



Ministero della Salute

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Guidelines on probiotics and prebiotics

INTRODUCTION

The use of lactic acid bacteria in Italy in food supplement began about 30 years ago. At the time those products were classified as dietetics and authorized prior to their marketing.

The earliest category of authorized products contained *Saccharomyces cerevisiae* or lactic acid bacteria such as *Streptococcus thermophilus* and *Lactobacillus bulgaricus* but in association with nutrients, mostly group B vitamins, in order to confer to those products a nutritional value, then deemed necessary for the classification as dietetics.

The above mentioned category of products was identified as "*biological-vitamin dietary supplements*," for which a specific guidelines, the so called "*discipline ministerial act*", related to the composition was defined by the Ministry. In this document, the minimum amount of alive cells, that have to be present in the product in order to bear an indication of the effect related to the equilibrium of intestinal bacterial microflora was identified.

In this context, the rationale for the association with vitamins was justified because of a possible downregulation of their bacterial synthesis due to the "disturbance" of the intestinal microbial ecosystem. Later on, the term "biological" was changed with the "probiotic" one, because of its equivalence in the Italian language with the word "organic", in order to avoid any misleading between this products and the one from organic agriculture.

Since 2002, with the EU Directive 2002/46/EC on food supplements which defined food supplements as "*concentrated sources*" of nutrients or other substances with "*physiological effect*", foodstuffs containing just "*probiotics*" without other nutrients in association have been legally marketed as food supplements.

At national level, the indication in food supplements of the nutritional or physiological effect attributed to the product has been considered as an appropriate way to correctly orient the choices of consumers.

For this reason since the 80s in product containing "*probiotic*" microorganisms the effect of "*promote the balance of intestinal flora*" has been accepted, provided that a sufficient number of alive cells was present in the suggested daily portion. Moreover, this effect was supposed to be beneficial for health.

In the task of evaluating claims under Regulation (EC) 1924/2006, the EFSA opinion reported in Journal 2009; 7(9) 1232 quotes: *“Increasing the number of any groups of bacteria in not in itself considered as beneficial. The Panel considers that no evidence has been provided that enhance levels of beneficial microflora are beneficial to human health. The Panel considers that support a balanced/beneficially affect intestinal microflora in the context of decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health”*.

According to this approach, the intestinal colonization by probiotics without a concurrent reduction on potentially pathogen intestinal microorganisms does not represent an health effect as referred to in Article 2, paragraph 2, point 5 of Regulation (EC) 1924/2006.

Subsequently from the legislative point of view the use of the indication *“promote the balance of intestinal flora”* without any link with decrease in pathogens does not appear to be an health claim to be authorized in accordance with Article 13.5 of Regulation (EC) 1924/2006 (and it has been already excluded from the list of claims authorized under Article 13.1 of the same Regulation).

Moreover, an analogous consideration applies to the so called *“prebiotics”*, considering their composition and the complex of scientific evidence available to support an indication for a physiological effect on the balance of intestinal bacterial flora.

Given all above, only products compliant with these guidelines may indicate on the label the effect *“able to support the balance of intestinal flora”* and/or the terms *“probiotic”* and/or *“prebiotic”*.

1. PROBIOTICS

Indication for the use in foods and food supplements of probiotic microorganisms (bacteria and/or yeasts), traditionally used for the balance of the intestinal flora

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

Microorganisms that may be used in foods and food supplements must meet the following requirements:

- be traditionally used for supplementation of the intestinal microflora (microbiota) in humans;
- be considered safe for human consumption. On this matter useful references are the criteria issued by the European Food Safety Authority (EFSA) on QPS (Qualified presumption of safety) status.

Anyway, the microorganisms used for the production of foodstuffs should not be carriers of acquired and/or transmissible antibiotic resistance traits, besides all the potential additional criteria that EFSA will deem as appropriate to include.

- be active and vital in the intestine in a sufficient amount to be vital and multiply in the gut (see the section *“Amount of microorganisms”*).

1.2 Identification of specie and strain

The assessment of the taxonomic position is a really important point to guarantee the safety of the used microorganism, because it allows to recognize the bacterial specie with a long history of safe use.

The specie assessment may be done using:

- Sequencing of DNA coding for 16S rRNA
- Nucleic acids hybridization;

the typing at the strain level may be achieved using:

- PFGE (Pulse Field Gel Electrophoresis).

The use of the taxonomic nomenclature, recognized by the International Union of Microbiological Societies, is required for the denomination of the species.

Moreover, it is recommended the deposit of strains in International Collections with the status of IDA (International Collections of Bacteria).

1.3 Amount of microorganisms

According to the available scientific literature, to obtain a temporary intestinal colonization by a strain of lactic acid bacteria it is sufficient an amount of at least 10^9 live cells per strain and per day. The portion of the product recommended for daily consumption has to contain the amount of 10^9 live cells for at least one strain among those present in the product, as above specified. The use of different amount of microorganism may be allowed when its rational has been demonstrated by significant scientific studies.

The amount of cells present must be listed on the label, and moreover, this amount has to be guarantee until the end of the product shelf-life, at the specified storage conditions, with uncertainty of 0,5 log.

It is emphasized that the analytical method of quantification of living bacterial cells may differ from specie to specie.

1.4 Safety of probiotics

The use in foodstuffs of new microbial strain, although belonging to an already used specie, will require a new assessment of the microorganism safety and efficacy. To assess the new microorganism safety, it is required the taxonomic identification, in terms of specie and strain, as above specified, including the antibiotic resistance profile (antibacterial or antifungal depending on the specific case). The antibiotic resistance profile must be determined for each single microbial strain used, in order to exclude the presence of acquired and even potentially transmissible antibiotic resistance traits.

However, the safety assessment of each strain is not considered necessary when the strain belongs to one of that specie extensively characterized in term of safe use, as defined by EFSA documents for the QPS status for some bacterial groups. Anyway, also in this case it has to be done the determination of antibiotic resistance profile.

1.5 Indication for use:

“It supports the intestinal flora balance”

2. PREBIOTICS

Indication for the use in foods and food supplements of prebiotics, traditionally used for the balance of the intestinal flora

2.1 Definitions

According to the FAO document "Technical Meeting Report: Prebiotics" (Rome, September 2007), the "prebiotics" are defined as follow:

“A prebiotic is a non-viable food component that confers a health benefit on the host associated with modulation of the microbiota”

Prebiotics that may be used in foods and food supplements must meet the following requirements:

- be safe for human with a significant history of consumption, excluding in such way the applicability of Reg. (CE) 258/97;
- be present in the suggested daily dose of the product in an amount able to carry out a "prebiotic" effect according to the available scientific evidence.

2.2 Indication for use:

“It supports the intestinal flora balance”

You may find the original Italian text at:

<http://www.salute.gov.it/alimentiParticolariIntegratori/newsAlimentiParticolariIntegratori.jsp?id=1729&menu=inevidenza&lingua=italiano>