

EXPLANATORY MEMORANDUM TO
THE FOOD FOR PARTICULAR NUTRITIONAL USES (ADDITION OF
SUBSTANCES FOR SPECIFIC NUTRITIONAL PURPOSES) (ENGLAND)
REGULATIONS 2009

2009 No. 3051

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. **Purpose of the Instrument**

2.1 The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes)(England) Regulations 2009 ('the Regulations') provide execution and enforcement provisions, in England, for Commission Regulation (EC) No. 953/2009 on the substances that may be added for specific nutritional purposes in foods for particular nutritional uses. The main purpose of the Regulations is to align domestic law with EC law to consolidate and amend the list of permitted substances for use in foods for particular nutritional uses ('Parnuts').

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

3.1 None

4. **Legislative Context**

4.1 Commission Regulation (EC) No. 953/2009 consolidates and amends current EC legislation providing for the addition of certain substances to Parnuts foods. This EC Regulation repeals Directive 2001/15/EC and Directive 2004/6/EC with effect from 31 December 2009.

4.2 The Regulations repeal the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 (SI 2002/1817);

5. **Territorial Extent and Application**

5.1 The Regulations apply to England. Separate but parallel legislation is being enacted for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

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

7. Policy background

7.1 EC legislation requires that foods for particular nutritional uses are safe and that they meet the nutritional requirements of the persons for whom they are intended. A Parnuts food is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional use. Examples of Parnuts foods include - infant formulae, follow-on formulae and medical foods.

7.2 To facilitate consumer choice, the widest possible choice of substances such as vitamins, minerals and amino acids should be available for use in foods for particular nutritional uses. To ensure consumer protection, it is also important that the safety of these substances is scientifically proven before they are used in the manufacture of foods for particular nutritional use.

7.3 In order to fulfil these requirements, a European Commission Directive was agreed in 2001 ('Directive 2001/15/EC') which listed the types of chemical substances that may be used in the manufacture of foods for particular nutritional uses. Any chemical substance that is listed in the Directive must have received a favourable scientific evaluation either by the European Food Safety Authority (EFSA), or its forerunner, the Scientific Committee on Food (SCF).

7.4 If a manufacturer wishes a new substance to be added to the list of authorised substances in Directive 2001/15/EC the new substance must first receive a positive assessment from EFSA. The European Commission Standing Committee on the Food Chain and Animal Health (SCoFCAH) must then agree that the new substance should be added to the relevant list in Directive 2001/15/EC.

7.5 Earlier this year the European Commission published Commission Regulation (EC) No. 953/2009 to consolidate and amend Directive 2001/15/EC. This increases the range of sources of vitamins and minerals and other substances that may be added to foods for particular nutritional uses and represents simplification of current legislation as the provisions will be consolidated into a single regulation making it easier to read.

8. Consultation outcome

8.1 The Food Standards Agency conducted a shortened 4-week consultation, which ran from 5 October to 2 November 2009 with parallel consultations undertaken in Scotland, Wales and Northern Ireland. The shortened consultation was to enable the Regulations to come into force on 1 January 2010.

8.2 Over 400 interested parties throughout the UK, including consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments, have been consulted on these draft Regulations. No responses were received. Meetings with interested parties confirmed the new regulation will not place additional burdens on industry and is welcomed by all stakeholders.

9. Guidance

9.1 As this is predominantly a consolidation and updating of existing legislation, no specific guidance has been produced to accompany this legislation.

10. Impact

8.1 The Food Standards Agency consulted over 400 interested parties on the proposed Regulations. The primary business sector that will be affected by the regulatory proposals will be manufacturers of foods for particular nutritional uses. The consultation did not generate any replies, therefore it is assumed that the measures proposed impose no new financial burdens. This view has been confirmed in other meetings with businesses.

8.2 The Regulations would not impose any significant new burden on Government or enforcement officers. Rural areas and members of the ethnic communities, or of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are unaffected by these proposals.

8.3 An Impact Assessment has not been prepared to accompany these Regulations as no costs have been identified.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 It is not thought that the proposed legislation will disproportionately impact small businesses as no costs were identified in the consultation.

12. Monitoring & review

12.1 The new rules will come into force on 1 January 2010. The Regulations will be reviewed three years after implementation.

13. Contact

9.1 Stephen Knight at the Food Standards Agency (Tel: 020 7276 8173 or e-mail: Stephen.knight@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.