Health claims made on food

Zdravstvene izjave i prehrabreni proizvodi

Jelena Jovičić, Budimka Novaković, Ljilja Torović

University of Novi Sad, School of Medicine, Department of Pharmacy, Novi Sad, Serbia

Key words:
food; food labeling; consumer health information; health promotion; legislation

Ključne reči:
hrana; hrana, obeležavanje; potrošači, zdravstvene informacije; zdravstvo, unapređenje; zakonodavstvo.

Introduction

According to the World Health Organization (WHO), 75% of all deaths in the year 2030 will be caused by mass noncommunicable diseases (NCDs) 1. Causes of NCDs are known and can be non-preventable (age and genetic heritage) and preventable or modifiable (unhealthy eating habits, insufficient physical activity, tobacco use) 2.

Social and economic burden of population caused by NCDs is enormous and growing, so WHO set a specific goal in 2005 – an additional 2% reduction in chronic disease death rates worldwide per year over the next 10 years 3. The WHO’s Action Plan 3 from 2008 promotes healthy eating habits enabling consumers to make informed choices.

Declarations of foodstuffs, promotional materials and advertising campaigns are considered as means of direct producer-consumer communication, making it vital for the information written on declarations (as well as on promotional materials and in advertising campaigns) to be scientifically-based and well-understood by the consumers. Advances in knowledge and understanding of the link between nutrition and health resulted in shift from nutrition claims to health claims written on food declarations. Health claims present health benefits for consuming certain foods by consumers. Public interest in health promotion is a driving force behind the use of health claims and an incentive for innovation in food industry and pharmaceutical industry. Therefore, a well-designed legal system for approval of the use of health claims should exist.

Codex Alimentarius, a joint body of the Food and Agriculture Organization of the United Nations (FAO UN) and WHO defined health claims in 1997 as “any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health” 4. Codex Alimentarius implies that national regulations concerning health claims should be harmonized in order not to disrupt free trade system 4.

Current legislation concerning health claims in different countries

Japan

Country that has introduced to the world the concept of “functional food” and, parallel, the idea of health claims is Japan. The use of health claims in Japan is controlled by the Ministry of Health, Labour and Welfare (MHLW) 5.

In 2001, MHLW divided foods bearing health claims into 2 groups: foods with nutrient function claims (FNFC) and food for specified health uses (FOSHU). FNFC standards and specifications so far have included nutrient function claims for 17 ingredients (12 vitamins and 5 minerals). FOSHU refers to foods containing ingredient with functions for health and is officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance or promotion of health or special use by people who wish to control health conditions. In order to sell food as FOSHU, health claims written on it must be approved by the MHLW. Specific requirements for FOSHU declarations limit their sales out of Japan 6–8.

United States of America (USA)

The American Food and Drug Administration (FDA) defined health claim as “any claim made on the label or in labeling food, including dietary supplements, that expressly or by implication, including “third party” references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g. a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition” 9,10. There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling food or dietary supplements:
1. The 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations author-
izing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted by food producer in health claim petitions concerning link between certain food component and health. Health claims authorized as described, have to comply with the NLEA (1990), Dietary Supplement Act (1992) and Dietary Supplement Health and Education Act (DSHEA, 1994). The most common NLEA authorized health claims are ones describing the link between fruit, vegetables and cereals and coronary artery disease, as well as the ones linking saturated fatty acid content and cholesterol content with the risk of cardiovascular disease.

2. The 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of a scientific body of the US government or the National Academy of Sciences. Such claims may be used after submission health claim notification to FDA.

3. The 2003 FDA Consumer Health Information for Better Nutrition Initiative provides for qualified health claims where the quality and strength of scientific evidence falls below that required for FDA to issue an authorizing regulation. Such health claims have to be qualified to assure accuracy and non-misleading presentation to consumers 10, 11.

According to the strength of supporting evidence, FDA recognizes 4 categories of health claims: A (supported by strong scientific evidence), B (moderate scientific evidence level), C (low scientific evidence level) and D (the lowest scientific evidence level) 10, 12.

Use of health claims in advertising campaigns is controlled by the Federal Trade Commission (FTC) leading to conflicting situations when health claims not approved by the FDA are used in advertising 11, 13.

**European Union**

Health claims in the European Union (EU) are covered by the European Commission Regulation No 1924/2006 on nutrition and health claims made on foods 14 in which a health claim is defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health". According to the authorisation protocol, health claims in EU are divided into "article 13 claims" and "article 14 claims" accordant with the Regulation 1924/2006. Health claims other than those referring to the reduction of disease risk and to children's development and health, describing or referring to the role of nutrient or other substance in growth, development and functions of the body or psychological and behavioural functions or slimming or weight control are considered "article 13 claims", as well as health claims based on newly developed scientific evidence which include a request for the protection of proprietary data. Reduction of disease risk claims and claims referring to children's development and health are "article 14 claims".

Health claims in use in the EU must be authorized by the European Food Safety Authority (EFSA). EFSA is supposed to publish a list of approved, well-defined health claims in January, 2010. Criteria for authorisation of health claims in Europe are defined in the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) project 15. The basic clause of PASSCLAIM is that the link between food constituent and disease risk reduction is confirmed by studies on humans 15.

Health claims are allowed only on food with certain nutrient profiles. Nutrient profile includes saturated fatty acids, sodium, dietary fiber and unsaturated fatty acid content of food. Definition of nutrient profiles is supposed to prevent "masking" of undesired nutrient profile of certain food by health claims 16.

**Republic of Serbia**

National regulation concerning health claims is currently underway.

Note: In July 2010, after this manuscript had been accepted, national regulation of health claim use was adopted. Now, in December 2010, the implementation of the regulation provisions concerning health claims is still pending.

Despite the regulation differences, requirements and limitations for the use of health claims are similar. A health claim must not attribute to food the property of preventing, treating or curing a human disease. Health claims should not be false, ambiguous or misleading, nor should it give rise to doubt about the safety and (or) the nutritional adequacy of other foods or a balanced and varied diet. It is not allowed for health claims to encourage or condone excess consumption of food, refer to changes in bodily functions which could give rise to or exploit fears in the consumer 14.

Health claims have to refer to food ready for consumption in accordance with the manufacturer's instructions and must relate to the quantity of a product that can reasonably be expected to be consumed provided that a significant quantity of the nutrient or other substance to which the claim relates will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence. Health benefit can be the result of the presence, absence or a reduced content in food or category of food of a nutrient or other substance in respect to which the claim is made 14.

Health claims that are not allowed are these suggesting that health could be affected by not consuming food bearing a health claim, making reference to the rate or amount of weight loss and referencing to recommendations of individual doctors or health professionals. Beverages containing more than 1.2% alcohol by volume shall not bear health claims 14.

The use of health claims in labeling, presentation and advertising is allowed if followed by statements indicating the importance of a varied and balanced diet and healthy lifestyle, the quantity of food and pattern of consumption required to obtain the claimed beneficial effect, a statement addressed to persons who should avoid using food (where appropriate) and an appropriate warning for products that are likely to present health risk if consumed to excess 14.

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**Limitations of free trade**

Different health claim regulation frameworks present a limitation in free trade systems. The most common conflicting situation is importing foodstuffs bearing a health claim into a country with different (or non-existent) health claim regulation. As a result, international community strives to harmonize regulatory systems.

Examples of health claims compliant and non-compliant with the mentioned regulations (US, EU, Serbia) are given in Table 1.

### Table 1: Health claims in EU, USA and Serbia

<table>
<thead>
<tr>
<th>Relevant data on foodstuffs</th>
<th>EU* (example of an authorized health claim)</th>
<th>USA† (example of health claim in use in USA – not in compliance with the regulation)</th>
<th>Serbia‡ (example of health claim in use in Serbia – sample product taken from the market)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food constituent</td>
<td>Mixture of long chain omega-3 polyunsaturated fatty acids</td>
<td>Water-soluble dietary fiber</td>
<td>Not defined</td>
</tr>
<tr>
<td>Health effect</td>
<td>Blood pressure reduction (3 g/day) and serum triglyceride level reduction (2–4 g/day)</td>
<td>Coronary artery disease risk reduction</td>
<td>Treatment of type 2 diabetes (according to the producer)</td>
</tr>
<tr>
<td>Health claim</td>
<td>On the label of a dietary supplement containing mixture of long omega-3 polyunsaturated fatty acids: “helping the reduction of serum triglyceride levels and maintaining normal blood pressure”</td>
<td>On breakfast cereal’s label: “reduces cholesterol by 4% in 6 weeks”</td>
<td>On the label of herbal tea: “proven efficacy in the treatment of type 2 diabetes: “one package of this tea is enough to reduce blood sugar levels by 10–15%”</td>
</tr>
</tbody>
</table>

Note:
- *On the basis of the data presented, the European Food Safety Authority (EFSA) concluded that a cause and effect relationship exists between the consumption of eicosapentaenoic and docosahexaenoic acid and blood pressure and serum triglyceride level reduction. Opinion based on relevant scientific data, including:*

Health claim linking water-soluble dietary fiber and coronary artery disease risk reduction is Nutrition Labeling and Education Act (NLEA) authorized. Food and Drug Administrations (FDA) position was that the health claim in question attributed the property of drug to food and in May 2009, asked the producer to provide scientific proof for the alleged cholesterol level reduction of 4% in 6 weeks. In June 2009, producer submitted 4 articles about the claim in question. In an public letter, FDA announced that the results of 3 out of 4 submitted articles were inconclusive and called for the revision of all available scientific data on the subject and the revision of possible health claim wording in order to prevent the misleading of consumers. The case is still pending.

*Health claim in question does not comply with either USA, EU or Japan regulations*  

**Consumers and health claims**

The basic purpose of health claims is consumers' benefit by providing information about healthy eating habits, but food industry often uses health claims for advertising purposes. A well educated and motivated consumer is able to make informed choices about his diet.

Studies done both in the USA and the EU showed that taste and price dictate food choices and that health benefits and nutritive characteristics of food are not among consumers' priorities. Consumers' attitudes are tightly related to their age, social status and education level. Various EU nations are concerned by different health issues, making it necessary for the development and marketing of new food products to be market-oriented.

The underlying principle of all regulatory frames is for health claims to be truthful, clear and understandable. In practice, this seems to be the most controversial and scientifically challenging principle. Inadequate wording of health claims may mislead consumers. Word “may” causes consumers to doubt a health claim, while words such as "proven" or "proof" are perceived as assuring. An average consumer prefers descriptive adjectives and visual representations over numbers. According to the consumers' associations, nutrition claims are often perceived as health claims.

The absence of health claims can decrease the use of foods with proven health benefits (fruits and vegetables).

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that food labels already contain too much information, making it hard for consumers to prioritize and demotivates them. In the USA, the majority of consumers are unable to make a distinction between different health claims categories (A, B, C, D), regardless health claims' wording, despite FDA efforts.

Conclusion

Food labeling is equally important for food producers and consumers. Health claims should be used cautiously, in order not to undermine the fact that diet as a whole, and not a specific food constituent, is the key to maintaining good health.

REFERENCES

26. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific Opinion on the substantiation of health claims related to EPA, DHA, DPA and maintenance of normal blood pressure (ID 502), maintenance of normal HDL-cholesterol concentrations (ID 515), maintenance of normal (fasting) blood concentrations of triglycerides (ID 517), maintenance of normal LDL-cholesterol concentrations (ID 528, 698) and maintenance of joints (ID 503, 505, 507, 511, 518, 524, 526, 535, 537) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA J 2009; 7(9):1263.