

Promoting competitiveness for
European SMEs Enabling Innovation
in Food/Food supplements

The Italian approach to probiotics

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GUIDELINES ON PROBIOTICS AND PREBIOTICS

Ministry of Health
www.salute.gov.it



Indication for use
in food and food supplements
of probiotic microorganisms
traditionally used for
intestinal microflora balance

GUIDELINES ON PROBIOTICS

1.1 Characteristics of microorganisms that may used in food and in food supplements

1.2 Identification of specie and strain

1.3 Amount of microorganisms
(usually at least 10^9 live cells per day)

1.4 Safety of probiotics

1.4 Indication for use
(intestinal microflora balance)

PROBIOTICS IN FOOD SUPPLEMENTS

The use of lactic bacteria in Italy in food supplement started about 35 years ago

Even before the directive 89/398/EC, these products were classified as « dietetics » and authorised in order to be marketed

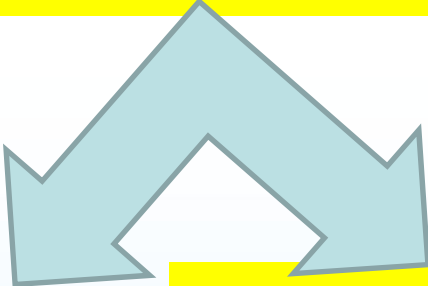
OLDEST « PROBIOTICS » USED IN FOOD SUPPLEMENTS IN ITALY (1)

Saccharomyces cerevisiae
or lactic acid bacteria
such as Streptococcus
thermophilus and
Lactobacillus bulgaricus

OLDEST « PROBIOTICS » USED IN FOOD SUPPLEMENTS IN ITALY (2)

Allowed:
indication of the favourable effect related to
the equilibrium of intestinal bacterial
microflora

minimum
amount
of alive cells



Presence of nutrients
(mostly group B vitamins)
in order to justify their
classification as dietetics
because of the nutritional
value

RATIONALE OF ASSOCIATION VITAMINS AND PROBIOTICS

The presence of vitamins was justified by the possibility of a downregulation of their synthesis due to the «unbalanced» intestinal microflora, for whom these products were intended

DIRECTIVE 2002/46/EC ON FOOD SUPPLEMENTS

Since 2002,
products containing « probiotics »
without other nutrients in association
can be legally marketed as food supplements



because of the FS definition as
« concentrated sources » of nutrients or other
substances with « physiological effect »

FOOD SUPPLEMENTS ROLE

At national level

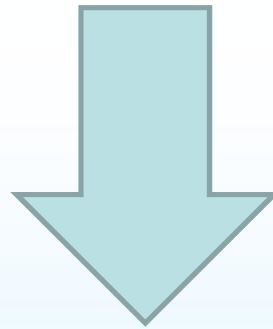


the indication in the label of the nutritional or physiological effect attributed to the food supplement has been always considered as an appropriate and necessary way to help consumers to make informed choices

PROBIOTICS FOOD SUPPLEMENTS ROLE

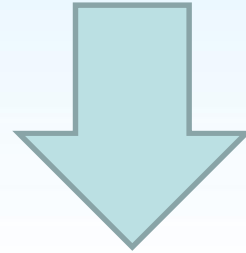
In line with this approach
since the 80s product containing
« probiotics » microorganisms may bear the
indication:

« Promoting the balance of
intestinal microflora »



This effect was supposed to be
beneficial for the human health justifying
per se the use of the term « probiotic »

EU COMMISSION
14 December 2007



GUIDANCE ON THE IMPLEMENTATION OF
REGULATION N° 1924/2006 ON NUTRITION
AND HEALTH CLAIMS MADE ON FOODS

CONCLUSIONS OF THE STANDING COMMITTEE
ON THE FOOD CHAIN AND ANIMAL HEALTH

GUIDANCE ON THE IMPLEMENTATION OF REGULATION (EC) 1924/2006 ON NUTRITION AND HEALTH CLAIMS MADE ON FOODS (1)

A claim is a nutrition claim if in the naming of the substance or category of substances, there is only factual information

Nutrition claims examples



Contains lycopene

Contains lutein

GUIDANCE ON THE IMPLEMENTATION OF REGULATION (EC) 1924/2006 ON NUTRITION AND HEALTH CLAIMS MADE ON FOODS (2)

A claim is a health claim if in the naming of the substance, or category of substances, there is a description or indication of a functionality or an implied effect on health

Health claim examples



Contains antioxidants
(the function is an antioxidant effect)

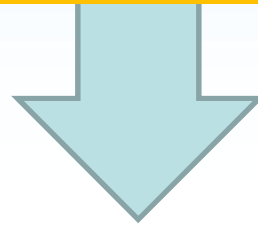
Contains probiotics/prebiotics
(the reference to probiotic/prebiotic implies a health benefit)

EFSA AND PROBIOTICS (1)

« Promoting the balance of intestinal microflora »

IT IS NOT A HEALTH CLAIM

EFSA opinion



- Increasing the number of any groups of bacteria is not in itself considered as beneficial.
- ...no evidency has been provided that ... enhanced levels of beneficial microflora are beneficial to human health.
- ... « support a balanced/beneficially affect » ... intestinal microflora in the context of decreasing potentially pathogenic intestinal microorganism might be beneficial to human health

EFSA AND PROBIOTICS (2)

Usually EFSA refers to the presence of lactic bacteria as « probiotics » presence

In a similar way EFSA refers to the vitamins presence

The term « PROBIOTICS » is just a synonymous of lactic bacteria. It cannot be considered different from « VITAMINES »

USE OF THE TERM PROBIOTICS



What is the best solution
in the current regulatory
framework ?

PROBIOTICS AND CLAIMS REGULATION



Article 1.4

Generic descriptor ?

(denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health ...

CONTAINS: HEALTH OR NUTRITION CLAIMS ?

“ CONTAINS... ”

To be honest...

any time a particular substance is underlined in the labelling preceded by the term “CONTAINS” the consumer perceives it as a possible benefit, also if the substance doesn't have an authorized health claim



Is it thinkable to limit the “CONTAINS”
to substances with authorized health
claims?



"CONTAINS PROBIOTICS":
THE BEST SOLUTION



Nutrition
claim

Thanks