

EU regulatory aspects in relation to fermented milks and health claims

Lorenzo Morelli
Istituto di Microbiologia UCSC

Via Emilia Parmense 84
29100 Piacenza – Italy

lorenzo.morelli@unicatt.it

Main bullets of this presentation:

❖ Some features of :

REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 December 2006

on nutrition and health claims made on foods

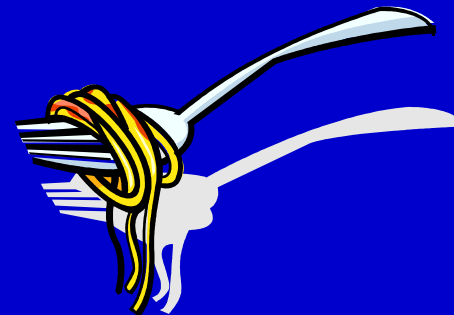
❖ Tips on probiotics
and health claims



The Regulation made short:

A nutrition claim states or suggests that a food has particular beneficial nutritional properties. Examples include “low fat”, “no added sugar” and “high in fibre”.

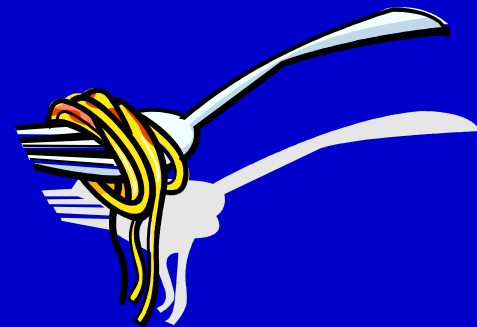
A health claim is any statement used on labels, in marketing or in advertising, that health benefits can result from consuming a given food or from one of its constituents.



The Regulation made short:

Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.

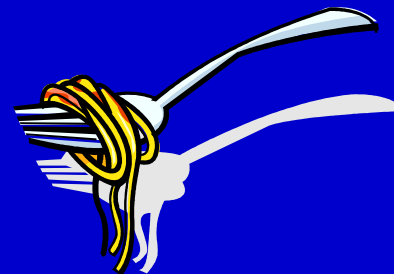
A food business operator making a nutrition or health claim shall justify the use of the claim.



The Regulation made short:

Conditions under which a nutrition or health claim can be made include “nutrient profiles” based on scientific advice provided by EFSA.

The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce scientific data establishing compliance with this regulation.



Health Claims

Based on
generally
accepted
scientific
evidence

Article 13.1

Based on
newly
developed
scientific
data/IPR
protection

Article 13.5

Reduction of
disease risk
and claims
referring to
children's
development
and health

Article 14

Article 13.1

Health claims other than those referring to the reduction of disease risk and to children's development and health

13.1 1. Health claims describing or referring to:

(a) the role of a nutrient or other substance in growth, development and the functions of the body;

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.



Article 13.2

Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification.

Article 13.3

After consulting the Authority, the Commission shall adopt, in accordance with the procedure referred to in Article 25(2), a Community list of permitted claims as referred to in paragraph 1, and all necessary conditions for the use of these claims by. 31 January 2010 at the latest.

Article 13.5

5. Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Article 18,

(full exam) except claims referring to children's development and health, which shall be authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19.

Practical steps to set the list of Article 13

- Member States to submit national lists
(National responsibility, but efforts to coordinate to ensure coherence)
- Commission to consult EFSA
- Compilation of lists to be submitted to EFSA
- Final list to be adopted by Regulatory Committee

Article 14

Reduction of disease risk claims and claims referring to children's development and health

1. Notwithstanding Article 2(1)(b) of Directive 2000/13/EC, reduction of disease risk claims and claims referring to children's development and health may be made where they have been

authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims.

Articles 15, 16, 17, 18

How to apply for authorisation

A food business operator intending to use a health claim not included in the list provided for in Article 13(3) may apply for the inclusion of the claim in that list.

Articles 15, 16, 17, 18

How to apply for authorisation

Authorisation procedure:

- Application to EFSA
- EFSA opinion within 5 months
- Community authorisation

From the Regulation to Probiotics



Health claims on probiotics, an ancient story:



“*Le Ferment*”

PRODUITS A LA LACTOBACILLINE

77. Rue Denfert-Rochereau. PARIS

Adr. télég.: FERMENTEL-PARIS • Téléphone: 819.88



Depuis un an, la Société “*Le Ferment*” a organisé un laboratoire dans lequel, avec un ferment lactique désigné sous le nom de *Lactobacilline*, elle prépare le Lait caillé d’après la méthode tracée par le Professeur Metchnikoff.

La *Lactobacilline* est préparée avec des cultures pures de bactéries lactiques à l’exclusion de toutes sortes d’autres microbes, inutiles ou nuisibles qui se trouvent dans les laits aigris, désignés sous les noms de *képhir*, *yahourt*, *varénets*, etc. Nous pensons que dans le Lait caillé à la *Lactobacilline* nos clients trouveront un aliment agréable au goût et en même temps irréprochable au point de vue de l’hygiène.

La *Lactobacilline* est présentée aussi sous forme de comprimés pour les personnes qui n’aiment pas ou ne peuvent pas supporter le Lait caillé.

Cette dernière préparation étant de la *Lactobacilline* pure, offre les mêmes avantages au point de vue thérapeutique que le Lait caillé.

La Société “*Le Ferment*” prépare aussi, sur demande, du Bouillon de *Lactobacilline*.

“*Le Ferment*”

Fournisseur de l’Assistance Publique

Seul Fournisseur du Professeur METCHNIKOFF

Health claims on probiotics, the future story:



FAQs:

Are probiotics included in the Regulation?

YES: art. 3/3 'other substance' means a substance other than a nutrient that has a nutritional or physiological effect;

Health claims on probiotics, the future story:



FAQs: items for probiotics

b) the nutrient or other substance for which the claim is made:

(i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;

Probiotics: dose-response studies are needed; analytical tools are also needed (standard methods)

Health claims on probiotics, the future story:



FAQs: items for probiotics

Article 6: “Substantiation based on generally accepted scientific evidence”

HOW WILL THE SCIENCE BE ASSESSED?

HOW MUCH SCIENCE DO YOU NEED?

WHAT KIND OF SCIENCE DO YOU NEED?

Probiotics: need of meta-analysis, guidelines, etc.

The problem of peer review journals

Health claims on probiotics, the future story:



FAQs: items for probiotics

Article 6: “Substantiation based on generally accepted scientific evidence”

National/international expert consensus report

Human intervention studies, including use

of biomarkers

Human observational/epidemiological studies

Animal and *in vitro* studies

Traditional knowledge/experience of use

Health claims on probiotics, the future story:



FAQs: How to measure efficacy of probiotics

The development of **VALIDATED** biomarkers is essential. Biomarkers must be validated both **ANALYTICALLY** and **BIOLOGICALLY**.

Probiotics: need of “claim focused” research

Health claims on probiotics, the future story:



FAQs: How to communicate efficacy of probiotics

It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims.

Probiotics: need to improve dissemination (clinicians, health professional, consumers organizations)

Health claims on probiotics, the future story:



FAQs: How to support companies applying for health claims for probiotics

Need of support by scientific institution: why not also FIL/IDF (a future challenging role?) directly or by promoting a "Metchnikoff Institute"?