Ministero della Salute

DIPARTIMENTO SANITA' PUBBLICA VETERINARIA, SICUREZZA ALIMENTARE E ORGANI COLLEGIALI PER LA TUTELA DELLA SALUTE
DIREZIONE GENERALE IGIENE E SICUREZZA DEGLI ALIMENTI E DELLA NUTRIZIONE
UFFICIO IV EX DGSAN

COMMISSIONE UNICA PER LA DIETETICA E LA NUTRIZIONE

Revision May 2012

Guidelines on 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

Characteristics of microorganisms that may be used in foods and food supplements (foodstuffs)

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").

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).

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.

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.

Indication for use:
"It supports the intestinal flora balance"*

*In the Opinion reported in: "EFSA Journal 2009; 7(9):1232", the NDA (nutrition, dietetic and allergy) panel of EFSA states: "Increasing the number of any group of bacteria is not in itself considered as beneficial".
The rationale for the above mentioned indication of use has been defined taking into account this Opinion.

You may find the original Italian text at:

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