

**EUROPEAN REGULATION (EC) NO 1924/2006 ON NUTRITION
AND HEALTH CLAIMS MADE ON FOODS**

**FOOD STANDARDS AGENCY
GUIDANCE TO COMPLIANCE VERSION 1
APRIL 2008**

Note : To be revised and updated prior to the adoption of a list
of authorised health claims expected to be January 2010.

Foreword

On 30 December 2006 a Regulation of the European Parliament and of the Council of the European Union on nutrition and health claims made on foods was published. A corrigendum, which amends the text published on 30 December¹ to reflect the agreed Regulation, was published on 18 January and is the text that food business operators must comply with. Please note, we do not include the text of this Regulation in this guidance, but provide a link at footnote 1 to the Commission website where the latest version may be found.

This guidance is designed to help you comply with this Regulation if you choose to make a nutrition or health claim on your food product. It also explains the requirements for authorisation of new claims. The guidance may be read from cover to cover, but food business operators might find it a more useful tool by following the steps relevant to them. Where you see a ★ you will need to select the appropriate statement to continue to the relevant section².

While only the courts can give a definitive view of the law, in preparing this guidance we have had to interpret certain provisions. Any interpretation remains the considered view of the Agency, and reflects consultation with stakeholders. Where possible the guidance also reflects discussions between European Member States on common understanding of the legal requirements and intentions of the Regulation. The guidance is not legally binding and should therefore be read together with the relevant EU and national legislation listed in Appendix I. Additional sources of advice and information (including Agency guidelines on the use of charity endorsements) are detailed in Appendix III.

¹ The latest version of this Regulation may be found on the Commission website by following this link:

[http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1924R\(01\):EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1924R(01):EN:NOT)

² As resources allow, the Agency will try to make this an interactive document with links to the appropriate section of the guidance and other information sources.

Contents

Foreword	2
Contents	3
Section 1 – Introduction and Summary	5
1.1 – Introduction	5
1.2 – Background	5
1.3 – What is a nutrition claim and what is a health claim?	5
1.4 – Key requirements of the Regulation	6
1.5 – Community Register of health claims	7
1.6 – Key dates (Article 28)	8
Table 1 – Key dates and requirements	8
1.7 – Flow diagram, how to make a claim	10
Section 2 – Scope	11
2.1 – Introduction	11
2.2 – Nature of the claim – Nutrition claim	11
2.3 – Nature of the claim – Health claim	12
2.4 – Where the claim is made – Commercial communication (Article 1) ...	14
2.5 – Where the claim is made – Final consumer (Article 1)	15
2.6 – Where the claim is made – Trade marks and brand names	15
2.7 – Why the claim is made	16
2.8 – Additional legislation controlling claims	17
2.9 – Flow diagram – Do I need to comply with the Regulation?	18
Section 3 – How To Make A Claim	18
3.1 – Introduction	19
3.2 – Prohibited claims (Article 4 and 12)	19
3.3 – General requirements that all claims must fulfil (Article 3, 5 and 6) ...	20
3.4 – Specific information about making nutrition and health claims	21
Section 4 – How To Make A Nutrition Claim	22
4.1 – Introduction (Article 8)	22
4.2 – Claims on the list in the Annex (Article 7 and 8)	22
4.3 – Claims not on the list (Article 28)	23
4.4 – Reduced and increased claims (Article 9)	23
4.5 – Future controls	24
4.6 – Checklist for making nutrition claims	25
Section 5 – Health Claims	26
5.1 – Using a health claim (Article 7 and 10)	26
5.2 – How to get a claim on the Community Register of authorised health claims	27
5.3 – Health claims other than those referring to the reduction of disease risk and to children’s development and health (Article 13)	27
5.4 – Reduction of disease risk claims and claims referring to children’s development and health (Articles 14, 15, 16 and 17)	28
5.5 – Health claims based on new or emerging science or proprietary data (Article 18, 15 and 16)	30
5.6 – EU guidance on the application process and tools for small businesses	31
Section 6 – Future Control of Nutrition and Health Claims	32
6.1 – Introduction	32

6.2 – Nutrient profiles (Article 4).....	32
6.3 – Labelling requirements for health claims (Article 10)	33
Section 7 – When Do I Need To Comply With The Regulation?.....	34
7.1 – Introduction	34
7.2 – Transitional periods (Article 28 and 29)	34
Table 2 – Summary of transitional periods and key dates	35
Section 8 – Enforcement and Compliance	38
8.1 – Enforcement and compliance.....	38
8.2 – Home Authority Principle.....	38
Section 9 – Questions and Answers	40
9.1 – Nutrition claims (Section 2.2 of the guidance).....	40
9.2 – Nutrition or health claims (Section 2.2 and 2.3 of the guidance)	40
9.3 – Scope (Section 2 of the guidance)	41
9.4 – Commercial communication (Section 2.4 of the guidance)	44
9.5 – Trade marks and brand names (Section 2.6 of the guidance)	45
9.6 – Prohibited claims – Rate or amount of weight loss claims and claims on alcoholic beverages (Section 3.2 of the guidance).....	47
9.7 – Prohibitions – Recommendations of doctors or health professionals (Section 3.2 of the guidance)	48
9.8 – General requirements (Section 3.3 of the guidance).....	51
9.9 – Criteria to make claims (Section 4.2 of the guidance).....	52
9.9 – Claims not in the Annex of permitted nutrition claims (Section 4.3 of the guidance)	56
9.11 – Criteria to make comparative claims (Section 4.4 of the guidance)	59
9.12 – Health claims (Section 2.3 of the guidance).....	60
9.13 – Process of authorisation.....	61
9.14 – Nutrient profiles (Section 6.2 of the guidance)	62
9.15 – Transitional periods (Section 7 of the guidance)	63
Appendix I – Associated Legislation and Guidance	67
Table 3 – Links to the Regulation and other legislation associated with this area of law	67
Table 4 – Links to Agency guidance associated with the above legislation	70
Table 5 – Other guidance referred to in this document	71
Appendix II – Sources Of Information.....	72
Appendix III – Glossary	73
Appendix IV – UK Legislation Controlling Claims	75
IV.1 – Overarching legislation	75
IV.2 – The Food Labelling Regulations 1996 (as amended)	75
Table 6 – Regulation 1924/2006 vs Food Labelling Regulations	76
Appendix V – Flow Chart Showing Process Of Authorisation Of Health Claims Based On New Or Emerging Science.....	80
Appendix VI – Flow Chart Showing Process Of Authorisation For Disease Risk Reduction Claims and Claims Referring To Children’s Development and Health	80
Appendix VIII – Interested Parties List.....	80

Section 1

Introduction and Summary

1.1 – Introduction

When making a voluntary nutrition or health claim you must comply with the requirements of European Regulation (EC) No 1924/2006 on nutrition and health claims made on food. This section provides background information about Regulation 1924/2006 and a brief summary of the key controls it introduces.

This is the first piece of specific legislation to deal with nutrition and health claims and seeks in much more specific terms to protect consumers from misleading or false claims. It harmonises legislation across the European Community making it easier to trade and aids food business operators in complying with the law. The Regulation will also make it easier for manufacturers to identify nutrition and health claims that can justifiably be used on a specific product.

If you make, or plan to make, a nutrition or health claim, as well as using the rest of these guidance notes, you are advised to consult your Home Authority³ to ensure you meet with the requirements of the Regulation. You should start by reading Sections 2 and 3 of the guidance, which outline the scope of the Regulation and give general information about making claims. By answering the questions at the end of Section 3 you can identify the additional sections of this guidance that are relevant to you. In addition you may find it helpful to read Section 9, which includes the answers to specific questions about the Regulation.

1.2 – Background

On 30 December 2006 a Regulation of the European Parliament and of the Council of the European Union on nutrition and health claims made on food was published as Regulation (EC) No 1924/2006. A corrigendum with the legal text of the Regulation was published on 18 January 2007. This amends the text that was originally published and reflects the agreed Regulation. It is this text that food business operators must comply with. A copy of this Regulation can be found at the following website address:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf

1.3 – What is a nutrition claim and what is a health claim?

Article 2 defines a nutrition claim as any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the

³ The Home Authority scheme is described at Section 8.2

presence, absence, increased or reduced levels of energy or of a particular nutrient or other substance, and includes claims such as “source of calcium”, “low fat”, “high fibre” and “reduced salt”.

Article 2 also defines a health claim as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. This would include claims such as “calcium helps build strong bones”. More general claims such as “good for you” may also be health claims, and the Regulation takes these into account.

Further advice about what is and isn't a nutrition or health claim and what does and doesn't have to comply with the Regulation can be found in Section 2.

1.4 – Key requirements of the Regulation

Although the key requirements of the Regulation are outlined below, there may be more specific requirements not mentioned here. You are, therefore, recommended to consult the rest of the guidance to ensure you comply with the Regulation.

- Claims must comply with the general requirements of the Regulation as specified in Article 3, which include not being false, ambiguous or misleading, not encouraging or condoning excess consumption of a food and not implying that a balanced diet cannot provide necessary nutrients.
- If a claim is made Article 7 makes it obligatory to provide nutrition labelling. However, a non-prepacked foodstuff put up for sale to the final consumer or to mass caterers, a foodstuff packed at point of sale at the request of the purchaser or pre-packed with a view to immediate sale, does not have to provide nutrition labelling.
- Article 8 means that only nutrition claims listed in the Annex to the Regulation can be made on food and only if the product meets with the specific conditions of use for that claim. For example, “low fat” can only be made on products containing no more than 3g of fat per 100g for solids.
- Claims must not be made on alcoholic beverages containing more than 1.2% by volume of alcohol, with limited exceptions for reduced energy or reduced alcohol and low alcohol content claims (Article 4).
- Health claims which suggest that health could be affected by not consuming the food cannot be made on food (Article 12).
- Health claims which make reference to the rate or amount of weight loss cannot be made on food (Article 12).
- Health claims which make reference to recommendations of individual doctors or health professionals cannot be made on food (Article 12).

- As specified by Article 10, health claims must be authorised and included in the list of authorised health claims in the Community Register⁴, to be used on food. Products will also have to meet the specific conditions of use stated. The list of authorised health claims in the Community Register has yet to be put in place; a summary of how claims are to be listed is given below, as are details of the dates when products will need to comply with these requirements.
- Article 4 of the Regulation puts in place provisions that may restrict the use of claims on certain foods or categories of foods based on their nutritional composition (nutrient profile). The profiles are currently being developed and will be adopted by 19 January 2009. Food business operators will then have two years to comply with these controls.

1.5 – Community Register of health claims

The list of authorised health claims in the Community Register is not yet in existence and the Regulation puts in place three ways to get claims authorised and added:

1. Member States must, before 31st January 2008, have submitted a list of claims based on generally accepted scientific evidence to the European Commission who, on the advice of the European Food Safety Authority (EFSA), will decide if they can be included in the list of authorised health claims in the Community Register. These claims must be accompanied by references to the relevant scientific justification and conditions of use applying to them (Article 13). The Agency submitted the UK list of candidate health claims on 30 January 2008.
2. Claims based on new or emerging science and/or proprietary data will need to be accompanied by a dossier of information in support of the claim. EFSA will assess this evidence before advising the Commission on a decision. For claims submitted in this way there is a maximum time limit of eight months for a decision by the Commission (Article 18).
3. Health claims which refer to a reduction in the risk of a disease or to children's development and health will also need to be submitted with a dossier of information in support of the claim for assessment by EFSA (Article 14).

Further information about the authorisation of health claims can be found in **Section 5**. It is however important that you also read **Section 2** and **Section 3**.

⁴ The Community Register will be built up gradually as claims are authorised and guidance published, and can be found at:

http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

1.6 – Key dates (Article 28)

Although the Regulation applied from 1 July 2007, Article 28 puts in place transitional measures that mean industry will have anywhere up to 15 years to comply with different specific aspects of the Regulation. For full details of the transitional periods please see Section 7. A table of the key dates for compliance is given below. In some instances the Regulation does not provide exact end dates for transition periods but instead allows for periods following certain decisions. For example there is a two year transitional period for products to comply with the controls relating to nutrient profiles, following their adoption. As nutrient profiles have to be adopted by 19 January 2009, the very latest date for this transitional period would therefore be 19 January 2011. In such cases the latest possible date for the end of the transitional period is stated in the table below and is indicated by #.

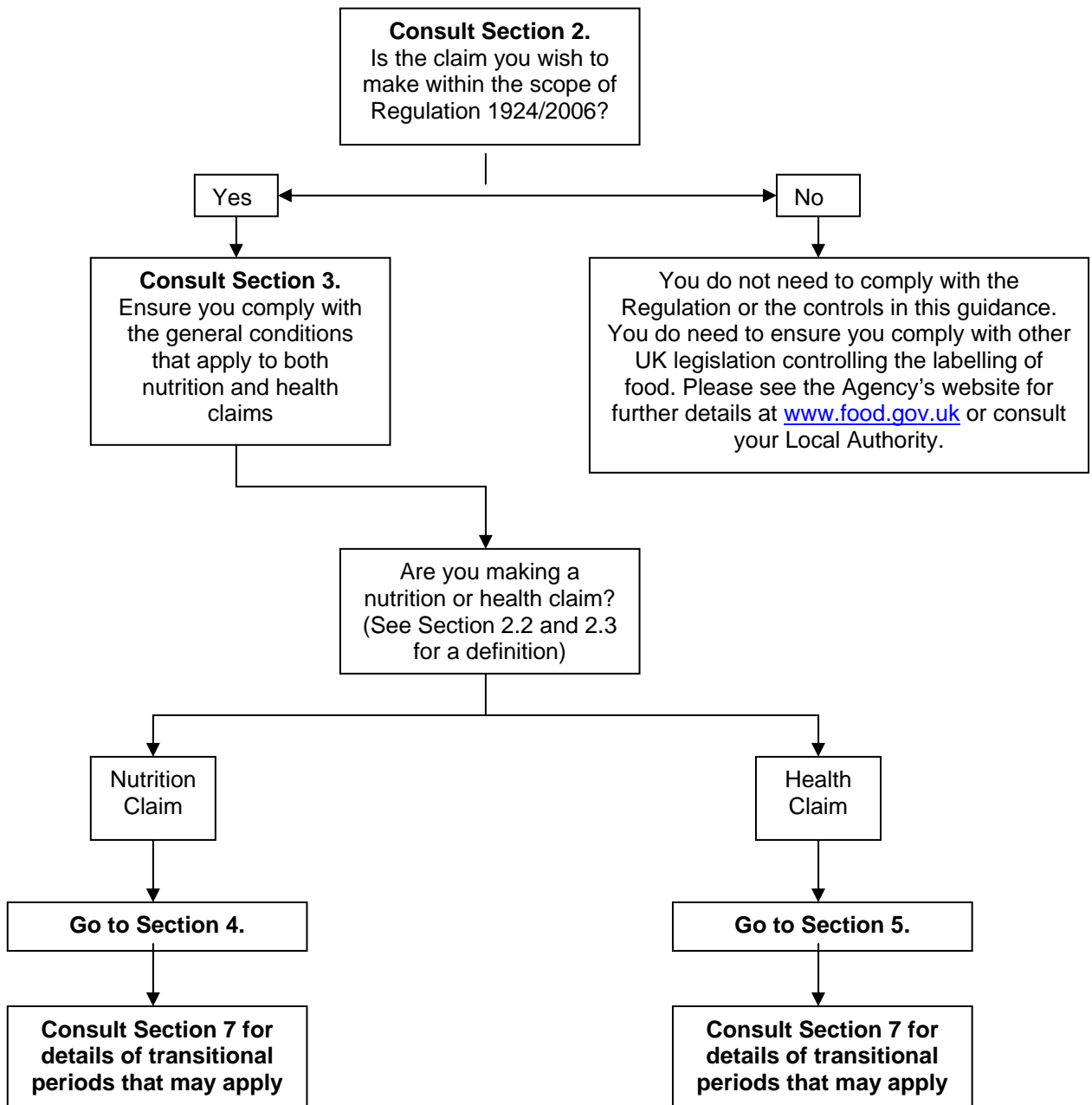
Table 1 – Key dates and requirements

Date	Requirements
<p>1st July 2007</p> <p>However, products placed on the market or labelled prior to 1st July 2007, which do not meet these requirements can continue to be marketed until their expiry date, but not later than 31st July 2009.</p>	<ul style="list-style-type: none"> • Nutrition claims included in the Annex can only be made on products that comply with the specified conditions of use. • Nutrition labelling must be provided (with limited exceptions) if a nutrition or health claim is made. • Claims must not be made on alcoholic beverages (with limited exceptions for reduced energy and alcohol content claims). • Health claims which suggest that health could be affected by not consuming the food cannot be made on food. • Health claims which make reference to the rate or amount of weight loss cannot be made on food. • Health claims which make reference to recommendations of individual doctors or health professionals cannot be made on food.
<p>19th January 2008</p>	<ul style="list-style-type: none"> • Health claims referring to psychological and behavioural functions, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to a reduction of the available energy from the diet cannot be made on food unless the claim was in use before 19th January 2007 and an application for authorisation has been submitted. • Claims referring to children’s development and health cannot be made on food unless the claim was in use before 19th January 2007 and an application for authorisation has been submitted.

19 January 2010	<ul style="list-style-type: none"> • Only nutrition claims included in the Annex can be used on food.
Date of adoption in the Community Register of the list of health claims: the latest this can be is 31st January 2010 [#]	<ul style="list-style-type: none"> • Only health claims included in the Community Register or awaiting authorisation can be used on food. • Health claims referring to general, non-specific benefits of the nutrient to overall good health, such as ‘good for you” must be accompanied by an authorised health claim. • Health claims must be accompanied by additional labelling requirements, such as a statement indicating the importance of a varied and balanced diet and a healthy lifestyle.
At the latest 19 January 2011 [#]	<ul style="list-style-type: none"> • Products must comply with the nutrient profile to make nutrition and health claims. The nutrient profile will be adopted by 19 January 2009.
19 January 2022	<ul style="list-style-type: none"> • Trade marks and brand names that could be construed as a claim must be accompanied by an authorised health or nutrition claim.

1.7 – Flow diagram, how to make a claim

The following flow diagram will tell you what to do if you want to make a nutrition or health claim.



Additional information of interest

Section 6 gives full details of the future control of nutrition and health claims.

Section 8 gives details about enforcement of the Regulation in the UK.

Section 9 gives answers to frequently asked questions.

Section 2 Scope

2.1 – Introduction

Whether a claim has to comply with the Regulation (is within scope) or not will depend on the nature of the claim, where the claim is made and why the claim is made. This section offers guidance on the scope of Regulation 1924/2006 and when claims will need to comply with its requirements.

For certain food types or products, there is specific legislation which may control the use of labelling, and which is not therefore a voluntary nutrition or health claim. This section includes guidance on when and how claims in these cases are controlled by the Regulation.

Section 2.9 includes a flow diagram to help you work out whether or not you need to comply with the requirements of the Regulation. This flow chart should be used in conjunction with the rest of the information in this section.

2.2 – Nature of the claim – Nutrition claim

Article 2 of the Regulation defines a nutrition claim as any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the presence, absence, increased or reduced levels of energy or of a particular nutrient or other substance. Nutrition claims provide factual information about the nutritional composition of the food. Some examples of nutrition claims are “reduced energy”, “contains calcium”, “low fat”, “high fibre” and “contains lycopene”.

As specified in the Annex, rather than control the exact wording of nutrition claims, the Regulation will control anything that has the same meaning to the consumer as one of the claims listed in the Annex. For example, it is the Agency’s view that “contains no fat” would be subject to the conditions for “fat free”. As well as controlling different wordings the Regulation also controls the use of pictorial or symbolic representations that have the same meaning to the consumer (Article 2) e.g:



It is a requirement of the Regulation (Article 5) that consumer understanding is taken into account when deciding whether a claim is controlled by the Regulation. Where a claim states, suggests or implies a nutritional benefit, and consumers are likely to view it as such, it will need to comply with the controls of the Regulation.

The Regulation only controls nutrition claims that refer to beneficial nutritional properties (Article 2) and does not control claims that refer to non-beneficial nutritional properties such as “high in fat” or “high in salt”. In some cases the context of the claim will need to be considered to decide if the nutritional property would be beneficial to the consumer. For example, in the Agency’s view “high in calories” on a ready meal is unlikely to be a beneficial nutritional property; however, the claim “high energy” on a drink aimed at athletes could be beneficial (see also Section 2.8).

In some cases the claim will be neither beneficial nor non-beneficial and will refer to statement of fact, such as “contains 10g of fat”. Such statements must not be misleading, and are controlled by the Trade Descriptions Act 1968 (soon to be replaced by the Consumer Protection from Unfair Trading Regulations), the Food Safety Act 1990⁵ and European Regulation 178/2002 which make it an offence to mislead consumers and give out false information. If, however, the information is presented in a way that implies it is beneficial to consumers, such as “contains **only** 10g of fat” or “contains **less than** 10g of fat”, the Agency’s opinion is that it would need to comply with Regulation 1924/2006 on nutrition and health claims made on foods. The presentation of nutritional information is controlled by Directive 90/496/ECC on nutrition labelling for foodstuffs and has been transposed into UK law by the Food Labelling Regulations, 1996. This Directive, which is currently under review, sets out the content and format of nutrition declarations whether or not they are given voluntarily.

Statements which do no more than highlight the presence or absence of an ingredient (as defined by the Food Labelling Regulations 1996), that has not been added, enhanced or removed for the purpose of highlighting a health or nutrition benefit, developing a health or nutrition function in the food, or improving the nutritional profile of the final food may be regarded as being outside the scope of the Regulation, unless presented in a way that suggests or implies to consumers that the product has beneficial nutritional properties as defined in the Regulation. Examples here might be “contains no additives”. Any claim included in the Annex has already been considered and deemed to be a nutrition claim. Use of a claim included in the Annex, such as “no added sugar”, must comply with the requirements of the Regulation.

The answers to frequently asked questions relating to this section can be found in Section 9.1 and 9.2.

2.3 – Nature of the claim – Health claim

Article 2 of the Regulation defines a health claim as any *claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*. Health claims are different to nutrition claims as they refer to, or imply, a function in the body. For example “contains calcium” only refers to the composition of the food and is a nutrition claim. In

⁵ When the Food Safety Act 1990 is referred to throughout this guidance, this should also be taken to include the Food Safety (Northern Ireland) Order 1991 in Northern Ireland

contrast “calcium helps build strong bones” refers to the function of calcium in the body and would be considered a health claim. Other examples of health claims include “omega-3 is good for your heart” and “helps you lose weight”.

Articles 10-14 of the Regulation divide health claims into different types, which are then controlled in different ways. If you intend to make one of the following types of claims you will need to read the rest of this guidance, in particular Sections 3 and 5, to ensure you comply with the requirements of the Regulation.

- Claims referring to *the role of a nutrient or other substance in growth, development and functions of the body*. For example “calcium helps maintain strong bones”.
- Claims referring to *psychological and behavioural functions*. For example “helps with concentration”.
- Claims referring to *slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet*. For example “keeps you feeling fuller for longer”.
- Claims about *general, non-specific benefits of the nutrient or food for overall good health or health-related well-being*. For example “good for you” or “healthy”.
- Claims which refer to children’s development and health. This includes health claims solely referring to the development and health of children (aged up to 18 years), and where the scientific substantiation only relates to children. It also includes health claims used on products intended exclusively to children, including follow on formulae and cereal-based baby foods, as defined by Directive 2006/141/EC and Directive 2006/125/EC.
- Claim *that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease*. This would cover claims that refer to the reduction of a risk factor of a disease, with or without mentioning the disease name.
- Prohibited claims (see Section 3.2).

The Food Labelling Regulations 1996 (as amended) state that medicinal claims, which claim that a food has the property of preventing, treating or curing a human disease, are **not permitted** to be used on or about food and this will continue to be the case. As a result it will NOT be possible to make statements such as “eating long chain omega-3 may prevent or improve symptoms of heart disease”. Products that make claims such as this may be subject to medicines legislation. For further information on medicine controls please see the Medicines and Healthcare products Regulatory Agency’s website at www.mhra.gov.uk

Statements referring to government health messages are not covered by the Regulation unless they make an explicit nutrition or health claim. For example, making a statement such as “in line with Food Standards Agency salt targets” or “the Food Standards Agency recommends eating two portions of oily fish a

week” are not, in the Agency’s view, controlled by the Regulation. Such statements would need to comply with Trade Descriptions Act 1968 (soon to be replaced by the Consumer Protection from Unfair Trading Regulations), the Food Safety Act 1990 and European Regulation 178/2002 which make it an offence to mislead consumers and give out false information. If, however, a nutrition or health claim is also made, such as “the Food Standards Agency recommends eating two portions of oily fish a week, **because it’s good for your heart**”, the additional health claim would need to comply with the requirements of the Regulation.

The answers to frequently asked questions relating to this section can be found in Section 9.2.

2.4 – Where the claim is made – Commercial communication (Article 1)

Article 1 means that the Regulation only applies to claims made in a commercial context. To decide whether or not you need to comply with the requirements of the Regulation you should consider why the claim is being made and in what context. If a health claim is made in a commercial context it will have to comply with the requirements of the Regulation. These are outlined in this guidance document and include the requirement for health claims to be authorised and listed in the Community Register. However, if the same claim is made in a non-commercial context it is outside of the scope of the Regulation, does not have to comply with the conditions laid down therein and is not a claim as defined in the Regulation, rather an independent statement.

In some cases it is easy to identify what is and what is not a commercial communication. Recital 4 gives some examples of non-commercial communications – dietary guidelines or advice issued by public health authorities and bodies, and information in the press and in scientific publications. In the Agency’s view, any form of product labelling or packaging to be delivered as such to the final consumer (see below) would be commercial. As would product specific advertising in any form, including in print, broadcast, internet or direct mail, promotional features in print media, in store promotion and catalogues or product directories, whether printed or on line (this is not an exhaustive list). In other cases it may not be so easy to define what is, and what is not, a commercial communication. As specific circumstances will vary, it is likely that decisions about whether a claim is being made in a commercial context would need to be made on a case-by-case basis. Although you should always consult your Local Authority for their view, below is some general guidance on what is a commercial communication.

To help you decide if a claim is being made in a commercial context you can apply the following tests. There will be many cases where no one test is determinative, but the combination of results may give an indication as to whether or not a claim is being made in a commercial context. Although these tests can be used to help you decide if a claim is being made in a commercial

context, it will ultimately be the courts who decide if this is the case and if a claim needs to comply with the requirements of the Regulation.

- What is the primary object of the claim and its context? If it is in the form of information to get people to change behaviour, such as decrease or increase consumption of certain substances for their own benefit, and is not directly used to advertise or promote a product, then this may be characterised as non-commercial. If the primary object is to induce the final consumer to eat a specific product, to the benefit of the manufacturer or retailer (either directly financial or indirectly, e.g. reputation), it is commercial.
- If a third party makes the claim, have they been paid to make the claim (commercial) or are they doing it to provide “information” (not commercial)?
- If the third party has not been paid, is the claim within the information they give likely to lead to gain in kind, or some intangible future benefit (indirectly commercial, in the sense that the inducement may call into question the independence of the information)?

Consideration should also be given to the context of the claim and how consumers view the information presented to them, in particular any information presented in the same field of vision. For example, on its own a magazine article about the benefits of oily fish, such as salmon, may not be commercial. However if an advertisement for salmon is made in the same field of view and consumers could be expected to link the article with the advertisement, any claims made about salmon in the article are probably commercial.

The answers to frequently asked questions relating to this section can be found in Section 9.4.

2.5 – Where the claim is made – Final consumer (Article 1)

The Regulation only applies to claims made in communications aimed at the final consumer (Article 1) and it is the Agency's opinion that it will not control claims made in communications within trade, to doctors or other health professionals, or to their organisations, whether the claim is in the labelling, presentation or advertising of the food. However, if the information were, at any time, conveyed to the final consumer within a commercial context, any claims made would need to comply with the requirements of the Regulation.

The Regulation (Article 1, paragraph 2) will also apply to claims made about foods intended for supply to restaurants, hospitals, schools, canteens and other mass caterers.

2.6 – Where the claim is made – Trade marks and brand names

If a trade mark or the brand name of a food is a nutrition or health claim, it will come within the scope of the Regulation. However, Article 1 of the Regulation exempts such brand names or trade marks from having to be authorised or be present in the Annex of nutrition claims or the Community Register of health claims. However, such brand names or trade marks must be accompanied by a prominent, related, authorised and listed claim.

The answers to frequently asked questions relating to this section, can be found in Section 9.5.

2.7 – Why the claim is made

Article 2 clarifies that the Regulation controls only voluntary nutrition and health claims made on foods and does not apply to statements or descriptions that are required to be present by other EU or UK food legislation. For example the Spreadable Fats (Marketing Standards) Regulations 1999 requires that products with a fat content of 60-62% must be labelled "three-quarter-fat" or may be described as "reduced fat" and in these cases use of the term "reduced fat" would not need to comply with the requirements of the nutrition and health claims Regulation.

The Food Labelling Regulations 1996 (as amended) require foods to be marked or labelled with the name of the food and where there is no legal or customary name, "the name used for the food shall be sufficiently precise to inform a purchaser of the true nature of the food and to enable the food to be distinguished from products with which it could be confused and, if necessary, shall include a description of its use". It may be that the only way of complying with this requirement is to include a statement that is tantamount to a claim. For example if zinc is added to an orange juice drink consumers would need to be made aware of this and reference would need to be made in the name of the product, such as "orange juice drink with added zinc". To the extent that wording is necessary to comply with mandatory labelling requirements, it is the Agency's view that this would not be a claim subject to the nutrition and health claims Regulation. However the name of the product is only required to appear once and so in our example any additional reference to zinc would go beyond this mandatory requirement and have to fully comply with the controls in the nutrition and health claims Regulation.

Please note, that when labelling with the name of the product, it is necessary to comply with Trade Descriptions Act 1968 (soon to be replaced by the Consumer Protection from Unfair Trading Regulations), the Food Safety Act 1990 and European Regulation 178/2002, which make it an offence to sell a food with a label that falsely describes a food or is likely to mislead consumers as to its nature or substance or quality. It is the Agency's view that to ensure the name does not mislead consumers, it should be consistent with compositional requirements of Regulation 1924/2006. So to try and ensure that reference to a vitamin or mineral in the name of the product is not likely to mislead consumers, the Agency recommends it should be present in a significant amount as required by the Annex of Regulation 1924/2006.

2.8 – Additional legislation controlling claims

Foods for particular nutritional uses (PARNUTS), natural mineral water, spring water and bottled water intended for human consumption are controlled by specific legislation. As specified by Article 1(5), both this legislation and the new Regulation on nutrition and health claims will apply to these products. Where the specific legislation controls claims it will take precedence. In all other cases the Regulation on nutrition and health claims will apply. Further guidance on application of the claims Regulation to PARNUTS is contained in the European Commission's guidance to interpretation⁶.

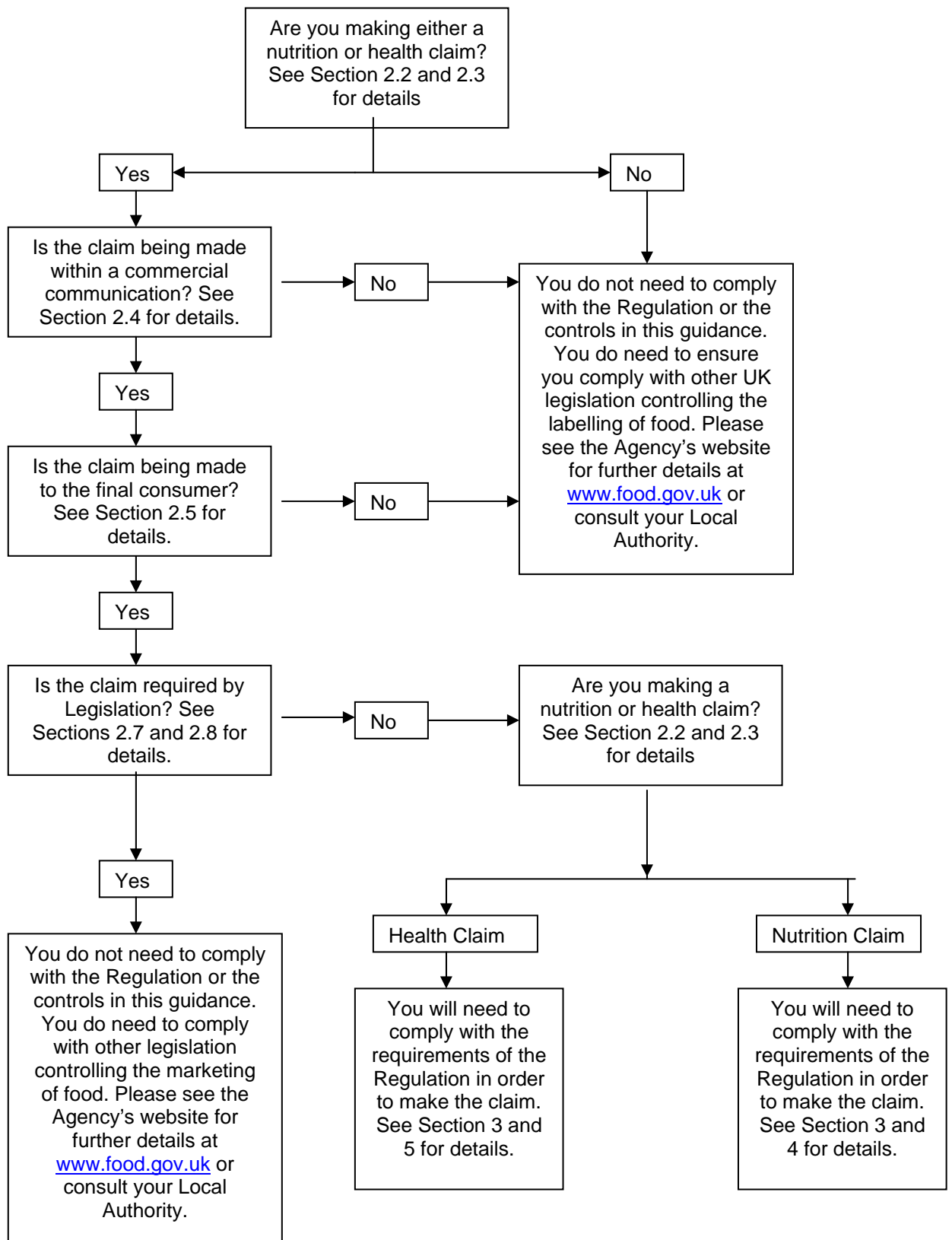
Further details of PARNUTS and water legislation can be found in Appendix I.

Regulation 258/97 concerning novel foods and novel food ingredients provides for the possibility of mandatory labelling, sometimes as a condition of approval. To the extent that statements are required to be made by the novel food approval, they will not have to comply with the requirements of the Regulation on nutrition and health claims. In the vast majority of cases the labelling requirements for novel foods are not in a form that constitutes a claim. An example of specific legislation on the labelling of novel foods that takes precedence over 1924/2006 on nutrition and health claims is Regulation 608/2004 concerning the labelling of foods, food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters. This requires products containing such substances to have a statement that the product is intended exclusively for people who want to lower their blood cholesterol level.

Article 11 of 1924/2006 on nutrition and health claims allows, but does not directly control, the use of endorsements by national associations of medical, nutritional or dietetic professionals and health-related charities. Instead these are to be controlled by national rules. The Agency is in the process of producing guidance on the use of such endorsements in the UK. If you would like to receive further information please fill in the form in Appendix VIII or contact the Agency.

⁶ This guidance can be found at:
http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

2.9 – Flow diagram – Do I need to comply with the Regulation?



Section 3

How To Make A Claim

3.1 – Introduction

As well as complying with any specific controls applicable to nutrition or health claims, as outlined in Sections 4 and 5, food business operators must also ensure they comply with the general requirements of the Regulation. This section gives further information on these requirements.

It is worth noting that Article 28 puts in place various transitional periods that give industry time to comply with the requirements of the Regulation. During these periods certain claims or products, which do not comply with the Regulation, may remain on the market. Full details of the transitional periods can be found in Section 7.

3.2 – Prohibited claims (Article 4 and 12)

The Regulation contains specific controls on the use of claims on alcoholic beverages. Article 4(3) prohibits beverages that contain more than 1.2% by volume of alcohol from making health claims and nutrition claims other than “low alcohol”, “reduced alcohol”, and “reduced energy” claims. The use of these claims in the UK will continue to be controlled by Schedule 8 of the Food Labelling Regulations 1996. If you are exporting products to other countries you will need to check the individual requirements of the importing country.

Beverages that normally contain alcohol but have had these levels reduced to 1.2% or less by volume of alcohol will be treated as any other non-alcoholic beverage and can make any of the nutrition claims in the Annex as long as the product meets the conditions of use of the claim. Article 4(4) makes it possible for these products to make “reduced alcohol” and “alcohol free” claims under national legislation. In the UK they will continue to be controlled by Schedule 8 of the Food Labelling Regulations 1996.

Article 12 of the Regulation does not allow the following health claims to be made on food:

- Claims which suggest that health could be affected by not consuming the food;
- Claims which make reference to rate or amount of weight loss (specific questions and answers associated with this prohibition are given in Section 9.6);
- Claims which make reference to recommendations of individual doctors or health care professionals (specific details are given in Section 9.7);

Claims which state, suggest or imply that a food has the property of preventing, treating or curing a human disease will continue to be prohibited

by the Food Labelling Regulations 1996 (as amended). Products that make claims such as this may be subject to medicines legislation. For further information on medicine controls please visit the Medicines and Healthcare products Regulatory Agency's website at www.mhra.gov.uk

The answers to frequently asked questions relating to this section, can be found in Section 9.6 and 9.7.

3.3 – General requirements that all claims must fulfil (Article 3, 5 and 6)

All claims that are made on food must comply with general criteria laid out in the Regulation. Articles 3, 5, and 6 require that:

- a) Claims are not false, ambiguous or misleading. (Authorisation of claims goes some way to guaranteeing this, but care is still needed over context and presentation.);
- b) Claims do not give rise to doubt about the safety and/or nutritional adequacy of other foods. (Article 9 specifically addresses comparative nutrition claims.);
- c) Claims do not encourage or condone excess consumption of a food;
- d) Claims do not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. (Although there are provisions in place to adopt exemptions to this requirement, none currently exist.);
- e) Claims do not refer to changes in bodily functions which could give rise to, or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations;
- f) The presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;
- g) The nutrient or other substance for which the claim is made:
 - i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence. In the case of vitamins and minerals Directive 90/496/EEC refers to 15% of the RDA when considering a significant amount. In all other cases there should be evidence to show it has a benefit; or
 - ii) is not present, or is present in a reduced quantity so as to produce the nutritional or physiological effect claimed, as established by generally accepted scientific evidence. This will apply to claims such as "low fat" or "reduced fat" etc;

- h) Where applicable, the nutrient or other substance for which the claim is made must be in a form that is available to be used by the body;
- i) The quantity of the product that can reasonably be expected to be consumed must provide a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- j) Compliance with the specific conditions set for nutrition and health claims (Section 4 and 5 deal with this respectively) as the case may be;
- k) If called upon to do so by the enforcement authorities a food business operator must be able to justify the claim. In some cases this may be by reference to the Community Register and uses of references to generally accepted scientific evidence, unless the scientific substantiation is subject to data protection. Food business operators will also have to show that the nutrient or other substance to which the claim relates, is present in a significant amount and is available to be used by the body; and
- l) Nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

The Regulation applies to the food ready for consumption in accordance with manufacturers' instructions (Article 5). In the Agency's opinion this should only apply where the food could not or should not be consumed otherwise. For example, the requirements of the Regulation would apply to a dehydrated product, only after water has been added in accordance with the instructions. Where the product can be consumed without following the manufacturer's instructions, the requirements would apply to the food as sold. For example breakfast cereal does not have to be eaten with milk and therefore the claim should apply to the cereal as sold and not rely on milk being added.

The answers to frequently asked questions relating to this section, can be found in Section 9.8.

3.4 – Specific information about making nutrition and health claims

If your claim complies with the general conditions of use outlined in this section you should now ensure you comply with the specific conditions of use applicable to nutrition and health claims. If you are unclear whether or not you are making a nutrition claim or a health claim you should consult Sections 2.2 and 2.3 for guidance.

- ★ If you want to make a nutrition claim please go to Section 4.
- ★ If you want to make a health claim please go to Section 5.

Section 4

How To Make A Nutrition Claim

4.1 – Introduction (Article 8)

Subject to transitional periods, Article 8 requires that nutrition claims be in the Annex of the Regulation in order to be used on food. To check that the claim is in the Annex please see the following website address, pages 16-18:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf

- ★ If the claim you wish to make is in the Annex please go to Section 4.2 – Claims on the list in the Annex (Article 7 and 8).
- ★ If you are making or wish to make a claim that is not in the Annex please go to Section 4.3 – Claims not on the list (Article 28).
- ★ If you want to make a reduced or increased claim please see the specific controls in Section 4.4 – Reduced and increased claims (Article 9).

4.2 – Claims on the list in the Annex (Article 7 and 8)

To use the claim you will need to ensure that your product meets the following requirements:

- Article 8(1) requires the product to meet the specific conditions of use of the claim as outlined in the Annex. For example in order to claim that a food is “fat free” the product must contain no more than 0.5g of fat per 100g or 100ml.
- Compliance with additional requirements (such as prohibition if an alcoholic beverage) as outlined in Section 3.
- Article 7 requires nutrition labelling to be presented, except for non-prepacked foodstuff put up for sale to the final consumer or to mass caterers, a foodstuff packed at point of sale at the request of the purchaser or pre-packed with a view to immediate sale, in which case nutrition labelling does not have to be provided. This has always been the case for nutrition claims, under the nutrition labelling Directive. If the claim relates to a specific nutrient that does not appear in the nutrition labelling, Article 7 requires that nutrient, and the amount present to be stated in the same field of vision as the nutrition labelling. For food supplements the nutritional information must be produced in line with food supplements legislation (Directive 2002/46/EC). For further advice and guidance on the provision of nutrition labelling please see the Agency’s guidance notes on nutrition labelling.

www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/nutlabelguid

The answers to frequently asked questions relating to this section can be found in Section 9.9.

4.3 – Claims not on the list (Article 28)

Article 28(3) of the Regulation puts in place a three year transitional period for nutrition claims that are not in the Annex. This only applies to claims in use before 1 January 2006 and allows them to continue to be used until 19th January 2010. In the Agency's view "in use" means in use in the European Union before 1 January 2006; and that during this period the claim must be used in compliance with national rules, in the UK that is the Food Safety Act 1990 and the Food Labelling Regulations 1996 (as amended). If the claim has not been added to the Annex after 19 January 2010 its use will be prohibited.

If the claim was not in use before 1 January 2006, Article 4(1) means it cannot be used, unless it is added to the Annex. The general transitional period in Article 28(1) will apply to actual products placed on the market or labelled before 1 July 2007. This transitional period allows existing stock to be sold until its expiry date or 31 July 2009, whichever is sooner.

Article 8(2) allows the list of permitted nutrition claims to be up-dated if an established claim is missing or to add new claims or amend existing claims. Additions to the list will be made via the Commission's Standing Committee procedure. If you wish to propose that a claim is added to the list please contact either the Agency, contact details can be found in Appendix II, or your trade association for further advice. It is the Agency's view that once a claim is added to the Annex the specific conditions associated with that claim will apply.

The answers to frequently asked questions relating to this section can be found in Section 9.10.

4.4 – Reduced and increased claims (Article 9)

First, Article 8(1) requires products to meet the conditions given in the Annex to make a reduced or increased claim. So, for example, to say "reduced fat" there must be at least a 30% reduction compared to a similar product. In addition, reduced and increased claims must comply with the following conditions laid out in Article 9:

- The comparison must be between foods of the same category. Although the Regulation does not provide a definition of food category, the European Commission has produced guidance⁷ on how this should be applied. They state that products being compared should be foods belonging to a group of foods that are similar in terms of nutritional content. For example, a "dairy products" category would be too large and would allow a comparison to be made between the fat content of cheese

⁷ This guidance can be found at:

http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

and the fat content of milk. Instead, narrower food categories such as "milks", "fresh cheeses", or "yoghurts" could be considered. The notion of food category should also take account of the occasion of consumption and/or the purpose of consumption and in particular alternatives of consumption, for example butter and margarine. The key requirement is that the comparison helps consumers make informed choices.

- The comparison must be between the product bearing the claim and a range of other products from the same category, which do not have a composition which allows them to bear a claim, including foods of other brands. This is to avoid a situation where a comparison with a single product may not be representative of the market and may mislead the consumer. It is the Agency's reading of the Commission guidance that in some cases it may be possible to compare with only one product if that one product is representative of other products on the market. For example to make a reduced sugar claim on lemonade the comparison could be with the full sugar version of the product range, provided the full sugar version has similar sugar levels to comparable lemonades on the market.
- The claim must state the difference in the quantity of the nutrient and/or energy (calorific value) between the same quantities of the two foods. This difference can be expressed as an average and as either a percentage or an absolute value.
- When the claim "light" is used, the Annex requires the characteristic(s) which make(s) the food 'light' to be indicated. Similarly, if the claim "reduced energy" is made the Annex requires the characteristics which make the food reduced in its total energy value to be indicated. In the Agency's view, a single indication can fulfil the requirements of both Article 9 and the conditions for using the "light" or "reduced energy" claim. For example, a label stating "light – X% less sugar". If the nutrient has been removed a statement indicating its absence can be made. For example "light – no sugar ". In the context of this statement, the % reduction need not meet the conditions in the Annex.

Within Commission guidance it is specified that "as much as" claims, such as "as much calcium as a glass of milk", are not subject to Article 9, which specifies that a comparative claim should indicate the **difference** in the quantity of a nutrient or energy value. Although this type of claim does not have to comply with the specific requirements in Article 9 it is still considered to be a nutrition claim and would need to comply with the requirements of the Regulation, such as being included in the Annex of permitted claims. At present "as much as" is not included in the Annex; since it has been in use before 1 January 2006, it may continue to be used until 19 January 2010; its use after this time will only be permitted if the Annex is amended to include it.

The answers to frequently asked questions relating to this section can be found in Section 9.11.

4.5 – Future controls

Several of the Regulation's requirements don't apply now, but will apply to the use of nutrition and health claims in future. Details of these requirements can be found in Section 6.

4.6 – Checklist for making nutrition claims

You will need to be able to tick all the following boxes in order to make a nutrition claim on your product.

- The claim is a nutrition claim as defined (see Section 2.2)
- I've consulted Section 2.4 and 2.5 and the claim is within the scope of the Regulation. If it's not in scope there is no need to continue with the check-list as you do not have to comply with the Regulation. You should contact your Local Authority to ensure you comply with other legislation applicable to food.
- I've consulted Section 2.6 and it's not subject to mandatory labelling. If it is subject to mandatory labelling there's no need to continue with the check-list as you do not have to comply with the Regulation. You should contact your Local Authority to ensure you comply with other legislation applicable to food.
- Use of the claim also complies with any relevant specific legislation. See Section 2.7 for details.
- It's not a prohibited claim. See Section 3.2 for details.
- The claim and the product comply with the general requirements outlined in Section 3.3
- The claim is included in the Annex or was in use before 1st January 2006 (and therefore can continue to be used until 19 January 2010).
- If it is in the Annex the product complies with the specific conditions of use stated.
- If it is a reduced or increased claim it complies with the conditions of Article 9, see Section 4.4
- Nutrition labelling has been provided, see Section 4.2 for details

Section 5 Health Claims

5.1 – Using a health claim (Article 7 and 10)

Article 10(1) only allows health claims that are on the list of authorised health claims in the Community Register to be used on food. The only exceptions to this are general, non-specific claims (Article 10(3)) and trade marks or brand names that are also health claims (See Section 2.6).

Article 10(3) of the Regulation puts in place special requirements for claims about general, non-specific benefits of the nutrient or food for overall good health or health-related well-being, such as “good for you” or “healthy”. These claims do not have to be added to the Community Register of authorised health claims to be made on food. Instead the claim may only be used if it is accompanied by an authorised claim that is included in the Community Register. The product would have to meet the criteria of use of the accompanying claim. In the Agency’s view this only becomes a requirement once the Community Register of authorised claims is adopted, likely to be **January 2010**.

The list of authorised health claims is, however, still being prepared and is due to be adopted in January 2010. Until the list of claims is adopted the transitional periods in Section 7 will apply and health claims will need to comply with existing national legislation as outlined in Appendix 5. They will also need to comply with the following aspects of the Regulation.

To use any health claim the Regulation requires the product to:

- comply with the general requirements (such as prohibitions if an alcoholic beverage) as outlined in Section 3;
- comply with the following labelling requirements:
 - Present full nutrition labelling as required by Article 7 unless it’s a non-prepacked foodstuff put up for sale to the final consumer or to mass caterers, a foodstuff packed at point of sale at the request of the purchaser or pre-packed with a view to immediate sale, in which case nutrition labelling does not have to be provided. The information should be that of group 2, as defined in Article 4(1) of Directive 90/496/EEC – implemented by Schedule 7 of the Food Labelling Regulations 1996. If the claim relates to a specific nutrient that does not appear in group 2, that nutrient and the amount present must be stated in the same field of vision as the nutrition labelling. For food supplements the nutritional information must be in line with food supplements legislation (Directive 2002/46/EC). For further advice and guidance on the provision of nutrition labelling please see the Agency’s guidance notes on nutrition labelling.

www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/nutlabelguid

- Article 14 of the Regulation requires products which make disease risk reduction claims to have a statement that the disease has multiple risk factors and altering one of these factors may or may not have a beneficial effect. These claims must be authorised before they can be used on food.

In future Article 10 of the Regulation will require other conditions to be met for health claims to be made, however these will not apply until the list of claims has been adopted in 2010. If you would like more information about these requirements, now, please see Section 6.

The answers to frequently asked questions relating to this section can be found in Section 9.12.

5.2 – How to get a claim on the Community Register of authorised health claims

The list of health claims is still being prepared and the Regulation has three mechanisms for the addition of claims to the list. Which of the three mechanisms will be the appropriate route to gain an authorisation will depend on the nature of the claim and the evidence it is based upon.

- ★ For claims, which do not fall into one of the categories below and are based on generally accepted scientific evidence, please go to Section 5.3
- ★ The Regulation puts in place specific requirements associated with disease risk reduction claims and claims referring to children's development and health that apply to both claims based on new science and claims based on generally accepted science. If you wish to make one of these claims please see Section 5.4.
- ★ If the claim is based on new or emerging science, or there is a request for data protection, please go to Section 5.5.

5.3 – Health claims other than those referring to the reduction of disease risk and to children's development and health (Article 13)

Health claims that are based on generally accepted scientific evidence and are well understood by the average consumer will not be required to go through the same authorisation process as claims which are based on new or emerging science or proprietary data, disease risk reduction claims or claims referring to children's development and health. Instead the Regulation allows the UK and other Member States to put together a list of candidate health claims which are based on generally accepted scientific evidence and submit this by 31st January 2008. Once the Member State lists have been consolidated, the resulting list will be sent to EFSA for an opinion before a decision is made about which claims should be included in the list of authorised health claims in the Community Register. It is a requirement of the Regulation that this list of claims is adopted before 31 January 2010. The UK

list of candidate health claims is not a list of authorised health claims. National legislation will continue to apply until 2010.

Authorised claims will be added to the list of authorised health claims in the Community Register, and will be accompanied by any conditions of use.

Member State lists can only comprise claims which describe or refer to:

- the role of a nutrient or other substance in growth, development and the functions of the body, such as “calcium helps maintain strong bones”, or
- psychological and behavioural functions, such as “helps you concentrate”, or
- without prejudice to Directive 96/8/EC⁸, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet, such as “helps you lose weight”.

Claims on the list will need to have references to supporting scientific justification that EFSA consider sufficient to be generally accepted scientific evidence. The Food Standards Agency opened the UK’s list on 18 October 2006 and closed it on 21st September 2007. The list was closed in September to allow time for claims to be logged, sorted and assessed to ensure eligibility under Article 13. If you would like further information about the UK list please see the following website:

www.food.gov.uk/foodlabelling/ull/claims/

5.4 – Reduction of disease risk claims and claims referring to children’s development and health (Articles 14, 15, 16 and 17)

The Regulation requires disease risk reduction claims and claims which refer to children’s development and health to be authorised prior to use and specifies a procedure for such authorisations. Once authorised, a claim will be added to the list of authorised health claims in the Community Register and can be used on any product that meets the conditions of the Regulation and the conditions of use specified.

In order to get the claim authorised an application with supporting information is required to be submitted to the Agency. The Agency is required to acknowledge receipt in writing within 14 days and forward the application to EFSA for their assessment. EFSA will then make the information available to other Member States and the Commission and a summary available to the public.

The Regulation requires that an application contains the following information about the claim:

- (a) the name and address of the applicant;

⁸ on foods intended for use in energy restricted diets or for weight reduction

- (b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- (c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;
- (d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification; [note: see Section 5.3 for claims based on proprietary data]
- (e) a copy of other scientific studies which are relevant to that health claim;
- (f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
- (g) a summary of the application (which EFSA will make public).

Once EFSA have received an application they have five months to give an opinion. EFSA have the option to request further information about the application if necessary. If EFSA request any further information the overall time limit will be extended by up to two months. In order to get a quick response and approval it is important to submit a well prepared dossier that includes all relevant information. EFSA has produced extensive guidance to this, which can be found at:

http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html

If EFSA approve the claim their opinion will contain details of the applicant, the claim and the nutrient it refers to, a proposal for the wording of the claim and where necessary any conditions or restrictions on use, including compulsory warnings. The opinion, whether negative or positive, together with details about the reasoning for EFSA's opinion will go to the Commission, Member States and will be made available to the public. The public and the applicant will have 30 days to comment.

The Commission has two months to refer the opinion and claim to Standing Committee (comprising representatives of all Member States, chaired by the Commission). The Standing Committee will consider the claim and decide whether it is necessary and appropriate to amend the list of authorised health claims.

Approved claims will be added to the authorised list of health claims in the Community Register, together with any conditions of use. If the claim is rejected it will be added to the Community Register together with the reasons for the rejection.

A flow chart of this process can be found in Appendix VI.

5.5 – Health claims based on new or emerging science or proprietary data (Article 18, 15 and 16)

Health claims based on new or emerging science or health claims based on proprietary data are required to be authorised prior to use and the Regulation specifies a procedure for such authorisations. In order to get the claim authorised an application with supporting information is required to be submitted to the Agency. The Agency will acknowledge receipt in writing within 14 days and send the application to EFSA for their assessment and to other Member States and the Commission for information.

Article 13(5) requires the dossier to contain the following information about the claim:

- (a) the name and address of the applicant;
- (b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- (c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;
- (d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- (e) a copy of other scientific studies which are relevant to that health claim;
- (f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
- (g) a summary of the application;
- (h) reasons for the request.

Once EFSA have received a valid application they have 5 months to give an opinion. EFSA have the option to request further information about the application if necessary. If EFSA request any further information the overall time limit will be extended by 1 month, with the applicant required to submit the requested information within 15 days. EFSA will forward its opinion to the Commission, Member States and the applicant as well as making it public. The applicant and members of the public have 30 days to make comments to the Commission. EFSA has produced extensive guidance to this, which can be found at:

http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html

The Commission will then have two months to decide if the claim should be authorised. The Commission will take into account EFSA's opinion, relevant provisions in EU law, any other relevant considerations and will consult with

Member States in reaching their view. Taking the above time limits into account this process will take no longer than 8 months. Approved claims will be added to the authorised list of health claims in the Community Register, together with any conditions of use. If the claim is rejected it will be added to the Community Register together with the reasons for the rejection.

A flow chart of this process can be found in Appendix V.

Once added to the list of authorised health claims in the Community Register, the claim will be available for use on any product that meets with the requirements of the Regulation and any conditions of use specified. If, however, any of the supporting scientific data or other information has been granted data protection it can not be used by any other applicant for five years. This is reliant on:

- a) the scientific data or other information being designated as proprietary by the applicant when the application is made.
- b) the prior applicant having exclusive right of reference to the proprietary data at the time the prior application was made; and
- c) the health claim not being able to be authorised without the submission of the proprietary data by the applicant.

This aims to protect proprietary data, but will also, to a certain extent, protect particular claims as the Regulation requires manufacturers to be in a position to scientifically justify any claims they make. It does not stop the same claim being submitted with another scientific justification by another food business operator. Also, if during this five year period, the Commission decides the claim could be authorised without the protected information, it can decide to make that information available.

5.6 – EU guidance on the application process and tools for small businesses

The Regulation gives the Commission powers to introduce more detailed rules on the preparation and presentation of the application. A Commission Regulation is expected in early 2008.

The Regulation also requires the Commission and EFSA to produce guidance to assist food business operators in the preparation and presentation of the application for scientific assessment (Article 15 (5)), particularly small businesses, where “tools” for their assistance are also required. EFSA has adopted its “scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim”. Copies of this guidance can be accessed at the following website address:

http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html

The answers to frequently asked questions relating to this section can be found in Section 9.13.

Section 6 Future Control Of Nutrition and Health Claims

6.1 – Introduction

Several of the Regulation's requirements don't apply now, but will apply to the use of nutrition and health claims in future. This section gives details about these controls and significant dates associated with them.

6.2 – Nutrient profiles (Article 4)

To prevent the use of claims misleading consumers about the true nutritional composition of the food, Article 4 requires the Commission, on advice from EFSA, to establish nutrient profiles for foods and food groups by **19 January 2009**. Use of authorised nutrition and health claims on foods failing the nutrient profile may be restricted, as explained below. Under transitional arrangements food business operators are not required to comply with the requirements associated with nutrient profiles until the end of the 2nd year following their adoption, at the latest **19 January 2011**.

Nutrient profiles will set certain nutritional criteria that a product must meet to make claims. When establishing nutrient profiles the Regulation requires EFSA to give advice and the Commission to consult stakeholders before adoption. It also requires the following to be taken into account when the profiles are developed:

- the quantities of certain nutrients, such as fat, salt and sugar, and other substances in the food;
- the role, importance and contribution of the food in the diet;
- the overall composition of the food including any nutrients that have been scientifically recognised as having an effect on health;

It will depend on the extent to which a product complies with the profile, what claims can be made.

- **Meets the profile** – Nutrition and health claims can be made, if they comply with the other requirements of the Regulation.
- **Fails on one nutrient** – No health claim can be made. Nutrition claims can only be made if the statement “high [name of nutrient that fails the profile] content’ is also made. This must be done in close proximity to, and with the same prominence as the nutrition claim. For example, a food high in sugar might carry the claim “low fat” only if the statement “high sugar content” is made. Article 4 specifies that this would have to be in the same field of vision as the claim and in the same size of typeface.

- **Fails on more than one nutrient** – No nutrition or health claim can be made, except for certain reduced claims. Article 4(2) exempts foods making “reduced” claims from having to respect the nutrient profile, but only where the reduced claim relates to a nutrient that fails the profile. For example if a product fails the profile due to its fat and sugar content, it cannot make a nutrition or health claim except “reduced fat” or “reduced sugar”.

The Regulation allows for further exemptions to the application of nutrient profiles to be set during their development.

The answers to frequently asked questions relating to this section can be found in Section 9.14.

6.3 – Labelling requirements for health claims (Article 10)

Article 10 requires additional statements to be made in the labelling (or if there is no labelling, in the presentation and advertising) of products that make health claims. It is the Agency’s view that these do not become requirements until the Community Register of authorised health claims is adopted, likely to be January 2010. Below is an outline of these additional labelling statements:

- Include a statement indicating the importance of a varied and balanced diet and a healthy lifestyle.
- Include information about the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect.
- Where appropriate, include a statement addressed to persons who should avoid using the food. Specific statements may be included within the conditions of use for a particular claim.
- An appropriate warning for products likely to present a health risk if consumed to excess. Specific statements may be included within the conditions of use for a particular claim.

In the Agency’s view the requirements in Article 10(3), which apply to claims about general, non-specific benefits of a nutrient or food to overall good health or health-related well-being only apply once the Community Register of authorised claims is adopted, likely to be **January 2010** (See section 5.1 for more details).

Section 7

When Do I Need To Comply With The Regulation?

7.1 – Introduction

Some of the requirements of the Regulation do not take immediate effect. Below is information about the transitional periods and key dates by which you will need to comply with the various requirements of the Regulation.

7.2 – Transitional periods (Article 28 and 29)

The Regulation came into force on 19 January 2007. This is the date on which the Regulation officially became law and the date by which other time periods and transitional periods in the Regulation are based.

The requirements of the Regulation applied from 1st July 2007. After this date any products put on the market carrying a claim must meet the requirements of the Regulation, unless there are specific transitional measures in place. Nutrition claims in use before 1 January 2006 and not in the Annex of authorised claims may continue in use until 19 January 2010, subject to the provisions of the Food Labelling Regulations 1996 (as amended) and the Food Safety Act 1990. Nutrition claims new to the market from 1 January 2006 must comply with the Regulation or be taken off the market by the product's expiry date or no later than 31 July 2009, whichever is the sooner.

Further information about transitional periods and when specific elements of the Regulation will take effect is given in the table below. Other than the transitional period explained above, it is the Agency's view that the transitional periods relate to the claim, rather than the product making the claim. For example although "high in omega-3" is not in the annex of nutrition claims, it was in use before 1st January 2006 and so the transitional period would apply, allowing this claim to continue to be used until 19 January 2010. During the transitional period "high in omega-3" could be used on any product, regardless of whether it is a new product or whether the product has used the claim in the past. During this period use of the claim would have to comply with existing UK legislation.

In addition the transitional periods apply to the type of claim and not the type of scientific substantiation.

During the transitional periods UK legislation will continue to apply. Details of this legislation are given in Appendix IV.

The answers to frequently asked questions relating to this section can be found in Section 9.15.

Table 2 – Summary of transitional periods and key dates

In some instances the Regulation does not provide exact end dates for transition periods but instead allows for periods following certain decisions. For example there is a two year transitional period for products to comply with the controls relating to nutrient profiles, following their adoption. As nutrient profiles have to be adopted by 19 January 2009, the very latest date for this transitional period could finish is 19 January 2011. In such cases the latest possible date for the end of the transitional period is stated in the table below and is indicated by #.

Date	Requirements	Article Reference
<p>1st July 2007</p> <p>However, products placed on the market or labelled prior to 1st July 2007, with claims which do not meet these requirements can continue to be marketed until their expiry date, but not later than 31st July 2009.</p>	<ul style="list-style-type: none"> • Nutrition claims included in the annex can only be made on products that comply with the specified conditions of use. This includes claims made in any form of commercial communication to the final consumer. • Only nutrition claims included in the annex, or in use in a Member State before 1st January 2006, can be made on food. • Reduced and increased claims must comply with the conditions of use specified in the annex and in Article 9. See Section 4.4 for details. • Nutrition labelling must be provided if a nutrition or health claim is made. For health claims this must consist of group 1 and 2 nutrition labelling. If the claim relates to a nutrient or other substance not included in the nutrition labelling, it must be stated, together with the amount present, in the same field of vision as the nutrition labelling. This does not apply to non-prepackaged foodstuffs put up for sale to the final consumer or to mass caterers and foods packed at the point of sale at the request of the purchaser or pre-packed with a view to immediate sale. • Claims must not be made on alcoholic beverages containing more than 1.2% by volume of alcohol, with limited exceptions for reduced energy and alcohol content claims (see Section 3.2). 	<ul style="list-style-type: none"> • 28(1)

	<ul style="list-style-type: none"> • Health claims which suggest that health could be affected by not consuming the food can not be made on food. • Health claims which make reference to the rate or amount of weight loss can not be made on food. • Health claims which make reference to recommendations of individual doctors or health professionals can not be made on food. • Disease risk reduction can not be made (this was also the case prior to the 1st July 2007) unless the claim has been authorised. • Health claims referring to psychological and behavioural functions, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to a reduction of the available energy from the diet can only be made, if they were in used, in compliance with national provisions, before 19th January 2007. 	
<p>19 January 2008</p> <p>Applications for authorisation of certain health claims to trigger the transition period.</p>	<ul style="list-style-type: none"> • Health claims referring to psychological and behavioural functions, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to a reduction of the available energy from the diet can not be made on food unless they were used in compliance with national conditions before 19th January 2007 and an application for authorisation has been submitted. Inclusion in the UK list of health claims is sufficient to fulfil this requirement. • Claims referring to children's development and health can not be made on food unless the claim was in use before 19th January 2007 and an application for authorisation has been submitted. 	<ul style="list-style-type: none"> • 28(6)
<p>Date of adoption of the Community Register of health claims, at the latest 31 January 2010[#]</p>	<ul style="list-style-type: none"> • Only health claims included in the Community Register of authorised health claims, or claims submitted for authorisation and awaiting a decision, can be made on food. 	<ul style="list-style-type: none"> • 20 (Community Register) • 28(5) • 28(6)

	<ul style="list-style-type: none"> • Health claims referring to general, non-specific benefits of the nutrient to overall good health, such as ‘good for you’ must be accompanied by an authorised health claim. • Health claims must be accompanied by additional labelling requirements, such as a statement indicating the importance of a varied and balanced diet and a healthy lifestyle. See Section 6.3 for details. 	<ul style="list-style-type: none"> • 10(3) • 10(2)
19 January 2010	<ul style="list-style-type: none"> • Only nutrition claims included in the annex can be used on food and only on products that meet with the specific conditions of use. 	<ul style="list-style-type: none"> • 28(3)
Two years following adoption of the nutrient profiles. At the latest 19 January 2011 [#]	<ul style="list-style-type: none"> • Products must comply with the nutrient profile in order to make nutrition or health claims. Nutrient profiles will be adopted by 19 January 2009. Full details of these controls can be found in Section 6.2. 	<ul style="list-style-type: none"> • 28(1)
19 January 2022	<ul style="list-style-type: none"> • Trade marks and brand names that could be construed as a claim must be accompanied by an authorised health or nutrition claim. This only applies to trade marks or brand names in use before 1st January 2005. This applies to the use of the trade mark or brand name and not any other claims made on the product. 	<ul style="list-style-type: none"> • 28(2)

The Regulation also puts in place transitional periods for;

- nutrition claims in the form of pictorial, graphic or symbolic representation that are used in accordance with specific conditions and criteria elaborated by national provisions and;
- health claims that refer to psychological and behavioural functions, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to a reduction of the available energy from the diet and which have been subject of evaluation and authorisation in a Member State.

There are no claims in the UK that would be eligible for these transitional periods.

Section 8

Enforcement and Compliance

8.1 – Enforcement and compliance

The enforcement of food law in the UK is the responsibility of Local Authorities and in some instances port health authorities. In each of the UK countries a domestic Regulation or Statutory Instrument⁹ is required to designate “competent authorities” who will enforce the requirements of the legislation as well as put in place enforcement and penalties. In the UK it will be Trading Standards Departments or Environmental Health Departments or equivalent in the Local Authority of the food business operator that is responsible for enforcing the requirements of the Regulation.

Trading Standards Officer (TSOs) and Environmental Health Officers (EHOs) or any other authorised officer of the Local Authority (as appropriate) would initiate any legal proceedings in connection with a product that they consider to be in breach of the Regulations.

To ensure that your product complies with the Regulation we would strongly recommend you contact your local TSO or EHO for advice.

The Advertising Standards Authority (ASA) is the UK body responsible for advertisements in broadcast (TV and radio) and non-broadcast media. There are three advertising content codes. The Committee on Advertising Practice writes and maintains the non-broadcast advertising code (The CAP code) and the broadcast committee of advertising practice writes and maintains the TV and radio advertising standards codes. The ASA is the independent body responsible for administering those codes and is able to require advertisers and broadcasts to remove non-compliant claims. The advertising codes will be up-dated to reflect the requirements of the Regulation. For more information on the advertising codes please see the ASA website at:

www.asa.org.uk/asa/

8.2 – Home Authority Principle

The Home Authority Principle allows local authorities to work with a business to provide consistent and coordinated Trading Standards and Food

⁹ Statutory Instrument 2007 No. 2080, The Nutrition and Health Claims (England) Regulations 2007
Statutory Instrument 2007 No. 349, The Nutrition and Health Claims (Northern Ireland) Regulations 2007
Statutory Instrument 2007 No. 383, The Nutrition and Health Claims (Scotland) Regulations 2007
Statutory instrument 2007 No. 2611 (w.222), The Nutrition and Health Claims (Wales) Regulations 2007

Enforcement Services across the UK. It assists those businesses that have outlets in more than one local authority and distribute goods and/or services beyond the boundaries of one local authority. Further information about the Home Authority Principle can be found on the Local Authorities Coordinators of Regulatory Services website at www.lacors.gov.uk

Section 9 Questions and Answers

9.1 – Nutrition claims (Section 2.2 of the guidance)

1. *Do I have to use the exact wording of the nutrition claim as set out in the Annex of the Regulation?*

Not necessarily, as explained in Recital paragraph 21 of the Regulation. The entries in the Annex give the most frequently used wording, but wording that means the same to the consumer may be used, subject to the same control. See Section 2.2 for more information.

2. *Does “contains calcium” mean the same as “source of calcium”?*

It will depend on the presentation of the claim and consideration should be given to how consumers would view it in context. However, the Agency’s view is that consumers are likely to view “contains calcium” and “source of calcium” as having the same meaning.

3. *Can I include statements such as “less than 5% fat”?*

The Agency is of the view that use of the term “less” in relation to fat content would, in this case, have the same meaning for consumers as “low fat”. The product would have to comply with the conditions of use for “low fat” claims specified in the Annex. See Section 2.2 for more information.

4. *Can I include statements such as “90g of fat per 100g”?*

Depending on the context, this could be a factual statement. Please see Section 2.2 for information on what is and what is not a nutrition claim.

5. *Will the Regulation control GDAs and traffic light front of pack labelling?*

The Agency is of the view that front of pack nutrition information is a form of nutrition labelling rather than a claim.

9.2 – Nutrition or health claims (Section 2.2 and 2.3 of the guidance)

6. *Are claims such as “contains antioxidants” nutrition or health claims?*

Following discussions at the European level, and publication of Commission guidance¹⁰, claims such as ‘contains antioxidants’, which refer to a function in the body, are defined as health claims and will need to be authorised via Article 13.

¹⁰ This guidance can be found at:
http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

7. *Is “probiotics and prebiotic fibre” a nutrition or health claim?*

Following discussions at European level it has been agreed that claims, such as ‘probiotics and prebiotic fibre’, refer to a function in the body, and are therefore defined as health claims and will need to be authorised via Article 13.

8. *Is “detox” a nutrition or health claim?*

In the Agency’s view this is referring to a function in the body and would be a health claim. As detox could refer to a range of functions, whether this is a health claim that should be listed in the Community Register of authorised claims or is a claim referring to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being, may depend on the nature of the product. Ultimately the claim will either have to be on the Community Register of authorised claims or be supported by a specific claim from the Community Register. It will be for you to decide which is the most suitable route for your specific detox claim.

9. *Is “lowers cholesterol” a disease risk reduction claim?*

Under Community legislation (EC/608/2004) sterols and stanols are already required to be labelled with a statement that the product is intended exclusively for people who want to lower their blood cholesterol. The Commission guidance makes a distinction, in determining which route for authorisation is required, between claims to maintain (Article 13) and those to lower (Article 14) a risk factor in a disease.

This indicates that in order to authorise “lowers cholesterol” claims, the Article 14 route must be used. Nevertheless, the Agency does not currently see any further implication of this interpretation for such claims on the UK market.

10. *What type of claim is “Isotonic” or “Hypotonic”?*

Although it is not clear at the moment whether these are nutrition or health claims, they will need to comply with the Regulation and will be permitted on the market until January 2010. To ensure they can continue to be used after this date they will need to be submitted for authorisation and addition to the list of permitted nutrition or health claims.

9.3 – Scope (Section 2 of the guidance)

11. *Do I need to comply with the Regulation if the name of the product required by the Food Labelling Regulations 1996 contains a claim, e.g. “fruit juice with added zinc”?*

The Regulation controls voluntary nutrition and health claims made on foods and if a manufacturer chooses to advertise or label the food in such a way to emphasise a fortified ingredient, compliance with this Regulation may be necessary. However, this Regulation does not apply to statements or descriptions that are required to be present by other EU or national food legislation. To the extent that wording is necessary to comply with mandatory labelling requirements it is not subject to the Regulation. See Section 2.6 for further information.

12. *Does the Regulation cover claims such as suitable for diabetics, lactose free, gluten free or other claims aimed at consumers with specific disorders?*

Recital paragraph 22 states that claims addressed to a group of consumers with specific disorders are not intended to be covered by the Regulation. The Agency has produced guidance on allergens, which refers to 'free-from' claims. This can be accessed at the following website address:

www.food.gov.uk/multimedia/pdfs/maycontaininguide.pdf

For information about the Agency's position on "suitable for diabetics" claims please see the following website address:

<http://www.food.gov.uk/multimedia/webpage/diabeticfoods>

If allergens are present in the product there are requirements within the Food Labelling Regulations 1996 (as amended) to label their presence.

13. *Does the Regulation cover additive claims such as "no colours or preservatives"?*

In the Agency's opinion this would be an ingredient claim and would not be controlled by this Regulation. Please see Section 2.2 for further information.

14. *Does the Regulation cover claims relating to 5-a-day or fruit and vegetable content?*

In the Agency's view references to 5-a-day and the number of portions a product provides are not within the scope of this Regulation. This was discussed during negotiations and a statement clarifying this was included in the minutes of the June 2005 Council. However, the general rules in the Trade Descriptions Act 1968 (soon to be replaced by the Consumer Protection from Unfair Trading Regulations), the Food Safety Act 1990 and European Regulation 178/2002, which make it an offence to mislead consumers and give out false information, continue to apply. Claims relating to 5-a-day should conform with the Government's criteria and advice on what constitutes a portion. If a health claim is made in addition to the reference to 5-a-day, such as "good for you because it contains one of your five-a-day", use of the term "good for you" would

come within the scope of the Regulation. For further information about the Government's 5-a-day message, in particular what constitutes a portion, please see the following website address: www.5aday.nhs.uk

15. *Does the Regulation control Government health messages?*

No. As Government health messages are not made in a commercial context they do not come within scope of the Regulation (Article 1) and do not have to meet with the requirements of the Regulation. This does not necessarily mean that they can be repeated by food business operators in a commercial context and enjoy the same exemption. More information can be found in Section 2.3.

16. *Does the Regulation control statements such as “digestive”, “tonic water”, or “light ale” which could be viewed as a claim, but are now seen by consumers as a category of food?*

Under Article 1(4) descriptors, which have traditionally been used to indicate a class of foods or beverages, can be granted a derogation (exemption) and would then not have to comply with the requirements of the Regulation. For information on applying for a derogation please contact the Agency. The Agency's contact details can be found in Appendix II.

17. *Does the Regulation cover generic health claims such as “good for you”?*

Yes, but they have specific requirements to meet. See section 5.1 for further information.

18. *Does the Regulation cover use of the term “superfood” on a product?*

You will need to carefully consider how consumers would view this claim and the context in which it's made. The term "superfood" is generally seen as short-hand for some non-specific but clear benefit of the food it describes, and generally seen as a health benefit. While only courts can give a definitive interpretation, consumers have been given to expect some general health benefit from use of this term. It is the Agency's view, therefore, that the term "superfood" is unlikely to be considered to be a specific health claim that would require authorisation and listing in its own right, but that it may be viewed to be a general reference to health under Article 10(3) of the EU Regulation 1924/2006 on nutrition and health claims made on foods. Article 10(3) claims do not have to be authorised and listed, so there is no requirement for a specific decision to be made at the Community level. Instead these are general references to health and have to be supported by a specific health claim from the authorised list, explaining to consumers why the product is beneficial to health, what makes it a "superfood".

19. *Does the Regulation control claims made on vending machines?*

In the Agency's view, if the claim relates to the products in the machine it would need to comply with the requirements of the Regulation. With regards to any labelling requirements, you must ensure that consumers have access to information that allows them to make an informed choice. In the Agency's view this information would need to be available before a purchase is made. This would apply to nutritional information that must accompany a claim.

20. *Does the Regulation control claims about sports performance?*

In the Agency's view, these are health claims and would need to meet with the requirements of the Regulation. For more details please see Section 5.

9.4 – Commercial communication (Section 2.4 of the guidance)

21. *I'm trying to decide if the information I want to give in a magazine article / on a website is a claim within a commercial communication. Section 2.4 mentions same field of view, what does this mean?*

Ultimately decisions will need to be taken on a case-by-case basis and only the courts will be able to decide what does and what doesn't have to comply with the requirements of the Regulation. The Regulation does, however place emphasis on consumer understanding and how consumers view the information presented to them. With this in mind, the Agency's view is if consumers could link a claim with a specific product it is likely to be a commercial communication. In the Agency's view, this is more likely to be the case where the product and claim are seen together, at the same time and without turning the page, for example on the facing page of a (general interest) magazine.

If the claim and the related product cannot be seen together, consideration should also be given to whether or not there is a direct link between the product and the claims being made, for example reference to a website. This is particularly relevant when we consider internet pages. In the Agency's view only claims which are on a separate internet site¹¹ and where there is no direct link to the purchase of products, would fall outside the scope of a commercial communication and outside the scope of the Regulation.

22. *I've got an in-store magazine, does this count as a commercial communication?*

In the Agency's view such publications are no different to other general interest magazines and it will depend on the type of information included and the way it is presented. For example if food retailer X produces an in-store magazine that gives consumers information about a healthy diet and includes an article on the benefits of oily fish, this alone would not

¹¹ This is the practice of the Medicines and Health products Regulatory Agency.

appear to be a commercial communication; information given is unlikely to be construed as a claim and would not have to meet the requirements of the Regulation. However, if the article also mentions that oily fish can be purchased in retailer X's shops or mentions a particular brand, this could be a commercial communication and any information given is more likely to be construed as a claim and would need to meet with the requirements of the Regulation. Similarly, if an advertisement for oily fish is made in the same field of vision, or consumers could link the claims in the article with a particular product, it would more likely be a commercial communication and would need to comply with the requirements of the Regulation.

23. *Is a press release a commercial communication?*

A communication between a company and the media is not likely to be commercial. The Regulation (Recital 4) states that 'claims' made in non-commercial communications and information in the press and in scientific publications are out of scope. However, use of a press release for commercial purposes, such as placement on a website to promote a product, or given out in store, etc are not 'information in the press' and would be commercial communications, subject to the Regulation.

24. *What is meant by generic advertising in Recital 4 of the Regulation?*

Recital 4 clarifies that the Regulation should apply to all nutrition and health claims made in commercial communication including generic advertising and promotional campaigns. The key consideration is whether or not the claim is made in a commercial context. Further guidance on what is a commercial communication is given in Section 2.4.

9.5 – Trade marks and brand names (Section 2.6 of the guidance)

25. *If I use a trade mark or brand name that could also be a claim are there any controls on the positioning of the associated claim?*

No. Although the Regulation does not specify where the accompanying claim should be made and there is no case law to inform an interpretation, it is the Agency's view the claim should be clearly visible and legible.

26. *Are there any controls on the type of claim I have to make to accompany the trade mark/brand name?*

Yes. The claim must be relevant to the trade mark or brand name. Article 1(3) requires the claim to be in either the Annex of approved nutrition claims or the Community Register of authorised health claims and the product must meet the requirements to make the accompanying claim.

27. *What if the trade mark or brand name is in a television advert, can the accompanying claim be in the labelling?*

Article 1(3) of the Regulation states that where the “*trade mark or brand name appearing in the labelling, presentation or advertising of the foodprovided it is accompanied by a related nutrition or health claim in **that** labelling, presentation or advertising*”. This would appear to require that claim to appear with the trade mark or brand name even where it is in an advert. However, this may depend on the circumstances and a test of reasonableness. Consult your Home Authority and the Advertising Standards Authority (ASA) for further guidance.

28. *What happens if a product, with a brand name or trade mark which could be a claim, does not meet with the nutrient profile?*

In order to use a brand name or trade mark that could be construed as a claim, Article 1(3) requires it be accompanied by an approved claim. The product must meet with the requirements of the Regulation to use the approved claim, including restrictions such as those based on nutrient profiles. If it cannot comply with these conditions it would not be able to use the brand name or trade mark. For brand names or trade marks existing before 1 January 2005, the 15 year transitional period would apply before they would need to comply with this requirement (Article 28(2)).

29. *When do I have to include the accompanying claim?*

For trade marks or brand names in use before 1 January 2005 there is a 15 year transition period, in Article 28, for products to comply with these conditions. See Section 7 for further details of the transitional periods.

30. *What is meant by “trade marks or brand names existing before January 2005” in Article 28?*

The Regulation does not define what is meant by “trade marks or brand names existing before January 2005”. In some cases the trade mark will have been registered before January 2005, showing that it existed. For brand names and other trade marks, manufacturers should be able to establish that it was in use on products before this date. The Agency takes the view that this interpretation is common across the EU, but in the case of exported products, it would be best to check with the importing country authorities.

31. *Can I add products to the range and still use the trade mark or brand name?*

Yes. The transitional period applies to the trade mark or brand name and not the products that it is used on.

9.6 – Prohibited claims – Rate or amount of weight loss claims and claims on alcoholic beverages (Section 3.2 of the guidance)

32. What is a rate or amount of weight loss claim (Article 12(b))?

This is a claim that states, suggests or implies a loss of a measurable amount of weight over a period of time, or loss of a measurable amount of weight.

In the absence of case law, it is difficult to make categorical assertions about the scope of this prohibition. Reference to periods of time alone, particularly in more general terms such as “rapid”, “fast”, etc should not mislead consumers, but may not be subject to this prohibition.

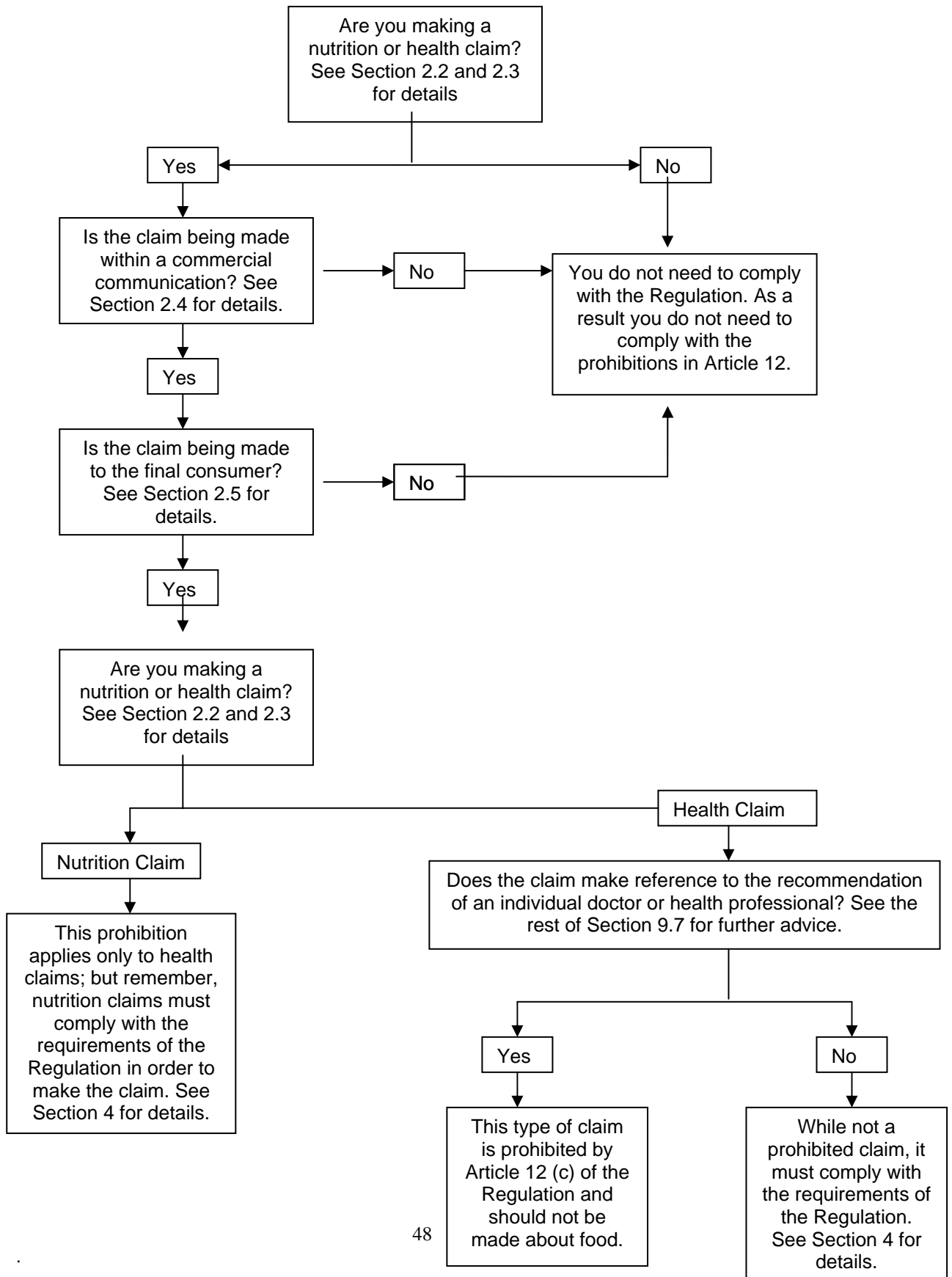
When considering compliance with this provision context will often need to be considered. For example, personal experiences and before and after photographs that can be substantiated and which are presented in a way that does not imply a guarantee of effect for the average consumer and which make no reference to an amount of weight or an amount of weight over a period of time, are probably beyond the scope of this prohibition. However, they are likely to be caught by the definition of health claim and as such may need to be either subject to a specific authorisation, or, as the case may be, under the provisions in Article 10(3) accompanied by an authorised claim.

33. Most claims on alcohol are prohibited, but does this include food supplements that contain more than 1.2% alcohol by volume?

No. Recital paragraph 13 of the Regulation draws a distinction between these products and alcoholic beverages. The product would need to comply with the definition of a supplement in Regulation 2(1)(a) of the Food Supplement Regulations 2003 and would need to comply with the other requirements of the Regulation on nutrition and health claims made on food.

9.7 – Prohibitions – Recommendations of doctors or health professionals (Section 3.2 of the guidance)

34. *How can I be sure I am not making claims caught by the prohibition in Article 12(c)?*



35. *What is meant by recommendations of individual doctors or health professionals?*

Article 12(c) prohibits health claims which make reference to recommendations of individual doctors, health professionals or associations other than national associations of medical, nutrition or dietetic professionals and health-related charities. In the Agency's view a doctor or health professional is not prohibited from recommending a product within a commercial communication, provided the recommendation is not seen by consumers as a health claim and the recommendation is not at variance with any recommendation made by a national association of health or nutrition professionals or a health-related charity. Care needs to be taken to ensure that any other claims made about the health benefits of the product are not understood by the consumer as being linked to the recommendation. For example, in the Agency's view it would be possible to say "Doctor X recommends this product", but it would not be possible to say that "Doctor X recommends this product because it's good for your heart".

Article 12 only applies to health claims and as a result would not prohibit nutrition claims which make reference to recommendations of individual doctors or health professionals. It would therefore be possible to say "Doctor X recommends this product because it contains calcium". If such a claim is made in a commercial communication use of this claim would still need to comply with the other requirements of the Regulation, for example the product should contain a significant amount of calcium.

36. *What is a health professional?*

In the context of the Regulation, the Agency takes the view that this would include anyone who is presenting themselves, or is understood by the consumer, as having expertise in the field of health or nutrition.

37. *Will the Regulation control advice given by doctors and health professionals to patients?*

The Regulation does not cover non-commercial communications such as independent advice given by dietitians, doctors, in-store pharmacies and health centres to patients. For more advice on what is a commercial communication please see Section 2.4

38. *Can a doctor or health professional recommend a product if a health claim isn't made?*

In the Agency's opinion it would be permitted, but care needs to be taken about context and presentation to ensure that consumers would not see it as a health claim.

39. *Can claims make reference to recommendations of individual doctors or health professionals if they are speaking on behalf of a charity or medical association?*

If it is clear that the recommendation or endorsement is that of the national association of medical, nutrition or dietetic professionals or health related charity, Article 11 would apply. Otherwise, Article 12 would apply.

40. *Can a doctor or health professional provide general healthy eating advice if it is not linked to a branded product?*

The Regulation will only apply to commercial communications. It will therefore depend whether the general healthy eating advice is in a commercial communication and can be construed as a claim making reference to a recommendation of a doctor or health professional. Only in these cases would the prohibition in Article 12(c) will apply. See Section 2.4 for more information about what is and what isn't a commercial communication.

41. *Can a doctor or health professional recommend a branded product that is also making a health claim?*

In the Agency's view this could be permitted, but it must be clear that the recommendation is not seen by consumers as a health claim, or the prohibition in Article 12(c) is likely to apply. Care also needs to be taken to ensure that any other claims made about the nutritional or health benefits of the product should be at a sufficient distance away from the Doctor's name, so as it is not understood by the consumer as a recommendation. You may wish to seek the advice of your local Trading Standards department, as this will be an issue that is subject to interpretation and very dependant on the individual facts of each case.

Remember, any health claim that is made must comply with the requirements of the Regulation outlined in Sections 3 and 5.

42. *Does the Regulation prohibit doctors and health professionals using health claims to recommend branded products in presentations to peers or industry?*

No, the Regulation only controls claims made in commercial communications directed at the final consumer.

43. *Can I refer to research conducted by a doctor or healthcare professional on my product label?*

In the Agency's view this would be permitted, as long as this isn't in the form of a recommendation and any associated claims comply with the requirements of the Regulation. For example, you could say "research conducted by Doctor X / institute X shows that calcium is good for your

bones” as a generic statement, but on a product containing calcium this would be an implied health claim. There would therefore have to be an authorised claim, such as “calcium is good for your bones” and the product must comply with the requirements for making such a claim and the labelling comply with the other general requirements in Sections 3 and 5.

44. *Can I use a celebrity endorsement?*

Celebrity endorsements do not appear to fall within the scope of the prohibition in Article 12(c) (unless the celebrity is a doctor or health professional). However any nutrition or health claim made in a commercial context would need to comply with the requirements of the Regulation in the same way as any other nutrition or health claim.

9.8 – General requirements (Section 3.3 of the guidance)

45. *How will “..in a form that is available to be used by the body...” in Article 5(1) be applied?*

Article 6 of the Regulation requires manufacturers to be in a position to justify the use of the claim. This will require evidence to show that the product contains a significant quantity and that it is available to the body. For example, making a “high in iron” claim on spinach could be misleading to consumers as, although it contains iron, it is likely to fail the test of being able to provide a significant quantity to produce the effect because it contains other substances that make it harder for the body to absorb the iron.

46. *What is a significant amount?*

Where possible this will be as defined by legislation, for example significant amounts for vitamins and minerals are defined in Directive 90/496/EEC and the corresponding Schedule 6 of the Food Labelling Regulations 1996. Where significant amounts are not defined by legislation food business operators are required by Article 5 and 6 of the Regulation to justify the use of the claim. You may want to consider looking at any levels set for any corresponding nutrition claims in the Annex or health claims in the Community Register of authorised health claims, once adopted.

47. *What is meant by the “average consumer”?*

The Regulation does not formally define the average consumer, but Recital paragraph 16 refers to previous adjudications by the European Court of Justice in this area. It will ultimately be for the courts to decide if a claim is understood by the average consumer. As a guide, the average consumer is someone who is reasonably well-informed and reasonably observant and circumspect. The Regulation does highlight that the concept of the average consumer should take into account social,

cultural and linguistic factors and also consider consumers whose characteristics make them particularly vulnerable to misleading claims. It also takes into account products that are aimed at particular groups of the population.

The Unfair Commercial Practices Directive has the same general definition of the average consumer (the average consumer, who is reasonably well informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors). As this is major horizontal EC consumer protection legislation, the courts may take this definition into account if asked to consider more general issues as to whether a consumer is likely to be misled by a claim.

9.9 – Criteria to make claims (Section 4.2 of the guidance)

48. What about claims that relate to a vitamin or mineral that's not in the Annex of Directive 90/496/EEC on nutrition labelling of foodstuffs and where no significant amount is defined?

The general principle to be followed when deciding what is a significant amount is what the scientific substantiation indicates is necessary for the desired effect, and what contribution to the diet the product making the claim would make.

Directive 90/496/EEC on the nutrition labelling for foodstuffs states that only vitamins and minerals contained in the annex may be included as part of the nutrition panel on food labels. The Commission has started the process to review and amend Directive 90/496/EEC, and one of the amendments to be considered is an update to the annex of vitamins and minerals and the setting of associated RDAs with reference to significant amounts. It is the Agency's view that until the annex of Directive 90/496/EEC has been revised and up-dated, claims about vitamins and minerals not included in the Annex can be made.

From 1 July 2007, claims about the vitamin and mineral content of a food must meet the criteria to claim "source of [name of vitamin/s] and/or [name of mineral/s]", or "high in [name of vitamin/s] and/or [name of mineral/s] which are included in the Annex of Regulation 1924/2006 on nutrition and health claims made on foods. Criteria in the Annex include ensuring that the product contains a significant amount of the claimed vitamin or mineral, and refers to Directive 90/496/EEC. This Directive states that 15% of the RDA.... "should be taken into consideration in deciding what is a significant amount". While this might act as a default amount, where there is no RDA the Agency takes the view that until the annex of Directive 90/496/EEC has been revised and up-dated, claims about vitamins and minerals not included here can be made, as long as they can show they are present at an amount that has a benefit to health. Article 3 of Regulation 1924/2006 requires food business operators to ensure that any claims made are not false, ambiguous or misleading and should provide consumers with access to a full nutritional

breakdown of the product so they can make an informed choice. Where a vitamin or mineral claim is made consumers should have information available about the amount of that vitamin or mineral in the product.

49. *If the criteria to make a claim are different under the Food Labelling Regulations 1996, which applies?*

For claims that are in the Annex of the claims Regulation, you will need to comply with those criteria (Article 8(1)). The general transitional period would apply to allow foods placed on the market or labelled prior to 1st July 2007 to be marketed until their expiry date, but no later than 31 July 2009 (Article 28(1)).

Full details of the interactions between the Food Labelling Regulations and the new claims Regulation can be found in Appendix IV.

The Regulation does put in place other transitional periods and in some cases refers to national legislation applying in the interim. In these cases the Food Labelling Regulations will apply.

50. *To make, for example, a “source of calcium” claim, how much calcium does there need to be in each **portion** of my product?*

Article 5 of the Regulation requires a **significant amount** of the nutrient or other substance for which a claim is made to be present in the quantity of the food that can reasonably be expected to be consumed.

For “source of [name of vitamin/s] and/or [name of mineral/s]” claims, the Annex of the Regulation refers food business operators to Directive 90/496/EEC when considering what constitutes a significant amount. This Directive states that 15% of the recommended daily allowance supplied by 100g or 100ml should be taken into consideration when deciding what constitutes a significant amount. The Agency’s interpretation is that this is intended as a guide, since the claims Regulation requires there to be a significant amount present in the amount that can reasonably be expected to be consumed. Ultimately you must ensure that consumers would not be misled by any claims you make. Therefore if you make a claim about the calcium content of a food, the consumer should get 15% of the RDA for calcium, from the amount they could reasonably be expected to consume.

51. *What does “quantity of the product that can reasonably be expected to be consumed” mean?*

This will need to be judged on a case-by-case basis taking into account the type of product. As an example, it is the Agency’s view that it would be unreasonable to require consumers to eat 100g of margarine a day in order to consume the levels of the nutrient needed to make the claim; however, for bread this would be a more acceptable expectation. Again it is important to remember that this requirement aims to protect

consumers from misleading claims and to ensure a significant level of consumption where a claim is made. If a 250ml bottle of fruit juice states that it “contains vitamin C”, is part of a balanced diet where there will be other sources of vitamin C and it is reasonable to expect a consumer to drink that amount as a serving, 15% of the RDA should be present in the 250ml. By contrast, a food presented as a single source of nutrition may need to contain the full daily requirement.

In situations where it is difficult to assess the amount of food that could reasonably be expected to be consumed, for example products such as milk, the Agency would consider it reasonable to ensure that a significant amount is present per 100g or 100ml.

The frequency of consumption should also be considered, especially where claims are based on longer consumption. For example it could be reasonable to make a health claim based on 5 portions of fruit and vegetables a day, whereas for oily fish it may need to be on a weekly basis. It is a requirement of Article 10(2(b)) that health claims are accompanied by a statement indicating the quantity of food and pattern of consumption required to obtain the claimed effect. In the Agency’s view this only becomes a requirement following adoption of the Community Register of health claims, likely to be in January 2010.

52. *If my product is sold as a solid, but consumed as a liquid, and I want to make a claim, which condition, per 100g or per 100ml, would apply?*

Article 5(3) states that the Regulation applies to the food ready for consumption in accordance with the manufacturer’s instructions and so the criteria for a liquid – per 100ml – will apply in this case.

53. *If my product could be sold as a liquid or a solid (e.g. a yoghurt) and the conditions vary per 100g and per 100ml, with which do I comply?*

The reason certain nutrition claims have different criteria for solids and liquids is to take account of different consumption patterns. For example consuming a 330ml can of drink is very different to consuming 330g of food. Bearing this in mind, which criteria should apply will depend on the nature of the product and the levels of consumption and decisions would need to be made on a case-by-case basis. You should consult your Local Authority for further advice on what criteria should be applied to your product.

54. *If I make a claim in a TV advert, do I have to provide nutrition labelling and if so how do I do it?*

The Regulation refers to Directive 90/496/EEC on nutrition labelling for foodstuffs for the requirements on nutrition labelling. This Directive already requires nutrition labelling to be provided where a nutrition claim is made and states what information must be presented and in what

format. In the UK this is implemented by the Food Labelling Regulations 1996. The Regulation requires the same conditions that apply to nutrition claims to also apply to health claims, although group 2 nutrition labelling should be provided in these cases. The Regulation also exempts non-prepacked foodstuff put up for sale to the final consumer, to mass caterers, a foodstuff packed at point of sale at the request of the purchaser or pre-packed with a view to immediate sale, from providing nutrition labelling.

If you make a claim in a TV advert, that falls within the scope of the Regulation (see Section 2), you don't have to provide the nutrition labelling in the advert, but it must appear on the labelling/packaging of the product advertised.

55. *What method do I need to use to measure fibre in order to make a claim?*

There is no legal definition of fibre. The Agency's guidance is that claims relating to fibre content should be based on the Englyst method of analysis, as it is the non-starch polysaccharides (NSP) measured by this method, that have been shown to have a benefit to health. Article 5 requires food business operators to ensure that there is a significant quantity present to have a benefit to health. Any fibre related claims on a product which does not contain non-starch polysaccharides, may mislead consumers about its nutritional benefit.

56. *The conditions for "no added sugar" claims includes "...or any other food used for its sweetening properties". What does this mean?*

This will have to be looked at on a case-by-case basis and will depend on the nature of the product, why ingredients are used and how it is labelled. The name of the product is likely to indicate why the other food is present – as a defining ingredient or as a sweetener. For example in a cranberry juice drink, the use of concentrated grape juice is usually to sweeten the product and is not included in the name; whereas in a mango and apple juice drink, the presence of apple juice is indicated in the name and is not added to sweeten the product (the sweetening effect is likely to be negligible with sweet mango juice).

57. *How much sugar has to be present to trigger the requirement to state "CONTAINS NATURALLY OCCURRING SUGARS" on a product making a "no added sugar" claim?*

The Regulation does not specifically mention how much sugar should be present to trigger the use of this statement. The Regulation does, however, define any product with no more than 0.5g of sugar per 100ml or per 100g as "sugar free". Taking this into consideration it is the Agency's view that only products that contain more than 0.5g of naturally present sugar per 100ml or per 100g should make the statement "CONTAINS NATURALLY OCCURRING SUGARS".

58. *Current legislation on spreadable fats allows “low fat” to be used under conditions not permitted by this Regulation – which applies?*

Recital paragraph 8 clarifies that products that meet the conditions of Regulation (EC) No 2991/94 laying down standards for spreadable fats, can make “low fat” claims that meet the criteria in that legislation. It also states in the recitals of the nutrition and health claims Regulation that the spreadable fats legislation should be adapted to the provisions of that Regulation on nutrition and health claims as soon as possible.

9.9 – Claims not in the Annex of permitted nutrition claims (Section 4.3 of the guidance)

59. *“Diet” is not mentioned in the Annex, can I still use this claim?*

In the Agency’s opinion using “diet” to distinguish one product from another is likely to be seen by consumers to mean the same as “light/lite”, and would need to meet the conditions of use for this claim. However in another context – that of weight control or loss, this would be a health claim.

60. *Omega-3, 6 and 9 claims are not in the Annex. Can I use these?*

For a product to make the claim "contains omega-3" the Regulation requires the product to comply with the conditions of use for the claim "contains [name of nutrient or other substance]" which is in the Annex. The Annex does not currently include the claim "high in omega-3". Article 28(3) allows claims which are not in the Annex, but which were in use before 1 January 2006, to continue to be used until 19 January 2010. The European Commission has already asked EFSA to consider claims relating to omega-3 fatty acids, monounsaturated fat, polyunsaturated fat and unsaturated fat and we therefore anticipate that specific claims relating to omega oils will be added to the list in future. Once specific omega-3 claims are added to the Annex, products will then need to comply with any specific conditions of use stated.

61. *Can I use GI claims?*

GI claims would be covered by the Regulation and unless authorised will only be permitted on the market until January 2010. To ensure these claims can continue to be used after this date they will need to be submitted for authorisation and added to the list of permitted nutrition and/or health claims. For information on getting health claims onto the Community Register of authorised claims please see Section 5.

62. *Can I use low carb claims?*

Low carb claims are currently not in the Annex of permitted nutrition claims. If the claim is not added to the Annex by 19 January 2010 the Regulation will prohibit these claims from being made on food.

63. *“Half fat” is not in the Annex, can I use this claim?*

It is the Agency’s view that “Half fat” is likely to mean the same to the average consumer as a reduced fat claim and products would need to meet with the requirements to make a claim in this category. See Section 4.4 for more details. The general rules in the Trade Descriptions Act 1968 (soon to be replaced by the Consumer Protection from Unfair Trading Regulations), the Food Safety Act 1990 and European Regulation 178/2002 which make it an offence to mislead consumers and give out false information, will apply. In this case it will need to have half the fat of the original (50% less).

64. *Can I make statements such as “90% fat free”?*

No. The Annex to the Regulation specifically prohibits this type of claim.

65. *Can I make multivitamin claims or claims such as “contains vitamins and minerals”?*

Although the Annex contains the claims “source of [name of vitamin/s] and/or [name of mineral/s]” and “high in [name of vitamin/s] and/or [name of mineral/s]”, it does not contain a non-specific vitamin or mineral claim, such as “source of vitamins and minerals”. It is likely that to ensure such claims can continue to be made after January 2010 such a claim will need to be added to the Annex.

66. *How do vitamin and mineral claims relate to multi-vitamin / -mineral supplements?*

It is a legal requirement of Food Labelling Regulations 1996 that foods are labelled with a name and to the extent that wording is necessary to comply with mandatory labelling requirements it is not subject to Regulation 1924/2006. See Section 2.6 for further information.

In addition it is a requirement of Directive 2002/46/EC relating to food supplements that supplements state the names of the categories of nutrients or other substances that characterise the product. It may be that this includes statements about the vitamin or mineral content. In this case it is a mandatory labelling requirement to present this information and does not need to comply with the requirements of the claims Regulation, although the product would need to comply with the requirements of Directive 2002/46/EC. Any additional statements about the vitamin or mineral content that are not required by that Directive would have to comply with the requirements of the claims Regulation.

67. *What about energy claims?*

The Annex of the Regulation already includes nutrition claims for low energy, reduced energy and energy-free and products will need to meet the compositional requirements listed, as well as the general requirements of the Regulation, in order to make these claims.

Claims which relate to a “source of energy” or “high in energy” or “gives you energy” may also be controlled by the Regulation. To decide how the Regulation controls these claims, consideration needs to be given to whether the claim is a nutrition or health claim. In the Agency’s view if the claim relates to the calorie content of the food, and consumers would view it as such, it would be a nutrition claim. However, if it refers to, or would be considered by consumers as relating to, the feeling of energy it provides following consumption, it is a health claim and would have to meet with the requirements in Section 5.

As discussed in Section 2.2, only nutrition claims that refer to the beneficial nutritional properties of a food are controlled by the Regulation. Therefore consideration also needs to be given to the context of any nutrition claim and the target audience. For example it is the Agency’s opinion that on a ready meal for average family consumption “high in calories” is unlikely to be claiming a beneficial nutritional property; however, on a drink aimed at athletes “high in energy” could be.

The Annex of permitted nutrition claims includes the generic claims “contains [name of nutrient or other substance]” and “increased [name of nutrient]”. The Regulation does not control the exact wording of claims but instead gives an example wording and then allows and controls claims which have the same meaning to the consumer. Consideration should be given to whether consumers are likely to view claims referring to energy to mean the same as “contains energy” or “increased energy”, in which case they would have to comply with the generic claims mentioned above. Products making “contains [name of nutrient or other substance]” claims must comply with Article 5 of the Regulation, which states that the nutrient should be present in a significant quantity (see Section 3.3 for details). “Increased [name of nutrient]” claims can only be made where the increase is at least 30% compared to a similar product, and the product meets with the criteria specified in Article 9 (see Section 4.4 for further details).

The Annex of permitted nutrition claims does not contain a specific “high in energy” claim or generic “high [name of nutrient]” claim. Nutrition claims that are not in the Annex, but were in use before 1 January 2006, can continue to be used until 19 January 2010 under transitional arrangements. If the claim has not been added to the Annex after this time it can no longer be used.

68. *Does the Regulation control claims such as “contains wholegrain” or “does not contain hydrogenated fat”?*

It may be possible to differentiate between a nutrition claim and an ingredient claim. Highlighting the presence, reduced content or absence of a nutrient or other substance is clearly covered in the definition of nutrition claim. However, ingredients might be listed in addition to the ingredients list or name of the product for good reason and in this context may fall outside the scope of the Regulation. Please see Section 2.2 for further information.

69. *How do I get a claim added to the Annex?*

The Regulation does not contain a specific application process for submitting nutrition claims, and it is the Agency's understanding that applications should be made directly to the Commission, rather than via a Member State. A decision about inclusion on the list would then be taken by Member States at Standing Committee and would be based on any opinion EFSA may give. For more information please contact the Agency. It would also be helpful if the Agency was kept informed of applications. Contact details for the Agency can be found in Appendix II.

9.11 – Criteria to make comparative claims (Section 4.4 of the guidance)

70. *The Annex of the Regulations requires products making reduced claims to have a 30% reduction compared to a similar product, but Article 9 requires the comparison to be with a range of products, which applies?*

So that consumers are not misled reduced claims should be compared to a range of similar products on the market. This is to prevent a situation where, for example, a product making a reduced sugar claim has more sugar than the majority of similar products on the market. The European Commission has produced guidance to interpretation¹² on this. The comparison must be between the product bearing the claim and a range of other products from the same category, which do not have a composition which allows them to bear a claim, including foods of other brands. In some cases it may only be possible to compare with one product, or within a manufacturer's range the comparator may be the 'standard' product in the range. However, that one product should be representative of other products on the market. For example, to make a reduced sugar claim on lemonade the comparison could be to the full sugar version of the same brand, provided the full sugar version has comparable sugar levels to other lemonades on the market that cannot make a nutrition claim.

71. *Article 9 requires the difference to be stated, how do I do this?*

This can be expressed as either a percentage or an absolute value and an average can be used. More information can be found in Section 4.4.

¹²This guidance can be found at:

http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

72. *It is a requirement that reduced energy and light claims are accompanied by an indication of the characteristics which make the food reduced in its total energy. What does this mean (Section 4.4)?*

In order to meet with this requirement the presentation of the product must explain to consumers how the energy content has been reduced. For example, if the energy has been reduced as a result of the sugar content being lowered this should be made clear to consumers, and in this case the condition that it must be at least 30% less does not apply. In addition “reduced” and “light” claims have to comply with Article 9, which requires the difference in the quantity of a nutrient or other substance to be stated. This has been discussed at the European level and there is agreement that a single indication can fulfil the requirements of both Article 9 and the conditions for using a “light” claim. For example, a label stating “light – 50% less sugar”.

73. *What happens if I make a reduced claim and the comparative product is taken off the market?*

The Regulation requires products making reduced claims to have a 30% reduction compared to similar products on the market. If this condition cannot be met the reduced claim should not be made.

74. *How can I indicate that my product is reformulated if the original product is not on the market?*

The Agency values industry's support of reformulation and is aware that industry wishes to communicate the work they are doing. The Agency would welcome approaches from food business operators wishing to indicate reformulation in line with the Agency's initiative to discuss how best to communicate this. There is the possibility that a specific claim could be added to the Annex in future to allow for these statements, together with other options outside the scope of the Regulation.

75. *Are claims comparing fruit juice to milk, such as “as much calcium as a glass of milk” or supplements to fruit, such as “contains as much vitamin C as an orange” also controlled by Article 9?*

Please see Section 4.4 for information about “as much as” claims.

9.12 – Health claims (Section 2.3 of the guidance)

76. *Will I have to use the exact wording of the permitted health claim?*

The European Commission has indicated that the Regulation will not control the exact wording of health claims covered by Article 13 and Article 14. We therefore anticipate that there will be some flexibility over wording, within conditions where deemed necessary.

77. *If I say “good for you” where does the accompanying claim have to be made?*

Although the Regulation does not specify where the accompanying claim should be made and there is no case law to inform an interpretation, it is the Agency’s view that it should be made clear to consumers why the product is good for them.

9.13 – Process of authorisation

78. *Who in the Commission makes decisions?*

The Commission may take decisions under delegated powers (“comitology”) after an opinion from EFSA and after discussion in and an opinion from the Standing Committee, in accordance with Article 25. The Standing Committee is comprised of representatives from each of the Member States and also of the Commission, and decisions are made by qualified majority voting. Some decisions may also be subject to scrutiny by the European Parliament and referred to the European Council. If either of these bodies feel the decision goes beyond the delegated powers, or does not comply with the aim of the Regulation or the decision is not proportionate, it can be overturned.

79. *Who is the competent Authority in the UK?*

Under the Food Standards Act 1999 the Food Standards Agency is the competent Authority in the UK for the nutrition and health claims Regulation at national level. For matters of local enforcement, the local food authority (including Port Health Authority where relevant) is the competent authority.

80. *Will a claim ever be taken off this list?*

Article 19 of the Regulation does allow for claims to be modified, suspended or revoked based on a further opinion by EFSA. If EFSA, the Commission, or a Member State request that the claim be reconsidered, EFSA will issue a further opinion. This opinion will be made public and the applicant or any member of the public will have 30 days to comment. As with all claims, the Standing Committee will consider if the approved wording or conditions of the claim should be changed, based on EFSA’s assessment.

81. *If I miss the deadline for submitting claims to Member State lists, can I still put forward claims without the full dossier or does it need to go through the process for claims based on new or emerging science?*

Article 13(4) allows for changes to the Community list of authorised claims, based on generally accepted scientific evidence, on the Commission’s own initiative or following a request from a Member State. It is the Agency’s opinion that “changes” includes additions. If you miss

the deadline for Member State lists and the deadline for claims to be submitted to the Commission, the claim can still be submitted in this format, but there is no guarantee a decision will be reached about the claim within the transitional period.

82. *How long will approval of claims based on new or emerging science take?*

Under Article 18 EFSA have five months to produce an opinion once a valid dossier is submitted. This timeframe may be extended by one month if additional information is required. The applicant will have 15 days to submit the required information. If EFSA's opinion is in favour of the claim the Commission will have two months to make a decision. During this time the Commission will consult with Member States. See Appendix V for further details.

83. *If the claim I wish to make has already been rejected can I still apply?*

Yes. The Regulation does not restrict the resubmission of claims, however in order to get a positive opinion you would need to consider what amendments or changes would need to be made to the application, including the submission of new evidence.

84. *How will protected data be indicated on the Community Register of authorised claims?*

The Regulation does not specify how protected data should be indicated. Implementing rules for the application process (Article 15)¹³ and EFSA guidance require protected data – confidential and proprietary data – to be kept separate within the application. This would allow separation of protected data in the case of disclosure. A reference to this is likely to be made in the published summary. You should contact the European Commission for further information about how protected data will be indicated.

9.14 – Nutrient profiles (Section 6.2 of the guidance)

85. *Will nutrient profiles apply to all foods including supplements?*

The nutrient profiles must be established by 19th January 2009. Until the nutrient profiles are agreed it is not possible to tell how they will apply to specific products or food groups. The Commission has indicated that they agree with the interpretation that food supplements should be subject to an exemption from the application of nutrient profiles.

¹³ At the time of publication a proposal to establish implementing rules for the application for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council was due to be adopted. These rules cite the EFSA guidance to be used when making applications.

86. *What will happen if I make a claim, but when the nutrient profiles are adopted my product fails?*

Products that fail the nutrient profile cannot make health claims. It will depend on how the product fails the profile if and how nutrition claims can be made. Full details of the conditions associated with nutrient profiles can be found in Section 6.2. Products that fail the nutrient profile will have two years, following adoption of the profiles, to comply with these conditions. Until the end of the transitional periods the product must comply with the other requirements of the Regulation to make the claim.

9.15 – Transitional periods (Section 7 of the guidance)

87. *What is meant by “foods placed on the market or labelled prior to the date of application” in Article 28(1)?*

The application date of the Regulation was 1st July 2007 and the transitional period in Article 28(1) will apply to items of a product placed on the market or labelled before this date. See Section 6.2 for further information.

“Placed on the market” is defined in European Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as meaning “the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.”

This transitional period allows products placed on the market or labelled prior to the date of application to marketed until their expiry date or 31 July 2009, whichever is earlier. This transitional period is to allow time for existing stock to be sold through. For short shelf life products, although not on the market, the labels and packaging may have already have been produced. To take this into account the transitional period refers to “labelled”. We would advise you contact your local authority for advice on how this transitional period will be applied to your particular product.

88. *How does this apply to nutrition and health claims made in commercial communications other than labels, does the transitional period in Article 28(1) apply?*

The transitional period in Article 28(1) is intended to allow products and labels that were produced before the 1st July time to be used. This aims to prevent a situation where material that had been produced before 1st July, and complied with the legislation at that time, had to be withdrawn on 1st July. Any new material produced on or after the 1st July would need to comply with the requirements of the Regulation to be used.

The Regulation does not specifically mention whether or not this should apply to claims made in other commercial communications. Where possible food business operators must ensure they comply with the requirements of the Regulation.

89. *Is the transitional period in Article 28(1), which refers to nutrient profiles, different to the general transitional period?*

Yes. Under the Regulation nutrient profiles must be developed by 19 January 2009. This transitional period allows products, which do not meet with the nutrient profiles, two years before they must comply with the controls associated with the profile.

90. *What happens if the nutrition claim I want to use has not been added to the list by the end of the transitional period in Article 28(3)?*

At the end of the transitional period nutrition claims which are not in the Annex can no longer be used (Article 28(3)). If you would like a claim added to the Annex please contact the Agency or your trade association for further information (See **Appendix II** for details).

91. *Does the transitional period for trade marks and brand names apply to the product or the brand name or trade mark?*

It applies to the trade mark or brand name. If you are using a trade mark or brand name that is also a nutrition or health claim, and it was in use prior to 1st January 2005, it can continue to be used until 19 January 2022. Any additional claims would need to comply with the requirements of the Regulation.

92. *What if my claim doesn't make it onto the list of health claims based on generally accepted scientific data and I haven't submitted a dossier under the route for claims based on new or emerging science, can I still use the claim?*

If the Community Register of authorised health claims has been adopted and the decision has been reached that the claim, as submitted, should not be included it will no longer be permitted for use on food. A further application can be submitted, under Article 13(5), and if a positive decision is reached, it would then be permitted for use on food.

93. *Why is there no transitional period for disease risk reduction claims and claims referring to children's development and health?*

Transitional periods are in place to provide time for products and claims currently in use to come into line with the requirements of the Regulation. Under current legislation disease risk reduction claims are not permitted to be made on food and so no transitional period was needed.

The controls on claims referring to children's development and health were added late during negotiations to the same provision for disease risk reduction claims and as a result did not have an associated transitional period. This has now been rectified with the adoption of EU Regulation 109/2008. This opens the transition period in Article 28(6) to claims referring to children's development and health.

94. *What if I want to bring a new claim on to the market after 1st July 2007, but before the list of health claims is authorised?*

This will depend on the nature of the claim. If the claim refers to the role of a nutrient or other substance in the growth development and functions of the body, Article 28(5) allows new claims to be used until there is a decision on the authorised list. This applies both to claims that have previously been used on food and claims that have never been used. Unlike other transitional periods this does not require an application for authorisation to be made. During this period the claim would need to comply with the general requirements of the Regulation (see Section 3) and with any national rules that are in place.

After 1st July 2007 new health claims which refer to psychological and behavioural functions, slimming, weight control, reduction in the sense of hunger, an increase in the sense of satiety, a reduction of the available energy from the diet, children's development and health and disease risk reduction claims will not be permitted unless authorised.

95. *Once the list of claims is adopted there doesn't appear to be a transitional period to allow food business operators time to make the necessary changes?*

The Commission is aware that there is no specific transitional period for claims which do not get accepted for inclusion on the Community Register of authorised claims. In the event that products bearing non-authorised claims must be removed from the market, it is advisable you contact your Home Authority for advice.

96. *Which claims can go through the procedures outlined in Article 28(6)(a) of the Regulation?*

Article 28(6)(a) specifies that it is only available for claims which have been the subject of evaluation and authorisation in a Member State and fall into one of the following categories of claims:

- Claims which refer to psychological and behavioural functions, are based on generally accepted scientific evidence, and are well understood by the average consumer.
- Claims which refer to slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet, which are based on

generally accepted scientific evidence and are well understood by the average consumer.

- Claims which are based on newly developed scientific evidence.

There are no such claims in the UK.

Appendix I Associated Legislation and Guidance

Table 3 – Links to the Regulation and other legislation associated with this area of law

Legislation	Website
Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of the European Union on nutrition and health claims made on food	http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf
Trade Descriptions Act 1968 ¹⁴	http://www.opsi.gov.uk/acts/acts1968/pdf/ukpga_19680029_en.pdf
Food Safety Act 1990 (as amended) Food Safety (Northern Ireland) Order 1991	http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900016_en_1.htm http://www.opsi.gov.uk/si/si1991/Uksi_19910762_en_1.htm
Food Labelling Regulations 1996 (as amended), SI No. 1499 Food Labelling Regulations (Northern Ireland) 1996, SR No. 383	http://www.opsi.gov.uk/si/si1996/Uksi_19961499_en_1.htm http://www.opsi.gov.uk/sr/sr1996/Nisir_19960383_en_1.htm
SI No. 2824, Food Labelling Regulations (Amendment) (England) (No.2) Regulations 2004 SSI No. 472, Food Labelling Regulations (Amendment) (Scotland) (No.2) Regulations 2004 NISR No. 469, Food Labelling (Amendment No.2) Regulations (Northern Ireland) 2004 WSI No. 3022, Food Labelling Regulations (Amendment) (Wales) (No.2) Regulations 2004	http://www.opsi.gov.uk/si/si2004/uksi_20042824_en.pdf http://www.opsi.gov.uk/legislation/scotland/ssi2004/ssi_20040472_en.pdf http://www.opsi.gov.uk/sr/sr2004/20040469.htm http://www.opsi.gov.uk/legislation/wales/wsi2004/wsi_20043022_mi.pdf
Directive 89/398/EEC relating to foodstuffs intended for particular nutritional uses. Implemented by: SI No. 181, The Notification of Marketing of Food for Particular Nutritional Uses (England)	http://www.opsi.gov.uk/si/si2007/pdf/uksi_20070181_en.pdf

¹⁴ The relevant parts of this legislation are likely to be replaced in 2008 by the Consumer Protection from Unfair Trading Regulations.

<p>Regulations 2007 SSI No. 37, The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 NISR No. 60, The Notification of Marketing of Food for Particular Nutritional Uses Regulations (Northern Ireland) 2007 WSI No. 1040, The Notification of Marketing of Food for Particular Nutritional Uses (Wales) Regulations 2007</p>	<p>http://www.opsi.gov.uk/legislation/scotland/ssi2007/pdf/ssi_20070037_en.pdf</p> <p>http://www.opsi.gov.uk/sr/sr2007/pdf/nisr_20070060_en.pdf</p> <p>http://www.opsi.gov.uk/legislation/wales/wsi2007/pdf/wsi_20071040_mi.pdf</p>
<p>General Food Regulations 2004, SI No. 3279 General Food Regulations (Northern Ireland) 2004, SR No. 505</p>	<p>http://www.opsi.gov.uk/si/si2004/uksi_20043279_en.pdf</p> <p>http://www.opsi.gov.uk/sr/sr2004/20040505.htm</p>
<p>SI No. 2785, The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 SSI No. 483, The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No.2) Regulations 2007 NISR No. 420, The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007 WSI No. 3165, The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007</p>	<p>http://www.opsi.gov.uk/si/si2007/uksi_20072785_en_1</p> <p>http://www.opsi.gov.uk/legislation/scotland/ssi2007/ssi_20070483_en_1</p> <p>http://www.opsi.gov.uk/sr/sr2007/nisr_20070420_en_1</p> <p>http://www.opsi.gov.uk/legislation/wales/wsi2007/pdf/wsi_20073165_mi.pdf</p>
<p>SI No. 1387, The Food Supplements (England) Regulations 2003 SSI No. 278, The Food Supplements (Scotland) Regulations 2003 NISR No. 273, The Food Supplements Regulations (Northern Ireland) 2003 WSI No. 1719, The Food Supplements (Wales) Regulations 2003</p>	<p>http://www.opsi.gov.uk/si/si2003/20031387.htm</p> <p>http://www.opsi.gov.uk/legislation/scotland/ssi2003/20030278.htm</p> <p>http://www.opsi.gov.uk/sr/sr2003/20030273.htm</p> <p>http://www.opsi.gov.uk/legislation/wales/wsi2003/wsi_20031719_mi.pdf</p>
<p>Regulation (EC) No 2991/94 laying down standards for spreadable fats (as amended by Commission</p>	<p>Reg (EC) 2991/94 http://eur-lex.europa.eu/LexUriServ/LexUriServ</p>

Regulation (EC) No 445/2007)	do?uri=CELEX:31994R2991:EN:HTML Reg (EC) 445/2007 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_106/l_10620070424en00240029.pdf
Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters	http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_097/l_09720040401en00440045.pdf
Regulation (EC) No 107/2008 of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:039:0008:0010:EN:PDF
Regulation (EC) No 109/2008 of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:039:0014:0015:EN:PDF

Table 4 – Links to Agency guidance associated with the above legislation

Legislation	Website address for Guidance
Trade Descriptions Act 1968 ¹⁵	www.dti.gov.uk/ccp/topics1/guide/tda1968.pdf
Food Safety Act 1990 (as amended)	www.food.gov.uk/foodindustry/regulation/foodlawguidebranch/foodlawguidech01/
Food Labelling Regulations 1996 (as amended)	www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/foodlabelregsguid
Food Labelling Regulations (Amendment) (No.2) Regulations 2004 Food Labelling (Amendment No.2) Regulations (Northern Ireland) 2004	www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/foodlabguidance http://www.food.gov.uk/northernireland/niregulation/niguidancenotes/foodlabel
Directive 89/398/EEC relating to foodstuffs intended for particular nutritional uses	www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/parnutsguidancenotes
The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 2007 The Natural Mineral Water, Spring Water and Bottles Drinking Water Regulations (Northern Ireland) 2007	http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/waterguidance http://www.food.gov.uk/multimedia/pdfs/enforcement/waterguideni07.pdf
The Food Supplements Regulations 2003	www.food.gov.uk/foodindustry/guidancenotes/foodguid/foodsupguidance

¹⁵ The relevant parts of this legislation are likely to be replaced in 2008 by the Consumer Protection from Unfair Trading Regulations.

Table 5 – Other guidance referred to in this document

EFSA guidance for the preparation and presentation of the application for authorisation of a health claim (Article 13(5) and Article 14)	http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html
Commission guidance on the implementation of Regulation (EC) No 1924/2006	http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

Appendix II Sources Of Information

- For further information about food standards and safety please visit the Food Standards Agency's website at www.food.gov.uk
- For further information about healthy eating advice please see the Agency's Eatwell website at www.eatwell.gov.uk
- For a copy of the Agency's Guidance on Allergen Management and Consumer Information please see the Agency's website at <http://www.food.gov.uk/multimedia/pdfs/maycontaininguide.pdf>
- For further information about the enforcement of food law please visit the Local Authorities Coordinators of Regulatory Services website at www.lacors.gov.uk
- For further information about what is considered a medicine and their control please visit the Medicines and Healthcare products Regulatory Agency website at www.mhra.gov.uk

For further information and advice on the Regulation or the guidance notes please contact the Agency at:

Fortification and Claims Unit
Nutrition Division
Food Standards Agency
125 Kingsway
London
WC2B 6NH

nutritionandhealthclaims@foodstandards.gsi.gov.uk

Appendix III Glossary

The Agency	The Food Standards Agency
The Annex	The list of permitted nutritional claims and the associated conditions of use. These are in the Annex to the Regulation
Authorised claim	A claim that has been assessed, approved and added to the list of permitted claims.
Claim	Any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics
Commission	European Commission
Community	European Community
Community Register	Centralised source of information about the Regulation, including the list of permitted nutrition and health claims
Community Register of authorised health claims	Centralised list of authorised health claims. Once adopted only health claims on this list, or claims awaiting a decision, can be made on food.
Disease risk reduction claims	A health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease
Dossier	The document containing information relevant to the application for authorisation of a claim
EFSA	European Food Safety Authority (referred to as the Authority in the Regulation)
EU	European Union
Food business operators	The natural or legal persons responsible for ensuring that the requirements of food laws are met within the food business under their control

Health claim	Any claim that states, suggests or implies that a relationship exists between a food category, a food or one of constituents and health
Nutrient	Protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the annex to Directive 90/496/EEC, and substances which belong to or are components of one of those categories
Nutrient profile	A set of nutritional criteria a product must meet to make a claim
Nutrition claim	Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy it provides, provides at a reduced or increased rate, does not provide or the nutrients or other substances it contains, contains in reduced or increased proportions or does not contain
Other substance	A substance other than a nutrient that has a nutritional or physiological effect
PARNUTS	Products for particular nutritional uses, which fall under Directive 89/398/EEC.
Scope	The products and type of claim the Regulation controls
Standing Committee	European Commission's Standing Committee on the Food Chain and Animal Health
Transitional period	A period of time set by the Regulation, during which its requirements will not apply, wholly or in part

Appendix IV UK Legislation Controlling Claims

IV.1 – Overarching legislation

The Food Safety Act 1990 and the General Food Regulations 2004, which enforce the food safety provisions of European Regulation 178/2002, make it an offence to falsely describe a food or provide misleading information regarding its nature, substance or quality. All claims need to comply with this legislation.

IV.2 – The Food Labelling Regulations 1996 (as amended)

Part III, Regulation 40 and 41, Schedule 6 and Schedule 8 of the Food Labelling Regulations 1996 put in place the following requirements on claims;

- Claims that a food has the property of preventing, treating or curing a human disease or any reference to such property are prohibited;
- Nutrition labelling is compulsory on any product for which a nutrition claim is made;
- Schedule 6 sets specific criteria a product must meet to make certain nutrition claims, all of which are included in the Annex of permitted claims in the new European Regulation, which will now apply;
- Schedule 8 sets criteria for other claims including claims relating to alcohol content;

A copy of the Food Labelling Regulations can be found at the following web address:

www.opsi.gov.uk/si/si1996/Uksi_19961499_en_1.htm#tcon

Where there may be any inconsistencies, Regulation 1924/2006 will in general take precedence over the Food Labelling Regulations 1996 and food business operators will need to ensure they comply with its controls. Further details of particular instances where 1924/2006 takes precedence and timescales associated with the new controls are given in Table 6 below.

IV.3 – Joint Health Claims Initiative

The JHCI was a tripartite alliance representing the interests of the consumer movement, the food industry and food law enforcement officers and developed a code of practice on health claims. As the list of authorised health claims, required by the Regulation, is still to be adopted the Agency would still advise manufacturers intending to make health claims to follow the Code of Practice on Health Claims during the associated transitional periods. Further details concerning the Code of Practice on Health Claims and the work of the JHCI can be found at:

www.jhci.org

Table 6 – Regulation 1924/2006 vs Food Labelling Regulations

1924/2006 Article	Food Labelling Regulations (as amended)	Which Applies	Timing
Article 1(2): requirements for non-prepacked foodstuffs	Regulation 29(1)(a): requirement for non-prepacked foods from vending machine	Although 1924/2006 will apply to non-prepackaged foodstuffs in general Regulation 29(1)(a) will continue to apply to non prepacked foodstuffs from vending machines	1 st July 2006
Article 2: definition of nutrition claim	Regulation 2: Definition of a nutrition claim	Both definitions will apply and will dictate what legislation a claim must comply with. Claims which are covered by the definition in Regulation 1924/2006 will need to comply with its requirements. Claims which do not meet with this definition, but do fall under the definition in the Food Labelling Regulations will only need to comply with its controls.	Art 28(1): expiry date, but not later than the 30 th month after entry into force.
Article 4(3): Claims relating to alcohol content	Schedule 8, part 1: Alcohol free Dealcoholised Low alcohol Non-alcoholic	The Food Labelling Regulations will continue to apply	No timescale – continuous
Article 5(3): nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturers instructions	Schedule 6, part II, point 8: Claims which depend on another food	1924/2006 will take precedence in these cases. As well as complying with Article 5(3) claims must also comply with Article 3 and should not be false, ambiguous or misleading.	Art 28(3): for claims on the market prior to the 1 st January 2006, that are not included in the annex, can continue to be used until 19 January 2010.

Annex : Low Energy	Schedule 6, part II, point 2: Low Energy Schedule 8: low calorie on soft drinks	1924/2006 will apply. Although both set the same limit on a per 100gm basis, there are different levels for liquids and also sweeteners. In these cases 1924/2006 will apply	Art 28(1): expiry date, but not later than the 30 th month after entry into force.
Annex: Reduced Energy	Schedule 6, part II, point 2: Reduced Energy	1924/2006 will apply to claims made on all foods including Sweeteners. Products will therefore need to have a 30% reduction, rather than the 25% specified in the Food Labelling Regulations. ¹⁶	Art 28(1): expiry date, but not later than the 30 th month after entry into force.
Annex: Source of protein	Schedule 6, part II, point 3: Source of protein	1924/2006. To be eligible to use this claim products must have at least 12% of the energy provided by protein. Products do not have to have 12g of protein as specified by the Food Labelling Regulations, which is not a requirement of 1924/2006.	Art 28(1): expiry date, but not later than the 30 th month after entry into force.
Annex: High Protein	Schedule 6, part II, point 3: rich excellent source of protein	1924/2006. To be eligible to use this claim products must have at least 20% of the energy provided by protein. Products do not have to have 12g of protein as specified by the Food Labelling Regulations, which is not a requirement of 1924/2006.	Art 28(1): expiry date, but not later than the 30 th month after entry into force
Annex: Source of [name of vitamin/s] and/or	Schedule 6, part II, point 4: Source of [name of vitamin]	1924/2006. to be eligible to use the claim a product must contain a significant amount of	Art 28(1): expiry date, but not later than the

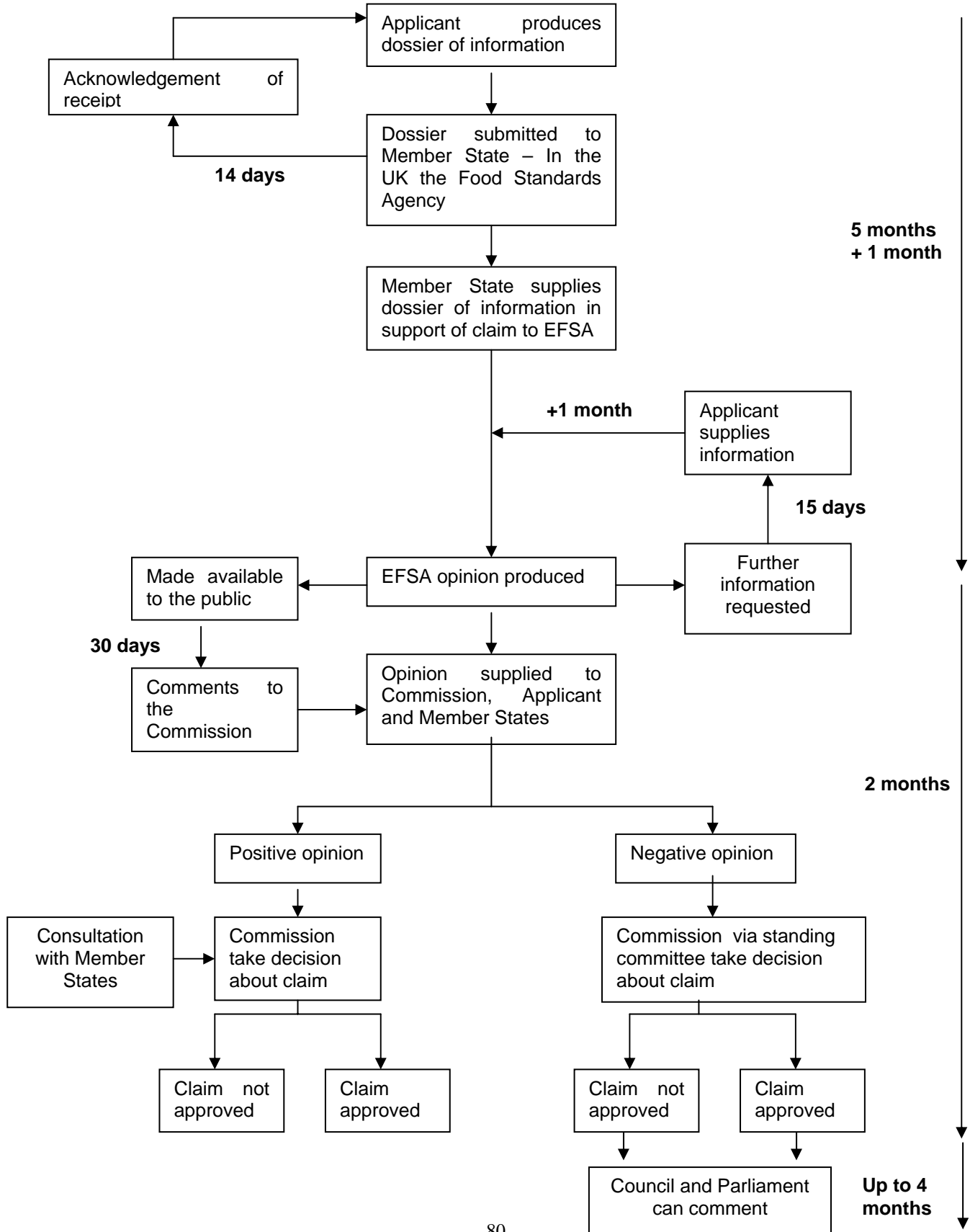
¹⁶ The Commission have indicated that they intend to review the 30% figure with the intention of reducing this to 25% to bring it into line with Codex standards. Please consult either the Agency or your Local Authority for advice.

[mineral/s]	Schedule 6, part II, point 5: Source of [name of mineral]	the vitamin or mineral. For those listed in Directive 90/496/EEC on nutrition labelling of foodstuffs this will be 15% of the RDA. Products will not be required to contain one sixth of the RDA or provide information about the % of the RDA contained in one serving, as required by the Food Labelling Regulations.	30 th month after entry into force
Annex: High in [name of vitamin/s] and/or [mineral/s]	Schedule 6, part II, point 4: Rich or excellent source of [name of vitamin] Schedule 6, part II, point 5: Rich or excellent source of [name of mineral]	1924/2006. To be eligible to use the claim a product must contain at least twice the significant amount of the vitamin or mineral. For those listed in Directive 90/496/EEC on nutrition labelling of foodstuffs this will be 30% of the RDA. Products will not be required to contain 50% of the RDA or provide information about the % of the RDA contained in one serving, as required by the Food Labelling Regulations.	Art 28(1): expiry date, but not later than the 30 th month after entry into force
Annex – no claim	Schedule 6, part II, point 4: rich or excellent source of vitamins Schedule 6, part II, point 5: Rich or excellent source of minerals	FLR initially and then 1924/2006. A generic claim “contains vitamins” or “contains minerals” is currently not in the annex of permitted nutrition claims. If this claim was in use prior to 1 January 2006 the 3 year transitional period in Article 28(3) will apply. During this period the controls in schedule 6 of the Food Labelling Regulations will apply.	Art 28(3): for claims on the market prior to the 1 st January 2006, that are not included in the annex, can continue to be used until 19 January 2010.
Annex – no claim	Schedule 6, part II, point 6: Claim relating to the presence or absence of Cholesterol	FLR initially and then 1924/2006. Claims relating to cholesterol content are currently not in the annex of permitted nutrition claims. If this claim was in use prior to 1 January 2006 the 3	Art 28(3): for claims on the market prior to the 1 st January 2006, that are not included in the

		year transitional period in Article 28(3) will apply. During this period the controls in schedule 6 of the Food Labelling Regulations will apply.	annex, can continue to be used until 19 January 2010.
Annex – no claim	Schedule 8, part 1: Starch reduced	FLR initially and then 1924/2006. The claim “starch reduced” is currently not in the annex of permitted nutrition claims. If this claim was in use prior to 1 January 2006 the 3 year transitional period in Article 28(3) will apply. During this period the controls in schedule 8 of the Food Labelling Regulations will apply.	Art 28(3): for claims on the market prior to the 1 st January 2006, that are not included in the annex, can continue to be used until 19 January 2010.

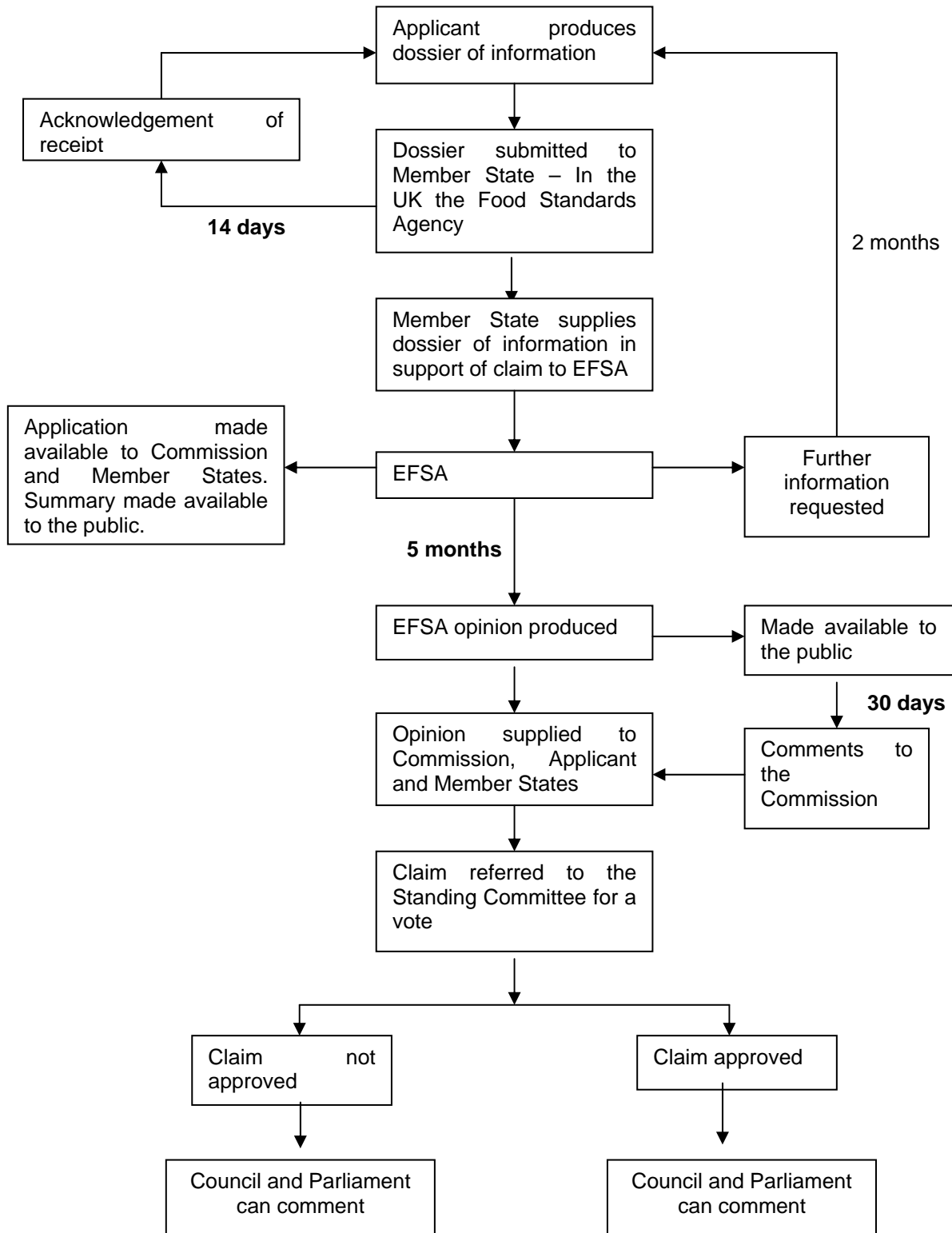
Appendix V

Flow Chart Showing Process Of Authorisation Of Health Claims Based On New Or Emerging Science



Appendix VI

Flow Chart Showing Process Of Authorisation For Disease Risk Reduction Claims and Claims Referring To Children's Development and Health



Appendix VIII Interested Parties List

The Agency holds electronic databases of contacts who wish to receive information from us on particular issues. These databases are confidential and are only used to contact you about issues that may be of importance to you.

If you wish to receive further information and up-dates on any of the following please tick the relevant box(es) and fill in your details and return to the address below.

- Nutrition claims
- Health claims
- Development of nutrient profiles
- Charity and health association endorsements

Name:.....

Company:.....

Address:.....

.....

Postcode:.....

E-mail address:.....

Telephone number:.....

Fax number:.....

Where possible the Agency will contact you by e-mail to save valuable resources. If you do not want to be contacted by e-mail please tick the following box and we will contact you by post .

If you are already on our interested parties list but wish to up-date your details or subject areas for which you receive information please fill in the above. If you want any previous details to be removed please fill in the following section*.

Details to be removed from our interested parties list:

Name:.....

Company:.....

Address:.....

.....

Postcode:.....

E-mail address:.....

Telephone number:.....

Fax number:.....

* Please note that if you no longer wish to receive up-dates your details will only be removed from the lists that apply to nutrition and health claims.

Please return to:

Fortification and Claims Unit
Nutrition Division
Food Standards Agency
125 Kingsway
London
WC2B 6NH

nutritionandhealthclaims@foodstandards.gsi.gov.uk