

**EXPLANATORY MEMORANDUM TO**  
**THE FOOD FOR PARTICULAR NUTRITIONAL USES (ADDITION OF**  
**SUBSTANCES FOR SPECIFIC NUTRITIONAL PURPOSES) (ENGLAND)**  
**(AMENDMENT) REGULATIONS 2006**

**2006 No. 3116**

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

2. **Description**

2.1 This instrument implements, in England, European Commission Directive 2006/34/EC of 21 March 2006 which amends Directive 2001/15/EC. The main purpose of the instrument is to permit the use of a number of chemical substances in foods for particular nutritional uses.

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

3.1 None

4. **Legislative Background**

4.1 This instrument implements, in England, Commission Directive 2006/34/EC of 21 March 2006 which amends Directive 2001/15/EC. Directive 2001/15/EC lays down requirements regarding substances that may be added for specific nutritional purposes to certain foods for particular nutritional uses ('parnuts' foods). Parnuts foods include infant formulas, weaning foods, slimming foods, and foods for special medical purposes. Infant formulas and weaning foods are outside the scope of Directive 2001/15/EC as lists of permitted nutritional substances are included in the specific Directives that apply to those types of foods.

4.2 This instrument amends The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 SI 1817 to permit the use of three substances in parnuts foods. The instrument updates the definition of Directive 2001/15 and changes the heading "FOLIC ACID" to "FOLATE" in the 2002 Regulations. The instrument also removes unnecessary wording from the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations in so far as they apply to England.

## **5. Extent**

5.1 This instrument applies 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. 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.

7.2 In order to fulfil these requirements, a European Commission Directive was agreed in 2001 which listed, under a number of different categories, 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).

7.3 If a manufacturer wishes to add a new substance to one of the categories listed in Directive 2001/15/EC they must first receive a positive assessment from EFSA on the safety of the new substance. 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.

7.4 Earlier this year, after receiving positive opinions from EFSA on the safety of calcium-L-methylfolate, magnesium L-aspartate and ferrous bisglycinate, the European Commission submitted a proposal to SCoFCAH which aimed to permit the use of these substances in the manufacture of foods for particular nutritional uses. The SCoFCAH agreed to this proposal which was formally published as Commission Directive 2006/34/EC on 21 March 2006. As a result, we are amending the UK Regulations, *via* this instrument, to implement Directive 2006/34/EC. This instrument will therefore increase the number of substances that can be added to certain parnuts foods, thereby increasing consumer choice and reducing the impact of Directive 2001/15/EC on industry.

## **8. Impact**

8.1 The Food Standards Agency consulted with 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. However, consultation has confirmed that the measures proposed impose no new financial burdens.

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

8.3 A Regulatory Impact Assessment is attached to this memorandum.

## **9. Contact**

Mark Toal at the Food Standards Agency (Tel: 02072768169 or e-mail: [mark.toal@foodstandards.gsi.gov.uk](mailto:mark.toal@foodstandards.gsi.gov.uk)) can answer any queries regarding the instrument.

**TRANSPOSITION NOTE: THE FOOD FOR PARTICULAR NUTRITIONAL USES (ADDITION OF SUBSTANCES FOR SPECIFIC NUTRITIONAL PURPOSES) (ENGLAND) (AMENDMENT) REGULATIONS 2006 S.I.**

Commission Directive 2006/34/EC amends Commission Directive 2001/15/EC to include certain substances in the Annex. This transposition note outlines how the main elements of the Directive are transposed into legislation in England.

<b>Article</b>	<b>Objective</b>	<b>Implementation</b>	<b>Responsibility</b>
Article 1 and Annex of 2006/34/EC	Amends the Annex to 2001/15/EC to include additional substances and to change the heading of a list of substances.	Regulations 3, 4 and 5.	Secretary of State.
Article 2(1) of 2006/34/EC, first sub-paragraph, first sentence.	Sets the latest date by which implementing legislation must be in force.	Regulation 1(2).	Secretary of State.

## **REGULATORY IMPACT ASSESSMENT**

### **THE FOOD FOR PARTICULAR NUTRITIONAL USES (ADDITION OF SUBSTANCES FOR SPECIFIC NUTRITIONAL PURPOSES) (ENGLAND) (AMENDMENT) REGULATIONS 2006**

#### **PURPOSE AND INTENDED EFFECT OF THE MEASURE**

##### **Objective**

1. These Regulations implement, in England, Commission Directive 2006/34/EC of 21 March 2006 amending Directive 2001/15/EC to include certain substances in the Annex. These new Regulations amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 SI 1817. Parallel implementing legislation will be made in Scotland, Wales and Northern Ireland.

##### **The background**

2. Directive 2001/15/EC, which is implemented in England by the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 SI 1817, lays down certain requirements regarding substances that may be added for specific nutritional purposes to certain foods for particular nutritional uses.
3. A food for a particular nutritional use (a 'parnuts' or 'PNU' 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 purpose. A particular nutritional use means the fulfilment of the particular nutritional requirements of certain categories of persons a) whose digestive processes or metabolism are disturbed or b) whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs or c) of infants or children in good health.
4. Parnuts foods include infant formulas and follow-on formulas, processed cereal-based foods and baby foods for infants and young children, certain weight reduction products, and foods for special medical purposes. Provisions regarding the addition of substances to infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children are laid down in separate Directives which apply to those specific categories of parnuts foods.
5. Foods intended for particular nutritional uses are regulated by framework Directive 89/398/EEC and by specific Directives adopted under that framework. Nutritional substances e.g. vitamins, minerals and amino acids may be added to foods for particular nutritional uses in order to ensure that the particular nutritional

requirements of the persons for whom those foods are intended are fulfilled and/or in order to satisfy legal requirements laid down in specific directives adopted pursuant to Article 4 of framework Directive 89/398/EEC.

6. Directive 2001/15/EC was adopted pursuant to article 4(2) of Directive 89/398/EEC which provides for the future adoption of a Directive containing a list of substances for specific nutritional purposes intended for addition to PNU foods together with the purity criteria applicable to those substances. This practice of adopting a so-called “positive list” is characteristic of EU food law.
7. The 2002 Regulations limit the sources of several categories of substances that may be added to certain parnuts foods to those sources listed under the relevant category in Schedule 1 or, in the case of foods for special medical purposes, Schedule 1 or 2 to the Regulations. The list of substances in the Annex to Directive 2001/15/EC currently does not include a number of substances that are used in the manufacture of certain parnuts foods currently on the market.
8. At the time of adoption of 2001/15/EC, a number of substances added to parnuts foods could not be included in the Annex because they had not been assessed by the Scientific Committee on Food (SCF), the forerunner of the European Food Safety Authority (EFSA). Thus, Commission Directive 2004/6/EC implemented a derogation which permitted the use of these substances in parnuts foods until 31st December 2006. The list of these substances is given in the Annex to Directive 2004/6/EC. Each substance listed in 2004/6/EC must be approved by EFSA and must be included in the Annex to 2001/15/EC before 31st December 2006 in order to permit their continued use in parnuts foods within the EC.
9. Directive 2004/6/EC and Directive 2004/5/EC (a further amendment which added a number of substances to several categories of Directive 2001/15/EC) were implemented in UK law *via* The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2004 SI 649.

### **Provisions in the Regulations**

10. The key proposals of these Regulations are:
  - To update the definition of “Directive 2001/15” (regulation 3).
  - To add calcium-L-methyfolate (under the vitamins category) and ferrous bisglycinate (under the minerals category) to the list of substances which may be added to all parnuts foods (regulation 4). Regulation 4 also changes the heading “FOLIC ACID” to “FOLATE” in the vitamins category
  - To add magnesium L-aspartate to the list of additional substances which may be added for special nutritional purposes in foods for special medical purposes (regulation 5).

- To remove unnecessary wording from the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations in so far as they apply to England (regulation 6).

### **Rationale for government intervention**

11. The new legislation will increase the number of substances that can be added to certain parnuts foods, thereby enabling wider consumer choice and reducing the impact of Directive 2001/15/EC on industry.

### **CONSULTATION**

12. Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments were consulted informally on the draft European legislation, and formally, on these draft Regulations.
13. During the negotiations of the amendment to the European Directive, the Agency consulted informally with the above stakeholders, including SMEs. We received one written response to our informal consultation, from the Infant and Dietetic Foods Association, who supported the proposed amendment to the European Directive.
14. The Food Standards Agency received five responses to the formal consultation on the draft Regulations. Responses from The Royal College of Nursing (Scotland), East Ayrshire Council, the British Medical Association (Northern Ireland) and the Wales Centre for Health either offered no specific comments, or outlined support for the implementation of the proposed Regulations. In their response, the Health Foods Manufacturers Association (HFMA) raised a question about the effect of the Regulations on the labelling requirements for Parnuts foods. The Agency responded to the HFMA, noting that the proposed Regulations would have no effect on the relevant labelling requirements. None of the respondents offered any comments on the drafting of the Regulations so no changes were made to the text of the SI as a result of consultation.

### **OPTIONS**

15. Options for transposing the provisions of the new Directive are as follows:

Option 1: do nothing i.e. fail to implement the Directive

Option 2: implement the provisions of the Directive by 31 December 2006 as required according to Article 2 of the Directive.

16. Option 1: failure to implement would bring risks and disbenefits to consumers, industry, enforcement authorities and Government. Failure to implement would represent an unjustified restriction on consumer choice and would disadvantage industry by preventing the use of a number of substances that could be used in the manufacture of parnuts foods. Failure to implement would also be a risk to Government in that it would result in a serious breach of the UK's obligations under the EC treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and the likelihood of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement.

17. Option 2: there are no risks or disbenefits attached to option 2.

### **Flexibility**

18. The Directives do not offer any implementation flexibility.

## **COSTS AND BENEFITS**

### **Business sectors affected**

19. Businesses benefited by the amending Directives, and hence the new Regulations, are food businesses producing/distributing certain parnuts foods. The parnuts food sector in the UK is dominated by approximately 10 large companies. Approximately 40 small companies are also involved in the production/distribution of parnuts products in the UK

### **Consumers affected**

20. The legislation will benefit consumers of parnuts foods. We do not envisage any differential effect of the legislation on consumers because of gender, age, health or income. We do not envisage that the legislation would have differential effects on disabled people or those living in different regions or in rural communities. We consider that the proposal will have no impact on racial equality issues.

### **Voluntary organisations and charities**

21. We are not aware of any charities or voluntary organisations that would be affected by the legislation.

### **Public sector**

22. Government and enforcement officers would be affected by the legislation.

## **Benefits**

23. Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government.
24. Option 2: implementation brings benefits to consumers, industry, enforcement authorities and Government. It benefits consumers by increasing consumer choice; benefits industry by permitting the safe use of a wider choice of substances when manufacturing parnuts foods; and benefits Government by removing the risk of incurring infraction proceedings.

## **Costs**

25. There are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of these new Directives apart from administrative costs to Government.
26. The environmental impact of the new Regulations is likely to be negligible.

## **SMALL FIRMS' IMPACT TEST**

27. Small businesses have been consulted and have not indicated that they will be put at any disadvantage as a result of the Regulations, in reality it will bring benefits to industry.

## **Impact on regions**

28. Any regional differences in benefit due to the new legislation would depend upon the location of the relevant businesses. We are not aware of any differential impact.

## **COMPETITION ASSESSMENT**

29. As Option Two does not have a cost impact on industry, neither will it have a significant negative impact on competition in the Parnuts industry. Indeed, the maintenance of the UK situation is likely to allow continued innovative product formulation in this industry. There are no further competition issues to be considered for the amendments proposed over and above those identified in the RIA for the principal Regulations (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 SI 1817).

## **ENFORCEMENT AND SANCTIONS**

30. Local food authorities are responsible for enforcing the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002.

### **POST-IMPLEMENTATION REVIEW**

31. The Directives do not provide for any specific review date and there is no provision in the main Directive for a review. However, it is likely that further amendments to the Annex of 2001/15/EC will be made by further amending Directives following future scientific evaluation of more substances by the EFSA.

### **SUMMARY AND RECOMMENDATION**

32. In summary, making these Regulations will enable us to fulfil our Community obligations and will benefit consumers and industry. Failure to make these Regulations, would result in a serious breach of the UK's obligations under the EC treaty and would attract infraction proceedings by the Commission against the UK and the likelihood of heavy fines.

33. For these reasons, the Agency recommends that the UK should implement the provisions of Directive 2006/34/EC *via* The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2006.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister:....Caroline Flint.....

Date:....20<sup>th</sup> November 2006.....

### **Contact point**

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