

A LEGAL FRAMEWORK FOR ACCREDITATION IN EUROPE

By Graham Talbot, Vice Chair, European cooperation for Accreditation (EA)

Monday 23 June 2008 will be remembered as a noteworthy day in the history of accreditation in Europe. On this date, the Council of the European Union and the European Parliament agreed on a Regulation that will, for the first time, provide a legal framework for the provision of accreditation services across Europe. The Regulation will apply from January 2010 and will cover the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. Under the Regulation, accreditation, when carried out against the recognised harmonised standards, is regarded as a public authority activity and EU Member States will be required to appoint a single national accreditation body for these activities. The national accreditation body can be a public or private organisation but, regardless of its status, it will be regarded as carrying out a public authority activity.

The Regulation has been developed against the background of a growing recognition of the importance of accreditation to the EU's economic infrastructure. The main aims of the Regulation are to reinforce the status of accreditation, to improve the consistency of the accreditation services offered and, ultimately, to increase confidence in accreditation as a tool for government and business. To this end, the Regulation sets common requirements for national accreditation bodies to be monitored by EU member state governments. In essence, the Regulation will require national accreditation bodies to be independent from the conformity assessment bodies they accredit; to be objective and impartial; to employ competent personnel for the tasks to be carried out; to operate on a not for profit basis; not to offer services offered by conformity assessment bodies; and not to compete with other national accreditation bodies.

The Regulation also recognises the European co-operation for Accreditation (EA) as the co-ordinating organisation for accreditation at the European level. National accreditation bodies in the EU member states will be required to be members of EA and to participate in the peer evaluation programme operated by EA as the preferred means of demonstrating compliance with the requirements.

A related EU Decision, agreed at the same time as the Regulation, will set a common framework for EU Directives relating to the marketing of products. The Decision establishes a model text for future directives and revisions to existing directives covering elements such as the use of standards, CE marking, conformity assessment procedures and the appointment of conformity assessment bodies to operate the conformity assessment procedures 'notified bodies'. The Decision places greater emphasis on the use of accreditation in the assessment of 'notified bodies', again with the intention of improving the consistency of approach across Europe.

EA has worked in close co-operation with the Commission as the Regulation has been developed and regards the outcome as positive for accreditation overall. EA members are excited by the prospect of greater recognition by their national authorities and increased opportunity for accreditation to support EU policy. They also recognise the challenge of ensuring that accreditation meets the raised expectations of governments across Europe. EA has a number of projects in place to ensure that members can respond to the increasing demands they expect to be placed on them as a result of the Regulation and Decision.

The agreement of these legal texts is the culmination of policy discussions going back almost 20 years. As early as 1989, the European Commission published the Global Approach to Certification and Testing, which set out many of the principles now adopted into European law. When published, these principles were seen as guidelines for member states but it has been clear for some time that a greater degree of formality was required and this has now been achieved by the adoption of the Regulation.

For many EU accreditation bodies, the Regulation will have little practical impact since legal frameworks for accreditation exist in many of the 27 EU member states. Many accreditation bodies are already part of government and are nominated as the sole national accreditation bodies for the countries concerned. This is not the case across all member states, and in some economies accreditation has developed as a private sector activity including an element of competition. In these countries, some rationalisation of the accreditation structure will be required and governments across the EU are now working to put systems in place that will meet the requirements of the Regulation. More changes will be required in some member states than others.

The EU legislative process is a complex one and compromises have had to be made to secure the adoption of the Regulation by the Council and the European Parliament. As a result, the impact of some elements of the new law is still not entirely clear and work is needed to ensure that there is a common understanding of the requirements. In addition, EA recognises that the Regulation will, in some ways, lead to requirements being placed on accreditation bodies in Europe that are not required elsewhere. EA is working with the Commission and its international partners in ILAC and IAF to ensure that the benefits of global mutual recognition of accreditation are not lost as the new requirements for Europe are implemented. Despite these outstanding questions, EA believes that the new legal framework will ultimately improve the understanding and acceptance of accreditation as a tool to assist free trade across Europe. Could this be the way forward internationally, too?

Further information on the EU Regulation and Decision, including links to the agreed legal texts, is available from the EA website at www.european-accreditation.org.