

**GENERAL GUIDELINES FOR THE COOPERATION BETWEEN THE EUROPEAN CO-OPERATION
FOR ACCREDITATION AND THE EUROPEAN COMMISSION, THE EUROPEAN FREE TRADE
ASSOCIATION AND THE COMPETENT NATIONAL AUTHORITIES**

(2009/C 116/04)

1. GENERAL

The Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (hereinafter referred to as 'the Regulation on accreditation') enshrines the Community policy in the area of accreditation. It introduces a comprehensive legal framework for accreditation which lays down at Community level the principles for its operation and organisation. It imposes obligations on national accreditation bodies, Member States and the European Commission and sets out the respective responsibilities as well as the co-ordinating role of the European co-operation for Accreditation (EA).

The present guidelines embody the policy commitment of EA, of the European Commission, of the European Free trade Association (EFTA) and of the competent national authorities. They are intended to widen and strengthen the co-operation in order to reflect the developments in policy and legislation, such as the adoption of the Regulation on accreditation, and to stabilise the position of accreditation, accreditation bodies in EU and EFTA Member States and EA with the view to prepare a successful implementation of the said Regulation. The present guidelines do not in any way introduce legal or financial obligations or conditions. These are set out in Regulation (EC) No 765/2008 and in the Framework partnership agreement between the European Commission and EA.

These guidelines should make possible a smooth transition to the new environment which is to be created following the adoption of the Regulation on accreditation. Its adoption was triggered by the lack of a common legal basis for accreditation, leading to different approaches and differing systems causing an uneven level of rigour throughout EU/EFTA Member States. The proposal, the adoption of which was also encouraged by Council Resolution of 10 November 2003 on the Communication of the European Commission 'Enhancing the Implementation of the New Approach Directives', should result in the development of a comprehensive framework for accreditation ensuring increasing coherence, transparency and co-operation of accreditation services within the EU and EFTA.

The European co-operation for Accreditation (EA) on one side and the European Commission, the European Free Trade Association (EFTA) and the competent national authorities on the other side, confirm that accreditation is an independent and authoritative attestation, delivered by accreditation bodies, of the competence, impartiality and professional integrity of conformity assessment bodies (CABs) and, therefore, of the value and credibility of the testing and inspection reports, calibration certificates, management system, product and personnel certificates and other attestations issued according to harmonized standards.

EA, the European Commission, EFTA and the competent national authorities acknowledge that accreditation serves as a credential for bodies operating at the conformity assessment level and is therefore a means of building confidence for their users. It thereby contributes to strengthening mutual confidence between Member States in the competence of conformity assessment bodies and consequently in the attestations of conformity issued by them. Accreditation ensures that bodies involved in conformity assessment activities possess the required competences and is thus fundamental for achieving a more consistent level of performance.

EA, the European Commission, EFTA and the competent national authorities recognise that accreditation has an effect on a number of areas of public concern, such as health and safety, the environment, the competitiveness of industry and others. It contributes to the safety of the market place and thus ensures confidence of users in the European market place which is crucial for the proper functioning of the Internal Market. Accreditation has been used as a tool for recognition of technical competence in various areas: environmental management systems, eco-management and audit schemes (EMAS) and testing in food analysis are among the examples. Accreditation can play an important role in public policy and can serve as a vital tool to support legislation and in particular to support the process of notification of conformity assessment bodies in the Member States in the frame of EU New Approach Directives. Accreditation thereby provides the means to ensure that all notified bodies operate to the same standards.

EA, the European Commission, EFTA and the competent national authorities acknowledge that in order for accreditation to have added value as an authoritative level of control, it needs to be performed as a public authority activity, to be carried out in full compliance with the applicable, evolving technical requirements, in conditions of independence and accountability towards all the interested parties, with no single interest predominating, free from commercial pressure and without competition between accreditation bodies and conformity assessment bodies as well as among accreditation bodies themselves, both in the regulated and non-regulated (market driven) areas for conformity assessment.

EA, the European Commission, EFTA and competent national authorities recognise that the effectiveness of accreditation services in the conformity assessment field is correlated to the consistency of the European accreditation model regardless the policy area. The model shall be built on common principles and implemented uniformly across the EEA through harmonised technical criteria specifically adapted to the policy sector and instrument.

These guidelines aim at building on the relations established under the Memorandum of Understanding concerning co-operation between the Commission of the European Communities and the European co-operation for Accreditation in the field of conformity assessment signed in 1999 as well as the Cooperation Arrangement between the Joint Research Centre, which is a Directorate General of the European Commission, and the European Co-operation for Accreditation concerning the demonstration of reliability and comparability of chemical measurements signed in 2005.

Since the situation regarding accreditation has evolved over the passed years, EA, the European Commission, EFTA and the competent national authorities agree that these guidelines should constitute an update in relation to the abovementioned existing cooperation documents in order to take account of this evolution.

2. THE EVOLUTION OF EUROPEAN ACCREDITATION

EA, the European Commission and EFTA consider that these guidelines should take into consideration the following elements:

- accreditation is by its nature a public authority activity. This very nature has been substantiated by various kinds of links to the national Governments without changing, however, the basic public authority character and responsibility of accreditation. Over the last years it has become evident that it is necessary to strengthen the public authority aspect of accreditation and consolidate the position of accreditation bodies in EU/EFTA Member States and their relationship with the relevant national authorities,
- the public authority relationship at the national level is established by different legal solutions in the case of each accreditation body. The regimes are different as are the degrees of responsibility and the extent of the mandates received. Nowadays it is clear that accreditation bodies should enjoy a status whereby they can be considered to exercise public authority,
- since the 1970s when accreditation started to be used by national authorities in order to put in place the means of measuring the competence of conformity assessment bodies, different approaches and differing systems developed throughout Europe and worldwide. The first initiative to bring the different accreditation services closer at regional and international level was the establishment, in 1976, of WECC — Western European Calibration Cooperation, followed by the creation of the International Laboratory Accreditation Cooperation (ILAC) in 1977. WELAC — Western European Laboratory Accreditation Cooperation was then established in 1987. WECC and WELAC merged in 1994 to form the European co-operation for Accreditation of Laboratories (EAL). Meanwhile, in 1991, the European Accreditation of Certification (EAC) was formed.

At the international level the International Accreditation Forum (IAF) in the certification area covering accreditation of certification and inspection bodies was also established. In 1997 EAL and EAC merged to create EA, which was later on in 2000 established as a legal entity. EA is registered under Dutch law as a not-for-profit association which gathers national accreditation bodies acting with public authority in the field of accreditation of all conformity assessment activities,

- cooperation at European (and international) level between accreditation bodies — aiming at harmonising accreditation rules, procedures and practices to promote and facilitate free global trade — needs to be accompanied and supported by a favourable legislative environment. The said Memorandum of Understanding constituted the first public recognition of EA,
- with the EEA Agreement, the EFTA States party to the Agreement committed themselves to participating in the Single Market, with the same rights and obligations as the EU Member States. Since the proposed Regulation on accreditation is to be a text of EEA relevance, it should create the same legal basis for the use of accreditation in the EFTA EEA States as in the EU,
- accreditation policy consistent with these guidelines and the development of quality infrastructure should be of primary importance in Turkey as an intrinsic aspect of the customs union between EU and Turkey and its proper functioning.

Given the facts outlined above, EA, the European Commission, EFTA and competent national authorities wish to confirm their mutual understanding on a number of policy objectives and the role of accreditation in that context, on the principles of their relationship and cooperation, and on their present intentions for the attainment of these objectives.

3. COMMON POLICY OBJECTIVES

EA, the European Commission, EFTA and the competent national authorities have a common understanding that accreditation plays an important role for the internal market and the quality of life of European citizens and that it constitutes an important instrument in support of European policy and legislation reflecting public interest, notably in the implementation of Community harmonisation legislation. European accreditation policy objectives are, therefore, as follows:

- to play a role in the proper functioning of the internal market, facilitating the free movement of goods and services by ensuring their ability of meeting the needs of the European economy and society taking into account all economic, social, environmental and other public interest aspects and in particular allowing for a high level of protection of health, safety, the environment and consumers,

- to contribute to the elimination of technical trade barriers by creating confidence in the accredited conformity assessment services and in the corresponding results, thus eliminating the need for multiple accreditations and multiple assessments for products, systems or services in every country where such products and services are marketed and, in this way, contributing to the competitiveness of the European economy,
- to disseminate and promote the European model of accreditation based on the principles that accreditation bodies act with public authority and that accreditation is carried out free from commercial motivation and in avoidance of competition, both between accreditation bodies and the conformity assessment bodies and also among accreditation bodies themselves,
- to maintain the role of accreditation as the central pillar of transparency and trust that public authorities and the market place can have in conformity assessment bodies whether operating in the regulated or the non-regulated area,
- to serve as the last and authoritative level of control of conformity assessment activities with regard to technical competence and professional integrity of conformity assessment bodies, in order to create mutual confidence,
- to be flexible in adaptation and responsive to the needs of the market as well as to the needs of national public authorities and to serve in this respect as an essential tool for backing up decisions of national public authorities, namely where accreditation is used in support of Community legislation, such as for a justified choice of conformity assessment bodies to be notified as capable to carry out tasks under the Community legislation,
- to further enhance a more substantial and equal degree of rigour of the accreditation services within EU/EFTA Member States through the development of a comprehensive framework for accreditation with the aim of increasing coherence, equivalence, transparency and co-operation of accreditation services, in both the regulated and the non-regulated area, taking into account the freedom of operators in the voluntary area to use them,
- to promote output focussed, quality driven and harmonised performance of accreditation bodies duly taking into account both system enablers and system results, ensured by a robust, effective and well-functioning system of peer evaluation between those bodies, with sound and transparent evaluation criteria and procedures,
- to continuously develop and increase the pertinent knowledge, competence and means that accreditation bodies possess in order to be able to properly assess the competence of a conformity assessment body by determining its technological knowledge and expertise and its capability to carry out assessment in accordance with the applicable requirements, both sector specific and legislative instrument oriented,
- to encourage accredited conformity assessment bodies to continuously develop and increase their pertinent knowledge, competence and means in order to be able to provide trustworthy and recognized conformity assessment services,
- to support a high level of quality for all conformity assessment activities whether they are undertaken in the implementation of legislation or not and to enforce transparency in pursuit of these activities. For that purpose, involvement of relevant stakeholders into the development of accreditation policy is essential in order to ensure overall acceptance and a coherent approach,
- to promote, in close cooperation with EU/EFTA Member States national public authorities, the use of accreditation in new sectors and fields of activity where the potential of accreditation has not yet been fully exploited, in particular in the regulated areas,
- to contribute to the development of accreditation at international level, especially with the view of strengthening the public interest aspects of accreditation and promoting mutual acceptance and recognition of accreditation certificates and corresponding conformity assessment results worldwide,
- to promote mutual recognition of testing and inspection reports, certificates and other attestations issued by conformity assessment bodies accredited in an EU/EFTA Member State so as they can offer their services throughout Europe and worldwide without any unjustified restrictions to their activities,
- to provide candidate countries, potential candidate countries and neighbouring countries with a major tool for reinforcing the adaptation of their economies to the Community market and to promote technical cooperation, assistance and Mutual Recognition Agreements (MRAs) with third countries,
- to promote research and development reflecting the rapid development of technologies and industrial and service processes, in all areas of conformity assessment, and fostering the use of inter-comparison activities and proficiency testing providing an effective indication of the quality of the outputs of the accredited conformity assessment activities.

4. PRINCIPLES OF RELATIONSHIP AND COOPERATION

In order to attain these objectives, EA, the European Commission, EFTA and the competent national authorities have a common understanding that:

- relations between EA and the public authorities at a European level, as well as with the national public authorities, should be based on the acknowledgement of the common objectives set out in detail in section 3 above, bearing in mind their distinct responsibilities and competencies. They emphasise that a permanent, open and transparent dialogue between them is a fundamental basis for cooperation,
- the national member bodies of EA have a vital role in the cooperation between EA, the European Commission, EFTA and competent national authorities Member States. Cooperation between all the relevant bodies and common understanding of the objectives set out in section 3 above is essential for these guidelines to be successful,
- the internal rules of EA should ensure that, whether in the regulated and the non-regulated area, stakeholders in accreditation are adequately represented, so that the broadest possible range of views is taken into account in drawing up accreditation guidelines and other documents and that the procedures are open and transparent,
- coherence and uniformity, both at European and national level, should be ensured in the development and implementation of accreditation policy, based on the establishment of the effective communication channels and the commitment to actively exchange information,
- it is essential that effort is made to respond readily and appropriately to differing market needs in different sectors and to the needs of national public authorities whose recourse to accreditation is expected to the utmost possible level, in particular in support of Community legislation.

5. IMPLEMENTATION

Against the background of the previous sections, the EA expects the European Commission, EFTA and the competent national authorities to:

- maintain a transparent legal and political framework for accreditation as a tool to develop trust and confidence in conformity assessment and mutual recognition in the corresponding results,

- make use of accreditation where it is appropriate in support of the implementation of Community legislation and policies, and promote recourse to it for those purposes,
- promote, in its international relations, the European model of accreditation based on the principles that accreditation bodies act with public authority and that accreditation is carried out free from commercial motivation and in avoidance of competition,
- 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,
- call upon EA to answer technical issues or provide necessary expertise on an ad hoc basis in developing specific arrangements to support Community initiatives,
- ensure the possibility of effective contribution of EA to different sectoral working groups responsible for the development and implementation of Community legislation in relation to accreditation and to call upon EA to develop and revise sectoral accreditation schemes which have to meet specific detailed technology or health and safety or environment related requirements in areas covered by Community legislation,
- make accessible to EA — when appropriate — the competence available at the Joint Research Centre, in particular at its Institute for Reference Materials and Measurements (IRMM) with respect to improving the quality of conformity assessment results,
- consider systematically recourse to EA in their international discussions with third countries or international organisations as well as in the implementation of third country trade agreements, when issues relating to the conformity assessment, quality, competence of conformity assessment bodies and accreditation are in question,
- seek, where appropriate, the advice and active cooperation of EA in the establishment and implementation of European programmes of technical assistance to, and cooperation with, third countries in the fields of accreditation and conformity assessment,
- facilitate, to the extent possible, a coordinated approach towards accreditation between EA and its member bodies and relevant national public authorities, in particular for the support of the implementation of Community legislation,

- promote the dissemination of knowledge about accreditation and its potential within its services,
- support EA in its role in promoting the European model of accreditation in international accreditation fora such as ILAC and IAF and in other regional accreditation co-operations,
- support EA in the efforts being undertaken in increasing the efficiency and effectiveness of its operation, by being a continually improving and ever more professional organisation.

For their part, the European Commission, EFTA and competent national authorities expect EA to:

- continue to serve as a co-operative network of European national accreditation bodies for the furtherance of equivalence, transparency, consistency and efficiency of accreditation operated throughout the EU/EFTA and beyond,
- serve the public mission of generating and maintaining confidence in conformity assessment bodies and in their results and to further a transparent and quality led system to evaluate their competence,
- operate a rigorous, transparent and uniform European peer evaluation system and continue to improve the system. Assurance should be provided that accreditation bodies that have successfully undergone the peer evaluation have the necessary technical expertise and capabilities to assess, attest and regularly monitor the technical competence of conformity assessment bodies, in particular, where members of the European accreditation infrastructure operate accreditation in support of the implementation of Community legislation,
- ensure that the peer evaluation between its members is operated in such a way that the results may be equivalent across the EU/EFTA and made public and can be justified on the basis of sound and transparent evaluation criteria and procedures, including appropriate appeals procedures. Peer evaluation should also serve as a benchmarking tool in order to stimulate further improvement,
- put in place an appropriate training system for evaluators to ensure reliable, equal and coherent assessments within the peer evaluation process,
- ensure that its member bodies are fully accountable towards all interested parties, operate accreditation as a non-profit distributing activity, do not provide any activities that conformity assessment bodies perform, do not compete with other accreditation bodies. Through its members, EA should also ensure that unnecessary burdens are not imposed on economic operators by conformity assessment bodies which they accredit. In addition the conformity assessment bodies which they accredit should, in their activity, take into account, the diversity of companies, their size and the nature of their activities, without reducing the necessary level of protection or quality required. The necessary requirements relating to confidentiality should be also ensured. Similarly, EA member bodies are expected to use the necessary technical expertise and capabilities to assess and attest the technical competence of conformity assessment bodies as well as to regularly monitor the accredited bodies. Where this is related to bodies operating in support of the implementation of Community legislation, necessary coordination with the EU/EFTA Member States' national authorities is to be ensured, bearing in mind the separation of responsibilities and tasks of EA member bodies from those of other national authorities,
- enable exchange of information on accreditation issues relevant in particular to the research and development topics. EA should assist the Joint Research Centre — IRMM of the European Commission in identification of priorities and practical arrangement of pan-European inter-laboratory comparisons and training activities. Where appropriate, EA is expected to encourage development of proficiency testing techniques and supply. Moreover EA should cooperate, whenever necessary and appropriate, with the Joint Research Centre's — IRMM in case of initiatives aiming at the diffusion of the metrological culture and practices through accreditation and accredited conformity assessment services,
- be responsive towards the European Commission and EFTA as well as the Member States' national authorities with regard to activities related to Community competencies,
- to respond readily and appropriately to differing market needs in different sectors and the needs of national public authorities, in particular as far as the implementation and development of Community legislation is concerned. EA shall identify and raise awareness for missing tools for activities linked to the implementation of Community legislation and where possible, participate, on request, in their development,
- take due account of advice and guidance offered by the European Commission and EFTA, after consultation with the Member States' national authorities, on policy matters related to accreditation,
- inform the European Commission and EFTA about policies and activities under development that are of mutual interest and regularly report on EA's strategic and policy development,

-
- cooperate with stakeholders and parties concerned and establish and maintain an appropriate mechanism for them to make their views known,
 - ensure openness, transparency, equivalence and competence in the operation of its procedures. In particular, the process for the preparation of the guidelines should be open to the views and contributions of all bodies representing the interested parties. Regular provision of information to the national authorities and conformity assessment bodies is to be guaranteed as well as coherence with the international level ensured, wherever appropriate,
 - be committed to the delivery of efficient and high quality accreditation that brings added value to the entire conformity assessment market. In particular, EA and its members are expected to develop and implement appropriate strategies and procedures for continuous improvement in terms of both efficiency and competence,
 - actively participate in the activities of international organisations in the field of accreditation and report on these activities to the European Commission and EFTA,
 - be committed at European and international level to adjust the existing rules for a successful peer evaluation so as to open the peer evaluation process to all nationally recognised accreditation bodies in all technical fields, independent of their size and number of accredited conformity assessment bodies,
 - undertake and support actions to improve the visibility of European accreditation and promote the European model of accreditation,
 - provide encouragement to the progress of accreditation bodies in the countries that have applied for EU or EFTA membership, in view of their full participation in and achieving membership of EA. Grant full membership once the appropriate and approved conditions have been met. Endeavour to encourage the development of the quality infrastructures of those countries,
 - cooperate with the European Commission, EFTA and the competent national authorities in the development and implementation of Community and EFTA programmes of technical assistance and cooperation with third countries.
-