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Designing Products for Nutrition and Health Claims

When designing products with nutrition or health claims in mind, or thinking about retrospectively adding a claim to an existing product, it is important that you fully understand the legislation involved, and the effects this could have on how you formulate your product or how you phrase the claims that you are making about it. Legislation could persuade you that a small change is required to your ingredients, but this small change may in fact lead to the product becoming less stable or less appealing to the consumer. It may result in a complete reformulation being required to achieve the desired end-point.

Product development requires a holistic approach, incorporating consumer acceptability, commercial viability, technical feasibility and legal compliance. For a general introduction to product development, Campden BRI's Product Development Guide (Guideline 8 2nd edition, 2007) is still of relevance.

This paper will highlight key aspects to consider when designing products for nutrition and health claims in Europe, which could save time and investment further along the development process. Although not discussed in this paper, it is important to note that, as with other aspects of global trading, the regulation of health and nutrition claims will differ outside Europe. For example, in the United States claims are regulated by the US Food and Drug Administration and in Japan by the Ministry of Health Labour and Welfare.

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Introduction

The use of health and nutrition claims on food and drink packaging, or in any advertising of food and drink products, has received a great deal of attention in recent years. This practice was subject only to general rules preventing false or misleading labelling information in Europe until 2007, after which Regulation (EC) No. 1924/2006 on nutrition and health claims (European Commission, 2006) was adopted. This Regulation states that nutrition and health claims must be reviewed by the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies. Only claims deemed to be scientifically substantiated and authorised by the European Commission (EC) may be permitted for use in the EU.

Authorised nutrition claims can be found in the annex of Regulation 1924/2006. Following a lengthy review of more than 44,000 general function health claims, the EU register of health claims was published in May 2012 (European Commission, 2012). From 14 December 2012 any unauthorised health claims that are not listed are no longer permitted for use on products sold in the EU. The EU register also includes the outcome of separate EC evaluations of health claims relating to new science or proprietary data, reduction of disease risk and children's development and health.

These published lists offer opportunities for food and beverage manufacturers to use authorised claims on current products (providing the conditions of use are met) or to reformulate in order to comply with the conditions. Another opportunity exists to submit a dossier for review in relation to new science or proprietary data, reduction of disease risk and children's development and health claims.

What are nutrition and health claims?

It is important to understand the definition of a health or nutrition claim in order to avoid using unauthorised wording on your product.

Nutrition claims refer to any inference that a food has specific beneficial nutritional properties (e.g. low fat, reduced sugar, high fibre or a source of 'x' vitamin or 'x' mineral).

Health claims relate to those claims which link a food, or a constituent within the food, to health and are further defined as:

a) *General function* (article 13.1) health claims (e.g. vitamin C contributes to normal functioning of the nervous system).

All European member states were asked to submit such general function claims to EFSA for which generally accepted scientific evidence was available. EFSA's opinions were then passed to the EC, who made a decision to authorise or reject each claim and ensure that the authorised wording would be understood by the average consumer. The EFSA review of all submitted claims is now complete (other than botanicals) and 222* general function health claims have been approved by the EC.

EFSA has also now published opinions on 91 claims for which additional data was submitted by Member States and these will be reviewed by the EC.

b) *New science or proprietary data* (article 13.5) health claims, which are based on newly developed scientific evidence and/or for which protection of proprietary data is requested.

Article 13.5 health claims are reviewed on a case-by-case basis following the submission of a scientific dossier to EFSA. 1* claim has currently been approved for Water Soluble Tomato Concentrate I and II.

c) *Reduction of disease risk* (article 14.1a) claims, which link the consumption of a food, or ingredient, with a significant reduction in a risk factor in the development of a disease (e.g. oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease).

Article 14 claims are reviewed on a case-by-case basis following the submission of a scientific dossier to EFSA. 7* claims have currently been approved for reduction of disease risk.

d) *Children's development or health* (article 14.1b) claims.

Article 14 claims are reviewed on a case by case basis following the submission of a scientific dossier to EFSA. 11* claims have currently been approved, which relate to children's development or health.

**As published in the EU Register of Nutrition and Health Claims on 9th November 2012*

Why develop new products?

New product development is required either to enter a new market for the first time or in order to replace older products, which are declining in sales and profitability. In particular 'added value' or 'premium' products are attractive to consumers and their novelty allows manufacturers to gain a much greater profit margin than from a 'commodity' product. In contrast commodity products can be described as being familiar, widely available, having low consumer appeal and being sold at a price which is well known.

The development of copy-cat products can also be important to food companies. If a competitor's new product appears to be successful it is important to match this product, and preferably improve upon it, as quickly as possible. This strategy may not increase profits, but could be vital in preventing their erosion.

Why develop products for nutrition and health claims?

Food and drink companies have long been committed to product development and £305m was reportedly spent on research and development activity in the UK food and drink market in 2010 (Food and Drink Federation, 2013). Also research by Mintel indicates that more than 700 product lines have been launched with new recipes since January 2007 (Food and Drink Federation, 2013). However, a more recent trend is the production of a wide range of food products carrying nutrition and health claims. Indeed the UK functional food market has experienced rapid growth in recent years (26% in 2004-2005 and 22% in 2005-2006). Although this rate of expansion now appears to be declining (8-10% per year from 2006-2009), this is still a healthy growth rate (Key Note Ltd, 2010). Furthermore, Mintel research shows that total sales of healthier eating options in some key food and drink categories are now worth £8bn, with some areas expanding at twice the rate of the market as a whole (Food and

Drink Federation, 2013). Key target areas for functional foods include cardiovascular health, bone health, immune health, and gut health. Claims on reductions of fat, salt and sugar are also popular.

Unfortunately consumers have become distrustful of, and confused by, the large number of claims on products. Whilst many claims are backed by scientific evidence, these have been somewhat undermined by other spurious claims. Indeed protection of consumers was one of the key objectives of Regulation 1924/2006. However, in the changing regulatory environment only EC approved claims are permitted from 14th December 2012. This regulation should refresh the market and increase consumer confidence, offering potential for manufacturers to create new products using authorised nutrition claims or article 13.1 or 14 health claims. Current products may also already meet the conditions for the use of certain claims.

Additionally, real potential exists to increase profit margins by developing a product, along with supporting evidence, for which a proprietary health claim can be made (article 13.5). This strategy requires greater investment and carries a higher risk; however, potential profits are also higher if a unique claim is authorised. Currently only one such claim has been approved ("Water Soluble Tomato Concentrate (I and II) helps maintain normal platelet aggregation, which contributes to healthy blood flow"). However in July 2012 EFSA issued a positive opinion for cocoa flavanols and maintenance of endothelium-dependent vasodilation (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2012). This claim is currently under review by the European Commission.

Whilst there has been some criticism of EFSA's stringent approach to the assessment of health claims, there is now greater understanding of their expectations for the level and type of evidence required in a dossier submission. Indeed much can be learnt from previously rejected applications. Furthermore EFSA has published guidance on the scientific requirements for health claims in the following key areas* to illustrate the approach of the NDA panel when evaluating dossiers:

- Physical performance
- Functions of the nervous system
- Bone, joints, skin and oral health
- Appetite ratings, weight management and blood glucose concentrations
- Antioxidants, oxidative damage and cardiovascular health
- Gut and immune function

**Complete list published in the EFSA Journal as of 9th November 2012*

Further guidance on the conditions surrounding proprietary health claims can be found in Regulation 1924/2006 (European Commission, 2006).

Considerations during development of products for nutrition and health claims

By including discussions regarding the use of health and nutrition claims at the product development stage manufacturers can assess the feasibility and risks at minimal cost, i.e. before buying ingredients, running production trials or undertaking human intervention studies.

In addition to the usual product development process, the following questions should be answered:

- What type of claim would you like to make?
- Could approved claims be applied to your product?
- Would reformulation of an existing product result in the product meeting the conditions for an approved claim?
- If targeting an article 13.5 claim, has a similar claim been previously rejected? If so, why was it rejected? What can be learnt from this?
- Has any previous work been carried out, which can support your claim? (for example *in vitro* work in support of the mechanism of action)
- What is your target market? (e.g. children and/or adults, healthy and/or patients)

Following development of a product it is important to determine the quantity of energy, nutrients and other substances (i.e. functional ingredients) present, and to ensure that these levels are maintained throughout the duration of the shelf life. It is recognised that it is not always possible for foods to contain the precise levels of energy, nutrients and other substances that are labelled, due to natural variations and variations in production and during storage. However, the nutrient content of foods should not vary substantially from labelled values, to the extent that such variations could mislead consumers. Therefore acceptable tolerances for nutrition labelling are being developed under the Food Information to Consumers Regulation (FIC). Another key requirement is to make sure that product labels comply with legal requirements, including those being introduced by the FIC.

Preparation of dossiers

In order to obtain an opinion on an article 13.5 claim a dossier must be submitted to EFSA for review. EFSA will publish an opinion (positive or negative) and the claim, including its wording, will then be evaluated by the European Commission and either authorised or rejected.

The key areas of the dossier are:

1. Characterisation of the food/constituent

The type of data to be provided includes the source, physical and chemical properties, composition, batch variability, stability, bioavailability, the manufacturing process and content of the constituent(s) related to the health claim.

2. Relevance of the claimed effect to human health

The claimed effect must be considered by EFSA to be a beneficial physiological effect to the target group specified in the dossier.

3. Scientific substantiation of the claimed effect

This should be based on human data, which is primarily from intervention studies. However, the totality of the data should be included in the dossier, including evidence in favour and not in favour, human and non-human studies and published or unpublished data, which are relevant for the substantiation of the claim. Details of the literature search should be provided, to include databases searched, search terms and exclusion criteria applied.

4. Proposed wording

The wording should be both scientifically correct and understood by the consumers for whom the claim is intended.

5. Conditions and restrictions of use

The dossier should state the required dose and pattern of consumption required to achieve the claimed effect, as well as defining the target population. This should be supported by the scientific evidence provided. Additionally consumption should be achievable within a balanced diet.

Consumer opinion and understanding

The EC regulations state that 'the use of 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' (European Commission, 2006). However, despite this criterion, there is speculation over the extent to which consumers really do understand the approved wording. Additionally consumer perceptions of claims are of considerable interest to the food industry. A large number of studies have been carried out in order to gain insight into consumer understanding and their opinions. This section reviews some of the most recent research in this area, as this will be most relevant to the current status of the Regulation.

A recent study assessed UK consumer understanding of *nutrition claims* relating to sugar, for example 'with no added sugars' and 'reduced sugars' (Patterson *et al.*, 2012). This research identified that consumers expect the same, or similar, reductions in calories when considering a reduced sugar product. In fact the conditions for a reduced sugars claim state that there must be a "≥30% reduction [of sugar] compared with a similar product; the amount of energy in the product bearing the claim is equal to or less than the amount of energy in a similar product". Alongside this, confusion was identified in relation to the calorie content of various nutrients, with many overestimating the number of calories present in sugar. Additionally the research indicated consumer preference for 'with no added sugar' claims over 'reduced sugars' claims due to the former being perceived as more natural. Consumers also expected that a product claiming 'with no added sugars' would contain some form of sugar and sweeteners.

Another recent publication reviewed European consumer responses to *health claims* (Wills *et al.*, 2012). The review identified that consumer responses differ substantially depending on the type of health claim, the carrier product, the functional ingredient or a combination of these factors. However, no clear consensus was identified on preferences regarding these components; for example, a study carried out by Saba *et al*. (2010) reported that UK consumers preferred general health claims, whereas German and Finnish respondents preferred disease risk reduction claims. It is also reported that, in a study comparing claims on dried fruit, Polish consumers prefer the presence of a vitamin claim, whereas Dutch subjects responded more favourably to a fibre claim (Jesionkowska *et al.*, 2009). Furthermore Dutch and Polish respondents were attracted to products claiming a reduction in cancer or heart disease, whereas French consumers also registered interest in the prevention of intestinal problems. Based on this review nationality appears to be an important factor in attitude towards health claims.

It may be expected that consumers with a positive attitude towards health claims would have greater understanding than those with a negative attitude. However, this hypothesis was disproved by Grunert *et al*. (2011), who found that a positive attitude resulted in an increased likelihood that claim understanding would be classed as 'risky', i.e. believing the product to be more beneficial than could be reasonably expected. This study only investigated consumer responses to one health claim ("Actimel helps strengthen the body's natural defences"), in a single country (Germany); however, the results are interesting and should be considered in future research.

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