

Explanatory Memorandum

THE FOOD FOR PARTICULAR NUTRITIONAL USES (MISCELLANEOUS AMENDMENTS) (WALES) REGULATIONS 2007

This Explanatory Memorandum has been prepared by The Food Standards Agency Wales and is laid before the National Assembly for Wales.

Description

These Regulations implement, in Wales, Commission Regulation 1609/2006 and Commission Directives 2006/82/EC, 2006/125/EC, 2007/26/EC and 2007/29/EC. The new Regulations are required to bring domestic legislation in line with the underlying EU legislation in the area of foods for particular nutritional uses (parnuts). They will enable Welsh companies to continue to market existing parnuts products and/or introduce new 'parnuts' products to the market which will facilitate increased consumer choice.

Matters of special interest to the National Assembly's Legislation Committee

None.

Legislative Background

The powers enabling the Regulations to be made are contained in the Food Safety Act 1990. Sections 17(1), 26(1) (a) and (3) and 48(1) of the Food Safety Act 1990 are exercisable by Welsh Ministers. The Regulations are subject to the negative resolution procedure.

Purpose and intended effect of the legislation

These Regulations:

- provide for the execution and enforcement of Commission Regulation 1609/2006, which allows partially hydrolysed infant formula based on hydrolysates of whey protein from cows' milk to be placed on the market, provided that the conditions set out in the Commission Regulation are met (Regulation 2),
- bring the use of hunger and satiety claims prohibited by the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 for slimming foods into line with the provisions on the use of such claims in relation to foods for general consumption (Regulation 3),
- update the reference to "the Directive" in the Medical Food (Wales) Regulations 2000 to reflect the accession of Bulgaria and Romania to the European Union (Regulation 4),
- extend the period of derogation provided for in the Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 to 1st January 2010 (Regulation 5),

- update the reference to “the Directive” in the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004 (Regulation 6).

Implementation

These Regulations were made on 18 September 2007 and are intended to come into force on 15 October. Similar legislation will simultaneously come into force in England, Scotland and Northern Ireland on 15 October 2007.

The implementation of these Regulations would fulfil the UK’s obligations under the EC Treaty and will provide Local Authorities with the power to enforce against food business operators who are not in compliance with the new Regulations. Failure to implement these Regulations in Wales by the coming into force date of 15 October would lead to inconsistency in UK law.

Consultation

The Food Standards Agency originally carried out a 12-week consultation from the 2 April to the 21 June 2007 on proposed Regulations to provide for the enforcement of Commission Regulation 1609/2006, and the implementation of Commission Directive 2006/82/EC and Commission Directive 2006/125/EC.

From 19 July to the 16 August 2007, the Food Standards Agency Wales carried out a further consultation to incorporate the implementation of Commission Directive 2007/26/EC and Commission Directive 2007/29/EC. These new Commission Directives are both minor, bringing only benefits to consumers and food manufacturers. As such, it was decided that a full 12-week consultation was not necessary on this occasion. The shortened consultation also means that these Commission Directives will be implemented before the European deadline of 30 November 2007

Stakeholders, including industry, enforcement, consumer representatives were invited to comment on the draft Regulations and the draft Regulatory Appraisal. Both consultation packages were posted on the Agency’s website. Forty seven interested parties were consulted in Wales, no comments were received. A total of 5 responses to the formal consultations were received UK-wide from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, the UK Very Low Calorie Diet Foods Industry group and LACORS. These offered no specific comments or outlined support for the implementation of the proposed Regulations.

No policy changes to the draft Regulations were identified as a consequence of the public consultation.

Regulatory Impact Assessment

The purpose of a Regulatory Impact Assessment (RIA) is to assess and record the likely costs and benefits of the forthcoming provisions for businesses, consumers and enforcement bodies. Given that the proposed changes in Regulations 4 and 6 do not change any of the requirements of national legislation we do not anticipate that implementation of these Regulations will impose any costs or savings on businesses. Therefore, a RIA has not been prepared to accompany Regulations 4 and 6. However, stakeholders were consulted on the changes and asked to provide any information relating to costs or savings if any were identified. Regulatory Impact Assessments for Regulations 2, 3 and 5 are set out below.

Regulatory Impact Assessment for Regulation 2 – derogation from specific compositional requirements of the infant formula and follow-on formula Regulations

Scope

1. Regulation 2 is required to implement a European Commission Regulation which is directly applicable in Member States.

Options

2. Options for transposing the provisions of Commission Regulation 1609/2006 are as follows:
 - Option 1: do nothing i.e. fail to implement Commission Regulation 1609/2006
 - Option 2: implement the provisions of Commission Regulation 1609/2006

Flexibility

3. The Commission Regulation does not offer any flexibility on the implementation of its provisions.

Costs and benefits

Business sectors affected

4. The new provisions affecting the composition of infant formula would benefit those businesses involved in the manufacture and sale of these products as well as those involved in the production of ingredients.

5. According to the Mintel.¹ UK retail sales of baby foods and drinks in 2004 totalled £319.5 million with £152.4 million (47.7% of the total) accounted for by sales of infant formula and follow-on formula. The supply structure for infant formula and follow-on formula is characterised by three major manufacturers accounting for 97% of sales. Infant formula and follow-on formula are distributed via a wide range of retail outlets, with around 15% sales by volume being through NHS baby clinics.

Consumers affected

6. The legislation will facilitate increased consumer choice. 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

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

Benefits

8. Option 1 – failure to implement would not bring any benefits to consumers, industry, enforcement authorities or the Welsh Assembly Government. Failure to implement would also be a risk to the Welsh Assembly Government as it would result in a 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. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement.
9. Option 2 – Implementation would benefit consumers by increasing consumer choice; benefit industry by allowing new products to be placed on the market; and benefit the Assembly by removing the risk of infraction procedures.

Costs

10. Option 1 – Failure to implement would prevent consumers having access to a product which has been approved for use in the EU and would disadvantage UK companies which would be unable to market a product suitable for infants. Lack of implementation could result in the Welsh Assembly Government facing potential infraction proceedings

¹ Baby Food, Drinks and Milk, UK, November 2005, Mintel

and inadequate regulation of the market which would impact on businesses and consumer choice.

11. Option 2 – There are no costs to consumers, businesses, enforcement authorities or the Welsh Assembly Government associated with implementation of this new Regulation.

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

Administrative Burden

13. The administrative burden is the cost of complying with a Regulation to provide information, less any costs that would be incurred during the normal course of business (i.e. if the legislative information requirement was not in place). There are currently less than 10 manufacturers of infant formula and follow-on formula in the UK, none of which is in Wales. We believe that the only additional administrative burden to these companies would be the one-off cost to read and understand this Regulation. There would be no other additional administrative costs.

Small Firms Impact Test

14. As the supply of infant formula and follow-on formula is characterised by a small number of large firms accounting for 97% of sales in this area the impact of these Regulations on small firms will be minimal.

Enforcement, sanctions and monitoring

15. Local authorities are responsible for enforcing the Regulations. The amending Regulations bring no new enforcement responsibilities.

Competition Assessment

16. As stated above, the supply structure for infant formula and follow-on formula is characterised by three major manufacturers accounting for 97% of the sales. It is possible that implementation of this amendment may act to encourage or facilitate new entry or growth within this market. As such we consider this amendment to have the potential of being pro-competitive.

Consultation

17. The Food Standards Agency originally carried out a 12-week consultation from the 2 April to the 21 June 2007 on proposed Regulations to provide for the enforcement of Commission Regulation 1609/2006, and the implementation of Commission Directive 2006/82/EC and Commission Directive 2006/125/EC.

18. From 19 July to the 16 August 2007, the Food Standards Agency Wales carried out a further consultation to incorporate the implementation of Commission Directive 2007/26/EC and Commission Directive 2007/29/EC.
19. These new Commission Directives are both minor, bringing only benefits to consumers and food manufacturers. As such, it was decided that a full 12-week consultation was not necessary on this occasion. The shortened consultation also means that these Commission Directives will be implemented before the European deadline of 30 November 2007. The Minister was notified of the shortened consultation in an earlier submission of 17 July 2007 (SF/GT/0010/07)
20. Stakeholders, including industry, enforcement, consumer representatives were invited to comment on the draft Regulations and the draft Regulatory Appraisal. Both consultation packages were posted on the Agency's website. Forty seven interested parties were consulted in Wales, no comments were received. A total of 5 responses to the formal consultations were received UK-wide from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, the UK Very Low Calorie Diet Foods Industry group and LACORS. These offered no specific comments or outlined support for the implementation of the proposed Regulations.
21. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

Post-implementation review

22. The Commission Regulation does not provide for any specific review date and there is no provision in the main Infant formula and follow-on formula Directive for a review. The UK would, however, participate in any future revision of the requirements of the EU legislation that may be taken forward at an EU level.

Summary and Recommendations

23. In summary, making these Regulations would enable us to fulfil our Community obligations and would 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 possibility of heavy fines.
24. For these reasons the Agency recommends that the UK should implement the provisions of Commission Regulation 1609/2006 and the related Commission Directives 2006/82/EC and 2006/125/EC via

the Food for Particular Nutritional Uses (Miscellaneous Amendments)
(Wales) Regulations 2007.

Regulatory Impact Assessment for Regulation 3 to allow the use of 'reduced hunger' and 'increased satiety' claims on foods intended for use in energy restricted diets for weight reduction

Scope

1. This RIA estimates the cost and impact of implementing Regulation 3 to bring the use of hunger and satiety claims prohibited by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 in relation to slimming foods into line with the provisions on the use of such claims in relation to foods for general consumption.

Options

2. Options for transposing the provisions of the new Regulation are as follows:
 - Option 1: do nothing i.e. fail to implement Directive 2007/29/EC
 - Option 2: implement the provisions of Directive 2007/29/EC as soon as possible as required by European law.

Flexibility

3. The Commission Directive 2007/29/EC does not offer any flexibility on the implementation of its provisions.

Benefits

Business sectors

4. The businesses which benefit by the amending Directive, and hence the new Regulation, are food businesses producing/distributing slimming foods. According to Mintel², the slimming food sector in the UK is estimated to worth 32 million pounds with one company accounting for 60% of the market share.

Consumers

5. 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.

² 2006 Mintel report on slimming foods

Voluntary Organisations and charities

6. We are not aware of any charities or voluntary organisations that would be affected by the legislation.
7. The Welsh Assembly Government and enforcement authorities would not be affected by the legislation.
8. Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or the Welsh Assembly Government
9. Option 2: implementation brings benefits to the Welsh Assembly Government by removing the risk of incurring infraction proceedings and benefits industry by restoring a level playing field with regard to the claims that can be made on slimming products in comparison to claims made on general foods.

Costs

10. Option 1: Failure to implement would also be a risk to the Welsh Assembly 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 possibility of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement. Failure to implement would bring risks and disbenefits to consumers, industry, enforcement authorities and the Assembly. Failure to implement would represent an unjustified restriction on a particular sector of industry and could mislead consumers.
11. Option 2: The Agency considers that there are no costs to consumers, enforcement authorities or the Welsh Assembly Government associated with implementation of Commission Directive 2007/29/EC. However, failure to implement would result in companies producing slimming foods being significantly disadvantaged. There may be costs to businesses who choose to relabel their products in light of this change in legislation but this would normally be done as part of normal label redesign.
12. The environmental impact of either option is likely to be negligible.

Administrative Burden on businesses

13. The administrative burden is the cost of complying with a Regulation to provide information, less any costs that would be incurred during the normal course of business (i.e. if the legislative information requirement was not in place). We believe that the only additional administrative burden to these companies would be a one-off cost to read and

understand this Regulation. There would be no other additional administrative costs.

Small Firms Impact Test

14. Small businesses have been consulted informally and have not indicated that they will be put at any disadvantage as a result of the Regulation.

Enforcement, sanctions and monitoring

15. Local authorities are already responsible for enforcing The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997. The responsibilities for enforcement, sanctions and monitoring would remain unchanged.

Competition Assessment

16. As Option Two does not have a direct cost impact on industry, neither will it have a significant negative impact on competition in the slimming foods industry. Indeed, the change in the UK situation is likely to allow continued marketing of products and promote innovative product formulation in this industry.

Consultation

17. From 19 July to the 16 August 2007, the Food Standards Agency Wales carried out a further consultation to incorporate the implementation of Commission Directive 2007/26/EC and Commission Directive 2007/29/EC.
18. These new Commission Directives are both minor, bringing only benefits to consumers and food manufacturers. As such, it was decided that a full 12-week consultation was not necessary on this occasion. The shortened consultation also means that these Commission Directives will be implemented before the European deadline of 30 November 2007. The Minister was notified of the shortened consultation in an earlier submission of 17 July 2007 (SF/GT/0010/07)
19. Stakeholders, including industry, enforcement, consumer representatives were invited to comment on the draft Regulations and the draft Regulatory Appraisal. Both consultation packages were posted on the Agency's website. Forty seven interested parties were consulted in Wales, no comments were received. A total of 5 responses to the formal consultations were received UK-wide from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, the UK Very Low Calorie Diet Foods Industry group and LACORS. These

offered no specific comments or outlined support for the implementation of the proposed Regulations.

20.No policy changes to the draft Regulations were identified as a consequence of the public consultation.

Post-implementation review

21.The Directive does not provide for any specific review date and there is no provision in the main Directive for a review. The UK would, however, participate in any future review of the Directive that may be taken forward at an EU level.

Summary and Recommendations

22.In summary, making these Regulations would enable us to fulfil our community obligations and would benefit industry. Failure to make these Regulations would result in a serious breach of the UK's obligations under the EC Treaty would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

23.For these reasons the Agency recommends that the UK should implement the provisions of Commission Directive 2007/29/EC via the Food for Particular Nutritional Uses (Miscellaneous Amendments) (Wales) Regulations 2007.

Regulatory Impact Assessment for Regulation 5 to implement the extension of the period of derogation for addition of substances that may be added to foods for particular nutritional uses.

Scope

1. This RIA estimates the cost and impact of implementing Regulation 5 to extend the period of derogation provided for in The Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002.

Options

2. Options for transposing the provisions of the new Regulation are as follows:
 - Option 1: do nothing i.e. fail to implement Directive 2007/26/EC
 - Option 2: implement the provisions of Directive 2007/26/EC as soon as possible as required by European law.

Flexibility

3. Commission Directive 2007/26/EC does not offer any flexibility on the implementation of its provisions.

Benefits

Business sectors

4. Businesses benefited by the amending Directive, and hence the new Regulation, are food businesses producing/distributing certain foods for particular nutritional uses (parnuts) foods. The parnuts food sector in the UK is characterized by approximately 10 large companies. Approximately 40 small companies are also involved in the production/distribution of 'parnuts' products in the UK.

Consumers

5. The legislation will benefit consumers of certain 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

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

7. Welsh Assembly Government and enforcement authorities would not be affected by the legislation.
8. Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or the Welsh Assembly Government
9. Option 2: implementation brings benefits to consumers, industry, enforcement authorities and the Welsh Assembly Government. It benefits consumers by maintaining consumer choice; benefits industry by permitting the continued marketing of valuable products; benefits enforcement officers as it does not introduce new burdens and benefits the Welsh Assembly Government by removing the risk of incurring infraction proceedings.

Costs

10. Option 1: Failure to implement would bring risks and disbenefits to consumers, industry and the Welsh Assembly Government. Failure to implement would also be a risk to the Welsh Assembly 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 possibility of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement. 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.
11. Option 2: The Agency considers that there are no costs to consumers, businesses, enforcement authorities or the Welsh Assembly Government associated with implementation of Commission Directive 2007/26/EC. However, as stated in the RIA that accompanied the 2002 Regulations, failure to implement would result in companies having to "reformulate certain products or remove them from the market; either of these outcomes would result in considerable costs".
12. The environmental impact of either option is likely to be negligible.

Administrative Burden on businesses

13. The administrative burden is the cost of complying with a Regulation to provide information, less any costs that would be incurred during the normal course of business (i.e. if the legislative information requirement was not in place). We believe that the only additional administrative burden to these companies would be the one-off cost to read and

understand this Regulation. There would be no other additional administrative costs.

Small Firms Impact Test

14. The new Regulations will allow companies to continue using certain products in these foods. This will allow small business, along with larger business, to continue to market parnuts foods, which contain substances, listed in the Annex. Small businesses have been consulted informally and have not indicated that they will be put at any disadvantage as a result of the Regulations.

Enforcement, sanctions and monitoring

15. Local authorities are responsible for enforcing The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002. Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the RIA for the original legislation

Competition Assessment

16. 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 original legislation.

Consultation

17. During the negotiations of the draft amendment to the Commission Directive 2007/26/EC, the Agency consulted informally with stakeholders, including small to medium sized enterprises (SMEs). The Agency UK received one written response to our informal consultation, from the Infant and Dietetic Foods Association, who supported the proposed amendment to the European Directive.
18. From 19 July to the 16 August 2007, the Food Standards Agency Wales carried out a further consultation to incorporate the implementation of Commission Directive 2007/26/EC and Commission Directive 2007/29/EC.
19. These new Commission Directives are both minor, bringing only benefits to consumers and food manufacturers. As such, it was decided that a full 12-week consultation was not necessary on this occasion. The shortened consultation also means that these Commission Directives will be implemented before the European deadline of 30 November 2007. The Minister was notified of the

shortened consultation in an earlier submission of 17 July 2007 (SF/GT/0010/07)

20. Stakeholders, including industry, enforcement, consumer representatives were invited to comment on the draft Regulations and the draft Regulatory Appraisal. Both consultation packages were posted on the Agency's website. Forty seven interested parties were consulted in Wales, no comments were received. A total of 5 responses to the formal consultations were received UK-wide from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, the UK Very Low Calorie Diet Foods Industry group and LACORS. These offered no specific comments or outlined support for the implementation of the proposed Regulations.
21. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

Post-implementation review

22. The Directive does 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. The UK would, however, participate in any future review of the Directive that may be taken forward at an EU level.

Summary and Recommendations

23. 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 would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.
24. For these reasons the Agency recommends that the UK should implement the provisions of Commission Directive 2007/26/EC via the Food for Particular Nutritional Uses (Miscellaneous Amendments) (Wales) Regulations 2007.