FDF COMMENTARY IN RESPONSE TO EC DISCUSSION PAPER (SANCO/1341/2001) ON NUTRITION CLAIMS AND FUNCTIONAL CLAIMS

1. EXECUTIVE SUMMARY

(i) FDF welcomes this Discussion Paper as a step towards clarification of the status of Nutrition and Functional Claims. Although the Commission states in the preamble that Health Claims will be the subject of a further Discussion Paper at a later stage, FDF believes that it is difficult to separate discussion on Nutrition and Functional Claims from discussion on Health Claims, in particular Disease Risk Reduction Claims. **We therefore urge that the scope of this document and any future provisions should cover all types of such claims, including Health Claims**.

(ii) **FDF supports the development of a common framework and rules on claims at European level, to ensure harmonisation and consistency of approach.** Harmonised rules should be incorporated within existing legislation such as the Labelling Directive (2000/13) and Nutrition Labelling Directive (90/496/EEC), and should take into account the principles of the Misleading Advertising Directive. It should not be in contradiction to other legislation such as the Medicinal Products Directive (65/65/EEC).

(iii) **Once their scientific validity has been established, claims should be able to express clearly and more directly the increasing knowledge about relationships between foods or food components and human health now being documented, through research**. The incorporation of nutrition research into food product design has a long and responsible record; the current and future research on reducing risk of disease and optimisation of human performance will no doubt create further opportunities for innovative product development for the ultimate benefit of consumers.

(iv) Claims for the types of attributes covered in the Discussion Paper, where permitted, are already made by industry, subject to specific legal provisions where established. **We consider that any rules on the use of such terms as may be proposed must be applied equally to all foods, regardless of their composition; the type of outlet from which they are sold; or whether or not they are pre-packed; and should be efficient, transparent, proportionate and predictable**.

(v) Given the complexity of this spectrum of claims and the practicalities of product labelling and marketing:

- **We have serious reservations about the use of a regulatory prior approval process for any claim;**
- **We believe that a process for obtaining pre-marketing advice addressing the legality and substantiation of certain claims, such as that offered by the UK Joint Health Claims Initiative (JHCI), may be helpful to consumers, industry and enforcement authorities alike.**

(vii) **An effective approach to the development of harmonised EU rules on claims should facilitate the provision of clear, understandable, relevant and consistent information to assist consumers to select foods in composing their diet or to follow recommended diets**. More specifically, it should:

- help consumers in the selection of foods at point of purchase;
- aid comparison between products;
- be applicable to all relevant categories of foodstuffs;
- ensure that the information does not over-emphasise or distort the role of a single food or component in promoting a healthy, balanced diet;
- ensure a consistent framework and provide necessary controls for fair trading and competition;
- permit product innovation;
- encourage confidence in the food supply;
- be capable of being applied at European level;

It also should ensure that such claims are:

- justifiable in terms of nutritional significance;
- quantifiable;
- capable of substantiation; and
- enforceable.

2. GENERAL COMMENTS

The Commission has invited comments in particular on three key aspects – **definitions; conditions under which claims may be made;** and **evaluation/authorisation**. Our views on each of these are summarised below and are expanded in specific, detailed comments on the individual paragraphs.

2.1 DEFINITIONS

Nutrition Claims, Functional Claims, Disease Risk Reduction Claims and Health Claims are closely and progressively related and are, in practice, part of a continuum. It is therefore questionable whether a statutory framework of definitions and rules for each category is either appropriate or even practicable. Such an approach would require the types of claims to be clearly and unambiguously defined, introducing artificial boundaries between potentially very similar claims. Unless these artificial boundaries are absolutely clear and precise, there will either be areas of overlap or, worse, gaps between the categories. Equally, claims close to, but on opposite sides of, the boundary, may be more similar than claims that lie at either end of a defined category. Legally, therefore, such definitions may become difficult to enforce.

Significantly, the UK Joint Health Claims Initiative (JHCI) went through just this debate some 4 years ago and concluded that there was little point in developing a complex "taxonomy" of claims when the important issue was ensuring that they were substantiated and conformed to specified principles. Consumers are not interested in the category of claim, only that it is truthful. There is, nevertheless, a clear need to have **uniform understanding, terminology and descriptions** of the types of claims to provide clarity in communication and presentation of the concepts and, particularly, in regard to the nature and extent of scientific substantiation that will ultimately be required. Descriptions that would be most appropriate are likely to be based on the experience developed internationally through Codex. The concepts elaborated by the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE)[1] project could also provide guidance. As a common definition for the generic term "claim", FDF would therefore support that of Codex[2]: "a claim is any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality".

Furthermore, we believe there are two broad categories of claims: (i) **Nutrient Content Claims** (i.e. "**What the product contains**"); and (ii) **Functional (including Health) Claims** (i.e. "**What the product, or components of the product, do/does**"):

(i) **Nutrient Content Claims.** These are factual statements that draw consumers' attention to an aspect of the product's nutrient content that may be of interest and benefit to them (e.g. "low fat" or "high fibre"). This might signal a change from the manufacturer's standard product or from the standard product of a competitor; or it may be that the product is particularly high or low in a specific nutrient, which would make that product of interest to groups of consumers seeking to increase or reduce their intake of that nutrient.

[1] British Journal of Nutrition (1999). *Scientific Concepts of Functional Foods in Europe: Consensus Document.* Vol 81 (Suppl. 1). CABI: London.

[2] The Codex General Guidelines on Claims adopted by the Codex Alimentarius Commission at its 13th Session, 1979. A revised version was adopted by the 19th Session of the Codex Commission in 1991.

(ii) **Functional (including Health) Claims**. In the context of the present debate, FDF would consider this category to encompass the following types of claims:

- Claims that promote the role of a nutrient in its broadest understanding (see further comments **Paragraphs 16 and 17**) in the normal physiological functions of the body, e.g. "calcium is needed to build strong bones and teeth". These claims are based on well-established and generally accepted scientific knowledge and are commonly referred to as Nutrient Function Claims.

- Claims that refer to official recommendations for healthy eating patterns, dietary guidelines or similar publications (e.g. "eat more oily fish for a healthy lifestyle"). Several national authorities have published recommendations on healthy eating patterns and others may do so in the future. Such claims are commonly referred to as Claims Related to Healthy Eating Patterns.

- Claims that refer to a specific health-related effect of a food or any of its constituents on the body, on a physiological function or on a biological parameter or indices of physiological, psychological or physical performance, e.g. "X helps improve gut function". Beneficial health effects of ingredients and non-nutritive substances are included. Diseases or disorders are not named. Such claims are commonly referred to as Enhanced Function Claims or Claims for Nutrient, Ingredient or Non-Nutritional Substance Related to Health Effects.

- Claims that refer to the fact that the consumption of a food may help to reduce the risk of a disease, "X can help to reduce the risk of heart disease" because the food contains nutrients or other substances the efficacy of which is known or can be proven. The disease or disorder is named and the risk reduction explicitly stated. Such claims commonly referred to as Claims Related to the Reduction of a Disease Risk, are currently illegal under the UK interpretation of labelling legislation.

2.2 CONDITIONS UNDER WHICH CLAIMS MAY BE MADE

With the Completion of the Single Market in 1992, European trade in foodstuffs has increased considerably and many food products are now traded throughout Europe, with the resulting requirement for harmonisation of legislation relating to composition and labelling. To exercise choice, consumers need to be well informed about the products they buy. Labelling is the usual means of providing this information; it is subject to laws which ensure that it is accurate, truthful, sufficient and not misleading (Labelling Directive 2000/13); more specific additional requirements on nutrition labelling are provided by the Nutrition Labelling Directive (90/496/EEC). In particular, the Nutrition Labelling Directive makes the provision of nutrition information compulsory if a nutrition claim is made about the product; and the same prescribed format must be used if nutrition information is given voluntarily.

The Labelling Directive in general provides that:

> "The labelling and methods used must not: (a) be such as could mislead the purchaser to a material degree, particularly: ..... (iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics." Article 2. 1. (a) (iii)

The proposed Regulation on general principles of food law etc (Article 8) provides that food law "shall aim at the prevention of:

a) fraudulent or deceptive practices;
b) the adulteration of food; and
c) any other practices which may mislead the consumer"

It further provides (Article 15a – presentation) that "..the labelling, advertising and presentation of food …..shall not mislead consumers."

Furthermore, all claims on food are already subject in the UK to the general provisions of the Food Safety Act (1990), which makes it an offence to falsely describe a food or to mislead as to its nature, substance or quality, and to the Trade Descriptions Act (1968), which prohibits trade descriptions, which are false to a material degree.

It is against this extensive legislative framework, that the need for any further measures should be evaluated.

As identified in the UK 's Food Advisory Committee's review[3], general labelling principles are applicable to the use of all food-related claims, such that:

- "foods should be sold without deceit and should be so labelled and advertised as to enable a prospective purchaser to make a fair and informed choice, based on clear and informative labelling;
- a food must be able to fulfil the claim being made for it and adequate information must be available to show that the claim is justified;
- where a claim is potentially ambiguous or imprecise, the likely understanding of an average consumer should prevail;
- controls should protect both consumers and honest traders;
- controls should allow fair comparison and competition between products, sectors and traders;
- if consumer and trader interests conflict" (and FDF believes such instances would be rare), "the interests of consumers must take precedence".

In addition to basic information given on labels and in advertisements (e.g. composition and storage instructions), manufacturers, retailers and caterers legitimately make a wide variety of claims about their products to draw consumers' attention to particular attributes or to distinguish between products. Such claims can play an important part in influencing consumer choice. Information or material that seeks to mislead consumers should be prohibited. We recognise that enforcement will always be difficult, and potentially contentious, in any subjective area and accordingly would support the development of appropriate guidance to enable a consistent approach to be taken by the enforcement authorities.

[3] FAC Review of the Use of Terms Fresh, Pure, Natural etc. in Food Labelling 2001. Food Standards Agency (July 2001). FSA/0334/0701.

2.3 EVALUATION/AUTHORISATION

FDF believes that all types of claims must be considered within the current review. Whatever form of control is ultimately put in place must be applicable to all claims within the Nutrient Content to Health Claims spectrum, with perhaps different degrees of scrutiny being required according to where in the spectrum a particular claim lies. The form of evaluation, authorisation and control should therefore be considered for all categories of claims from the outset. There appear to be three options that merit further careful consideration and FDF looks forward to contributing to further discussions on the suitability of each.

(i) Statutory provisions for each type of claim determined by the category into which the claim is allocated.

(ii) A voluntary co-regulatory approach, i.e. a statutory framework setting out the general principles, leaving the detail to Codes of Practice developed by the key stakeholders (industry, consumers and enforcement authorities).

(iii) A mixed approach whereby statutory provisions will be established for certain types of claims (e.g. Nutrient Content Claims), and a voluntary co-regulatory approach will apply to others (e.g. Health Claims).

Based on our experience to date, we favour option (iii).

3. SPECIFIC COMMENTS

INTRODUCTION

Paragraph 1

In the interests of consumer protection and fair trade, **FDF agrees that it is important that claims are true, accurate and not misleading**. **We support the concepts, enshrined in the Nutrition Labelling Directive (90/496/EEC) that nutrition information should be simple and easily understood.** Furthermore, information provided on pack about foodstuffs and their nutritional value should be presented in an understandable and usable format.

Paragraph 2

See our views on harmonisation of rules on claims, and existing legislative framework, in the EXECUTIVE SUMMARY and GENERAL COMMENTS. Regulations concerning Nutrient Content Claims vary from one country to another and problems may arise for food manufacturers and enforcement authorities owing to the lack of harmonisation. There is also potential for consumer confusion if terminology is not well defined. The Directives on Labelling and Nutrition Labelling are only applicable, in practice, to pre-packed food and consideration needs to be given to increasing EU harmonisation on consumer information on foods sold loose. There is other legislation at national and EU level relating to Misleading Advertising and to Medicines that is also applicable to the issue of food claims. It is the legally unavoidable (at the present time) contradictions between the law relating foods and medicines - highlighted by a number of ECJ rulings - that is the root cause of the current difficulties with 'health' claims on foods. Clearly "proper enforcement" will be very difficult unless, and until, these contradictions are eliminated. **On balance, we agree with the sentiment expressed by the Commission that a more consistent interpretation and enforcement of the existing rules, across and between Member States, would have prevented much, if not all, of the present confusion. We recognise that enforcement will always be difficult and potentially contentious in any subjective area and accordingly would support the development of appropriate guidance to enable a consistent approach to be taken by the enforcement authorities.**

Paragraph 3

Paragraph 1, of the Commission Discussion Paper, rightly points out that consumers "are more interested in their diet, its relationship to health, and more generally, the composition of foodstuffs they are selecting". **It is logical and appropriate for food manufacturers and retailers to convey these benefits to consumers. Once their scientific validity has been established, claims should be able to express clearly and more directly the increasing variety of relationships between foods or food components and human health now being documented by research.** Also see comments above on 2.2 CONDITIONS UNDER WHICH CLAIMS MAY BE MADE.

Paragraph 4

Extensive discussion of claims is already taking place and we are aware that the issue is a topic of major interest in most Member States, some of which are known to be developing regulatory proposals. **Different approaches are likely to lead to barriers to trade and distortions in the Single Market, and indeed in trade on a wider, global basis. We therefore agree that it is**

important to secure a harmonised approach. However, we would question the Commission's assertion that "a high level of consumer and public health" is being put at risk by current practice. Also see our comments concerning harmonisation of rules and existing legislative framework under EXECUTIVE SUMMARY and GENERAL COMMENTS.

Paragraph 5

Our comments on EXECUTIVE SUMMARY and 2.1 DEFINITIONS are relevant to this section.

GENERAL CONSIDERATIONS

Paragraph 6

Within any potential legal framework, it would be necessary to consider precisely what is meant by "all similar products" and to what extent the presence of a low level of any particular beneficial ingredient -naturally or by deliberate addition- would change consumers' and/or legal perceptions of a given food. **We note that an over-rigid interpretation of such a provision could preclude the benefits of broad categories of wholesome foods from being conveyed to consumers, e.g. calcium in milk or fibre and micronutrients in cereals. It is important to allow flexibility in the making of claims, as long as these are truthful, accurate and not misleading.** Claims should not overstate benefits or imply that a balanced diet of ordinary foods cannot supply adequate amounts of all essential nutrients. Industry recognises that the most important factor influencing the development of a food claiming a positive effect on health is consumer perception and acceptance. If a consumer is not interested, or does not believe in the product's ability to provide the stated benefit, the product will not succeed. **The concept of foods which claim to have a positive effect on health is now generally accepted in many countries, and hence it is important that any special health benefits can be communicated to the public otherwise there is little point in developing and marketing the product.** Also see comments on 2.2 CONDITIONS UNDER WHICH CLAIMS CAN BE MADE.

Paragraph 7

We agree with the provision that "claims made on specific foods" should "not imply that a varied and adequate diet cannot provide sufficient quantities of nutrients" nor emphasise "the presence or absence of a nutrient or other substance or ingredient" as a special characteristic when in fact it is common to all similar products with the exception of certain nutrients (e.g. folic acid), where an adequate and varied diet cannot provide sufficient quantities. We note that with beneficial influences of food constituents progressively being uncovered, it will be important to take account of developments in science and to allow the responsible provision of appropriate information, for the benefit of consumers. It may be necessary to refer to other "lifestyle" parameters.

Paragraph 8

Care will need to be taken in seeking to address the communication and presentation of claims on a statutory basis. We believe that the totality of any message must be taken into account when considering whether it may be misleading (to a material degree) and whether the product is able to deliver what is claimed. **We do not believe it will be possible to legislate for all the details of every potential claim, particularly where it is the consumers' subjective perception that is critical to the concept of "implied" claims.** The inference to be drawn by an individual

consumer from the use of particular words, logos and images will differ according to the nature of the claim, their existing knowledge and understanding about the potential benefits of a particular food and the overall, subjective effect of the communication in the context of the surrounding circumstances. **Accordingly, we believe that prescribed or set wording for claims is inappropriate, inflexible and may not give consumers the most useful information.** We acknowledge that information provided on labelling and in advertising, especially on television, is by its nature limited by the time and space available. The importance of providing additional information and education opportunities, is critical to ensuring people understand nutrition information and claims. Industry uses other means to provide additional information, for example point-of sale leaflets, consumer care-lines and websites. There is also an onus on the Community and Member State Governments to invest in improved consumer education as a general approach to ensuring that improved food choice will lead to enhanced nutritional status.

Paragraph 9

We refute completely the concept that individual foods can be classified as "good" or "bad". Products containing ingredients with a potential beneficial effect may also contain levels of other ingredients not generally regarded as likely to make a significant contribution to a healthier diet. However, if eaten as part of an overall balanced diet, such products can still have a beneficial effect on an individual's health. **We do not therefore accept that 'nutritional standards' can or should be applied to individual products. From a nutritional point of view, the composition of individual foods is relatively unimportant. What matters is the nutrient content and overall balance of the diet of individuals as a whole, over time.** Furthermore, we note that the majority of UK manufacturers already provide nutrition information about their products, either voluntarily or to meet the requirements of the Nutrition Labelling Directive when a claim is made. This enables consumers to make an informed choice in selecting products according to their particular dietary needs or specific taste preferences. Information may also be provided to individual consumers "off-label", for example by way of leaflets, care-lines and websites.

Paragraph 10

We agree that any component for which a claim is made must be present in a quantity (whether naturally present, added, augmented or reduced) to enable the claim to be fulfilled throughout the declared minimum durability period of the food concerned. However, there is need to recognise the factors that may contribute to the precision of declared quantities and of which account needs to be taken where relevant, as follows:

- Raw materials: composition influenced by geography, climate, season, breed, variety, agricultural practice and preparation.
- Process effects e.g. attributable to heating, mixing, metering.
- Ingredient interactions.
- Product heterogeneity e.g. multi-component products, complete meals.
- Product seasonality e.g. harder fats in summer months.
- Storage/distribution e.g. thermal effects (constituent migration, degradation) physical effects (separation, desiccation).
- Preparation differences where the declaration relates to the product after domestic preparation, ready for consumption.
- Sampling error.
- Clarity of analytical definition and analytical methodology.
- Analytical error.

- Within and between laboratory variation.

Nutrient bioavailability may also, need to be taken into account. However, we note that in practice this is highly complex and difficult to implement. It can depend on an individual's dietary status, the combination of foods being consumed and the specific nutrient under consideration. Iron is a good example whereby consumption with phytate, can reduce bioavailability, and consumption with ascorbic acid, can enhance it.

Paragraph 11

The criteria for claims in this respect should be the same as for nutrition labelling in general as set out in the Nutrition Labelling Directive:

> "The amounts mentioned shall be those of the food as sold. Where appropriate, this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption" [Article 6 (4.)]

DEFINITION OF THE TERM CLAIM

Paragraphs 12 to 14

See our comments on 2.1 DEFINITIONS.

Paragraph 15

We agree with the observation that the different types of claims may overlap and recognise that the average consumer may not draw a clear distinction between different types of claims. Consumers tend not to be interested in the category of claim, only that it is truthful and accurate. Our comments on 2.1 DEFINITIONS are also relevant to this section.

NUTRITION CLAIMS

Paragraphs 16 and 17

The current definition of a "nutrition claim" is provided by the Nutrition Labelling Directive (90/496/EEC): "any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it provides, at a reduced or increased rate or does not provide; and/or due to the nutrients it contains, in reduced or increased proportions or does not contain". It is substantially dependent on the term "nutrient" but, to date, **has adequately served the purpose of defining when quantitative "nutrition information" is required by law to appear on a food label. However, as the Commission paper recognises, an increasing number of other substances that are not currently regarded as classical nutrients are being identified as beneficial and are increasingly the subject of claims. To ensure an unambiguous framework for the future control of all types of "nutrition" and "function" claims, we believe it is necessary to consider "nutrient" in its broadest sense. That is to encompass all the foods, ingredients and their components that are increasingly being shown to play a significant role in bodily development and maintenance, and the maintenance of health, including the avoidance of disease.**

In order to take account of developments in science and the identification of additional elements in the diet (e.g. phytochemicals) that may be beneficial to the consumer, **it is important that the declarable components listed in the Nutrition Labelling Directive can be appropriately and readily augmented**. It may be useful to consider the development of a list of nutrients and components, within the Nutrition Labelling Directive, containing**:**

- the vitamins and minerals currently listed in the Annex;
- the components listed in Article 4 of the Directive (e.g. starch, polyols); and
- other components in the diet that may be useful to the consumer.

This would allow manufacturers to make a claim on one or more items of this list, always provided that a Group 1 or 2 declaration was also given. There is a need for a mechanism whereby the list can be reviewed and augmented in a timely way, perhaps by placing the list in an Annex that could be amended by Standing Committee procedure.

Paragraph 18

In the development of clear and simple rules concerning the use of nutrition claims, it will be important to take into account both existing guidelines in Member States, e.g. the UK Food Advisory Committee[4], and the Codex Alimentarius Guidelines. FDF has not commented on the detail of the Annex at this stage. However, we note a typographical error, under *FAT-FREE/WITHOUT FAT*. The Codex guideline is not more than 0.5g per 100g (solids) or 100ml (liquids), and not "0.15g" as stated.

DIFFERENT TYPES OF NUTRITION CLAIMS:

Paragraph 19

Nutrition claims currently in use fall into two broad groups:

(i) "Absolute" claims, e.g. "a low fat food", "a high fibre food"; and
(ii) "Comparative" claims, e.g. "a reduced fat sausage", "a biscuit with increased fibre".

The second group, "comparative claims", can be further broken down into claims for:

a.	high in (or rich in/low in)	)	
b.	reduced (or light/lite; increased)	)	of any nutrient
c.	more/less	)	

FDF has previously suggested that the threshold at which each of the above three terms of "comparative" claim would be triggered, should be, respectively:

a. an increase (or reduction) of at least 50%
b. an increase (or reduction) of at least 25%
c. an increase (or reduction) which is "nutritionally significant" (i.e. at least 10%).

[4] JFSSG (November 1999). Guidelines for the use of certain nutrition claims in food labelling and advertising. Based on recommendations made by the Food Advisory Committee.

The "comparative" approach recognises that consumers seeking to make changes to their diet may do so in two ways: by quantifying the amount of energy or particular nutrient as a daily consumption target; or by choosing reduced/increased options of particular products as a means to an overall shift in the nutrient content pattern of their diet. Consumer research indicates that a combination of these methods is generally used.

FDF suggests that standardisation in the percentage thresholds for increase or reduction in nutrient content would encourage order in the marketplace and, if properly communicated to consumers, would reduce confusion. We do not accept that reduced and light/lite are, or should be considered as, synonymous. The term "reduced" is the corollary of "increased" and should be subject to the same numerical criteria as may be established. The description "light" relates to a wider spectrum of parameters (see comments on **paragraphs 21 and 22**) but should be subject to the criteria for "reduced" if used with that meaning.

Paragraph 20

If claims such as "**Contains 10% less fat",** "**Without added salt/sodium**" or "**No added sugars**" are made, they trigger a requirement for nutrition labelling information. **We are firmly of the opinion that, as a general principle, any true statement should be permitted providing that it is not likely to mislead the consumer.** In this respect, therefore, we believe that quantified claims of the form "contains X% more / less" must continue to be allowed, where X is a verifiable, measurable and nutritionally significant amount (e.g. at least 10%). The generic terms "increased / reduced" would be reserved for a specified minimum change of, for example 25% (see **paragraph 19** above). **Statements such as "No added…" and "Free from…" are not restricted in their use to nutrients and should be interpreted in their literal sense. If they are untrue, they are illegal, whatever the subject of the claim.**

Paragraph 21

The expression **"light" (or "lite")** has a wider usage than in nutrition-related claims, some of which may be considered to be potentially misleading, others are wholly legitimate. It is often used to imply that a product is a 'healthier' version of a standard one, but it is frequently unclear how the traditional product has been adjusted – if at all. It may be used to describe the taste of a product and has been used to describe a lightly carbonated mineral water. **We note that if "light" (or "lite") is to be constrained as a labelling term, care will be needed to avoid unwittingly prohibiting contexts in which the term is of descriptive value e.g. light texture, light colour. We agree that the characteristic to which the "light" (or "lite") refers should always be stated or clarified on a label or advertisement if there is likely to be any confusion in the mind of a consumer.**

It is of note that the term "light" is permissible under the Regulation on spreadable fats (2991/94)[5] for products with less than 41% fat. The term has been used throughout the EU since the mid-1960s and consumers are therefore familiar with it. We fully support the retention of the possibility to use the term "light" in this context.

[5] Council Regulation (EC) No. 2991/94 laying down standards for spreadable fats.

Paragraph 22

The term **"diet"** is a linguistic issue that varies from country to country. In the UK and Ireland we know that consumers understand a "diet" soft drink to indicate a low- or reduced-calorie (e.g. low sugar) version, not a "dietary" product intended for use by only a certain sector of the population. **Whilst we appreciate that the term "diet" may have different connotations in other languages, we would want to retain the flexibility to use "diet" as a descriptor in the UK and other countries where it is understood in the same way.**

Paragraph 23

We support the principal that for comparative claims it should be made clear which products are being compared. However we do not believe the comparative product has to be the same brand as long as it is in the same category. The basis for comparative claims is clearly fundamental to the concept. Where a 'same brand' standard product already exists, the basis for comparison is straightforward. Where other 'standard' products exist, made by a different manufacturer, it remains legitimate for a new product to be compared against the existing product. Furthermore, if a manufacturer chooses to select particular variants of the traditional ingredients (e.g. lower fat, salt or sugar), it should remain acceptable to describe the finished, new product accordingly subject to the general requirement in terms of accuracy etc.

It is of note that "Reduced", in the context of spreadable fats, is also allowable under Regulation 2991/94[6] if the fat content is more than 41%, but not more than 62%. We support the continuance of this practice.

Paragraphs 24 and 25

FDF agrees that misconceptions surrounding dietary cholesterol exist. This is a matter for public information/education rather than a food labelling issue. In relation to such claims, we believe that:

- **"cholesterol content" claims have a place in the range of allowable claims. It is of note however that members of the UK Margarine and Spreads Association do not make, or make reference to, "low in cholesterol" or "cholesterol free" claims.**
- **"cholesterol lowering claims" should be permitted as long as these are justifiable and capable of substantiation.**

Paragraph 26

We understood – and support - that low/very low sodium products have been removed from the Annex of the Parnuts[7] Directive (89/398/EEC). We believe that claims relating to the sodium / salt content should be generally permitted in accordance with the general rules for other nutrients. However, we note that the low sodium criteria of 0.04g/ 100g of product is too low to be of use on manufactured foods and can only really apply to foodstuffs such as fruits and vegetables. As such, it does not help consumers to choose lower sodium products. We feel consideration should be given to developing a higher limit that could be applied in a meaningful way to help the consumer select products according to their particular dietary needs or individual taste preferences. The widespread public confusion between sodium and salt is primarily a matter

[6] Annex to Council Regulation (EC) No. 2991/94 laying down standards for spreadable fats.
[7] Council Directive (89/398/EEC) relating to food stuffs intended for particular nutritional uses.

for the medical and public authorities to address. **We believe that food labelling aspects should be related to the sodium content, rather than the derived theoretical 'salt equivalent' values, in order to avoid further public confusion, particularly in cases where foods do not contain any added salt but may contain significant amounts of sodium from other sources. This issue has been discussed in detail in the UK.**

Paragraph 27

We agree that every food has a function and believe that there is no justification for creating a separate category of "functional foods". 'Functional Claims' are valid for all foods and the creation of a separate category of 'Functional Foods' would be unjustified and only lead to confusion. **We further believe that any rules on claims should apply, as a matter of principle, to all foods, including foods for particular nutritional uses (Parnuts Directive (89/398/EEC)).**

Paragraph 28

We consider that the increasing use of "X% fat free" on higher and higher fat foods to be potentially misleading and support the Commission paper and the UK FAC recommendations that such claims should not be used, unless the products concerned meet the requirements for a low fat food, e.g. <3% fat. For foods with fat content above 3%, the "**less than X% fat**" and "**only X% fat**" should be permitted as a means of drawing consumers' attention to the fat content. However it would not be acceptable to use the "**only X% fat**" wording if the fat content of the product was greater than the average of other similar products with which it might reasonably be compared.

Paragraph 29

We accept that it is misleading to claim that a food is "Free from X" or contains "No Added Y" when such presence or addition is forbidden by law. We also have reservation about the use of the latter type of claim when the product contains the component, which is the subject of the claim, from other sources. In general, we believe that the UK FAC recommendations[8], that the following claims, at least, should not be made, provide a pragmatic framework:

- "a claim that a food is 'free from X', if all foods in the same class or category are free from 'X';
- statements or implications which give *undue* emphasis to the fact that a product is 'free from certain non-natural additives or categories of additives', when the product contains other non-natural additives;
- a claim that a food is 'free from one category of additive', when an ingredient or an additive of another category having broadly similar effect, has been used."

Nevertheless, there is widespread and often generic criticism of modern food production and agricultural practices by the media and others. It is, therefore, understandable and legitimate for industry to wish to indicate that certain foods have not been produced in the way being criticised and to indicate wherever possible that certain categories of foods do not receive such treatments

[8] Appendix 2 (Recommended criteria for the use of the term natural in food labelling and advertising). FAC Review of the Use of Terms Fresh, Pure, Natural etc. in Food Labelling 2001. Food Standards Agency (July 2001). FSA/0334/0701.

or additions. The use of such claims will, in these circumstances, provide consumers with accurate information, which is important in assisting their right to informed choice.

Paragraph 30

The descriptions ('low / naturally low') are those used in the UK. We believe these claims provide useful information to consumers. It is of note that the term "low fat" is permissible under the Regulation on Spreadable fats (2991/94)[9] for products with less than 41% fat, and we support the retention of this possibility.

Paragraph 31

Any claim should take account of normal portion size and daily pattern of use, and the expression of the claim on the pack should reflect this. The current provisions require that the information provided relates not so much to the product itself as to the quantity in which it is sold. For example, when expressed per 100 ml, milk does not qualify as "a good source of calcium", since the calcium content is below 15% of RDA. However, given normal daily consumption patterns in the UK, milk is probably the most important dietary source of calcium. Furthermore, a beverage sold in a 330ml can, may contain 15% of the RDA for vitamin C and may thus declare this fact on the nutrition panel. If the note in the Annex were interpreted strictly, this would not be allowed if the same beverage were sold in a 1 litre bottle. This is clearly illogical and potentially confusing. **The UK legislation defines the quantities of minerals and vitamins[10] that must be present in a food to justify a "source / rich" claim in terms of the quantity of that food "that may reasonably be expected to be consumed in a day". This, we believe, is a more practical approach.**

Paragraph 32

We believe that claims for numerical differences must continue to be allowed (e.g. "20% less fat"), providing they are accurate, verifiable and of dietary significance.

Paragraph 33

The level of 25% increase or reduction of a nutrient that is the subject of an "increased/reduced" claim is well established and acceptable.

Paragraph 34

We agree that the 25% minimum difference is sensible. Reduced vitamin and mineral claims are hardly likely. The one-sixth and one-half RDA criteria in a reasonable daily amount of food, in justification of a straightforward or an enhanced claim respectively, have worked well in the UK and we suggest their wider adoption: with, perhaps, the choice of 15% rather than one sixth (16.7%). **Reference is made to the 25% minimum difference set by Codex, and the use of other levels in some Member States. It would be helpful for both consistency, and to promote product innovation, if the energy reduction criteria in the Sweeteners Directive were reduced to 25%.**

[9] Annex to Council Regulation (EC) No. 2991/94 laying down standards for spreadable fats.

[10] For Vitamin claims (section 4) and Mineral claims (section 5), the requirement is that: "For "rich or excellent source" claims, a reasonable daily intake of the food must contain at least a half of the RDA of 2 or more of the tabulated vitamins for a general vitamin claim and of the named vitamin for a specific vitamin claim. For other claims the proportion is one sixth of the RDA".

Paragraph 35

The term NRV (Nutrient Reference Value) should be defined. We believe every attempt must be made to construct the simplest framework, compatible with a sound objective scientific basis, in order to promote consumer understanding and confidence in the system and its controls. Such simplicity would also facilitate its application by small and medium enterprises, which do not have the resource to interpret complex criteria.

Paragraph 36

See comments on **paragraphs 20, 23, 32 and 33** above.

FUNCTIONAL (INCLUDING HEALTH) CLAIMS

Paragraph 37

This paragraph and the two succeeding ones, **paragraphs 38 and 39**, require clarification of the terminology if further ambiguity is to be avoided (Also see comments on 2.1 DEFINITIONS). **Nutrition, Functional (including Health) Claims are a closely inter-related part of a continuum. That this Discussion Paper does not deal with this spectrum, including Disease Risk Reduction Claims, is a regrettable oversight.**

Paragraph 38

This definition begs the question of what is meant by "nutrient" and "normal functions". See comments on **paragraphs 16 and 17** above.

Paragraph 39

We have considerable doubt whether a statutory framework of definitions and rules to be followed for each defined category is practicable. Also see comments above on 2.1 DEFINITIONS and paragraph 15.

CRITERIA FOR THE USE OF FUNCTIONAL (INCLUDING HEALTH) CLAIMS

Paragraph 40

The failure to address the full spectrum of claims may lead to a system of control that is inappropriate and insufficiently flexible to deal with future developments in the more complex area of 'Health Claims'. To be practical and operable, whatever form of control is put in place must be applicable to all types of claims, with perhaps different degrees of scientific scrutiny being required according to where in the spectrum a particular claim sits. The form of control should therefore be considered for all claims from the outset of this discussion. **Also see our comments on 2.1 DEFINITIONS, 2.2 CONDITIONS UNDER WHICH CLAIMS MAY BE MADE, and paragraph 5 above.**

Paragraph 41

We strongly support the Commission comment that there are no "good" or "bad" foods *per se* and the consequence that Functional (including Health) Claims must be considered in the context of a balanced diet and healthy lifestyle.

Paragraph 42

We agree with the sentiment of this paragraph, but believe that terms such as "*significant source*" and "*recommended*" are too vague and need to be clarified or avoided. An alternative means of achieving the same aim, based on experience in developing the UK JHCI Code[11], would be to refer to the need for the food to cause or contribute to a significant physiological or psychological benefit. In any case, the issue addressed in **paragraph 46** is key and should be adequate.

Paragraph 43

The quoted examples of "lactose-free" or "low-lactose" are not good ones. Firstly, we would regard these claims as being "content" claims, rather than "function" claims. Secondly, we cannot accept that the removal of a component that is a nutrient for the majority of the UK and European population can be said to meet the Commission's criterion of "not modifying the normal nutrition value or other related properties of the food". **These concepts will require a great deal of further consideration before they could be put onto a scientifically sound and legally binding basis.** With regard to the elimination of a particular substance (e.g. "a protein") in order to reduce the risk of an allergenic response, the consumer should certainly be informed if this change significantly modifies the normal nutritional value or other related properties of the food.

Paragraph 44

It should be noted that much of the recent scientific evidence for the benefits of certain foods and food components is based on strong epidemiological evidence. **There will be cases where analytical control of the chemical identity and the quantity of the "nutrient" will not be scientifically possible.**

Paragraph 45

We fully accept that it is essential that the consumer should be able to understand the claim and the context in which it is made. The general principle must be that no claim should be misleading to a material degree, as already laid down in legislation. **Our comments in relation to 2.2 CONDITIONS UNDER WHICH CLAIMS MAY BE MADE and paragraphs 8 and 48 are also relevant to this section.**

Paragraphs 46 and 47

We support the Commission's view that claims should be '*based on generally accepted scientific evidence*'. The individual company making a claim should be obliged to keep the validity of that under review. However, we note that these paragraphs discuss the type of scientific substantiation expected when "Enhanced Function" or Disease Risk Reduction Claims

[11] http://www.jhci.org.uk/code.pdf

are made. While Nutrient Function Claims must clearly be based on sound science, claims such as "protein helps build and repair body tissue" are generic claims based on text book science and as such do not need to be scrutinised and reviewed regularly as might be the case for "Enhanced Function" or Disease Risk Reduction Claims. The question of scientific substantiation of the full spectrum of nutrition and health claims has been considered in great depth by several organisations, in the UK and elsewhere, and various mechanisms have been developed. We would refer the Commission to these initiatives and would be pleased to provide more details as appropriate.

Paragraph 48

The issue of uniform application and enforcement of any framework for the control of claims is fundamental to the current debate. The Commission refers to this aspect in paragraph 2 concluding that "proper enforcement" would go a long way to resolving the issue. We support the Commission's broad conclusion, whilst accepting that there are a few remaining areas that could best be clarified by means of pan-European guidelines to be applied through a co-regulatory mechanism involving appropriate stakeholders. We have deep concerns about the possible structure and practicality of a list of approved claims.

Superficially, it may seem an attractive solution to generate a list of permitted claims as a means of giving consumers a uniform statement on all comparable products. However, we believe this is inappropriate and unlikely to give consumers the most useful information. A fixed list, with specific, defined wording for individual claims:

- does not – and cannot - take into account all the information which may be needed to explain a benefit to the consumer. Specified, detailed wording is too restrictive and will result in only bold, simplistic statements on labels or advertisements. According to circumstances, it may be appropriate or necessary to expand the message;
- may actually provide misleading information. The criteria permitting the claim can never be so detailed as to cover all the subtle differences that exist between different products (e.g. nutritional profile of the food, bioavailability etc.) and the needs of individual consumers;
- would be an impediment to innovation. If all operators are obliged to use the same detailed claim, they will not invest in research and product development for something their competitors can easily copy. This would ultimately not be to the benefit of the consumer;
- even if it is initially "open", the list will become "closed" in practice because of the complex mechanisms likely to be needed to add new claims to the list, in the light of evolving scientific findings.

Thus we are of the firm opinion that even if a list of broad generic claims is ultimately to be developed, it should define only the areas that may be covered by a claim, not the detailed wording to be used. Selective messages from a list on certain foods will increase the perceived distance between "good" and "bad" foods. Given that foods are eaten not only for nutritional reasons but also for enjoyment and pleasure, this could lead to a situation where consumers perceive the message incorrectly (not completely unlike the egg and cholesterol example mentioned in the Discussion Paper) and unjustifiably change their dietary habits in a negative way or restrict their dietary choice.

We do not believe that it will be necessary to obtain pre-marketing approval to avoid disputes at national or intra-Community level. We believe that it is sufficient that claims are monitored on a national basis by the appropriate regulatory and voluntary bodies. Our comments under EXECUTIVE SUMMARY, sections 2.1 DEFINITIONS and 2.2 CONDITIONS UNDER WHICH CLAIMS MAY BE MADE, and those relating to pictorial representations under paragraph 45, are also relevant.

Paragraph 49

See our comments on pre-marketing approval in the EXECUTIVE SUMMARY. We do not support the need for a regulatory notification procedure.

Paragraph 50

We note the reference in the Discussion Paper to the Swedish System. We believe that all existing national Codes should be taken into account in further consideration by the Commission, of the development of EU rules on claims.