

# The European co-operation for Accreditation

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**WHO WE ARE**



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# The European co-operation for Accreditation

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## 1. ABOUT EA



# 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 (CABs)**.
- **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**.

# ABOUT EA – BASIC FACTS

- **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 EU/EFTA Member States
- **13 associate members**
- **34 full members** are signatory to the EA MLA
- **5 Associate members** are signatory to the MLA through a bilateral agreement with EA
- Permanent **EA-Secretariat** of 8 persons

# ABOUT EA – EA'S MISSION (1)

**The EA Strategy 2025, adopted at the EA General Assembly in November 2016 and implemented as from 2017, defines EA's mission as follows :**

*“To ensure confidence in accredited conformity assessments results through harmonized operation of accreditation activities in support of European and global economies”.*

# ABOUT EA – EA'S MISSION (2)

- 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;

# ABOUT EA – EA'S MISSION (3)

- **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**;



# ABOUT EA – EA'S VISION

- The **EA Strategy 2025** defines EA's vision as being *“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”*.
- To achieve EA's vision, **3 strategic objectives** are set out in the Strategy:
  - good governance to deliver consistent and sustainable results;
  - close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level;
  - continue to develop accreditation to support innovation and growth in existing and new areas.

# EA'S 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 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 provide confidence**

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

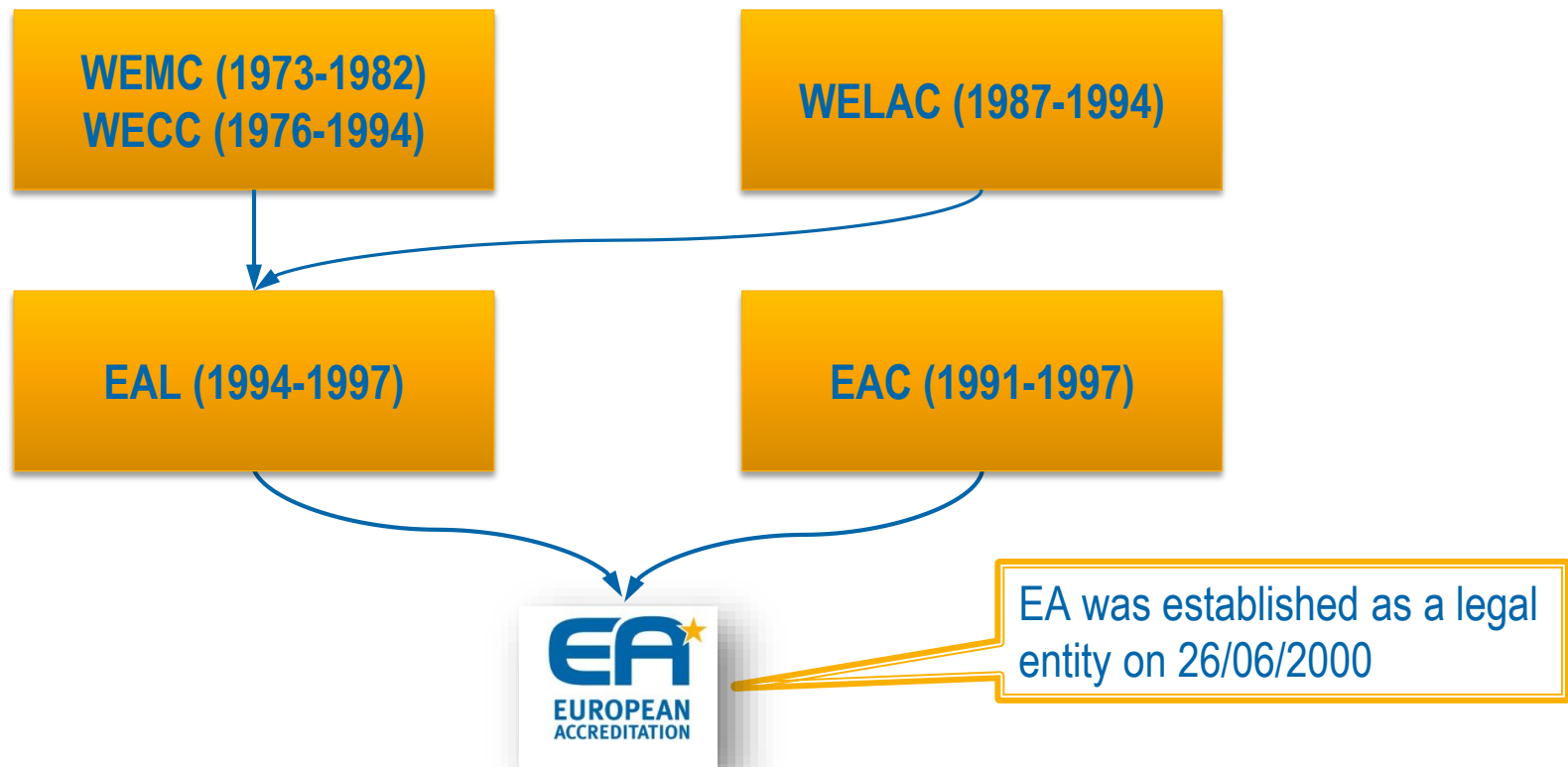
## **We are competent**

- By being efficient and professional
- By using our resources
- By exercising leadership
- By supporting development and innovation
- By continuously improving

*EA's core values are developed out of EA's mission and vision, highlighting the expected behaviours and skills on which all work of EA is based. The core values support the implementation of the strategy and the basis of EA, enabling the membership organization to speak with one voice and to reach the desired position 2025.*

# ORIGINS OF EA

EA was created in 1997 but its origins extend back further



# The European co-operation for Accreditation

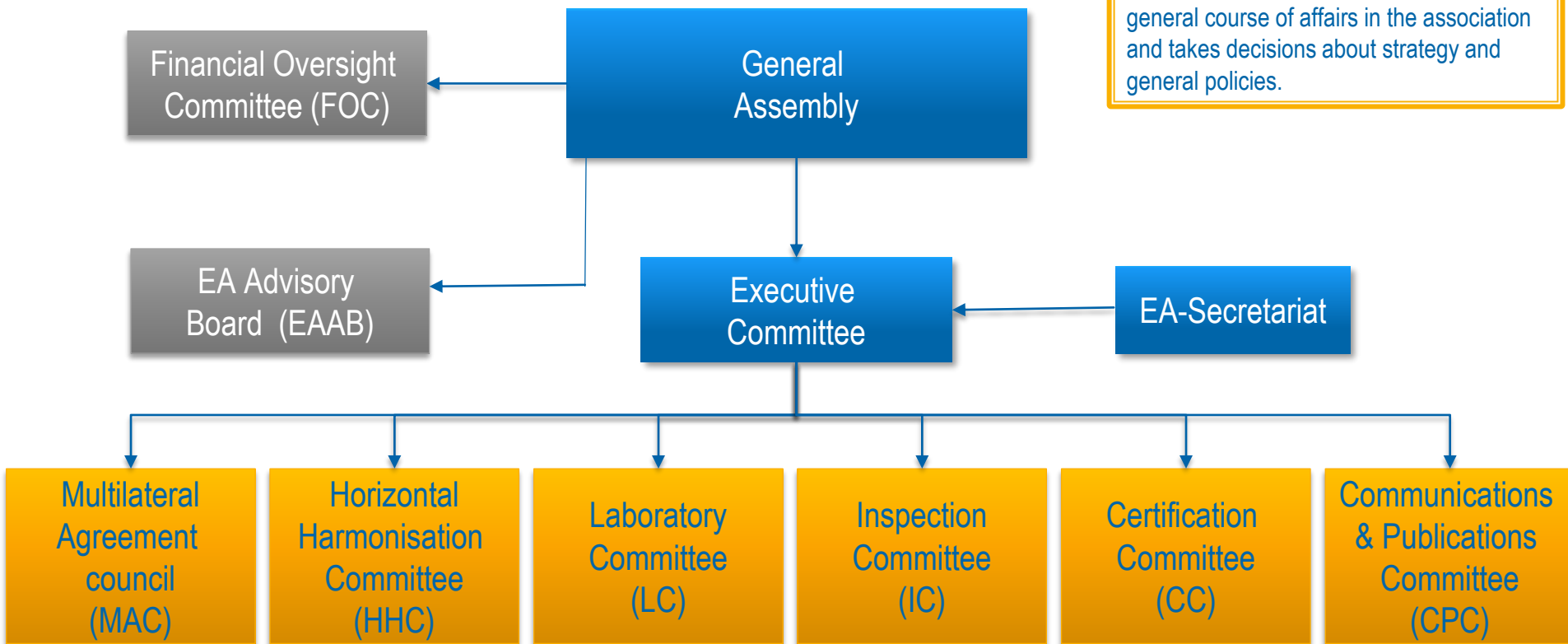
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## 2 . EA ORGANISATIONAL STRUCTURE



# EA ORGANISATIONAL STRUCTURE

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 about strategy and general policies.



# EA EXECUTIVE COMMITTEE (EA EX)

- EA EX is responsible for implementing EA policies and managing the association.
- Members of the EA Executive Committee (Mandate starting on the 1st January 2016)



# EA Advisory Board (EAAB) - 1

- 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
  - the relevant provisions of the “General Guidelines for Co-operation between EA and the EC, EFTA and the competent national authorities”.

# EA ADVISORY BOARD (EAAB) - 2

- The EAAB composition constitutes a **well-balanced representation** of the parties which rely on and contribute to the European accreditation system:

Conformity  
Assessment  
Bodies

Industry, Services  
and Trade

EU Member  
States' National  
Authorities

Consumer  
Associations

Metrological  
Institutions

European  
Commission and  
EFTA

European  
Standardisation  
Organisations

EA  
Representatives



# EA SECRETARIAT



# EA ORGANISATIONAL STRUCTURE



Learn more about the structure  
of EA on our website:  
[http://www.european-  
accreditation.org/structure](http://www.european-accreditation.org/structure)

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## 3 . THE EA MULTILATERAL AGREEMENT (EA MLA)



# EA MULTILATERAL AGREEMENT (EA MLA)

- 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 provides a framework to realise the objective '**Accredited once, accepted everywhere**'.
- The **MLA** creates **confidence** in, and acceptance of, accredited certifications, inspections and test reports
- The MLA **eliminates the need** for suppliers **to be certified in each country** where they sell their products or services

# EA BILATERAL AGREEMENT (EA BLA)

- EA Associate Members can 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.

# SCOPE OF THE EA MLA

- The scope of the EA MLA covers the following **activities (level 2)** and **standards (level 3)**:

**Testing**  
(ISO/IEC 17025)

**Calibration**  
(ISO/IEC 17025)

**Medical  
Laboratories**  
(ISO 15189)

**Inspection**  
(ISO/IEC 17020)

**Certification of  
products,  
processes and  
services**  
(ISO/IEC 17065)

**Certification of  
persons**  
(ISO/IEC 17024)

**Validation and  
verification**  
(ISO 14065)

**Certification of  
management  
systems**  
(ISO/IEC 17021)

**Proficiency  
Testing  
Providers**  
(ISO/IEC 17043)

# STATISTICS ON ACCREDITATION

## AT 31.12.2016 - 1

- **3253** accreditations in Calibration
- **18733** accreditations in Testing laboratories
- **3410** accreditations in Medical laboratories (ISO 15189)
- **1742** accreditations in Product Certification
- **1365** accreditations in Management System Certification
- **484** accreditations in Certification of Persons
- **5204** accreditations in Inspection



# STATISTICS ON ACCREDITATION

## AT 31.12.2016 - 2

- **176** accreditations in Proficiency Testing Providers
- **44** accreditations in Reference Material Producers
- **133** accreditations in EU ETS Verifications
- **79** accreditations in EMAS Regulation
- **181** accreditations in Quality Management System for Medical Devices
- **196** accreditations for Information Security Management System (ISMS)
- **231** accreditations for Food Safety Management System (FSMS)

# SEARCH FACILITY

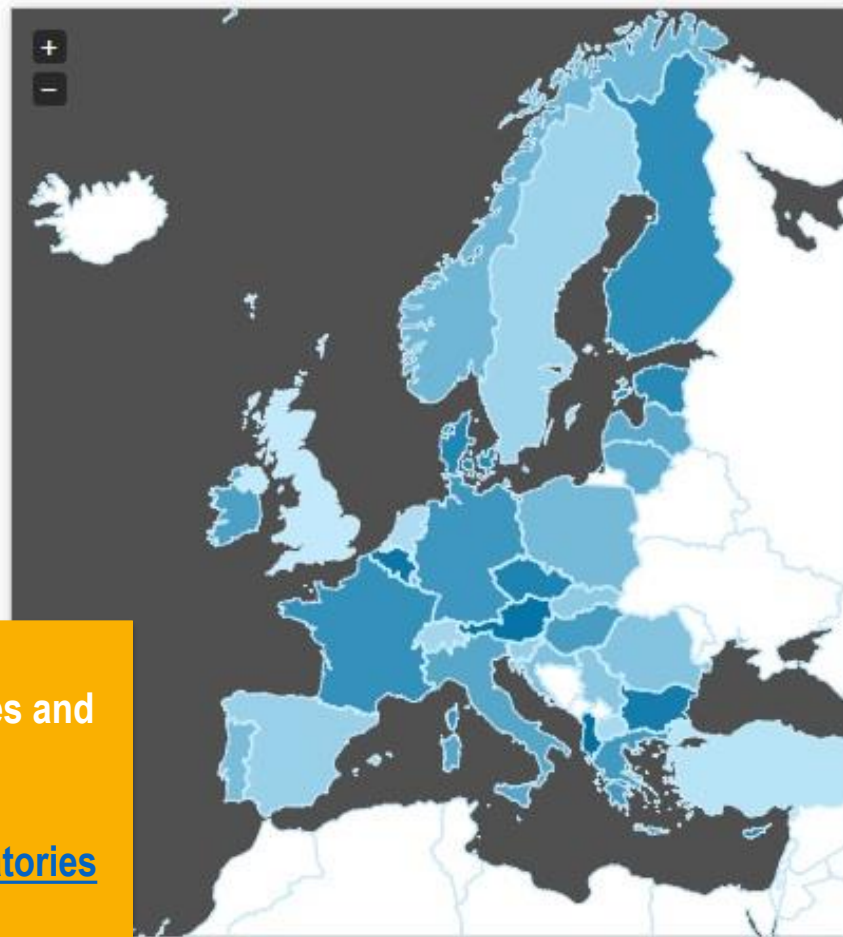
- A search system enables everyone to seek out information about accredited conformity assessment bodies (CABs) directly on the websites of EA Members.
- It is available from the EA webpage listing **“MLA & BLA Signatories”**: customers to CABs or third parties can click on “(search)” near the conformity assessment activity for which they would like to find a CAB accredited by one given NAB in one given country to have direct access to the NAB’s database of accredited CABs.
- A similar system gives access to data on accredited EN ISO 14065 verifiers directly from **“Quick Links”** on the EA homepage.

# EA MLA SIGNATORIES AT OCTOBER 2017

- 34 EA MLA signatories
- 5 EA BLA signatories
  - Bosnia & Herzegovina : BATA
  - Georgia : GAC
  - Israël : ISRAC
  - Tunisia : TUNAC
  - Ukraine : NAAU

Full list of all MLA & BLA signatories and  
scopes on EA's website:

[http://www.european-  
accreditation.org/mla-and-bla-signatories](http://www.european-accreditation.org/mla-and-bla-signatories)



# EA PEER EVALUATION SYSTEM

- 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**

**Relevant standards for  
conformity assessment  
bodies** including any  
additional requirements  
(e.g. by the EC)

# EA PEER EVALUATION SYSTEM

Learn more about the  
process of EA's Peer Evaluation:  
<http://www.european-accreditation.org/peer-evaluation-process>

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## 4 . EA IN THE GLOBAL NETWORK



# INTERNATIONAL NETWORK

- **EA members** may also be members of the two organisations with worldwide representation:



- **ILAC**  
International Laboratory Accreditation Cooperation



- **IAF**  
International Accreditation Forum

- EA is a **recognised region in ILAC and IAF** and a signatory to their mutual arrangements

# INTERNATIONAL NETWORK AT SEPTEMBER 2017



ILAC

- 94 AB Full Members (signatories to the ILAC MRA)
- 16 AB Associate Members
- 12 AB Affiliate Members
- 3 Recognised Regional Cooperation Bodies (EA, APLAC, IAAC)
- 3 Regional Cooperation Bodies (ARAC, AFRAC, SADCA)
- 26 Stakeholder Members



IAF

- 81 AB Members and 66 MLA signatories
- 20 Associate Members
- 3 Recognised Regional Accreditation Groups (EA, IAAC, PAC)
- 3 Regional Accreditation Groups (AFRAC, ARAC, SADCA)
- 1 Observer Organisation



# ILAC AND IAF MULTILATERAL AGREEMENTS

- EA MLA signatories and the accreditations they grant are **internationally recognised** through the **ILAC and IAF Multilateral Agreements**. The MLA/MRA marks can be used to demonstrate international recognition.



Find more information on  
IAF/ILAC Recognition  
on EA's website:  
<http://www.european-accreditation.org/iaf-and-ilac>

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## 5 . EA'S ROLE IN EUROPE



# EA'S ROLE IN EUROPE

- 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.
- EA's role in **supporting** the effective operation of the **Single Market** is recognised by
  - **Regulation (EC) No 765/2008**
  - the **General Guidelines** for cooperation
  - the **Framework Partnership Agreement** signed with the European Commission and EFTA.

# EA AS THE EUROPEAN ACCREDITATION INFRASTRUCTURE

- EA has been **formally appointed** as the body responsible for the European accreditation infrastructure in Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, Article 14, paragraph 6.

# EA AS THE EUROPEAN ACCREDITATION INFRASTRUCTURE

- 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:

## General Guidelines

- **General Guidelines** for the Cooperation between the European cooperation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities.

## Framework Partnership Agreements (FPA)

- 4-year FPA sets out the financial obligations and conditions between the EC and EA.
- provide for annual operational grants and specific action grants based on EA's annual work programmes to be approved by the EC every year.

# REGULATION (EC) NO 765/2008

- Regulation (EC) No 765/2008 provides a **legal framework** for the provision of accreditation services across Europe
- The Regulation
  - strengthens EA's role in both **voluntary and regulated sectors**
  - places an **obligation** on EU Member States **to accept results** issued by the conformity assessment bodies accredited by any of the EA MLA signatories
  - strengthens the use of accreditation and the EA MLA as a **basis for notification**

# 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

# COMMUNICATIONS WITH THE EUROPEAN COMMISSION

- EA is enhancing its communications with the European Commission:
  - EA is attending every meeting on accreditation held by the Senior Officials Group for the **Expert Group on the Internal Market for Product (IMP)**
  - EA is attending meetings of the **EC Inter-Service Steering Group** for Accreditation
  - DG GROW is EA major contact in the European Commission
  - For certain specific projects, the EA is also collaborating directly with **DGs** Environment, Climate Action, Transport, Health and Food Safety, Agriculture.
  - EA offers workshops for EC DGs officers to raise awareness on accreditation as a tool for regulation.



# PARTNERSHIP ON THE CETA

- 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)**. This Protocol provides mutual recognition of European and Canadian ABs and CABs results based on acceptance of each other's accredited certificates.

# PARTNERSHIP ON THE CETA

- To support implementation of the Protocol, a **Bilateral Cooperation Agreement (BCA)** between the **European co-operation for Accreditation (EA)** and the **Standards Council of Canada (SCC)** was signed on 10<sup>th</sup> June 2016.



# PARTNERSHIP ON THE CETA

- **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.

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## 6. BENEFITS OF ACCREDITATION



# WHAT IS ACCREDITATION ?

- The **accreditation process** determines the technical competence and integrity of organisations that offer testing, examination, verification, inspection, calibration and certification services (collectively known as **conformity assessment**).
- Accreditation operates in the **public interest** across all market sectors, providing a **transparent and impartial assessment** of these services against internationally recognised standards and other national or sectoral requirements.

# GENERAL BENEFITS OF ACCREDITATION

## Delivers Public Confidence

- Despite a complex global marketplace, accreditation gives us confidence through ensuring consistently high standards in the quality of products or services purchased.

## Minimises product failure or recalls

- Product testing carried out by a reliable independent organisation will minimise products failing or potential recalls.

## Facilitates cross border trade

- Accreditation is of major importance for the development of Europe's internal market, as this facilitates cross border trade and eliminates barriers to trade

# BENEFITS FOR BUSINESSES

- **accurate** calibration, measurement and testing, performed in accordance with best practice, can
  - limit errors and product failure,
  - control production costs and
  - contribute to an innovative environment.
- **essential tool** for decision-making, risk management and supplier selection
- provides a **competitive advantage** in domestic markets through access to public sector contracts, and also overseas with greater acceptance in export markets

# BENEFITS FOR GOVERNMENTS AND REGULATORS

## Accreditation...

- is the preferred **mechanism for identifying competent bodies** to implement government policies and regulations aimed at safeguarding the public and building public confidence in activities that impact on such fields as health, welfare, security, the environment, education, and financial services
- delivers a multi-discipline solution that can be applied to support or act as an **alternative to legislation**.



EA Brochure – Accreditation, a tool to support regulators



# BENEFITS FOR CONSUMERS

## Accreditation...

- helps to increase access to goods and services of **consistent and reliable quality and safety**
- increases confidence in certificated products and services, tests, examinations and measurements.

# EUROPEAN CO-OPERATION FOR ACCREDITATION

**You want to learn more about EA and  
accreditation?  
Visit our website and check our promotional  
materials:**

**[http://www.european-  
accreditation.org/promotional-information](http://www.european-accreditation.org/promotional-information)**

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