

10th PROBIOTICS, PREBIOTICS & NEW FOODS

The Italian approach to probiotics

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Since many years Italy adopted:

GUIDELINES ON PROBIOTICS

Ministry of Health

www.salute.gov.it



**Guidance for use
in food and food supplements
of probiotic microorganisms**

ITALIAN GUIDELINES ON PROBIOTICS

Characteristics of the micro-organisms that may be used in food and in food supplements

Characterisation: identification of specie and strain

Quantity of micro-organisms (minimum amount)

Safety of probiotics

Indication for use

ITALIAN GUIDELINES ON PROBIOTICS

TWO SPECIFIC POINTS

VIABLE AMOUNT OF MICRO-ORGANISMS

(usually at least a billion live cells per day)

INDICATION FOR USE

... promotes the intestinal microflora balance



For this purpose it is necessary to have evidence that the micro-organism is able to colonize with the viable amount which is provided by the daily intake of the product recommended for the use

PROBIOTICS IN FOOD SUPPLEMENTS

The use of *lactic acid bacteria* in Italy began about 40 years ago in products such as food supplements, which at the time were classified as dietetic products

FIRST «PROBIOTICS» USED IN FOOD SUPPLEMENTS IN ITALY

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

PROBIOTICS USED IN FOOD SUPPLEMENTS IN ITALY

Two conditions for the use of probiotics:

- 1) Need to associate micro-organism with nutrients (es. vitamins), in order to justify at the time their classification as dietetic products for a nutritional value**
- 2) Minimum amount of live cells with the recommended daily intake of product**



Indication of the beneficial effect related to the equilibrium of intestinal microflora

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»**

PROBIOTICS FOOD SUPPLEMENTS ROLE

In line with this approach from about 40 years food and food supplements containing «probiotics» microorganisms may bear the indication:

«... promote the balance of intestinal microflora»



We have always considered this effect as a beneficial effect because the balance of intestinal microflora is commonly considered, in itself, as an important health index

**WHAT ARE THE
ISSUES?**

THE MAIN ISSUE ARISES FROM



**Guidance on the implementation of Regulation
(EC) 1924/2006 on nutrition and health claims
made on foods**

14 December 2007

Conclusions of the Standing Committee
on the food chain and animal health

GUIDANCE ON THE IMPLEMENTATION OF REGULATION (EC) 1924/2006

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

Instead, 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 the use of the naming is a **health claims**

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Contain PROBIOTICS

**according to this approach
should be considered a HEALTH CLAIM
because the reference to probiotic would
imply a health benefit**

ANOTHER ISSUE



**How EFSA considers the
beneficial physiological effects
of probiotics**

EFSA AND PROBIOTICS

Increasing the number of any groups of bacteria is not in itself considered as beneficial effect

...no evidency has been provided that ... enhanced levels of beneficial microflora are beneficial to human health



«Promotion of the balance of intestinal microflora»

is not a beneficial effect and therefore it's not a property that can be authorised as health claim according to regulation (EC) 1924/2006

CONSIGLIO SUPERIORE DI SANITA'

The Health Superior Council, that is an advisory board for the Ministry on health, examined recently the "microbiota" in all its health implications and the probiotics in foods and in their different clinical applications



SCH considers that promote the balance of the intestinal microflora, according to current scientific evidence, can be considered in itself a beneficial effect on health when documented with suitable methodologies

CONTAINS "PROBIOTICS"



**What is the best way
to solve the problem in the
current regulatory
framework?**

CONTAINS "PROBIOTICS"

or

CONTAINS LACTIC BACTERIA



**has the same meaning for the consumer
because it generates the same
expectations**

CONTAINS "PROBIOTICS"



Consider this indication in itself as a health claim is disproportionate and penalizing



Every nutritional claim implies the health benefits of the nutrient of the substance with physiological effect highlighted in the label

NUTRITION CLAIM SUGAR FREE

**It's really only
a nutritional information which
does not generate expectations of
health benefits for consumers?**

SUGAR FREE

The claim “sugar free” is a nutritional information but at the same time it implies a beneficial health effect



Contribution to the maintenance of normal blood glucose levels

SATURATED FAT-FREE

“Nutritional claim” that implies a beneficial health effect



Contribution to the maintenance of normal blood cholesterol levels

SODIUM-FREE or SALT FREE

“Nutritional claim” that implies a beneficial health effect



Contribution to the maintenance of normal blood pressure

CONTAINS ...

“Nutritional claim”



It generates the expectations of all the beneficial effects, real or presumed, advertised for a substance with physiological effect that is highlighted in the label

beyond any assessment of their scientific basis

CONTAINS RESVERATROL

“Nutritional claim”



It generates the expectations of all the beneficial effects advertised for resveratrol

even if at the moment there are not health claims authorized

CONTAINS...



**It should always be considered a
NUTRITION CLAIM**

without distinctions that appear penalizing
without any real advantage in terms of
information

**Otherwise "Contains ..." should be allowed
only for substances that have at least one
authorized health claim**

PROBIOTICS

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 ...



It could be a possible solution
even if it is not the most logical

EFSA AND USE OF «PROBIOTICS» TERM

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 «VITAMINS»

CONCLUSIONS

“Probiotic” is a term that can not be considered in different way compared to “lactic bacteria”

The Commission’s Guidance of 2007, on this point, was adopted without taking into account the negative and disproportionate impact that it would have had and the resulting damage to probiotics

Contains “probiotics” in our approach is a nutritional claim and as such it should be considered

THIS IS THE BEST SOLUTION

Thanks