

PARTIAL REGULATORY IMPACT ASSESSMENT

1. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON NUTRITION AND HEALTH CLAIMS MADE ON FOODS COM(2003) 424 FINAL / 2003/0165 (COD)

2. PURPOSE AND INTENDED EFFECTS OF THE MEASURE

(i) Objective

2.1 The proposed 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.

(ii) Background

2.3 The proposed Regulation would establish:

- a positive 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 (claims as to the effect of the food on health, such as 'helps maintain a healthy heart' or 'may reduce the risk of heart disease'). The European Food Safety Authority (EFSA) would be consulted on the supporting scientific evidence before authorisations were given. For these purposes the proposal envisages two types of claims; for one type only, 'generally accepted' claims - those which describe the role of a nutrient or other substance in growth, development and normal functions of the body - claims would be allowed subject to national provisions during a transitional period of 3 years pending adoption of a Community list of such claims. 'Generally accepted'

claims would have to be based on generally accepted scientific data.

2.4 The proposal would also:

- require the Commission to establish nutrient profiles¹ for foods which 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 The proposal seeks to meet the changing demands of consumers for more information about food on offer and how it contributes to their diet and health. Agency research shows that over half (52%) of UK consumers are 'fairly' concerned about the accuracy of health claims. Between 2001-03 the ASA upheld 23 complaints against health claims in advertising made on food products. 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.

2.6 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 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.

2.7 In the absence of detailed Community rules on the use of nutrition or health claims on food, Member States' rules vary widely. The UK operates a voluntary system via the Joint Health Claims Initiative (JHCI) which has an agreed code of practice and a system to authorise health claims manufacturers wish to use, but this provides only patchy coverage (at time of writing JHCI has authorised 6 health claims).

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.

(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 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 the prediction that by 2010 obesity will cost the nation some £3.6 billion a year² gives an indication of the benefits that could accrue from ensuring that labelling helps consumers to choose a healthy diet.

2.9 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 4,250 products on the market with a value of over £1 billion³). In the absence of any EU legislation, the Agency has produced guidance on how such claims should be used (which is similar to provisions on nutrition claims in the draft proposal).

2.10 The products likely to be most affected by this legislation are those bearing health claims. The proposal would not ban any foods, but it is possible that some may become commercially non-viable should they not be allowed to bear claims (as the consumer would not be attracted to the product 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, although the Agency is in the process of conducting an audit to collect this information. Early results indicate that there are health claims on some 1000 different products, of which about 75% are food supplements.

2.11 The food supplements sector, worth an estimated at £350 million in 2003⁴, is likely to be significantly affected by the Regulation, but to what extent will depend upon how many of the health claims included on these products will fall outside the 'generally accepted' category. Limited information available indicates that many of the health claims on food supplements may do so. We are checking information sources to clarify this. For other food

² Tackling Obesity in England, National Audit Office 2001

³ Information from the British Retail Consortium

⁴ Mintel

products, as well as for a proportion of supplements, it is anticipated that many health claims will fall into the 'generally accepted' category.

Business sectors and charities affected

2.12 The Regulation would affect all food and food supplement manufacturing businesses or retailers with their own labelling wishing to make a claim for the nutrition or health benefits of the food. The degree to which the business sector will be affected will depend on the text of the final Regulation. However, it is clear that as currently drafted there could be implications in relation to the cost of re-labelling, the production of dossiers to substantiate claims, the range of "healthy option" products offered, and future innovation in the food industry.

2.13 Where there is no intention of making a nutrition or health claim, these regulations will have no effect.

2.14 The Agency has identified some 12 health-related charities which might be affected by the proposed prohibition on charity tie-ins with food manufacturers or retailers. Not all of these involve a financial transaction, but there may be other benefits, such as publicity of the charity's objectives.

3. OPTIONS

[NB: In effect, the only option at this stage is to continue to engage in the negotiations on the proposal]

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 is not a credible option. This is a proposal for an EU Regulation, which would have direct legislative force.

3.2 **Option 2: oppose adoption of the Regulation.** There is general support from all Member States for this proposal and the UK acting alone would not have the voting capacity to defeat it in Council. Without cooperating and influencing in the negotiations we would be forced to accept a situation likely to be less advantageous to the UK consumer or to UK industry.

3.3 **Option 3: Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate.** This is the preferred option and the one likely to minimise any negative impact of this Regulation while retaining its benefits. These are discussed below.

Prohibited health claims (Article 11)

3.5 Despite the proposal requiring a pre-approval process for health claims via the European Food Safety Authority, the regulation as currently drafted would specifically prohibit certain types of health claims. These include claims about general wellbeing, those which make reference to psychological and behavioural functions, slimming and weight control claims, and claims that make reference to the advice of doctors, health professionals or charities.

3.6 The UK has argued that specific prohibitions appear unnecessary since a pre-approval system is proposed, and that they could stifle innovation (a major concern of the industry who believe that technological advances could lead to foods which will have positive effects on the nation's health). However most Member States wish to retain at least some of these prohibitions, therefore arguing for deletion is not likely to be successful. The UK should therefore lobby for amendments which make the text less restrictive, and in particular which allow claims which can be substantiated.

3.7 The industry are also concerned that the proposed prohibition on general, non-specific benefits of the nutrient or food for overall health and well-being is too broad a catch-all and would, in particular, catch many "healthy option" brands. These can be useful indicators to consumers that a range of foods have particular nutritional qualities. These concerns may be unfounded as if the products make a clear nutrition claim (e.g. a 'healthy eating' sandwich is clearly marked as low-fat) and meet the relevant criteria, then our view is that they comply with the proposal, i.e. the "healthy option" brands would be considered as merely signposting the claim. However, the UK has sought to confirm its interpretation of the legislation and proposed

wording to clarify the text. This has not yet been taken on board by the Commission or all Member States, but the UK will continue to press this.

3.8 The UK should also press for changes to allow claims linked to charities and to ensure that public health messages linked, for example, to the Chief Medical Officer's advice are not prohibited. The UK should resist the addition of a prohibition on claims on foods aimed at children unless it can be clearly justified that such action is appropriate.

Transitional Arrangements (Article 26)

3.9 There are many products on the UK market which make claims covered by the proposal and the proposed transitional period of 12 months to take full effect is too short to allow a smooth adjustment from the current arrangements. As such, the UK should press for a longer transitional period.

List of Nutrition Claims in the Annex

3.10 Amendments are required to ensure that the Annex is not unduly restrictive or the wording for specific nutrition claims unclear (although it should be noted the proposal includes a mechanism whereby additional nutrition claims can be added in the future). The UK has proposed text to ensure that fruit and vegetable content claims are allowed and that factual nutritional information (i.e. the precise of amounts of fat, salt and calories) in a food can be provided on the front of packs, in addition to and separate from the nutrition panel. Both of these types of information can be useful to the consumer.

3.11 There are potentially some nutrition claims currently used on the UK market which are not covered in the Annex. The UK would be prepared to put forward such claims at the request of the industry, for example 'high energy', where sufficient justification is provided, including detailed criteria for use of the claim.

Nutrient Profiling (Article 4)

3.12 This is an Article which is causing significant concern to the industry, specifically on how profiling would work in practice. The issue being that

depending on the 'severity' of the profiling, both nutrition and health claims could be prohibited on certain products. As the marketing of these may be dependent on the claim, products might be taken off the market or require reformulation to fall within the nutrient profile. However, without nutrient profiling there is the possibility that nutrition and health claims on foods high in fat, sugar or salt might undermine public health advice to reduce intake of these nutrients. For example, you might see 'low fat' claims on foods high in sugar, or claims relating to a healthy heart on foods high in salt.

3.13 It is important to recognise that the proposal does not set nutrient profiles, but rather establishes a framework for their development, with the specific details to follow within 18 months of adoption. It is only when these details begin to be worked up, and the Commission has emphasised that Member States and stakeholders will be involved in this process (with the former voting on any proposal in Standing Committee), that it will be possible to assess the precise implications of nutrient profiling.

4. COSTS

(i) Compliance costs

4.1 **Option 1: do nothing.** Compliance costs would apply when the Regulation is adopted (see option 3 below).

4.2 **Option 2: oppose adoption of the Regulation.** As a harmonisation measure, industry would be disadvantaged by this option with lost opportunity costs. It is not possible to quantify these.

4.3 **Option 3: Negotiate for adoption of a Regulation which delivers consumer and trade benefits and is proportionate.** Set out below are those areas where costs are likely to be incurred and an attempt, with the information available, to estimate what these might be.

Re-labelling

4.5 Re-labelling will be necessary where claims currently in use do not conform to the requirements of the regulation. This would include a nutrition

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

4.6 It is difficult to estimate the extent of re-labelling that may be required because of this Regulation, as this will depend on manufacturers decisions as to whether or not to support health claims they are making. The vast majority of nutrition claims would be unaffected, because the criteria in the Annex to the regulation are already met. The worse-case scenario is that 'healthy option' brands are seen as being 'health' claims rather than signposting a nutrition claim, and that including factual nutrition information on the front of packs (which occurs on a smaller number of products), and separate to the nutrition panel, becomes prohibited. There are about 4,000 'healthy option' products on the market.

4.7 The amount of re-labelling required in relation to health claims will depend on manufacturer's decisions (see above). If 10% of products carry claims which are not supported, about 100 products will be affected.

4.8 In relation to re-labelling costs, it is important to take account of routine changes businesses will make to the product ranges because of products being taken off the market, new products added, changes because of reformulation, updating of designs, etc. As long as there are suitable transitional arrangements in the Regulation, re-labelling will be minimised. Our experience suggests 24 months is a suitable period to achieve this. For example, one large multiple retailer suggests re-labelling takes place across all ranges on regular cycles that would comfortably fit a 24 month transition. Small businesses could find this more challenging, as labels are generally required to last longer. Maximum re-labelling costs are estimated at £1,000 per product⁵. With no allowance for routine changes, for 4000 products, the worst case total cost estimate would be £4million.

Product re-formulation / withdrawal

⁵ Information from the British Retail Consortium

4.9 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. Where this is not possible, product withdrawal may be the alternative. It is difficult to estimate how many products might be affected, or the exact costs of re-formulation. However, industry has indicated that the cost of developing a new product is £25,000⁶.

Innovation

4.10 UK food industry claims to be among the most innovative in Europe, making products aimed at specific groups (children, the elderly, diabetics, etc – but not medicinal foods), and reacting to diet based health concerns with products to meet evolving consumer expectation. Industry fears innovation without being able to make a claim will be greatly impaired. It is difficult to put a cost on the effect prohibiting certain types of claims could have on innovation.

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 or the level of information that EFSA will require. The former will become clearer following the audit of claims on the market and an assessment of how many of these are likely to be included in the list of 'generally accepted' claims that the UK will put forward to the Commission (such claims will not require a dossier). EFSA will make their requirements clearer before the regulation comes into force (currently 6 months after publication).

(ii) Other costs

4.12 None foreseen at present.

⁶ Information from the British Retail Consortium

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

4.14 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 at this stage to speculate on costs for a typical business in addition to the costs shown in the rest of the RIA. A major cost will be re-labelling and since manufacturers re-label on a regular basis (once or twice a year), costs here could be absorbed into normal overheads. Where health claims are to be used, choice of a 'generally accepted' claim would further restrict costs, but for innovative products and disease risk reduction claims, businesses would be faced with the cost of a scientific dossier. Data collection here would probably be worked into product development costs and is therefore likely to be less burdensome than a "one-off" dossier. Where "one-off" dossiers may be needed is in substantiating a claim already in use, but which would not be included on the 'generally accepted' claims list.

5. BENEFITS

5.1 **Option 1: *do nothing.*** This option is likely to afford no benefit.

5.2 **Option 2: *oppose adoption of the Regulation.*** The only benefit of this option, if successful, would be that of saving industry and enforcement any compliance costs from implementation of the proposal. These are discussed in Section 4 above.

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

5.5 The regulation on Nutrition and Health Claims made on Foods and Food Supplements is proposed because of the potential benefits of having a more regulated uniform system across the EU. The proposal identifies these as:

- a high level of consumer protection by providing 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

5.6 The current situation could be described as resulting in imperfect information, a prime reason for market failure; a situation in which the market does not attain economic efficiency. In this case, the regulation is expected to result in:

- the elimination of bogus claims; and
- a label which gives only accurate information.

The provision to allow disease risk reduction health claims will benefit consumers looking for a particular nutrition effect from a food product or food supplement; and industry will benefit from more accurate and improved marketing of these products.

Benefits from Reduced Prices

5.7 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 cost as much as ten times the price of comparable food without the health claim.

5.8 It can thus be expected that a segmented market will develop with products carrying approved health claims and other products, which are no longer allowed to carry any claims. The former will continue to demand a premium price whilst the others will have to compare with other non-health related food and food supplements. A more effectively functioning internal market, leading to increased competition, will also increase the pressure on prices.

Public Health Benefits

5.9 The public health benefits and reduced costs for public health (direct and indirect) costs are expected to derive from increased consumer 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 consumers to choose a healthy and balanced diet.

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.

5.12 The cost of diet related illness and premature death to the UK economy is very high. Estimates related to obesity alone have recently been placed in the region of £2.5 billion annually. 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 costs⁷.

6. CONSULTATION WITH SMALL BUSINESSES

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. The extent of this would depend on the use of 'generally accepted' claims which will not require scientific dossiers. One respondent said they had got into the market on the basis of supplying a product about which they could make a claim. The claim was seen as integral to the product and an important marketing tool. The claim was considered scientifically sound, but it was clear no specific work such as would likely be needed for a scientific dossier had been done. There seemed to be more reliance in small companies on

⁷ The FSA is currently conducting further work on these costs but these are not yet available

'generally accepted' type claims or on expert recommendation, such as *ad hoc* discussions with academics or reading the scientific literature.

6.2 When questioned about whether work would be undertaken to substantiate claims if necessary, and if not what action would be taken, the supplement suppliers indicated that they would be more likely to put scientific dossiers together where necessary, whereas the drink supplier thought they would probably market the drink without the claim. This choice would be made on cost grounds, and the same costs discussed in 4.12 for scientific dossiers would apply.

6.3 It was recognised that a number of the claims used by these types of companies 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. Costs of innovative claims, made in order to gain a market advantage, would fall wholly on the company wishing to use such a claim.

6.4 The cost of re-marketing without claims was thought 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). 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.

6.5 The Food Standards Agency has been in close contact with the Small Business Service (SBS) and will continue to consult with small businesses to look at implementation issues and find ways to ease any burden on the small business sector as a result.

7. COMPETITION ASSESSMENT

7.1 Two main markets 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 of these goods who would be influenced by any competition effects.

7.2 Information on the size and nature of the market for food and drinks with health and nutrition claims is poor. This is partly because it is a rapidly

evolving market, but also because these products are a sub-set of general groceries. For example, whilst some ready meals do not carry health claims, many others do. They thus represent a premium sub-set of mainstream groceries⁸. However, food supplements are a quite distinct and fast growing market, and better data are available on these products⁹.

Market Share

7.3 Available information indicates that neither foods with health claims nor food supplements sectors are dominated by a small number of suppliers. With regard to food with health claims, there are numerous producers, plus supermarket own-label varieties. As noted above, these foods should in any case be regarded as a subset of normal groceries. With regard to food supplements, although there are a small number of well-established brands, a quick 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 affected. However, the costs of preparing dossiers to justify health and nutrition claims, which will be one-off costs determined by research needs rather than sales volumes, will obviously be more justifiable for producers whose products are sold in large volumes.

Effects on Market Structure (Size and Number of Firms)

7.5 Because the costs of preparing dossiers will be common to similar products, regardless of production volume/sales value, it is possible that some producers with small market shares will cease to produce some of their lines if they cannot market them without the claim. Thus the regulation is likely to lead to some consolidation of the market. The effect of restricted use of claims is likely to have a much bigger impact in the food supplements sector, because the producers are more specialised and the products are a distinct category (rather than a subset of a broader category).

Impact on Set-up Costs

⁸ Food Commission research has indicated that prices for foods marketed as healthy are about 51 percent higher than for “normal” products in the same category

⁹ although key data relating to market shares could not be identified for this RIA

7.6 In the short-term, the regulations are unlikely to have an impact on the set-up costs for use of these claims between existing and new entrants to the market. This is because both existing and new products must conform to the new regulations. In the longer-term, there may be some discouragement of new entrants as the regulations will add to the costs of producing new products on which a claim will be made, which will tend to limit the extent of product innovation and market entry by new firms.

Impact on On-going Costs

7.7 There are unlikely to be any differential impacts on on-going costs between new and existing firms.

Technological Change

7.8 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 seems likely to slow this, at least in the short-term.

7.9 However, the regulations are 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

7.10 The regulations are likely to have significant impacts on three of these issues:

- **Price** As noted above, foods with health and nutrition claims are generally premium products for which prices can be several times 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 supplement, 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 inevitably be affected downwards.

- **Quality** The requirement for scientifically justified and documented health and nutrition claims will mean that only those products with actual (evidence based) health or nutritional benefits will be able to carry claims. Therefore, the quality of these products (as measured by their effectiveness in contributing to specified health and nutritional goals) is likely to rise significantly. Consumers will also be able to make more informed judgements.
- **Range** If all health and nutrition claims cannot be supported (as is likely to be the case), the range of products carrying claims will inevitably be reduced (for both food and food supplements), although the products can still be sold without claims. However, in the context of this regulation, this is a positive development, as it will mean that only products that meet the expectations of consumers will be available.

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

Conclusion

7.11 The proposed regulation is likely to have a significant impact on competition with the foods with claims and food supplement industries:

- the range of products carrying claims is likely to 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 a 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, meaning product innovation and new entrants may be reduced; however
- the quality of remaining 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 The reference in Article 3.1 to Directive 84/450/EEC on misleading advertising would require small changes to the enforcement regime of misleading claims in labelling. However, the Commission has signalled that it considers that there is little need to make this proposal with reference to this Directive. In this case there is no change from enforcement and sanctions currently in force. After implementation, this Regulation will be enforced by

food authorities, with offences and penalties applied in line with the Food Safety Act 1990 or the European Communities Act 1972.

9. MONITORING AND REVIEW

9.1 The proposal has monitoring and review by the Commission and Member States in the Standing Committee on the Food Chain and Animal Health built in (Article 25). Monitoring of labels placed on the market by individual Member States is permitted (Article 24 - but see Option 3 above).

10. CONSULTATION

(i) Within Government

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

(ii) Public consultation

10.2 A full 12 week consultation by the Food Standards Agency took place with between July 24 and October 24 2003. Information from this consultation has informed this RIA. The Food Standards Agency continues to provide information to interested parties and will continue during the course of negotiations, and take note of any feedback in that process, amending this RIA as necessary.

11. SUMMARY AND RECOMMENDATIONS

11.1 Given the nature of the proposal, the cost implications are mostly for the food industry, although there could also be implications for charities if amendments to the specific prohibitions are not secured. There are a number of uncertainties about the impact on industry, particularly for 'healthy eating' brands, and on how the detail of nutrient profiling and the suggested prohibitions might affect innovation. It may be possible to minimise potential costs here by agreeing amendments to the proposed Regulation during negotiations. We have identified two other main areas of potential costs:

- Label changes, the cost of which would be largely offset by the costs of planned label changes so long as an appropriate transition period is allowed.
- Preparation of dossiers. Manufacturers making claims should have access to supporting data, however compilation of dossiers and supporting them through the approval process will incur costs. These are difficult to estimate because the assessing authority, the European Food Safety Authority, has no experience in dealing with dossiers of this nature.

11.2 Option 3 is recommended as the most likely to achieve a proportionate measure, minimising costs to industry and maximising benefits to consumers and public health while achieving the objectives of the proposal for harmonised 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.

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