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### FOREWORD



The EA Multilateral Agreement (MLA) was signed by 44 EA Members by end of 2023. ATCG, the National Accreditation Body (NAB) of Montenegro, was recognised as a new EA MLA signatory in October 2023, whereas the EA membership and MLA signatory status of BSCA, the NAB of Belarus, terminated in May 2023.

In December 2023, ARMNAB, the NAB of Armenia, has applied for becoming a new EA MLA signatory.

The number of signatories for each scope of the EA MLA remains stable in 2023 compared to 2022, with a slight progress in the numbers of signatories for medical examinations, products certification, proficiency testing provision and reference material production.

The number of peer evaluations performed in 2023 remained stable compared to 2022, thus showing that the situation prior to the pandemic years has been fully recovered. Likewise, all the peer evaluations could be carried out on-site in 2023, except in those extraordinary circumstances preventing the peer-evaluation teams from going to Ukraine and the Republic of Moldova.

To further improve the priority issue of peer evaluator resources and still make up lost pandemic time, an additional newcomer training session was organised in 2023 before the one normally planned in 2024. This session has permitted EA to gain 16 new peer evaluators, whose total number could progress by 7% in 2023.

The MAC project to reengineer the peer-evaluation system has been fully completed in 2023, when the MAC has finalised two last documents related to the competence of evaluators and the mechanism to feedback any lessons learned during the peer evaluations.

Finally, the MAC endorsed the procedure for launching the EA MLA for accreditation of biobanking according to EN ISO 20387, which was approved by the EA General Assembly in May 2023. The peer-evaluation activities in the field of biobanking are ready to be started as soon as the EN ISO 20387 standard is confirmed to be harmonised.

The strongest commitment of all those involved in the EA MLA process made the progress achieved in 2023 possible. I am very grateful for their outstanding contribution to maintaining and improving the EA MLA as a sustainable mechanism for ensuring both European and International reliable equivalence and mutual acceptance of certificates and reports issued by accredited conformity assessment bodies. Strong but also flexible accreditation and peer-evaluation systems are vital to maintain the confidence in the public service that we provide.

Maria Papatzikou (ESYD) Chair of the EA Multilateral Agreement Council

## **1 - INTRODUCTION**

This report provides information on the signatories to the EA MLA, as well as an overview of the key activities completed in 2023 to further develop the coverage of the MLA and to strengthen the operation of the peer-evaluation system, including management of evaluators.

The main objective of peer-evaluation activities is to evaluate the ongoing compliance of national accreditation bodies (NABs) with Regulation (EC) No 765/2008 and the internationally-agreed requirements, as well as to ensure that regulators, stakeholders and the business community can have confidence in the certificates and reports issued by accredited conformity assessment bodies (CABs) under the EA MLA.

According to article 14 of Regulation (EC) No 765/2008 Setting out the requirements for accreditation, EA has been recognised by the European Commission (EC) as the European Accreditation Infrastructure and to operate the peer-evaluation system of national accreditation bodies.

Initially signed by the parties on 1 April 2009, the General Guidelines for Cooperation between the European *co-operation for Accreditation and the European Commission, the European Free Trade Association and the Competent National Authorities* aim to widen and strengthen the co-operation in order to reflect the developments in policy and legislation. It shall also strengthen the position of accreditation, national accreditation bodies in EU and EFTA Member States and EA with the view to prepare a successful implementation of Regulation (EC) No 765/2008.

On 30 August 2022, the fourth Framework Partnership Agreement (FPA) was signed with the European Commission for the period 2023-2026. A similar agreement was signed with EFTA on 16 November 2022.

Following article 11 of Regulation (EC) No 765/2008, a national authority shall recognise the equivalence of services delivered by a national accreditation body from the European Economic Area (EEA) which has successfully undergone peer evaluation by EA. Accordingly, a national authority in the EEA shall accept the reports and certificates issued by a conformity assessment body accredited by the national accreditation bodies from the EEA that are EA MLA signatories.

Maintaining a sound and reliable evaluation system also requires that EA supports the further improvement of EA's pool of evaluators through both newcomer and refresher training sessions.

### 2 - THE EA MLA

The EA MLA is an agreement signed between national accreditation bodies – Members of EA which are successfully peer evaluated – to recognise and accept the equivalence of the accreditation systems and the reliability of the conformity assessment results.

EA MLA signatories apply the international standards for accreditation of conformity assessment bodies in a harmonised way and the services delivered by those national accreditation bodies are equivalent. All of those EA Members that are signatories of the EA MLA aim to establish mutual confidence in the respective accreditation systems and in their accredited attestations of conformity.

Therefore, the marketplace can have confidence in activities of the EA MLA signatories and their accredited conformity assessment bodies. The EA MLA provides the European market with a network of conformity assessment bodies that are competent within their scope of accreditation to issue reliable and credible statements of conformity for products and services, thereby reducing costs and adding value to business and consumers. This contributes to the freedom of trade by eliminating technical barriers.



Map of MLA signatories in December 2023

Accreditation of	Scope/Activity (Level 2)	Standards (Level 3)
Laboratories	Testing and Medical Examinations Calibration	EN ISO/IEC 17025 EN ISO 15189 EN ISO/IEC 17025
Certification Bodies	Certification of Products Certification of Persons Certification of Management Systems	EN ISO/IEC 17065 EN ISO/IEC 17024 EN ISO/IEC 17021-1
Validation and Verification Bodies	Validation and Verification	EN ISO/IEC 17029 EN ISO 14065
Inspection Bodies	Inspection	EN ISO/IEC 17020
Proficiency Testing Providers (PTP)	Proficiency Testing Provision	EN ISO/IEC 17043
Reference Material Producers (RMP)	Reference Material Production	EN ISO 17034
Biobanks	Biobanking	EN ISO 20387

### The EA MLA covers the following activities and standards:

During 2023, EA Members delivered about 35,439 accreditations under the scopes for which they have signed the EA MLA, representing a 6% decrease compared to 2022. This slight diminution mainly results from a 12% fall in the number of accreditations delivered for testing, due to BSCA's termination of the EA MLA signatory status. Validation and Verification is the scope registering the biggest increase (+ 30%) in accreditations.

Type of accreditation	2021	2022	2023
Calibration	3,277	3,374	3,437
Testing	18,651	18,962	16,621
Medical Examinations	3,831	3,903	3,928
Products Certification	2,062	2,113	2,103
Management Systems Certification	1,436	1,553	1,438
Persons Certification	812	842	859
Validation & Verification	146	144	188
Inspection	6,252	6,396	6,543
Proficiency Testing Provision (PTP)	226	244	248
Reference Material Production (RMP)	72	74	74
TOTAL	36,765	37,605	35,439

#### Numbers of accreditation certificates issued under the EA MLA

## **4 - SIGNATORIES OF THE MLA**

National accreditation bodies are accepted under the EA MLA only after stringent evaluation of their operations and activities.

The evaluation is conducted by a peer-evaluation team entrusted with the task to determine national accreditation bodies' compliance with the requirements laid down in:

- Regulation (EC) No 765/2008;
- EN ISO/IEC 17011, the internationally-accepted standard for accreditation bodies;
- the relevant standard for conformity assessment bodies including any additional requirements, e.g. those set out by the European Commission in relevant sector-based legislations, or in conformity assessment schemes established in the non-regulated sector, as well as those covered in relevant EA and IAF/ILAC documents.

# A list of EA MLA signatories and scopes (on 6 December 2023) is annexed to this report. For the latest information, please visit the <u>EA website</u>.

Out of 49 EA Members, 44 have signed the MLA.

The individual EA Multilateral Agreement Signatories are listed by MLA scope in <u>EA-INF/03</u>: Signatories to the EA <u>Multilateral Agreements</u>.

The numbers of member signatories for each scope of the EA Multilateral Agreement remain stable compared to those registered in 2022, with a slight increase in the numbers of signatories for medical examinations, products certification, proficiency testing provision and reference material production. Moreover, the numbers of signatories for management system and persons certification have slightly decreased due to the termination of EA membership of BSCA, the National Accreditation Body of Belarus, in May 2023.

Type of accreditation	2021	2022	2023
Calibration	41	41	41
Testing	42	42	42
Medical Examinations	37	38	39
Inspection	42	43	43
Management Systems Certification	36	36	35
Products Certification	36	37	38
Persons Certification	33	33	32
Validation and Verification	25	25	25
Proficiency Testing Provision	20	20	21
Reference Material Production	12	12	13

#### Numbers of member signatories to the MLA by scope

### **5 - OPERATION OF THE MLA COUNCIL**

The EA MLA Council is responsible for the effective and impartial management and monitoring of the peer-evaluation process. It is the decision-making body for acceptance of national accreditation bodies' entering into the Multilateral Agreement (MLA) of EA.

#### **MLA Council (MAC)**

The MAC is composed of one representative from each Member of EA, one observer from the EA Advisory Board and one observer from the European Commission. All EA MLA signatories have the voting right within the MAC on peer evaluations and the EA MLA signatory status.

Maria Papatzikou from ESYD (Greece) has been chairing the MAC since 2021.

Karine Vincent from COFRAC (France) vice-chaired the MAC in 2023.

The MAC held its 48<sup>th</sup> meeting on 26-27 April 2023 in Belgrade, Serbia, and its 49<sup>th</sup> meeting on 4-5 October 2023 in Brussels, Belgium.

#### MAC Management Group (MG)

The MAC MG is composed of 12 members from different NABs who were elected by the MAC members. The task of the Management Group (MG) is to achieve a more effective management and harmonisation of the peer evaluations and operations of the MAC.

#### Secretariat

The Secretariat is responsible for the daily management of the peer evaluations, including peer evaluators, and the organisation of MAC and MAC MG meetings.



Daniela lonescu is the MAC Secretary and the Manager of the peer-evaluation system..



In March 2023, Ankica Barišić, the previous Acting Director General of HAA, the Croatian National Accreditation Body, who was a MAC member since 2013 and EA peer evaluator since 2018, became the Manager of Peer Evaluations and Evaluators at the EA Secretariat. She works together with Daniela Ionescu, and is also responsible for the training and monitoring of EA evaluators.

### **5 - OPERATION OF THE MLA COUNCIL**

#### Decisions made by the MAC in 2023

ATCG, the National Accreditation Body (NAB) of Montenegro, was recognised as a new EA MLA signatory in the fields of calibration (EN ISO/IEC 17025), testing (EN ISO/IEC 17025) including medical examinations (EN ISO 15189), inspection (EN ISO/IEC 17020) and certification of products (EN ISO/IEC 17065).

CAI, the Czech NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing providers (EN ISO/IEC 17043), certification of management systems (EN ISO/IEC 17021-1), certification of products, certification of persons (EN ISO/IEC 17024), validation and verification (EN ISO 14065: 2013) and reference material producers (EN ISO 17034). Afterwards the EA MLA status of CAI for validation and verification has been updated to EN ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3 standard<sup>1</sup>) + EN ISO 14065:2020 (level 4 standard).

CYS-CYSAB, the Cypriot NAB, remained an EA MLA signatory in the fields of certification of products and inspection.

GAC, the Georgian NAB, became an EA MLA signatory in the field of proficiency testing providers.

INAB, the Irish NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons and reference material producers.

LATAK, the Latvian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons, and validation and verification (EN ISO 14065: 2013).

Afterwards the EA MLA status of LATAK for validation and verification has been updated to EN ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

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



<sup>1</sup> For the different MLA levels, see EA-1/06 EA Multilateral Agreement - Criteria for Signing - Policy and Procedures for Development.

### **5 - OPERATION OF THE MLA COUNCIL**

NA, the Norwegian NAB, became an EA MLA signatory in the field of reference material producers. NAH, the Hungarian 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 (EN ISO 14065: 2013). Afterwards the EA MLA status of NAH for validation and verification has been updated to EN ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

NAAU, the Ukrainian 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.

SA, the Slovenian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons, and validation and verification (EN ISO 14065: 2013).

Afterwards the EA MLA status of SA for validation and verification has been updated to EN ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

SNAS, the Slovakian 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 (EN ISO 14065: 2013). Afterwards the EA MLA status of SNAS for validation and verification has been updated to EN ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

TUNAC, the Tunisian National Accreditation Body (NAB), became an EA MLA signatory in the fields of medical examinations and certification of products.

TUNAC remained an EA MLA signatory in the fields of calibration, testing, inspection, certification of management systems.



### **6 - PEER-EVALUATION PROCESS AND ACTIVITIES**

The reliability of the MLA is maintained through a robust peer-evaluation process, whose main objectives are to evaluate the ongoing compliance of EA NABs to the internationally-agreed requirements, and to ensure that regulators, stakeholders and the business community can have confidence in those certificates and reports issued by conformity assessment bodies accredited by EA Members having signed the EA MLA.

#### **1 - PEER-EVALUATION PROCESS**

The peer-evaluation process is carried out in accordance with <u>EA-2/02 M:2022 EA Procedure for the evaluation of</u> <u>a National Accreditation Body</u>.

The national accreditation body applies for the MLA signatory status, specifying the scope for which it applies.

The Secretariat reviews the application documents and appoints a peer-evaluation team composed of a Team Leader, a Deputy Team Leader, Team Members and Trainees.

This peer-evaluation team performs the document review. Where applicable, a pre-evaluation is conducted. Then, the team carries out the on-site evaluation, which combines evaluation of the management system at the NAB's office and observation of assessments carried out by the NAB. At the end of the evaluation, the team drafts the evaluation report. Findings are agreed upon with the NAB at a closing meeting.

A task force group appointed by the MAC Management Group makes a careful study of the evaluation report in order to provide the MAC with a recommendation on the result of the peer evaluation. The MAC makes the final decision, which is reflected in relevant EA publications and on the website.

The European Commission attends MAC meetings and NABs under evaluation are encouraged to invite national authorities to observe the EA peer evaluation.

#### **2 - PEER-EVALUATION ACTIVITIES**

For 2023, the MAC had scheduled 15 peer evaluations, out of which 14 were performed as follows:

- 7 re-evaluations: ACCREDIA (Italy), ALGERAC (Algeria), ESYD (Greece), HAA (Croatia), MOLDAC (Republic of Moldova), IPAC (Portugal) and OLAS (Luxembourg);
- 1 anticipated re-evaluation: CYS-CYSAB (Cyprus);
- 1 re-evaluation with extension for proficiency testing providers (PTP) and reference material producers (RMP): SAS (Switzerland);
- 1 re-evaluation with extension for Validation & Verification: NAAU (Ukraine);
- 1 extension for RMP: NA (Norway);
- 1 witnessing for PTP: SWEDAC (Sweden);
- 2 extraordinary evaluations: CYS-CYSAB (Cyprus) and NAH (Hungary).

Since the membership of BSCA (Belarus) has been terminated in May 2023, the re-evaluation scheduled for December 2023 was cancelled.

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### **6 - PEER-EVALUATION PROCESS AND ACTIVITIES**

Besides, in December 2023, ARMNAB (Armenia) has applied for becoming a new EA MLA signatory in the fields of calibration, testing, certification of products and certification of management systems. The process of ARMNAB's new evaluation started in December 2023 and will be continued in 2024.

As planned in 2022 when the COVID-19 pandemic situation and restrictions came to an end, all the peer evaluations could be carried out on-site in 2023 – except for NAAU and MOLDAC whose re-evaluations were performed remotely owing to the war in Ukraine and threats coming from Russia.

#### EA peer-evaluation activities

	2019	2020	2021	2022	2023
Total numbers of evaluations performed <sup>1</sup>	16	7	25	13	14
Total numbers of reports discussed <sup>2</sup>	17	31 <sup>3</sup>	13	15	17
Total man-days for evaluation	935	335	1,764	1,070	940
Extraordinary evaluations	3	0	2	0	2
Suspension	0	0	1	0	0

<sup>1</sup> Initial evaluations, re-evaluations with or without scope extensions and extraordinary evaluations (performed on-site in the specific year).

<sup>2</sup> Reports of evaluations, but not necessarily conducted in the specific year.

<sup>3</sup> 31 reports, out of which 18 related to transition to EN ISO/IEC 17011:2017.

The total number of evaluations performed in 2023 remained stable compared to 2022, thus confirming that the situation prior to the pandemic years has been fully restored.

The evaluation teams reported a total of 93 non-conformities for those peer evaluations carried out in 2023.



## 7 - EA PEER EVALUATORS

EA peer evaluators are highly qualified and experienced national accreditation body staff members who attend training programs on a frequent and regular basis. Peer evaluators' performance is regularly reviewed by the Secretariat. They can be mandated for peer evaluation at the ILAC or IAF levels.

#### **1 - MANAGEMENT OF EVALUATORS**

The EA MAC is responsible for the management of peer-evaluation resources by organising evaluator training sessions and harmonisation events, ensuring that enough peer evaluators with the skills necessary to cover the full scope of the MLA are available.

The management of peer evaluators is carried out in accordance with <u>EA-2/02 M:2022 EA Procedure for the</u> <u>Evaluation of a National Accreditation Body. Annex 1: Process and procedures for selection, qualification and</u> <u>monitoring of evaluators and the appointment and composition of the evaluation team.</u>

The initial selection and qualification (authorisation) of evaluators are carried out by the Secretariat, which may give priority to specific candidate evaluators in order to fulfil the needs of the peer-evaluation system and to ensure a balanced contribution of all MLA signatories. Newcomer trainings for new Team Members (TMs) are designed to ensure that the evaluators meet the competence criteria, and to provide participants with a comprehensive understanding of the peer-evaluation processes and requirements.

The Secretariat also monitors the performance of evaluators on an on-going basis by monitoring the feedback collected from the evaluated NAB and evaluated by the Team Leader (TL) and TMs, the evaluation of TMs by the TL, and the feedback from the TMs on the TL. At least once every three years, the performance of the evaluators is re-evaluated based on this monitoring, their updated curriculum vitae and their participation in refresher trainings. The authorisation of an evaluator is re-confirmed by the Secretariat.

In order to improve the performance and harmonisation of evaluators' work, the MAC and Secretariat regularly organise refresher trainings and exchange of experiences between evaluators, inform them about new requirements, changes in the peer-evaluation procedures and areas for improvement, and take necessary action based on the feedback received on the evaluators' performance.

#### 2 - NUMBER OF EVALUATORS

By the end of December 2023, a total number of 190 evaluators (including trainees) are authorised to perform peer evaluations on behalf of EA, i.e. acknowledged for having all technical competences to perform peer evaluations under specific accreditation scopes.

In 2023, 40 evaluators have been re-approved for a period of three years (8 Team Leaders, 13 Deputy Team Leaders and 19 Team Members).

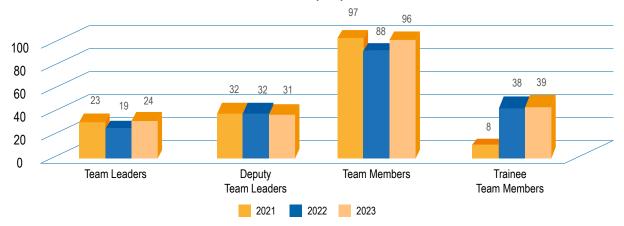
#### Number of evaluators per qualification

By the end of December 2023, the 190 authorised evaluators are broken down as follows:

- 24 Team leaders (TLs)
- 31 Deputy Team Leaders (DTLs)
- 96 Team Members (TMs)
- 39 Trainee Team Members (Trainee TMs)

## 7 - EA PEER EVALUATORS

Number of evaluators per qualification from 2021 to 2023

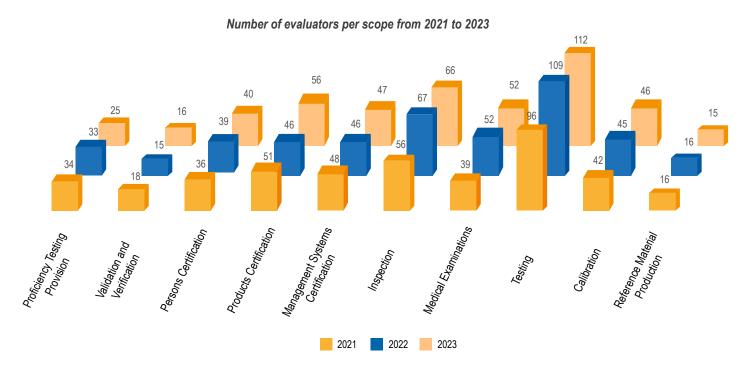


The progress by 7% in the total number of evaluators in 2023 is supported by a 26% progress in the number of TLs and a 9% progress in the number of TMs. It is also worth noting that the number of Trainee TMs, which surged in 2022 and enabled to restore the number of evaluators registered before the pandemic crisis, remains at the same high level.

Despite this increased number of evaluators in 2023, a large number of them (21 evaluators in 2023 in addition to 14 evaluators in 2022) ended their participation for various reasons (leaving NABs, retirement or withdrawal of evaluator status at the request of NABs).

#### Number of evaluators per scope

In the table below, the number of evaluators includes all approved evaluator statuses for the Trainee TMs, TMs, DTLs and TLs competent for each scope, knowing that one evaluator is competent for one or several scopes.



The number of evaluators for each scope of the EA MLA remains stable in 2023 compared to 2022. The biggest developments are the progress in the number of evaluators for products certification (+ 22%) and the decrease in the number of evaluators in the area of proficiency testing provision (- 24%).

### 7 - EA PEER EVALUATORS

#### Number of evaluators per NAB

The newcomer training session held in 2023 have allowed to authorise new evaluators, several of whom belong to those 10 NABs which increased their total number of evaluators. In 2023, 2 NABs decreased their total number of evaluators.

Considering both the total number of evaluators (including trainees) and the number of MLA signatories for each scope, the highest ratios of evaluators by end of 2023 are observed for testing (2.67), inspection (1.53) and products certification (1.47). The most critical ratio of evaluators is noticed for verification and validation (0.64).

### **3 - TRAINING OF PEER EVALUATORS**

In 2023, 4 trainings were specifically organised for EA evaluators, i.e. 1 newcomer training session as well as 3 refresher trainings dedicated to Team Members, Deputy Team Leaders or Team Leaders. All of them were organised on-site to alternate with the remote sessions held in 2022.

#### **Newcomer training session**

The issue of evaluator resources is a constant priority on the MAC agenda. Further to the pair of newcomer training sessions held in 2022, an additional newcomer training session was organised on 12-14 December 2023 before the one normally planned in 2024 in order to make up lost pandemic time and to further improve the situation.

This newcomer training session, which gathered 21 participants from 19 NABs at the EA Secretariat's office in Paris, France, has permitted EA to gain 16 new peer evaluators, 7 of whom could be directly assigned as Team Members and 9 of whom were first assigned as Trainee Team Members.

The next newcomer training session will take place on 3-5 December 2024.

#### **Refresher training sessions**

In accordance with EA-2/02, the peer evaluators shall normally attend a refresher training 3 years after the newcomer training or after their first two evaluations as a Team Member, whichever is soonest; thereafter Team Leaders and Team Members are expected as a minimum to attend a refresher training every 5 years. Since the evaluators are mainly authorised for more than one scope, the Secretariat invites them to attend the refresher trainings planned in all their authorised scopes.

72 out of the total pool of 190 peer evaluators participated in the refresher trainings in 2023.

The first refresher training session held on 6-7 June 2023 in Paris, France, was dedicated to products certification and inspection. 26 Team Members from 20 NABs took part in the training programme.

The second session gathered 21 Team Members from 18 NABs on 22-23 November 2023 in Brussels, Belgium, to focus on testing, medical examinations and proficiency testing provision (PTP).

The last refresher training session, hosted by DAkkS on 13-14 December 2023 in Berlin, Germany, was specially targeted at Deputy Team Leaders and Team Leaders. 25 participants (9 DTLs and 16 TLs) from 15 NABs notably considered the implementation of <u>EA-2/02 S3: Risk-Based Approach for the Planning of a Peer Evaluation</u>.

#### **1 - IMPROVING THE PEER-EVALUATION PROCESS**

The peer-evaluation process is under ongoing review by the MAC, peer evaluators and EA internal auditors.

#### MAC project on reengineering the peer-evaluation system

Regulation (EC) No 765/2008 reinforces the role of EA and its peer-evaluation system in both voluntary and regulated sectors. EA shall support and harmonise the implementation of stringent accreditation rules to achieve consistency throughout Europe, as well as greater transparency and acceptability to all interested parties, including national authorities. The peer-evaluation process is also further strengthened to accommodate the specific needs of regulatory fields in order to raise the reassurance of regulators and stakeholders that national accreditation bodies' technical competence is thoroughly assessed.

The MAC project to reengineer the peer-evaluation system, one of the key actions of the EA Strategy 2025, has been fully completed in 2023. Further to the revision of <u>EA-2/02</u>: <u>EA Procedure for the Evaluation of a National</u> <u>Accreditation Body</u> achieved in 2022 together with the adoption of the five supplements to EA-2/02, the MAC has finalised two last documents related to the competence of evaluators and the mechanism to feedback any lessons learned during the peer evaluations.

#### 2 - DEVELOPMENT OF THE MLA

#### EA MLA signatory status for EN ISO/IEC 17029

Further to the launching of the EA MLA for EN ISO/IEC 17029:2019 in October 2022, the MLA signatory status in the field of validation and verification was updated to EN ISO/IEC 17029 for the following 20 NABs by the end of December 2023: AA (Austria), ACCREDIA (Italy), BAS (Bulgaria), BELAC (Belgium), CAI (Czech Republic), COFRAC (France), DAkkS (Germany), EAK (Estonia), ENAC (Spain), ESYD (Greece), FINAS (Finland), LATAK (Latvia), NAH (Hungary), PCA (Poland), RENAR (Romania), RvA (The Netherlands), SA (Slovenia), SNAS (Slovakia), SWEDAC (Sweden) and TURKAK (Türkiye).

In May 2023, EA Members were informed of the extension by 6 months of the transition deadline for EN ISO/IEC 17029 (level 3) + ISO 14065:2020 (level 4).

#### Extension of the EA MLA to biobanking

Further to the decision made by the General Assembly in November 2022 to expand the EA MLA for biobanking as a level 2 conformity assessment activity using EN ISO 20387:2018 *Biotechnology* — *Biobanking* — *General Requirements for Biobanking* as a new level 3 normative document, the MAC had to define the prerequisites for the launch of the MLA on biobanking.

In April 2023, the MAC endorsed the procedure for launching the EA MLA for accreditation of biobanking according to EN ISO 20387.

Finally, acting upon recommendation from the Executive Board and based on the proposal made by the MAC in April, the General Assembly resolved in May 2023 that the peer evaluations in the field of biobanking against EN ISO 20387:2018 shall be performed according to the above-mentioned MAC procedure, and that the MLA shall come into effect provided that at least two members have been successfully peer evaluated. Besides it was resolved that EA applies to ILAC to extend the scope of EA as a recognized region for the scope "Biobanking - ISO 20387". This EA Resolution 2023 (53) 14 will come into effect on the date that the standard EN ISO 20387 is confirmed to be harmonised.

The peer-evaluation activities in this field could not begin in 2023 and were postponed until the EN ISO 20387 standard is harmonised and cited in the Official Journal of the European Union.

### 8 - IMPROVEMENT OF THE MLA AND PEER-EVALUATION PROCESS

#### **3 - INCREASED VISIBILITY OF THE MLA**

According to *EA Strategy 2025*, EA has been establishing a MLA mark for the purpose of identifying EA MLA signatories and their accredited CABs. After EA Members selected their preferred option for the MLA mark at the General Assembly in November 2019, the previous Executive Committee has been mandated to proceed with the formal registration of the MLA mark as a collective mark of the European Union (EU) in a first stage, and then to extend registration to non-EU countries at the international level based on the Madrid Agreement.

The formal registration as a collective mark of the EU was completed in June 2022.

As agreed in November 2019, the EA MLA mark shall not be used until it is registered in the countries of all MLA signatories.

The process for registering the EU mark as an international mark is nearing completion for those EA MLA signatories which are not EU Members: further to EA's formal application to the World Intellectual Property Organization (WIPO), the EA MLA mark has been successfully registered dated 12 April 2023 as an international collective mark with the WIPO in the non-EU countries of MLA signatories. The mark is now examined by the national offices of the countries concerned; notifications may be issued until 18 months after notification of the registration of the EA MLA mark in each country. This means that the full process is expected to be completed by summer 2025.

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 MLA signatories.

#### **4 - MANAGEMENT OF TRANSITIONS OF STANDARDS AND IAF/ILAC DOCUMENTS**

The MAC has strengthened its process for ensuring continuing compliance with the MLAs transitions.

The transition periods of the following six standards and documents having come to an end in late 2022 or in 2023, the MAC carried out surveys on each transition to monitor EA Members' compliance with the requirements during 2023:

- ISO 14064-2:2019 Greenhouse gases Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements;
- IAF MD 9:2022 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485);
- ISO 22301:2019 Security and resilience Business continuity management systems Requirements;
- ISO/IEC 27001:2022 Information security, cybersecurity and privacy protection, Information security management systems – Requirements;
- ISO 14064-3:2019 Greenhouse gases Part 3: Specification with guidance for the verification and validation of greenhouse gas statements;
- ISO 50003:2021 Energy management systems Requirements for bodies providing audit and certification
  of energy management systems (survey from 29 December 2023 to 31 January 2024).

Besides, based on the Technical Management Board Resolution 2022 (10) 01, the MAC monitored the transition to EA-2/17 M:2020 *EA Document on Accreditation for Notification Purposes*, whose implementation date was 17 April 2023.

The feedback received from each survey indicated that all members completed the transitions within the agreed timeframe. : 17

### 9 - COOPERATION WITH IAF/ILAC: PEER EVALUATION OF EA

EA is a regional cooperation body recognised by IAF and ILAC: the EA MLA is recognised by both organisations and covered by their respective arrangements. In concrete terms, a test report or certificate accredited by an EA MLA signatory is recognised by the signatories to the IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation) multilateral agreements. The EA MLA acts as a world-wide passport to trade.

#### 1 - EXTENSION OF EA'S MLA SIGNATORY STATUS

In November 2023, EA and its members have been recognised by IAF for IFS Food sub-scope under the IAF MLA on products certification (ISO/IEC 17065) as follows:

- level 4 IFS Food Version 7, Part 1, Section 2 & 3 and Part 4\*
- level 5 IFS Food Version 7, Part 2\*

\* Note: This scope adds requirements at Level 1 - IFS Food Version 7, Part 3, Section 1.

In December 2023, EA applied to IAF for the recognition of the following sub-scopes under the IAF MLA on products certification (ISO/IEC 17065):

- BRC Global Standard Food Safety Level 4 – Food Safety, Part III & IV Level 5 – Food Safety, Part II
- BRC Global Standard Agents and Brokers
   Level 4 Agents and Brokers, Part III & IV
  - Level 5 Agents and Brokers, Part II
- BRC Global Standard Packaging Materials Level 4 – Packaging Materials, Part III & IV Level 5 – Packaging Materials, Part II
- BRC Global Standard Storage and Distribution Level 4 – Storage and Distribution, Part III & IV Level 5 – Storage and Distribution, Part II
- BRC Global Standard Gluten Free Certification Program Level 4 – Gluten Free Certification Program, Part III & IV Level 5 – Gluten Free Certification Program, Part II
- BRC Global Standard Consumer Products Personal Care Household Level 4 – Consumer Products Personal Care Household, Part III & IV Level 5 – Consumer Products Personal Care Household, Part II
- BRC Global Standard Consumer Products General Merchandise Level 4 – Consumer Products General Merchandise, Part III & IV Level 5 – Consumer Products General Merchandise, Part II
- Global G.A.P. Produce Handling Assurance (PHA) Level 4 – Global G.A.P. PHA General Regulations Level 5 – Global G.A.P. PHA CPCCs

### 9 - COOPERATION WITH IAF/ILAC: PEER EVALUATION OF EA

In December 2023, EA also applied to IAF for the recognition of the following sub-scopes under the IAF MLA on management systems certification (ISO/IEC 17021-1):

• IAQG (International Aerospace Quality Group)

Level 4 – IAQG 9104-1 Level 5 – IAQG 9100, IAQG 9110, IAQG 9120.

EA will apply in early 2024 to IAF for the transition of the IAF MLA from ISO 14065:2013 to ISO/IEC 17029 + ISO 14065:2020.

#### 2 - FULL RE-EVALUATION OF EA BY IAF/ILAC

The re-evaluation of EA by IAF/ILAC started in early September 2022 with the evaluation of the EA Secretariat, continued with the evaluation of the scopes of medical examinations, inspection, persons certification as well as validation and verification in 3 NABs, and terminated with the evaluation of the MAC decision-making process at the MAC meeting held in October 2022 in Turin, Italy.

In December 2023, the ILAC Arrangement Council (ARC) has confirmed the continuation of EA as a recognised regional cooperation body of ILAC, i.e. the continuation of recognition of the EA MLA to the ILAC MRA for the accreditation of calibration and testing laboratories using ISO/IEC 17025, medical testing laboratories using ISO/IEC 17020, proficiency testing providers using ISO/IEC 17043 and reference material producers using ISO 17034.

The IAF decision on the related MLA scopes is expected in 2024.

It is recommended that the next re-evaluation of EA is scheduled to begin no later than July 2026.

Besides, for the sake of cooperation between the regions, EA provided Inter-American Accreditation Cooperation (IAAC) with one Team Member competent in the field of reference material production in order to support IAAC in the evaluation of one accreditation body within the IAAC region.



# ANNEX - MULTILATERAL AGREEMENT SIGNATORIES (6 DECEMBER 2023)

	CALIBRATION LABORATO- RIES	TESTING LABORATO- RIES	MEDICAL LABORATO- RIES	INSPECTION BODIES	CERTIFICA- TION BODIES - PRODUCTS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	CERTIFICATION BODIES - PERSONS	VALIDATION & VERIFICATION BODIES	PROFICIENCY TESTING PROVIDERS	REFERENCE MATERIAL PRODUCERS
ALBANIA - DPA		$\checkmark$		$\checkmark$		√	$\checkmark$			
ALGERIA - ALGE- RAC	$\checkmark$	$\checkmark$		$\checkmark$						
AUSTRIA - AA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$		
BELARUS - BSCA					EA membe	rship terminated				
BELGIUM - BELAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
BOSNIA & HERZEGOVINA - BATA	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$					
BULGARIA – BAS	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	İ	
CROATIA - HAA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		
CYPRUS – CYS	√	$\checkmark$	$\checkmark$	$\checkmark$						
CZECH REPUBLIC - CAI	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$	√	$\checkmark$
DENMARK - DANAK	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
EGYPT - EGAC										
ESTONIA - EAK	√	$\checkmark$		$\checkmark$	V	√	V	√		
FINLAND - FINAS	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$		
FRANCE – COFRAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
GEORGIA - GAC	$\checkmark$		$\checkmark$	$\checkmark$			$\checkmark$		0	
GERMANY - DAkkS	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$	√	
GREECE - ESYD	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$	√	
HUNGARY – NAH	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		
ICELAND - ISAC				$\checkmark$						
IRELAND - INAB	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	√				
ISRAEL - ISRAC										
ITALY - ACCREDIA							$\checkmark$			
LATVIA - LATAK			√	√		√		√		
LITHUANIA - LA	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$			
LUXEMBURG - OLAS	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		√				
Malta - Nab-Malta	$\checkmark$	$\checkmark$		$\checkmark$						
MONTENEGRO - ATCG	O	O	O	O	0					
NORWAY - NA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	O
POLAND - PCA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
PORTUGAL - IPAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$		
REPUBLIC OF MOLDOVA - <b>MOL-</b> DAC	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
REPUBLIC OF NORTH MACEDO- NIA - <b>IARNM</b>	$\checkmark$		$\checkmark$	V	$\checkmark$	$\checkmark$				

Signatory in 2023

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# ANNEX - MULTILATERAL AGREEMENT SIGNATORIES (6 DECEMBER 2023)

	CALIBRATION LABORATO- RIES	TESTING LABORATO- RIES	MEDICAL LABORATO- RIES	INSPECTION BODIES	CERTIFICA- TION BODIES - PRODUCTS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	CERTIFICATION BODIES - PERSONS	VALIDATION & VERIFICATION BODIES	PROFICIENCY TESTING PROVIDERS	REFERENCE MATERIAL PRODUCERS
ROMANIA - RENAR		$\checkmark$	$\checkmark$	$\checkmark$			$\checkmark$	$\checkmark$		
SERBIA - ATS		$\checkmark$	$\checkmark$	$\checkmark$						
SLOVAKIA - SNAS		$\checkmark$	$\checkmark$	$\checkmark$				$\checkmark$		
SLOVENIA - SA		$\checkmark$		$\checkmark$				$\checkmark$		
SPAIN - ENAC			$\checkmark$	$\checkmark$				$\checkmark$	$\checkmark$	
SWEDEN – SWE- DAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
SWITZERLAND - SAS	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$			
NETHERLANDS - <b>RvA</b>	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
TUNISIA - TUNAC	$\checkmark$	$\checkmark$	0	$\checkmark$	O					
TURKEY – TURKAK			$\checkmark$	$\checkmark$				$\checkmark$	$\checkmark$	
UKRAINE – NAAU	$\checkmark$	$\checkmark$								
UNITED KINGDOM - <b>UKAS</b>	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$			$\checkmark$	$\checkmark$	

Signatory in 2023

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