Market and product assessment of probiotic/prebiotic-containing functional foods and supplements manufactured in South Africa

M Brink, M Senekal, L M T Dicks

Objectives. Probiotic and prebiotic products manufactured in South Africa were identified and health and content claims stated on the labels were evaluated according to available scientific evidence, the proposed South African regulations in the Foodstuffs, Cosmetics and Disinfectants Act (Act No. 54 of 1972, **www.doh.gov.za**), and microbial assessment.

Results. The range of products identified included probiotic- and/or prebiotic-containing supplements (capsules), food items fortified with probiotics and/or prebiotics, and fermented food containing probiotics, e.g. dairy products. Most of the health-related claims on the labels of the identified products do not comply with proposed South African regulations. However, results also indicate that the proposed South African regulations should be reconsidered to include an additional 5 claims, for which scientifically sound evidence is available. The claims regarding probiotic strains, viable cell numbers, prebiotic type and concentration stated on the labels of the products are mostly in line with the proposed South African regulations. The actual viable cell content of 3 out of 5 probiotic supplements readily available on the South African market did not comply with the content claim stated on the label. However, this problem did not seem to affect the inhibitory activity of the probiotic strains against indicator strains isolated from faeces of patients diagnosed with AIDS. To validate this finding *in vivo* assessments should be implemented before considering the need to include a wider range of prescribed viable cell numbers in the proposed South African regulations.

Conclusions. The proposed South African regulations regarding probiotic- and prebiotic-containing products should be revised based on the results of this research, and the manufacturers of these products should be held responsible for providing the consumer with scientifically sound and legally correct information.

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Consumers are becoming more aware of functional foods and supplements and the potential role of these products in a balanced diet and in ensuring good health.[1] Functional foods are defined as foods that contain physiologically active components, which provide health benefits beyond basic nutrition[2] by affecting one or more functions in the body in a targeted way.[3] 'The functional component could include an essential macronutrient with specific physiological effects such as an essential micronutrient'[3], 'components that have some nutritive value but are not classified as "essential", such as oligosaccharides, or food components with no nutritive value, such as live microorganisms or plant chemicals'.[3] 'A dietary supplement is defined as a product intended for ingestion as a supplement to the diet'.[4] Supplements may contain one or more of the following ingredients: vitamins, minerals, herbs, botanicals, or other plant-derived substances; amino acids, enzymes, concentrates and extracts. Dietary supplements can be manufactured as pills, tablets, capsules, gelcaps, liquids and powders.[4]

In many countries the functional food market seems to be dominated by gut health products, in particular probiotic- and prebiotic-containing products.[5] Fuller[6] defines a probiotic as 'a live microbial food supplement that beneficially affects the host animal by improving its intestinal microbial balance'. Probiotics are available in the form of various pharmaceutical preparations, e.g. powders, liquid suspensions and tablets, or are incorporated in, for example, fermented food products to produce functional foods.[6,7]

The latest trend in the functional food market is to combine probiotics with prebiotics to enhance the effect of probiotics.[5] Prebiotics are defined as 'non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of probiotic bacteria in the colon'.[8] However, prebiotics also have health benefits that are not related to the simultaneous intake of probiotics. Inulin and fructo-oligosaccharides are among the most common prebiotics included in breakfast cereals and nutritional drinks or used in combination with probiotics in nutritional supplements.[9]

Because of the presence of potentially pathogenic species such as *Enterococcus faecium* and *E. faecalis* in probiotic products,[1,10] the production and marketing of functional foods

Department of Physiological Sciences, Stellenbosch University, W Cape
M Brink, MSc
M Senekal, PhD
Department of Microbiology, Stellenbosch University, W Cape
L M T Dicks, PhD
Corresponding author: *L M T Dicks (lmtd@sun.ac.za)*

should be strictly controlled and carefully monitored.[11] Information on the label of the product, especially regarding the composition and identity of the probiotic strains included, needs to be accurate to guarantee safety and functionality.[12] Recent studies conducted on probiotic supplements and dairy products in Europe and South Africa revealed possible irregularities in this regard. In most cases the identity and number of viable strains recovered did not correspond with the information on the label.[12-14]

One solution in addressing the problems mentioned with product content involves relevant and effective legislation. However, despite the large market segment occupied by probiotic foods and supplements in Europe, no specific regulations regarding the labelling of these products exist in that region.[15] On the other hand, although this particular market has not yet been that well developed in the USA, the United States Food and Drug Administration (FDA) strictly regulates the labelling and marketing of conventional foods containing probiotic bacteria. In South Africa permissible statements regarding the health benefits of probiotic and prebiotic claims are included in the proposed regulations governing labelling and advertising in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972 (referred to as 'proposed South African regulations' from here onwards), **www.doh.gov.za**). However, despite the fact that these regulations are being finalised, limited information is available regarding the probiotic- and prebiotic-containing product market in South Africa.

In view of the above, the aims of this study were to complete a market and product assessment of probiotic- and prebiotic-containing products manufactured in South Africa. This involved identifying the range of products available on the South African market and evaluating claims made on the labels.

Materials and methods

Identification of probiotic and prebiotic products on the South African market

For the purposes of this study 'probiotic- and prebiotic-containing products manufactured in South Africa' are defined as all products manufactured in South Africa that contain probiotics and/or prebiotics. For the identification of such products available on the South African market during the period 1 February - 1 September 2003, the following information sources were scrutinised or visited: general grocery outlets, health food stores, websites, published information including scientific literature, advertisements and pamphlets. Every identified product was listed and the following information was recorded: type of product (tablet, syrup or powdered form), specific target group (if applicable), probiotic strains (strain, number of viable cells (colony forming units (cfu)/g) and prebiotic (type and concentration).

Evaluation of claims on probiotic- and prebiotic-containing products manufactured in South Africa

For the purposes of this study 'claims' are defined as: (*i*) health-related claims, e.g. 'treatment and prevention of diarrhoea'; and (*ii*) probiotic and prebiotic content-related claims, i.e. strain and viable cell numbers of probiotics and concentration of prebiotics included.

Evaluation of health-related claims based on proposed South African regulations

The health-related claims regarding probiotics and prebiotics on each identified product were listed and similar claims were grouped together. To determine whether it complied with the regulations or not, the wording/content of each of the claims was subsequently compared with the prescribed wording/content claim as proposed by the South African regulations.

Evaluation of health claims based on scientific soundness

The scientific soundness of each of the identified claims was assessed by searching the scientific literature for any published study providing data in support of the claim. In this process it was assumed that the publication of a paper in a scientific journal is not necessarily final proof of the scientific soundness of such a claim. To address this issue, the quality of each identified paper was assessed based on the study design applied. According to Farnworth,[16] it is generally accepted that health claims concerning specific nutrients/foods/functional components need to be assessed using a randomised controlled trial (RCT). The following criteria of RCTs in humans[4] were therefore used to assess the quality of the identified papers: (*i*) the measurements used must be objective — subjective claims, referred to as anecdotal evidence, which include individual testimonials or opinions, are not acceptable objective measurements; (*ii*) the experimental population must be appropriate, i.e. human, and the subjects used must be in line with those for whom conclusions were drawn and recommendations formulated — for example, it is not acceptable to use adult subjects and formulate health claims for children; (*iii*) the study must include a control group; (*iv*) the study must include an experimental group; (*v*) subjects must be randomly assigned to an experimental and control group; (*vi*) control subjects must receive a placebo; (*vii*) the study must be at least single-blinded, but preferably double-blinded; and (*viii*) the journal in which the study was published must be peer reviewed.

Although sample size is a very important factor to consider in a study design, it was not possible to specify a minimum sample size for a scientifically sound study for the assessment of probiotic- and prebiotic-related health claims. A criterion in this regard was therefore not formulated.

A study was classified as scientifically sound if at least 7 out of 8 of the mentioned criteria were met. If any 2 or more of the criteria were not met, the study was classified as lacking in

scientific soundness, although not necessarily completely worthless. Although *in vitro* studies supply important evidence regarding microbial activity and potential health benefits, the final proof lies in the execution of well-planned RCTs. *In vitro* studies were therefore not accepted as a scientific basis for the formulation of a health claim.

Evaluation of content claims regarding strains included, viable cell numbers and prebiotic type and concentration based on the proposed South African regulations

The probiotic strains and viable cell numbers, and prebiotic type and concentration were listed for each identified product and compared with the proposed South African regulations in this regard.

Microbial assessment of viable cell numbers included in 5 selected probiotic supplements

Five probiotic supplements readily available in pharmacies were selected to determine the viability (growth and inhibitory activity) of the probiotic strains and to compare the actual viable cell numbers with the 'label' claim in this regard.

The content of the capsule was resuspended in 10 ml sterile distilled water, serially diluted and plated out, in duplicate, onto a De Man Rogosa Sharpe (MRS) agar (Biolab, Diagnostics, Midrand, South Africa). Plates from each dilution were incubated aerobically and anaerobically at 37°C and colonies were counted after 24 hours.

To assess the viability of the probiotics included in the products, probiotic strains isolated from each of the 5 products were screened for inhibitory activity against the following 10 indicator strains isolated from the faeces of patients diagnosed with AIDS: *Salmonella typhi*, *S. typhimurium*, *Salmonella* Gr.B., *Shigella flexneri 1*, *S. flexneri* 3, *S. sonnei*, *S. boydii*, *Shigella* spp., *Yersinia* spp. and *Vibrio parahaemolyticus*. The probiotic strains were cultured in MRS broth (Biolab) for 18 hours at 37°C and 10 μl was spotted on MRS agar (Biolab). The plates were incubated for 24 hours at 37°C and then lawned with active cells of the indicator strains (approximately 10^6 cfu/ml), embedded in soft agar (0.8%, m/v). The plates were incubated at 37°C for 24 hours and the colonies examined for the formation of zones, which indicates the level of inhibitory activity and therefore viability. The study was done in triplicate and the average determined.

Results

The identified range of probiotic- and prebiotic-containing products manufactured in South Africa includes 3 fortified infant foods, 7 yoghurt products selected from a variety of dairy products containing live cultures targeted at children and adults, and 16 probiotic supplements of which 3 are targeted at infants/children and 13 at adults. A combination of probiotics and prebiotics was found in 6 supplements, of which only 1 is targeted at children, 2 energy drinks and 1 dairy product targeted at children and adults. Sixteen food items naturally containing or fortified with prebiotics, including 2 supplements, 2 breakfast cereals, 11 nutritional drinks and 1 muesli bar, were identified. Four of these are targeted at infants/children, 4 at children and adults, and 8 at adults only.

Comparison of the health claims stated on the label of probiotic- and prebiotic-containing products manufactured in South Africa with the proposed South African regulations is presented in Table I. Scientific publications that seem to support a particular claim are listed in the table.

These data indicate that only 3 of the 26 claims on the identified products comply with the proposed South African regulations, but that sound scientific evidence seems to be available for all 3 of these claims. It is of importance to note that sound scientific evidence is also available for at least 5 claims not included in the proposed South African regulations, including diarrhoea prevention in infants, diarrhoea prevention in adults, improvement of digestive health and stool quality and prevention of constipation, treatment of irritable bowel syndrome, and treatment of food allergies. Furthermore, no sound scientific evidence could be traced for 16 of the 26 claims that appeared on the identified products.

Probiotic strain claims made on the labels of identified products all comply with the proposed South African regulations with the exception of 4 dairy products and 1 supplement. The claims concerning the included viable cell numbers varied between 1 x10^8 cfu/g and 6 x10^9 cfu/g, which is in line with the proposed South African regulations. The prebiotic type claims made on the labels of the identified products include fructo-oligosaccharides, raftilose and chicory, which are all permissible according to the proposed South African regulations. The labels of 3 products did not specify the type of prebiotic but only claimed prebiotic fibre content, which is not in line with the proposed South African regulations. The prebiotic concentration claims varied between 3 g and 15 g per 100 g, which is in line with the proposed South African regulations.

Comparison of viable cell numbers stated on the labels of the supplements with the actual viable cell numbers is presented in Table II. Based on these results, the viable cell numbers in supplements 1 and 5 are in line with the viable cell numbers as stated on the labels. The viable cell numbers in supplement 2 were 2 log-cycles lower, and in supplements 3 and 4, 1 log-cycle lower than the claimed number. The actual viable cell numbers in supplement 4 do not comply with the proposed South African regulations.

The results of the screening of the probiotic strains isolated from the 5 selected supplements against a panel of 10 indicator strains are presented in Table III. It is evident that all strains showed good inhibitory activity against the panel of indicator strains isolated from faeces of patients diagnosed with AIDS, as is indicated by the diameter recorded for each of the inhibition zones.

Table I. Claims stated on the labels of probiotic- and/or prebiotic-containing products, publications supporting claims and compliance with the proposed South African regulations

Claims	References complied with 7/8 criteria	Complies with SA regulations
Prevention of diarrhoea in infants	Kaila *et al.*,[17] Saavedra *et al.*,[18] Shornikova *et al.*,[19] Guandalini *et al.*,[20] Haschke *et al.*,[21] Hatakka *et al.*[22] Szajewska and Mrukowicz[23]	No
Assists in prevention and treatment of nappy rash	None	No
Assists in prevention and treatment of constipation	None	No
Assists in protection of infants in hygienically compromised situations	None	No
Decreases symptoms of lactose intolerance	Vesa *et al.*[24]	Yes
Treatment of colon disorders	None	No
Replenishes intestinal flora of adults (after antibiotic treatment)	Sittonen *et al.*,[25] Orrhage *et al.*,[26] Cremonini *et al.*[27]	Yes
Helps the body to alleviate diarrhoea naturally in adults	Sittonen *et al.*,[25] Orrhage *et al.*,[26] Cremonini *et al.*[27]	No
Improves digestive health, improves stool quality, prevents constipation	Saavedra *et al.*,[28] Haschke *et al.*[21]	No
Helps the body to alleviate flatulence naturally	None	No
Reverses the negative effects of antibiotics on the digestive tract	None	No
Reverses the negative effects of alcohol on the digestive tract	None	No
Reverses the negative effects of stress on the digestive tract	None	No
Reverses the negative effects of poor diet on the digestive tract	None	No
Inhibits intestinal and food poisoning pathogens including *Escherichia coli, Streptococci* and *Salmonella* and feeds friendly bacteria, balances intestinal pH	None	No
Assists in promotion of healthy bowel flora for treatment of acidity, heartburn, indigestion and digestive upsets	None	No
Very effective in treating irritable bowel syndrome/colitis/ radiation-caused enterocolitis	Pelto *et al.*,[29] Gionchetti *et al.*,[30] Niedzielin *et al.*[31]	No
Very effective in treating Crohn's disease	Pelto *et al.*[29]	No
Very effective in preventing dyspepsia	None	No
Restores and maintains the normal vaginal flora (mainly lactic acid bacteria) frequently destroyed by the administration of broad-spectrum antibiotics and the use of disinfectants, soaps and deodorants	None	No
Treatment of food allergies	Heyman *et al.*,[32] Majamaa *et al.*,[33] Isolauri *et al.*[34]	No
Treatment of acne	None	No
Boosts immune system	Link-Amster *et al.*,[35] Schiffrin *et al.*,[36] Mattila-Sandholm and Kauppila,[1] Fisberg *et al.*,[37] Haschke *et al.*[21]	Yes
Treatment during steroid therapy	None	No
Treatment during chemotherapy	None	No
Treatment during radiotherapy	Hendriksson *et al.*[38]	No

Discussion

The probiotic- and prebiotic-containing product market is a fast-growing industry worldwide and the list of available products increases on a daily basis.[39] In the USA, Europe and Japan the probiotic and prebiotic market seems to be dominated by dairy products, including yoghurt and fermented drinks.[40,41] Although not an exhaustive list, a large

Table II. Comparison of the actual viable cell numbers with the claims on the labels of 5 probiotic supplements manufactured in South Africa

Supplement	Viable cell numbers stated on the label of the supplement (cfu/g)	Actual viable cell numbers identified (aerobic/anaerobic (cfu/g))
1	1×10^8	$1 \times 10^8 / 1.7 \times 10^8$
2	1×10^8	$2.8 \times 10^6 / 3 \times 10^6$
3*	1×10^8	2×10^7
4	1×10^8	$4 \times 10^5 / 1.4 \times 10^7$
5*	1×10^7	1.5×10^7

*Supplements 3 and 5 contained no bifidobacteria and cell counts were not determined from anaerobically incubated plates.

variety of probiotic- and prebiotic-containing products manufactured in South Africa were identified in this study. The range of products on the South African market includes probiotic and prebiotic supplements (capsules) and fortified food items, fermented foods containing probiotics, e.g. dairy products, and probiotics used in combination with prebiotics in supplements and food fortification. Dairy products seem to be prominent in the market, although fortified cereals, especially baby cereals, and supplements also seem to be growing markets.

It is important that the health claims stated on the labels of products supply the consumer with reliable information because such claims influence consumer behaviour and potentially affect public health.[42] From this research it was evident that quite a number of claims stated on the labels of products cannot be substantiated by scientific evidence and are therefore misleading. Besides the fact that the consumer is being manipulated into buying a product under false pretences, it could potentially be dangerous if such products are used to treat a condition instead of the individual seeking medical help.[43] Manufacturers and marketers of these products should therefore be held accountable for health-related claims on products via appropriate legislation.

Unlike the European situation,[40] South African legislators have formulated proposed regulations for labelling of probiotic- and/or prebiotic-containing products in the Foodstuffs, Cosmetics and Disinfectants Act (Act No. 54 of 1972, **www.doh.gov.za**). Only 3 of 26 claims complied with proposed South African regulations. Sound scientific evidence was found for 5 additional claims not included in these regulations. Because of incomplete information on labels, the consumer is misinformed. We propose a revision of the South African regulations to include the following 5 claims: diarrhoea prevention in infants, diarrhoea prevention in adults, improvement of digestive health and stool quality and prevention of constipation, treatment of irritable bowel syndrome, and treatment of food allergies.

The probiotic and prebiotic content-related claims (strain, viable cell number, type of probiotic and prebiotic concentration) on the labels were mostly in line with the proposed South African regulations. Probiotic cultures most commonly claimed on the labels of supplements and functional foods include *Lactobacillus acidophilus, Bificobacterium bifidum* and *B. longum*, which are the same species generally claimed to be included in European probiotic supplements.[12] It is of concern that quite a number of products on the South African market only claim *L. acidophilus* and *Bifidobacterium* sp. (AB-culture) content or prebiotic fibre content without specifying probiotic species, viable cell numbers, prebiotic type and concentration. This situation indicates that the proposed South African

Table III. Inhibitory activity of probiotic strains from 5 probiotic supplements manufactured in South Africa against a panel of indicator strains

	Supplement 1	Supplement 2	Supplement 3	Supplement 4	Supplement 5
Human pathogens	Zone size (mm)				
Salmonella typhi	26 - 30	26 - 30	26 - 30	26 - 30	26 - 30
Yersinia spp.	26 - 30	20 - 25	26 - 30	20 - 25	20 - 25
Shigella flexneri 1	31 - 35	26 - 30	26 - 30	20 - 25	26 - 30
Salmonella typhimurium	31 - 35	31 - 35	20 - 25	26 - 30	20 - 25
Shigella flexneri 3	31 - 35	31 - 35	26 - 30	20 - 25	31 - 35
Shigella sonnei	26 - 30	≥ 36	26 - 30	26 - 30	≥ 36
Shigella boydii	≥ 36	≥ 36	26 - 30	31 - 35	≥ 36
Salmonella Gr. B	26 - 30	31 - 35	31 - 35	26 - 30	31 - 35
Shigella spp.	≥ 36	31 - 35	31 - 35	26 - 30	≥ 36
Vibrio parahaemolyticus	31 - 35	26 - 30	26 - 30	26 - 30	31 - 35

regulations are not being enforced and that it is not possible for the consumer to make a well-informed decision on the use of these products. It is vitally important to rectify this.

Despite the fact that product label claims regarding viable cell numbers are in line with the proposed South African regulations, the same is not always true for the actual viable cell numbers in products, as seen for 3 of the 5 probiotic supplements tested. This phenomenon is not uncommon as Hamilton-Miller *et al*.,[13] Temmerman *et al*.[12] and Elliot and Treversham[14] also reported that the identity and number of viable strains recovered from probiotic supplements and dairy products in the UK, Europe and South Africa did not correspond with the information on the label in many instances. Hamilton-Miller and Shah[44] suggested that manufacturers should ensure careful manufacturing practices and proper storage of probiotic-containing products to ensure cell survival. All the probiotic strains tested in this study showed good inhibitory activity against the indicator strains. These results might indicate that lower viable cell numbers could be effective and therefore *in vivo* assessments should be considered.

Conclusions and recommendations

A large variety of probiotic- and prebiotic-containing products are available on the South African market. Marketers of these products are misleading consumers with a number of health claims that are not scientifically sound and that do not comply with legislation. The proposed South African regulations should be revised. The content-related claims on the labels mostly comply with the proposed South African regulations, although a number of products do not provide this information. It is also evident that the number of viable cells listed on labels is not always correct. The fact that this problem does not seem to affect the inhibitory activity of the probiotic strains might point to the need to implement *in vivo* assessments. If this finding is validated, a wider range of prescribed viable cell numbers in the proposed South African regulations should be considered. We recommend that the proposed South African regulations be revised regularly to accommodate the results of ongoing scientific research in the field of probiotics and prebiotics.

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