EXPLANATORY MEMORANDUM

The Nutrition and Health Claims (Wales) Regulations 2007

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

Description

1. These Regulations ("the Regulations") provide for the execution and enforcement of Commission Regulation (EC) 1924/2006 which controls the voluntary use of claims on food and establishes a positive list of nutrition claims, and the criteria a product must meet to use them. It also seeks to harmonise legislation across the EU making it easier to trade.

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

2. None.

Legislative Background

3. The powers enabling the Regulations to be made are contained in the Food Safety Act 1990. Sections 16(1)(e) and (f), 17(2), 26(1) (a) and (3) and 48(1) of the Food Safety Act 1990 were transferred to the National Assembly for Wales and are now exercisable by Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales 2006. The Regulations are subject to the negative resolution procedure.

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

5. EC 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 Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007 (SI 1984/2007) (W.165) , putting in place enforcement provisions for Regulation 1925/2006, came into force in Wales on 7th August 2007.

Purpose and intended effect of the legislation

6. The objective of the Regulations is to harmonise Community rules to seek to further protect consumers from misleading claims and also harmonises

legislation across the EU making it easier to trade. 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 unauthorised health claims. EC Regulation 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. 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, EC 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 19 January 2009 and will require products to comply with those profiles and the associated controls within a two year period.

8. As detailed in the Regulatory Impact Assessment (RIA) the Food Standards Agency, including in Wales, consulted widely through the development of EC 1924/2006 and kept interested parties up-dated on negotiations. In general stakeholders welcomed the proposal for EC 1924/2006 as both a means of further protecting consumers and 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.

Implementation

9. These Regulations were made on 6 September 2007 and are intended to come into force on 1 October 2007. Similar legislation will simultaneously come into force in England, Scotland and Northern Ireland.

10. The implementation of these Regulations would fulfil the UK's obligations under the EC Treaty and will provide Local Authorities with the power to enforce against food business operators who are not in compliance with the new Regulations. Failure to implement them in Wales by the coming into force of 1 October 2007 would lead to inconsistency in the law.

Consultation

11. The Agency consulted widely throughout the development of EC 1925/2006, including a full 12 week public consultation. Forty seven replies were received to the English consultation. In Wales, approximately 50 interested parties were invited to respond to the consultation exercise, however no responses were received from Welsh stakeholders. In general, stakeholders have welcomed the proposal as both a means of further protecting consumers and also to aid trade.

12. The consultation on implementation of EC 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 the Agency decided not to enact this provision. The consultation also highlighted interpretative problems, in particular the Regulation is restricted to control 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 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.

Compliance

13. The proposed legislation is compatible with the provisions contained in section 80 (Community law), section 82 (Human rights) and section 82 (International obligations) of the Government of Wales Act 2006.

Regulatory Impact Assessment

14**. OPTIONS**

Option 1: do nothing

Option 2: oppose adoption of EC Regulation 1924/2006

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

14.1 ***Option 1: do nothing.*** This was not a credible option and was not the position taken in negotiation. The resulting EC Regulation 1924/06 has direct legislative force and it was necessary for the UK to be involved in influencing its shape.

14.2 ***Option 2: oppose adoption of EC Regulation 1924/2006.*** In a qualified majority vote the UK acting alone would not have had the voting capacity to defeat EC Regulation 1924/2006. 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.

14.3 ***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 EC Regulation 1924/2006 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.

BENEFITS

14.4 ***Option 1: do nothing.*** This option would not have afforded any useful benefit.

14.5 ***Option 2: oppose adoption of EC Regulation 1924/2006.*** This option would not have afforded any useful benefit either, as in the event there was a strong qualified majority in favour of EC Regulation 1924/2006.

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

Overall Benefits

15. The Regulations 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

16. 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 Regulations are expected to result in:

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

17. 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

18. 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.

19. 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.

20. 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

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

22. 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.

23. 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.

24. 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.

25. 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[1], 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.

COSTS

26. Compliance costs

26.1 ***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 above would have been lost and additional costs therefore levied.

26.2 ***Option 2: oppose adoption of EC Regulation 1924/2006.*** As noted above, opposition would not have changed the final shape of EC Regulation 1924/2006, so no costs other than those discussed for option 3 would have arisen.

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

26.3 ***Option 3: Negotiate for adoption of an EC 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

27. 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

28. 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.

29. Re-labelling for health claim requirements can be made as late as 2010 and based on industry figures estimated at £1,000 per product[2] 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

30. 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

[2] Information from the British Retail Consortium

31. 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 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.

32. 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[3]. 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[4]. However, most manufacturers and retailers routinely undertake reformulation and redesign which could offset some of these costs.

Innovation

33. 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;

[3] Figure from the PARTIAL REGULATORY IMPACT ASSESSMENT for the Choosing Health White Paper

[4] Information from the British Retail Consortium

moreover there are time-limited periods for these processes which can make planning by industry more accurate.

Scientific dossiers

34. 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 the European Food Safety Authority (EFSA) will require[5]. 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.

35. 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+).

36. 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

[5] 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.

previously prohibited, so any such voluntary claims coming on the market would be new and part of normal commercial decisions and developmental costs.

Claims referring to children's development and health

37. 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.

Other costs

38. 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.

Costs for a typical business

39. 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.

Administrative costs/burdens for business

40. 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 [Art. 13] to be made to the Agency, on the appropriate form template, the cost to industry will be approximately £10,000.

Enforcement Costs

41. EC Regulation 1924/2006 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 below.

Brand names

42. Industry had made strong representations about the risk of EC 1924/2006 to establish brands and trade marks that also amount to claims under the definitions in EC Regulation 1924/2006. While EC Regulation 1924/2006 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)

43. There was great concern that in order to allow industry time to adapt to the new Regulation EC 1924/2006, 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 EC 1924/2006 to provide a transition period.

List of Nutrition Claims in the Annex

44. 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

45. 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).

46. 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).

47. 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.

48. 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.

SMALL FIRMS IMPACT TEST

49. The Small Business Service in England 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.

50. 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.

51. 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.

52. 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.

53. 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 were a key consideration here.

COMPETITION ASSESSMENT

54. 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.

55. 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[6].

Market Share

56. 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

57. 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)

58. 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.

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

Impact on Entry Barriers

59. 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

60. 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 above) on product innovation.

61. 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

62. 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.

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

Conclusion

64. 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 EC 1924/2006 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.

Consultation

(i) Within Government

65. Other Departments with an interest have been kept abreast of progress.

(ii) Public consultation

66. 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. 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 London 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.

67. 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.

Post Implementation and Review

68. The Nutrition and Health Claims (Wales) 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 England, Scotland, and Northern Ireland.

69. 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.

SUMMARY AND RECOMMENDATIONS

70. 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.

71. 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.

72. 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.

73. 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.