

EXPLANATORY MEMORANDUM TO
THE NOTIFICATION OF MARKETING OF FOOD FOR PARTICULAR
NUTRITIONAL USES (ENGLAND) REGULATIONS 2007

2007 No. 181

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, Articles 9 and 11 of European Commission Directive 89/398/EEC, as amended by Directive 1999/41/EC. The main purpose of the instrument is to allow the Food Standards Agency to temporarily suspend or restrict trade in certain foods for particular nutritional uses (parnuts foods) which are not clearly distinguishable from foods for normal consumption, which endanger human health, or which are not suitable for their claimed particular nutritional use. The Regulations also continue the existing arrangements which require companies to notify the Food Standards Agency when they place parnuts foods on the market for the first time.

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, Articles 9 and 11 of Commission Directive 89/398/EEC, as amended. Article 9 of Commission Directive 89/398/EEC requires companies to notify (followed, where necessary, by provision of supplementary material) the competent authority when they place parnuts foods which are not listed in the Annex to the Directive on the market for the first time. Article 11 of Directive 89/398/EEC allows a Member State to temporarily suspend or restrict trade in foods for particular nutritional use which are not clearly distinguishable from normal foods, which are not suitable for their claimed nutritional purpose, or which endanger human health.

4.2 This instrument also revokes the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002.

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 A food for a particular nutritional use (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 purpose.

7.2 Commission Directive 89/398/EEC lays down rules regarding the definition, labelling and advertising of parnuts foods marketed within the EU. The Directive requires that foods for particular nutritional uses meet the nutritional requirements of the persons for whom they are intended and that they are marketed as suitable for consumers with disturbed digestive processes or metabolism or who are in a special physiological condition. Parnuts foods marketed in the EU must also be safe for human consumption.

7.3 In order to facilitate monitoring of parnuts products, Article 9 of Commission Directive 89/398/EEC lays down a 'notification' requirement on companies which market certain parnuts food within the EU. When a company markets a parnuts food not listed in the Annex to Directive 89/398/EEC, they must notify the competent authority of the Member State in which the product is first marketed. The competent authority may request supplementary material from the company after the product has been notified.

7.4 Directive 1999/41/EC made some amendments to Directive 89/398/EC by extending its scope to two additional groups of foods, low-sodium foods and certain gluten free foods.

7.5 Article 11 of Directive 89/398/EEC allows each competent authority to temporarily suspend or restrict trade, within its own territory, of parnuts products that have been placed on the market that are not clearly distinguishable from foods for normal consumption, not suitable for their claimed nutritional purpose, or endanger human health. After consulting with the Standing Committee on the Food Chain and Animal Health (SCoFCAH), the European Commission would then decide whether the restriction should apply throughout the EU.

7.6 This instrument will ensure that the Food Standards Agency has the power to restrict trade in parnuts foods that do not meet with the requirements of Directive 89/398/EEC and thereby protect the UK consumer. This instrument will also ensure continued compliance with the European Commission's requirement to monitor parnuts foods as they are placed on the market.

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 significant 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) can answer any queries regarding the instrument.

Regulatory Impact Assessment

Title of proposal

1. The Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007.

Purpose and intended effect

Objective

2. The proposed Regulations, which implement, in England, Articles 9 and 11 of Commission Directive 89/398/EEC, will allow the Food Standards Agency to suspend or restrict trade in certain foods for particular nutritional uses (particular nutritional foods) which are not clearly distinguishable from foods for normal consumption or which are not suitable for their claimed particular nutritional use. The Regulations will also allow the Agency to suspend or restrict trade in certain foods for particular nutritional uses which endanger human health and thereby protect the consumer. The Regulations continue the existing arrangements which require companies to notify the Food Standards Agency when they place certain particular nutritional foods on the market for the first time. The Regulations will not impose any new burden on companies which legally market particular nutritional foods in the UK.
3. The Regulations will revoke the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002 SI 333.

Devolution

4. The proposed Regulations would apply in England only. Separate parallel legislation will be implemented in Scotland, Wales and Northern Ireland.

The background

5. Article 9 of Directive 89/398/EEC on foodstuffs for particular nutritional uses requires notification (followed, where necessary, by provision of supplementary material) to competent authorities when particular nutritional foods not listed in the Annex to the Directive are placed on the market for the first time.
6. Directive 1999/41/EC made some amendments to Directive 89/398/EEC. The amending Directive did not change the general notification measure but did extend its scope to two additional groups of foods, low-sodium foods, including sodium free dietary salts, and certain gluten-free foods.

7. Article 9 of Council Directive 89/398/EEC, as amended by Directive 1999/41/EC, was implemented by the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002 SI 333. Parallel legislation was implemented in Scotland and Northern Ireland. These Regulations prohibited the sale of products by manufacturers/importers covered by Article 9 unless they had been notified. To notify a new product manufacturers/importers provide the competent authority with a model of the label used for the product. In England and Wales, the Food Standards Agency is the competent authority.
8. Should the competent authorities of any EU Member State have detailed grounds to demonstrate that a certain parnut food is not clearly distinguishable from foods for normal consumption, is not suitable for its claimed particular nutritional use, or endangers human health, Article 11 of Directive 89/398/EEC allows that competent authority to temporarily suspend or restrict trade in the product within its own territory.
9. The current Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002 do not implement Article 11 of the Directive. The new Regulations must be implemented to ensure that the Agency has the power to take action to suspend or restrict the sale of certain foods for particular nutritional uses which are not clearly distinguishable from foods for normal consumption, which are not suitable for their claimed particular nutritional use, or which endanger human health. Implementing the new Regulations will thus enable the Food Standard Agency to protect the consumer.

Provisions in the proposed Regulations

10. The key proposals of the new Regulations are:
 - To implement, in England, Article 9 of Directive 89/398/EEC, which prohibits the sale of products covered by Article 9 unless they have been notified. The new Regulations would implement the same notification requirements as the existing Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002. Thus, the new Regulations would not impose any new burden on companies which market Parnuts foods which comply with Directive 89/398/EEC.
 - To implement Article 11 of Directive 89/398/EEC, which will ensure that the Food Standards Agency can suspend or restrict trade in certain foods for particular nutritional uses (Parnuts foods) which are not clearly distinguishable from foods for normal consumption, which are not suitable for their claimed particular nutritional use, or which endanger human health. The Agency would ensure that it had detailed grounds to demonstrate that a Parnuts food was not compliant with Directive 89/398/EEC before suspending or restricting the marketing of the product. Trade in products would be restricted by the Agency making a

- 'Declaration' which would suspend or restrict (by means of conditions) trade in that product. Declarations would be published in such a manner as the Agency thinks fit.
- To revoke The Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002, which implement Article 9 of Directive 89/398/EEC.

Rationale for government intervention

11. The Regulations are required to:
- Ensure continued compliance with the EC requirement to notify Article 9 foods for particular nutritional uses.
 - Provide maximum protection for UK consumers by ensuring that the Food Standards Agency can suspend or restrict trade in certain foods which are marketed as foods for particular nutritional uses, but which do not comply with the requirements of Directive 89/398/EEC.

Consultation

12. Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other Government departments were formally consulted on these draft Regulations.
13. The Agency received seven responses to the formal consultation, from VEGA (Vegetarian Economy & Green Agriculture), IDFA (Infant and Dietetic Foods Association), the Department of Culture, Media and Sport, Dailyceer Limited, The Royal Pharmaceutical Society of Great Britain, LACORS (the Local Authorities Coordinators of Regulatory Services) and the TSI (Trading Standards institute). All of the respondents stated their support for or had no specific comments regarding the implementation of the Regulations. None of the respondents objected to the implementation or offered any drafting comments, so no changes were made to the text of the SI as a result of consultation.

Options

14. Option 1 - Do nothing. This would mean that Article 11 of the Directive would not be implemented. The current Notification of Marketing of Food for Particular Nutritional Uses Regulations, which implement Article 9 of Directive 89/398/EEC would remain in force in England, Wales, Scotland and Northern Ireland.
15. Option 2 – Revoke the current Notification of Marketing of Food for Particular Nutritional Uses Regulations and replace them with the proposed Regulations which would implement Articles 9 and 11 of Directive 89/398/EEC.

Costs and benefits

Business sectors affected

16. Businesses producing/distributing certain parnuts foods would be affected by the proposed Regulations. The parnuts food sector in the UK is understood to be dominated by 10 large companies. Approximately 40 small companies are also involved in the production/distribution of parnuts products in the UK.

Consumers affected

17. 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

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

Public sector

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

Benefits

20. Option 1 – Would ensure continued compliance with the EC requirement to notify Article 9 foods for particular nutritional uses. There would be no additional benefits associated with maintaining the existing Regulations. The European Commission could bring infraction proceedings against the UK for not implementing part of the Directive.

21. Option 2 – Replacing the existing Regulations would allow the Agency, where appropriate, to take action under Article 11 of Directive 89/398/EC to suspend or restrict trade in certain foods for particular nutritional uses which are not clearly distinguishable from foods for normal consumption, which are not suitable for their claimed particular nutritional use, or which endanger human health. Implementing the Regulations will thus enable the Food Standards Agency to fully protect the consumer. The proposed Regulations would also ensure continued compliance with the EC requirement to notify Article 9 foods for particular nutritional uses.

Costs

22. Option 1 – Costs of potential infraction proceedings and potential costs to public health associated with the marketing of foods which are not suitable for particular nutritional uses.
23. Option 2 – The proposed Regulations implement the same notification requirements as the existing Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002. Consequently they would not impose any additional burden on companies marketing parnuts products which are compliant with Directive 89/398/EEC.
24. Implementing Article 11 would have no new policy cost impact on any company marketing parnuts foods which are compliant with Directive 89/398/EEC because their products would not be subject to a restriction in trade. There will, however, be a requirement for certain members of staff in these companies to check that the proposed Regulations do not impose any additional requirements beyond those incurred by complying with the requirements of the existing legislation. The Agency estimates that the time requirement will represent a one off administration cost of approximately £63.72 to an individual company. This estimate assumes that the task would be carried out by a corporate manager, on an hourly rate of £21.24, and that it takes three hours to carry out the task. As there are approximately 40 small companies in the UK involved in parnuts manufacturing/marketing, the total cost of checking the new Regulations to that sector is therefore approximately £2549. The total cost to all 10 large companies in the UK manufacturing/marketing parnuts products would be £638.
25. In their response to the Agency consultation on these proposals, the Infant and Dietetic Foods Association noted that the introduction of the Regulations would have no significant financial implication on manufacturers which belong to their trade association.
26. The environmental impact of either option is likely to be negligible.

Small Firms Impact Test

27. Small businesses have been consulted as part of the formal consultation. They have not indicated that they will be put at any disadvantage as a result of the Regulations.

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. The Agency considers that neither option will have a significant impact on competition in the parnuts industry. Although there will be a small one-off administration cost associated with introducing new legislation, this will not have a significant impact on the competitiveness of compliant firms in this market.

Enforcement, sanctions and monitoring

30. Enforcement of the Regulations would be the responsibility of food authorities. Persons convicted of an offence under these regulations would be liable to a fine not exceeding level 5 of the standard scale (currently £5,000).

Post-implementation review

31. There is no provision in the main Directive for a post-implementation review.

Summary and recommendation

32. In summary, making these Regulations will enable the Agency to:

- take action to protect the consumer under Article 11 of Directive 89/398/EEC and
- ensure continued compliance with the EC requirement to notify Article 9 foods for particular nutritional uses.

33. For these reasons, the Agency recommends that the relevant provisions of Directive 89/398/EEC should be implemented by the Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007.

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:.....20th January 2007.....

Contact point

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TRANSPOSITION NOTE: THE NOTIFICATION OF MARKETING OF FOOD FOR PARTICULAR NUTRITIONAL USES (ENGLAND) REGULATIONS 2007

Commission Directive 89/398/EEC lays down rules regarding the definition, labelling and advertising of particular nutritional uses foods marketed within the EU. This transposition note outlines how Articles 9 and 11 of the Directive are transposed into legislation in England.

Article	Objective	Implementation	Responsibility
Article 9	Sets out the notification procedure which Member States must put in place to facilitate efficient monitoring of particular nutritional uses foods that do not fall into any of the categories listed in the Annex	Regulations 2 and 3.	Secretary of State.
Article 11	Allows competent authorities to temporarily suspend or restrict trade in certain particular nutritional uses foods that are not distinguishable from foods for normal consumption, that are not suitable for their claimed particular nutritional use or that endanger human health	Regulation 4.	Secretary of State.