The place of accreditation in Europe

The importance of accreditation of conformity assessment bodies has substantially increased over the last decades. Consumers, businesses, regulators and other organisations all over the world want to be able to trust and have confidence in the goods and services they buy and use. Consequently, there has been a growth in specified national and international requirements for products, processes and services.

Accreditation consists in:

• the formal demonstration of conformity assessment bodies’ (CABs) competence to carry out specific conformity assessment tasks (EN ISO/IEC 17000 series);
• the independent and authoritative attestation of the competence, impartiality and integrity of CABs;
• the elimination of technical barriers to trade and contributing to the protection of fundamental rights of people;
• the harmonization of accreditation rules and procedures at world-wide level.

The European Commission (EC) and the European Free Trade Association (EFTA) member states have recognized that accreditation is essential for the correct operation of a transparent and quality-oriented market and in order to safeguard a high level of protection of public interests, such as health and safety and protection of the environment.

Accreditation has further been strengthened following the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, to:

• provide a legal framework for the provision of accreditation services across Europe. Furthermore, Regulation (EC) No 765/2008 contains provisions for acceptance of certificates and reports issued by accredited conformity assessment bodies. Decision No 768/200/EC constitutes a general horizontal framework for future European legislation that harmonises the conditions for the marketing of products;
• cover the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by European legislation. It provides Commission Directorates with the legal basis to ensure confidence in the consistent and harmonised implementation of legislation across Europe based on accreditation;
• reinforce the existence of the EA Multilateral Agreement (EA MLA) by which national authorities in Member States can recognise - in accordance with article 11 (2) of Regulation (EC) No 765/2008 - the equivalence of accreditation services provided by peer evaluated national accreditation bodies and therefore the equivalence of reports and certificates issued by the conformity assessment bodies they have accredited.

This legal framework identifies EA as an important association with clearly defined responsibilities and obligations.

The formal relationship between EA and the European Commission is elaborated in a Framework Partnership Agreement that was signed initially by EA and the European Commission in 2010 for a 4-year period. It has been renewed since then regularly. The purpose of the FPA is to define the respective roles and responsibilities of the European Commission and EA in implementing their partnership. It further establishes the means for developing specific operating or action grant agreements. A similar FPA exists with EFTA.
European co-operation for Accreditation, the official guardian of the European accreditation infrastructure

The European co-operation for Accreditation (EA) is an association of national accreditation bodies in Europe, set up in 1997, that are officially recognised by their national Governments to assess and accredit - against international standards - organisations that carry out conformity assessment services such as certification, verification, inspection, testing and calibration.

For 20 years, EA has provided a framework for the mutual recognition of accredited conformity assessment results to promote development and transfer of knowledge, improve accreditation and conformity assessment activities in Europe and at a global level together with International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF).

Our mission:
Ensure confidence in accredited conformity assessment results through harmonized operation of accreditation activities in support of European and global economies.

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, three strategic objectives have been defined that translates EA Strategy 2025:

1. **Good governance** to deliver consistent and sustainable results;
2. **Close cooperation** with regulators and stakeholders to strengthen accreditation at the European and international levels;
3. **Continue to develop accreditation** to support innovation and growth in existing and new areas.

**CORE VALUES**

**WE ARE HARMONIZED**

By being transparent in our rules and actions
By being coordinated in word and deed
By being accessible both internally and externally
By having and promoting a common understanding of NABs promise to the market and society

**WE PROVIDE CONFIDENCE**

By establishing consistent deliverables
By being open, impartial and independent
By being non-discriminating
By practicing what we preach
By being democratic

**WE ARE RESPONSIBLE**

By involving and listening to regulators, industry and other stakeholders
By being loyal and dedicated and work for the public interest
By being proactive
By maintaining our integrity

**WE ARE COMPETENT**

By being efficient and professional
By using our resources
By exercising leadership
By supporting development and innovation
By continuously improving
### 2016 Key figures on Accreditation

<table>
<thead>
<tr>
<th>Accreditations delivered by EA Members</th>
<th>2016</th>
<th>2012</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration</td>
<td>3,245</td>
<td>2,369</td>
<td>37%</td>
</tr>
<tr>
<td>Testing</td>
<td>18,625</td>
<td>12,439</td>
<td>37%</td>
</tr>
<tr>
<td>Medical examinations</td>
<td>3,407</td>
<td>1,957</td>
<td>74%</td>
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<tr>
<td>Product certification</td>
<td>1,752</td>
<td>1,192</td>
<td>47%</td>
</tr>
<tr>
<td>Management System Certification</td>
<td>1,355</td>
<td>1,332</td>
<td>2%</td>
</tr>
<tr>
<td>Persons certification</td>
<td>480</td>
<td>359</td>
<td>34%</td>
</tr>
<tr>
<td>Inspection</td>
<td>5,158</td>
<td>4,742</td>
<td>9%</td>
</tr>
<tr>
<td>Proficiency Testing Providers</td>
<td>176</td>
<td>108</td>
<td>63%</td>
</tr>
<tr>
<td>Reference Materials Producers</td>
<td>44</td>
<td>25</td>
<td>76%</td>
</tr>
<tr>
<td>Validation and verification</td>
<td>133</td>
<td>57</td>
<td>133%</td>
</tr>
<tr>
<td>Eco-Management and Audit Scheme</td>
<td>79</td>
<td>75</td>
<td>5%</td>
</tr>
</tbody>
</table>

### International Cooperation & Recognition

Cooperation in the global accreditation system is through the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). EA operates as a Recognized Region in both associations and manages its peer evaluation system to qualify EA members to be signatories to the global Mutual Recognition Agreements (ILAC MRA/IAF MLA).

EA and its members are working actively in both associations to ensure that the European accreditation system is recognized at the global level and that the development of the international accreditation system as far as possible is in line with the accreditation policy adopted and implemented in Europe.

EA has also been developing relationships with a number of stakeholder organisations over the years, to establish confidence in accordance with Regulation (EC) No 765/2008. Parties interested in accreditation are invited to put their views forward to EA by participating in the EA technical committees and General Assembly meetings.
36 FULL MEMBERS
ALBANIA - Directorate of Accreditation (DPA)
AUSTRIA - Akkreditierung Austria (AA)
BELGIUM - Belgian Accreditation Council (BELAC)
BULGARIA - Executive Agency «Bulgarian Accreditation Service» (BAS)
CYPRUS - Cyprus Organization for the Promotion of Quality (CYS-CYSAB)
CZECH REPUBLIC - Czech Accreditation Institute (CAI)
DENMARK - Danish Accreditation (DANAK)
ESTONIA - Estonian Accreditation Centre (EAK)
FINLAND - Finnish Accreditation Service (FINAS)
FRANCE - Comité français d’accréditation (COFRAC)
GERMANY - Deutsche Akkreditierungsstelle GmbH (DAkkS)
GREECE - Hellenic Accreditation System (ESYD)
HUNGARY - National Accreditation Authority (NAH)
ICELAND - Icelandic Board for Technical Accreditation (ISAC)
IRELAND - Irish National Accreditation Board (INAB)
ITALY - Ente Italiano di Accreditamento (ACCREDIA)
LATVIA - Latvian National Accreditation Bureau (LATAK)
LITHUANIA - Lithuanian National Accreditation Bureau (LA)
LUXEMBURG - Office Luxembourgeois d’Accréditation et de Surveillance (OLAS)
MALTA - National Accreditation Board (NAB-Malta)
MONTENEGRO - Accreditation Body of Montenegro (ATCG)
NORWAY - Norsk akkreditering (NA)
POLAND - Polskie Centrum Akredytacji (PCA)
PORTUGAL - Instituto Português de Acreditação (IPAC)
REPUBLIC OF CROATIA - Croatian Accreditation Agency (HAA)
ROMANIA - Romanian Accreditation Association (RENAR)
SERBIA - Accreditation Body of Serbia (ATS)
SLOVAKIA - Slovak National Accreditation Service (SNAS)
SLOVENIA - Slovenska akreditacija (SA)
SPAIN - Entidad Nacional de Acreditación (ENAC)
SWEDEN - Swedish Board for Accreditation and Conformity Assessment (SWEDAC)
SWITZERLAND - Swiss Accreditation Service (SAS)
THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA - The Accreditation Institute of the former Yugoslav Republic of Macedonia (IARM)
THE NETHERLANDS - Raad voor Accreditatie (RVA)
TURKEY - Turkish Accreditation Agency (TURKAK)
UNITED KINGDOM - United Kingdom Accreditation Service (UKAS)

13 ASSOCIATE MEMBERS
ALGERIA - Organisme algérien d’accréditation (ALGERAC)
ARMENIA - Armenian National Accrediation Body (ARMNAB)
BELARUS - Belarusian State Centre for Accreditation (BSCA)
BOSNIA & HERZEGOVINA - Institute for Accreditation of Bosnia and Herzegovina (BATA)
EGYPT - Egyptian Accreditation Council (EGAC)
GEORGIA - Unified National Body on Accreditation - Accreditation Centre (GAC)
ISRAËL - Israel Laboratory Accreditation Authority (ISRAC)
JORDAN - Jordan Accreditation & Standardization Systems – Accreditation Unit (JAS-AU)
KOSOVO UNDER THE UNSC RESOLUTION 1244/1999 - Accreditation Directorate of Kosovo (DAK)
MOROCCO - Moroccan Accreditation Service (SEMAC)
REPUBLIC OF MOLDOVA - National Center of Accreditation of the Republic of Moldova (MOLDAC, former CAECP)
TUNISIA - Tunisian Accreditation Council (TUNAC)
UKRAINE - National Accreditation Agency of Ukraine (NAAU)
The EA Multilateral Agreement (EA MLA)

The EA MLA is an agreement signed between national accreditation bodies (NABs) – Full and Associate Members of EA – to recognise the equivalence, reliability and therefore acceptance by the European market, of certification, verification, inspection and calibration certificates and test reports issued by CABs. This agreement enables to recognise the equivalence of accreditation services provided by peer evaluated NABs and therefore the equivalence of reports and certificates issued by the CABs they have accredited. EA shall support and harmonize the implementation of rules in order to achieve consistency throughout Europe, as well as greater transparency and acceptability to all, including national authorities.

The peer evaluation process is further strengthened to accommodate the specific needs of regulatory fields and reinforce reassurance of sector based stakeholders and regulators that the accreditation bodies’ technical competence is thoroughly assessed. The purpose of on-site evaluations, every four years, is to verify the accreditation body signatories’ continuing compliance with the internationally agreed criteria for accreditation bodies.

EA and its member accreditation bodies invest significant efforts and resources to maintain the integrity and robustness of the EA MLA through this rigorous peer evaluation process, such as developing a new IT system to facilitate online exchanges for peer evaluation, monitoring of the process, and to strengthen interactions with major stakeholders such as the European Commission and all involved in peer evaluation. Moreover, the results of a survey made in 2016 give EA guidance for re-engineering EA’s peer evaluation system, guaranteeing continuous improvement of its processes.

It is important to note that EA also undergoes peer evaluation by ILAC/IAF every four years. As a result of the peer review of EA, ILAC and IAF have renewed their confidence in EA and its members in October 2016 by deciding to maintain EA in their MLA/MRA respectively for testing, medical testing, calibration, inspection, management systems, products certification, and certification of persons.

More information about the EA MLA is available on the EA website: www.european-accreditation.org/the-mla
2016 EA MLA KEY FIGURES

38 members signatories to the MLA
(34 Full Members and 4 Associate Members through a bilateral agreement with EA out of a total of 36 Full Members and 13 Associate Members)

101 assigned peer evaluator team members and 12 trainees

19 peer evaluations (PE) performed for a total of 1138 man-days provided by EA NABs

34 MAC Members appointed in the Task Force Groups for the review of PE reports

9 MAC Management Group members in addition to the MAC Chair and Vice Chair

More than 34,450 accreditations delivered by EA MLA signatories at end 2016
EA’s cooperation with the European Commission and the European Free Trade Association

As the European guardian of accreditation in Europe, EA maintains close relationships with several Directorates-General (DGs) and services or agencies of the European Commission, notably with:

- **DG Internal Market, Industry, Entrepreneurship and SMEs (GROW)**
  Discussions regarding the Comprehensive Economic and Trade Agreement (CETA) that includes a Protocol on the Mutual Acceptance of the Results of Conformity Assessment.

- **DG Environment (ENV)**

- **DG Climate Action (CLIMA)**
  Discussions on Delegated Act regarding Regulation on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport. Discussions to implement accreditation and the National Accreditation Bodies (NABs)’ peer-evaluation according to EN ISO 14065 and Commission Regulation (EU) N° 600/2012 for EU emissions trading system (EU ETS).

- **DG Mobility and Transport (MOVE)**
  Discussions about Railway sector and Interoperability of the railway system within the Community, elaboration of an accreditation scheme for railways Notifies Bodies under the auspices of the European Railway Agency (ERA).

- **DG Justice (JUST)**
  Discussions on General Data Protection Regulation.

- **Joint Research Centre (JRC) - European Commission Initiative on Breast Cancer – ECIBC.**
  EA/ JRC joint project on the development of an European quality assurance scheme for breast cancer services.

- **EGNOS (European Geostationary Navigation Overlay Service).**
  Discussions and technical support to DG GROW for the elaboration of an accreditation scheme.

Furthermore, EA attends every meeting on accreditation held by the Senior Officials Group for the Expert Group on the Internal Market for Product (IMP), plus meetings of the EC Inter-Service Steering Group for Accreditation. EA also offers workshops for EC DGs officers to raise awareness on accreditation as a tool for regulation.

In addition to issues regarding European accreditation policy and according to Article 13 of Regulation (EC) No 765/2008, the cooperation also includes development of new services and maintenance of existing services supporting the implementation of Community and national legislation. EA and the NABs contribute to the development of Community legislation and to evaluate how technical requirements in proposed legislation can be assessed within the European accreditation system.

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**Increase confidence in notified bodies.**

Accreditation under Regulation (EC) No 765/2008, performed by nationally recognised accreditation bodies that are EA members, is the technical assessment of the competence of the conformity assessment body seeking notification. It is an important instrument for evaluating the competence and integrity of the bodies to be notified. For this reason, accreditation should be considered by national notifying authorities as the preferred route providing the most appropriate technical basis for notification. Used widely in Europe and supported by a strong, recognized MLA, accreditation helps to reduce differences and ensure harmonization in the criteria applied for notification and, subsequently, results issued by notified bodies.

Accreditation gives an authoritative statement of the competence, professional integrity and impartiality of the bodies to be notified to the European Commission and the other Member States. When used for notification, accreditation reduces the administrative burden for CABs and industry operating on the single market. Regulation 765/2008, as the legal framework for the European quality infrastructure, enhances public control over accreditation so that it has become an essential tool for the functioning of the internal market.
Partnership with Standards Council of Canada on the Comprehensive Economic and Trade Agreement

Signed at the EU-Canada Summit on 30th October 2016, the Comprehensive Economic and Trade Agreement (CETA) is a trade agreement, designed to strengthen economic relations and develop business between the European Union and Canada.

CETA includes a Protocol on the Mutual Acceptance of the Results of Conformity Assessment (the CA Protocol). With this Protocol, the EU and Canada have agreed to accept each other’s conformity assessment certificates in areas such as electrical goods, electronic and radio equipment, toys, machinery or measuring equipment. To facilitate the development of more compatible regulatory measures and benefit Canadian and European industries generally a Bilateral Cooperation Agreement (BCA) between EA and the Standards Council of Canada (SCC) was signed. This agreement establishes the terms, conditions and procedures of cooperation to technically support the activities aimed at mutual recognition of accreditation bodies and designation of accredited conformity assessment bodies operating in EU and Canada.

The BCA covers inter alia:
• exchange of relevant information on matters regarding the CA Protocol, including standards, technical regulations and conformity assessment procedures, as well as information on application and interpretation of criteria for the assessment of conformity assessment bodies;
• exchange of experts for on-site assessments to conformity assessment bodies; mutual information on progress of work related to activities and the development in the cooperation.

The implementation of the BCA between EA and SCC started with the selection of a first pilot project, based on the ATEX/HAZLOC systems (equipment allowed in explosive atmosphere) as ATEX is very similar to HAZLOC in Canada. The work to be done is to identify the technical issues and their consequences in terms of assessment by the accreditation body.

A first set of concrete measures were taken to enable:
• Exchange of relevant information, notably regarding the applicable standards, technical regulations and conformity assessment procedures,
• Setting up of an assessor pool,
• Assessment of a Canadian conformity assessment body by SCC for European legislation, together with an EA expert as observer or assessor,
• Assessment of a European conformity assessment body by an EA National Accreditation Bodies (COFRAC) for Canadian legislation, together with a SCC expert as observer or assessor

At the end, this agreement will ensure that accreditation of conformity assessment bodies will be considered and used in the EU and Canada on the same basis. It will build confidence between their respective accreditation systems, for the benefits of regulators, governments, businesses, citizens and consumers.

John Walter, SCC Chief Executive Officer, with Andreas Steinhorst, EA Executive Secretary, signing the SCC-EA bilateral cooperation agreement.
CONTACT

The EA Executive Secretary is the focal point for relation with the EC and EFTA. He is responsible for coordinating discussions and works for the development of accredited schemes supporting Community legislation.

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