NUTRITION LABELING AND CLAIMS: CONCERNS AND CHALLENGES

***[1]Bîrcă Adriana, [2]Gaceu Liviu, [1]Paladi Daniela**

[1]Technical University of Moldova – Chişinău, Moldova
[2]Transilvania University of Brasov – Brasov, Romania

***Bîrcă Adriana, birca_adriana@yahoo.com**

Abstract: A EU Regulation No.1924/2006 on nutrition and health claims established the first fully harmonized regime on the use of nutrition and health claims made on foods in the European Union.. The Regulation will apply to any health and nutrition claims made on food or drink products produced for human consumption to be sold in the EU/ Member States' market. In this paper we explore some of the issues surrounding nutrition and health claims, looking at some examples from around Europe and also the EU legislation to harmonise claims across member states.
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Introduction

In January 2007, ***Regulation 1924/2006 on nutrition and health claims made on foods***, was published. This regulation is the first piece of scientific legislation to deal with nutrition and health claims and aims to provide a higher level of consumer protection as well as harmonize legislation across the EU to facilitate intra-Community trade.

The Regulation requires the European Commission to establish nutrient profiles as criteria that foods must meet to bear claims. Its aims are:

• To ensure a high level of consumer protection by guarding against unsubstantiated, exaggerated or untruthful claims about foodstuffs. With the new legislation, consumers can rely on clear and accurate information on food labels, enabling them to be properly informed on the food they choose.

• To harmonize legislation across the EU by providing food producers and manufacturers with clear, harmonized rules that will enable fair competition to help protect innovation in the food industry, by ensuring that manufacturers make genuine health and nutrition claims and are not competing with false or inaccurate claims.

The Regulation will apply to any health and nutrition claims made on food or drink products produced for human consumption to be sold in the EU/ Member States' market, including all commercial communications, generic advertising and promotional campaigns. It is also applicable to foodstuffs for particular nutritional uses and supplements.

A nutrition claim is a statement that either declares or implies that a food contains a particular nutrient. This type of claim can go further and highlight whether the amount of a given nutrient in the food is high or low. Within the European Union (EU), a regulation on nutrition and health claims came into force in 2007 (1924/2006/EC). This specifies the conditions under which a nutrition claim can be made and in 2010 a list of approved health claims for use on foods will be published. Until this time those wishing to make a claim must submit this to the EC.

In this paper we explore some of the issues surrounding nutrition and health claims, looking at some examples from around Europe and also the EU legislation to harmonise claims across member states.

1. Nutrition claims

Nutrition claims refer to any statement, other than nutrition labelling declarations, which declares or implies that a food contains, or has a high or low amount, of one or more nutrients. Reference values for selected vitamins and minerals are increasingly used on food labels and it is comparison with these reference values which determines whether a food is a 'source' or 'rich' in a particular nutrient. In this context, they are described as Recommended Daily Allowances (RDAs) and the quantities to which they refer are often different from the dietary reference values used in individual member states. The table below outlines the criteria for micronutrient claims as outlined in the annex to the regulation.

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Table 1. Criteria for Micronutrient Claims

Nutrient	**RDA***	**Source (sixth RDA) (min amount per daily serving)**	**Rich source (half RDA) (min amount per daily serving)**	**Label declarations (min amount per 100g or 100ml)****
Vitamin A	800mcg	133mcg	400mcg	120mcg
Vitamin D	5mcg	0.83mcg	2.5mcg	0.75mcg
Vitamin E	10mg	1.7mg	5mg	1.5mg
Vitamin C	60mg	10mg	30mg	9mg
Thiamin	1.4mg	0.23mg	0.7mg	0.21mg
Riboflavin	1.6mg	0.27mg	0.8mg	0.24mg
Niacin	18mg	3mg	9mg	2.7mg
Vitamin B_6	2mg	0.3mg	1mg	0.3mg
Folic acid	200mcg	33.3mcg	100mcg	30mcg
Vitamin B_{12}	1mcg	0.16mcg	0.5mcg	0.15mcg
Biotin	0.15mg	0.025mg	0.075mg	0.023
Pantothenic acid	6mg	1mg	3mg	0.9mg
Calcium	800mg	133mg	400mg	120mg
Phosphorus	800mg	133mg	400mg	120mg
Iron	14mg	3mg	7mg	2.1mg
Magnesium	300mg	50mg	150mg	45mg
Zinc	15mg	2.5mg	7.5mg	2.25mg
Iodine	150mcg	25mcg	75mcg	22.5mcg

** RDA figures defined within EU labelling legislation may vary from the dietary reference values used in individual member states.*

*** Minimum levels apply as a rule although exceptions are generally considered to be situations where the single serving differs significantly from 100g.*

Food manufacturers often like to make reference to the relative amount of a nutrient, outside the declarations made within the nutrient panel on the food packaging. This is also considered to be a form of nutrient claim. Before the regulation on nutrition and health claims was published, the various Member States used different criteria to categorise a food as high or low in some nutrient. The table below shows the criteria used by food manufacturers (tab.2).

Table 2. Previous EU *Member States* Guidelines on Nutrient Content Claims

Nutrient	**Low**	**No added**	**…Free**
Fat	< 3g/100g or 100ml		< 0.15g/100g or 100ml
Saturates	< 1.5g/100g and should not make up more than 10% total energy of the product		< 0.1g/100g or 100ml
Sugars	< 5g/100g or 100ml	No sugars or foods composed mainly of sugar added to the food.	< 0.2g/100g or 100ml
Salt/Sodium	< 40mg Na/100g or 100ml	No salt or sodium added to food or its ingredients.	< 5mg Na/100g or 100ml
Fibre	Either 3g/100g or at least 3g in the amount of food likely to be eaten each day.	> 25% more than a similar food for which no claim is made.	Either > 6g per 100g or at least 6g in the amount of food likely to be eaten each day.

Additionally, there are international guidelines relating to nutrient claims. The Codex Alimentarius Commission was created in 1963 by the Food and Agricultural Organization (FAO) and World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The Codex committee on food labelling proposed draft regulations for nutrition claims in 2001. The purpose of the Codex guidelines is to ensure that nutrition labelling is effective in providing the consumer with information about a food so that a wise choice of food can be made; conveying information on the nutrient content of a food on the label; encouraging the use of sound nutrition principles in the formulation of foods which would benefit public health; and providing an opportunity to include supplementary nutrition information on the label. It is essential that nutrition labelling does not describe a product or present information about it which is in any way false, misleading, deceptive or insignificant in any manner. It is a requirement of the Codex guidelines that if a nutritional claim is made that there is adequate supporting nutrition labelling. The table below outlines the conditions (as described by Codex) which must be met for a manufacturer to make claims about the nutrient content of a particular food (tab.3).

Table 3. Codex Alimentarius Criteria

Nutrient	**Claim**	**Conditions – not more than…**
Energy	Low Free	40kcal per 100g (solid) OR 20kcal per 100ml (liquid) 4kcal per 100ml (liquid)
Fat	Low Free	3g per 100g (solids) OR 1.5g per 100ml (liquids) 0.5g per 100g (solids) or 100ml (liquids)
Saturated fat	Low Free	1.5g per 100g (solids) OR 0.75g per 100ml (liquids) AND 10% energy. 0.1g per 100g (solids) or 100ml (liquids)
Sugars	Free	0.5g per 100g (solids) or 100ml (liquids)
Sodium	Low Very low Free	0.12g per 100g 0.04g per 100g 0.005g per 100g
Conditions – not less than….		
Protein	Source High	10% DRV per 100g (solid) OR 5% DRV per 100ml (liquid) OR 5% DRV per serving OR 10% DRV per 100kcal 2 times the value for a source
Vitamins and minerals	Source High	15% DRV per 100g (solid) OR 7.5% DRV per 100ml (liquid) OR 5% DRV per serving OR 15% DRV per 100kcal 2 times the value for a source

For EU Member States these content claims are now defined by the annex to the nutrition and health claims regulation (tab. 4).

Table 4. Nutrition claims and conditions applying to them

Nutrition claim	**Conditions applying to nutrition claim**
Low energy	Product contains no more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids; for table top sweeteners limit of 4 kcal (17 KJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approx. 1 teaspoon of sucrose).
Energy-reduced	Energy value is reduced by at least 30%, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.
Energy-free	Product does not contain more than 4 kcal (17 kJ)/100 ml; for table-top sweeteners limit of 0.4 kcal (1.7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approx. 1 teaspoon of sucrose).
Low fat	Product contains no more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100 ml for liquids (1.8 g of fat per 100 ml for semi-skimmed milk).
Fat-free	Product contains no more than 0.5 g of fat per 100 g or 100 ml; claims expressed as 'X % fat-free' shall be prohibited.
Low saturated fat	The sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1.5 g per 100 g for solids or 0.75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10% of energy.
Saturated fat-free	Sum of saturated fat and trans-fatty acids does not exceed 0.1 g of saturated fat per 100 g or 100 ml.
Low sugars	Product contains no more than 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 ml for liquids.
Sugars-free	Product contains no more than 0.5 g of sugars per 100 g or 100 ml.

Continue Table 4.

With no added sugars	Product does not contain any added mono- or disaccharides or any other food used for its sweetening properties; if sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURING SUGARS'
Low sodium/salt	Product contains no more than 0.12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml; for waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.
Very low sodium/salt	Product contains no more than 0.04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml; this claim shall not be used for natural mineral waters and other waters.
Sodium-free or salt-free	Product contains no more than 0.005 g of sodium, or the equivalent value for salt, per 100 g.
Source of fibre	Product contains at least 3 g of fibre per 100 g or at least 1.5 g of fibre per 100 kcal.
High fibre	Product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.
Source of protein	At least 12% of the energy value of the food is provided by protein.
High protein	At least 20% of the energy value of the food is provided by protein.
Source of [name of vitamin/s] and/or [name of mineral/s]	Product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.
High [name of vitamin/s] and/or [name of mineral/s]	Product contains at least twice the value of 'source of [name of vitamin/s] and/or [name of mineral/s]'
Contains [name of the nutrient or substance]	A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in the Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.
Increased [name of the nutrient]	A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 30% compared to a similar product.
Reduced [name of the nutrient]	Reduction in content is at least 30 % compared to a similar product, except for micronutrients, where a 10 % difference in the reference values as set in Directive 90/496/EEC shall be acceptable, and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.
Light/lite	A claim stating that a product is 'light' or 'lite', and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.
Naturally/natural	Where a food naturally meets the condition(s) laid down here for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim.

For a food to be labelled a ‘source of omega 3 fatty acids’, they recommend that the food must contain more than 15% of the Recommended Nutritional Intake (with this set at 2g/day for an adult male) of the omega 3 fatty acids concerned per 100g or 100ml or 100kcal. The food must contain more than 30% of the Recommended Nutritional Intake for an adult male of the omega 3 fatty acids concerned per 100g or 100ml or 100kcal to be labelled ‘high in omega 3 fatty acids’.

2. Healh claims

Nutrient profiling refers to Article 4 of Regulation 1924/2006 on nutrition and health claims, which indicates the EC must establish specific nutrient profiles (i.e., conditions regarding the nutrient content of foods), that foods or certain categories of foods must respect in order to bear nutrition and health claims. Nutrient profiling has been used for different purposes, e.g.: for nutritional classification of foods, product development purposes, or for the regulation of claims. Reviews of existing schemes for nutrient profiling, including comparisons and critical discussions, are available and exists those schemes intended for nutrition education, product labeling and product development.

Nutrient profiling for other purposes than regulation of claims is available, such as nutrition education by health professionals, and as guidance to help consumers to make ‘healthy’ choices from the wide range of available food products. Nutrient profiling schemes are also increasingly used as a (voluntary or private) basis for product labeling by food producers and retailers who use graphic or symbolic representations (logos) on food products to communicate nutrition information to the consumer and/or to mark products as “healthy” food choices. Such classifications are also applied in product development and (re)formulation by serving as a tool to evaluate and improve the overall nutritional quality of a producer’s product portfolio. In the UK, a nutrient profile was established by the Food Standards Agency to regulate the promotion of food to children, i.e. to restrict (broadcast) advertisements to children of products high in fat, saturated fatty acid, salt, and/or sugar.

Only those nutrient profiling schemes and a short description of schemes that have been used for the purpose of permitting products to bear claims which have been used for the regulation of claims will be discussed here.

According to regulations in the US, Canada, Australia/New Zealand and Sweden, foods must comply with general or specific criteria for nutrient composition to bear a nutrition or health claim. Such regulatory schemes are not intended to convey direct messages to purchasers, but aim to ensure that claims on foods will not mislead the consumer by masking the overall nutrient composition of the product.

Nutrient profiling schemes generally used (or proposed) for regulatory purposes are based upon general (‘across the board) or category-based nutrient criteria. Rather than using one nutrient profiling scheme for all claims and covering all foods, nutrient profiles and conditions in the US and Sweden are set for individual claims, or certain types of claims.

How does this relate to potential health claims and their approval? The big issue is that Article 13 submissions are all but closed, although an established nutrient profile list is not expected until January 2009. So while it may be possible to claim cocoa polyphenols from chocolate may be heart healthy, it is likely these polyphenols are delivered in a delivery form high in sugars and fats. It is therefore likely chocolate will be defined as unhealthy in regards to its nutrient profile, meaning a company could not use the approved claims for chocolate based on its content of polyphenols, even if the claim was granted. The

fallout across the EU could be major, as each member state has a different view on what is and is not the right way to profile.

One food/ingredient group currently under fire from the new EU regulations is PARTNUTS foods. These are foods for use in situations of "intense muscular efforts," i.e., sports foods and drinks. Many of these products include high doses of nutrients such as sodium and sugar for purposes of hydration; yet, under nutrient profiling regulations these products may be classed as "nonhealthy." This would still be the case regardless of the huge volume of evidence demonstrating PARTNUTS foods as vital for well-being during intense exercise.

Finally, there is the Human Medicinal Products (Pharmaceuticals) Directive (Directive 2004/27/EC), a key directive sometimes referred to as the "pharmaceuticals directive," controlling the use and sale of pharmaceutical products across the EU. The big issues here could be the inclusion of ingredients such as glucosamine or fish oils if their use is deemed to be medicinal following review by EFSA. As such, applications for additional product/marketing licenses will have to be applied for, increasing costs to large and small businesses alike.

Claims are used to present products as having an additional health or nutritional benefit. In most cases, consumers perceive products carrying certain claims to be better for their health and wellbeing. However, at the moment, a food which is high in fat, salt and/or sugar, can still use claims such as "rich in vitamin C" or "high in fibre", even if the overall health and nutritional benefits of the product are low.

The Nutrition and Health Claims Regulation aims to protect consumers from being misled, by controlling nutrition and health claims. In the case of Health claims, this will be achieved by establishing a positive list of claims, which will be generated in three steps. Member States will first send the list of the claims they consider are valid, based on generally accepted science in their country (by January 2008). Then EFSA will evaluate those claims received within two years. Finally, the accepted list of Health Claims will be in the public register. For new Health claims, a file with the supporting evidence will need to be submitted to EFSA, by the company wishing to make the claim on a food or drink, and the approval procedure followed. For disease risk factor reduction claims and claims on children's health, more elaborate procedures have been foreseen.

The Regulation requires the European Commission to establish nutrient profiles as criteria that foods must meet to bear claims. The nutrient profiles will be based on the scientific opinion of the EFSA. Within 24 months of the Regulation entering into force, the Commission will consult the relevant stakeholders, and present proposals for nutrient profiles to Member State experts. If they support these proposed nutrient profiles, they will be adopted by the Commission and used as a condition for making claims.

The term 'health claim' is potentially open to a variety of interpretations. They are generally considered to be statements about the beneficial effect on the body of a food, or its ingredients. However, there can be confusion regarding how far a claim should go. Food manufacturers are developing products that have potential health benefits on top of providing nutrients for general health and well being. To draw attention to this, manufacturers are placing health claims in prominent places on the front of food packaging with the aim of informing consumers of the functional properties of these new products. Examples include omega-3 fats and heart health, probiotics and gut health or soy protein and cholesterol lowering. There is now specific legislation covering health claims in the EU Labels, along with other forms of marketing, are not allowed to claim that food can treat,

prevent or cure any disease or medical condition as these sorts of claims can only be made for licensed medicines. The regulation on health claims states that a list of permitted claims will be published (2010) and only these will be legal for use in the EC. Health claims in this regulation are divided into two kinds; article 14 health claims that refer to children's' health or disease risk reduction, or article 13 claims that do not refer to these things. Within article 13 health claims there are those claims that are based on 'generally accepted scientific evidence' although the meaning of this phrase has not been formally defined, it appears to refer to evidence at the level that would appear in mainstream text books on nutrition and health. Lists of these claims have been submitted by each Member State to the EC for approval. Health claims concerning more emerging nutrition and health relationships, possibly concerning specific formulations or functional foods produced by a single company may also be included in article 13 claims. Dossiers of evidence for these claims will have to be submitted to the EC for approval, as will be the case for article 14 claims.

Nutrient content claims such as 'low fat' provide short-hand information on pertinent nutrient features of food products, and so provide greater ease-of-use for consumer decisions. There is some scope for confusion if terminology and formats are not adequately defined or are open to misinterpretation, and the selective basis of the use of such claims may lead to incorrect impressions of the overall dietary modifications achieved when products making nutrient claims are used to replace foods not making such claims.

Claims describing direct nutrient or food associations with a disease (i.e. medicinal claims) are currently not permitted within the EU. The prohibition on medicinal claims applies to the labelling of food, regardless of the scientific accuracy of any statement made. Information on labels describing nutrient function claims or nutrient and health relationships have previously been described as the 'grey area' of legislative control as they are regulated only implicitly by other pieces of legislation. There is now specific regulation covering nutrition and health claims, although it will take some time for the list of permitted claims to be published by the EC (2010). Research and development within the food industry is giving rise to food products designed to provide positive health benefits. The consumer must be protected from spurious claims but also provided with useful information about these products, where there is robust evidence of beneficial effects from their consumption. The EC nutrition and health claims regulation should help to harmonise the health claims used across the EU and to ensure they are based on robust scientific evidence.

CONCLUSIONS

The relationships between food and nutrient intakes and short- and long-term effects on health and disease risk are complex, and our understanding of all these relationships is ever-evolving. While labelling claims should not replace nutrition education, they make a useful contribution to the understanding of nutrition concepts and recommendations. The food industry, legislators and the enforcers of legislation can, by working in partnership, ensure that labels and the information they contain serve the interests of the public. Other channels of information, however, are also needed to convey the detail of the relationship between food and nutrient patterns and health associations. Such general nutrition education also needs to convey to consumers the appropriate use of labelling information in supporting sensible dietary choice.

It is also important that the nutrient composition information is correct as the conditions to trigger a claim are dependent on there being a particular amount of the nutrient in the food. Many food manufacturers rely on food composition data to compile nutrition information panels. Rather than analysing nutrient content of a product in the laboratory, many manufacturers instead calculate the nutrient content by using food composition tables. Thus it is essential that these resources contain as complete and accurate a data set as possible.

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