EXPLANATORY MEMORANDUM TO

THE NUTRITION AND HEALTH CLAIMS (ENGLAND) REGULATIONS 2007

2007 No. 2080

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

2. Description

2.1 This Statutory Instrument puts in place provisions, including offences and penalties, to allow European Regulation 1924/2006 on nutrition and health claims made on foods ("1924/2006") to be enforced in England.

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

3.1 None.

4. Legislative Background

4.1 Explanatory Memorandum numbered 11646/03, on the original proposal for 1924/2006, went to the Commons and Lords Select Committees on 29 August 2003. A supplementary Explanatory Memorandum, also numbered 11646/03 and up-dating on the progress of the negotiations, went to the Committees on 11 March 2004. This cleared scrutiny in the Commons Select Committee on 6 May 2004, and in the Lords Select Committee on 21 October 2004.

4.2 1924/2006 is directly applicable in England and there is no need to transpose it into English law. Instead the Regulations put in place provisions which will allow action to be taken in England, for failure to comply with the controls in 1924/2006. For this reason a transposition note has not been included.

4.3 1924/2006 has been negotiated in tandem with and cross-refers to European Regulation 1925/2006 on the addition of vitamins and minerals and certain other substances to foods. The Statutory Instrument putting in place enforcement provisions for Regulation 1925/2006 has already been laid and is due to come into force on 7th August.

5. Extent

5.1 This instrument applies to England. Parallel legislation is being made in Scotland, Wales and Northern Ireland. Due to the recent elections to the devolved administrations the process of implementation through the making of enforcement powers was delayed and it was not possible to coincide with the application date of the EC Regulation. The English Statutory Instrument and the parallel

legislation have been drafted with a common coming into force date to ensure even enforcement across the UK.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 EC Regulation 1924/2006 seeks to further protect consumers from false or misleading claims and also harmonises legislation across the EU making it easier to trade.

7.2 It controls the voluntary use of claims on foods and establishes a positive list of nutrition claims and the criteria a product must meet to use them, and a process to establish a similar list of authorised health claims. 1924/2006 will, for the first time, allow claims that make reference to the reduction in the risk of disease to be made on food, where they have been assessed and authorised.

7.3 In addition to putting in place specific controls a product must meet to make a claim, for example containing no more than 3g of fat per 100g to make a "low fat" claim, 1924/2006 also requires nutrient profiles to be established at Community level and used by food businesses to ensure claims do not mislead consumers about the overall nutritional composition of a food. The EC Regulation requires nutrient profiles to be established by 19th January 2009 and will require products to comply with those profiles and the associated controls within a further two years.

7.4 As detailed in the accompanying RIA the Food Standards Agency has consulted widely throughout the development of 1924/2006 and kept interested parties up-dated on negotiations. In general stakeholders have welcomed the proposal for 1924/2006 as both a means of further protecting consumers and also to aid trade. There was some concern about the proportionality of the provisions of the EC Regulation. The UK secured several amendments to address this.

7.5 The European Select Committees followed the negotiation and were kept updated on developments in supplementary memoranda and correspondence.

7.6 The consultation on implementation of 1924/2006 asked about the usefulness against the additional burden of implementing the monitoring provision of claims being put on the market. Based on an analysis of responses and the potential burden on industry we decided not to enact this provision. The consultation also highlighted interpretative problems, in particular the EC Regulation is restricted to control of claims in "commercial communication"; the scope of this and how it fits with the prohibition on claims which make reference to recommendations of health professionals. Another problem for

implementation is the lack of a transition period for claims referring to children's development and health. In the first instance, the Food Standards Agency has developed notes on guidance to compliance, has consulted widely on these and is in the process of revising them to ease these interpretative problems. On claims referring to children's development and health, the European Commission has recently proposed an amendment to provide a transition period.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum

8.2 The impact on the public sector is outlined in Appendix 1 of the attached Regulatory Impact Assessment.

9. Contact

Noel Griffin

Fortification and Claims Unit
Nutrition Division
Consumer Choice and Dietary Health Directorate
Food Standards Agency
Noel.Griffin@foodstandards.gsi.gov.uk

FINAL REGULATORY IMPACT ASSESSMENT

The Nutrition and Health Claims (England) Regulations 2007

1. 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)]

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 will 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 – first, claims describing growth, development or function (such as 'helps maintain a healthy heart' – Article 13), psychological and behavioural and slimming claims; second, claims about the reduction of risk factors in human disease (such as 'may reduce the risk of heart disease' – Article 14); and third, 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 (a small number of claims may have longer) 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[1] 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 implements European Community rules (Directives 2000/13/EC and 90/496/EEC) and is found in the Food Labelling Regulations 1996 and the Food Safety Act 1990 (and parallel legislation in Northern Ireland) and in the Trade Descriptions Act 1968. This legislation clarifies the position of some nutrition claims, and effectively requires that all

[1] 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.

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 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[2]. 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 operated a voluntary system via the Joint Health Claims Initiative (JHCI) based on an agreed code of practice and a system to authorise health claims manufacturers wish to use. This provided patchy coverage (the JHCI authorised 6 generic health claims). Limited uptake of this useful service and application of the code had 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 useful 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

[2] Annual Consumer Survey

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 estimated that by 2000 obesity cost the nation some £2.5 billion a year[3]. 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 is estimated that there are some 6,000 products on the market with a value of over £1 billion[4]). In the absence of specific legislation, the Agency had 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. Nutrition claims in use before the Regulation came into force and not in the Annex may continue to be used until 19 January 2010, giving time to apply to amend the Annex.

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 informal audit to provide more information here that indicated that there were in the region of 1000 health claims, of which more than half were on food supplements. It would appear that

[3] 2000 figure. Tackling Obesity in England, National Audit Office 2001
[4] Information from the British Retail Consortium

the biggest impact of the proposed Regulation would be on the food supplements sector.

2.12 The food supplements sector was worth an estimated £350 million in 2003[5]. The likely impact of the proposed 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 from work being done in 2007 by the European trade bodies that most would qualify for listing under 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.

Business sectors and charities affected

2.13 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 for industry is likely to be in relation to the cost of re-labelling, and for some producers 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. The greater longer-term trade opportunities of a harmonised market could off-set short term costs here and lead to innovation opportunities. This area should be reviewed during the evaluation of the legislation in 2013. However, all parties in the consultation agreed that unsubstantiated claims should not be brought to market.

2.14 The Regulation controls voluntary nutrition or health claims; where no claim is made, the Regulation will have no effect.

2.15 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,

[5] Mintel

but there may be other benefits, such as publicity for the charity's objectives. The Regulation now requires that national measures to ensure that endorsements or recommendations by charities do not mislead consumers, with, of course, any claims required to conform to the controls of the Regulation. Early discussions with charities involved indicated that the impact of this is manageable and should be limited.

2.16 While consulting on implementation of the Regulation, health professionals indicated that too wide an interpretation of the prohibition on claims making reference to a recommendation of a health professional could reduce their income from commercial companies looking for expert advice in communications to consumers. Provided there is no direct recommendation in the claim and care is taken about commercial communications, this should have little effect. The Agency is looking closely at guidance to minimise the impact of this.

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 defeat the proposal. 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 to be within the scope of the Regulation;
- 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 – nutrition claims

4.4 Re-labelling will be necessary where claims currently in use do not conform to the requirements of the Regulation, or to implement the revised labelling conditions in relation to health claims in Article 10. Nutrition claims should be little affected since the conditions required are equal to or in places more relaxed than Agency guidance previously in place. There may be some effect on nutrition claims in use when the Regulation came into force, but not currently in the Annex. However, food business operators have until 19 January 2010 to make changes or have the Annex amended. The requirement for nutrition labelling has always been in place. There is a possible future cost as a result of the operation of nutrient profiles once these are set. We will consult separately on establishment of nutrient profiles.

Re-labelling – health claims

4.5 Health claims face a number of potential costs, including re-labelling. A cost likely to apply in most cases will be the Article 10 labelling requirements about context of the claim which hitherto have not applied. Food Business operators will have until 31 January 2010 to implement these changes to the label. Another possible change will be removal of claims if authorisation is not achieved. Most claims are expected to be authorised under the Article 13 process, the list of 'generally accepted claims. Food Business operators will have until 31 January 2010 before non-authorised claims will have to be removed from the label. Claims not eligible under the Article 13.1 process may have recourse to a second route to authorisation, under Article 13.5 and where applications are lodged have at least as long as Article 13.1 claims, and possibly longer before labelling changes might be necessary. 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 6,000 'healthy option' products on the market that are likely to have to make a change to the label to conform to the rules on health claims. See nutrient profiles below.

4.6 Re-labelling for health claim requirements can be made as late as 2010 and based on industry figures estimated at £1,000 per product[6] on a broad range of up to 6,000 healthy option lines, would cost as much as £6 million. Further iterations would add costs, up to another £6 million per iteration. Withdrawn unused labels could add as much as £1 million to this figure. Given the likely event that the transition period that coincides with the standard two-year commercial cycle, these costs could be integrated into normal re-labelling during this cycle. In addition to these 6,000 healthy option lines, there will be food supplement and other sundry products carrying health claims. We do not have a figure for the number of product lines this represents, but the retailer sector estimates are likely to be representatives of the lion's share of products carrying claims on the market. Food supplements carry labelling very close to that required in Article 10 and any minor change here and changes on other products carrying claims should be able to be accommodated within the standard commercial cycle.

Nutrient profiles

4.7 While the discussion above relates to a single iteration by industry that may by and large be integrated into the normal commercial cycle, other label changes would lead to a second iteration that would probably fall outside of this cycle. While it is not possible to say exactly the likely effect of nutrient profiles, some of the 6,000 lines are likely to be affected. Food supplements will not be affected by nutrient profiles. Nutrient profiles must be established by 19 January 2009 and this will be done in consultation with industry. It may be possible, therefore to integrate costs of re-labelling here within the normal commercial cycle and within the £6 million estimate.

Product re-formulation / withdrawal

4.8 The proposal 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

[6] Information from the British Retail Consortium

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 wholly 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[7]. 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[8]. 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 will be greatly impaired by this Regulation. Changes to earlier drafts where more claims were prohibited have diminished this fear, but the time-scales and processes for authorisation of claims may still have an affect. It is difficult to quantify this and the off-setting factors. These include the capability to use emerging science and to protect proprietary data; moreover there are time-limited periods for these processes which can make planning by industry more accurate.

[7] Figure from the PARTIAL REGULATORY IMPACT ASSESSMENT for the Choosing Health White Paper
[8] Information from the British Retail Consortium

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[9]. 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+).

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 force (currently 6 months after publication). 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.

[9] 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.

Claims referring to children's development and health

4.14 A problem that emerged late in the negotiation of the Regulation was the insertion of controls on claims referring to children's development and health. This was included within the process for disease risk reduction claims which does not have a transition period. This and difficulty of interpretation of what claims exactly these controls apply to could have added to re-labelling costs twice over as claims were effectively suspended, but resurrected later after authorisation. A proportionate interpretation of this provision and the proposed transition period have reduced this possibility considerably. Despite specific questions about the effect of this in the recent consultation, and apart from raising their obvious concerns, no data were forthcoming from stakeholders; largely because industry were given more confidence that this issue would be properly dealt with, as appears to have been the case.

(ii) Other costs

4.15 The Regulation covers advertising and presentation as well as labelling and while it is difficult to estimate these without the same level of quantification as labelling, change to leaflets, posters and other media is likely. A significant proportion of this should be able to be accommodated in frequent print runs, but there could be material that will have to be withdrawn and changed, such as recipe cards. Following discussions with the retail sector, the Agency has estimated that this could cost up to £5 million as a separate exercise. There have also been some costs involved in recruiting and training technical and regulatory staff to comply with the whole range of general legislation (the retail sector has estimated these costs to be up to £3 million, thus far within the scope for them to be able to run at £1m per annum for the life of the regulatory review). It is unclear how to quantify a portion of this potential cost for this particular Regulation. The Food Standards Agency has produced extensive guidance notes, and as far as the use of claims is concerned 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. Finally, the Agency recognises that in some cases label changes will involve a scope (e.g. symbols, pictorials) that exceeds the "standard" label change costs of £1,000 per product. After discussion with industry the Agency considers that an additional cost of up to £1m per labelling change iteration seems appropriate.

(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 not therefore an unexpected cost. Any cost to take advantage of this opportunity should be low given that normal commercial activities should lead to the collection of the relevant information for a dossier. The main burden 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) Administrative costs/burdens for business

4.17 Apart from the need to read and understand the salient legislation and/or guidance, following submissions from industry, the Agency considers that for approximately a thousand claims to be made to the Agency, on the appropriate form template, the cost to industry will be approximately £10,000.

(v) Enforcement Costs

4.18 This Regulation would help enforcement of 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. See section 8 below.

Brand names

4.19 Industry had made strong representations about the risk of the Regulation to established brands and trade marks that also amount to 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 case that this might prove necessary.

Transitional Arrangements (Article 28)

4.20 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.

List of Nutrition Claims in the Annex

4.21 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 is 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.

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 above for detail).

4.23 Re-labelling will be necessary where claims currently made do not conform to the regulation. 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 the 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 and associated with training on compliance.

Scientific dossiers (see above for detail).

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.

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.

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. These are identified 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
- labelling 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 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/Heath 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 towards those that can.

5.12 In addition, as explained in Section 5.9, 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. The House of Commons Health Committee's 2002 study[10], updating earlier work by the NAO, finds that obesity alone cost England £3.3-£3.7 billion for 2002 (comprising direct NHS costs of £990-£1,225 million, lost output due to premature mortality of £1.05-£1.15 billion and lost output due to sickness absence of £1.3-£1.45 billion). Uplifting this annual estimate of the cost of obesity in England to the UK population level yields an annual cost of £4.0–4.5 billion. 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.

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 which were particularly vulnerable to association in the consumer mind with this type of producer.

[10] House of Commons Health Committee. Obesity. Third Report of Session 2003-04. Tackling Obesity in England: HC 220 Session 2000-2001: 15 February 2001.

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 cooperation 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 £1,000 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.

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[11].

Market Share

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.

[11] although key data relating to market shares could not be identified for this RIA

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 applies equally 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. The point above in 7.4 relating to low initial volumes for new entrants and similar one-off dossier costs to existing firms/product lines is also relevant here.

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 a 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. In addition, the increased scope for trade could also affect price.

- ***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 (highly unlikely 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. Any product range reduction is also likely to be a short term phenomenon that may be assuaged or even overtaken by potential increased incentives to invest in such products, as claims for genuinely beneficial foods/supplements gain more weight in the minds of consumers.

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

Conclusion

7.10 The proposed 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 viable;
- 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. Local Authorities Co-ordinators of Regulatory Standards (LACoRS) have indicated that a small additional cost for analysis of samples to check the vitamin or mineral source would be incurred. Based on an estimate that approximately 2000 samples per year may be taken at a cost of £50 per sample, even accounting for additional staff time and costs, the total additional cost would not be expected to exceed £50,000 per year.

9 IMPLEMENTATION AND DELIVERY PLAN

9.1 The Nutrition and Health Claims (England) Regulations 2007 will provide for the enforcement of EU Regulation 1924/2006 on nutrition and health claims made on foods. Separate but parallel legislation will be made for Wales, Scotland, and Northern Ireland.

9.2 Guidance to the food industry and enforcement stakeholders on compliance with this Regulation has been drawn up by the Food Standards Agency which will help businesses to comply with the legislation in a proportionate fashion. This guidance has been subject to public consultation and was generally welcomed by all stakeholders. It is currently being revised in the light of comments received and will be published on the Agency's website in due course.

10. MONITORING AND REVIEW

10.1 The Regulation contains built-in monitoring and review by the Commission and Member States in the Standing Committee on the Food Chain and Animal Health (Article 27). Monitoring of labels placed on the market by individual Member States is permitted, but is not being taken up in the UK (Article 26 - but see Option 3 above).

CONSULTATION

(i) Within Government

11.1 Defra, the main Department outside of the Food Standards Agency with an interest, and other Departments have been kept abreast of progress.

(ii) Public consultation

11.2 A full 12 week consultation by the Food Standards Agency took place with between July 24 and October 24 2003 during the proposal stage of the Regulation. A brief summary of comments is attached at Appendix 3. The Food Standards Agency continued to provide information to interested parties by means of regular bulletins following Council working group meetings. 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 were also held on request, including with the food supplements sector. Note was been taken of any feedback during consultation, amending this RIA as necessary.

11.3 Once adopted and in force, a further 12 week consultation ending on 24 May 2007 was held on enforcement provisions and on guidance to compliance. The SI and this RIA have been further amended in light of comments received during this consultation, and the guidance notes are in the process of revision.

12 SUSTAINABLE DEVELOPMENT

12.1 The Food Standards Agency does not consider that implementing these Regulations will have any impact on sustainability issues. In the case that the new controls call into question labelling in use on the market, there was a concern about withdrawal of product and re-labelling. This cannot be completely discounted, but the transition periods should minimise this to ensure this is not a significant concern for sustainability.

13 RACIAL EQUALITY

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

14 PUBLIC SERVICES THRESHOLD TEST

14.1 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.

15 SUMMARY AND RECOMMENDATIONS

15.1 This Regulation has far-reaching benefits to consumers, both in providing lists of authorised claims and other conditions to ensure consumers will not be misled and in helping shape consumer choice to healthier products. It benefits industry by harmonising the European market and reducing trade barriers, while introducing enhanced legal certainty and routes to innovation across Europe. The requirements laid out are comparable to international markets (Japan and the USA) which remain healthy and innovative.

15.2 These benefits carry potential costs to industry from re-labelling of products and in development of innovative products in the shape of provision of substantiating evidence for claims. The cost is variable depending on a number of factors: the time from development to market, the level of science to substantiate claims, whether re-labelling can be rolled up in one or more changes. Some additional administrative costs from training for compliance with this and other labelling legislative changes may be expected. There are still some uncertainties about the impact on industry, particularly on how the detail of nutrient profiling and the authorisation process might add to or mitigate costs. The Article 13 process for claims based on generally accepted evidence should help minimise costs to industry, and allow most claims on the market to be registered and authorised. 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.

15.3 In pursuing option 3 the UK was able to reduce the number of blanket prohibitions and inject a degree of proportionality into meeting the 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). The likely effect of nutrient profiles remains unknown, at least until 12 January 2009. The UK will press for impact assessments during the process of establishing this process to ensure a proportionate approach, and will consult fully. Already industry in response to policy developments in the UK has begun moving 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.

15.4 Industry has pointed out that re-labelling will be necessary and possibly on more than one occasion, and we have had revised costs for this since the previous revision of this RIA. Nevertheless, where possible we have taken favourable interpretations to minimise the likely occasions of re-labelling (e.g. on Article 10), and even with the uncertainty of nutrient profiles, industry should be able to plan much of the re-labelling as may be necessary in the transition periods available. We are working to ensure proportionate interpretations on use of claims in advertising and presentation to help reduce any additional costs here. Costs are summarised in Appendix 2.

Declaration:

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

Signed: *Dawn Primarolo* Minister of State for Public Health

Date: *18th July 2007*

CONTACT POINT

Noel Griffin

Nutrition Division

Food Standards Agency

Room 115B Aviation House

125 Kingsway

London

WC2B 6NH

Tel: 0207 276 8163

Fax: 0207 276 8192

Email: nutritionandhealthclaims@foodstandards.gsi.gov.uk

Appendix 1

PUBLIC SERVICES THRESHOLD TEST: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON NUTRITION AND HEALTH CLAIMS 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 this new Regulation 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

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

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.

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

[12] Figure based on LACORS' estimate of these costs

Appendix 2

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.	Re-labelling 6,000 'healthy eating' nutrition claims and 1000 health claims Incremental effect of the Regulation is up to £8million, per iteration but in reality will only be a fraction of this due to lead times and normal commercial labelling cycles Promotional Materials Up to £5m per iteration but in reality will be less due to lead times and frequent print runs etc.	Better consumer information and increased confidence from pre-approved claims. This may help combat obesity (costed at £4.25billion in 2000) and other dietary related health problems in the UK.

	Re-formulation An estimate of 10% of health claims would potentially equate to £2.5million **OR** Substantiation An estimate of 10% of health claims would potentially equate to around £1.5 million Public Enforcement Costs Following comments from LACoRS these are expected to be less than £60,000 Administrative Costs Business faces the costs of reading and understanding the salient legislation and guidance (these are subsumed within the increased regulatory inputs section) as well as an approximate £10,000 cost of completing claim forms for the Agency Increased Regulatory Staff/Inputs A proportion of the overall forecast £6m up to 2010 extra regulatory management spending being driven by general labelling regulatory considerations. Total Costs FSA estimate that the total cost faced by UK business and the public enforcement bodies of Option 3 would be less than £10-15m for the whole process.	Unquantified benefits from freer single market trade, and possible research advantages leading to innovation.