FINAS
customer day and 25th anniversary
26th January 2017
EA strategy and future scene of accreditation

Thomas Facklam, EA chair
ABOUT EA

- EA is an association of national accreditation bodies in Europe.
- EA’s members are officially recognised by their national Governments to assess and verify conformity assessment bodies (CAB).
- CAB are organisations that carry out — against international standards — evaluation services such as certification, verification, inspection, testing and calibration.
- EA is responsible for harmonising accreditation within Europe, with the aim of reducing barriers to trade and protecting health, safety and the environment.
As the **official guardian of the European accreditation infrastructure**, EA has the overall strategic objective to **safeguard the value and credibility** of accredited conformity assessment services delivered by its Members and accredited conformity assessment bodies within the European market.

In accordance with Article 14, paragraph 2 in this Regulation, an agreement has been concluded between EA and the European Commission (EC) to specify, inter alia, EA’s detailed tasks as well as funding and supervision provisions.
This agreement includes:

<table>
<thead>
<tr>
<th>General Guidelines</th>
<th>Framework Partnership Agreements (FPA)</th>
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<tr>
<td>• <strong>General Guidelines</strong> for the Cooperation between the European co-operation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities.</td>
<td>• 4-year FPA sets out the financial obligations and conditions between the EC and EA.</td>
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<td>• provide for annual operational grants and specific action grants based on EA’s annual work programmes to be approved by the EC every year.</td>
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THE EUROPEAN ACCREDITATION MODEL

- a service of general interest
- public authority
- last level of control of conformity assessment
- voluntary and mandatory fields
- mandate of the government
- full compliance with applicable rules
- accountability to stakeholders
- no predominance of any single interest group
- non-profit distributing
- no competition
appointed by the EC to manage the accreditation infrastructure within the EU, EFTA and candidate countries.

not-for-profit association of nationally recognised accreditation bodies

established in 1997 and registered in NL in 2000

36 full members representing 36 European economies

13 associate members

permanent EA-Secretariat of 6 persons
"EA exists to coordinate and lead the **European accreditation infrastructure** to allow the **results of conformity assessment services** in one country to be **accepted** by Regulators and the market place in another country **without further examination**, for the benefit of the European community and the global economy."
Defining, **harmonising and building consistency in accreditation in Europe**, by ensuring common interpretation and application of the standards used by its members;

- **Ensuring transparency** of the operations (including assessments) performed and results provided by its members;

- Maintaining a **multilateral agreement on mutual recognition** between accreditation activities and reciprocal acceptance of accredited conformity assessment services and results;
Managing a peer evaluation system consistent with international practices;

Acting as a technical resource on matters related to the implementation and operation of the European policies on accreditation;

Cooperate with the European Commission and other European and international stakeholders;

Develop accreditation criteria and guidelines supporting harmonisation of practices;
EA was created in 1997 but its origins extend back further.

- **WEMC (1973-1982)**
- **WECC (1976-1994)**
- **WELAC (1987-1994)**
- **EAL (1994-1997)**
- **EAC (1991-1997)**

EA created as a legal entity on 26/06/2000.
The General Assembly, the highest decision-making body of the association, supervises the management and the general course of affairs in the association and takes decisions in respect of strategy and general policies.
Next election May 2017 for the term 2018-2019
EA ADVISORY BOARD (EAAB)

- EAAB constitutes the primary organ within EA to ensure the effective and balanced involvement of all interested parties in European accreditation regarding policy and strategy issues.

- EAAB shall serve as the main stakeholder forum for EA to deal with issues pursuant to the requirements of Regulation (EC) 765/2008 and to the relevant provisions of the “General Guidelines for Co-operation between EA and the EC, EFTA and the competent national authorities”.

Regulation (EC) 765/2008

General Guidelines for Co-operation between EA and the EC, EFTA and the competent national authorities
The EAAB's composition constitutes a well-balanced representation of the parties which rely on and contribute to the European accreditation system:

<table>
<thead>
<tr>
<th>Conformity Assessment Bodies</th>
<th>Industry, Services and Trade</th>
<th>EU Member States' National Authorities</th>
<th>Consumer Associations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metrological Institutions</td>
<td>European Commission and EFTA</td>
<td>European Standardisation Organisations</td>
<td>EA Representatives</td>
</tr>
</tbody>
</table>
36 Full members

According to the EA Articles of Association, full members are accreditation bodies located in an EU/EFTA Member State or a candidate country.

13 Associate members

Associate members are accreditation bodies located in countries listed as potential candidate members to the EU or covered by the EU Neighbourhood policy.
EA Multilateral Agreement (EA MLA) is a signed agreement between the EA full members.

The signatories...

- recognise and accept the equivalence of the accreditation systems operated by the signing members,

- and the reliability of the conformity assessment results provided by conformity assessment bodies accredited by the signing members.
BENEFITS OF THE EA MLA

- The MLA creates **confidence** in, and acceptance of, accredited certifications, inspections and test reports.

- MLAs **eliminate the need** for suppliers to be certified in each **country** where they sell their products or services.

- The EA MLA provides a framework to realise the objective ‘Accredited once, accepted everywhere’.
EA Associate Members are eligible to enter into a **Bilateral Agreement (EA BLA)** with the EA signatories of the EA MLA with the aim of establishing mutual confidence in the respective accreditation systems and in their accredited attestations of conformity.

The **EA BLA** has the same purpose and bilateral signatories to the EA MLA shall comply with and meet the same requirements as EA Full Members.
The scope of the EA MLA covers the following activities and standards:

- **Testing** (ISO/IEC 17025)
- **Calibration** (ISO/IEC 17025)
- **Medical Laboratories** (ISO 15189)
- **Inspection** (ISO/IEC 17020)
- **Certification of management systems** (ISO/IEC 17021)
- **Certification of products, processes and services** (ISO/IEC 17065)
- **Certification of persons** (ISO/IEC 17024)
- **Verification of greenhouse gas emissions** (ISO 14065)
**EA MLA SIGNATORIES**

- **EA MLA** signatories: 35 full members
- **EA BLA** signatories: 4 associate members

(June 2016)

Full list of all MLA & BLA signatories and scopes on EA’s website:
http://www.european-accreditation.org/mla-and-bla-signatories
EA and its member accreditation bodies invest significant effort and resource to maintain the integrity and robustness of the EA MLA through a peer evaluation process.

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

- ISO/IEC 17011: internationally accepted standard for accreditation bodies
- Regulation (EC) No 765/2008
- The relevant standard for conformity assessment bodies including any additional requirements (e.g. by the EC)
EA MLA SIGNATORIES

- EA MLA signatories:
  35 Full members

- EA BLA signatories:
  4 Associate members

Full list of all MLA & BLA signatories and scopes on EA’s website:
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35 Full members are signatories of the EA MLA

Full Member signatories to the EA MLA 2016
Calibration 33
Testing 34
Inspection 32
Management Systems 30
Products 31
Persons 28
GHG Verification 25
4 Associate members are signatories of the EA BLA

<table>
<thead>
<tr>
<th>Associate Member signatories to the EA BLA</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration</td>
<td>4</td>
</tr>
<tr>
<td>Testing</td>
<td>4</td>
</tr>
<tr>
<td>Inspection</td>
<td>4</td>
</tr>
<tr>
<td>Management Systems</td>
<td>2</td>
</tr>
<tr>
<td>Products</td>
<td>1</td>
</tr>
<tr>
<td>Persons</td>
<td>1</td>
</tr>
<tr>
<td>GHG Verification</td>
<td>0</td>
</tr>
</tbody>
</table>
PTP MLA

- Several NABs have been already peer evaluated for PTP, others in progress
- The first NABs will sign the MLA for PTP April 2017
- EA has applied to ILAC to be peer evaluated to extend its status as recognized region to PTP
RMP MLA

- Peer evaluations for extension of scope to RMP accreditation will start to be planned in 2017, as part of the routine peer evaluations.

- Harmonisation training is planned to be organized next year under the EA Laboratory Committee auspices.
Peer Evaluations 2017 and 2018

- 18 PE planned for 2017
- 15 PE planned for 2018 plus PE for RMP
- Plus resources for ILAC/IAF
STATISTICS ON ACCREDITATION

- 3044 accreditations in Calibration
- 17859 accreditations in Testing laboratories
- 2966 accreditations in Medical laboratories (ISO 15189)
- 1606 accreditations in Product Certification
- 1218 accreditations in Management System Certification
- 433 accreditations in Certification of Persons
- 4948 accreditations in Inspection
- 160 accreditations in Proficiency Testing Providers
- 40 accreditations in Reference Material Producers
- 135 accreditations in EU ETS Verifications
EA is enhancing its communications with the European Commission:

- EA is attending every meeting on accreditation held by the Expert Group on the Internal Market for Products (IMP)

- EA is attending meetings of the EC Inter-Service Steering Group for Accreditation

- For certain specific projects, the EA is also collaborating directly with DGs Environment, Clima, Transport, Health and Consumer Protection Agriculture.
Breast Cancer Service – Project with the European Commission

- BCS scheme, based on a revision of the European Quality Assurance Guidelines for Breast Cancer Screening and Diagnosis, underpinned by accreditation in accordance with Regulation (EC) 765/2008.

- All aspects of BCS including diagnosis, surgery, treatment, nursing care and palliative care will be covered by the QA scheme.

- According the new project plan BCS project shall be concluded 2019.
Approximation of EU and RF Accreditation System

Project to approximate the accreditation systems of the Russian Federation and the European Union for the benefit of mutual recognition and trade, finalized 2015

The Accreditation for Notification project

Harmonization is one of the main missions of EA, which is e.g. defined by the phrase:

One specific conformity assessment, one level 3 standard to be used worldwide
Examples for 2016/2017

- EA – ERA Accreditation scheme for the Interoperability Directive in the Railway sector
- General Data Protection Regulation
- Ship Recycling Regulation
- EU – Environmental Technology Verification (ETV)
- Delegated regulation on the verification activities and accreditation of verifiers pursuant to Regulation (EU) 2015/757 on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport (MRV)
- The CETA Agreement
Framework Partnership Agreement 2018 – 2021

The negotiation on the FPA for 2018 – 2021 started mid 2016.

The differences with reference to the current FPA is an increase of expenditures because of extended activities in relation to peer evaluation, the implementation of the CETA agreement, the cooperation with the EC, the extension of tasks of the EA secretariat and others. It is assumed that the financial support financed by the EU and the membership fees will focus mainly on the EA secretariat and the peer evaluation team leaders. The calculated increase of the yearly budget is about 20%.
The new EA strategy 2025 has been endorsed at the EA GA on 24\textsuperscript{th}/25\textsuperscript{th} November 2015 in Boros, Sweden. The implementation plan has been discussed the last two days at the EA executive committee meeting and will be presented and further developed at the next EA GA in May in Bled, Slovenia.
While looking into the EA strategy 2025 it should be clear that EA is a membership organization that works for the benefit of its members and the common goals and tasks.

The technical work is mainly carried out by experts provided by the EA members with the administrative and technical support of the EA secretariat.

Especially the participants of the peer evaluation teams are provided by the EA members and FINAS has contributed to that task to a high extend during the existence of the system.
EA Strategy 2025

Purpose

“The aim of the project “EA Strategy 2025” is to define the objectives that describe what EA expects to achieve throughout the period 2017 – 2025 and what is EA’s vision.”

What will the new EA look like meeting 2025?
In-depth analysis: 10 Main areas investigated.

EA

**Mission**
Why we exist

**Harmonized**

- Organisation
- Internal work

- Core values

- Competence

- Members

- Stakeholders

- Funding

**Communication**

Market demands
NAB
CAB
Regulators
Standardization
Consumers

**Vision**

Peer evaluation
Mission
To ensure confidence in accredited conformity assessments results through harmonized operation of accreditation activities in support of European and global economies.

Vision
To be a reference in the world for accreditation that enables an open and global market for competitive business and providing reassurance to consumers in a sustainable society.
Desired position 2025, in broad terms – internal

- The EA secretariat is recourse to handle the daily operations of EA including technical assistance to committees.

Today the EA secretariat handles most of the administrative activities, finances, peer evaluation planning, the secretariats service to the committees, MAC, EX and GA and part of the direct communication with stakeholders, especially with the EC services in case new legislations are planned and might include conformity assessment requirements.

The members are involved to a different extent to all of these activities. It is planned to establish a more effective governance comprising of a small board of directors and additional technical resources in the EA secretariat.

The EA members would still be the main resource of technical competence but better served by the EA internal infrastructure.

- The decision-making capacity is high and lies in relevant part of the organization.
Desired position 2025, in broad terms – internal

- There are useful and ongoing exchanges of experience between the members. Members should work together in combined assessment teams as well as in technical WGs while developing application documents.
- Peer evaluations are performed and communicated in an extent to establish confidence in the marketplace. The peer evaluators should be supported by an EA staff member providing input on experiences already gathered and applications of rules and requirements.
- EA is financed in a well-balanced, stable and long term model comprising of EA members, EC, EFTA and other interested public parties without interfering with objectivity and impartiality. That means that the financing provided by external bodies should not exceed the contribution of the members. While implementing this strategy the cost will increase and the membership contribution in money will increase as well.
**Desired position 2025, in broad terms – internal**

- Results from CABs are clearly identifiable as being inside or outside the EA MLA.
  
  EA and its members shall clearly list the different schemes they offer accreditation for. Each EA member should keep a list of the schemes it covers and for the same scheme the same level 3 standard shall be used as basis for accreditation. The competence to execute assessments for a scheme should be defined as specific as necessary and assessors should be exchanged as needed to ensure the competence of assessment teams.

- The organization is harmonized and its members speaks with one voice.
  
  There should be measures in place which provides information to all members what specific issues are dealt with by the members and what solutions are developed to handle specific issues. A common understanding should be developed to enable a common position of all members even without consultation on a specific issue.
Desired position 2025, in broad terms - external

EA has good cooperation with stakeholders and other interested parties.

- Relevant partners and stakeholders contribute to and acknowledge that they are influencing the work in EA.
  
  EA members should take care that their stakeholders are covered within EA directly or indirectly. Each member shall make available to its stakeholder the information about developments in the accreditation arena, regional and international.

- A single global accreditation organisation exists aiming at developing international guidance documents and at harmonizing and coordinating the work between regions.
  
  Based on the fact that APLAC and PAC are going to form a unique regional accreditation bodies group it is the time to push ILAC and IAF to merge and form one single international accreditation organization. The members should support this idea at all levels, e.g. in relevant committees, at stakeholder discussions, etc.

- EA is considered as a good reference in accreditation by all the parties involved.
  
  EA and its members should provide information how they implement the requirements for accreditation and how they support the needs of stakeholders and the society.
Desired position 2025, in broad terms - external

EA proactively works with regulators and stakeholders in order to develop accreditation into new fields where assurance of conformity assessment activities is needed.

- EA and its delivery is communicated and well known by its partners and stakeholders and potential interested partners are identified and being informed and updated.
  
  It is the role of the members to distribute the information on a national level and explain the processes as needed to ensure that everybody is informed correctly.

- The EU Commission sees EA as the natural know-how point when developing new and existing areas that comprise attestation of competence and impartiality.

Besides the EA staff the members need to provide expertise to cover the needs for information of the EC.
Possible need to revise regulation 765/2008 EU

The definition of accreditation in the regulation restricts accreditation of conformity assessment bodies to be based on harmonized standards, it might be considered to broaden this definition to enable flexibility in the development of accreditation and conformity assessment schemes and not to loose the back up provided by accreditation.

Another issue might be a more clear mandate of EA implemented in regulation 765/2008 EU to define the rights and obligation of EA especially in relation to the peer evaluation process.
EA Values

- We are harmonized
- We are responsible
- We provide confidence
- We are competent
Thanks much for your attention

Questions?
EA Secretariat

75 avenue Parmentier
FR - 75544 Paris Cedex 11
France

Tel: + 33 (0)1 40 21 24 -62

Email: secretariat@european-accreditation.org

www.european-accreditation.org