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Probiotics in dietary guidelines and clinical recommendations outside the European Union

Stephan Ebner, Linda N Smug, Wolfgang Kneifel, Seppo J Salminen, Mary Ellen Sanders

Stephan Ebner, Wolfgang Kneifel, University of Natural Resources and Life Sciences Vienna, 1190 Vienna, Austria

Linda N Smug, Department of Bioprocess Engineering, Wrocław University of Economics, Komandorska 118/120, 53-345 Wrocław, Poland

Seppo J Salminen, Functional Foods Forum, University of Turku, 20014 Turku, Finland

Mary Ellen Sanders, Dairy and Food Culture Technologies, Centennial, CO 80122, United States

Author contributions: Ebner S, Smug LN, Kneifel W and Salminen SJ conceived and designed the study, acquired and analyzed the data; Ebner S drafted the article; all authors revised and critically evaluated the article for important intellectual content; all authors have given a final approval of the revised version.

Correspondence to: Seppo J Salminen, Professor, Functional Foods Forum, University of Turku, Itäinen Pitkätatu 4 A 5th floor, 20014 Turku, Finland. seppo.salminen@utu.fi

Telephone: +358-2-3336880 Fax: +358-2-3336884

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Abstract

Fermented foods have been consumed for centuries across many geographical locales and have traditionally been considered healthy foods, partly because of the live microbes contained in them. The concept of "probiotics" further requires that the microbes be defined and their health effects be demonstrated through human intervention studies or other suitable investigations before marketing with corresponding health messages. Here, we review recommendations for fermented foods and probiotics in several countries outside the EU, focusing on food-based dietary guidelines. We emphasize recommendations on yoghurt and probiotics made by expert bodies. We found that dietary guidelines commonly advocate the consumption of yoghurt or similar products, but specific comments on probiotics are rare. Further, we reviewed guidelines from clinical associations. In general, they acknowledge the beneficial ef-

fects of probiotics, but often suggest the need for further research. This is true despite good quality evidence supporting the role of probiotics for certain health effects, such as prevention of eczema in infants, management of side effects from antibiotics and alleviation of functional bowel symptoms. Additional research to support future dietary recommendations should focus on determining effect size, identifying responders and non-responders, clarifying strain-specificity of effects and confirming mechanisms.

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Key words: Fermented foods; Probiotics; Dietary guidelines; Health claims

Core tip: Probiotics are by definition beneficial to health. Benefits can be nutritional, clinical, medical and treatment-related. Nutritional benefits of probiotics and fermented foods have been recognized in varying degrees in European Union dietary recommendations. This review summarizes the nutritional and therapeutic recommendations for probiotics and fermented foods outside European Union countries.

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INTRODUCTION

Food-based dietary guidelines may include beneficial microbes or dairy products as recommended foods for specific dietary purposes. In Europe, for instance, five countries include yoghurt and/or beneficial microbes in their

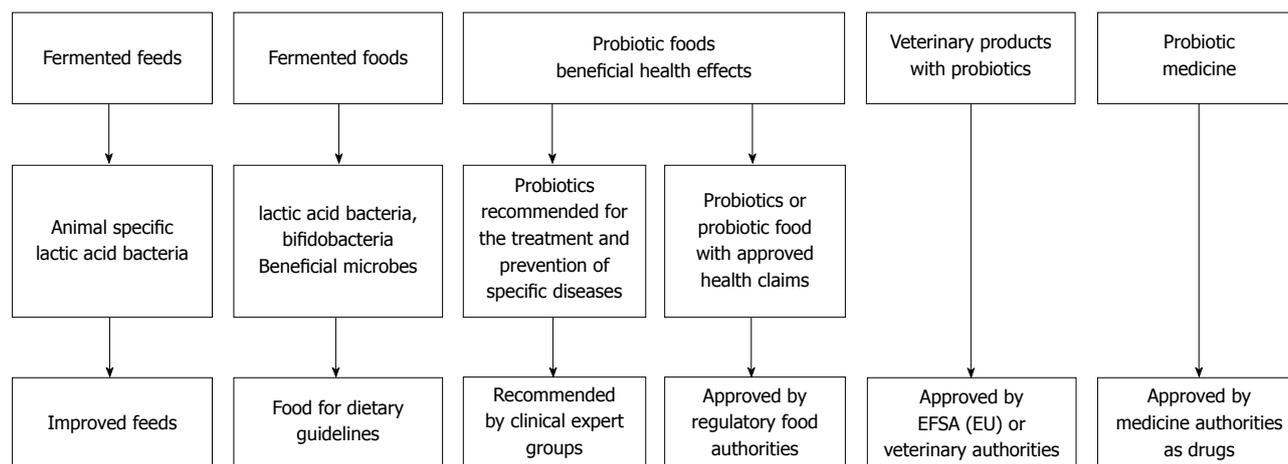


Figure 1 Possible regulatory pathways related to probiotics in food, supplements, feed and probiotic formulations in medicine.

dietary guidelines^[1,2] Beneficial microbes have been used in food for centuries. In particular, the use of fermented milk has been described in several historical documents. The term “yoghurt” was defined in 1925 and specifies a typical milk fermented with *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus*^[1]. Fermented foods have a long history of safe use. The European Union further reviews microorganisms and compiles a list known as the “Qualified Presumption of Safety” (QPS) list, which delineates biological agents deemed safe for use in foods, such as bacteria, yeasts, filamentous fungi and viruses for food and feed additives^[2]. The International Dairy Federation lists 62 genera and 264 species used in mainly in dairy products, but also in other food matrices^[3].

Probiotics are defined as “live microorganisms which when administered in adequate amounts confer a health benefit on the host”^[4]. Elie Metchnikoff introduced the concept of probiotic microorganisms, from the Greek “pro bios” (for life), in 1907. The term “probiotics” was proposed in several sources: by Ferdinand Vergin in 1954 for “active substances that are essential for a healthy development of life”^[1], by Werner Kollath in 1953^[5] and was used by Lilly and Stillwell in 1965^[6]. Several *Lactobacillus* and *Bifidobacterium* species have been investigated intensely, and certain strains of *Saccharomyces*, *Enterococcus*, *Lactococcus*, *Propionibacterium* and *Streptococcus* species have been considered as microorganisms with probiotic properties^[7].

A large collection of bacteria, yeasts and filamentous fungi with a history of safe use is being used for the fermentation of foods. In general, the primary aim is to produce healthy and easily digestible foods, which have an enhanced shelf life and also contain live microorganisms. Specific microbes have been reported to exert general beneficial effects on human health, such as competing with pathogens, enhancing the gut barrier against pathogens, modifying digestion of nutrients and by modulating the gut-associated lymphoid tissue^[8]. Microbes fulfilling the requirements set up by the WHO/FAO (2002) can further be considered to be probiotics-as beneficial as microbes in fermented foods generally, but with additional

documented health effects. Intervention trials are the best for establishing causality; however, well-controlled observational studies can also provide evidence of probiotic function^[2,3].

PROBIOTICS TODAY

The biological effects of probiotics are strain specific, thus it is not possible to extrapolate failure or success of one strain to another, even for taxonomically closely related strains, unless a common efficacy mechanism functions in both strains^[9]. Nevertheless, numerous meta-analyses provide evidence that multiple probiotics may function similarly with respect to certain benefits to health.

An overview of the possible regulatory pathways for fermented foods and probiotics is given in Figure 1. Areas of intensive research with specific probiotics comprise acute gastroenteritis or diarrhea in various forms, such as acute infectious diarrhea^[10,11]; antibiotic associated diarrhea and its side effects^[12,13] or traveller’s diarrhea^[14]; irritable bowel syndrome symptoms^[15,16]; inflammatory bowel disease^[14,17]; *Helicobacter pylori* infections^[18]; and oral health^[19], including reducing the risk of caries and gingivitis.

Probiotics in nutritional recommendations and/or dietary guidelines

Nutritional recommendations vary from country to country, because the nutrient intake and the priority in the selection of principal nutrients may depend on available foods and food preferences. In the EU member states, the main food groups within national dietary guidelines do not differ considerably, but the differences in the types of foods within the groups and the recommended amounts deviate substantially. To date, there are no harmonized guidelines on an EU level because of a lack of representative consumption data^[20]. Similar challenges are present in other parts of the world.

In an earlier study, the nutrition guidelines given by

Table 1 Occurrence of yoghurt and/or probiotics as relevant issues in different food-based dietary guidelines

Country	Organization	Document	Yoghurt recommendation	Probiotic recommendation
New Zealand	Ministry of Health	Part 1: New Zealand Food and Nutrition Guidelines ^[24]	Milk and milk products, including yogurt. Provide energy, protein, fats (mostly saturated), vitamins (riboflavin, B12, A) and minerals (calcium, iodine, phosphorus, zinc). They are important for children and young people to ensure optimal bone health. Reduced or low fat particularly, milk and milk products are the best choices because these foods include less saturated fat, and often more protein and calcium than high-fat alternatives	Not mentioned
Canada	Agriculture and Agri-Food Canada; Health Canada	Probiotics- understanding them will lead to greater use ^[25] ; Canada's Food Guide ^[26]	Yoghurt (as lower fat milk alternative; milk per se as source of Vitamin D)	Approved by Health Canada as Functional Food with Added Probiotics ^[27] : Activia® with <i>Bifidobacterium (animalis) lactis</i> DN-173 010; DanActive® with <i>Lactobacillus casei</i> DN-114 001; Yoptimal® and iÖGO ProBioTM with <i>Bifidobacterium lactis</i> BB-12 and <i>Lactobacillus acidophilus</i> LA-5)
United States	United States Department of Agriculture	Dietary Guidelines for Americans, 2010 ^[28]	All milks, including yogurts, frozen yogurts and cheeses. Most choices should be fat-free or low fat. Milk and milk products contribute many nutrients, such as calcium, vitamin D (for products fortified with vitamin D), and potassium, to the diet. Moderate evidence shows that intake of milk and milk products is linked to improved bone health, especially in children and adolescents. Moderate evidence also indicates that intake of milk and milk products is associated with a reduced risk of cardiovascular disease and type 2 diabetes and with lower blood pressure in adults. Choosing fat-free or low-fat milk and milk products provides the same nutrients with less solid fat, and thus, fewer calories. In addition, selecting more milk group intake as fat-free or low-fat fluid milk or yogurt rather than as cheese can increase intake of potassium, vitamin A, and vitamin D and decrease intake of sodium, cholesterol, and saturated fatty acids	Not mentioned
India	National Institute of Nutrition	Dietary Guidelines for Indians ^[29]	Recommended as curd	Not mentioned
Australia	The Department of Health and Ageing; The Australian Nutrition Foundation;	The Australian Guide to Healthy Eating ^[30] Australian Dietary Guidelines ^[31]	Milks, including buttermilk, yoghurt (all yoghurts including reduced fat or full cream-without added sugar), soy yoghurt (calcium fortified), and cheese Milk, cheese and yoghurt provide calcium in a readily absorbable and convenient form. They have various health benefits and are a good source of many nutrients, including calcium, protein, iodine, vitamin A, vitamin D, riboflavin, vitamin B12 and zinc. Avoiding dairy foods and not making suitable alternative choices, such as the ones recommended in this food group, can affect your long-term health	Not mentioned
Brazil	The Ministry of Health	The Food Guide ^[32]	Milk is an important source of vitamin B2 and main source of calcium in the feed; dairy products such as yoghurt and cottage cheese have the same profile	Not mentioned
China	The Ministry of Health	China's Dietary Guidelines (2007) ^[33] , Chinese Dietary Guidelines ^[34]	Yogurt, as source of calcium	Not mentioned
Israel	Ministry of Health	The Food Pyramid ^[35]	Yogurt as source of calcium in the group of protein-rich foods	Not mentioned
Japan	Health and Agriculture ministries	The Food Guide ^[36]	Yoghurt as a source of calcium	Not mentioned
Mexico	Department of Nutrition and Health Promotion	The Plate of Good Eating ^[37]	Recommended	Not mentioned
Thailand	Ministry of Public Health ^[38]		Mentioned in general along with milk	A list of approved microorganisms for food use provided, but no recommendation made.
Turkey	Ministry of Health	Basic Food Groups ^[39]	Yogurt, cheeses contain important nutrients: proteins, calcium, phosphorus, vitamin B2 (riboflavin) and vitamin B12; eating yogurt and drinking ayran (buttermilk) help in treatment of diarrhea	Not mentioned

All the reviewed countries (except India, which recommends curd) suggest yoghurt in their dietary guidelines. For the time being Canada is the only country mentioning probiotics.

Table 2 Recommendations on probiotics from scientific associations

Scientific society	Area of application	Recommendations
National Institute for Health and Care Excellence (NICE)	Diarrhoea and vomiting in children under 5: NICE guideline ^[44]	Probiotic specificity for each target should be considered available studies report benefits in reduced duration of diarrhea or stool frequency BUT: published studies have methodological limitations - in specific evaluated probiotics and treatment regimes Many of the studies were conducted in developing countries - response to probiotic therapy may differ Good quality randomized controlled trials should be conducted in the United Kingdom
European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and European Society for Paediatric Infectious Diseases (ESPID)	Evidence-based Guidelines for the Management of Acute Gastroenteritis in Children in Europe ^[39]	Selected probiotics may reduce the duration and intensity of symptoms Oral rehydration solution with <i>Lactobacillus</i> GG may be beneficial in children with acute gastroenteritis; however, because of insufficient evidence, routine use is not recommended <i>Lactobacillus</i> GG and <i>Saccharomyces boulardii</i> showed benefits in the management of diarrhea but evidence of a lack of risk of antibiotic resistance transfer is required
European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)	Supplementation of infant formula with probiotics and/or prebiotics ^[45]	Probiotic-supplemented formula: no safety concerns with regard to growth and adverse effects for healthy infants Administration of probiotic-supplemented infant formula during early life does not result in any consistent clinical effects Administration of a few probiotics supplemented to infant or follow-on formulae and given beyond early infancy may have clinical benefits; however there is too much uncertainty to draw reliable conclusions No extrapolation of safety and clinical effects of one probiotic microbe to another ones Generally there is a lack of data on the long-term effects of the administration of formula supplemented with probiotics; would be of particular importance Routine use of probiotic-supplemented formula in infants is not recommended by the Committee

governments or government-related expert organizations of 13 EU member states (Austria, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Poland, Spain, Sweden, the Netherlands and the United Kingdom) plus Switzerland, were reviewed, with the particular aim of comparing the dietary guidelines concerning yoghurt and probiotic products^[21]. All countries included yoghurt as part of a healthy diet. Interestingly, none of countries mentioned yoghurt as an alternative for people with lactose intolerance, even though there is an approved “function claim” on live cultures in yoghurt or fermented milk to “improve lactose digestion of the product in individuals who have difficulty digesting lactose” in the European Union^[22]. Yoghurt is easily digestible, it normally contains less lactose and supports further lactose hydrolysis *via* bacterial lactase activity. This information is important for countries with populations commonly unable to digest lactose. Moreover, only five of the countries considered in the survey explicitly recommended yoghurt because of live bacteria or even probiotic properties, even though accumulating evidence supports the benefits of ingestion of live cultures^[23]. In this paper, we extend our research approach to ten countries outside the European Union (Table 1). Different approaches were used to search the websites of the responsible organizations for dietary guidelines. There, the search was conducted by targeting “nutrition guidelines” or “dietary guidelines” and “yoghurt” or probiotics. Any statements recommending yoghurt, probiotics or probi-

otic yoghurt were assessed.

Probiotics and guidance of scientific societies

Several clinical organizations have assessed probiotics and probiotic foods for their evidence-based health effects. Such evaluations have resulted in clinical recommendations made by medical organizations that suggested specific well-defined probiotics for specific clinical conditions, such as treatment and prevention of acute gastroenteritis, necrotizing enterocolitis, or antibiotic associated diarrhea or, more broadly, to supplement infant formula to make it resemble the composition and microbial content of human milk^[40-41]. Recently, other studies suggested that the benefits of probiotics can positively impact healthcare costs. This nutritional economics approach applies both to general community health care and to specialist care in hospitals^[42,43] (Table 2).

CONCLUSION

Probiotics and fermented foods, specifically fermented milks, may benefit human health in many ways. Fermented foods are usually easily digestible. They provide live beneficial microorganisms to the human diet and have a long history of safe use. There are many products with the label “probiotic”. However, such products often do not meet minimum criteria, such as defined content, appropriate viable count at end of shelf life and suitable evidence of health benefit. Therefore, a

recent panel of International Scientific Association of Probiotics and Prebiotics recommended that the term “probiotic” should be used only for products that deliver live microorganisms with a suitable viable count of well-defined strains with a reasonable expectation of delivering benefits for the wellbeing of the host^[46]. Evidence from well-conducted observational studies and numerous randomized, controlled trials supports their potential contribution to human health. Their role in dietary guidelines of many nations has been illustrated; however, a deeper understanding of probiotic health benefits needs to be analyzed from the already existing human studies to identify opportunities to develop evidence-based dietary and clinical recommendations for probiotics.

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