#### EXPLANATORY MEMORANDUM TO

#### THE ACCREDITATION REGULATIONS 2009

### 2009 No. 3155

1. This explanatory memorandum has been prepared by the Department for Business, Innovation and Skills and is laid before Parliament by Command of Her Majesty.

## 2. Purpose of the instrument

- 2.1 This Statutory Instrument appoints the United Kingdom Accreditation Service to be the National Accreditation Body for the United Kingdom in support of EC Regulation 765/08.
- 3. Matters of special interest to the Joint Committee on Statutory Instruments
- 3.1 None.

## 4. Legislative Context

- 4.1 On 9 July 2008 the European Parliament and the Council of the European Union adopted EC Regulation 765/08, a new European-wide directly applicable law that establishes for the first time a legal framework of rules and principles for the provision of accreditation services across Europe, setting out the provisions for the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. EC Regulation 765/08 in addition sets out a similar framework in respect of market surveillance. EC Regulation 765/08 applies from 1 January 2010.
- 4.2 Article 4(1) of Regulation 765/08 requires each Member State to appoint a single National Accreditation Body to undertake accreditation as defined in the Regulation in that Member State. Article 5(5) requires provision to be made in respect of appeals in relation to accreditation decisions.
- 4.3 This Statutory Instrument appoints the United Kingdom Accreditation Service to be the National Accreditation Body for the UK. This Statutory Instrument also establishes a process for the resolution of appeals made against the United Kingdom Accreditation Service's accreditation decisions and gives the United Kingdom Accreditation Service the right to charge fees for accreditation undertaken in respect of EC Regulation 765/08.
- 4.4 This Statutory Instrument will be supported by a Memorandum of Understanding between the United Kingdom Accreditation Service (hereinafter referred to as UKAS) and the Department for Business, Innovation and Skills. The Memorandum of Understanding establishes the way the UKAS and the Department for Business, Skills and Innovation will work together to maintain and promote a strong national accreditation service for the United Kingdom.

## 5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom. It also applies to the Channel Islands and the Isle of Man to the extent that EC Regulation 765/2008 applies to them.

# 6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

# 7. Policy background

- 7.1 Accreditation is part of an overall system which includes conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements. Regulation 765/08 is intended to boost intra-community trade by supporting the marketing and free movement of goods throughout the European Community and the principle of mutual recognition, that a product lawfully marketed in one Member State, and not subject to Community harmonisation, should be allowed to be marketed in any other Member State. It does this by establishing a system of accreditation that functions by reference to binding rules, thus helping to strengthen mutual confidence between Member States in respect to the competence of conformity assessment bodies and consequently the certificates and test reports issued by them. Appointing the UKAS as the National Accreditation Body for the United Kingdom allows the United Kingdom to operate accreditation as envisaged in the Regulation.
- 7.2 By appointing the UKAS as the National Accreditation Body for the United Kingdom, the Department for Business, Innovation and Skills clarifies to both the conformity assessment industry and the wider business community who the National Accreditation Body is to be, as well as confirming that companies in the United Kingdom will have recourse to accreditation from a National Accreditation Body in the United Kingdom.
- 7.3 Business interest in this Statutory Instrument is in the main restricted to direct customers of accreditation bodies: the conformity assessment bodies.
- 7.4 Three ways in appointing the UKAS as the National Accreditation Body were considered. The first was by awarding a contract, the second by a letter of appointment from the Secretary of State, and thirdly by Statutory Instrument. The first was rejected as the Department for Business, Innovation and Skills was not seeking or paying for a service: accreditation will instead be operated as a public authority activity. The second was rejected as the Regulation confers rights on individuals and requires the establishment of an appeals process and this is best achieved through a Statutory Instrument.
- 7.5 If the United Kingdom does not appoint a National Accreditation Body for the United Kingdom it will be in breach of the directly applicable EC Regulation 765/08 and subject to infraction proceedings issued by the European Commission.

7.6 This Statutory Instrument itself carries little or no political impact or importance as it is solely a vehicle to implement the EU Regulation in the United Kingdom.

### 8. Consultation outcome

- 8.1 On 9 March 2007, during EU negotiations, the Department for Trade and Industry launched a public consultation on proposals for a Regulation on Accreditation and Market Surveillance. The government response and the consensus amongst respondents suggested that there were no significant barriers or negative impacts toward a directly applicable Regulation on Accreditation.
- 8.2 Given that a Department of Trade and Industry public consultation was held during EU negotiations on EC Regulation 765/08, it was considered that an additional public consultation on implementation of the accreditation aspects of the Regulation would not bring significantly more information.

### 9. Guidance

9.1 Not appropriate.

## 10. Impact

- 10.1 As this Statutory Instrument brings the United Kingdom in line with the provisions of EC Regulation 765/08, changing only the status of the UKAS and not its role, there is no impact on business, charities or voluntary bodies, or the public sector.
- 10.2 An Impact Assessment has not been prepared for this instrument.

# 11. Regulating small business

11.1 The legislation does not apply to small business.

# 12. Monitoring & review

12.1 The success criterion for this Statutory Instrument is that the United Accreditation Service meets the requirements for national accreditation bodies as set out in Article 8 of Regulation 765/08. These requirements are part of the monitoring of the UKAS by the Department for Business, Innovation and Skills as required by Article 9 of the Regulation. If the monitoring reveals that the UKAS is not meeting these requirements the Department for Business, Innovation and Skills will take appropriate corrective action and should such corrective action fail, the Department for Business, Innovation and Skills will repeal this Statutory Instrument and appoint a new National Accreditation Body for the United Kingdom following due process in that regard.

### 13. Contact

John Mortimer at the Department for Business, Innovation and Skills, Tel: 020 7215 5434 or email: john.mortimer@bis.gsi.gov.uk can answer any queries regarding the instrument.