

Regulation 765/2008

IS-15

EU Regulation 765/ 2008 (hereafter known as the Regulation), which for the first time provides a legal framework for the provision of accreditation services for conformity assessment activities across Europe, has been developed against the background of a growing recognition of the importance of accreditation to the EU's economic infrastructure. The Regulation covers the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. The Regulation is part of a legislative suite aimed at maximising the potential of the Single Market in the free movement of goods throughout the European Union.

The legislative suite, available from www.inab.ie, comprises:

- Regulation 765/2008 - setting out the requirements for accreditation and market surveillance relating to the marketing of products
- Regulation 764/2008 - laying down procedures relating to the application for national technical rules to products lawfully marketed in another member state
- Decision 768/2008 - on a common framework for the marketing of products

Accreditation has been defined in the Regulation (Article 2(10)) as *'the attestation by a National Accreditation Body that a CAB meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out specific conformity assessment activity'*.

Under the Regulation, accreditation, when carried out against the recognised harmonised standards (Article 2(9)) is considered a public authority activity and EU Member States will be required to appoint a single national accreditation body for their economy. INAB has been appointed as the sole national accreditation body for Ireland by the Department of Enterprise, Trade and Employment (DETE).

The objectives of this Regulation are many; to ensure that one accreditation is sufficient across the whole of the European Union, to avoid multiple accreditations which add cost without necessarily adding value and to recognise Accreditation as affording the top-most level of control in providing an authoritative statement of the technical competence of conformity assessment bodies.

The overall aim of the Regulation therefore, is to make the operation of accreditation more consistent across Europe, thus encouraging the mutual recognition of conformity assessment results and certificates.

A significant change arising from the Regulation will occur when Conformity Assessment Bodies (CABs) established in Ireland seek to become accredited, they must do so from the National Accreditation Body (NAB) for Ireland. The justification for this is that competition between national accreditation bodies could lead to the commercialisation of their activity, which would be incompatible with their role in providing a public authority service and as the last level of control in the conformity assessment chain.

There are, however, some circumstances when CABs may seek accreditation from another NAB specified in Article 7.

The Regulation came into effect on 1st January 2010. Until then current practices continue and accreditation certificates issued before 1 January 2010 will remain valid until the date of their expiry, but no later than 31 December 2014.

The **European Co-Operation for Accreditation (EA)** has been recognised as the body under Article 14 of the Regulation with responsibility for the management of the European accreditation infrastructure. EA will therefore continue to operate the robust peer evaluation system which confirms compliance of an Accreditation Body to ISO 17011 - "*requirements for accreditation bodies accrediting conformity assessment bodies*" and to the requirements of Article 8 of the Regulation.

The Regulation provides for a more stringent enforcement regime particularly in the area of product market surveillance. Procedures for cross border co-operation, rapid reporting and national market surveillance programmes will be enhanced and requirements for product manufacturers/importers more clearly specified.

The Regulatory package also proposes to increase the market awareness of and value in the CE Mark, which indicates that all product regulatory requirements have been fulfilled.

Decision 768/2008

For those Conformity Assessment Bodies (CABs) wishing to become a Notified Body (NB) under a particular Directive, this Decision lays down responsibilities for both the NB and the Member State Notifying Authority. It additionally details the conformity assessment procedures to be adopted under each Directive.

The European Co-operation for Accreditation (EA) has published a mandatory document, EA-2/17 (available from www.inab.ie) which lays down horizontal requirements for the assessment of CABs for the purposes of notification. While comprehensive, it must be utilised in conjunction with the relevant standard and legislation, both national and international.

Further information may be obtained at www.inab.ie and www.european-accreditation.org