The evaluation of health claims in Europe
What have we learned? – Part 1

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ABSTRACT: The implementation of health claims legislation in the European Union has involved a steep learning curve for everyone. While a few years ago many food companies were quite enthusiastic about the ideas of the easier circulation of goods within the community and protecting the consumer from misleading claims, the picture today is no longer so clear. Due to the high standards needed for the scientific substantiation of health claims, many currently used health claims will soon be banned from the market. Scores of them are indeed not very supported, but at least some of them might be correct, albeit not sufficiently substantiated. It is therefore very important for the industry to learn from the existing evaluations to enable better research in this area and to improve the chances of success of following applications. This paper focuses on the experiences of existing evaluations, leading to a better outcome not only for the industry but also for consumers.

KEYWORDS: Health claims wording, scientific substantiation, functional foods, food supplements.

INTRODUCTION

About 10 years ago the scientific concepts of Functional Foods in Europe consensus document was published by the International Life Sciences Institute Europe (ILSI) (1) and since then the European market of functional foods has grown rapidly. Later the *Codex Alimentarius Guidelines for use of nutrition and health claims* were accepted in 2004, and amended in 2008 and 2009, followed by *Recommendations on the scientific basis of health claims* (2). In the European Union *Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods* entered into force in 2007, while final provision terms for health claims are starting to run out in 2010.

The general funcion of the extensive and complex modern food legislation is to protect the consumer, assure they have non-misleading information and an informed choice and to ensure the free circulation of goods and fair trade within the community (3). While the regulation represents a major step forward in providing a unified approach to claims and harmonisation of the European market (4), its implementation is sometimes controversial and brings major consequences for marketing, research and innovation (5). The principle of the regulation is that all health claims on foods (and food supplements) need to be scientifically substantiated by generally accepted scientific evidence and pre-approved. Claims are scientifically evaluated by the European Food and Safety Authority (EFSA) and authorised by the European Commission. Authorised claims are included in the Community Register, together with conditions and restrictions of use (6). The decisions about specific health claims in the European Union (EU) are extremely important for the use of functional foods not only in the EU market, but world-wide. Many countries are still developing their health claims regulation and decisions in the EU have therefore often been monitored very closely. Basically, under European legislation health claims can be arranged in four groups:

- **General function claims**
  (Article 13) describing or referring to the role of a food or food constituent in the growth, development and functions of the body, psychological and behavioural functions and body-weight connected functions, including the sense of hunger or satiety (not referring to children).
- **New general function claims**
  (Article 13(5)) which were not in use before 2008 or are based on newly developed scientific evidence (and might include a request for 5 years of the protection of proprietary data).
- **Disease risk reduction claims**
  (Article 14(1) a) stating, suggesting or implying that the consumption of a food or food constituent significantly reduces a risk factor in the development of a human disease.
- **Children's development and health claims**
  (Article 14(1) b) which are considered on a case-by-case basis since no exact definition is given.

While all claims covered by the last three mentioned groups are to be submitted directly by applicants, lists of general function claims were provided by EU member states in collaboration with the industry and included in a consolidated list which forms the basis for the EFSA evaluation. In 2009 it became clear that the process of evaluating existing general function health claims would be much more demanding than expected. After examining over 44,000 claims supplied by the EU member states, the EFSA has received a consolidated list of over 4,600 general function claims which are now in the evaluation process (7). As of August 2010, the EFSA had published 125 opinions providing scientific advice for about 900 general function health claims. Other evaluations are expected to be finished by 2012.

THE EVALUATION OF HEALTH CLAIMS

In 2007 the *Guidance for the preparation and presentation of the application for health claims* was published by the EFSA (8), following by *Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of disease risk reduction claims and children's development claims*. Substantiations are performed by taking into account the totality of the available pertinent scientific data and by weighing the evidence, in particular whether:

- the effect is relevant for human health;
- there is an established cause-and-effect relationship between the consumption of the food and the claimed effect in humans;

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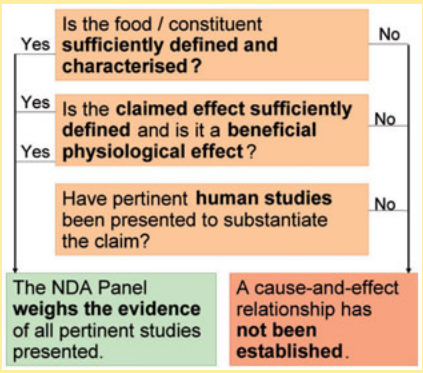
- the effect has been shown on a study group which is representative of the target population; and
- the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet.



Scheme 1. Key questions addressed by the EFSA in the scientific evaluation of health claims (9).

While two years ago the industry was hoping to see the EFSA's "weighing the evidence" also move in favour of observational studies, we can now see that this is not the case. After many published opinions in connection with general function claims it is now clear that a similar approach to the evaluation of all health claims has been adopted (Scheme 1, (9)).

LEARNING FROM EXISTING EVALUATIONS

Since the process of scientifically evaluating health claims is not regulated in detail it is very important to learn from the EFSA's existing opinions. This will not only mean easier work for the EFSA but also significantly stronger chances of success with further applications, particularly in projects where research is still in the planning phase. It has been shown that truly relevant human intervention studies are critically important for the proper substantiation of a health claim, and that many negative opinions could also be connected with some basic errors which might be avoided.

THE WORDING OF A HEALTH CLAIM

From the marketing aspect the wording of a health claim is vital. Such claims can have a major impact not only in relation to health but also on the perception of other product attributes (10). The use of health claims is unfortunately often connected with intentions to mislead the consumer. While this is clearly prohibited by law (11), companies are employing innovative strategies to avoid these rules so as to make greater profit. Living in the Internet era means that the problem is often connected with information on websites which cannot be controlled successfully.

In a health claim application the wording must be provided in English. The wording must reflect the scientific evidence and should not be too general or non-specific (12); however, experience shows that inappropriate wording might not result in a negative EFSA opinion. In such cases, the EFSA can propose an appropriate wording which reflects the scientific evidence. During the authorisation other aspects are also considered by the Commission, including the fact that a health claim should be easily understood by consumers. An example of such a procedure can be shown in an application for a health claim for water-soluble tomato concentrate (13). The wording "Helps to maintain a healthy blood flow and benefits circulation" was proposed by the applicant, yet the EFSA considered that such wording did not reflect the scientific evidence because only measures of platelet aggregation have been used, whereas blood flow and circulation also depend on many other factors. It was concluded that the wording "Helps maintain normal platelet aggregation" reflects the scientific evidence, although the Commission later reworded this claim to be understood by consumers to arrive at its final version "Helps maintain normal platelet aggregation, which contributes to healthy blood flow". The decision was criticised on the basis that such wording is far from the "understanding of consumers", but we must all be aware that putting any science into sentences is most likely connected with low understanding rates. Since health claims regulation allows a reference to general, non-specific benefits if accompanied by a specific health claim such wordings will probably finish up in small text, whereas the marketing will particularly target the more general benefits.

When discussing the wording of health claims it should also be noted that, for reduction of disease risk claims, the wording should refer to the specific risk factor for disease and not to disease alone. This can be exemplified with an application for plant sterols (14). The wording "Plant sterols lower blood cholesterol and reduce the risk of coronary heart disease" was proposed by the applicant, but since the reference should not be addressed to disease the following wording was authorised: "Plant sterols have been shown to lower blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease". During the authorisation the Commission neglected the opinion of the EFSA, stating that blood cholesterol lowering "may" reduce the risk of heart disease.

In the next issue we will consider some additional examples to show how to perform better human intervention studies. We will also focus on the sufficient characterisation of foods or food constituents, specific conditions of use and the target population, the relevance of the claimed effect on human health and the overall quality of human studies for a successful scientific substantiation of the claimed effect.

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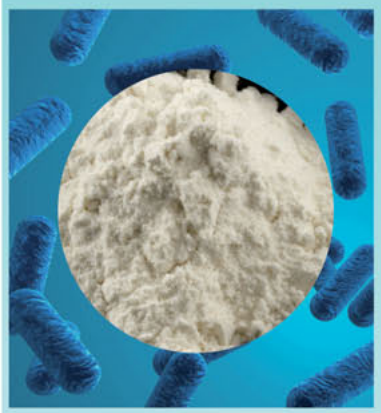

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