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S T A T U T O R Y   I N S T R U M E N T S

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**2007 No. 0000**

**FOOD, ENGLAND**

**The Nutrition and Health Claims (England) Regulations 2007**

<i>Made</i> - - - -	2007
<i>Laid before Parliament</i>	2007
<i>Coming into force</i> - -	***

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(e) and (f), 17(2), 26(1)(a), and (3), and 48(1) of the Food Safety Act 1990(a), and now vested in her(b).

In accordance with section 48(4A) of that Act, she has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title, application and commencement**

1. These Regulations may be cited as the Nutrition and Health Claims (England) Regulations 2007, apply in relation to England only and come into force on [—] 2007.

**Interpretation**

2.—(1) In these Regulations —

“the Act” means the Food Safety Act 1990;

“food authority” does not include —

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- (a) 1990 c. 16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- (c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended as at the date these Regulations are made by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

## CONSULTATION DRAFT

- (a) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple); or
- (b) the council of a district of a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change;

“port health authority” means —

- (c) in relation to the London port health district, the Common Council of the City of London, and
- (d) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984<sup>(a)</sup>, a port health authority for that district constituted by order under section 2(4) of that Act;

“the Regulation” means Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods<sup>(b)</sup>.

(2) Expressions used in these Regulations and in the Regulation have the same meaning in these Regulations as they do in that Regulation.

(3) Any reference to a numbered Article is a reference to the Article so numbered in the Regulation.

### Competent Authorities

3. The competent authority for the purposes of the Regulation —

- (a) in relation to Articles 1(4), 15(2), 16(2), 18(2) [and 26] is the Food Standards Agency, and
- (b) in relation to Article 6(3) is —
  - (i) each port health authority in its district, and
  - (ii) outside such districts, each food authority in its area.

### Enforcement

4. Each port health authority within its district and each food authority within its area shall execute and enforce the provisions of these Regulations and of the Regulation.

### Offences and Penalties

5.—(1) Subject to the derogation contained in Article 1(3) (relating to trade marks etc) and to the transitional measures contained in Article 28, any person who contravenes or fails to comply with the provisions of the Regulation specified in paragraph (2) is guilty of an offence and liable —

- (a) on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both;
- (b) on summary conviction to a term of imprisonment not exceeding three months or to a fine not exceeding the statutory maximum or both.

(2) The specified provisions referred to in paragraph (1) are —

- (a) Article 3 (general requirements relating to all claims);
- (b) Article 4(3) (restrictions on claims that may be made on alcoholic beverages);
- (c) Article 6[(1)] and (2) (requirement for scientific substantiation of claims);
- (d) Article 7 (requirements for nutrition information);
- (e) Article 8(1) (requirements for nutrition claims);
- (f) Article 9 (requirements for comparative claims);

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(a) 1984 c.22.

(b) The revised text of this Regulation is now set out in a Corrigendum (OJ No. L12, 18.1.2007, p.3).

- (g) Article 10(1), (2) and (3) (requirements for health claims);
- (h) Article 12 (prohibition of certain health claims);
- (i) Article 14(2) (requirements for reduction of disease risk claims).

#### **Application of various provisions of the Act**

6. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations —

- (a) section 2 (extended meaning of “sale” etc);
- (b) section 3 (presumption that food is intended for human consumption);
- (c) section 20 (offences due to the fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 14 or 15;
- (e) section 22 (defence of publication in the course of business);
- (f) section 30(8) (which relates to documentary evidence);
- (g) section 34 (time limit for prosecution);
- (h) section 36 (offences by bodies corporate);
- (i) section 36A (offences by Scottish partnerships); and
- (j) section 44 (protection of officers acting in good faith).

#### **Obstruction of officers and provision of information etc**

7.—(1) Any person who —

- (a) intentionally obstructs any person acting in the execution of these Regulations;
- (b) fails to comply with a request under Article 26 made by the competent authority; or
- (c) without reasonable cause, fails to give to any person acting in the execution of these Regulations any assistance or information which that person may reasonably require of him,

is guilty of an offence and liable on summary conviction to a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 on the standard scale or both.

(2) Any person who, in purported compliance with any requirement mentioned in paragraph (1)(c), knowingly or recklessly provides information that is false or misleading in any material particular, is guilty of an offence and liable —

- (a) on conviction on indictment, to a term of imprisonment not exceeding two years or to a fine or both;
- (b) on summary conviction to a term of imprisonment or to a fine not exceeding the statutory maximum or both.

(3) Nothing in paragraph (1)(c) shall be construed as requiring any person to answer any question or give any information if to do so might incriminate him.

#### **Amendment of the Food Labelling Regulations**

8.—(1) The Food Labelling Regulations 1996<sup>(a)</sup> are amended in accordance with paragraph (2).

(2) After paragraph (4) of regulation 41, insert the following paragraph —

“(5) Nothing in regulation 40 or in Schedule 6 or 8 shall operate to prohibit or, as the case may be, restrict a claim made in accordance with the conditions of Regulation (EC)

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(a) S.I. 1996/1499. There have been amendments to these Regulations, but none are relevant.

CONSULTATION DRAFT

1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods(a).”.

Signed by authority of the Secretary of State for Health

0th Month 2007

*Caroline Flint*  
Minister of State  
Department of Health

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(a) The revised text of this Regulation is now set out in a corrigendum (OJ No. L12, 18.1.2007, p.3).

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

**NATIONAL ASSEMBLY FOR WALES**

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**S T A T U T O R Y   I N S T R U M E N T S**

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**2007 No. (W. )**

**FOOD, WALES**

**The Nutrition and Health Claims  
(Wales) Regulations 2007**

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

**2007 No. (W.)**

**FOOD, WALES**

**The Nutrition and Health Claims  
(Wales) Regulations 2007**

*Made* 2007

*Coming into force* 2007

The [National Assembly for Wales] makes the following Regulations in exercise of the powers conferred by sections 16(1)(e) and (f), 17(2), 26(1)(a), and (3), and 48(1) of the Food Safety Act 1990<sup>(1)</sup>, and now vested in it<sup>(2)</sup>.

In accordance with section 48(4A) of that Act, he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(3)</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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- (1) 1990 c. 16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990
- (2) Functions formerly exercisable by “Secretary of State” so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act.
- (3) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended as at the date these Regulations are made by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

## **Title, application and commencement**

1. These Regulations are called the Nutrition and Health Claims (Wales) Regulations 2007, apply in relation to Wales and come into force on [—] 2007.

## **Interpretation**

2.—(1) In these Regulations —

“the Act” (“*y Ddeddf*”) means the Food Safety Act 1990;

“food authority” (“*awdurdod bwyd*”) has the same meaning as in section 5(1A) and (3)(a) and (b) of the Act;

“port health authority” (“*awdurdod iechyd porthladd*”) means in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984(a), a port health authority for that district constituted by order under section 2(4) of that Act;

“the Regulation” (“*—*”) means Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods<sup>(1)</sup>.

(2) Expressions used in these Regulations and in the Regulation have the same meaning in these Regulations as they do in that Regulation.

(3) Any reference to a numbered Article is a reference to the Article so numbered in the Regulation.

## **Competent Authorities**

3. The competent authority for the purposes of the Regulation —

(a) in relation to Articles 1(4), 15(2), 16(2), 18(2) [and 26] is the Food Standards Agency, and

(b) in relation to Article 6(3) is —

(i) each port health authority in its district, and

(ii) outside such districts, each food authority in its area.

## **Enforcement**

4. Each port health authority within its district and each food authority within its area will execute and enforce the provisions of these Regulations and of the Regulation.

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<sup>(1)</sup> The revised text of this Regulation is now set out in a Corrigendum (OJ No. L12, 18.1.2007, p.3).

## **Offences and Penalties**

**5.**—(1) Subject to the derogation contained in Article 1(3) (relating to trade marks etc) and to the transitional measures contained in Article 28, any person who contravenes or fails to comply with the provisions of the Regulation specified in paragraph (2) is guilty of an offence and liable —

- (a) on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both;
- (b) on summary conviction to a term of imprisonment not exceeding three months or to a fine not exceeding the statutory maximum or both.

(2) The specified provisions referred to in paragraph (1) are —

- (a) Article 3 (general requirements relating to all claims);
- (b) Article 4(3) (restrictions on claims that may be made on alcoholic beverages);
- (c) Article 6[(1)] and (2) (requirement for scientific substantiation of claims);
- (d) Article 7 (requirements for nutrition information);
- (e) Article 8(1) (requirements for nutrition claims);
- (f) Article 9 (requirements for comparative claims);
- (g) Article 10(1), (2) and (3) (requirements for health claims);
- (h) Article 12 (prohibition of certain health claims);
- (i) Article 14(2) (requirements for reduction of disease risk claims).

## **Application of various provisions of the Act**

**6.** The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations —

- (a) section 2 (extended meaning of “sale” etc);
- (b) section 3 (presumption that food is intended for human consumption);
- (c) section 20 (offences due to the fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 14 or 15;
- (e) section 22 (defence of publication in the course of business);

- (f) section 30(8) (which relates to documentary evidence);
- (g) section 34 (time limit for prosecution);
- (h) section 36 (offences by bodies corporate);
- (i) section 36A (offences by Scottish partnerships); and
- (j) section 44 (protection of officers acting in good faith).

**Obstruction of officers and provision of information etc**

7.—(1) Any person who —

- (a) intentionally obstructs any person acting in the execution of these Regulations;
- (b) fails to comply with a request under Article 26 made by the competent authority; or
- (c) without reasonable cause, fails to give to any person acting in the execution of these Regulations any assistance or information which that person may reasonably require of him,

is guilty of an offence and liable on summary conviction to a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 on the standard scale or both.

(2) Any person who, in purported compliance with any requirement mentioned in paragraph (1)(c), knowingly or recklessly provides information that is false or misleading in any material particular, is guilty of an offence and liable —

- (a) on conviction on indictment, to a term of imprisonment not exceeding two years or to a fine or both;
- (b) on summary conviction to a term of imprisonment or to a fine not exceeding the statutory maximum or both.

(3) Nothing in paragraph (1)(c) may be construed as requiring any person to answer any question or give any information if to do so might incriminate that person.

**Amendment of the Food Labelling Regulations**

8.—(1) The Food Labelling Regulations 1996(1) are amended in accordance with paragraph (2).

(2) After paragraph (4) of regulation 41, insert the following paragraph —

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(1) S.I.1996/1499. There have been amendments to these Regulations, but none are relevant.

“(5) Nothing in regulation 40 or in Schedule 6 or 8 operates to prohibit or, as the case may be, restrict a claim made in accordance with the conditions of Regulation (EC) 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods(1).”.

[Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(2)]

Date

*Dafydd Elis Thomas*

The Presiding Officer of the National Assembly]

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(1) The revised text of this Regulation is now set out in a corrigendum (OJ No. L12, 18.1.2007, p.3).

(2) 1998 c.38.

## **DRAFT FINAL REGULATORY IMPACT ASSESSMENT**

### **1. The Nutrition and Health Claims (England) Regulations 2007 and The Nutrition and Health Claims (Wales) Regulations 2007**

implementing

**REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL OF 20 DECEMBER ON NUTRITION AND HEALTH  
CLAIMS MADE ON FOODS [formerly COM(2003) 424 FINAL / 2003/0165  
(COD)]**

**[Please note: Section 4 addresses administrative burdens for the first  
time; we are asking specific questions here and in other parts of Section  
4 to which we would like you to pay particular attention.]**

### **2. PURPOSE AND INTENDED EFFECTS OF THE MEASURE**

#### **(i) Objective**

2.1 The Regulation aims to harmonise Community rules on the use of nutrition and health claims on food (including food supplements) in order to protect consumers from false and misleading claims and to enable free movement of goods within the Community.

#### **Devolution**

2.2 The Regulation will be directly applicable throughout the UK. Statutory instruments in each of the Administrative areas will be required to establish offences and penalties.

#### **(ii) Background**

2.3 The Regulation controls the use of nutrition and health claims (as defined in Article 2) made on foods. Voluntary claims may be made, but only if they are substantiated by science and have been authorised and placed on a Community list. These lists will then make up the Community Register. The Regulation would establish:

- a list of permitted nutrition claims (claims as to the nutrient content of the food, such as 'low fat' or 'reduced salt') and the conditions under which they may be made;
- procedures for pre-market authorisation of health claims. There will be three main routes for authorisation – claims describing growth, development or function (such as 'helps maintain a healthy heart' – Article 13), claims about the reduction of risk factors in human disease (such as 'may reduce the risk of heart disease' – Article 14), and claims referring to children's development and health (such as 'to help children grow strong bones' – also Article 14). Where emerging science or proprietary data is to be submitted for any of these claims, a fourth route for authorisation is allowed (Article 18). The European Food Safety Authority (EFSA) is to be consulted on the supporting scientific evidence before authorisations are given. For Article 13 claims, these may continue in use in Member States during a transitional period of 3 years pending adoption of a Community list of such claims. These are to be substantiated by reference to generally accepted scientific data. Authorisation of all other claims will require the submission of specific dossiers (as outlined in Articles 15 – 18).

#### 2.4 The Regulation will also:

- require the Commission to establish nutrient profiles<sup>1</sup> to qualify which foods may carry claims, based on criteria for fat, sugar and salt content;
- prohibit some specific categories of health claims; and
- require certain labelling information on foods carrying health claims, including information on nutrient content.

2.5 UK legislation on claims has been the Food Labelling Regulations 1996 and the Food Safety Act 1990 (and parallel legislation in Northern Ireland) and in the Trade Descriptions Act 1968, which also implements European Community rules (Directives 2000/13/EC and 90/496/EEC). This legislation clarifies the position of some nutrition claims, and effectively requires that all claims, including health claims, should not be false or mislead consumers. It also prohibits attributing to food the property of preventing, treating or curing a

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<sup>1</sup> Nutrient profiles – the amount of the main nutrients in a food, with an indication of whether they are "a lot" or "a little" - could be used, for example, to prevent heart health claims on foods high in salt.

human disease, or referring to such properties. Member States interpret this differently. Nutrition labelling is compulsory when a nutrition claim is made.

2.6 Agency research shows that over half (52%) of UK consumers are 'fairly' concerned about the accuracy of health claims<sup>2</sup>. Between 2001-03 the ASA upheld 23 complaints against health claims in advertising made on food products that did not comply with its Code. The Code requires health claims to be substantiated with an appropriate level of scientific evidence – this is that which its panel of experts deems necessary to support the claim. Food enforcement authorities complain that the lack of specific legislation in this area stays their hand in a number of cases where they believe action is merited, particularly as health claims become more complex and subtle. This Regulation recognises the changing demands of consumers for more information about food on offer and how it contributes to their diet and health, yet seeks to meet the challenge of communicating this without misleading consumers. It would also allow foods carrying claims to circulate within the single market without restriction, which is not currently the case.

2.7 In the absence of detailed Community rules on the use of nutrition or health claims on food, Member States' rules vary widely, e.g. Spain classifies many food supplements as medicinal products, partly because of the claims made. The UK operates a voluntary system via the Joint Health Claims Initiative (JHCI) which has an agreed code of practice and a system to authorise health claims manufacturers wish to use, but this provides only patchy coverage (at time of writing JHCI has authorised 6 generic health claims). Limited uptake of this useful service and application of the code has been disappointing, and strengthened the need for a regulatory approach.

### **(iii) Risk assessment**

2.8 The main risk to be considered from the use of nutrition and health claims is the potential for the consumer to be confused or misled. Agency surveys indicate that consumers find claims influential in forming purchasing decisions. As such, it is important that claims are accurate and clear so that the consumer can make an informed choice about buying the product. Confusing or misleading information could undermine healthy eating messages and act as a barrier to improved public health outcomes. Estimating the benefits of reducing this risk is difficult; however it was

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<sup>2</sup> Annual Consumer Survey

estimated that by 2000 obesity cost the nation some £2.5 billion a year<sup>3</sup>. This gives an indication of the scope for benefits that could accrue from ensuring that labelling helps consumers to choose a healthy diet.

2.9 The Regulation seeks to address the use on an increasing number of foods in labelling and advertising of nutrition claims, such as 'low fat' and 'sugar free', and health claims such as 'helps maintain a healthy heart', 'good for your bones', etc. Such claims are often influential and can be useful in helping consumers make decisions about what foods to eat, but only if the claims are true and not presented in a way which undermines advice on healthy diets and lifestyles. At a time when there is increasing obesity and diet related diseases such as type 2 diabetes and osteoporosis, an appropriate level of control over claims of the kind illustrated above is of clear public health benefit.

2.10 Nutrition claims are common, especially on the 'healthy option' brands that most of the major retailers now have (for which it was estimated in 2003 that there are some 4,250 products on the market with a value of over £1 billion<sup>4</sup>). In the absence of specific legislation, the Agency has produced guidance on how such claims should be used. This Regulation imposes conditions similar to our guidance, although they are based on Codex standards which in some cases are less exacting than Agency guidance. However, this was seen as a positive move to improve trade opportunities and a small concession when moving to regulation rather than advisory guidelines.

2.11 The products likely to be most affected by this legislation are those bearing health claims. The Regulation would not ban any foods, but industry indicates that some products may become less commercially viable should they not be allowed to bear claims (as the consumer would not be attracted to the product or understand its role in the diet without a claim). There is a lack of data on the number of products with health claims on the market, and which foods might be affected. The Agency conducted an audit to provide more information here and this indicated that there were in the region of 1000 health claims, of which more than half are food supplements. However, this is a dynamic market and this figure may well have changed as new claims come onto the market (although others will disappear which could balance the effect). It would appear that the biggest impact of the Regulation would be on the food supplements sector.

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<sup>3</sup> 2000 figure. Tackling Obesity in England, National Audit Office 2001

<sup>4</sup> Information from the British Retail Consortium

The food supplements sector was worth an estimated £350 million in 2003<sup>5</sup>. The likely impact of the Regulation could be significant, but to what extent will depend upon how many of the health claims included on these products will fall outside the 'generally accepted' category. Claims on food supplements can be divided into those on vitamins and minerals and those on "other substances". Of the vitamin and minerals, it would appear that about half could meet the "generally accepted" criteria. While we have limited data on claims on "other substances", at a meeting in January 2005 food supplement industry representatives were confident that a similar situation would exist. Industry is currently compiling a list of generally accepted health claims and when presented to the Agency should indicate more accurately how many claims will need to be supported by full scientific dossiers.

### **Business sectors and charities affected**

2.12 The Regulation would affect all food and food supplement manufacturing businesses or their suppliers, or retailers with their own labelling, wishing to make a claim for the nutrition or health benefits of the food. It is clear that the largest cost implication will be in relation to the cost of re-labelling, and for some products in the production of dossiers to substantiate claims. Another potential cost is that of future innovation in the food industry because of timing of authorisation and getting products to market (where costs of scientific studies can be recouped), or in some cases the actual cost of substantiation. However, all parties in the consultation agreed that unsubstantiated claims should not be brought to market. The real cost here, then, is likely to be the level of substantiation required (see [4.14]).

2.13 Where there is no nutrition or health claim, this Regulation will have no effect.

2.14 During the consultation the Agency identified some 12 health-related charities which might be affected by a proposed prohibition on charity tie-ins with food manufacturers or retailers. Not all of these involve a financial transaction, but there may be other benefits, such as publicity of the charity's objectives. The Regulation now requires that national measures to ensure that endorsements or recommendations by charities do not mislead consumers,

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<sup>5</sup> Mintel

with, of course, any claims required to conform to the controls of the Regulation.

### 3. OPTIONS

***Option 1: Do nothing***

***Option 2: Oppose adoption of the Regulation***

***Option 3: Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate***

3.1 ***Option 1: Do nothing.*** This was not a credible option and was not the position taken in negotiation. The resulting Regulation has direct legislative force and it was necessary for the UK to be involved in influencing its shape.

3.2 ***Option 2: Oppose adoption of the Regulation.*** In a qualified majority vote the UK acting alone would not have had the voting capacity to defeat the Regulation. In the event Member States with smaller voting capacity did not vote positively. The UK vote would not have tipped the balance to opposing opposition. However, the UK had also made some important gains in the negotiation for consumer protection balanced with a proportionate approach that would only have been protected by a positive vote, which was the UK's final position.

3.3 ***Option 3: Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate.*** This was the UK negotiating position. Factors that allowed us to measure success here and vote positively for the Regulation were:

- clarification of scope, particularly exclusion of traditional generic descriptors;
- retention of nutrient profiles, but with disclosure for one out of profile nutrient on nutrition claims, and stakeholder involvement in establishing them;
- clarification that nutrition claims must be beneficial, or be out of scope;
- a route for authorisation of health claims that is more timely to favour innovation;

- a reduction in the number of prohibitions, particularly the exclusion of weight loss and satiety claims, behavioural and psychological function claims and recommendations and endorsements of charities and national medical, dietetic or nutrition associations; and
- removal of requirement to present applications in all languages.

## 4. COSTS

### (i) Compliance costs

4.1 **Option 1: Do nothing.** If the UK had not taken part in the negotiation we would have had no influence over the final shape of the Regulation and unforeseen compliance costs. Those discussed below for option 3 would have some relevance, but the gains listed in 3.3 above would have been lost and additional costs therefore levied.

4.2 **Option 2: Oppose adoption of the Regulation.** As noted above, opposition would not have changed the final shape of the Regulation, so no costs other than those discussed for option 3 would have arisen.

4.3 **Option 3: Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate.** Based on the final outcome of the Regulation, set out below are those areas where costs are likely to be incurred. Where possible these have been quantified.

#### **Re-labelling**

4.4 Re-labelling will be necessary where claims currently in use do not conform to the requirements of the Regulation. This would include a nutrition claim that does not conform to the prescribed format in the Annex; a health claim that does not get EFSA approval, or becomes subject to a prohibition; or a claim that does not meet nutrient profiles, once these are set. (See section 5 for re-labelling resulting from disease risk reduction claims.) Where a health claim appears on the list of 'generally accepted claims', or where approval from EFSA is sought within the transition period, re-labelling would be minimal (e.g. comparative claims may require some small label adjustments).

4.5 It is difficult to estimate the extent of re-labelling that may be required because of this Regulation, as this will depend on manufacturers' decisions as to whether or not to support health claims they are making. While the number of prohibitions have been reduced obviating the need for automatic removal from the label, these health claims will still need to be authorised and some re-labelling is possible as a result. One gain here is that for these claims there are now longer transition periods. The vast majority of *nutrition claims* would be unaffected, because the criteria in the Annex to the Regulation are already met, although some claims are absent (such as "high energy"), transition periods should allow these to be included on application. The requirement on *trade marks and brand names* may also require small label changes, but there is 15 years for this. Factual *nutrition information* on the front of packs may also require some presentational changes, but the Agency policy on front of pack signpost labelling has already changed the labelling environment here. There are about 4,000 'healthy option' products on the market that will continue to conform to the rules with little or no change to the label.

4.6 The amount of re-labelling required in relation to *health claims* will depend on manufacturer's decisions (see above). If, for example, 10% of claims are not supported (as prohibitions still apply or for lack of substantiation) about 100 would be affected.

4.7 In relation to re-labelling costs, it is important to take account of routine changes businesses will make to the product ranges because of products being taken off the market, new products added, changes because of reformulation, updating of designs, etc. The transitional arrangements in the Regulation (e.g. 15 years for trade marks to adapt), would allow required changes to be made together with routine changes and additional re-labelling costs should be minimised. For example, one large multiple retailer suggests re-labelling takes place across all ranges on regular cycles that would comfortably fit a 24 month transition. The Regulation allows until date of expiry or 30 months – whichever is the shortest. This may yet be a challenge for products with short shelf lives if action is not planned well in advance of the application date (July 2007), but most businesses should be able to accommodate this. Maximum re-labelling costs are estimated at £1,000 per product<sup>6</sup>. With the extreme scenario in the case of re-labelling the 4,000 healthy option brands, and with no allowance for routine changes, the total cost estimate would be £4million. In addition, if health claims require some re-labelling, this could cost up to another £1million.

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<sup>6</sup> Information from the British Retail Consortium

### ***Product re-formulation / withdrawal***

4.8 The Regulation does not ban products, nor will it stop products being marketed, but industry is concerned that the restrictions it will introduce on the use of claims, such as nutrient profiling, may so restrict marketing as to make some products commercially non-viable. Products may be re-formulated to meet the criteria required to allow nutrition or health claims to be made, and in some cases this would benefit consumers by widening the availability of healthier choices. This fits well with commitments under the FSA's salt reduction campaign – and would support future sugar and fat reduction strategies. Where this is not possible, product withdrawal may be the alternative, but only in the rare cases that sales are contingent on a claim.

4.9 It is not possible to estimate how many products might be affected, and the exact costs of re-formulation will vary. It is possible that where a product carries a claim that it could not substantiate and remain viable, a 'generally accepted' claim, or one more easily substantiated, could be substituted after some re-formulation of the product. Costs will vary because substitution of one substance for another, or of one amount for another, could represent a saving on manufacturing costs. Re-labelling costs would inevitably follow. One example of estimated costs for fat, sugar and salt reduction submitted by Cadbury Schweppes was a range of £35,000 - £50,000<sup>7</sup>. An average cost for developing a new product for the range of retail food products currently on offer has been put at approximately £25,000<sup>8</sup>. However, most manufacturers and retailers routinely undertake reformulation and redesign which could offset some of these costs.

### ***Innovation***

4.10 The UK food industry is among the most innovative in Europe, making products aimed at specific groups (children, the elderly, diabetics), and reacting to diet based health concerns with products to meet evolving consumer expectation. Industry fears innovation without being able to make a claim will be greatly impaired. This is now less of a concern where prohibited claims are concerned, since the Regulation now allows many claims that

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<sup>7</sup> Figure from the PARTIAL REGULATORY IMPACT ASSESSMENT for the Choosing Health White Paper

<sup>8</sup> Information from the British Retail Consortium

would have been prohibited under earlier drafts of the proposal to seek an authorisation and thus to stay on the market. Moreover, where science is emerging towards solid substantiation of a claim EFSA will now have an opportunity (Article 18) to reward innovation by allowing the claim based on this level of science. This is a step forward in that claims based on less certain science now have a chance of a hearing. However, EFSA and the Commission have yet to issue guidance on the process of application for an authorisation and it is still uncertain how useful this provision may prove to be.

### ***Scientific dossiers***

4.11 The cost of preparing scientific dossiers to substantiate claims is difficult to calculate because we do not yet know the number of dossiers that will need to be submitted and scope for collaboration, nor the level of information that EFSA will require<sup>9</sup>. The sector most likely to be affected will be the food supplements sector. Information from various sources put the cost of a straightforward dossier at £15,000. Once the guidance mentioned above is available, a more accurate estimate might be possible, but probably on a case by case basis, and it would not be possible to see ahead of time what applications are to be made. To put this in context, it is necessary to consider the non-dossier route.

4.12 Early estimates put more than half of claims on vitamin and mineral supplements as likely to be included in the list of 'generally accepted' claims. The UK invited industry to submit such claims in October 2006, and by January 2007 only 2 claims had been submitted; but industry commentators have said that extensive lists with supporting references to generally accepted scientific evidence should be expected before the deadline for submission in October 2007. This is encouraging as claims put forward to the Commission in this way will not require a dossier and costs will be significantly reduced. The Commission and European industry representatives foresee most claims on the market as eligible for this list. Any claims expected to make this list, but unsuccessful, could yet be the subject of an application to EFSA. Until this process has been gone through, we cannot know what numbers of claims would be involved (Finland has reported 600 submissions, paring down to some 250 claims, and industry Europe wide is looking at claims in the region of 1000+).

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<sup>9</sup> Previous estimates of the costs of dossier preparation to substantiate additive/supplement safety have ranged from £10,000-£100,000. Health claims would be expected to fall at the lower end of this scale.

4.13 For the rest, (disease risk reduction and innovative claims) EFSA will make their requirements for scientific justification clearer before the Regulation comes into effect on July 1<sup>st</sup> 2007. Whether they should be the subject of this RIA is questionable, as disease risk reduction claims were previously prohibited, so any such voluntary claims coming on the market would be new and part of normal commercial decisions and developmental costs.

4.14 One area of concern to industry with attached costs is the level of evidence that will be required to substantiate claims. Despite pressing for information this is still obscure (the expected guidance should begin to clear this up, and when EFSA gives its first opinions things should become clearer). We believe that the level of science required will depend upon the ambition of the claim and that to some extent the cost of producing the evidence will be in the applicant's control. The most costly claim is likely to be for the most innovative of product that will reap the greatest market reward. Manufacturers, through their trade organisations, will be able to co-operate on some research (checking literature, collecting references, etc.) and further minimise costs. Recent meetings with the industry indicate that this process has already started; the FSA is keeping this area under review and will continue to advocate proportionality.

**(ii) Other costs**

4.15 None foreseen at present. For example, there is unlikely to be significant administrative costs to industry, as the register of available claims will be in the public domain, and this will also indicate claims that have been refused. A summary of the dossier will also be public, as will EFSA's opinion.

**(iii) Costs for a typical business**

4.16 Nutrition and health claims are used on a variety of products across the food and drink sector, by large multiple retailers, by small single product supplement manufacturers and all shades and colours in between. It is therefore not realistic to speculate on costs for a typical business. A potentially significant cost comes with re-labelling, however as described above and within transition periods these can be minimised. Where health claims are to be used, choice of a 'generally accepted' claim would act to restrict cost, but for innovative products and disease risk reduction claims,

businesses would be faced with the cost of a scientific dossier. However, as noted above this is a new opportunity and will be a commercial decision about making a voluntary health claim. The main cost to a business - and industry as a whole – will be where a claim made at present will not be eligible for the ‘generally accepted’ claims list, or where the science on which it is based is found insufficient by EFSA. In these cases alternative claims would have to be sought which could involve reformulation. Alternatively more research might provide the evidence, but this would be costly and time consuming and only undertaken if the cost can be off-set by future sales. All these costs have been discussed above and are summarised in the Appendix.

#### **(iv) Enforcement costs**

4.17 This Regulation would add to legislation aimed at protecting consumers from being misled by nutrition and health claims. Increased confidence from the list of approved claims could lead enforcement authorities to increase the number of prosecutions, with attendant costs. But it should also result in a greater number of successful prosecutions.

#### **Brand names**

4.18 Industry had made strong representations about the risk of the Regulation to established brands and trade marks that are also claims under the definitions in the Regulation. While the Regulation will control these brand names, the UK inspired solution does not require brand names to go through the authorisation process, and risk rejection. Rather, they remain on the label accompanied by a related nutrition or health claim which has been authorised. Moreover, the European Parliament in response to industry concerns applied a 15 year transition period, based on the ten year EU registration period for trade marks, which would allow time for new trade marks to be developed in the rare cases that this might prove necessary.

#### ***Transitional Arrangements (Article 28)***

4.19 There was great concern that in order to allow industry time to adapt to this new Regulation transitional periods would have to be adequate. This now appears to be the case for all types of claim, with the unfortunate exception of claims referring to children’s development and health where no transition period exists. This was not so much an oversight as an unfortunate result of

the European Parliament's insistence that these claims be afforded the same level of control as disease risk reduction claims, and resulted in them being linked in Article 14. However, unlike disease risk reduction claims which being novel needed no transition period, these claims may be on the market already. The Commission has undertaken to introduce an amendment of the Regulation to provide a transition period, and will have until July 2007 when the Regulation applies.

### ***List of Nutrition Claims in the Annex***

4.20 Amendment of the Annex is possible through a mechanism whereby additional nutrition claims can be added in the future. A three year transition for claims on the market before 1 January 2006 will allow missing claims time to be added, and there are likely to be administrative costs to companies putting the argumentation and paperwork together to support these claims. The Commission has promised and is in the process of adding certain claims to the list at no cost to industry and a case may be made for other missing claims. However, the more esoteric claim limited to one Member State is unlikely to receive similar support.

### ***Nutrient Profiling (Article 4)***

4.21 As a result of the consultation on this Regulation, the UK came to the view that nutrient profiles were important to ensure consumer protection, and argued for their retention in the Regulation. The ability to continue to make nutrition claims where one nutrient is out of profile allows flexibility to industry that was not present in the original proposal. It also is in line with developments elsewhere for front of pack nutrition labelling giving at-a-glance information for informed consumer choice. Until the profiles are established it will not be possible to estimate what products making claims will be affected and the Agency has undertaken to press for an impact assessment on the Commission decision on nutrient profiles. Costs involved are likely to be disclosure of the out of profile nutrient by use of the statement "High [name of nutrient] content", and possible reformulation costs to continue to make claims. As reformulation is in process to reduce high levels of the key nutrients, fat, sugar and salt, the effect of profiles may be more limited than our original consultation indicated. In addition, developments on nutrition labelling may well cut across labelling requirements. In any event, the potential cost of this provision was considered balanced by the consumer benefit.

## **Administrative burden**

4.22 Businesses wishing to make nutrition and health claims on food under this Regulation will incur some administrative costs and these are highlighted in the RIA. We would welcome comments, and evidence, from business on the administrative burdens arising from the Regulation.

### **Re-labelling** (see paragraph 4.7)

4.23 Re-labelling will be necessary where claims currently made do not conform to the regulation. Estimated re-labelling costs are estimated to be at £1,000 per product. The transitional arrangements of 30 months will allow required changes to be made with routine changes made during the normal course of business. Where expiry date of the product is earlier, it may not be possible to coincide with routine changes made during the normal course of business; nevertheless, any additional administrative burden on business from re-labelling is likely to be limited.

### **Scientific dossiers** (paragraph 4.11)

4.24 Scientific dossiers need to be submitted to substantiate claims. The evidence during the earlier formal consultation was that a dossier would cost £15,000 to prepare. This may include the cost of work business would do themselves during the normal course of business, and include non-administrative costs, such as substantiating the properties of the foods to the companies' own satisfaction before they make claims. Evidence from the Administrative Burdens Measurement Exercise carried out in 2005 suggests a much lower figure for preparing similar dossiers. ***[We would welcome comments and evidence from business of the administrative cost of producing dossiers for EFSA which are over and above what a business would do commercially.]***

### **Template for submitting UK health claims.**

4.25 Businesses are asked to submit health claims to the FSA using a template which is available on the FSA website <http://www.food.gov.uk/foodlabelling/ull/claims/> We estimate that that it would take 30 minutes to complete the template for each health claim. ***[We would***

**welcome comments from business on the estimated time to complete the template and the job title/role of staff that would do this.]**

**[We would welcome comments and evidence on other administrative costs, over and above what a business would do commercially, that this regulation may introduce.]**

## **5. BENEFITS**

**5.1 Option 1: Do nothing.** This option would not have afforded any useful benefit.

**5.2 Option 2: Oppose adoption of the Regulation.** This option would not have afforded any useful benefit either, as in the event there was a strong qualified majority in favour of the Regulation.

**5.3 Option 3: Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate.** The likely benefits of this option are outlined below:

### **Overall Benefits**

**5.4** The Regulation on nutrition and health claims made on foods will put in place a more uniform system across the EU. The proposal identified these as:

- a high level of consumer protection in the provision of further voluntary information, beyond the mandatory information foreseen by EU legislation;
- improved free movement of goods within the internal market;
- increased legal security for economic operators;
- fair competition in the area of foods; and
- promotion and protection of innovation in the area of foods.

### **Benefits from Improved Information**

**5.5** The current situation could be described as resulting in imperfect information for consumers, such that they are not in a position to both

maximise their healthy diet choices and encourage the market to allocate resources optimally when they make food consumption choices. In this case, the regulation is expected to result in:

- the elimination of bogus claims (thus also increasing consumer confidence); and
- a label which gives more accurate information.

The provision to allow disease risk reduction health claims will benefit consumers looking for a particular nutrition effect from a food product or food supplement; and industry will benefit from more accurate and improved marketing of these products. The additional protection to children will be beneficial only where more general claims would have been unsuitable for children and may have misled parents or guardians into less healthy dietary practices. However, the general provisions of the Regulation call upon EFSA to take specific populations and dietary needs into account and this specific reference to children may be more one of emphasis than effect.

### **Benefits from Reduced Prices**

5.6 Food supplements and food products, which carry nutrition and health claims are sold at premium prices. Food Commission research has indicated that prices for foods marketed as “healthy” are about 50 percent higher than for “normal” products in the same category and some products were found to retail at as much as ten times the price of comparable food without the health claim. It is very unlikely that there exist underlying cost differentials between these foods that fully explain these retail price differences.

5.7 It can thus be expected that whilst products carrying approved health claims may be in a position to continue charging a premium for their products, those which are no longer allowed to carry such claims may see certain consumers reducing their demand levels thus resulting in a lower price for this category of products. In addition a more effectively functioning internal market as claims are harmonised (and some rejected) across the EU, which is expected to lead to increased competition, will also act to increase the pressure on prices pan-EU.

5.8 These potential price pressures, UK firms now accessing a wider-EU market and the legal certainty of claims being recognised pan-EU may all act to actually increase investment in innovative food manufacture within the UK.

## ***Public Health Benefits/Health Impact***

5.9 The public health benefits are expected to derive from increased consumer information and confidence and the related reinforcement of public health initiatives.

5.10 Once consumers know that the labelling is more than a mere marketing tool and that the claims have to be approved, consumers are likely to put more trust in the labelling. It is expected that more scientifically based, clear and reliable health claims can help increasing numbers of consumers to choose a healthy and balanced diet and have confidence that this is what is being delivered.

5.11 It is expected that accurate information will reinforce public health initiatives to improve understanding of sound nutritional values and the implications of unhealthy diets. This could improve health and reduce costs of diet-related diseases in the long term. Both consumers and the NHS would thus reap the benefits in the UK. For example, consumers may choose to substitute away from foods which cannot substantiate health claims with those that can.

5.12 In addition, as explained in Section 5.7, potential increased demand and pan-EU competition may lead to increasingly cheaper healthy food choices in the future.

5.13 The cost of diet related illness and premature death to the UK economy is very high. Estimates related to obesity alone have recently been placed in the region of £2.5 billion annually (in 2000)<sup>10</sup>. This UK figure is comprised of an annual £480m spend on treating obesity and its associated diseases, together with a £2bn loss in productivity. This estimate does not currently take account of other diet related illness and death or the monetary value of pain, grief and suffering (illness and premature death) associated with both obesity and non-obesity diet related conditions and is therefore a significant underestimate of economic costs.

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<sup>10</sup> 2000 figure. Tackling Obesity in England, National Audit Office 2001

## **6. SMALL FIRMS IMPACT TEST**

6.1 The Small Business Service was contacted and advised interviewing 3 small businesses. Telephone interviews were conducted with two food supplement suppliers (one manufacturer, one importer) and one energy/stimulant drink supplier. Feedback was constrained by lack of familiarity with the proposal. However, small businesses have the same concerns as larger businesses and will face the same issues, such as re-labelling and presentation of scientific dossiers for substantiated claims. Subsequent consultations with representatives of small businesses and again a small business forum (with, incidentally more informed interlocutors) confirmed this view. One benefit expressed was that the rogue “cowboy” element would be more easily detected and prosecuted, important to small businesses who were particularly vulnerable to association in the consumer mind with this type of producer.

6.2 Of clear importance to small businesses will be the availability of ‘generally accepted’ claims and access to the scientific substantiation. The Regulation helps here in that this list will be published, with references to the scientific substantiation. Use of this data may incur administrative costs, but not beyond what is already foreseen as due diligence in food law. As described above, innovative claims or disease risk reduction claims would require production of a dossier with attendant costs. But this is a commercial decision, where the costs would be balanced by improved sales. In addition, the Regulation makes reference to SMEs in the context of applications for authorisation and the requirement for the Commission, in co-operation with EFSA, to “make available appropriate technical guidance and tools” to assist, particularly SMEs.

6.3 When questioned about whether work would be undertaken to substantiate claims if necessary, and if not what action would be taken, the small businesses interviewed indicated that they would put scientific dossiers together where necessary, and saw this as a business necessity not too different to what they would do to comply with current legislation, although noted that at present it was more haphazard without specific guidelines. The provision of guidelines would be useful, but could also require steps involving additional costs. It was not possible to quantify this without access to the guidelines.

6.4 It was recognised that a number of the claims used by these small businesses are likely to be considered 'generally accepted'. Food supplement suppliers also thought that for some claims companies might be willing to share the burden of dossier preparation through their trade associations, although for very small businesses competition considerations might inhibit this. Costs of innovative claims, made in order to gain a market advantage, would fall wholly on the company wishing to use such a claim. Data gained during product development should provide the basis for an application for an authorised claim, minimising additional costs.

6.5 Total cost of re-labelling without claims was thought by the interviewed companies to be less than that quoted by larger retail multiples, generally due to there being fewer products in any one product range (sometimes just one). Unit costs would probably not vary too much, estimated at £1000 per product. Costs in addition to re-labelling would depend on the level of advertising used, and whether a full product re-launch was required, but could probably be subsumed into pre-planned advertising programmes. Long transition periods to enable fewer label changes was a key consideration here.

## **7. COMPETITION ASSESSMENT**

7.1 Two main sectors are affected by the Regulation: (1) food and drink with health and nutrition claims; and (2) food supplements with health and nutrition claims. It is the producers and retailers of these goods who would be influenced by any competition effects at the firm level.

7.2 Information on the size and nature of the sector for food and drinks with health and nutrition claims is poor. This is partly because it is a rapidly evolving sector, but also because these products may be seen as a sub-set of general groceries. For example, whilst some ready meals do not carry health claims, many others do. However, food supplements are a quite distinct and fast growing area, and better data are available on these products<sup>11</sup>.

### **Market Share**

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<sup>11</sup> although key data relating to market shares could not be identified for this RIA

7.3 Available information indicates that neither foods with health claims nor food supplements sectors are characterised by a small number of suppliers. With regard to food with health claims, there are numerous producers, plus supermarket own-label varieties. With regard to food supplements, although there are a small number of well-established brands, an examination of product lines held by retailers suggests that there is a plurality of producers.

### **Differential Effects on Firms**

7.4 The requirements for substantiating nutrition and health claims are common to all products. Therefore, all firms are similarly bound by these. However, the costs of preparing dossiers to justify health and nutrition claims, which will be one-off costs largely determined by research and evidence requirements, rather than sales volumes, will in the first instance be more justifiable for producers whose products are sold in large volumes.

### **Effects on Market Structure (Size and Number of Firms)**

7.5 Because the costs of preparing dossiers will be common to similar products, regardless of production volume/sales value, it is possible that some lower volume producers (with relatively small market shares) may cease to produce some of their lines. This may be the case if at these volumes the cost of dossier production is seen as prohibitive such that the products cannot be marketed with a health claim, be these foods or food supplements. The more specialised supplement companies dependant on certain product lines may spend disproportionately more on defending these lines than more diverse general food producers. Nevertheless, the Regulation may lead to some consolidation of these sectors. In advance of knowing the requirements of dossiers it is not possible to quantify this potential effect.

### **Impact on Entry Barriers**

7.6 The Regulation equally applies to existing and new entrants to these sectors. Existing companies will be required to invest in dossiers as will new entrants, as such both will incur the costs associated with this. New entrants are not placed at a disadvantage. Indeed as with new entrants, existing companies seeking to develop innovative products will require dossiers for these products as well.

## Technological Change

7.7 Both foods with health claims and the nutritional supplements sectors are characterised by high levels of product innovation, with new products introduced frequently. The requirement to justify health and nutrition claims may have either a negative effect (as costs increase) or a positive effect (as the geographic market and consumer confidence grow – see Section 5.9) on product innovation.

7.8 In addition, the Regulation is also likely to stimulate research and development in order to justify claims. This in itself is likely to become a source of innovation and, more importantly, ensure that product innovation actually delivers the health and nutrition claims made for the products. This should increase the health benefits of product information, and hence yield long-term benefits to consumers.

## Impacts on Price, Quality, Range and Location of Products

7.9 The Regulation is likely to have significant impacts as follows:

- **Price** As noted above, foods with health and nutrition claims are generally premium products for which prices can be higher than for comparable products without health claims. The Food Commission found that prices of “health foods” were 51 percent above “normal” foods. With regard to food supplements, their *raison d’être* is improving health or nutrition, and there are many more claims in this sector. If claims cannot be substantiated, prices of these products will probably be affected downwards. But for the others, whose claims are substantiated, as consumer confidence rises, so they may be willing to pay even higher premiums where as rising demand may allow scale economies to reduce the costs. As such, for these products the price effect is unpredictable. There are also a number of food supplements on the market that do not carry claims.
- **Quality** The requirement for scientifically justified and documented health and nutrition claims will mean that only those products with actual (evidence based) health or nutritional benefits will be able to carry claims. Therefore, the quality of these products (as measured by their effectiveness in contributing to specified health and nutritional goals) is

likely to rise significantly. Consumers will also be able to make more informed judgements.

- **Range** If all health and nutrition claims cannot be supported (as is likely to be the case), the range of products carrying claims will inevitably be reduced (for both food and food supplements), although the products can still be sold without claims. However, in the context of this Regulation, this is a positive development, as it will mean that only products that meet the expectations of consumers will be available.

There are anticipated to be no significant impacts on the location of activity within these sectors.

## **Conclusion**

7.10 The Regulation is likely to have some impact on competition within the foods with claims and food supplement industries as:

- the range of products carrying claims could decrease because of the costs of producing dossiers, and the fact that some products are inevitably making claims which will not be scientifically justifiable;
- this could lead to some reduction in the number of producers or importers, although substitute marketing may be possible;
- the requirements may also increase the costs of developing new products, but growth in the geographic market, increased consumer confidence and the impact of the Regulation falling on both existing firms and new entrants should work to protect product innovation and continue to induce new entrants. As such, in the longer term product line numbers may increase; and
- the quality of remaining and new products, as measured by their ability to deliver the claimed health and nutritional benefits, is likely to improve substantially, which will bring considerable benefits to the consumer.

## **8. ENFORCEMENT AND SANCTIONS**

8.1 This Regulation will be enforced by Local Authorities, with offences and penalties put in place by a Statutory Instrument, made under the Food Safety Act 1990.

## **9. MONITORING AND REVIEW**

9.1 The Regulation has monitoring and review by the Commission and Member States in the Standing Committee on the Food Chain and Animal Health built in (Article 27). Monitoring of labels placed on the market by individual Member States is permitted (Article 26 - but see Option 3 above).

## **10. CONSULTATION**

### **(i) Within Government**

10.1 Defra, the main Department outside of the Food Standards Agency with an interest, and other Departments have been kept abreast of progress and will continue to be consulted as negotiations progress.

### **(ii) Public consultation**

10.2 A full 12 week consultation by the Food Standards Agency took place between July 24 and October 24 2003. A brief summary of comments is attached at Appendix 3. The Food Standards Agency continues to provide information to interested parties by means of regular bulletins following Council working group meetings and this will continue during the course of further negotiations. Three stakeholder meetings were held in September and October 2004 to take stock of the position and to invite comments on the UK lines. Individual meetings have also been held on request, including with the food supplements sector. Note has been taken of any feedback during consultation, amending this RIA as necessary.

## **11. Sustainable Development**

11.1 The Food Standards Agency does not consider that implementing this Regulation will have any impact on sustainability issues.

## **12. Racial Equality**

12.1 The Food Standards Agency does not consider that implementing this Regulation will have any impact on racial equality issues.

### **13. Public Services Threshold Test**

13.1 UK public enforcement costs are likely to be largely unaffected by this Regulation. The way enforcement authorities organise protection of consumers from misleading claims would change to respond to the system of pre-approval of claims. This would lead to more confidence in prosecutions, and after an initial increase should settle into a similar pattern as is discernible today. The total additional monetary costs to all UK enforcement authorities will be well below the threshold criteria of £5m.

## **14 SUMMARY AND RECOMMENDATIONS**

14.1 Given the nature of the Regulation, the cost implications are mostly for the food industry, including food supplement suppliers. There are still some uncertainties about the impact on industry on how the detail of nutrient profiling and the guidance on authorisation might add to or mitigate costs. The list of “generally accepted” health claims should help minimise costs to industry, provided not too many claims fall out in this process. Industry has been bullish about its ability to meet the criteria here and the UK will continue to take a proportionate approach to decisions in Standing Committee on the exclusions from the list.

14.2 Option 3 as the UK negotiating position appears to have delivered a Regulation that meets its twin objectives of harmonising Community legislation and ensuring a high level of consumer protection (as recognised by organisations such as Which? and the NCC in the UK), but has been modified to ensure greater proportionality to UK industry which has enjoyed a liberal regime in this area. Two areas of uncertainty remain in the effect of nutrient profiles and the guidelines on authorisation. On the former, policy developments in the UK have begun moving industry towards reformulation of products with lower levels of fat, sugar and salt; and developments on front of pack nutrition labelling has started a movement to convergence with the objective of disclosure to ensure consumers are not misled. On the latter, the key to minimising impact will be the level of science required to substantiate claims. This will depend in part on the nature of the claim, that what is claimed remains consistent with the available science. While the Commission and Member States do not favour qualified claims (such as allowed in the

USA), some flexibility here will help safeguard innovation and use of emerging science. That the Regulation recognises newly developed scientific evidence and allows an authorisation process is encouraging here.

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**PUBLIC SERVICES THRESHOLD TEST: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON NUTRITION AND HEALTH CLAIMS MADE ON FOOD - COM(2003) 424 FINAL / 2003/0165 (COD)**

In line with Cabinet Office guidance, a Public Services Threshold Test must be carried out for any proposal impacting on the public sector. For proposals impacting on the public sector only, the Test determines whether a regulatory impact assessment (RIA) should be completed.

Local Authorities Co-ordinators of Regulatory Services (LACoRS) have indicated that an additional cost to enforcement authorities and to public analysts to analyse foods to check compliance with these new Regulations would be incurred. The following Public Services Threshold Test was completed in accordance with Cabinet Office guidance and in consultation with LACoRS.

**1. Cost calculation table**

<b>Number of public service staff Affected</b>	<b>Time impact per person</b>	<b>Time impact per group</b>	<b>Total monetary costs per annum</b>
28 public analysts (plus enforcement officers)	Not available	Not available	£20-50,000 <sup>12</sup>
<b>Totals</b>			<b>£20-50,000</b>

**2. Threshold criteria for undertaking an RIA**

The total additional monetary costs to all UK enforcement authorities and public analysts is anticipated to be up to £20-50,000, which is well below the threshold criteria of £5 million. As such, an RIA to address impacts on public services or staff is not required.

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<sup>12</sup> Figure based on LACORS' estimate of these costs

The new Regulation may attract political or media interest and a partial RIA has been produced which addresses the potential costs and benefits involved.

## SUMMARY OF COSTS (SECTION 4) AND BENEFITS (SECTION 5)

Option	Costs	Benefits
1. Do nothing	Infraction proceedings if Regulation adopted but not enforced.	0
2. Oppose adoption of the Regulation	Infraction proceedings if Regulation adopted but not enforced.	If successful, potential saving of industry compliance and public enforcement costs. However, there is an insignificant chance of success.
3. Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate.	<p><u>Re-labelling</u></p> <p>4,000 'healthy eating' nutrition claims and 1000 health claims</p> <p>Incremental effect of the Regulation is up to £5million, but in reality will only be a fraction of this due to normal commercial labelling cycles</p> <p><u>Re-formulation</u></p> <p>An estimate of 10% of health claims would potentially equate to £2.5million</p> <p><b>OR</b></p> <p><u>Substantiation</u></p> <p>An estimate of 10% of health claims would potentially equate to around £1million</p>	<p>Better consumer information and increased confidence from pre-approved claims.</p> <p>This may help combat obesity (costed at £2.5billion in 2000) and other dietary related health problems in the UK .</p> <p>Unquantified benefits from freer single market trade, and possible research</p>

	<p><u>Public Enforcement Costs</u></p> <p>Following comments from LACoRS these are expected to be less than £50,000</p> <p><u>Total Costs</u></p> <p>FSA estimate that the total cost faced by UK business and the public enforcement bodies of Option 3 would be less than £5m.</p>	<p>advantages leading to innovation.</p>

### List of Interested Parties

A G Barr  
A H Allen and Partners  
Abbot Laboratories Ltd  
ABR Foods  
Adams Pork Products  
Advertising Association  
Advertising Standards Authority  
Advisory Body for Social Services Catering  
Allchem International  
Allergy Alliance  
Alliance for Natural Health  
Allied Technical Centre  
Allsports International Ltd  
Alpro UK Ltd  
Amicus  
Animal Medicines Inspectorate  
APCO Europe  
Arkarius Ltd  
Arkopharma (UK) Ltd  
Arla Foods UK Plc  
ASDA Stores Ltd  
Ashurst  
Ashwell Associates  
Associated British Foods Plc  
Association of British Paediatric Nurses  
Association of the British Pharmaceutical Industry  
Associate Parliamentary Food and Health Forum  
Association of Port Health Authorities  
Association of Radical Midwives  
Aviation Health  
Baby Milk Action  
Barbour Index Plc  
Bayer PLC  
BBH  
Bernard Matthews Ltd  
Berry Ottaway and Associates Ltd  
Berwin Leighton Paisner  
BIBRA Information Services Ltd  
Bird and Bird  
Birmingham Children's Hospital  
Biscuit, Cake, Chocolate and Confectionery Association  
Blue Rubicon  
Booker Ltd  
Boots the Chemist  
Borough of Reigate and Banstead  
Brakes  
Breakthrough Breast Cancer  
Bristol City Council  
Britannia Health Products Ltd  
British Beer and Pub Association  
British Chambers of Commerce  
British Coffee Association  
British Dental Association  
British Diabetic Society  
British Dietetic Association  
British Egg Industry Council  
British Fermentation Products  
British Goat Society

British Heart Foundation  
British Herbal Medicine Association  
British Hospitality Association  
British Meat Processors Association  
British Medical Association  
British Nutrition Foundation  
British Retail Consortium  
British Soft Drinks Association Ltd  
British Sugar Plc  
British Trout Association  
British Veterinary Association  
Britvic Soft Drinks Ltd  
Bureau European des Unions Consommateurs  
Bureau Veritas  
Burson-Marsteller  
Business in Sport and Leisure  
Cadbury Schweppes Plc  
Camacom Law (Solicitors) Ltd  
Cambridge Health and Weight Plan  
Cambridge Manufacturing Limited  
CAMedica  
Campden and Chorleywood Food Research Association  
Cantox Health Sciences International  
Cardinal Health  
Cargill Flavor Systems  
Centre for Food and Health Studies Ltd  
Cereal Partners UK  
Chartered Institute of Environmental Health  
Chemist and Druggist  
Child Action Prevention Trust  
Christchurch Borough Council  
Clarke Willmott Solicitors  
Clearspring Ltd  
Coca-Cola Company  
Coeliac UK  
Community Dietetics  
Community Foods Ltd  
Community Practitioners and Health Visitors Association  
Confederation of the Food and Drink Industries of the EU  
Consensus Action on Salt and Health  
Contract Food Ltd  
Co-operative Group  
Coors Brewers Plc  
Cosucra  
Council for Responsible Nutrition  
Counsel Ltd  
Country Markets Ltd  
Courage Ltd  
Crookes Healthcare Ltd  
Crop Protection Association  
Cumbria County Council  
Custom Pharmaceuticals Ltd  
D and T Association  
Dabur India Ltd  
Dabur Research Foundation  
Dailycer Ltd  
Dairy Council  
Dairy Crest Group  
Dairy UK Ltd  
Danisco-Cultor

## Annex C

Danish Bacon Company Plc  
Danone Waters and Dairies UK Ltd  
Del Monte Foods (UK) Ltd  
Delamere Dairy Ltd  
Department for International Development  
Department of Health  
Department of Local Government and the Environment  
Department of Trade and Industry  
Divine Juice  
Dow Europe GmbH  
DPR Nutrition Ltd  
Dr Stuart's Botanical Teas  
Eclipse Scientific Group  
Embassy of the Federal Republic of Germany  
English Institute of Sport  
Environmental Data Services  
Essential Trading Co-operative Ltd  
Eurofins Laboratories Ltd  
European Federation of Health Product Manufacturers Association  
Express Dairies  
F I Data Services  
Faccenda Group Ltd  
Federation of Danish Pig Producers and Slaughterhouses  
Federation of Small Businesses  
Federations of Synagogues  
Fibrisol  
First Thought Consulting  
Food and Drink Federation  
Food and Health Research  
Food Additives and Ingredients Association  
Food and Drink Federation  
Food Commission (UK) Ltd  
Food Labelling Database  
Food Standards Australia New Zealand  
Foodaware  
For Children  
Foresight  
Forum of Private Business  
Forum Products Ltd  
Fresenius Kabi Ltd  
Fresh Produce Consortium  
Friday's Ltd  
G R Lane Health Products Ltd  
General Dietary Ltd  
Gin and Vodka Association  
GIRACT  
GlaxoSmithKline  
Good4U  
Goodman Derrick  
Greenwoods Solicitors LLP  
H J Heinz Co Ltd  
HT Webb and Co Ltd  
Hampstead Tea and Coffee Co Ltd  
Harrods Ltd  
Health and Diet Centres Ltd  
Health Care Products  
Health Food Manufacturers Association  
Health Promotion Department  
Heather Paine Associates  
Heinz UK and Ireland

## Annex C

Herbison  
Hildred and Cocker Ltd  
Hill and Knowlton (UK) Ltd  
Holland and Barrett  
Honey International Packers Association  
Honeyrose Products Ltd  
Hong Kong Food and Environmental Hygiene Department  
Horticulture Research International  
Howard Foundation Research Group  
HUSH (Haemolytic Uraemic Syndrome Help)  
Hygiene and Nutrition in Food Service  
ILS Ltd  
Independent Nutrition Logic  
Infant and Dietetic Foods Association  
Innocent Ltd  
Institute of Food Science and Technology  
Institute of Grocery Distribution  
International Fish Meal and Oil Manufacturers Association  
International Soft Drink Council  
Irish Yogurts Ltd  
J Ralph Blanchfield Consultancy  
J Sainsbury Plc  
John Russell Associates  
Johnston Consulting  
Joint Health Claims Initiative  
Julian Graves Ltd  
Kellogg Company (GB) Ltd  
Kerry Group Plc  
Kettle Foods  
Kitchen Rnage Foods Ltd  
L Hepner and Associates Ltd  
La Leche League GB  
Laboratory of the Government Chemist  
Lancashire County Council  
Law Laboratories Ltd  
Lawdata Ltd  
Lawrence Graham  
Leatherhead Food International  
Lee Kee Kum (Hong Kong) Foods Ltd  
Leicestershire County Analyst's Lab  
Leicester Reference and Information Library  
Leon Prosky Associates  
LGC Ltd  
Local Authorities Co-ordinators of Regulatory Services  
London Borough of Brent (Environmental Health)  
London Borough of Ealing Council  
London Retail Meat Traders Association  
Lovell White Durrant Solicitors  
Lyons Tetley Ltd  
LYSI HS  
Macfarlanes  
Manchester Metropolitan University  
Mannatech Ltd  
Marks and Spencer Plc  
Mars Confectionery Ltd  
Masterfoods  
Martlet Health Food  
Maternity Alliance  
Matthew Clark Ltd  
McDonald's Restaurants Ltd

McIntyre Consultants Ltd  
McNeil Nutritionals Ltd  
Mead Johnson Nutritionals  
Meat and Livestock Commission  
Medical Research Council  
Medicines and Healthcare products Regulatory Agency  
Meridian Foods  
Merrydown Plc  
Midwives Information and Resource Service  
Milupa Ltd  
MJSR Associates  
MotherHemp Ltd  
Muller Group UK  
National College of Food Technology  
National Association of Health Stores  
National Association of Master Bakers, Confectioners and Caterers  
National Childbirth Trust  
National Consumer Council  
National Consumer Federation  
National Council of Hindu Temples  
National Edible Oil Distributors Association  
National Farmers Union  
National Federation of Meat and Food Traders  
National Federation of Women's Institutes  
National Heart Forum  
National Heart Foundation of Australia  
National Institute For Health and Clinical Excellence  
National Institute of Medical Herbalists Ltd  
National Pharmaceutical Association  
Nature's Own Ltd  
NCH Action for Children  
Nestle UK Ltd  
Neville Craddock Associates  
Newcastle-upon-Tyne City Library  
NMB Consulting  
North Hertfordshire NHS Trust  
Northamptonshire Trading Standards Service  
Novartis Medical Nutrition  
Nutragen Ltd  
Nutralife (UK) Ltd  
Nutrasweet Kelco Company Ltd  
Nutricia Ltd  
Nutrilaw  
NutraTech Consultancy  
Nutrition Society  
OceanC Ltd  
Omya UK Ltd  
ORAFIT  
Orangina Group  
Organix Brands Plc  
Pepsico International Ltd  
Perrigo UK  
Pizza Hut (UK)  
Plymouth Consumer Group  
Poole Trading Standards Department  
Potters Herbal Supplies Ltd  
Power Health Products Ltd  
Premier Grocery Products Ltd  
Premier International Foods  
Procter and Gamble UK

Proprietary Association of Great Britain  
Protein Technology International  
Provision Trade Federation  
Quest Vitamins Ltd  
R Twining and Co Ltd  
Reading Scientific Services Ltd  
RHM Group  
RHM Technology Ltd  
Rio Trading Company (Health) Ltd  
Ross Youngs International Ltd  
Rotherham Health Authority  
Royal College of Midwives  
Royal College of Paediatrics and Child Health  
Royal Institute of Public Health  
Royal London Hospital  
Royal Pharmaceutical Society of Great Britain  
Russell Jones and Walker  
Safeparm Laboratories Ltd  
Safeway Stores Plc  
School of Science and Technology  
Scientific Advisory Committee on Nutrition  
Seafood Laboratories Ltd  
Sefcol Ingredients Ltd  
Seven Seas Ltd  
Shropshire Borough Council  
SHS International Ltd  
Simkins Partnership  
SiS (Science in Sport) Ltd  
SMA Nutrition Ltd  
Small Business Service  
Small Independent Brewers Association  
SMH Consultancy  
Snack, Nut and Crisps Manufacturers Association  
Soil Association  
Somerfield Stores Ltd  
Sonnenberg  
Sopexa UK  
SPRING Singapore  
St George's Hospital Medical School  
Stoke Mandeville Hospital  
Stute Foods Ltd  
Sugar Bureau  
Surrey County Council Trading Standards  
Sustain  
Tate and Lyle Plc  
Taylor Joynson Garrett  
Tesco Stores Plc  
Thomas Lowndes and Co Ltd  
Thompson and Capper Ltd  
TOAST (Obesity Awareness and Solutions Trust)  
Tower Hamlets Primary Care Trust  
Transport and General Workers Union  
UK Association of Frozen Food Producers  
UK Tea Association  
UK VLCD Industry Group  
Unigreg Ltd  
Unilever UK Ltd  
Uniq  
United Biscuits (UK) Ltd  
United Business Media Plc

## Annex C

University of Birmingham  
University of Central Lancashire  
University of Liverpool  
University of Reading  
University of Southampton  
Univ-Vibe Export Ltd  
VEGA  
Vegan Society  
Vegetarian and Vegan Foundation  
Vegetarian Society of the UK Ltd  
Ventress Technical Services Ltd  
Vinegar Brewers Federation Waitrose Ltd  
Waitrose Ltd  
Walkers Charnwood Bakery  
Walsall Metropolitan Borough Council  
Westler Foods Ltd  
Which?  
Whitehouse Consultancy Ltd  
Wm Morrison Supermarkets Plc  
Women's Farmers Union  
Women's Food and Farming Union  
Worcestershire County Council  
Wyeth Consumer Healthcare  
Yoplait Dairy Crest Ltd  
Zest Juice Ltd

### Welsh Stakeholders

Abergavenny Fine Foods Ltd  
ADAS Wales  
All Wales Dietetic Advisory Committee  
Association of Public Analysts  
B Sidoli & Sons Ltd  
Bangor University  
Bar & Restaurant Foods Ltd  
Biotrace Limited  
British Institute for Allergy & Environmental Therapy  
Business Eye  
Clark's Original Pies  
Dee Dairy Services  
Department of Food Science & Technology  
Farmers' Union of Wales  
Federation of Small Businesses (South Wales)  
Federation of Small Businesses (North Wales)  
Friends of the Earth Cymru  
G C Hahn & Co Ltd  
Good Food Distributors  
Halo Foods Ltd  
Health & Social Services Committee  
Hospital Caterers Association  
Iceland Foods Plc  
Institute of Rural Health  
LACORS (Wales)  
Meridian Foods  
National Association of Health Stores  
National Farmers Union Cymru  
National Federation of Women's Institutes  
O P Chocolate Limited  
Organic Centre Wales  
Peters Food Service Ltd  
Public Health Alliance Wales  
Rachel's Dairy  
Red Star Bioproducts  
Shoda Sauces Europe  
T/A Source Foods  
Tillery Valley Foods Ltd  
Tom Soya & The Waterfront Corporation Ltd  
Tovali Ltd  
University of Wales  
UWIC  
Vydex Nutrition  
Wales Centre for Health  
Wales Council for Voluntary Action  
Welsh Assembly Government  
Welsh Consumer Council  
Welsh Food Alliance  
Woodwards Foodservices  
Zedzfoods  
Zorba Foods