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## Editorial

### Where does the new EU Regulation on claims leave fruit & vegetables promotion?

Given the current debate on obesity and the role that fruit and vegetables can have in any serious solution to address this epidemic, it seems more than reasonable that the new Regulation on Nutrition and Health Claims should allow the fruit and vegetable sector, along with public authorities, to continue promoting without restriction the unique nutritional health benefits of consuming more fresh fruits and vegetables.

However, on what refers to the sector's freedom to do this, the Regulation is very unclear and leaves many open queries on what the final outcome will be: Will fresh fruit and vegetables finally be exempted from nutrient profiles, as requested by the sector? This would free them from having to comply with the profiles in order to make a nutrient claim. Will the sector manage to put together a list of health claims under article 13 and have them approved by EFSA? These could then be automatically used by the sector without further authorisation needed.

The Regulation at least gives clarity on what a claim is, defining it as "any message or representation (...) including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics". Will this finally protect fresh fruit and vegetables from the use (rather abuse) of the positive image of these products by other processed foods? A positive point to be further explored.


**Raquel Izquierdo de Santiago**
Food Policy Advisor, Freshfel Europe, European Fresh Produce Association


## Editorial Board









## IFAVA Contact info

**HEAD OFFICE**
**International Fruit And Vegetable Alliance**
**c/o Canadian Produce Marketing Association**
**9 Corvus Court**
**Ottawa, ON K2E 7Z4 Canada**

## IFAVA

**CHAIRMAN:**
R. Lemaire, Canada
E-mail : chairman@ifava.org

**VICE CHAIRMAN:**
P. Dudley, New Zealand
E-mail: vicechairman@ifava.org

**INFORMATION OFFICER:**
A. Clark
E-mail: aclark@ifava.org

# Healthy claims for fruit and vegetables – arrival of the EU Regulation on Nutrition and Health Claims

— Melanie Ruffell —
Independent Consultant, Surrey, UK

After several years of debate and negotiation, the EU Regulation on Nutrition and Health Claims (1924/2006)[1] was adopted late last year and is now due for implementation on 1st July 2007. The Regulation will control the use of nutrition and health claims in any commercial communication, including on labels and in advertising, and will limit the use of claims on food products that contain high levels of fat, sugar and salt or that carry endorsements.

Once the legislation is fully implemented and various transition periods have passed, consumers can expect to see on the market only those nutrition and health claims that have been pre-approved and published by the European Commission. There will also be a public register of rejected claims, so any interested party wishing to determine the truthfulness of any given claim can check its status on the Commission website.

A nutrition claim describes the nature of a food, for example:

- 'low fat'[1]
- 'high fibre'[1]
- 'source of vitamin C'[1]

A health claim describes or implies a relationship exists between food and health, for example:

- 'Eating 3 g weekly, or 0.45 g daily, long chain omega-3 polyunsaturated fatty acids, as part of a healthy lifestyle, helps maintain heart health'[2]
- 'Folate is necessary for the normal structure of the neural tube in developing embryos'[3]

Fruit and vegetables and other non-prepackaged foodstuffs (such as bread) will also be covered by the Regulation[1]. Food companies wishing to make comparative claims in relation to other products will need to comply with the new rules, for example if they intend to claim that their fruit juice contains 'as much calcium as a glass of milk.' There has been some debate about whether '5-a-day' statements would fall under the new Regulation[1] as an implied nutrition or health claim. It has been confirmed that this is not the case, but companies should refer to the UK Department of Health's advice on what constitutes a portion (www.5aday.nhs.uk) and further information.

In general, government dietary advice and messages from health professionals are not regarded as commercial communications and therefore are exempt from food law. However, if a food company presents government advice in relation to their product it would be regarded as a stated or implied claim and they would have to comply with the relevant food legislation. In the UK, as in most of Europe, health claims are legally acceptable, but disease risk reduction and medicinal claims for food are not permitted under current legislation. This misalignment between the use of government health messages and commercial health messages has in the past created confusion where companies have used government dietary advice in relation to their products and fallen foul of the law.

The JHCI (Joint Health Claims Initiative) has previously looked at evidence regarding fruit and vegetable consumption and certain types of cancers to help demonstrate the need for change in European food law and allow scientifically proven health messages about the role of the diet in helping to reduce the risk of disease to be used, responsibly, on food products:

- 'Eating more fruit and vegetables may help reduce the risk of stomach cancer.'[4]
- 'Eating more fruit may help reduce the risk of lung cancer. This does not overcome the adverse effects of smoking on lung cancer.'[4]
- 'Eating more vegetables as part of a healthy lifestyle may help reduce the risk of bowel cancer.'[4]

In developing the new claims legislation[1], the European Commission has reviewed its position on disease risk reduction claims and has concluded that this prohibition will be lifted under the new rules. From 1st July 2007, companies will be allowed to make disease risk reduction claims, which are clearly defined in the Regulation[1] when they have been approved for use in the EU by the European Food Safety Authority (EFSA). All disease risk reduction claims, claims about children's health and development, or claims based on new or emerging data will need to be submitted to EFSA in dossier form. An additional list of claims will be published by the European Commission to include health claims which are deemed to be 'based on generally accepted scientific evidence and well understood by the average consumer.'

Ultimately it is hoped that, by harmonising rules across the EU food companies will help support dietary advice through their claims, such as increasing fruit and vegetable consumption, by providing greater choice and availability of foods for consumers whilst ensuring that they are not being misled by unsubstantiated and spurious claims.

REFERENCES

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# The European and French position on health claims, particularly concerning fruits and vegetables

— Ambroise Martin —

Professor of Nutrition, Claude Bernard University-Lyon I, France
Member of the working groups on claims of Efsa (European Food Safety Authority) and Afssa (French Agency for Food Safety)

The adoption of the Regulation is still recent. For the moment, there is no official position of the European or French food safety agencies on the topic. Thus, this short paper can only reflect my personal view of what is currently going on in the different groups at the national or European level and which is publicly available. There are two related issues: claims and nutrient profiles.

Concerning claims, the European Food Safety Authority (Efsa) has communicated the work in progress. There is a focus on developing a guidance document for applicants to submit claims relevant to article 14 (disease risk reduction claims and claims on child development and growth). As discussed at the Bologna Conference, organized by Efsa in November 2006, it is highly probable that the criteria will be similar to those put forward by the European project Passclaim[1]. For a long time, scientific experts have agreed on the general principles of claim substantiation, even if some minor differences may still exist. For generic claims, the collection of generally accepted claims in each member state has begun. Expert members of the European panel are still waiting the result of this collection and, above all, of the European discussions at the Commission level on the ways to manage perhaps several thousand claims. In addition, some issues remain to be solved, especially the qualification of borderline claims and thus the clarification of boudaries between nutrition, function and disease risk reduction claims. In some countries, like France, the National agencies have already begun to examine the claims submitted by industry organizations. The French Food Safety Agency (Afssa) will, probably within few months, release an opinion on the list of claims submitted by the French industry. However, scientific evaluation of claims is only one of the many aspects linked to the new regulation. Implementation by all the stakeholders, especially small industries, is thought to be a challenge, with even more difficulties related to the existence of transition periods. On the other hand, communicating information to consumers is also a crucial issue. The French National Food Council, which offers a permanent discussion forum to all the stakeholders of the food chain, has launched a working group to examine all these aspects and to propose recommendations for accompanying the implementation of the regulation.

The request of the Commission to Efsa concerning nutrient profiles has been made public. The document recalls the five questions which are raised by the regulation (profiles by category or transversal, choice and balance of nutrients, reference basis, calculation, feasibility and testing) and makes some orientations discussed and agreed by Member States. The principle suggestion concerns the preference for a transversal system, with specific categories which could be exempted from the application of profile or have specific profiles. For the moment, no trend can be indicated on what could be the final result. It seems clear however that at least some of the more than 20 existing schemes will be scrutinized and that some ideas implemented in these systems would constitute a starting point for the proposal of Efsa. A group in Afssa is also working on the subject. Its objective is not to propose a system (it is the role of Efsa), but to thoroughly examine the scientific issues. Similar works are performed in other organizations or countries. It is hoped that, taking into account all these works, the proposition of Efsa will be strongly scientifically based. However, the constraints of management (implementation by industries and control bodies) will also somewhat balance or limit the possibilities. In France, it is considered that the implementation on nutrient profiles will not solve all the issues and that there is still a place for research on the topic. The French National Research Agency has proposed the profile issue as one of the eligible themes for its research program devoted to food and nutrition for the year 2007.

Concerning basic products in general, and fruits and vegetables in particular, it is recognized that the regulation, especially nutrient profiles, raises concerns for these basic products (including also meat, for example), which cannot adapt their composition to comply with profiles. Fruits and vegetables are one of the possible exceptions to profiles suggested by the Commission. However, this should not be a necessity. It is noteworthy that in almost all the systems published so far, most of crude fruits and vegetables comply with profiles, so that the issues are more likely to originate from fruit and vegetable-based products. It remains to decided and justified as to what could be included in an exempted category. Indeed, introducing some categories as exceptions raises the challenge of how to unambiguously define categories and what could the objective basis to include a category in the list of exceptions. Clear rules must be defined, since it appears to be unrealistic to decide on a case-by-case basis. Some criteria could be extracted from existing regulations or practices. As an example, in France, sanitary messages in advertising are not mandatory for some raw products, which are precisely defined as products which have been processed only by mechanical means (slicing or freezing for example) or packed or stored only with added water.

The majority of nutritionists do not wish that traditional healthy raw products be penalized by any profiling system.


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# Review of Evidence In Support of Health Claims

— Kathy Hoy —
Produce for Better Health Foundation, USA

## What are health claims?

Health claims on food labels provide information to consumers to help reduce their risk of disease, and are one of the ways they receive scientifically valid information about the foods they eat. A health claim for a food describes the relationship between a food or food component and a disease or health-related condition, and is limited to claims about disease risk reduction. Claims about the cure, mitigation treatment or prevention of disease are considered to be drug claims.

## Unqualified and qualified health claims

In the U.S., oversight for determining which health claims may be used in food labeling is through the Food and Drug Administration (FDA). For authorized health claims (also referred to as unqualified), FDA issues a regulation authorizing a health claim that meets the scientific standard as stated in the 1990 Nutrition Labeling and Education Act (NLEA). These claims are based on evidence that constitute "significant scientific agreement" (SSA) and are based on a high level of confidence in the disease-substance relationship from systematic review of the literature. An example is "Diets low in saturated fat and cholesterol, and rich in fruits, vegetables and grain products that contain certain types of dietary fiber may reduce the risk of heart disease, a disease affected by many factors".

When the strength of the scientific evidence for a health claim falls below that required for authorizing a claim, the FDA may issue a letter of enforcement discretion for qualified health claims (QHC) as provided by FDA Consumer Health Information for Better Nutrition Initiative in 2003. These types of health claims must be qualified to ensure clear and accurate presentation of information to consumers.

The goal of the review process for QHCs is to stimulate the flow of meaningful, up-to-date information to consumers about the health consequences of their dietary choices, and to stimulate competition among food producers to improve the healthfulness of their products.

## Review process for health claims

The process for review of the scientific evidence begins with identification and classification of relevant studies suitable for an evidence-based review: randomized controlled clinical trial (RCT), observational, research synthesis studies such as meta-analyses, or animal/in-vitro studies. Human studies should be used to support a health claim. Animal and in vitro studies are considered useful, but are not sufficient on their own to substantiate a claim. Meta-analysis studies and review articles can help to identify studies to be examined. The RCT is considered the "gold standard"; however, it is not always possible or feasible to conduct such studies on food and food components. Thus, the available studies are generally observational, which, although less persuasive, are reviewed for their relevance to support the claim, with consideration of control for confounders and bias, appropriateness of the study population, the validity of the measurements used, and soundness of the experimental design and analysis. The strength of the evidence to support the claim is evaluated based on the quality of the studies, the consistency of results, and the relevance to the asserted health claim relationship.

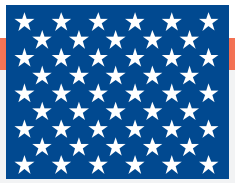
A QHC is distinguished from an SSA claim by language that characterizes the quality and strength of the scientific evidence. For a QHC to appear on a food product, the claim must go through the FDA review process, which may include an expert evaluation of the supporting scientific evidence for the claim and how accurately the language included in the claim conveys the scientific evidence supporting it. A four point scale is used to evaluate and classify the scientific evidence in support of a health claim:

A: Unqualified (authorized) health claims are supported by evidence that meets the current standard of "significant scientific agreement."

B: QHC includes such qualifying language as "although there is scientific evidence supporting the claim, the evidence is not conclusive".

C: QHC includes qualifying language as "evidence is limited and not conclusive".

D: QHC contains qualifying language such as "very limited and preliminary scientific research suggests that FDA concludes that there is little scientific evidence to support this claim".

**Detailed information about the review process can be found at:**

**http://www.cfsan.fda.gov/~dms/ssaguide.html**

**Information for this article was obtained from:**

Schneeman, B. "FDA's Review of Scientific Evidence for Health Claims" Journal of Nutrition. 137:493-94, 2007

"Dear Manufacturer Letter Regarding Food Labeling"
**http://www.cfsan.fda.gov/~dms/flguid.html**

"FDA implement enhanced regulatory process to encourage science-based labeling and competition for healthier dietary choices"
**http://www.cfsan.fda.gov/~dms/nuttfbg.html**

"Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements"
**http://www.cfsan.fda.gov/~dms/ssaguide.html**