

## **Enriched Foodstuff on Basis of European Regulations N.1924 and N. 1925 Introduced in 2006: An Analysis of Consumer Protection**

by

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*Abstract.* The goal of this work is to analyse the underlying reasons of the EC Regulations nos. 1924 and 1925 of 2006 which rule the nutrition and health claims used in commercialising some categories of food products. In particular, we investigated the importance of enriched foods, the different types existing in the market and their characteristics that depend on the adding process of specific elements or substances. The commonest enriched foods are produced with small amounts of minerals and vitamins, even though the mentioned EC regulations do not exclude the addition of other substance with beneficial effect for health. Recent studies highlighted that in the labyrinth of diversified food innovations, consumers are not always provided with appropriate information to correctly understand the nutrition label of food products in order to make rational choices according with nutritional requirements. Moreover, just a few years after the introduction of EC Regulations nos. 1924 and 1925 of 2006, the high number of messages conveyed by the advertising of enriched products and the lack of comprehensive legislation make the understanding of nutrition messages more difficult and reduce the consumer protection.

*Key words:* multiple source assessment, human resource management, performance.

JEL classification: D18, L66

### **1 Introduction**

The food industry has a central role in the Italian economy, with 124 billion turnover in 2010 - the year when the first signs of recovery were seen after the scarcely dynamic trends caused by the reduction in consumption due to the international crisis (Federalimentare, 2011). Contrary to the general trends of the sector, some foodstuffs have had a strong growth. They are health-enhancing products, the most important of which are those enriched with vitamins and minerals or other substances that are added to those naturally contained in the food (Federalimentare, 2009).

On the demand side, this growth is due to the increasing demand from consumers for special products that combine service with health and respond to the spreading of physical well-being oriented life styles, a better care for the person, a continuous research for a perfect physical form, the enhancement of body functions, as well as the reduction of the risk of developing diseases. All this led to the development of multiple categories of foods, including enriched

products, that are marketed under different names and boast properties and attitudes that are not always easy to understand for consumers. The spreading of these products has also been the result of convincing advertising campaigns aimed at highlighting their nutritional and healthy properties. However, chemical studies conducted on certain foodstuffs marketed as having these additives showed that they do not always contain the ingredients claimed on the product labels or contain them to a lesser extent, with the result of being materially equivalent to traditional products. In order to protect consumers from this type of fraud, national and supranational authorities have taken action since the 80's and have issued more accurate and stricter labelling regulations. In this regard, we should point out that an investigation conducted by BEUC, the organisation that gathers consumer associations throughout the European Union, showed that purchasers are more attracted to appealing wordings written in large characters on the front side of the packaging and are less inclined to read nutritional facts labels, particularly if these are printed on the

back of the package, in very small characters and filled with difficult words (Altroconsumo, 2008).

A recent survey on Italian consumers conducted by the Research Institute “ISPO”, with the support of Coca Cola Italia, has spread some light on the difficulties for consumers to handle the excessive amount of information given on food products, so much so that no less than 62% of the sample surveyed said that the information transmitted by the different sources on the subject of correct nutrition is often contradictory and generates confusion. As a consequence, the efforts made in the course of 2006 to establish correct definitions led the Parliament and Council of the European Union to issue Regulations no. 1924 and no. 1925 to control the nutritional and health claims made on food. These regulations, *inter alia*, provide an accurate definition of the conditions for the use of the phrase “source of” (specifically referred to enriched foods) and all the other phrases with a similar meaning.

After analysing the spreading of enriched products throughout Europe, this work will analyse the characteristics of these products in the light of the new regulations issued by the European Union.

## 2 Methodology: diffusion, regulation, scientific and commercial profile of enriched products

### *The European regulatory framework for enriched products*

The significant developments of nutritional science and modern food chemistry have considerably changed the composition of food products with the aim of improving their beneficial effects and the health-enhancing properties of their individual constituents. In fact, over the last few years, a wide range of nutritional substances and various types of ingredients has been selected and introduced in the modern food industry, leading to the creation of new categories of products that are called with various names: enriched foods, functional foods, novel foods, and fortified foods, just to mention a few. The use of these substances had been left unregulated until the issuing of EC Regulations no. 1924 and no. 1925 of 2006, with national lawmakers free to define their own regulations and the consequent creation of extremely different situations. This accounts for the fact that nutritional deficiencies may be due either to incorrect nutrition habits or to specific climate and geographical conditions, with only specific population groups being exposed to nutritional risks; therefore, the adoption of food enrichment practices is not justified in all European countries. As a matter of fact, the governments of some countries, for public health reasons, produced complete and exhaustive regulations for the compulsory addition of certain nutritional substances in certain foods and on how to inform consumers correctly, while others have left legislative gaps, as shown in Table 1 below.

Table 1: List of the main enriched products in each individual European Country

Country	Nutrient	Food/Food Category
Austria	Iodine	Salt
Belgium	Vitamin A	Margarine, low-fat margarine, cooking fats
	Vitamin D	Margarine, low-fat margarine, cooking fats
Denmark	Iodine (13 mg per kg of salt)	Cooking salt and salt used for the production of bread and other bakery products
Estonia	No specific legislation	
France	No specific legislation	
Germany	No specific legislation	
Italy	Iodine (potassium iodide and/or iodized potassium)	Salt, obligation for the retailers selling salt for direct consumption to ensure the availability of iodine-enriched salt in addition to common salt
Lithuania	Iodine (20-40 mg per kg of iodine)	Salt (all retailers must sell iodized salt; restaurants and bakers must use it)
Holland	Vitamin A	Spreading fats

Country	Nutrient	Food/Food Category
	Vitamin D	Spreading fats
	Iodine	They replace salt, bread, meat-based products
Poland	Vitamin A	Normal or low-fat margarine, low-fat butter, butter and oils
	Vitamin D	Normal or low-fat margarine, low-fat butter, butter and oils
	Iodine	Common salt for human consumption
Sweden	Vitamin D	Mill with max 1.5% fat content and, for direct use, it must contain 3.8-5.0 micrograms of Vitamin D per litre. The Swedish National Food Administration may permit exceptions.
	Vitamin A	Margarine and fats, as well as the corresponding low-fat products, must contain 0.9-1.5 RE of Vitamin A and 7.5-10 micrograms of Vitamin D per 100 grams. The Swedish National Food Administration may permit exceptions.
Slovenia	Iodine	Salt
Slovakia	Potassium iodide and Iodized potassium	Salt for food use
United Kingdom	Vitamin A	Margarine
	Vitamin D	Margarine
	Calcium carbonate	Flour, except for: (a) whole flour (b) flour with yeast and a calcium content not lower than 0.2% (c) malt flour
	Ammonium ferric citrate, ferrous sulphate	Flour, except for whole flour, where the addition is necessary to reach the legal level
	Thiamine	Flour, except for whole flour, where the addition is necessary to reach the legal level
	Nicotinic acid or nicotinamide	Flour, except for whole flour, where the addition is necessary to reach the legal level
	Bivalent ions with calcium as the main ion	Desalinated or sweetened bottled water and spring water

This situation posed the risk of generating obstacles to the free movement of some products, with direct implications for the individual markets and the competitive scenario. After consulting the parties concerned, the European Union concluded that there was a need to provide a higher level of information on the nutritional contents of enriched foods, as pointed out in the Proposal for a Regulation of the European Parliament and Council on the availability of information for consumers (EC, 2008). This initiative confirms, indeed, the need to keep going along the path towards the harmonization of the legislation of the various Member States, since the multifaceted picture that emerges from Table 1 can be detrimental to the functioning of the internal market, create unequal conditions in competition, promote food products accompanied by inconsistent and scarce information, and generate confusion among consumers. Finally, different protection

levels had been created for European citizens in consideration of the more or less rigorous – or even completely lacking, as sometimes was the case – measures undertaken by individual national laws. For these reasons, in December 2006 the European Parliament and Council issued Regulation no. 1924 regarding the nutritional and health claims made on foods and Regulation no. 1925 on the addition of vitamins and minerals, as well as some other substances, to foods (and subsequent amendments and supplements), in order to harmonize manufacturing, marketing and communication practices concerning the products that claim nutritional and health-enhancing benefits.

### 3 The European regulation of enriched food products: state of the art, types and characteristics.

The most reliable Italian scientific literature describes enriched products not as a category in itself, but rather in connection with the so-called 'fortified foods', which are defined as foods whose nutritional composition has been changed without affecting their total energy value. This means that only vitamins and minerals are added. However, these products do not cover all the innovative types of products that have been introduced in the food industry in recent years. For a complete classification, it could be useful to recall the conceptual framework developed by Cannella et al. (2007), who suggested the following categorization:

*Fortified food*: foods made more nutritious without altering their energy value. Fortification is a technological process used to add non-energy producing nutrients (minerals and/or vitamins) to traditional foods of widespread consumption such as, for example, iodized salt or cereals fortified with folic acid. These substances are of paramount importance to increase the content of specific nutrients in a given population when nutritional deficiencies have been shown to exist.

*Enriched food*: foods whose concentration of one or more nutrient/s, already existing in nature but that are often lost during processing, is increased. An example is the addition of vitamins and/or minerals to breakfast cereals or the addition of calcium to fruit juices or soy milk.

*Supplemented food*: in this case the addition consists in introducing a nutrient that was not originally contained in the food, such as omega-3 fatty acids or phytosterols in milk and its derivatives, or carotenoids and Vitamin D added to margarine in order to make its profile more similar to that of butter.

These definitions were used by nutrition experts even in the absence of a corresponding classification at legislative level, since the only Italian products included in the notification of the Ministry of Health were fortified products, which also included, as can be seen in Table 1, iodized salt. From a nutritional point of view,

vitamins and minerals are considered to be essential substances that cannot be synthesized by our body, so the demand for these nutrients must be fulfilled with an appropriate diet. The nutritional demand of these substances is very small, although there is no food in nature that contains all the vitamins or minerals. The total content of a nutrient, however, provides only an approximate indication of the quality of a given food since, from a nutritional point of view, we must consider the bioavailability of the element, which is defined as the percentage of the total content absorbed and subsequently used by the body for its specific functions (Costantini et al., 1999). For this reason, article 1 of Regulation no. 1925/2006, regarding enriched foods, established that only the vitamins and minerals listed in a positive list be used (Annex I and II); that they must be supplied in their bioavailable form, so that the body can use them, based on scientific evidence obtained by specific studies; and that they are meant for specific population groups with evidence of nutritional deficiencies. The lack of one or more vitamins in the diet or the presence of antagonistic factors that reduce their bioavailability can cause deficiency syndromes. In addition to that, we should remember that, if daily recommended doses are exceeded, an opposite process to nutrition may take place, which may cause toxicity for certain liposoluble vitamins. The mineral content in foods derives from the original soils and irrigation water used. Minerals can be distinguished into macroelements, which are found in tissues in amounts that can be measured in grams, and microelements or oligoelements, which are found in amounts that can be measured in milligrams. They are equally important – although in different amounts – to ensure the well-being of the body. However, while no evidence has been found of diseases being caused by the excessive intake of most of them, some minerals have been proven to cause veritable intoxications. Iodine, fluorine and selenium are some examples. As a confirmation of the aforesaid, the Memorandum of the Ministry of Health no. 4075 of 6 March 2008, with which the Ministry passed (EC) Regulation no. 1925/2006, specified that the enrichment process must lead to the availability

of safe foods, suitable to supplement the intake of said nutrients, based on scientific evidence - this is the meaning of enriched foods: food with the addition of vitamins and minerals.

#### **4 The main criticalities in the adoption of the nutrition claim «SOURCE OF»**

In 2006, the trade name of enriched, fortified and supplemented foods was connected by European lawmakers to a single nutrition and/or health claim (EC Regulation no. 1924/2006), «IT CONTAINS», followed by the indication of the nutritional substance or other type of substance. The phrase at issue only applies to foods that contain a nutritional or other substance for which no specific condition has been provided for in the regulation, only if said foods are compliant with all the provisions of the same regulation. In particular, it is specified that for the addition of vitamin and minerals, the indication «SOURCE OF» can be used «only if the product contains at least a significant amount, as specified in the annex to Directive 90/496/ EEC or the amount specified in the exceptions mentioned in article 7 of (EC) Regulation no. 1925/2006». In the case at issue, only the latter phrase, «SOURCE OF», identifies the category of enriched products, as also inferred from the more recent Memorandum of the Ministry of health no. 4075 of 6 March 2008. It follows that a first problem concerns the definition of «significant amount» (article 6, point 6). The Directive 90/496/ EEC states that for an amount to be considered significant in 100 g or 100 ml, or any package if it contains a single portion, reference should be made to 15% of the recommended dose indicated in the Annex to the Directive, which also indicates which vitamins and minerals can be claimed and the related recommended daily allowance (RDA). This is to avoid the affixing of promotional claims on food products showing extremely small or non-significant amounts of vitamins and minerals that would bring no benefit to the consumer, and could therefore be misleading. A second problem stems from the fact that Regulation no. 1925/2006 contemplates the possibility for food manufacturers to add

substances to food other than vitamins and minerals, such as microelements (“traces”), amino acids, essential fatty acids, fibre, plants and herbal extracts (so-called ‘fortified foods’). The Regulation suggests that the legislation of individual Member States be harmonized concerning the addition of said substances and requires that a special Community Register be created. By enforcing the European legislation, the application Memorandum of the Ministry of Health recalled above (no. 4075/2008) authorizes the use of substances other than vitamins and minerals and divides them into substances present only in food supplements and to be considered as «innovative food» (e.g. phytosterols) and substances with functional purposes already used in the Community as food ingredients, apart from food supplements (e.g. coenzyme Q10 and lutein), which were not included in the application of (EC) Regulation no. 258/97 for novel foods. For both categories, Italian lawmakers required the manufacturer’s notification for exclusive monitoring purposes. As a matter of fact, since the substances used, such as lutein (an antioxidant with eye protection properties that defends from certain diseases) and Q10 (an antioxidant with a protective function against free radicals), sometimes claim properties or effects directly related to health, they should rather fall under articles 13 or 14 of Regulation no. 1924/2006, which respectively regulate health indications other than those referring to the reduction of disease risks and claims concerning the reduction of disease risks. In this case, the food products that claim said health-related effects must follow the stricter requirement of obtaining an authorization from EFSA (THE European Food Security Authority) to use that claim, and this authorization is issued after a careful assessment of the substances used to enrich the foods, based on authoritative scientific opinions. The authorization also extends its effects to the conditions for the use of health-related claims. This certainly ensures a higher level of safety and protection of consumers. Need only recall, in this regard, that, as at 6 May 2011, only 16 claims had been authorized and 62 rejected, to prove the rigour of the procedures followed by EFSA in the



authorization process. However, we should point out that the very definition of “nutrition and health claim” contains, in embryo, the risk of confusing the different indications for consumers. In fact, art. 2 of Regulation 1924/2006 defines a «NUTRITION CLAIM» as «any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: a) the energy (calorific value) it provides, provides at a reduced or increased rate or does not provide, and/or b) the nutrients or substances it contains, contains in reduced or increased proportions or does not contain» and «HEALTH CLAIMS» as «any claim which states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health» and, finally, as «REDUCTION OF DISEASE RISK CLAIM» as «any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduced a risk factor in the development of a human disease ». A second problem that arises is that, to date, the register of the «other substances» that can be used pursuant to Regulation no. 1925/2006 has not yet been published. In addition to that, we should not neglect that enriched products are the result of the manipulation and transformation of traditional products, and therefore need very complex technological processes that can considerably modify the global nutritional value of the food, while reducing its praiseworthy constituents or increasing less praiseworthy constituents, such as thickeners, sweeteners and aromas. It is therefore important to evaluate the final global nutritional value of the food and not only the value of the individual nutrient. In order to protect consumers, the (EC) Regulation no. 1925/2006 introduced some limits to the enrichment of products in order to prevent consumers from being excessively conditioned by the health claim and be pushed to prefer fortified foods to similar foods to which said substances have not been added. In particular, article 4 excludes non-processed foods from enrichment, including, but not limited to, fruits, vegetables, meat, fowl, and fish. In fact, fresh unprocessed products have always been considered as the most useful, from a nutritional

point of view, according to the most authoritative food guidelines (MIPAF, INRAN, 2003; U.S. Department of Agriculture, U.S. Department of Health and Human Services, 2010), which makes it appropriate for these foods not to be manipulated to the detriment of their nutritional value. Drinks with an alcohol content exceeding 1.2% are excluded from the addition of vitamins and minerals because this could induce consumers to increase their alcohol intake to assimilate the micronutrients in it, with a severe damage to their global health conditions (even though, paradoxically, chronic vitamin deficiency is a well-known condition in alcoholics). Even in the case of salt used as a carrier of iodine, the guidelines suggest that iodized salt should always be presented with the indication to avoid excessive sodium chloride consumption because a high intake of this substance can increase the risk of cardiovascular diseases (Ministry of Health, 2005). The aim is to reach a compromise between the satisfaction of taste and the prevention of risks related to sodium. In addition, we recall that excessive intakes of iodine may become dangerous if 2 mg/die are exceeded, a value that is difficult to reach with a normal balanced diet. The same applies for the addition of minerals in confectionery products or chocolate, to avoid their overuse. It follows that the attraction of enriched products should never induce consumers to exceed in the consumption of products that should be eaten in limited quantities.

It is useful to remember that the problems connected with the use of nutrition and health claims specifically concerns the European legislation. Indeed the USA Food and Drug Administration (FDA), after issuing the Nutrition Labeling and Education Act (NLEA) in 1990, started a huge classification work that led to the identification of requirements for the use of health claims and the classification of these last into health claims and qualified health claims (also provided in articles 13 and 14 of the (EC) Regulation no. 1924/2006). Then the FDA published the list of authorized claims. The nutrition claims were defined as indications regarding the content of a substance by FDA who, consequently, included them in

the comparative claims, eliminating any risk of confusing the meanings and types.

### **5 Some summarising remarks on the future developments of enriched products**

The widespread availability in the market of many categories of innovative food products that boast beneficial and health-enhancing properties in connection with the introduction of particular substances in these foods has increasingly placed consumers in the condition of being affected by advertising in their buying habits rather than basing their selection on real and conscious scientific knowledge. As a result, some foods, such as enriched foods, have conquered significantly larger market shares without being supported by an improvement in the consumers' awareness of nutritional issues. We should not forget that commodity studies, as pointed out by authoritative authors, have recorded a passage from the «science of merchants» to the «science of citizens», which aims at privileging the interests and rights of consumers, expressed not only by the possibility of paying less for a given good, but also – and most of all – by that of having the availability of goods and foods that are not harmful for the health (Nebbia, 1991). Many of the enriched products introduced in the market are not supported by the scientific evidence that artificial additions actually ensure the same assimilation or play the same function as those deriving from the consumption of traditional foods. Indeed, it is often the composition of the food and the combination of more substances that ensures the beneficial effect for our body. In some cases, the claimed enrichment does not even correspond to the actual composition of the product (Altroconsumo, 2011), up to veritable commercial fraud.

The Community legislation was issued precisely to systematically regulate the manufacturing and trading of products enriched with vitamins, minerals, and other substances in the European market. However, while, on the one side, the first applications of Regulation no. 1924 and n. 1925 del 2006 have created a taxonomy of reference for nutritional nomenclatures, on the other side, a number of application issues

emerged, among which we have seen the risk of confusion between nutritional and health-enhancing trademarks. The introduction of increasing numbers of enriched products in the market without promoting comprehensive information and dietary education campaigns is a road that is only apparently shorter towards an improvement of the intake of nutrients for the population. Consumers may be puzzled when they have to choose among extremely wide ranges of food for the cultural and scientific knowledge available to them and they can end up by being merely convinced by health claims that are not always supported by documentary evidence.

We hope that the complex legislative framework will produce communication tools that are easier to use for the businesses and easier to understand for consumers, as they, indeed, are the weak link of the food chain, having to face the difficult situation of choosing on the basis of easier-to-read messages compared to the most authoritative, but often hard to understand, nutritional labels. Consumers must be placed in the condition to understand the effects of the individual enriched foods, so that their buying choices may have favourable implications on their wellbeing and health conditions. A valid aid in this direction comes from nutritional standards and food guidelines. While the former indicate the coverage, with good safety margins, of the specific demand for nutrients and energy (RDA, *Recommended Daily Allowance*, for Americans and LARN, *Livelli di Assunzione giornalieri Raccomandati di energia and Nutrienti* [recommended daily energy and nutrient intake levels] for Italians), the latter identify the most appropriate types of foods to protect and maintain health. Both these tools can be used together with any other indication, such as, for instance, the food guide pyramid, which may provide additional information helpful to follow an adequate and complete diet.

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