



ACCREDITATION

A BRIEFING FOR EUROPEAN COMMISSION OFFICIALS

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;
- 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 a worldwide 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 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 the acceptance of certificates and reports issued by accredited conformity assessment bodies. Decision No 768/2008/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 shall recognise - in accordance with article 11 (2) of Regulation (EC) No 765/2008 - the equivalence of accreditation services provided by EA peer-evaluated national accreditation bodies and therefore accept 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 4 years. 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 operations or action grant agreements. A similar FPA exists with EFTA.

EA's cooperation with the European Commission and the European Free Trade Association

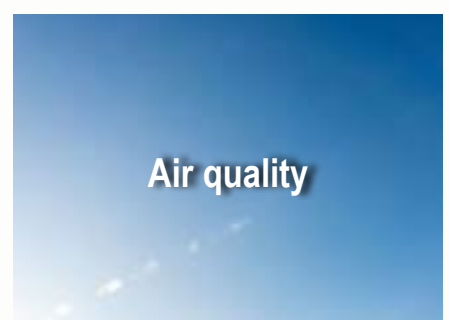
The cooperation between EA and the European Commission, EFTA and the competent national authorities is set out in the guidelines published in the Official Journal of the EU.

According to these guidelines the European Commission, EFTA and the competent national authorities consult and cooperate with EA on, and involve EA in, technical matters related to the uniform implementation and operation of Community legislation and policy in the field of conformity assessment and to accreditation, in particular in view of promoting a harmonised, consistent and credible application of relevant standards in relation to Community policy and legislation. Hence, EA maintains close relationships with several Directorates-General (DGs) and services or agencies of the European Commission, notably with and in regard to (examples):

DG Agriculture and Rural Development (AGRI)



DG Climate Action (CLIMA)



DG Communications Networks, Content and Technology (CONNECT) / EU Agency for Cybersecurity (ENISA)



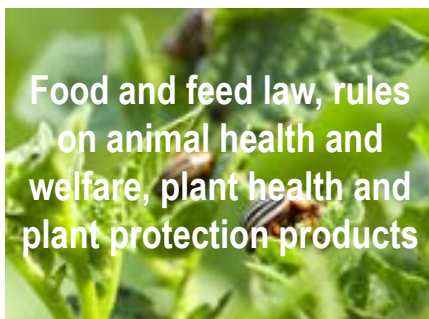
DG Energy (ENER)



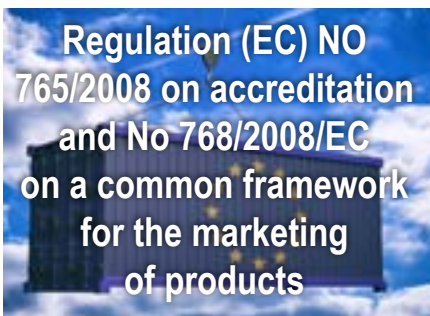
DG Environment (ENV)



DG Health and Food Safety (SANTE) / Joint Research Centre (JRC)



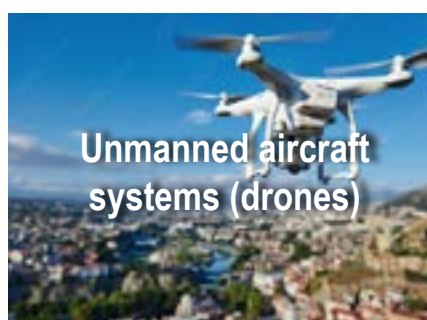
DG Internal Market, Industry, Entrepreneurship and SMEs (GROW)



DG Justice and Consumers (JUST)



DG Mobility and Transport (MOVE) / EU Agency for Railways (ERA)



There are more than 100 EU legislations, which take recourse to accreditation and conformity assessment (see EA-INF/05 on EA's website <https://european-accreditation.org/information-center/ea-publications/>).

Increase confidence in notified bodies

According to Regulation (EC) No 765/2008 accreditation means an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity. 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 industries operating in the single market for goods. Regulation 765/2008, as the legal framework for the European accreditation infrastructure, enhances public control over accreditation so that it has become an essential tool for the functioning of the internal market.

Accreditation, an important instrument for reducing technical barriers to trade

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.

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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 and electronic equipment, toys, construction products, machinery, or measuring equipment. To facilitate the implementation of the CETA CA Protocol, 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 aimed at mutual recognition of national accreditation bodies and accredited conformity assessment bodies operating in the EU and Canada.

In 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 in their respective accreditation systems, for the benefit of regulators, governments, businesses, citizens, and consumers.



Chantal Guay, SCC Chief Executive Officer, with Andreas Steinhorst, EA Executive Secretary, renewing the SCC-EA bilateral cooperation agreement.

European co-operation for Accreditation, the official guardian of the European accreditation infrastructure

The European co-operation for Accreditation (EA) is the association of national accreditation bodies in Europe. It is recognised by the European Commission as the European Accreditation Infrastructure.

EA has 49 members. Each of them is the sole national accreditation body in its country. The EA national accreditation bodies come from:

- EU / EFTA member states,
- Candidate countries to the EU,
- Member states of the Council of Europe,
- Countries covered in the EU Neighbourhood Policy.

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



The EA Multilateral Agreement (EA MLA)

The EA MLA is an agreement signed between national accreditation bodies (NABs) 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 successfully 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 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 the reassurance of sector-based stakeholders and regulators that the national accreditation bodies' technical competence is thoroughly assessed. The purpose of on-site evaluations, every four years, is to verify that the national accreditation bodies continuing compliance with the requirements set out in Regulation (EC) No 765/2008 and the harmonised standards for accreditation.

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 several 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. Currently, EA cooperates with around 40 European Organisations - so-called recognised stakeholders - relevant for the European Quality Infrastructure.



Accreditation **Inspection** **Testing** **International**
Notification **Standards** **Confidence** **Competence** **Verification**
Cross border trade **Calibration** **National Accreditation Bodies**



49 NAB MEMBERS

ALBANIA - Directorate of Accreditation (DPA)

ALGERIA - Organisme algérien d'accréditation (ALGERAC)

ARMENIA - Armenian National Accreditation Body (ARMNAB)

AUSTRIA - Akkreditierung Austria (AA)

AZERBAIJAN - Azerbaijan Accreditation Centre (AzAK)

BELGIUM - Belgian Accreditation Council (BELAC)

BOSNIA & HERZEGOVINA - Institute for Accreditation of Bosnia and Herzegovina (BATA)

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)

EGYPT - Egyptian Accreditation Council (EGAC)

FINLAND - Finnish Accreditation Service (FINAS)

FRANCE - Comité français d'accréditation (COFRAC)

GEORGIA - Unified National Body on Accreditation - Accreditation Centre (GAC)

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)

ISRAEL - 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)

ITALY - Ente Italiano di Accreditamento (ACCREDIA)

LATVIA - Latvian National Accreditation Bureau (LATAK)

LITHUANIA - Lithuanian National Accreditation Bureau (LA)

LUXEMBURG - Office Luxembourgeois d'Accreditation 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)

REPUBLIC OF MOLDOVA - National Center of Accreditation of the Republic of Moldova (MOLDAC, former CAECP)

ROMANIA - Romanian Accreditation Association (RENAR)

SAN MARINO - San Marino Accreditation Service (SMAS)

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)

REPUBLIC OF NORTH MACEDONIA - Institute for Accreditation of the Republic of North Macedonia (IARNM)

THE NETHERLANDS - Raad voor Accreditatie (RVA)

TUNISIA - Tunisian Accreditation Council (TUNAC)

TURKEY - Turkish Accreditation Agency (TURKAK)

UKRAINE - National Accreditation Agency of Ukraine (NAAU)

UNITED KINGDOM - United Kingdom Accreditation Service (UKAS)



CONTACT

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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