



FOOD20006 Assignment Project Exam Help

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Food Microbiology & Safety

Helen Billman-Jacobe

Reading: Ray and Bhunia Ch 16

Hill, C., F. Guarner, et al. (2014). "Expert consensus document: The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic." Nat Rev Gastroenterol Hepatol **11**(8): 506-514.





Intended learning outcomes

Critically assess the factors that influence the likelihood of beneficial effects foods or supplements which claim to contain probiotics

Explain the strength and weaknesses of the scientific data about the effects of use of food or supplements containing probiotic bacteria

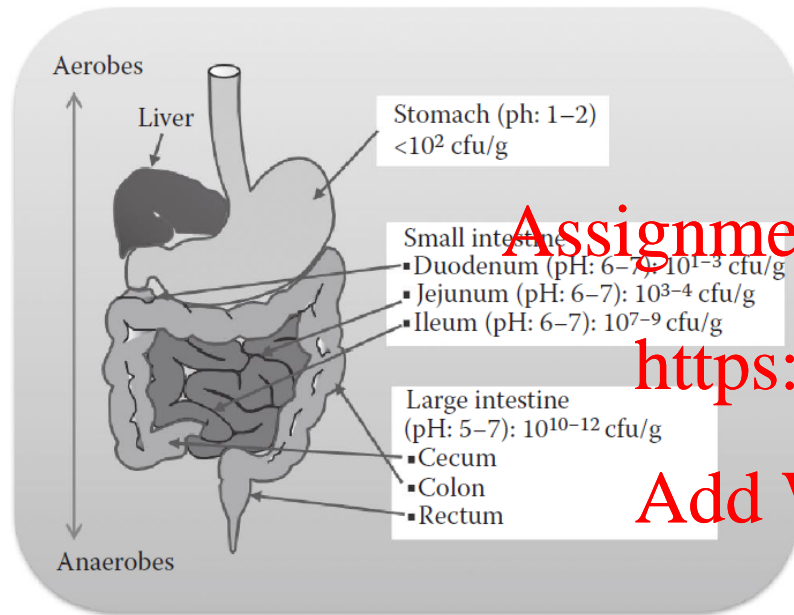
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Ch 16 synopsis



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Figure 16.1 Microbial counts in different parts of the gastrointestinal tract.

Ch 16 synopsis

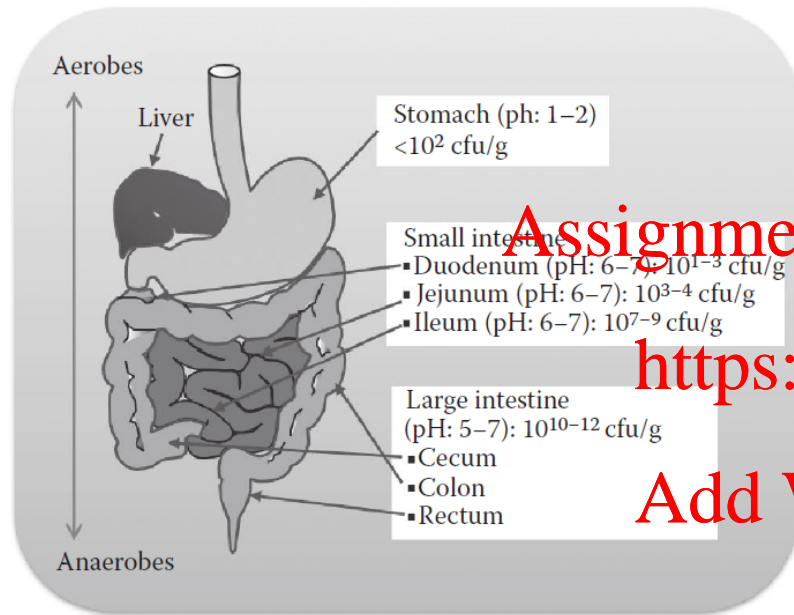


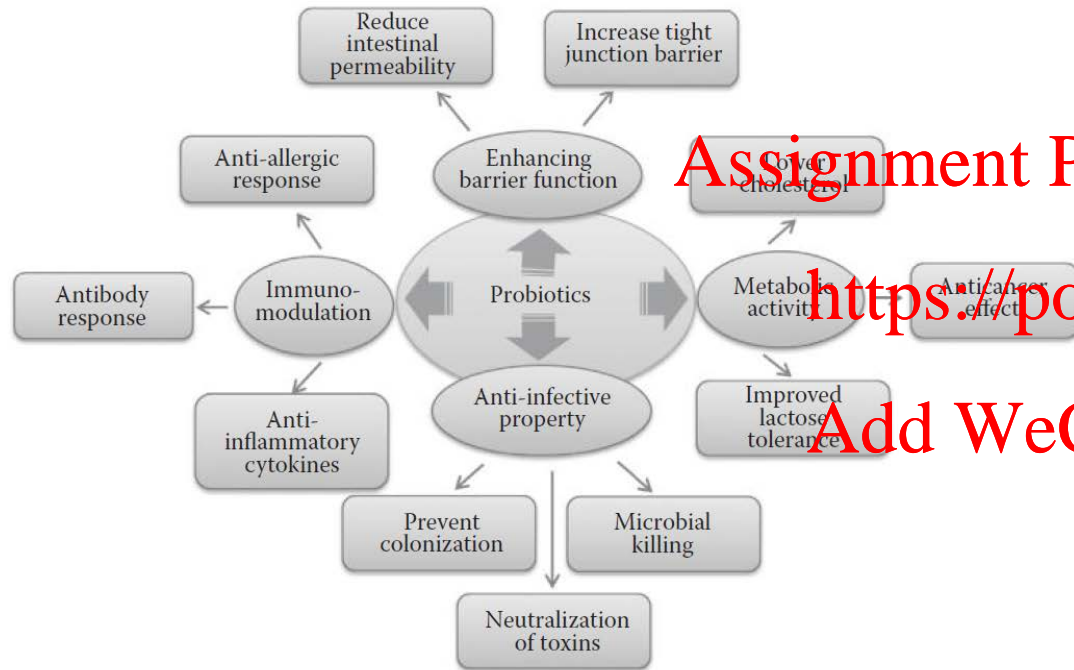
Figure 16.1 Microbial counts in different parts of the gastrointestinal tract.

Probiotics

The word “probiotic” is derived from the Greek word meaning “for life.” Probiotics are defined as live microorganisms, which, when administered in adequate amounts, confer a health benefit on the host.

- (1) as fermented milk products, such as yogurt
- (2) supplementation of foods and drinks with live cells of one, two, or more types of probiotics,
- (3) as pharmaceutical products of live cells of a monoculture or a mixture in the form of tablets, capsules, granules, and freeze-dried sachets.

Ch 16 synopsis



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Probiotics?



Inner Health Plus may:

- Aid in the maintenance of a normal healthy gastrointestinal system and digestive function.
- Be useful for the symptoms of bloating, gas or flatulence.
- Aid in maintaining a normal healthy immune system.
- Help improve general wellbeing.



The new PRObiotic liquid laundry detergents with probiotics and unique ActiveProbiotics technology were launched.

The new technology allows to prolong vitality, activity and other qualitative parameters of probiotic bacteria



GutRight is a Modbiotic™ formulation. It is a concentrated form of naturally healthy modbiotic compounds that were once found in abundance in our traditional diet, which was loaded with skins, peels, seeds and fiber.



Formulated based on scientific evidence. This multi-action FODMAP friendly formula is specifically formulated to help relieve symptoms of medically diagnosed IBS.

CONSENSUS STATEMENTS

OPEN

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EXPERT CONSENSUS DOCUMENT
The International Scientific Association for
Probiotics and Prebiotics consensus statement on
the scope and appropriate use of the term probiotic
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Colin Hill, Francisco Guarner, Gregor Reid, Glenn R. Gibson, Daniel J. Merenstein, Bruno Pot, Lorenzo Morelli, Roberto Berni Canani, Harry J. Flint, Seppo Salminen, Philip C. Calder and Mary Ellen Sanders

Hill, C., F. Guarner, et al. (2014). "Expert consensus document: The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic." Nat Rev Gastroenterol Hepatol **11**(8): 506-514.



Abstract | An expert panel was convened in October 2013 by the International Scientific Association for Probiotics and Prebiotics (ISAPP) to discuss the field of probiotics. It is now 13 years since the definition of probiotics and 12 years after guidelines were published for regulators, scientists and industry by the Food and Agriculture Organization of the United Nations and the WHO (FAO/WHO). The FAO/WHO definition of a probiotic—“live microorganisms which when administered in adequate amounts confer a health benefit on the host”—was reinforced as relevant and sufficiently accommodating for current and anticipated applications. However, inconsistencies between the FAO/WHO Expert Consultation Report and the FAO/WHO Guidelines were clarified to take into account advances in science and applications. A more precise use of the term ‘probiotic’ will be useful to guide clinicians and consumers in differentiating the diverse products on the market. This document represents the conclusions of the ISAPP consensus meeting on the appropriate use and scope of the term probiotic.

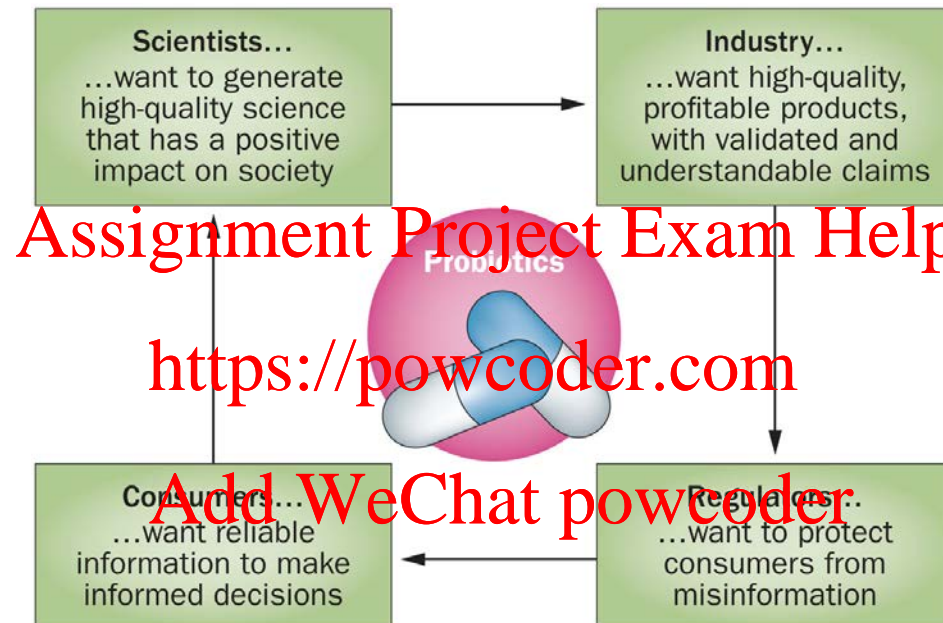
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Figure 1 Objectives of stakeholders in the probiotic field



Hill, C. *et al.* (2014) The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic
Nat. Rev. Gastroenterol. Hepatol. doi:10.1038/nrgastro.2014.66



Box 1 | Consensus panel recommendations for the scope of probiotics

- Retain the FAO/WHO definition¹ for probiotics, with a minor grammatical correction as “live microorganisms that, when administered in adequate amounts, confer a health benefit on the host”; inconsistencies between the Expert Consultation² and the FAO/WHO Guidelines³ were clarified
- Include in the framework for definition of probiotics microbial species that have been shown in properly controlled studies to confer benefits to health
- Any specific claim beyond “contains probiotics” must be further substantiated
- Keep live cultures, traditionally associated with fermented foods and for which there is no evidence of a health benefit, outside the probiotic framework
- Keep undefined, faecal microbiota transplants outside the probiotic framework
- New commensals and consortia comprising defined strains from human samples, with adequate evidence of safety and efficacy, are ‘probiotics’

Abbreviation: FAO, Food and Agriculture Organization of the United Nations.



Commensals vs probiotics

istered primarily for their health benefits. The distinction between commensal microorganisms and probiotics is also inferred from this definition. Although commensals in the gut are often the source of probiotic strains, until these strains are isolated, characterized and a credible case presented for their health effects, they cannot be called 'probiotics'. In the 13 years that have passed since

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Q *Are there core benefits that can be ascribed to the general category of probiotics, and, if so, should the probiotic classification include live microbes identified to the species level, which can be reasonably expected to impart general benefits?*

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Health Canada has accepted the following bacterial species, when delivered in food at a level of 1×10^9 colony forming units (CFU) per serving, as probiotics for which nonstrain-specific claims might be made: *Bifidobacterium* (*adolescentis*, *animalis*, *bifidum*, *breve* and *longum*) and *Lactobacillus* (*acidophilus*, *casei*, *fermentum*, *gasseri*, *johnsonii*, *paracasei*, *plantarum*, *rhamnosus* and *salivarius*).³ This list represents a core group of well-studied species likely to impart some general benefits.

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The Italian Ministry of Health has regulated the use of probiotic bacteria in the food sector over the past 12 years and in 2013, confirmed the use of the word probiotic for food and food supplements under certain conditions, including a minimum number of viable cells (1×10^9 CFU) administered per day, a full genetic characterization of the probiotic strain and a demonstratable history of safe use in the Italian market.⁹

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Opinion vs evidence

Thus, Canada and Italy consider the general benefit of supporting a healthy gut microbiota to be a core benefit of probiotics. The consensus panel agrees with this approach, while acknowledging that the current state of science does not allow the clear definition of a healthy gut microbiota based on microbial composition.¹⁰

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Body of research

The panel concluded that the general benefit of supporting a healthy digestive tract was reinforced by evidence gathered on a large number of different probiotic strains representing commonly studied species. This conclusion was based on a body of available research, including high-quality meta-analyses, on a diversity of clinical end points (such as infectious diarrhoea, antibiotic-associated diarrhoea, gut transit, IBS, abdominal pain and bloating, ulcerative colitis and necrotizing enterocolitis¹¹⁻¹⁵), as well as potential mechanistic actions suggesting that most strains of these species can be expected to have such 'generic' or 'core' effects on gut physiology and

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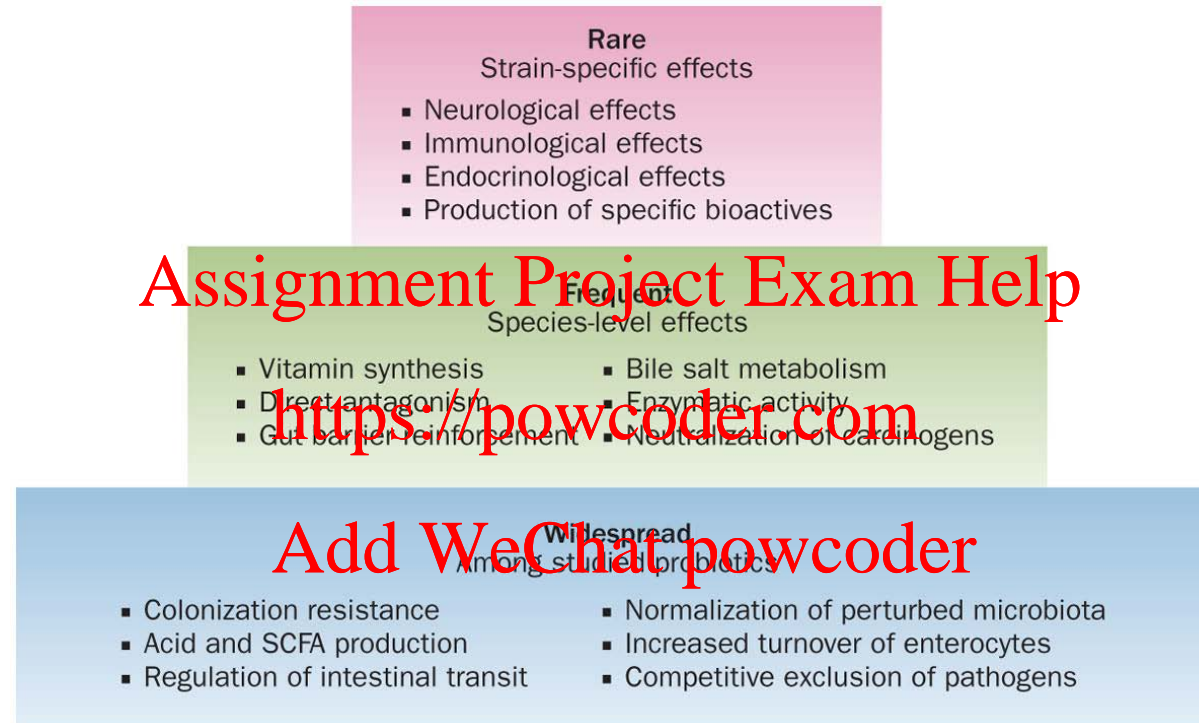


Core benefit

The core benefit of supporting a healthy immune system was considered by the panel to be widely acknowledged, but probably more strain-specific. The diverse meaning of 'supporting a healthy immune system', which ranges from preventing allergic disease to downregulation of inflammation to the enhancement of anti-infection activities was considered to be too broad to be considered a core benefit.



Figure 2 Possible distribution of mechanisms among probiotics



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Underlying mechanisms

Widespread mechanisms can be associated with effects that are observed across taxonomic groups, such as inhibition of potential pathogens or the production of useful metabolites or enzymes.^{18,19} Other effects at the intestinal or extraintestinal level, including immune effects, are more likely to be strain-specific²⁰ and claims of such benefit can only be made for strains or species in which the mechanistic basis has been demonstrated.^{21,22} In many cases, a given probiotic might exert several health-promoting effects. Although multiple mechanisms are often represented in a single strain, no individual probiotic would be expected to have all the effects listed in Figure 2.



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Q

Should the probiotic framework include traditional fermented foods containing live microbes?

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Q

*Should the probiotic framework include
well-defined beneficial commensal microbes?*

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Q

Should the probiotic framework include undefined consortia of commensals derived from sampling human body sites?

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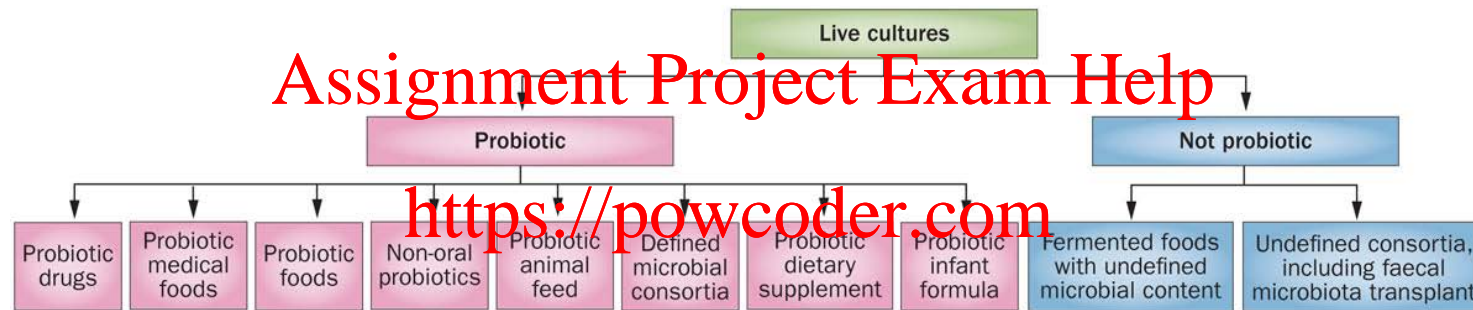
Q

*What is an appropriate level of evidence for
determining a health benefit for probiotics?*

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Figure 3 Overall framework for probiotic products



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Table 1 Categories of live microorganisms for human use as defined by the expert panel

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Description	Claim	Criteria*	Minimum level of evidence required to make claim	Comments
Not probiotic				
Live or active cultures	"Contains live and active cultures"	Any food fermentation microbe(s) Proof of viability at a minimum level reflective of typical levels seen in fermented foods, suggested to be 1×10^9 CFU per serving ⁷³	No product-specific efficacy studies needed	The terms 'live' or 'active' do not imply probiotic activity Fermented foods containing live cultures might also qualify as a 'probiotic' if they meet the criteria for that category (e.g. evidence that yogurt can improve lactose digestion in lactose maldigesters would qualify as a probiotic ⁷⁷⁵)
Probiotic				
Probiotic in food or supplement without health claim	"Contains probiotics"	A member(s) of a safe ^{76,77} species, which is supported by sufficient evidence of a general beneficial effect in humans OR a safe microbe(s) with a property (e.g. a structure, activity or end product) for which there is sufficient evidence for a general beneficial effect in humans Proof of viability at the appropriate level used in supporting human studies ⁷³	Well-conducted human studies (e.g. these could involve RCT(s), observational studies, systematic reviews, or meta-analyses supporting the observed general beneficial effect for the taxonomical category concerned) The evidence does not have to be generated for the specific strain included in the product	Extrapolation of evidence must be based on reasonable expectations that the strain(s) incorporated in the product would have similar general beneficial effects in humans This evidence could be based on taxonomical or functional comparisons
Probiotic in food or supplement with a specific health claim	Specific health claim, such as "helps to reinforce the body's natural defences in children" or "helps reduce the risk of antibiotic-associated diarrhoea"	Defined probiotic strain(s) Proof of delivery of viable strain(s) at efficacious dose at end of shelf-life ⁷³	Convincing evidence needed for specific strain(s) or strain combination in the specified health indication Such evidence includes well-conducted studies in humans, including: positive meta-analyses on specific strain(s) or strain combinations, as per principles outlined by Cochrane, ⁷⁸ PASSCLAIM, ⁷⁹ or GRADE; ⁸⁰ well-conducted RCT(s) OR strong evidence from large observational studies ⁸¹	Well-designed observational studies are useful to detect the effect of foods on health in 'real life', that is, outside the controlled environment of an RCT (e.g. data on health benefits by dietary fibre are mostly observational) Sample sizes must be large enough to manage confounding factors
Probiotic drug	Specific indication for treatment or prevention of disease, such as "useful for the prevention of relapse of ulcerative colitis"	A defined strain(s) of live microbe Proof of delivery of viable probiotic at efficacious dose at end of shelf-life Risk-benefit assessment justifies use	Appropriate trials to meet regulatory standards for drugs	What constitutes a drug claim varies among countries
*Unless otherwise indicated, all criteria indicated must be met. Abbreviations: CFU, colony forming unit; GRADE, Grades of Recommendation Assessment, Development and Evaluation; PASSCLAIM, Process for the Assessment of Scientific Support for Claims on Food; RCT, randomized controlled trial.				

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FSANZ

Nutrition content claims and health claims are voluntary statements made by food businesses on labels and in advertising about a food. Standard 1.2.7 sets out the rules for food businesses choosing to make nutrition content claims and health claims.

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FSANZ – nutrient content

Nutrition content claims are claims about the content of certain nutrients or substances in a food, such as **low in fat** or **good source of calcium**. These claims will need to meet certain criteria set out in the Standard. For example, with a 'good source of calcium' claim, the food needs to contain at least the amount of calcium specified in the Standard.

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FSANZ- Health claims

Health claims refer to a relationship between a food and health rather than a statement of content. There are two types of health claims:

General level health claims refer to a nutrient or substance in a food, or the food itself, and its effect on health. For example: **calcium for healthy bones and teeth**. They must not refer to a serious disease or to a biomarker of a serious disease.

High level health claims refer to a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. For example: **Diets high in calcium may reduce the risk of osteoporosis in people 65 years and over**. An example of a biomarker health claim is: **Phytosterols may reduce blood cholesterol**.





FSANZ-food/medicine

In the Food Standards Code, if a yoghurt or fermented milk contains at least 10^8 cfu/g of the bacteria *Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophilus* a manufacturer may make a general level claim that the product improves lactose digestion for those individuals who have difficulty digesting lactose. This is called a pre-approved claim, and no other claims are currently allowed for products containing living organisms.

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TGA- Food/medicine

Probiotics that are regulated as foods

Probiotic products that are clearly covered by a food standard, or that are traditionally used as foods in Australia or New Zealand in the form they are presented in, are regulated as foods.

For example, yoghurt and yoghurt drinks are covered by Food Standard 2.5.3 for fermented milk products. Accompanying general level health claims for such products would be limited to lactose digestion covered by the nutrition, health and related claims set out in Food Standard 1.2.7. High level health claims need to be separately approved by FSANZ.

A probiotic that is not covered by a food standard or that is not traditionally used as a food in Australia or New Zealand, however, is not automatically considered a therapeutic good.

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Randomly selected products. Probiotic?



GutRight is a Modbiotic™ formulation. It is a concentrated form of naturally healthy modbiotic compounds that were once found in abundance in our traditional diet, which was loaded with skins, peels, seeds and fiber.

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A Modbiotic® is a group of natural compounds including polyphenols that help to maintain a healthy diverse microbiome. Probiotics add certain strains but you may already have enough of those same kinds or other tougher ones that won't allow the probiotics to stick around and grow. Prebiotics may indiscriminately feed your bugs. Modbiotics® have a microbiome modifying effect



Randomly selected products. Probiotic?



Each capsule contains:

Lactobacillus Acidophilus (NCFM) 12.5 Billion Live Bacteria.

Bifidobacterium Lactis (Bi-07) 12.5 Billion Live Bacteria.

Bovine Colostrum Powder 67mg.

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The new technology allows to prolong vitality, activity and other qualitative parameters of probiotic bacteria

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- it prevents from unpleasant odors in the washing machine, enriches natural microflora on fabrics and skin, immediately provides additional protection from multiplication of pathogenic bacteria

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Randomly selected products. Probiotic?



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Formulated based on scientific evidence. This multi-action FODMAP friendly formula is specifically formulated to help relieve symptoms of medically diagnosed IBS.

It contains five clinically trialled probiotic strains* providing 27 billion good bacteria, plus prebiotic FODMAP friendly fibre. It helps support digestive health and daily wellbeing

Waller et al Scand J Gastroenterol 2011 Sept 46191:1057-64
(effect of *Bifidobacterium lactis* HN019 on whole gut transit time)

Williams et al, Aliment Pharmacol Ther 2008 29:97-10

Participants were randomized to receive either a probiotic preparation comprising two strains of *Lactobacillus acidophilus* CUL60 (NCIMB 30157) and CUL21 (NCIMB 30156), *Bifidobacterium lactis* CUL34 (NCIMB 30172) and *Bifidobacterium bifidum* CUL20 (NCIMB 30153) at a total of 2.5×10^{10} cfu/capsule or a placebo for 8 weeks. Participants reported their IBS symptoms using a questionnaire fortnightly during the intervention and at 2 weeks post-intervention.

Lactobacillus acidophilus
CUL60 (9.375 billion CFU)
9.375 mg

Lactobacillus acidophilus
CUL21 (9.375 billion CFU)
93.75 mg

Bifidobacterium bifidum
CUL20 (312 million CFU)
1.4 mg

Bifidobacterium animalis subsp
lactis
CUL34 (5.938 billion CFU)
26.4 mg

Bifidobacterium lactis
HN019
2 billion CFU

Total live good bacteria
27 billion CFU

Platago ovata (psyllium) husk
powder (prebiotic)
4 g (4,000 mg)

Starch – maize high amylose
(corn starch, dietary fibre 1.8 g)
(prebiotic)
3 g (3,000 mg)





Questions from textbook

1. Discuss the following terms with examples: indigenous bacteria, transient bacteria, beneficial bacteria, and undesirable bacteria in the GI tract of humans.
2. Experimental data do not always support the health benefits from the consumption of fermented foods and live cells of beneficial intestinal bacteria. If you are planning to conduct such a study, what are some of the experimental factors you should consider?
3. List the important characteristics of beneficial bacteria present in the GI tract.
4. List the factors that could adversely affect the presence of beneficial bacteria in the human GI tract.
5. What is lactose intolerance? Explain the possible mechanisms by which consumption of some fermented dairy products or live cells of beneficial intestinal bacteria can help overcome this problem.

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