

## Healthcare industry BW

# The European Nutrition and Health Claims Regulation - an interesting recipe

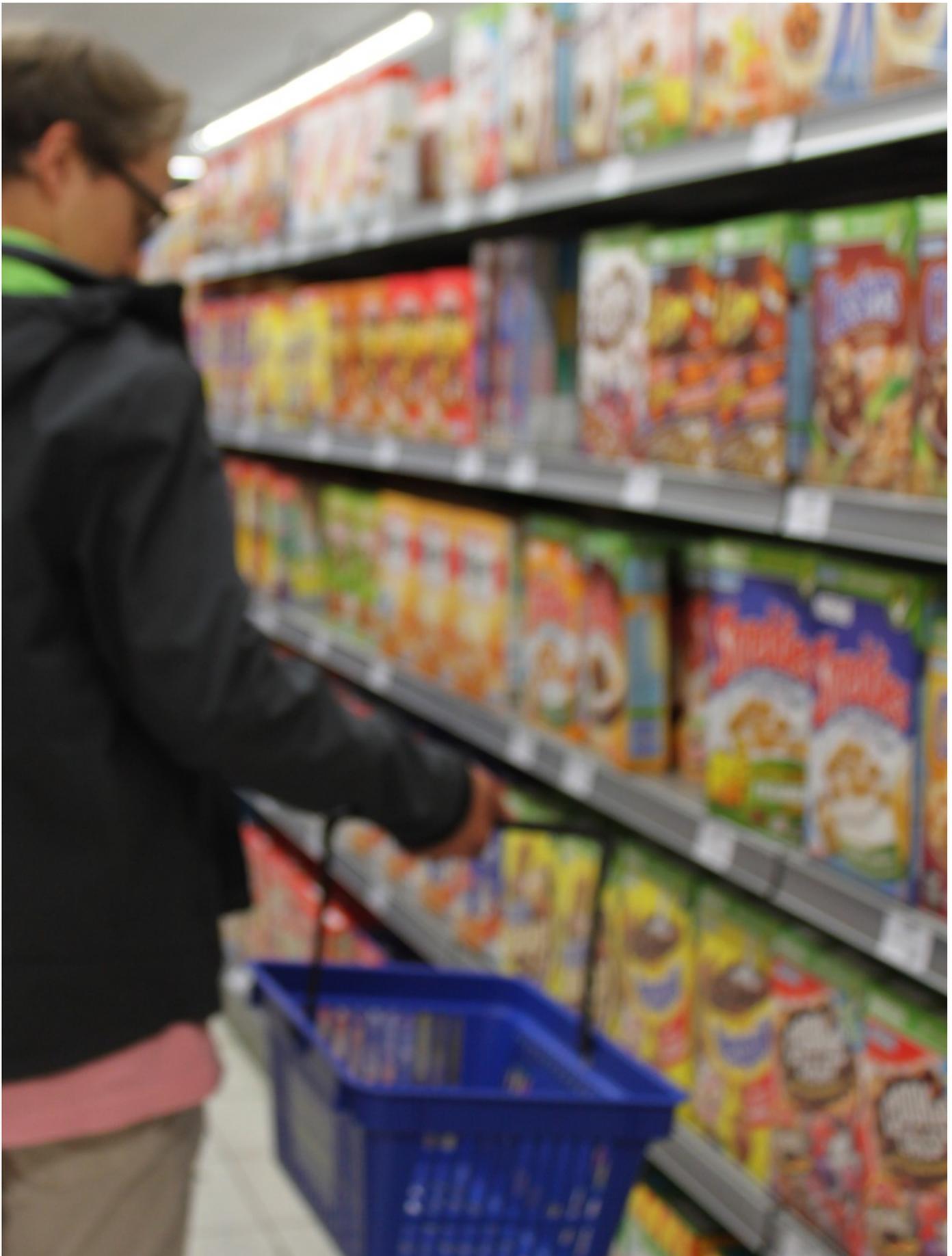
**The EU Nutrition and Health Claims Regulation applies to all nutrition and health claims made in commercial communications, including the advertising and labelling of food and promotional campaigns. While the information related to nutrition is now clear, the list of permitted health claims is still under development.**

The EU Regulation No. 1924/2006 on nutrition and health claims made on foods became effective on 18th January 2007. Its objective is to ensure a high level of consumer protection throughout the European Community and to facilitate consumers' choice of healthy food with adequate labelling of food ingredients and nutritional values.

The regulation is also aimed at harmonising the various national regulations on nutrition and health claims on foods throughout the European Community, which will also bring with it economic advantages. Before the EU Nutrition and Health Claims Regulation came into force, the regulations on the labelling of foods of the different European states differed considerably, hindering the free circulation of foods to all areas in Europe and giving rise to unfair competitive disadvantages. In Germany, the new regulation has also boosted the domestic market by doing away with inequalities between the different states.

As it had the status of a regulation, rather than a directive, Regulation No. 1924/2006 was enforced throughout the European Community from the date of adoption without having to be implemented into national law first, as was the case with the EU 2000/13/EC Labelling Directive. This Labelling Directive prohibited the use of information that would mislead purchasers or attribute medicinal properties to foodstuffs. Regulation No. 1924/2006 goes a lot further and applies to all nutrition and health claims on foods made in commercial communications, including the generic advertising of food.

## Regulation for commercial products



Not sure what you're buying? Do food labels provide accurate information about ingredients and nutritional values, as stipulated by the EU Nutrition and Health Claims Regulation?

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The EU Nutrition and Health Claims Regulation was brought in to improve the safe and adequate labelling of food. It not only applies to written information, but also to the use of images, symbols and graphics. In addition, the claims must be supported by “scientific evidence that outweighs opposing evidence or opinion” to attest the relationship between food and health. The regulation therefore presents both food manufacturers and researchers with the challenge of establishing a fundamental relationship between foods and the claim that they play a role in improving normal functions of the body or in preventing, treating or curing diseases, for example. The combination and form in which specific nutrients are offered to consumers also plays an important role in such considerations. This dossier will look at some foods that are claimed to have a positive effect on human health, including a spice called curcumin in articles entitled [“Curcumin for the treatment of Alzheimer’s disease and cancer: healthy plant substances and their transport into the body”](#) and [“Erbasens: Using the power of nature”](#). In some cases, well-founded scientific evidence is available to prove the positive effect of foods on human health, even though detailed molecular relationships are not yet known. One such example is cloudy apple-juice. The article entitled [“Does cloudy apple juice prevent colon cancer?”](#) describes the current state of nutrition research at the Max Rubner-Institut (MRI).

The European Food Safety Authority (EFSA) is the body that is responsible for evaluating the scientific evidence supporting nutrition and health claims and it also deals with applications for the authorisation of a nutrition and health claim from the manufacturers of regulated substances and products. Based on the EFSA’s evaluation, the EU Commission approves or rejects a nutrition or health claim. In order to keep the regulation as innovation friendly as possible, an accelerated approval procedure based on state-of-the-art scientific evidence is available for health claims.

The preparation of health claims lists is rather complex



Vitamin-supplemented sweets – are they any healthier than normal sweets? The “EU Nutrition and Health Claims Regulation” was brought in to improve the safe and adequate labelling of food.

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Despite the numerous benefits, feedback from manufacturers about the EU Nutrition and Health Claims Regulation varies. Although the EU-wide harmonisation and the establishment of clear rules is generally seen as a positive move, some manufacturers see the regulation as too restrictive and believe it has too much red tape. The article “Who’s for a nice cup of tea?” shows how a company called Anoxymer, a research-driven manufacturer of plant extracts, is taking on board the new regulation. Some manufacturers have also criticised the replacement of the notion “it is allowed if not expressly prohibited” with a more general prohibition. In other words, only those nutrition and health claims on foods specifically named in the EU Community list, and that have been specifically approved, are allowed.

Prior to being adopted on 18th January 2007, the proposed EU Nutrition and Health Claims Regulation was heavily criticised and rejected by many. The European Economic and Social Committee’s 2004 statement rated the approval procedure as too complicated. In its first reading, the European Parliament came up with more than 70 suggestions for modification, including the recommendation to delete nutrient profiles from existing EU nutrition and health claims. However, the EU Council adopted the European Commission’s proposition in October 2006 without comprehensive modifications and including the provision of the controversial nutrient profiles.

## A matter of great controversy – nutrient profiles

The regulation anticipates the development of nutrient profiles by the European Commission in cooperation with EU member states and the provision of information on the nutrient composition of “healthy” foods. Nutrient profiles determine whether foods are eligible to carry nutrition and health claims on the basis of their nutrient composition. Groups of foods can also be combined. If a specific food contains more than one component in a quantity that is deemed unhealthy, the overall product is no longer rated as healthy and no longer allowed to carry nutrition and health claims even though they are separately valid. To put it another way, the regulation stipulates that in the future, a product will only be allowed to carry nutrition and health claims if it has appropriate nutrient profiles.

### **Nutrient profiles – quote from the 046/2010 statement of the German Federal Institute for Risk Assessment BfR**

“...Nutrient profiles are intended to ensure that foods that are advertised to have a positive health effect do not also have nutrients which are linked with chronic illness if consumed in excess. Consumers can thus be protected from misleading information. Nutrient profiles are not meant to provide information to the end user and do not replace or supplement nutritional labelling provisions...”

Chapter 3 of the EU Nutrition and Health Claims Regulation relates to the specific conditions of nutrition claims and chapter IV to the specific conditions of health claims. At the time of publication, the Annex of the regulation already listed permitted nutrition claims and respective criteria. For example, the Annex provides information on the conditions under which a food item can be labelled and commercially advertised as “low-fat” or “rich in fibre”. At the beginning of 2010, the Annex was amended for the first time and expanded to include five further nutrition facts, such as “high quantities of omega-3 fatty acids”. The health claims list has not yet been finalised. The reason for this is that an extraordinarily high number of health claim applications was submitted to EFSA,

which made it impossible to scientifically evaluate the information given in the period of time allocated. In addition, the EU Commission needs to give its consent before a health claim can be used. The publication of the list of health-related data was originally planned for January 2010; however, a first draft of the first part of the health claims list was published in summer 2011 and revised shortly after. The final list will probably not be published until the beginning of 2012. The article "The basics of substance testing" shows how BioTeSys GmbH, an analytical company that carries out clinical studies for assessing the bioactive potential of nutrients, foods and food substances, is approaching the issue of nutrition and health claims.

## Exemptions

The new regulation does not apply to all classes of foods. For example, the regulation stipulates that claims must not be made on alcoholic beverages containing more than 1.2% by volume of alcohol. In addition, denominations that have traditionally been used to indicate a particularity of a class of food such as "digestive" or "cough drops" are exempt from the application of the EU Nutrition and Health Claims Regulation. Also exempt from the regulation are entire groups of traditional foods such as fruit, vegetables, milk, meat and bread. The exemption of bread is very much in the interest of the German bakery products industry as German bread contains an average of 1.8 to 2.2 g salt per 100 g flour, a higher level than that considered to be healthy (1.2 to 1.3 g) by the EU Commission.

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