

Summary: Intervention & Options

Department /Agency: Food Standards Agency	Title: Impact Assessment of the setting of nutrient profiles under Regulation (EC) 1924/2006 on nutrition and health claims	
Stage: Options	Version: 1.0	Date: 16 October 2008
Related Publications:		

Available to view or download at:

<http://www.>

Contact for enquiries:

Telephone:

What is the problem under consideration? Why is government intervention necessary?

Regulation (EC) 1924/2006 states that consumers may understand that foods bearing nutrition and health claims have a nutritional or health advantage over other similar products. Government intervention already ensures that consumers are protected by requiring nutrition and health claims to be authorised on the basis of science. This further intervention seeks to ensure consumers are not misled as to the true nutritional value of foods by prohibiting claims on foods high in nutrients that should be eaten less of in a healthy diet.

What are the policy objectives and the intended effects?

Regulation EC No 1924/2006 on nutrition and health claims made on foods aims to protect consumers from being misled by establishing nutrient profiles and thresholds that products must comply with in order to make claims. Establishing nutrient profiles aims to ensure that claims do not mask the overall nutritional status of a food, which should help prevent consumers from being misled when trying to make healthy dietary choices.

Furthermore, the setting of nutrient profiles across the EU will help to facilitate the free movement of such products across Member States.

What policy options have been considered? Please justify any preferred option.

1. Do nothing - accept the Commission's proposed nutrient profiles 'as is' without modification by negotiation.
2. Negotiate for the adoption of nutrient profiles which deliver consumer and trade benefits and are proportionate - preferred option as it delivers clear benefits to the consumer and industry.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? January 2014

Ministerial Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

.....Date:

Summary: Analysis & Evidence

Policy Option:	Description:
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COSTS	ANNUAL COSTS	Description and scale of key monetised costs by 'main affected groups' Not yet known (N/K)		
	One-off (Transition) Yrs			
	£ N/K			
	Average Annual Cost (excluding one-off)			
	£ N/K	Total Cost (PV)	£	
Other key non-monetised costs by 'main affected groups'				

BENEFITS	ANNUAL BENEFITS	Description and scale of key monetised benefits by 'main affected groups'		
	One-off Yrs			
	£ N/K		0	
	Average Annual Benefit (excluding one-off)			
	£ N/K	Total Benefit (PV)	£	
Other key non-monetised benefits by 'main affected groups'				

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £
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What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	2009
Which organisation(s) will enforce the policy?	Local Authorities
What is the total annual cost of enforcement for these organisations?	£ N/K
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£ N/K
What is the value of changes in greenhouse gas emissions?	£ N/A
Will the proposal have a significant impact on competition?	No
Annual cost (£-£) per organisation (excluding one-off)	Micro Small Medium Large
Are any of these organisations exempt?	No No N/A N/A

Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)
Increase of £	Decrease of £	Net Impact £ N/K

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

1. Background

Legislation controlling the use of nutrition and health claims

European Regulation (EC) No 1924/2006 on nutrition and health claims made on food harmonises Community rules on the use of nutrition and health claims. Nutrition claims are claims that state, suggest or imply that a food has particular beneficial nutritional properties due to the presence, absence, increased or reduced levels of energy or a particular nutrient or other substance, for example “low fat” and “no added sugars”. Health claims are claims that state, suggest or imply that a relationship exists between a food and health, for example “reduces blood cholesterol for a healthier heart”. The Regulation has two objectives, to enable free movement of foods within the Community thereby facilitating intra-Community trade, and seeking to protect consumers from false and misleading claims.

Consumer protection is achieved by the requirement for claims to be authorised and listed to be used on food. The Annex of the Regulation contains a list of authorised nutrition claims and criteria for using them, and there are provisions in place that allow this list to be amended and added to in future. The authorisation process for health claims requires food business operators to submit claims, accompanied by conditions of use and supporting science, to the European Food Safety Authority (EFSA) for assessment. Claims based on generally accepted scientific evidence were compiled by Member States. The European Commission has now compiled Member States' lists into a single consolidated Community list which has been sent to EFSA for assessment before Member States agree the final list. The Agency was responsible for compiling this list of claims for the UK and food business operators were invited to submit claims to us between October 2006 and September 2007. For claims based on newly developed scientific evidence, disease risk reduction claims and claims referring to children's development and health, a dossier of information needs to be submitted in justification of the claim for assessment by EFSA.

A regulatory impact assessment (RIA) for the full EC Regulation 1924/2006, which includes costs and benefits for the provisions mentioned above can be found by following this link:

<http://www.food.gov.uk/consultations/consulteng/2007/claims2007eng>

Requirement to establish new provisions on nutrient profiling

The Regulation requires an additional control to protect consumers from being misled when foods high in saturated fats, sugars and salt may be made to seem healthier choices when accompanied by a nutrition or health claim. For example, a food with the claim “low in fat” may appear to be a healthy choice, but it could also be high in salt and a less healthy choice for people with high blood pressure. In order to help avoid consumers being misled in this way, nutrient profiles are to be established to categorise foods on the basis of their nutrient composition. Nutrient profiles will operate in addition to the above requirement for claims to be authorised – all claims must be authorised and listed to be used on food, and only foods that meet the nutrient profiles will be able to bear these authorised claims. Nutrient profiles do not categorise food as good or bad, nor are they to be used for any purpose other than deciding whether a health claim may be made or how a nutrition claim may be made.

The effect of the application of the nutrient profiles will be as follows:

If a product fails the profile on one nutrient:

- no health claim can be made; a nutrition claim can be made, but only if a statement reading “high [name of the nutrient exceeding the profile] content” is made near to and with the same prominence as the claim. For example, if a food is claiming to be low in fat but it is also high in sugars, then the statement “high sugar content” should also be made.

If a product fails the profile on two or more nutrients:

- no claim can be made.

The only exception to this is a “reduced” claim where the nutrient about which the claim is made does not count toward calculating the effect of the nutrient profile. For example, to make a “reduced saturated fat” claim, the product does not need to comply with the threshold set for saturated fat. However, if the product is also high in salt then the statement “high salt content” would need to be made.

Nutrient profiling

- Nutrients to be taken into account

- salt, saturated fat and sugars as appropriate (EFSA deemed these as nutrients too high in the European diet that consumers should seek to reduce)
- Adapted profiles may implicitly take account of additional nutrients that EFSA deemed particularly important in the European diet (e.g. the cereal category takes account of contribution of fibre in the diet, vegetable oils and fat spreads of unsaturated fatty acids); some Member States have asked if this might be made more explicit

- Validation of nutrient profiles

- By reference to food based dietary guidelines (FBDG), as recommended by EFSA. There are no EU FBDGs, but the Commission’s paper summarises those in operation in Member States. In addition to FBDGs the UK has a reformulation policy for salt, saturated fats and energy and it is important that controls on consumer choice as represented by nutrient profiles are consistent with these.

- *The health rationale*

The accompanying European Commission working document is based on work done by EFSA to establish the scientific basis of nutrient profiles, which was published as an opinion in February 2008. It can be found at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178689506673.htm

The nutrient profiles will be based on salt, saturated fat and sugars as appropriate, as EFSA judged consumption of these nutrients to be too high in the European diet so consumers should reduce intake. EFSA’s opinion on the setting of nutrient profiles cites evidence of an established link between intake of saturated fatty acid and cardiovascular disease, intake of sodium and increased blood pressure which is a risk factor for heart disease, stroke and renal disease, and intake of sugar and dental caries.

The Agency is currently working with industry to reduce levels of saturated fat, added sugars and salt in food. These commitments form part of a broad goal for the Agency, to improve consumer’s diet and health by making it easier for them to make healthy choices.

Further information on the Agency’s work to reduce saturated fat can be found on our website at: <http://www.food.gov.uk/news/newsarchive/2008/jul/satfat>

Further information on the Agency’s salt reduction strategy can be found on our website at: <http://www.food.gov.uk/news/pressreleases/2008/jul/sodiumrep08>

Consultation

At the time of writing the original impact assessment for EC Regulation 1924/2006 we did not have a clear idea of the form and nature of the EU nutrient profiles and so costs and benefits were calculated at a more general level and included estimates within those for the Regulation as a whole. The accompanying working document from the European Commission now provides that level of detail to enable stakeholders to see how their products might perform in comparison to the options available and make an analysis of the direct effect of not being able to continue to make nutrition or health claims, or not being able to make them in the future without product reformulation.

We are therefore seeking three levels of information for this impact assessment:

- ***how products currently making claims perform against options***
- ***how products which you intend to make claims for perform, and***
- ***if and where reformulation is possible.***

Costs of loss of claims and reformulation should be indicated. Other comments on the content of the Commission paper and the detail of the profiles should be made separately to comments on this impact assessment. When you reply, please include evidence to substantiate your comments.

2. Provisions in the proposal

The key provisions in the Commission paper are:

- General exemptions from the profiles

The following products are to be exempt from having to comply with nutrient profiles due to their legal composition, importance in the diet without reformulation or incompatibility with the reference quantity (see below):

- Food supplements as defined in Article 2(a) of Directive 2002/46/EC
- Other low energy foods with minimal nutritional impact (such as chewing gum) that provide less than 25kcal for a typical daily consumption
- Foods for particular nutritional use (PARNUTS) and for which composition is regulated by the following legislation:
 - Cereal based foods and baby foods covered by Commission Directive 2006/125/EEC
 - Infant formulae and follow-on formulae covered by Commission Directive 2006/141/EEC
 - Foods intended for energy-restricted diets covered by Commission Directive 96/8/EC
 - Dietary foods for special medical purposes covered by Commission Directive 1999/21/EC
- Raw fruit and vegetables (fresh, frozen, chilled, dried) and fruit and vegetable juices without added sugar

- A generic profile and adapted¹ profiles within food categories

Reference quantities for the threshold levels

- the profiles will operate on a per 100g basis (EFSA proposed this measure, or a measure of energy – per 100kcal – and testing by the Commission (see limited test basket) indicates little difference between the two. Per 100g is more practical and will allow use of the nutrition panel to calculate and control for compliance).

Table 1 shows the proposed threshold levels in the Commission's working document (including a possible figure for sodium in spreadable fats). "Other food" acts as a 'generic' profile with which all foods that do not fall within the defined food categories for adapted profiles must comply.

¹ The adapted profiles have thresholds that differ from the generic profile for particular food categories, to take account of the particular contribution these foods make to the diet.

Table 1

Food category	Sodium (mg/100g)	Saturated fat (g/100g)	Sugars (g/100g)
	Current proposal	Current proposal	Current proposal
Non alcoholic beverage	-	-	5
Vegetable oil and spreadable fat	-*	30	-
Fruit, vegetable, and their product	400	5	15
Nut, seed or kernel	300	10	10
Meat or meat product	500	5	-
Fish and fish products	500	10	-
Dairy products except cheese	300	2	15
Cheese	600	10	15
Cereal and cereal product except breakfast cereals	400	5	15
Breakfast cereal	700	5	25
Ready meal, soup and sandwich	400	5	10
Other food	300	2	10

* It is proposed to insert a threshold here, not yet decided but possibly 300mg/100g

IAQ1 Given these projected limits, how many of your products will:

- **Meet the thresholds and not require new labelling**
- **Meet the threshold but require re-labelling**
- **Not meet the threshold and require reformulation and re-labelling**
- **Not meet the threshold and can not be reformulated so must be re-labelled in line with the Regulation i.e. no longer be able to make nutritional and health claims**

It would be useful if you could tell us the number of products affected and what percentage of your overall food products this represents.

- Definition of categories of foods for adapted thresholds

Table 2

Nutrient profile food category	Eligibility Criteria
Non-alcoholic beverages	Water and water based drinks, excluding milk, fruit juices, soups No eligibility criterion needed
Fruits, vegetables, nuts and their products ²	Minimum 50g/75g of fruit, vegetable and/or nuts per 100g of products
Cereal and cereal products except breakfast cereals	Minimum [30g - 50g/75g] of cereal per 100g of products
Breakfast cereals	As above
Meat and meat products	Minimum 50g /75g of meat per 100g of products
Cheese	Minimum 50g/75g of dairy constituent per 100g of products
Dairy products, except cheeses	As above
Fish and fish products	Minimum 50g/75 of fish per 100g of products
Vegetable oils and spreadable fats	As defined in Council Regulation (EC) No 1234/2007, (a) milk fats falling within CN codes 0405 and ex 2106; (b) fats falling within CN code ex 1517; and (c) fats composed of plant and/or animal products falling within CN codes ex 1517 and ex 2106; with a fat content of at least 10 % but less than 90 % by weight, intended for human consumption. The fat content excluding salt must be at least two-thirds of the dry matter.
Ready meal, soup, sandwich	Minimum 200g Two categories minimum among fruit, vegetable or nuts products, cereal and cereal products, meat and meat products, fish and fish products Minimum 30g/50g to count for one category

IAQ2 *How do these criteria affect your products; at the borderline between categories what would be the effect of your product falling in one or the other? Please tell us the number of products affected and what percentage of your overall food products this represents.*

² Nuts have not been separated out here as they have in the table for threshold levels, but the same criteria for the category as this is expected to apply

3. Options

The following options are available prior to the adoption of the proposed nutrient profiles:

1. Do nothing - accept the Commission's proposed nutrient profiles 'as is' without negotiation.
2. Negotiate for the adoption of nutrient profiles which deliver consumer and trade benefits and are proportionate. This would take account of Agency policies on nutritional health and product reformulation.

Each option carries risks and benefits to consumers, industry and Government: these are discussed below.

OPTION 1 – DO NOTHING

Regulation 1924/2006 was adopted in December 2006 and has direct legislative force in the UK. It requires the European Commission to establish nutrient profiles by January 2009. If the UK was not involved in influencing the shape of the profiles then, without co-operating and influencing in the negotiations, the UK would have to implement a proposal that would not take into account the needs of UK consumers and industry.

OPTION 2 – NEGOTIATE FOR THE ADOPTION OF NUTRIENT PROFILES WHICH DELIVER CONSUMER AND TRADE BENEFITS AND ARE PROPORTIONATE

This option will allow UK stakeholders' views to be taken into consideration together with progress on salt reduction in UK products when negotiating nutrient profiles, and will fulfil the two main aims of the Regulation of facilitating intra-Community trade and ensuring that consumers are not misled. The profiles may also encourage industry to reformulate products so that they are within the thresholds and so eligible to make claims, with potential public health benefits to consumers.

In pursuing this option the Agency will focus on three key issues:

- Exemptions - These should be as few as possible and based on sound evidence. The Agency supports the principle that products which have a fixed composition in legislation to fulfil a particular nutritional use may be unfairly discriminated against, as there is no possibility of reformulation; yet benefits that may help consumers make healthier choices could be communicated. These products could benefit from an exemption. Raw fruit and vegetables with nothing added may have high intrinsic sugars content, yet it is a policy objective to encourage consumption of these products and to help this the benefits of choosing fruit and vegetables should be communicated.
- Thresholds - The thresholds represented in Table 1 are partly based on the Commission's interpretation of Member States' food based dietary guidelines (FBGDs). However, these FBGDs are about the whole diet, whereas thresholds are fixed for specific foods. As a consequence, a direct correlation is difficult to make and as such the thresholds will need to be tested against the diet as a whole. The Agency considers some of the salt thresholds to be out of step with its reformulation strategy and will look at better alignment between the two. The Agency is currently consulting on revised salt reduction targets for a range of foods, and details of this consultation can be found on our website at: <http://www.food.gov.uk/consultations/ukwideconsults/2008/saltreductiontargets>

We will also look at how levels of other nutrients fit with the government's nutrition policy.

- Definitions of food categories - The structure of the EU nutrient profiles requires categorisation of foods, yet there will be a number of borderline decisions about the category to which a food should belong. In participating in this decision process the Agency will seek to minimise the number of food categories. We will also seek to test the effect of one categorisation against another to limit cases where a food may fall into a category that would allow it to make claims when these could mislead consumers. For example, the current criteria for defining foods into categories in table 2 might see a pizza categorised as a cereal (bread) or a ready meal. Under one threshold a claim might be possible, under the other, not.

4. Sectors affected by the proposal

This will affect consumers, who will be better protected against misleading claims and will be in a better position to make informed choices about food. Food business operators that voluntarily make nutrition or health claims and enforcement bodies will also be affected by this proposal.

The following does not provide a comprehensive overview of the market that will be affected by the proposal. However, it provides an illustrative snapshot on the growing importance of this market within food retail and for consumers.

According to a recent Mintel report³, the 'healthy' foods market has recently been a key area of growth in retail sales, growing at twice the rate of the market as a whole since 2003. It is also a key area of new product developments, particularly for the UK. A Mintel global new products database sample of 7,409 'healthy' food launches (defined as 'food minus' or 'functional' in the database) in 2007 showed the UK as a market leader in Europe with 36% of the total (from UK, France, Germany, Italy and Spain).⁴ Although food descriptors of 'functional' or 'food minus' may not accurately encompass foods with a health or nutrition claim, it does illustrate that 'healthy' foods are particularly important to the UK.

% of UK retail value sales of selected 'healthy' food by type in 2007		
	'healthy' claim	no claim
confectionary	9.6	90.4
crisps and snacks	4.3	95.7
baked goods	21	79
soft drinks	41.6	58.4
dairy	44.3	55.7
TOTAL	28.7	71.3

The data above only covers five markets but they represent roughly a third of total expenditure on food and non-alcoholic drink.⁵ Healthy eating options, including sales of reduced fat, reduced calorie (RFRC) foods in other markets are worth approximately £8 billion.

This industry overview does not accurately show how many products or potential sales will be affected by the new proposal because: firstly, Mintel's definition of 'healthy' may not necessarily reflect products that make nutrition or health claims as defined by Regulation 1924/2006. Secondly, it is not yet known how many products of those making nutrition or health claims will not comply with the (as yet unset) thresholds in the nutrient profiles.

5. Costs and Benefits of the Options

The costs imposed by the proposal may arise from any necessary changes to labelling and any voluntary reformulation. There will also be some administrative costs and changes in enforcement requirement. It is important to note that this proposal will only apply to products bearing voluntary nutrition and health claims, as where no claim is made on food Regulation 1924/2006 has no effect.

OPTION 1 – DO NOTHING – ADOPT THE COMMISSION'S PROPOSED NUTRIENT PROFILES 'AS IS' WITHOUT NEGOTIATION

Costs

This option would incur similar costs to option 2 but without UK input it would be likely to be a less favourable outcome for the UK. It could potentially lead to trade barriers with other Member States and lost business if UK interests are not protected. As Regulation 1924/2006 has direct legislative force, the UK would be forced to accept a situation which may be less advantageous to the UK consumer and more onerous to industry and enforcement than if we positively engage and negotiate. Not implementing nutrient profiles would constitute a breach of the UK's obligations under the EC treaty, resulting in significant costs to the UK Government in the event of possible infraction proceedings, and would fail to improve consumer protection against misleading claims.

Benefits

Similar benefits to option 2 will accrue: less potentially misleading information to consumers and maintaining the UK's position in the EU common market. However, without negotiation the nutrient profiles will not take into account the specific needs of UK consumers and industry.

³ Mintel oxygen report - Healthy Eating and Drinking - UK - September 2008

⁴ *ibid.*

⁵ Mintel oxygen report - Healthy Eating and Drinking - UK - September 2008

OPTION 2 – NEGOTIATE FOR THE ADOPTION OF NUTRIENT PROFILES WHICH DELIVER CONSUMER AND TRADE BENEFITS AND ARE PROPORTIONATE

Costs

Labelling/advertising/presentation costs

Re-labelling will be necessary where products bearing claims do not comply with the nutrient profiles.

In the RIA for Regulation 1924/2006, industry figures estimated re-labelling costs for every iteration, including nutrient profiles, at £1,000 per product. On a broad range of up to 6,000 healthy option lines, this means a cost of as much as £6 million if all products failed the profiles.⁶ Regulation 1924/2006 puts in place transitional measures that allow up to two years for any necessary labelling changes to be made. Given the likely event that the transition period will allow for changes within the standard two-year commercial cycle, these costs could be integrated into normal re-labelling during this cycle and therefore reduce the £6 million estimated cost.

In addition to these 6,000 healthy option lines, there will be other miscellaneous products carrying health claims subject to profiles. We do not have a figure for the number of product lines this represents, but the retailer sector estimates are likely to be the majority of products carrying claims on the market. Other food labelling policies may also require re-labelling and the Agency will argue in negotiation for co-ordination of these to reduce iterations required. Where possible we would take advantage of flexibilities in the UK.

IAQ3 *The Agency would welcome information and evidence on how much of these estimated re-labelling costs could be attributed to the introduction of nutrient profiles, and could not be absorbed within standard re-labelling cycles. Do you agree with the information provided above?*

The Regulation covers advertising and presentation as well as labelling and while it is difficult to estimate the effect of nutrient profiles here with the same level of quantification as labelling, change to leaflets, posters and other media is likely. Generic claims would be unaffected, but where claims are made on specific foods with a definable nutrient profile some costs might be involved.

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 if all were affected by nutrient profiles.

Reformulation costs

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 restrict marketing and make some products commercially non-viable. Manufacturers can choose to re-formulate products to meet the criteria that allow nutrition or health claims to be made, and in some cases this would benefit consumers by widening the availability of healthier choices. There is the possibility of synergy with manufacturers’ activities to meet commitments under the Agency’s salt reduction campaign – and any future activity in support of saturated fat and energy reduction strategies. Where this is not possible, claims will be restricted.

It is not possible to estimate how many products might be affected as this will vary depending on the levels at which the eventual thresholds are set, and the exact costs of re-formulation will vary. At the levels in table 1 a certain number of products may be affected. However, the Agency sees a mismatch here with policies on product reformulation and we would expect salt levels to become more restrictive, particularly in the breakfast cereals, fruit, vegetables and nuts, and nut seed or kernel categories. If threshold levels are reduced then more products will be affected. Re-labelling costs would inevitably follow.

One example of estimated costs for fat, sugar and salt reduction submitted by a confectionary manufacturer was a range of £35,000 - £50,000⁷. An average cost for developing a new product for the range of retail food products currently on offer has been put at approximately £25,000⁸. However, manufacturers currently choose to

⁶ Information from the British Retail Consortium in response to consultation on proposal to regulate nutrition and health claims made on foods

⁷ Figure from the PARTIAL REGULATORY IMPACT ASSESSMENT for the Choosing Health White Paper

⁸ Information from the British Retail Consortium in response to consultation on proposal to regulate nutrition and health claims made on foods

reformulate products for a number of reasons, such as part of normal product development programmes and to fulfil commitments to the Agency's work on reducing salt and saturated fat in food. The routine reformulation and redesign manufacturers undertake, which is likely to happen particularly frequently in the growing healthy foods market⁹, could offset some of the costs detailed above.

Reformulation costs will only apply to products currently being developed or on the market. Manufacturers intending to make nutrition and health claims on new products developed in future are making a business choice so any costs involved with ensuring that new products comply with the nutrient profiles, and so are able to make claims, will be undertaken by manufacturers voluntarily. Therefore, compliance with the nutrient profiles should not result in an additional cost. The profiles will have no impact on foods that do not bear claims.

IAQ4 Do you agree with the estimates above?

The Agency would welcome information on any costs associated with reformulating products to comply with the nutrient profiles, that is over and above the cost of any voluntary reformulation undertaken for other reasons.

Assessing compliance - Testing/analysis costs

Food business operators may bear some increased administrative costs to determine whether products are eligible to make claims. To do this they will need to know the amount of sugars, saturated fat and salt in their products to establish whether their product meets the nutrient profile to make a claim. There may be some additional costs associated with testing/analysis of foods to determine the content of these nutrients. However, in many cases this will be offset by the requirement already laid down by Regulation 1924/2006 to provide full nutrition labelling whenever a health claim is made and to provide information about energy, protein, carbohydrate or fat when a nutrition claim is made. With the per 100g reference quantity, it will be possible to assess a product's compatibility with the nutrient profiles from the nutrition labelling panel. For nutrition claims about energy, protein, carbohydrate or fat, only these nutrients need to be declared in nutrition labelling so some additional testing may be required. This fits well with the Agency's recommendation to provide full nutrition labelling whether or not a claim is made, to ensure that consumers can make fully informed food choices.

IAQ5 The Agency would welcome information and evidence on the number of products that will require additional testing/analysis to establish whether they comply with the nutrient profiles and any costs associated with this.

It is the Agency's view that any future testing costs for new products will be absorbed as part of the process for putting a claim on a product. The Regulation already requires nutrition labelling to be given on any product for which a claim is made, as detailed above, and requires claims to be authorised. Fit with the nutrient profiles can be checked at the same time as ensuring that a product complies with the conditions of use for an authorised claim. The costs associated with compliance with the other aspects of Regulation 1924/2006 were detailed in the previous RIA.

It is not thought that enforcement bodies will have to do any additional testing/analysis to ensure compliance with this legislation other than any they may already carry out to check nutrition labelling is accurate. Food business operators will be responsible for demonstrating that their products comply with the nutrient profiles.

IAQ6 The Agency would welcome views on any additional analysis/testing that would be required to check fit with nutrient profiles and the associated cost of this

Assessing compliance - reading/familiarisation costs

There will be a one-off cost to industry and enforcement for reading and familiarising themselves with the nutrient profile model.

IAQ7 How much time did it take you to familiarise yourself with the nutrient profiling system? It would be useful if food authorities and trade associations could indicate how many businesses are likely to be affected by this proposal?

Administrative costs

⁹ Mintel oxygen report - Healthy Eating and Drinking - UK - September 2008

There will be an ongoing administrative cost to enforcement authorities for monitoring and enforcing this aspect of the Regulation. Local authority bodies already have responsibility for enforcing the rest of Regulation 1924/2006 and it is not thought that enforcing this aspect of the Regulation will create significant additional burden.

It is important that the final nutrient profiles are easily understood and it is thought that the calculations necessary to determine whether a claim can be made will be possible from checking the nutrition labelling where full nutrition labelling has been provided. As mentioned above, for cases where full nutrition labelling is not provided the food business operator should be able to demonstrate that their product complies with the nutrient profiles. The administrative costs will be dependent on the complexity of the final nutrient profile model.

IAQ8 The Agency would welcome information and evidence on administrative costs which are over and above what a business would do normally

Benefits

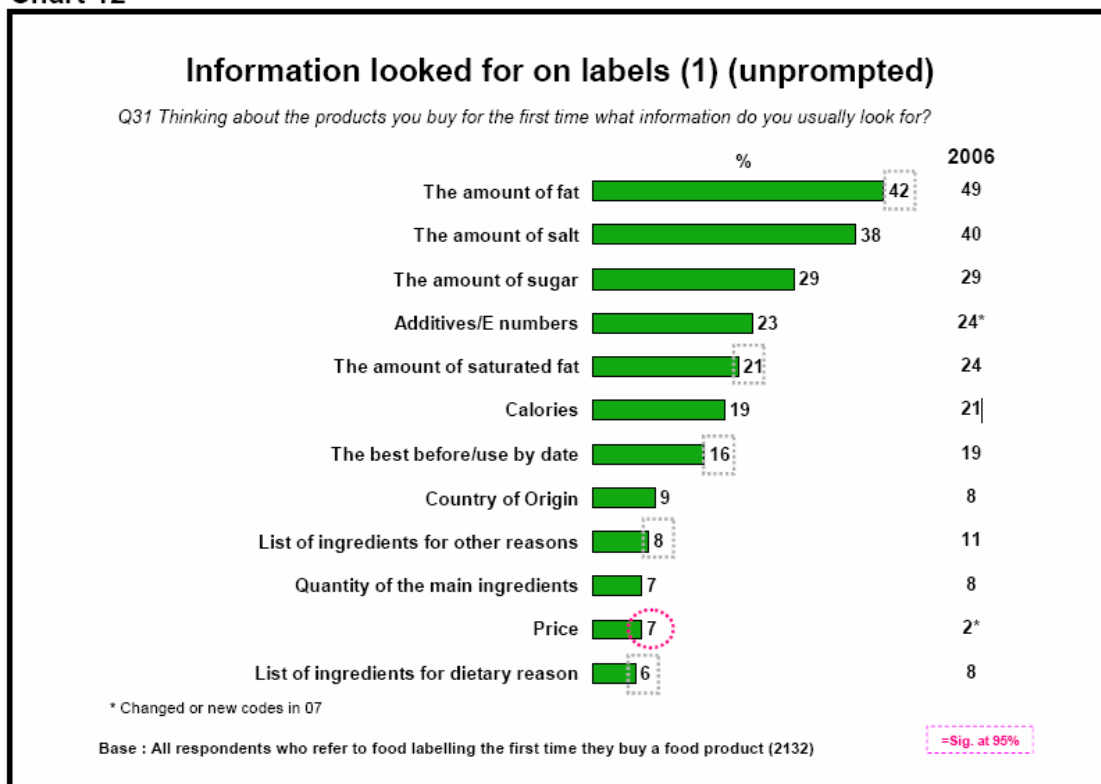
Consumer protection/public health benefits

As mentioned in the RIA for Regulation 1924/2006, Agency surveys indicate that consumers use claims when forming purchasing decisions so it is important that claims are not confusing or misleading. Misleading information, such as portraying that a product is a healthy option by promoting it with claims when it contains high levels of nutrients that people should be eating less of, could undermine healthy eating messages and act as a barrier to improved public health outcomes. Full details of the benefits associated with improving public health can be found in the previous RIA.

Nutritional information is important to consumers

The Agency's annual consumer research has shown that when consumers look at products for the first time, the most important type of information they seek on labels is nutritional¹⁰, with 66% of unprompted responses in 2007 stating that they sought nutritional information when choosing a product for the first time. The chart below shows the specific information and nutrients consumers look for:

Chart 12



The nutrients chosen for the nutrient profiles in this proposal feature as some of the top information concerns for consumers, as illustrated above.

Nutrition and health claims influence purchasing decisions

¹⁰ Consumer Attitudes Survey 2007: UK report, available at: <http://www.food.gov.uk/science/socsci/surveys/foodsafety-nutrition-diet/eighthcas2007>

The Agency also commissioned a review and analysis of current literature on consumer understanding of nutrition and health claims made on food.¹¹ A common finding in many countries was that where there is a health claim on a product consumers will perceive it as healthy and are more likely to purchase it. The literature also indicates that nutrition claims are liked by consumers and influence purchasing decisions. One of the key findings across all literature was that despite a large deviation of how consumers understood and interpreted label claims, they were influenced by them.

Consumer understanding of claims

A key finding of the research was that there can be no generalisations of how consumers understand claims, as each consumer will be looking for different things and have a different level of nutritional and scientific knowledge. However, consumers are generally sceptical about claims and often cannot distinguish between nutrition or health claims. Despite this scepticism, consumers are still influenced by these claims and there have been specific findings about how consumers may commonly misinterpret labelling. Wansink and Chandon (2006) found that low fat claims can lead consumers, particularly those who are overweight, to believe they are 'low' in other nutrients such as salt, sugar and calories, which doesn't necessarily follow.¹² The Agency's literature review also found, from a range of studies, that consumers appear very likely to misinterpret comparative claims and that health claims cause consumers the most confusion in terms of interpretation and understanding.

The above consumer research indicates that consumers are concerned about the nutrients covered by the proposed nutrient profiles and, though no general theory of how consumers understand labelling can be made, consumers are influenced by claims and commonly misinterpret them. The benefit of negotiating for thresholds will be to ensure that consumers are not exposed to misleading information, which could lead them to make purchasing decisions against their healthy eating intentions. This adjustment to increase consumer protection from being misled cannot be sensibly quantified but this should not detract from its importance.

Facilitation of trade within the European Community

The UK benefits considerably from its membership of the EU internal market, which facilitates trade with its EU partners. Harmonised legislation on nutrition and health claims will enable effective functioning of the internal EU market. Specifically, the setting of nutrient profiles at the European level will ensure improved free movement of foods within the internal market and fair competition within the EU.

6. Consultation

Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other Government Departments are being consulted on the European Commission's nutrient profile proposal and this IA is part of the consultation. The Agency has also consulted these stakeholders via informal mechanisms such as interested party letters and during negotiation of Regulation 1924/2006 when a full RIA was also conducted.

The Agency would welcome comments from all stakeholders on any aspect of the proposal, the proposed options or the draft impact assessment.

¹¹ Review and analyses of current literature on consumer understanding of nutrition and health claims made on food (2007), available at: <http://www.food.gov.uk/news/newsarchive/2007/jul/healthconfuse>

¹² Wansink, B. and Chandon, P. (2006) Can Low Fat Nutrition Labels Lead to Obesity?, *Journal of Marketing Research*, Vol. 43(4), pp. 605-617

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

Claims are used by manufacturers to compete with other foods that do not or cannot bear claims. If products fail the nutrient profiles because their sugars, salt and/or saturated fat content exceeds the threshold value then they will not be able to bear claims. If products cannot be reformulated to meet the profiles then they may be ineligible to bear a claim, which could cause a competitive disadvantage. However, this proposal applies to all food business operators equally and the thresholds set will apply across all foods, or all foods within a particular category.

IAQ9 *The Agency would like information and evidence from stakeholders who feel they would be at a competitive disadvantage if their product fails the nutrient profile*

Small Firms Impact Test

During our informal consultation no issues specific to small businesses have been raised. It is not thought that the introduction of nutrient profiles will disproportionately impact on small business, as it only applies to businesses that make nutrition and/or health claims voluntarily. If small businesses have chosen to make claims they would already have invested time and money in doing so – please refer to the RIA for Regulation 1924/2006. Checking whether products fit the nutrient profiles is just one step in the process for ensuring that the claim complies with the requirements of Regulation 1924/2006 and can be built into this procedure. The impact on small businesses will depend on the complexity of the final nutrient profile model, but it is likely that in many cases compliance with the profiles will be able to be calculated from the nutrition labelling that is required to be present when claims are made. However, the Agency recognises that the burden of any regulation is proportionately larger for small businesses. It is also possible that there may be increased reformulation and re-labelling costs for small businesses as product development cycles are generally longer.

IAQ10 *The Agency would welcome views from small businesses and their representatives on the impact this proposal will have on them. We would also be interested to know how many small businesses make nutrition or health claims on their products, and how many of their products bear claims.*

Sustainable Development

A preliminary sustainability assessment has been carried out on the proposed options in the light of the information we have to date concerning the costs and benefits listed in section 5 above.

Option 1 does not create any new economic or social benefits.

Economic

It may incur economic disadvantages to the Government which may be subject to infraction proceedings for not implementing enforcement sanctions related to the Regulation.

Social

This option may bring social disbenefit in terms of consumer protection from misleading claims which may impair their ability to make informed dietary decisions. This could lead to further social disbenefit from the effects of increasing obesity and other diet-related diseases such as cardiovascular disease and strokes.

Option 2 may bring economic costs to the industry due to possible re-labelling and/or reformulation.

Economic

In light of the evidence currently available to the Agency these economic costs cannot be quantified.

Environmental

The long transitional time to enable compliance with the profiles and any changes that need to be made to labelling, will allow companies to use up existing packaging. Therefore, it is expected that there will not be any significant amounts of wasted product, packaging or labels. It is unlikely that there will be any considerable implications for greenhouse gas emissions or negative impacts on natural resources. This option also brings social benefits in terms of improving food information to consumers and preventing claims from masking the true nature of foods.

The Agency considers that the social benefits (health and consumer information) of adopting this proposal outweigh the possible economic costs to businesses. Environmental impacts will not be significant and the possible negative affects of the legislation on waste will be minimised by the lengthy transitional period. Option 2 is relatively more sustainable than option 1.

IAQ11 The Agency would welcome comments from stakeholders on the social and environmental costs and benefits of the proposed options so that a sustainability assessment can be completed.

Race equality issues

The proposed legislation does not impose any particular restrictive compliance on any person from a particular race.

Gender equality issues

The proposed legislation does not impose any particular restrictive compliance on any person of a particular gender.

Disability equality issues

The proposed legislation does not impose any particular restrictive compliance on any person with a disability.

Summary of questions asked in this document

The Agency is seeking three levels of information for this impact assessment:

- *how products currently making claims perform against options*
- *how products which you intend to make claims for perform, and*
- *if and where reformulation is possible.*

Costs of loss of claims and reformulation should be indicated. Other comments on the content of the Commission paper and the detail of the profiles should be made separately to comments on this impact assessment. When you reply, please include evidence to substantiate your comments.

IAQ1 Given these projected limits, how many of your products will:

- *Meet the thresholds and not require new labelling*
- *Meet the threshold but require re-labelling*
- *Not meet the threshold and require reformulation and re-labelling*
- *Not meet the threshold and can not be reformulated so must be re-labelled in line with the Regulation i.e. no longer be able to make nutritional and health claims*

It would be useful if you could tell us the number of products affected and what percentage of your overall food products this represents.

IAQ2 How do these criteria affect your products; at the borderline between categories what would be the effect of your product falling in one or the other? Please tell us the number of products affected and what percentage of your overall food products this represents.

IAQ3 The Agency would welcome information and evidence on how much of these estimated re-labelling costs could be attributed to the introduction of nutrient profiles, and could not be absorbed within standard re-labelling cycles. Do you agree with the information provided above?

IAQ4 Do you agree with the estimates above?

The Agency would welcome information on any costs associated with reformulating products to comply with the nutrient profiles, that is over and above the cost of any voluntary reformulation undertaken for other reasons.

IAQ5 The Agency would welcome information and evidence on the number of products that will require additional testing/analysis to establish whether they comply with the nutrient profiles and any costs associated with this.

IAQ6 *The Agency would welcome views on any additional analysis/testing that would be required to check fit with nutrient profiles and the associated cost of this*

IAQ7 *How much time did it take you to familiarise yourself with the nutrient profiling system? It would be useful if food authorities and trade associations could indicate how many businesses are likely to be affected by this proposal?*

IAQ8 *The Agency would welcome information and evidence on administrative costs which are over and above what a business would do normally*

IAQ9 *The Agency would like information and evidence from stakeholders who feel they would be at a competitive disadvantage if their product fails the nutrient profile*

IAQ10 *The Agency would welcome views from small businesses and their representatives on the impact this proposal will have on them. We would also be interested to know how many small businesses make nutrition or health claims on their products, and how many of their products bear claims.*

The Agency considers that the social benefits (health and consumer information) of adopting this proposal outweigh the possible economic costs to businesses. Environmental impacts will not be significant and the possible negative affects of the legislation on waste will be minimised by the lengthy transitional period. Option 2 is relatively more sustainable than option 1.

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