The Italian approach to probiotics

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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)
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

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

minimum amount of alive cells
The presence of vitamins was justified by the possibility of a download of their synthesis due to the «unbalanced» intestinal microflora, for whom these products were intended.
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»
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
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
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)
Increasing the number of any groups of bacteria is not in itself considered as beneficial.

...no evidence 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.
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 ...
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