

## **Executive Note**

### **The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 SSI/2007/37**

The above instrument is being made in exercise of the powers conferred by sections 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990, and is subject to negative resolution procedure.

#### **Policy Objectives**

The purpose of this instrument is to implement, in Scotland, Articles 9 and 11 of Commission Directive 89/398/EEC, which will allow the Food Standards Agency to suspend or restrict trade in certain foods for particular nutritional uses (Peanut foods) which are not clearly distinguished 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 key proposals of the instrument are as follows:

- To implement, in Scotland, Article 11 of Directive 89/398/EEC which will ensure the Food Standards Agency in Scotland can suspend or restrict trade in certain foods for particular nutritional uses (Peanut foods) which are not clearly distinguished from foods for normal consumption, which are not suitable for their claimed particular nutritional use, or which endanger human health
- To implement, in Scotland, the same notification requirements (Article 9 of Directive 89/398/EEC) as the existing Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002
- To revoke the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002

Parallel implementing legislation will be made in England, Wales and Northern Ireland.

#### **Policy background**

The new Regulations are required because the original 2002 Regulations did not implement Article 11 of Directive 89/398/EEC. To ensure that the Agency has the power to take action to temporarily 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, Article 11 must be implemented.

#### **Consultation**

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.

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, Dailycer 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 SSI as a result of consultation.

### **Regulatory Impact**

There is a small one-off administration cost to companies to check that the new Regulations do not impose any additional requirements beyond those incurred by complying with the requirements of the existing legislation. This cost is estimated at £3,187 for the UK parnuts sector as a whole, which comprises 10 large and 40 small companies. Implementing the Regulations would have no other cost impact on any company marketing parnuts foods which are compliant with Directive 89/398/EEC.

The major UK manufacturers of parnuts foods noted that the introduction of the Regulations would have no significant financial impact. None of the small businesses consulted indicated that they will be put at any disadvantage as a result of the Regulations. A final Regulatory Impact Assessment is attached to this Executive Note.

### **Contact**

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### **Partial Regulatory Impact Assessment**

#### **1. Title of proposal**

1.1 The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007

## 2. **Purpose and intended effect**

### **Objective**

2.1 The proposed Regulations which implement, in Scotland, Articles 9 & 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 (Parnuts 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.

2.2 The Regulations also continue the existing arrangements which require companies to notify the Food Standards Agency when they place certain Parnuts foods on the market for the first time. The Regulations will not impose any new burden on companies which legally market Parnuts foods in the UK.

2.3 These Regulations will revoke the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002 [SSI 50/2002].

## 3. **Devolution**

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

## 4. **Background**

4.1 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 Parnuts foods not listed in the Annex to the Directive are placed on the market for the first time.

4.2 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 new groups of foods: low-sodium foods (including sodium-free dietary salts), and certain gluten-free foods.

4.3 Article 9 of Council Directive 89/398/EEC, as amended by Directive 1999/41/EC, was implemented in Scotland by the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002. Parallel

legislation was implemented in England 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 Scotland the Food Standards Agency is the competent authority.

- 4.4 Should the competent authorities of any EU Member State have detailed grounds to demonstrate that a Parnuts 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.
- 4.5 The current Notification of Marketing of Food for Particular Nutritional Uses (Scotland) 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 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.

## 5. **Provisions in the proposed Regulations**

The key proposals of the new Regulations are:

- 5.1 To implement, in Scotland, Article 9 of Directive 89/398/EEC, which prohibits the sale by manufacturers/importers of products covered by Article 9 unless they had been notified. The new Regulations would implement the same notification requirements as the existing Notification of Marketing of Food for Particular Nutritional Uses (Scotland) 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.
- 5.2 To implement, in Scotland, Article 11 of Directive 89/398/EEC, which will ensure that the Food Standards Agency can restrict trade in 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 and restricting the marketing of the product. Trade in products would be restricted via the use of 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.
- 5.3 To revoke The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002, which implement Article 9 of Directive 89/398/EEC.

## **6. Rationale for government intervention**

The Regulations are required to:

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

## **7.0 Consultation**

7.1 Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other Government Departments were formally consulted on these draft Regulations.

7.2 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, Dailyce Limited, The Royal Pharmaceutical Society of Great Britain LACORS (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 SSI as a result of the consultation.

## **8. Options**

### **Option 1**

- 8.1 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 would remain in force in Scotland, England, Wales and Northern Ireland.

### **Option 2**

- 8.2 Revoke the current Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002 and replace them with the proposed Regulations which would implement Articles 9 and 11 of Directive 89/398/EEC.

## **9. Costs and benefits**

### **Business sectors affected**

- 9.1 Businesses producing/distributing certain Parnuts foods would be affected by the proposed Regulations. The Parnuts food sector in the UK is dominated by

10 large companies. Approximately 40 small companies are also involved in the production/distribution of Parnuts products in the UK.

### **Consumers affected**

- 9.2 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 affected**

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

### **Public sector affected**

- 9.4 Government and enforcement officers would be affected by the legislation.

### **Benefits**

#### **Option 1**

- 9.5 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.

#### **Option 2**

- 9.6 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 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 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**

#### **Option 1**

- 9.7 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.

## **Option 2**

- 9.8 The proposed Regulations implement the same notification requirements as the existing Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002. Consequently, they would not impose any additional burden on companies marketing Parnuts products which are compliant with Directive 89/398/EEC.

- 9.9 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 a 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.

- 9.10 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 belonged to their trade association.

- 9.11 The environmental impact of either option is likely to be negligible.

## **10. Small Firms Impact Test**

- 10.1 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.

## **11. Impact on regions**

- 11.1 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.

12. **Test run of business forms**

12.1 There are no new forms associated with this piece of legislation

13. **Competition assessment**

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

14. **Enforcement, sanctions and monitoring**

14.1 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).

15. **Post-implementation review**

15.1 In line with Scottish Executive guidance, we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

16. **Summary and recommendation**

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

- Take action to protect the consumer under Article 11 of Directive 89/398/EEC. If we did not implement Article 11 of Directive 89/398/EEC, we would not be able suspend or restrict trade in foods which are marketed as foods for particular nutritional uses, but which do not comply with the requirements of Directive 89/398/EEC; and
- Ensure continued compliance with the EC requirement to notify Article 9 foods for particular nutritional uses. If we did not implement Article 9, we would not be able to prohibit the sale by manufacturers/importers of products covered by Article 9 unless they had been notified.

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 (Scotland) 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.....

Date.....

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