EXPLANATORY MEMORANDUM TO THE

SMOKE FLAVOURINGS (ENGLAND) REGULATIONS 2005

2005 No.464

1 This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty. This memorandum contains information for the Joint Committee on Statutory Instruments.

2 **Description**

This Instrument introduces in England measures relating to the safety assessment and authorisation of primary products and/or derived smoked flavourings intended for use in or on foods.

3 Matters of special interest to the Joint Committee on Statutory Instruments

The validity of the Treaty base of the EC Regulation in relation to which this instrument provides enforcement powers is currently being challenged before the European Court of Justice by the United Kingdom Government in case C-66/04. A date for hearing has yet to be allocated.

4 Legislative Background

General

- 4.1 The Smoke Flavourings (England) Regulations 2005 are being made to provide enforcement powers for Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods. The Regulations allow national provisions concerning smoke flavourings and their use in or on foods to continue to apply until 16 June 2005.
- 4.2 The ministerial powers under which it is made are Sections 16(1) (a), (c), (e) and (f), 17(2), 26 (1) and (3) and 48 (1) of and paragraph 1 of Schedule 1 to the Food Safety Act 1990.

EU Legislation

- 4.3 A Transposition Note for Regulation (EC) No. 2065/2003 is attached at Annex A.
- 4.4 Regulation (EC) No. 2065/2003 of 10 November 2003 was published in the Official Journal of the European Communities (L309) on 26 November 2003. It establishes Community procedures for the evaluation and authorisation of primary products from which smoke flavourings may be made, lays down the conditions for their production and the information necessary for their

evaluation. Smoked foods produced using the traditional smoking processes are not affected.

- 4.5 There are no specific national provisions in place that govern the authorisation and use of smoke flavourings. The use of smoke flavourings in the UK has been subject to the general requirements of UK Food Law.
- 4.6 The Parliamentary Scrutiny Committees considered the proposal to adopt Regulation (EC) No. 2065/2003 on two occasions. Both Committees did not view this measure as legally important.
- 4.7 When the proposal was first deposited 16 July 2002 (11055/02), the House of Lords (HoL) EU Scrutiny Committee and the House of Commons (HoC) EU Scrutiny Committee cleared the proposal (on 4 September 2002 and 16 October 2002 respectively).
- 4.8 The Commission's proposal was amended to update the procedure for submitting a dossier for evaluation. A Ministerial letter (11388/03) deposited on 8 July 2003 was cleared by both Committees.

5 Extent

The Regulations apply to England only.

6 European Convention on Human Rights

The Parliamentary Under Secretary for Public Health has made the following statement regarding Human Rights:

In my view the Smoke Flavourings (England) Regulations 2005 are compatible with the Convention Rights.

7 **Policy Background**

- 7.1 Council Directive 88/388/EEC (the Flavourings Framework Directive) provides under Article 5 for the adoption of appropriate provisions concerning source materials used in the production of smoke flavourings and the reaction conditions under which they are prepared.
- 7.2 The key elements of Regulation (EC) No. 2065/2003 are:
 - to specify the information necessary for the scientific evaluation and authorisation of primary products to be conducted by the European Food Safety Authority (EFSA) according to a transparent procedure within a specific timeframe,
 - to produce a positive list of primary products and specify their conditions of use in or on foods,
 - to require approved products to be re-submitted for evaluation and renewal of the authorisation at 10-yearly intervals,

- to place traceability requirements on businesses involved in sale of authorised smoke extracts or flavourings derived from such extracts.
- 7.3 This Instrument provides for the enforcement of Regulation (EC) No. 2065/2003 in England and formally states that the Food Standards Agency is the National Competent Authority to which applications for authorisation can be made. Although there are no known UK manufacturers of smoke flavourings at present, the Food Standards Agency is in a position to receive applications from any manufacturer who wishes to have their products evaluated and authorised.
- 7.4 The new Regulations will apply to both manufacturers of primary products and/or smoke flavourings and food producers who use smoke flavourings in their products. A Transposition Note is attached at Annex A to indicate how the main requirements of the EC Regulation are to be enforced.
- 7.5 A full public consultation was carried out on the new Regulations. Although there are no known UK manufacturers of smoke flavourings (the smoke flavourings industry is very specialised) we needed to determine the impact on UK food manufacturers who use smoke flavourings in their products. It was concluded that no disproportionate burden would be placed on businesses (including small businesses) as a result of implementing the provisions of Regulation (EC) No. 2065/2003. Details of the responses to the consultation are included in the Regulatory Impact Assessment at Annex B.
- 7.6 The level of public interest was low for this consultation exercise as shown by the limited number of responses received (seven responses to the consultation).

8 Impact

A Regulatory Impact Assessment is attached at Annex B. Copies can be obtained from Donna Griffith-Sackey¹. There are no identifiable costs to the public or the Exchequer.

9 **Contact Point**

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