



Clarification of the Definition of a Probiotic

Probiotics are live microorganisms, which when administered in adequate amounts confer a health benefit on the host (FAO 2001)¹

The field of probiotics is developing rapidly as evidenced by expansion of research and increased familiarity of probiotics to the general public. Over the years the FAO/WHO definition of probiotics remains applicable to scientific, industrial and regulatory communities, as long as it is interpreted correctly. Examples of misuse of the term exist both in the commercial arena, when the term is used on products with no substantiation of human health benefits, and in the scientific arena, where the term has been used to describe bacterial components, dead bacteria² or bacteria with uncharacterised health effects in humans³. The clarifications below provide more detailed insight into the correct use of the term “probiotics.” The intent is to enhance precision for basic and clinical research efforts on probiotics as well as facilitate the work of regulatory bodies concerned with issues of probiotic safety and consumer protection.

FOOD USE

When combined with the specifications outlined by the FAO/WHO Working Group for the Evaluation of Probiotics in Food (2002), the key aspects of this definition include:

- A probiotic must be alive when administered
- A probiotic must have undergone controlled evaluation to document health benefits in the target host^{4, 5, 6, 7, 8}
- A probiotic must be a taxonomically defined microbe or combination of microbes (genus, species and strain level)
- A probiotic must be safe for its intended use

Two types of claims are allowable on foods in the United States. As established by the US Nutrition Labeling and Education Act of 1990 (codified into regulations on January 6, 1993)⁹, only “disease/substance relationship” or more specifically “disease risk reduction” claims” are acceptable for food products. In addition, claims which relate the food to the normal structure of functioning of the human body are also allowable. Both types of claims require substantiation. In Europe, the Council Directive 2000/13/EC on labeling, presentation and advertising of foodstuffs¹⁰ prohibits the attribution to any foodstuff of the property of preventing, treating or curing a human disease, or reference to such properties. In addition, the regulation (EC) 1924/2006 on Nutrition and Health Claims made on Food¹¹ specifies that health claims could describe or refer:

- to the effect of a nutrient or other substance on body functions, including psychological and behavioral functions, as well as slimming and weight control
- to the reduction of disease risk and to children’s development and health.

In general terms, United Nations members differ in their approach to health claims and food, but nevertheless, a probiotic food substance must contain a taxonomically defined microorganism(s) and be shown in human studies to provide measurable benefits for the host after its consumption.

NON FOOD USE

The FAO/WHO activities^{1, 4} were specifically focused on food uses of probiotics; however, the definition advanced by this group was sufficiently broad to encompass a range of probiotic preparations and intentions of use. In addition to being a food or a dietary supplement, a probiotic microorganism(s) may be used in drug applications (referred in some instances as a live

biotherapeutic), microbial feed (animal uses), genetically modified organisms, and live vaccines if administered orally.

Requirements for establishing efficacy and safety for probiotics are different for the different subcategories for probiotics. For example, a probiotic used as a drug must not only fulfill the general FAO conditions stipulated above, but also conform with existing national regulations (e.g., US Food, Drug, and Cosmetic Act and EU Directive 2004/27/EC on substances used for treating or preventing disease) and guidelines on good clinical practices.

REFERENCES

1. Food and Agriculture Organization of the United Nations (FAO). 2001. Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria, http://www.who.int/foodsafety/publications/fs_management/en/probiotics.pdf
2. Briand V, Buffet P, Genty S, et al. Absence of efficacy of nonviable *Lactobacillus acidophilus* for the prevention of traveler's diarrhea: a randomized, double-blind, controlled study. *Clin Infect Dis* 2006; 43:1170–5.
3. Southcott E, Tooley KL, Howarth GS, Davidson GP, Butler RN. Yoghurts containing probiotics reduce disruption of the small intestinal barrier in methotrexate-treated rats. *Dig Dis Sci*. 2008 Jul;53(7):1837-41.
4. Food and Agriculture Organization of the United Nations (FAO). 2002. Guidelines for the Evaluation of Probiotics in Food. <ftp://ftp.fao.org/es/esn/food/wgreport2.pdf>
5. International Life sciences Institute Europe (ILSI). 2004. Process for the Assessment of scientific Support for Claims on Food (PASSCLAIM). <http://europe.ilsa.org/publications/ecprojects/passclaimphase2.htm>
6. U.S. Food and Drug Administration (FDA). 2007. Evidence Based review System for the Scientific Evaluation of Health Claims. <http://www.cfsan.fda.gov/~dms/hclmqui6.html>
7. U.S. Food and Drug Administration (FDA). 2004. Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act. <http://www.cfsan.fda.gov/~dms/dsclmqui.html>
8. Evidence for Health Claims on Food: How Much is Enough? Canadian Nutrition Congress meeting, Winnipeg, CANADA. 2007. <http://jn.nutrition.org/cgi/content/full/138/6S-1/1189S>
9. Guide to Nutrition Labeling and Educational Act (NLEA) Requirements http://www.fda.gov/ora/inspect_ref/igs/nleatxt.html#EXEMPTIONS%20AND%20SPECIAL
10. Council Directive 2000/13/EC on labeling, presentation and advertising of foodstuffs http://www.fsai.ie/legislation/food/eu_docs/Labeling/General%20Labelling%20Provisions%20for%20Foodstuffs/Dir%202000.13%20EC.pdf
11. Regulation (EC) 1924/2006 on Nutrition and Health Claims made on Food http://www.fsai.ie/legislation/food/eu_docs/Labeling/Cor_Reg1924_2006.pdf