

# Lights and shadows about health claims: analysis of food labels in a field survey in Florence

G. Bonaccorsi<sup>1</sup>, M. Chellini<sup>2</sup>, M. Bertini<sup>3</sup>, D. Salvi<sup>3</sup>, C. Lorini<sup>1</sup>

*Key-words: Health claim, food label, EU regulation, retail distribution*

*Parole chiave: Health claims, etichette alimentari, regolamento europeo, vendita al dettaglio*

## Abstract

**Background.** Health claims (HC) are those statements on food labels that state, suggest, or imply that a relationship exists between a food category, a food product, or one of its constituents, and health of consumer. The European legislation on the use of HC aims to encourage responsible consumption by people. The aim of this study is to assess the adherence of HC to EU norms in foodstuffs sold in the large-scale retail distribution in Florence.

**Methods.** Two independent researchers have separately selected and assessed the foodstuffs with HC sold in at least two of four supermarkets identified randomly in Florence. Each selected product was assessed by a checklist with seven macro-criteria, extrapolated from the 'Specific Conditions' and 'Restrictions of Use' provided by EU regulations, rating the adherence of the chosen foods to the legislation.

**Results.** Seventy-seven products were assessed. Only a limited number of products show full compliance to all the criteria. Specifically, noncompliance related to Criterion 3 ("the amount of the food and pattern of consumption required to obtain the claimed beneficial effect are reported") is the most significant: the absence of indications about the maximum amount to be consumed or the modality of consumption could represent a risk of overconsumption and, consequently, a risk for health.

**Conclusion.** According to the results, we hypothesize a lack of knowledge of the EU norms on the part of the manufacturer. A great deal of work is still to be done to assess and manage these products in the right way, as well as to communicate the right messages to the consumers.

## Introduction

Health claims (HC) are those statements on food labels that state, suggest, or imply that a relationship exists between a food category, a food product, or one of its constituents, and health (1).

This kind of message publicizes the beneficial health effects derived from the consumption of a specific food product (2),

and can induce or increase the consumer's purchase (3-5), depending on consumers' and HCs' characteristics (6-9). In the scientific literature, food that has beneficial effects on human health is generically defined 'functional food' (FF) (10, 11).

The concept of FF has been thoroughly discussed in recent years worldwide (12-15), but the specific definition of FF remains a matter of debate. In Europe, the

<sup>1</sup> Department of Health Science, University of Florence, Italy

<sup>2</sup> School of Specialization in Hygiene and Preventive Medicine, University of Florence, Italy

<sup>3</sup> School of Human Health Science, University of Florence, Italy

operational definition developed and given by the Functional Foods Science in Europe (FUFOSE) project is commonly accepted: *A food can be regarded as “functional” if it is satisfactorily demonstrated to beneficially affect one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction in the risk of disease* (16). Functional food products are not pills or capsules but part of a normal diet and they must demonstrate their effects in amounts normally consumed in the diet (17). The European legislation does not consider FF as a separate food category, but it defines and regulates the transparent communication of what they are and what they are expected to yield in terms of health, in order to make the consumers aware and informed and prevent potential unfair practices aimed at maximizing sales by use of false or misleading indications on the package (18-20). In this sense, any food matrix may potentially have an HC if it complies with the conditions of use, and any single claim must be submitted to an authorization procedure, which requires a first technical opinion by the European Food Safety Authority (EFSA) and a second opinion by the European Commission (21, 22). The result - positive or negative - of this process is recorded in the Register of EU Nutrition and Health Claims, which is publicly available on the European Commission website<sup>1</sup>.

Unlike the European system, in Japan (where FF originated), the product itself, instead of the reported HC, is subjected to an authorization that allows the introduction of all the authorized FF in a specific catalogue, which is available on the Japanese Health Ministry website<sup>2</sup> (23).

Although the European legislation that regulates the use of HC aims to encourage responsible, informed consumption by people, there are many pitfalls in which the consumers could incur, owing to the way of wording or to a misleading interpretation of these messages, which EU regulation cannot completely control, or, sometimes, the failure - voluntary or involuntary - to comply with the law (24).

This paper describes the results of a pilot study designed to assess the adherence of HC to the European legislation, as defined by the Regulation EC no. 1924/2006 and taking into account the Regulation EU no. 1169/2011 (25), which outlines the legal framework for labelling of the food products commercialized by some Italian large-scale retail distribution points of sales.

## Methods

### *Sample selection*

Using a simple random sampling, a sample of four supermarkets (A, B, C, D) from the large-scale retail distribution in Florence has been selected, each supermarket belonging to a different trade group. In each supermarket, two independent researchers identified on the shelves all the food products showing one or more HC.

### *Analysis of health claims*

HCs placed on the packages of products sold in at least two of the supermarkets were analysed to evaluate compliance to the conditions established by the EU Regulation 1924/2006. As the products sold in the supermarkets change rapidly, we decided to include only those sold in at least two of them in order to have the picture of some of the most commercialized products on the market. To evaluate compliance to the EU Regulation, a specific checklist including seven macro-criteria, extrapolated from the Specific Conditions for HC (Reg.

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1) [http://ec.europa.eu/food/safety/labelling\\_nutrition/claims/register/public/?event=register.home](http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home)

2) [www.niid.go.jp](http://www.niid.go.jp)

(EC) 1924/2006 Art.10) and the Career Restrictions (Reg. (EC) 1924/2006 Art. 12), has been drafted (Table 1).

Each criterion has been judged through a blinded independent assessment led by two researchers on the basis of what is reported on the product label, in a dichotomous way, in terms of the presence (YES) or absence (NO) of the expected legal characteristics that define the criterion (Table 1).

To establish the fulfilment of the first criterion, the detected HCs were compared to those reported in the EU Register on nutrition and health claims (26). This Register, developed in accordance with

Reg. 1924/2006, collects all the permitted HCs, including those mentioned in the annex of Reg. 432/2012 (27) and subsequent amendments, reporting the conditions of use. In addition, the Register contains information about the specific authorization with the normative reference and EFSA declaration. To verify these correspondences, the indication that appears when accessing the Register was considered: “Some flexibility of wording of the claim is possible provided its aim is to help consumer understanding, taking into account factors such as linguistic and cultural variations and the target population. Adapted wording must have

Table 1 - Checklist built according to the requirements provided in Reg. (EC) 1924 / 2006 Art.10) and Reg. (EC) 1924/2006 Art. 12, used to assess how many Italian food products reporting HC comply with the EU norms.

<b>Product ID Code:</b>
1. Health claims found on the product are authorized according to the Annex to Regulation (EU) 432/2012 and subsequent amendments or the EU Register established under the Regulation (EC) 1924/2006 Chapter V Article 19. YES <input type="checkbox"/> NO <input type="checkbox"/>
2. On the label, a statement is cited indicating the importance of a healthy and balanced diet and a healthy lifestyle, in accordance with Regulation (EC) 1924/2006 Chapter IV, Article 10, Paragraph 2, Letter a. YES <input type="checkbox"/> NO <input type="checkbox"/>
3. On the label, the amount of the food and pattern of consumption required to obtain the claimed beneficial effect are reported, in accordance with Regulation (EC) 1924/2006 Chapter IV, Article 10, Paragraph 2, Letter b. YES <input type="checkbox"/> NO <input type="checkbox"/>
4. On the label, a statement is provided addressed to people who should avoid the consumption of the food, where appropriate, in accordance with Regulation (EC) 1924/2006 Chapter IV Article 10 Paragraph 2 Letter c. YES <input type="checkbox"/> NO <input type="checkbox"/>
5. On the label, an appropriate warning is provided for products that may represent a health risk if excessively consumed in accordance with Regulation (EC) 1924/2006 Chapter IV Article 10 Paragraph 2 Letter d. YES <input type="checkbox"/> NO <input type="checkbox"/>
6. The operating restrictions laid down in Regulation 1924/2006 Chapter IV Article 12 are followed. Specifically, the following disallowed claims are not present: Claims which suggest that health could be affected by not consuming the food. Claims which consider the percentage or amount of weight loss. Claims which refer to opinions of a single doctor or health professional and other associations not included in Article 11. YES <input type="checkbox"/> NO <input type="checkbox"/>
7. Every indication on health reported on the product meets the individual conditions of use provided in Annex of the Regulation (EU) 432/2012 and subsequent amendments with regard to the information referred to in Article 13, paragraph 1 of Regulation (EC) 1924/2006 ‘Health claims other than those referring to the reduction of disease risk’ or those provided by the EU Register established under Regulation 1924 / 2006 Chapter V Article 19 with regard to the information referred to in Article 14, Paragraph 1 of Regulation (EC) 1924/2006 ‘reduction of disease risk and claims referring to the development and health of children’. YES <input type="checkbox"/> NO <input type="checkbox"/>

the same meaning for the consumer as the authorized claims in the EU Register”.

The comparison and the correspondence between each HC found on the food labels with what reported in the EU Register has been used to assess the compliance with legislation.

For the second and third criteria, compliance is deemed to occur when the indications required by law are reported on the package.

Criteria 4 and 5 investigate the presence of specific mandatory warnings on the packaging when the product has (or claims to have) particular nutritional characteristics, negative for specific persons or for the amount of food beyond which it can represent a health risk.

This kind of statement is sometimes specified as mandatory in the terms of use related to the authorization. For this reason, these criteria are applicable only in certain circumstances.

For the fulfilment of the sixth criterion, we searched on the packaging for the presence of indications expressed as “not permitted”. Their absence is the condition of compliance with legislation.

For the seventh criterion, we searched and found in the EU Register on nutrition and health claims the expected conditions of use for each HC reported on the packages. We compared the declarations on the label and the requirements, including the minimum content of food substance, food product, or category of food product, provided as the conditions of use. In some cases, this assessment required cross-reference to the Annex to Reg. 1924/2006 (European Parliament and the Council of the European Union 2006) and Annex XIII of Reg. 1169/2011 (European Parliament and the Council of the European Union 2011).

The correspondence between the conditions of use and information on the package establishes the compliance to legislation.

The collected data were processed using the SPSS 24™ statistical software.

## Results

Table 2 shows the distribution of the number of products identified in every supermarket. Of the 129 identified products, 30 (23.2%) were detected in all the supermarkets and 52 (40.3%) in only one of them.

The most common products selected for the assessment of the compliance with EU norms numbered 77, and were placed in eight categories of similar foodstuffs:

- Soft drinks: eight samples
- Crackers, bakery products, and cereals: 18 samples
- Nuts: 12 samples
- Soy products: 10 samples
- Childcare products: eight samples
- Milk: seven samples
- Fermented milk and yoghurt: eight samples
- Oils and seasonings: six samples.

Table 2 - Number and percentage of food products with HC in the four selected hyper/supermarkets (A, B, C, D).

Presence in Supermarkets	Number of products	%
A	23	17.8
B	7	5.4
C	10	7.8
D	12	9.3
A plus B	2	1.6
A plus C	5	3.9
A plus D	3	2.3
B plus C	0	0.0
B plus D	7	5.4
C plus D	2	1.6
A plus B plus C	5	3.9
A plus B plus D	11	8.5
A plus C plus D	12	9.3
B plus C plus D	1	0.8
A plus B plus C plus D	29	22.5
<b>Total</b>	<b>129</b>	<b>100.0</b>

Table 3 - Percentage of products in each food category that meets the criteria included in the checklist. NA: not applicable.

Food categories (%)	Criteria						
	1	2	3	4	5	6	7
Soft drinks (N = 8)	100	87.5	75	NA	NA	100	100
Crackers, bakery products and cereals (N = 18)	72.2	55.6	50	NA	NA	100	88.9
Nuts (N = 12)	75	75	58.3	NA	NA	100	91.7
Soy products (N = 10)	100	100	40	NA	NA	100	100
Childcare products (N = 8)	100	87.5	0	NA	NA	100	100
Milk (N = 7)	100	85.7	62.5	NA	NA	100	100
Fermented milk and yoghurt (N = 8)	100	87.5	62.5	NA	NA	100	100
Oils and condiments (N = 6)	100	83.3	33.3	NA	NA	100	83.3
TOTAL (N=77)	89.6	79.2	48	NA	NA	100	94.8

Table 3 summarizes the results.

The first criterion is satisfied in 89.6% of the cases. Six of the eight categories meet the requirements of the norm. Gaps are observed in the “crackers, bakery products, and cereals” and “nuts” categories about a quarter of the products in each of these two categories have one or more unauthorized HCs.

For the second criterion, the only fully compliant category is “soy products”. The other categories have percentages of compliance ranging from 55.6% of “crackers, bakery products and cereals” to 87.5% of “soft drinks”, “childcare products”, and “fermented milk and yoghurt.”

The third criterion is largely disregarded, with full compliance in only 48% of cases. The most critical category is “childcare products”, in which no sample meets the norm. Results for other categories are unsatisfactory as well: only 33.3% in “oils and seasonings”, 40% in “soy products”, and 50% in “crackers, bakery products, and cereals” are compliant with the norm. In the “nuts”, “milk”, and “fermented milk and yoghurt” categories, just over half of the samples are compliant, with percentages of 58.3%, 62.5% and 62.5%, respectively. “Soft drinks” is the most compliant category, with 75% compliance.

The fourth and fifth criteria are not applicable. In fact, the norm provides the obligation to report on the packaging the statement relating to people who should avoid the consumption or the warning that excessive consumption may create a health risk, but it does not specify the cases in which these statements are required.

The sixth criterion is completely satisfied in all the analysed products.

The seventh criterion achieves 100% compliance in all categories except for “crackers, bakery products, and cereals”, “nuts”, and “oils and seasonings”, which have a compliance of 88.9%, 91.7%, and 83.3% respectively.

## Discussion and Conclusions

The results of this study show an inhomogeneous situation in regard to compliance with EU norms. Concerning the first criterion, in most cases a claim is found to be unauthorized not because it is absent from the EU Register but because it is formulated differently from the indications given in the same register. The lack of compliance related to the second criterion seems to be mainly due to a lack of knowledge of the norm, since the fulfilment

of the legal requirement does not represent a cost to the manufacturer or a disincentive to purchase for the customer. Noncompliance related to Criterion 3 is the most significant, not only because it is the most disregarded criterion, but also due to its potential impact on consumers' health: the absence of indications about the maximum amount to be consumed or the modality of consumption could represent a risk of overconsumption and, consequently, a risk for health. Criteria 4 and 5 are not applicable - although the law requires informing the consumers about the risks of over-consumption, when necessary, and/or warnings for people for whom this consumption should be discouraged, it does not give indications about the cases in which such information must be present on food labels/packages or how to present such information. Such warnings are absent in all the samples. Since the law is generic and does not prescribe specific indications, it is impossible to determine whether the absence of such warning is due to a noncompliance or because a warning is not deemed necessary. The only exception is for foods that have HC related to the presence of plant sterols and stanols; these products must show labels declaring a maximum daily consumption of 3 grams and indicate that people who want to lower their blood cholesterol level must consume the product under medical supervision, especially if they are following a cholesterol lowering therapy. However, they are regulated by Annex III of the EU Reg. 1169/2011 and not by HC norms, despite being substantially in accordance with Criteria 4 and 5. The consumption of these products is also not recommended for pregnant women, lactating mothers, and children under five years of age. For these food products, the assessed compliance with law is 100%.

Criterion 6 is fully satisfied in all the analysed samples.

Finally, the noncompliance found in the assessment of Criterion 7 is due to two

different factors: the absence of conditions of use expressly foreseen by law; claims related to authorized HC but expressed with formulations too different from the indications provided as condition of use.

In any cases, all the products, in their labels, show nutritional values that support HC even when these are formulated in ways that do not follow the authorization norms. This consideration seems to support the hypothesis that the food manufacturers have poor or incomplete knowledge of the specific legislation on HC and tend to use them for commercial purposes, that is to increase the sells at the points of sale, rather than to adopt a conscious illegal behaviour; in fact, they have proved to be very careful in regard to the nutritional requirements - the analysis of the nutrition fact sheets was correct for all the foodstuffs - but not to the information to be provided in HC.

The study has some important limitations. The first is related to the identification and collection of food products presenting HC; this has been done by direct visual inspection of labels and packages and we cannot exclude the possibility that some products presenting HC have not been identified. In addition, it is possible that certain foods were not on sale on the shelves at the time of inspection.

A second limitation is specifically related to probiotics and prebiotics. These food products, which contain lactic acid bacteria, are largely available on the market and their role in promoting health is a widely shared concept among consumers, although they have received neither authorization from the European Commission nor positive opinions from EFSA, in spite of the many submitted applications. To address this situation, the Italian Ministry of Health published in May 2013 the latest revision of the Guidelines on prebiotics and probiotics (28), in which it indicated the conditions of use of HC in food and food supplements and defined the criteria to be followed if they were being labelled as a product that 'promotes the

balance of intestinal flora'. The assessment made in this study is based on the criteria specified by European regulation and does not consider this national guideline, so we have excluded any assessment on these bases, even for products assessed elsewhere in this study for different HC.

Moreover, we did not express any opinion on the wording of HC, which refer to an "average consumer" who is not clearly identified in any way and let a window opened to a series of pitfalls in which he/she could incur (24).

## Conclusions

The study proves that the current system of HC authorization is often far from the consumers' product evaluation and the use that the producer makes of the HC. The EU Commission, through the technical support of EFSA, has full control over HC authorization, but no power over the use of the same claim once authorized. A producer who is going to use HC on his own products must respect the conditions and restrictions of use without any additional control, and he is not obliged to give any notification about compliance. The consequences of this situation are two-fold: on the one hand, it is impossible to know how many and which products reporting HC are on the market, without conducting specific studies (see, as example: Kaur, 2015 (29)); on the other, there is a considerable burden of responsibility on the authorities devoted to official control in assessing their actual compliance with current legislation. These consequences produce a negative synergic effect: the lack of knowledge about the actual presence and number of food products reporting HC makes it more difficult to implement an effective supervision on the part of the public authorities; in fact, there are no well-defined identified product categories to be subjected to such control, as provided in countries

outside the EU. In this regard, for instance, there is a great difference with the Japanese System of Public control, which created for such products the Foods for Specified Health Use (FOSHU) denomination - a trademark that unambiguously identifies the category of FF, so as to trace, track, and easily find these for effective supervision and control. This safeguards the consumers' right to be correctly informed in order to make appropriate food choices.

A great deal of work still has to be done to assess and manage these products in the right way, as well as to communicate the right messages to the consumers.

## Riassunto

*Luci e ombre sugli health claims: analisi delle etichette alimentari in uno studio condotto a Firenze*

**Introduzione.** Gli *health claims* (HC) sono quelle dichiarazioni presenti sulle etichette alimentari che affermano, suggeriscono o implicano la presenza di una relazione tra la salute e una categoria alimentare, un alimento o uno dei suoi costituenti. La legislazione Europea relativa all'utilizzo degli HC è finalizzata a incoraggiare un consumo responsabile da parte della popolazione. Lo scopo del presente studio è quello di valutare l'aderenza alle normative europee degli HC presenti sulle etichette di alimenti in vendita nei supermercati a Firenze

**Metodi.** Due ricercatori hanno selezionato e valutato i prodotti alimentari con HC venduti in almeno due tra i quattro supermercati selezionati casualmente a Firenze. Ogni prodotto selezionato è stato valutato utilizzando una *checklist* costituita da sette macro-criteri estrapolati dalle 'Condizioni specifiche' e 'Restrizioni di utilizzo' presenti nella normativa EU, al fine di stabilire l'aderenza alla regolamentazione.

**Risultati.** I prodotti valutati sono stati 77 e soltanto un numero limitato di questi ha mostrato una completa aderenza alla normativa. Nello specifico, la non aderenza al criterio 3, riferito alla presenza in etichetta del quantitativo dell'alimento o della modalità di consumo richiesta per ottenere i benefici per la salute, è risultata quella più importante: l'assenza di tali indicazioni potrebbe portare ad assunzione eccessiva dell'alimento, con probabili conseguenze nocive per la salute dei consumatori.

**Conclusioni.** Sulla base dei risultati ottenuti possiamo ipotizzare che esista una mancanza di conoscenza delle norme europee da parte dei produttori. È ancora neces-

sario condurre studi e iniziative per valutare e riuscire a gestire questi prodotti nel modo giusto, oltre a approfondire la modalità di comunicazione del messaggio ai consumatori.

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Corresponding author: Dr Chiara Lorini, Department of Health Science, University of Florence, Viale GB Morgagni 48, 50134 Florence, Italy  
e-mail: chiara.lorini@unifi.it