing	34	8	42
Medical Examination	31	2	33
Inspection	34	7	41
Management Systems	32	4	36
Products	31	4	35
Persons	28	3	31
Validation and Verification (GHG)	24	0	24
Proficiency Testing Providers	16	0	16







EA Multilateral Agreement Signatories

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION AND VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALBANIA - DPA		V				V		√ ·	
AUSTRIA - AA	1	√	V	V	V	1	V	√	
BELGIUM - BELAC	V	V	√	√	V	V	√	√	V
BULGARIA – BAS	√	V	V	√	√	V	V	√	
CROATIA - HAA	√	√	V	√	V	√	√	√	
CYPRUS - CYS-CYSAB	V	V	√					√	
CZECH REPUBLIC - CAI	V	V	V	V	V	√	V	√	V
DENMARK - DANAK	√	√	V	√	V	√	V	√	V
ESTONIA - EAK	√	√	√	√	V	V	V	√	
FINLAND - FINAS	√	√	√	√	√	√	V	1	√
FRANCE - COFRAC	√	√	√	√	V	√	V	1	V
FYROM - IARM	√	V	V	√		√		√	
GERMANY - DAkkS	√	√	V	√	V	√	V	1	√
GREECE - ESYD	√	√	V	√	V	V	V	√	V
HUNGARY - NAH	√	√	٧	√	V	V	√	1	
IRELAND - INAB	√	√	٧	√		V		√	
ITALY - ACCREDIA	√	√	√	√	V	V	√	√	V
LATVIA - LATAK	√	V	V	√	1	√	V	√	
LITHUANIA - LA	√	V	V	√	V	√		1	
LUXEMBURG - OLAS	√	V	V	√		V		√	
MALTA - NAB-MALTA	√	V						1	
NETHERLANDS - RvA	√	V	V	√	V	V	V	1	√
NORWAY - NA	√	V	√	√	V	V	V	1	√
POLAND - PCA	√	V	V	V	V	V	V	√	√
PORTUGAL - IPAC	√	V	V	V	V	V	V	√	
ROMANIA - RENAR	V	V	V	V	V	V	V	1	1
SERBIA - ATS	V	V	√	V	V	V		√	









EA Multilateral Agreement Signatories

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION AND VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
SLOVAKIA - SNAS	√ .	V	V	√	V	√	V	V	
SLOVENIA - SA	V	√		V	V	V	V	V	
SPAIN - ENAC	V	V	V	√	V	√	V	1	V
SWEDEN - SWEDAC	V	V	√	√	V	√	V	1	V
SWITZERLAND - SAS	√	√	√	√	V	V		V	
TURKEY - TURKAK	V	√	V	√	V	√		√	V
UNITED KINGDOM - UKAS	V	1	٧	V	V	√	V	√	1

EA Bilateral Agreement Signatories

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION AND VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALGERIA – ALGERAC	٧	٧						٧	
BELARUS - BSCA	V	٧		1	V	٧			
BOSNIA&HERZEGOVINA – BATA	٧	V						4	
GEORGIA - GAC	1	V		٧	V			٧	
ISRAEL - ISRAC	V	V	٧					٧	
REPUBLIC OF MOLDOVA - MOLDAC	٧	٧	٧	√		1		٧	:
UKRAINE - NAAU	V	٧		٧	V	٧	*	٧	:
TUNISIA - TUNAC	V	V				٧	*	V	









3 - EA Recognised Stakeholders

EA cooperates with about 40 Recognised Stakeholders.

AEBIOM, the European Biomass Association, is the last organisation that signed the EA Recognised Stakeholder Agreement in November 2018 in accordance with EA-1/15: EA Policy for Relation with Stakeholders.

II - EA MLA and peer-evaluation issues

1 - Latest developments relating to the EA MLA

Upon decisions made by the EA MLA Council at its last meeting on 3-4 October 2018 in Budapest, Hungary:

- BSCA, the Belarusian NAB, became an EA BLA signatory in the fields of calibration, testing, as well as management systems, products and persons certification;
- IARM, the NAB of The Former Yugoslav Republic of Macedonia (FYROM), while remaining an EA MLA signatory for calibration, testing (including medical examinations according to ISO 15189), inspection and product certification, became a signatory to the EA MLA in the field of management systems certification.

Still in October 2018, RvA, the Dutch NAB, and UKAS, the UK NAB, became the first two EA Members having been successfully evaluated for accreditation in the field of Reference Materials Producers (RMP) according to ISO 17034. RvA and UKAS will effectively become EA MLA signatories for RMP as soon as the EA MLA is launched for this scope during the MAC meeting in May 2019, provided that at least three members are successfully peer-evaluated by that date.

In October 2018, the EA MLA Council also endorsed a new work item proposal for the revision of EA-2/02: *EA Procedure for the evaluation of a National Accreditation Body* in order to include provisions related to the respective responsibilities of EA and NABs for the peer evaluators carrying out peer evaluations in (third) countries with security problems.

The issue of evaluator resources is a priority. How to improve monitoring of transition to standards, how to better manage the process for dealing with changes notified to the MAC by NABs' members, how to translate the IAF resolution adopted in New Delhi on peer evaluation of IAF sub-scopes in the EA peer evaluation system are also being carefully considered in the MAC.

The MAC project to reengineer the peer-evaluation system, one of the key actions of the *EA Strategy* 2025 implementation plan, is nearing its goal. The 9 Task Force Groups appointed in 2017 to support the reengineering of EA peer-evaluation system presented their proposals resulting from the final recommendations of the EA MAC Management Group (MG) at the MAC meeting in April 2018. Due to the complexity of the project, the MAC MG decided at their last meeting in October to meet in the beginning of 2019 and consolidate the document on re-engineering, based on the TFGs' final reports. The document will be presented at the MAC meeting to be held in May 2019.









2 - Latest developments relating to the EA peer evaluations

2.1 - Peer evaluations in 2018

A total number of 18 peer evaluations have been performed in 2018, including:

- 1 initial evaluation for PTP accreditation;
- 1 extension evaluation to RMP accreditation;
- 6 re-evaluations with scope extension to RMP accreditation:
- 2 re-evaluations with scope extension to PTP accreditation;
- 1 re-evaluation with scope extension to medical examination;
- 1 re-evaluation with scope extension to medical examination and management system certification;
- 3 re-evaluations:
- 3 re-evaluations (second part).

Among the first 7 peer evaluations performed in 2018 for extension of scope to RMP accreditation, two have already been concluded positively with the decision for both future EA MLA signatories in the field of RMP to come into force as soon as at least three members are successfully peer-evaluated by May 2019 for the EA MLA for RMP to be launched.

In October 2018, one EA MLA signatory was confirmed to have successfully made the transition from ISO/IEC 17011:2004 to ISO/IEC 17011:2017; the decisions for other 41 EA MLA signatories (either to be peer-evaluated against, or to demonstrate document review compliance with the requirements of new ISO/IEC 17011) are to be made prior to November 2020.

The MAC Secretariat appointed a total of 114 evaluators (15 Team Leaders and 99 Team Members, among which 23 trainees) who spent 1,393 man-days to carry out the peer evaluations in 2018.

2.2 - Peer-evaluator trainings

EA organised a training workshop on the ICAO Carbon Offsetting and Reduction Scheme for International Aviation (CORSIA) on 29 August 2018 in Roissy, near Paris. The CORSIA scheme, adopted in 2016 by the International Civil Aviation Organization (ICAO) as the first global market based measure scheme for any industry sector, aims to achieve ICAO's global aspirational goal of carbon neutral growth from 2020. In order to determine the baseline emissions of the scheme, aeroplane operators will be monitoring their emissions from 2019 onwards with the first verification of an emissions report taking place in early 2020. Given the global nature of the scheme and in order to reduce market distortions, the aim of ICAO is to establish a common accreditation and verification framework, potentially with support of IAF. 27 participants from 18 EA NABs attended the training led by Peter Hissnauer (DAkkS, Germany).

A refresher training session focusing on greenhouse gas (GHG) validation and verification as well as management systems certification was organised by the EA MLA Council on 10-11 December 2018. The training hosted by the EA Secretariat was led by Niels-Christian Dalstrup (DANAK, Denmark) and Phil Shaw (UKAS, UK); Daniela lonescu attended the training as the MAC Secretary. 25 participants









from different EA NABs discussed some aspects of ISO/IEC 17011: 2017 in combination with ISO/IEC 17021-1, such as competence of NABs' personnel, scope of accreditation, evidence of CBs' competence management systems, witnessing of management systems, reporting/records of CABs' effective fulfilment of requirements, and the IAF Mandatory Documents to be applied, especially IAF MD 20: Generic Competence for AB Assessors: Application to ISO/IEC 17011. Regarding GHG validation and verification, discussions mainly concerned how NABs confirm (record) to demonstrate that verification bodies satisfy with Regulation (EU) 600/2012, how they demonstrate a representative sampling of verifiers staff's competence and performance, and how they demonstrate witnessing of a representative part of scopes.

Two refresher training sessions will be organised in 2019. The first one aimed at Team Leaders and Deputy Team Leaders will be held on 18-19 June 2019 in Brussels. Hosted by BELAC, the Belgian NAB, the training will be led by Paulo Tavares (IPAC, Portugal), the EA MAC Chair, Ed Wieles (RvA, The Netherlands) and Varpu Rantanen (FINAS, Finland). The second refresher training session dedicated to proficiency testing providers (PTP) and person certification is planned to take place in December 2019.

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

Further to the approval of EA's application for the extension of its IAF MLA signatory status to the subscopes Information Security Management System (ISMS), Food Safety Management System (FSMS), Energy Management Systems (EnMS) and Medical Devices - Quality Management Systems (MDMS) in April 2018, EA has been recognized by IAF for the Level 5 sub-scopes FAMI-QS (The Quality and Safety System for Speciality Feed Ingredients asbl) under management system certification, and "IPC Management System Auditors Certification Scheme" under person certification, in October 2018.

Further to ILAC's formal decision in May 2018 to extend EA's MRA status to proficiency testing providers (ISO/IEC 17043), the effective recognition of EA for this field of accreditation will come into force after a second region in ILAC is successfully evaluated for the PTP scope.

The full re-evaluation of EA by ILAC and IAF started with witnessing activities in INAB, the Irish NAB, and ACCREDIA, the Italian NAB, respectively in September and November 2018. The IAF/ILAC team carried on with the re-evaluation by visiting the EA Secretariat in Paris on 3-4 December 2018. The re-evaluation will end in May 2019 when the decision-making process of the EA MLA Council will finally be evaluated during its next meeting. The outcome of EA's re-evaluation is expected in autumn 2019.









IV - Status of EA documents

1 - Documents published since July 2018

EA-1/17 S5 EA Rules of Procedure – Levying of Membership Fees

EA-4/22 Accreditation of Pesticide Residues Analysis in Food and Feed

2 - Documents under revision

EA Articles of Association (AoA)

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-2/02	Procedure for the Evaluation of a National Accreditation Body
EA-2/13	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
EA-2/13 S1	Interpretation of Terminology Used in Clause 5.1 and Guidelines to Assessment Focus
EA-2/15	Requirements for the Accreditation of Flexible Scopes
EA-2/17	Document on Accreditation for Notification Purposes
EA-3/01	Use of Accreditation Marks and Reference to MLA Signatory Status
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-4/20	Guidance for the Assessment of Laboratories against EN ISO 15189 and EN ISO 2870 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

EA-INF/13 The Assessment and Accreditation of Opinions and Interpretations

using ISO/IEC 17025:2005

3 - New documents under development

EA-1/23 EA Policy to Speak with "One Voice"

 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

4 - Documents withdrawn since July 2018

No EA document was withdrawn since summer 2018.









V - Activities to promote the IAF MLA and/or ILAC MRA

EA was much involved in the promotion of the agreement on mutual recognition at the global level. The decisions made by IAF and ILAC were still regularly promoted on the EA Homepage and through EA Twitter account, notably those based on successful regional peer evaluations resulting on maintained IAF/ILAC MLA recognized regions, those relating to the EA re-evaluation by IAF and ILAC, as well as the 2017 IAF MLA Annual Report and the 2018 IAF/ILAC Joint Annual Meetings in Singapore.

Above all, in December 2018, EA thoroughly revamped <u>its website</u> which promotes IAF/ILAC recognition in a more clarified and efficient way. Especially, IAF and ILAC are now highlighted through a summarized <u>presentation</u> indicating clear facts and figures. Moreover all the <u>signatories of IAF MLA and ILAC MRA</u> are listed, not only for EA Members, but also for all recognized regions.

VI - Major other developments in EA

The UK NAB in EA

According the *EA Articles of Association* (AoA), Full Members are national accreditation bodies legally appointed as referred to in regulation (EC) number 765/2008 in:

- a. a member state of the EU; or
- b. a member state of the EFTA; or
- c. a country which has been formally identified by the EU or EFTA as a candidate country for membership in the EU or EFTA.

If the BREXIT were confirmed in March 2019, the UK Accreditation Service (UKAS) would not meet the EA membership criteria anymore and, according to the current provisions, a decision by the EA General Assembly would be needed for official termination of UKAS' membership.

But it is important for EA that UKAS will remain an EA member, even after the BREXIT. Therefore the General Assembly has endorsed the revision of the AoA and agreed to add as first step the following clause:

In case that one or more of the criteria for countries established in article 5 paragraph 1 of any Member is no longer fulfilled by reasons not attributable to the Member, the General Assembly can decide, upon the recommendation of the Executive Committee, to maintain the membership, in the same membership category, of the Member for a period of time no longer than two years, to be determined by the General Assembly.

Furthermore, the revision of the AoA concerns Article 9 which has been amended in order to reflect the decision by the EA General Assembly to give decision-making power to the EA MLA Council for EA MLA signatory status.









Renewal of 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; industry, services and trade; the EU Member States' national authorities; the consumer associations; the European metrological institutions; the European standardisation organisations; the European Commission and European Free Trade Association (EFTA).

On 17 October 2018, the whole EAAB membership was renewed for the next 3-year term. A new EAAB Chair was unanimously elected, Maureen Logghe (National Authorities College - Federal Public Service (FPS) Economy of Belgium), who succeeds to Michael Nitsche (BAM, Germany). Christian Priller (CAB College - CEOC International) and Martin Stadler (Industry College - SIEMENS) were elected as Vice-Chairs for a third term.

At its previous meeting in May, the EAAB had decided to extend its membership and grant one additional seat within the Board to a representative of those European private scheme owners that are also EA Recognised Stakeholders. Emmanuel Geneiatakis from FAMI-QS (the Quality and Safety System for Speciality Feed Ingredients asbl), an EA Recognized Stakeholder since June 2013, was elected in October 2018 to fulfil the new seat. He is also involved in the EA Horizontal Harmonization Committee.

Consistency in the action of EA-member NABs at the international level and recognition of the EAAB's work by EA are a couple of new key topics awaiting the new Board.

Changes in the EA Secretariat's staff

Daniela Ionescu has replaced Lydie Mauger as the EA MAC Secretary in September 2018. Previously Daniela was the EA MAC Vice-Chair as well as an EA evaluator for products certification and GHG validation and verification. She worked in RENAR, the Romanian NAB, as Director of Quality Management and International Relations as well as Lead Assessor for products certification and GHG validation and verification.

Amandine Combe has also been recruited as the new EA Communications and Marketing Manager in October 2018. She has a master degree both in communication and Japanese language. In pharmaceutical and optical fiber industries, then in import-export business between Europe and Japan, she worked as project manager, graphic designer, web master as well as in community management and public relations.









Brand-new EA website

On 13 December 2018, EA released its newly designed <u>website</u>: more fluent, user-friendly and responsive new tools have been developed to facilitate visits on the EA website.

"The main objective of this new website is to galvanize the relationship between EA, its members and our Stakeholders. We have rebuilt entirely our approach to give a much easier access to the information our visitors are looking for (members, MLA signatories, publications, news). We also wish to attract new visitors and help them understand how accreditation is functioning in Europe, the wide range of fields accreditation has a role into and how closely connected to European market and citizens we are.", said Dr Andreas Steinhorst, the EA Executive Secretary.

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

The implementation of the *Strategy* includes inter alia the building up of the most efficient management structure to achieve efficient governance in EA. For this purpose, a task force group chaired by the EA Chair, Ignacio Pina, provided a proposal for a new EA management structure. This proposal, which has been adopted by the EA General Assembly in November 2018, 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 number of details remain to be further discussed and developed. A substantial revision of the *EA Articles of Association* and EA-1/17: *Rules of Procedure* shall be made to reflect the change in the EA management structure.

The EA Strategy's implementation has also been progressing with other issues such as the location of the EA Secretariat in future, the improvement of the peer-evaluation process, cooperation with stakeholders and the process for EA to input to international discussions.

FPA 2019-2022 with European Commission (EC) / EFTA

After finalizing negotiations with the European Commission and EFTA, the new FPA was signed in December 2018 in order to renew the Framework Partnership Agreement for the period 2019-2022.









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.

A pilot project, based on the very similar EU Directive ATEX and Canadian Regulation HAZLOC for equipment for potentially explosive atmospheres, was completed and the first assessments have taken place.

Since then, the application process got started. For the time being, applications are restricted to areas where there is training material available, i.e. so far for ATEX and HAZLOC only. Further training material for construction and electrical equipment should be made available soon. NABs should use the training material for its relevant personnel/assessors and then apply to a Steering Group which issues recommendations for recognition. Two applications respectively from UKAS for HAZLOC and SCC for ATEX have been examined and recommendations for recognition by the relevant Recognizing party of the EU and Canada are positive. Machinery is the next technical area to be subject to mutual recognition.

A training workshop on CETA implementation with two trainers from SCC was co-organized by EA and SCC on 18-19 December 2018 in Paris-Roissy. Specific information about HAZLOC as well as product sectors such as electrical equipment and construction products was delivered to 21 participants from 15 EA NABs. The training also included a report by the EC on recognition of NABs and CABs.

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)

Andreas Steinhorst (EA Executive Secretary)
Maria Papatzikou (ESYD, Greece)
Kevin Belson (UKAS, UK)
Paulo Tavares (IPAC, Portugal)
Paulo Tavares
Andreas Steinhorst,
Gokhan Birbil (TURKAK, Turkey),
Cecilie Laake (NA, Norway),
Rolf Straub (SAS, Switzerland), N.N.
Amandine Combe (FA Communications Manage

Amandine Combe (EA Communications Manager)
Andreas Steinhorst

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)

Andreas Steinhorst
Andreas Steinhorst
Laurent Vinson (COFRAC, France)
Amandine Combe
Andreas Steinhorst
Paulo Tavares
Andreas Steinhorst
Rolf Straub

Joint IAF/ILAC Committee meetings

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

JWG Communications and Marketing (JCMC) JWG Developing Countries JWG A-series Maria Papatzikou, Andreas Steinhorst Paulo Tavares, Andreas Steinhorst, Gokhan Birbil, Cecilie Laake, Rolf Straub, N.N. Amandine Combe Andreas Steinhorst Paulo Tavares, Andreas Steinhorst



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