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A review on global market and trends of probiotics

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Abstract

Probiotics are gaining importance because of the numerous health benefits, for example, treating diarrhea, irritable bowel disease, cardiac diseases, lactose intolerance, asymptomatic bacterial vaginosis, hypercholesterolemia, atherosclerosis, arteriosclerosis, etc. The ability of probiotics to prevent diseases and improve health at all ages is increasing the market potential at a high rate.

Probiotic market is showing continuous growth globally, which indicates a boom in the economy in near future. In India amiable investment climate with proactive government support, qualified manpower and constant supply of raw materials are some of the fundamental factors which are paving the way for the probiotic industry to make huge pace in Indian market. There are excellent growth opportunities to capitalize the prevailing situation and produce booming results for domestic and foreign companies. Therefore, Marketing and distribution of the product is a great challenge for Indian probiotic industry.

Keywords: Probiotics, prebiotics, global trends, global market, Indian scenario.

Introduction

What are probiotics?

Etymologically, Probiotic stands for *pro* ("for") and the Greek adjective *bios* ("life").

According to FAO/WHO: Probiotics are "Live microorganisms which when administered in adequate amounts confer a health benefit on the host".

Probiotic bacteria in general belong to a special category of friendly bacteria *viz.* lactic acid bacteria (LAB). Lactobacilli and bifidobacteria are the two key members of this group used extensively as probiotics. However, certain yeasts like *Saccharomyces boulardii* is also included in this group and found to be helpful in promoting human health. (Garvie *et al.* 1984) Probiotics are commonly consumed as part of fermented foods with specially added active live cultures; such as in yogurt, dahi, yakult or as dietary supplements. Probiotics are live microorganisms that are intended to have health benefits. Products sold as probiotics include foods (such as yogurt), dietary supplements, and products that aren't used orally, such as skin creams. (Boylston *et al* 2004) [2].

Although people often think of bacteria and other microorganisms as harmful "germs," many microorganisms help our bodies function properly. (Gilliland *et al* 1985) [6] For example, bacteria that are normally present in our intestines help digest food, destroy disease-causing microorganisms, and produce vitamins. Large numbers of microorganisms live on and in our bodies. Many of the microorganisms in probiotic products are the same as or similar to microorganisms that naturally live in our bodies.

Probiotics, prebiotics, and synbiotics

Prebiotics are not the same as probiotics. The term "prebiotics" refers to dietary substances that favor the growth of beneficial bacteria over harmful ones. The term "synbiotics" refers to products that combine probiotics and prebiotics.

Probiotics can be bacteria, moulds or yeast. But most probiotics are bacteria. Among bacteria, lactic acid bacteria are more popular. *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus lactis*, *Lactobacillus helveticus*, *Lactobacillus salivarius*, *Lactobacillus plantrum*, *Lactobacillus bulgaricus*, *Lactobacillus rhamnosus*, *Lactobacillus johnsonii*, *Lactobacillus reuteri*, *Lactobacillus fermentum*, *Lactobacillus del-brueckii*, *Streptococcus thermophilus*, *Enterococcus faecium*, *Enterococcus faecalis*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, *B. longum* and *Saccharomyces boulardii* are commonly used bacterial probiotics.

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A probiotic may be made out of a single bacterial strain or it may be a consortium as well. Probiotics can be in powder form, liquid form, gel, paste, granules or available in the form of capsules, sachets, etc.

Mechanism of action of probiotics

Mechanisms include

1. Regulation of intestinal microbial homeostasis
2. Antimicrobial activity
3. Immuno-modulation
4. Pathogen exclusion

1) Regulation of intestinal microbial homeostasis

In a healthy gut, there is an optimum balance among gut flora, the beneficial bacteria, such as *Lactobacilli* and *Bifidobacteria* are predominant. Altered equilibrium of microbial community may change luminal immune and inflammatory response as well as metabolism of epithelial cells. Probiotics can regulate intestinal homeostasis by using different mechanisms (Bhadoria PB, Mahapatra SC, 2011) [1].

2) Antimicrobial activity

The antimicrobial attribute of probiotics is related to production of some active metabolites capable of inhibiting or killing potential pathogens

3) Immuno-modulation

Probiotics interact with epithelial cells and dendritic cells (DC) and exert immuno-modulatory effect. The effects are strain dependent, induced by profiles of cytokines secreted by lymphocytes or dendritic cells. Interaction of probiotics with these cell's surface receptors activates some intracellular signaling pathways and induce immune systems.

4) Pathogen exclusion

A process by which an organism is prevented from colonizing a given environment because of the prior presence of other organisms that are better able to establish and maintain themselves in that environment. Probiotics share the same receptor sites on host cells with pathogens. This property makes them able to exclude pathogens from host intestine, urogenital tract and other host sites.

Recommended dose of probiotics

The minimum effective microorganism count in the product is of critical importance with regard to the use of probiotics in food products and their intended health benefits. (Ishibashi and Shimamura, 1993) [7] Although the minimum recommended level of viable probiotics present in foods for any health benefits to be achieved can show a discrepancy, in general the food industry has adopted the recommended level of 10⁶ cfu/ml at the time of consumption. This standard appears to have been introduced to achieve bacterial populations that are technologically attainable and cost-effective. US FDA has also recommended that the minimum probiotic count in a probiotic food should be at least 10⁶cfu/ml. However, in most cases, daily intake of 10⁸ to 10⁹ probiotic microorganisms is necessary to achieve probiotic action in the humans. It is recommended that the probiotic culture must be present in the product at minimum numbers of 10⁷ cfu/ml and even higher numbers have been recommended.

Indian scenario of probiotics

Within the functional foods, probiotics is the rapidly

expanding, active arena. In probiotic revolution, India can play a key role as being the largest producer of milk and having world's highest cattle population. Indian probiotic industry is in its infancy stage and presently accounts for only a small fraction i.e. less than 1% of the total world market turnover in the probiotic industry. But Probiotic industry is evolving at a steady pace with conditions set for tremendous growth in near future. India is emerging as a major probiotic market of the future with annual growth rate of 22.6% until 2017 with a handful of players in Indian probiotic industry are Amul, Mother Dairy, Yakult Danone and Nestle along with other minor players operating in different regions in their own capacities. With their advent, the Indian probiotic market turnover is expected to reach \$10 million by the year 2020. Probiotics in India generally comes in two forms, milk and fermented milk products with the former occupying 62% of the market share and the latter having 38% market share (Starling, 2010) [14]. Major players in the probiotics drug market in India include companies like Ranbaxy (Binifit), Dr. Reddy's Laboratories, which has four probiotic brands, Zyudus Cadila, Unichem, JB Chem, and Glaxo SmithKline. While probiotics in the form of drugs are widely accepted, probiotic foods are still viewed with scepticism. Acceptance is growing slowly, but it will take a long time while before changing the mindset of Indian consumers. (Raja and Arunachalam, 2011) [11].

1) Yakult Danone

Yakult Danone India Pvt. Ltd (YDIPL), is a 50:50 joint venture between Japan's Yakult Honsha and The French-Danone Group, with its offering Yakult, a probiotic drink made from fermented milk, *Lactobacillus*. Yakult is a world leader in probiotic drinks and has a rich heritage dating back to 1935. Yakult was launched in India in the late 2007. The brand was initially available only in Delhi. Now Yakult is being launched nationally in a phased manner. Yakult is fermented milk that contains healthy bacteria *Lactobacillus casei* strain *Shirota*. According to the brand site, a 65-ml Yakult bottle contains 6.5 bn probiotic bacteria.

2) Amul

Amul was the first to foray into the category with its probiotic ice creams prolife in February 2007. Amul, on the other hand, having tasted success in the probiotics category with its ice cream in February earlier this year, is already in the process of test-marketing pouched lassi (sweetened curd) in Gujarat and some parts of Maharashtra, with plans of introducing it in the other parts of the country soon. Probiotic products contribute to 10% to its ice-cream sales and 25 per cent of its Dahi (Indian yoghurt) sales.

3) Nestle

Nestle, having recently declared dairy as its key area of growth, is all set to introduce probiotics in its other dairy products as well. The total packaged curd market in India is estimated at 40,000-60,000 tonnes per annum, of which Nestle has a 30 per cent market share. Internationally, the average contribution of probiotic products to total dairy products is estimated between 10 and 20 per cent depending on the country and business. Nestle also has introduced flavoured milk varieties of probiotic nature.

4) Mother dairy

Mother Dairy was established in Delhi in 1974 under the Operation Flood Programme, which is a wholly owned subsidy of the National Dairy Development Board (NDDB).

Currently, Mother Dairy is one of the largest milk (liquid/unprocessed) plants in Asia selling more than 25 lakh liters of milk per day, and having a market share of 66% of the branded milk sales in Delhi and National Capital Region (NCR) of India. Mother Dairy is also operating in other cities of India including Mumbai, Saurashtra and Hyderabad. Mother Dairy is supplying the different probiotic formulation in the market, which includes B-Activ Probiotic Dahi, B-Activ Probiotic Lassi, B-Activ Curd and Nutrifit Probiotic drink. These probiotic products are contributing to 15% of the turnover of their fresh dairy products, which is expected to go up to 25% in the next 3–4 years. Probiotic curd of Mother Dairy contains BB-12 probiotic strain.

Global scenario of probiotics

Knowledge in probiotic continues to expand on daily basis. The progressive interest in these ‘magic bugs’ has grown enormously during the last few years due to their protective role in the gut to keep our gut healthy and fit. Probiotics have gained tremendous popularity amongst individuals searching for alternative and “natural” means to promote intestinal health.

The growth of probiotic products in the developed world has been quite amazing. According to a new market research report, the global probiotics market is expected to be worth US \$ 45 bn with the Europe and Asia accounting for nearly 42 and 30% of the total revenues respectively. Europe forms the

largest market for probiotics with an estimated \$13.5 billion by 2014. Asia is the second largest segment, growing at with an estimated CAGR of 11.2% to reach \$9.0 billion. A Frost and Sullivan study estimates that the probiotic ingredient market in the US was \$450 million in 2010. Probiotics, with a market of \$3.23 billion is a large part of Japanese functional foods. The Japanese spent \$126 per person per year on functional foods and it is higher than other countries including US (\$67.9), Europe (\$51.2) and Asia (\$3.20). According to Euromonitor International’s packaged food data, in 2000, pro/prebiotic yogurt (both drinking and spoonable combined) accounted for one-quarter of global yogurt sales by value. (Stanton *et al* 2001)^[13] A decade later, in 2010, it accounted for one-third. Global value for sales of probiotic dietary supplements almost tripled, amounting to US\$2.2 billion in 2010, thereby, further suggesting that probiotics are spreading like wildfire around the globe. Normalization of the properties of unbalanced indigenous microflora of the intestinal tract by ingestion of specific strains of the healthy microflora forms the rationale of probiotic therapy. It is now well recognized that probiotics hold great promise and have the prospects to serve as candidate bio therapeutics in the management of inflammatory metabolic disorders including cardiovascular diseases such as atherosclerosis, hypertension and stroke etc. So many food companies are expanding their market profile to the most promising growth markets for probiotics. (Sanders, 2012)^[12].

Table 1: The Probiotic and Bacteria

Probiotic Bacteria	Company
<i>L. acidophilus</i> NCFM®	Danisco (Madison WI)
<i>Bifidobacterium infantis</i> 35264	Procter & Gamble (Mason OH)
<i>L. fermentum</i> VRI003 (PCC)	Probiomics, Eveleigh, Australia
<i>L. rhamnosus</i> R0011	Institute Rosell (Montreal, Canada)
<i>L. acidophilus</i> R0052	Institute Rosell (Montreal, Canada)
<i>L. acidophilus</i> LA-1	Chr. Hansen (Milwaukee WI)
<i>L. paracasei</i> CRL 431	Chr. Hansen (Milwaukee WI)
<i>B. lactis</i> Bb-12	Chr. Hansen (Milwaukee WI)
<i>L. casei</i> Shirota	Yakult (Tokyo, Japan)
<i>B. breve</i> strain Yakult	Yakult (Tokyo, Japan)
<i>L. casei</i> DN114001	Danone (Paris, France)
(“ <i>L. casei</i> Defensis™”, <i>B. animalis</i> DN173 010 “ <i>Bifidus regularis</i> ™”)	Dannon (Tarrytown NY)
<i>L. reuteri</i> RC-14™	Chr. Hansens (Milwaukee WI)
<i>L. rhamnosus</i> GR-1™	Urex Biotech (London, Ontario, Canada)
<i>L. johnsonii</i> Lj-1 (Same as NCC533 and formerly <i>L. acidophilus</i> La-1)	Nestlé (Lausanne, Switzerland)
<i>L. plantarum</i> 299V	Probi AB (Lund, Sweden)
<i>L. rhamnosus</i> 271	Probi AB (Lund, Sweden)
<i>L. reuteri</i> SD2112	Biogaia (Stockholm, Sweden)
<i>L. rhamnosus</i> GG (“LGG”)	Valio Dairy (Helsinki, Finland)
<i>L. rhamnosus</i> LB21	Essum AB (Umeå, Sweden)
<i>Lactococcus lactis</i> L1A	Essum AB (Umeå, Sweden)
<i>L. salivarius</i> UCC118	University College (Cork, Ireland)
<i>B. longum</i> BB536	Morinaga Milk Industry Co., Ltd. (Zama-City, Japan)
<i>B. lactis</i> HN019 (DR10)	Danisco (Madison WI)
<i>L. rhamnosus</i> HN001 (DR20)	Fonterra (Wellington, New Zealand)
<i>L. acidophilus</i> LB	Lacteol Laboratory (Houdan, France)
<i>L. paracasei</i> F19	Medipharm (Des Moines, Iowa)

Government regulations of probiotics

Government regulation of probiotics in the United States is complex. Depending on a probiotic product’s intended use, the FDA might regulate it as a dietary supplement, a food ingredient, or a drug. Many probiotics are sold as dietary supplements, which do not require FDA approval before they are marketed. Dietary supplement labels may make claims about how the product affects the structure or function of the

body without FDA approval, but they cannot make health claims (claims that the product reduces the risk of a disease) without the FDA’s consent. (For more information about dietary supplements, see the National Center for Complementary and Integrative Health’s fact sheet *Using Dietary Supplements Wisely*.) If a probiotic is marketed as a drug for specific treatment of a disease or disorder in the future, it will be required to meet more stringent

requirements. (Manisha and Prajapati, 2001) [10] It must be proven safe and effective for its intended use through clinical trials and be approved by the FDA before it can be sold.

About the safety and side effects of probiotics

Whether probiotics are likely to be safe for you depends on the state of your health. In people who are generally healthy, probiotics have a good safety Record. Side effects, if they occur at all, usually consist only of mild digestive symptoms such as gas. On the other hand, there have been reports linking probiotics to severe side effects, such as dangerous infections, in people with serious underlying medical problems. The people who are most at risk of severe side effects include critically ill patients, those who have had surgery, very sick infants, and people with weakened immune systems. Even for healthy people, there are uncertainties about the safety of probiotics. (Crittenden *et al* 2005) [4] Because many research studies on probiotics haven't looked closely at safety, there isn't enough information right now to answer some safety questions. Most of our knowledge about safety comes from studies of *Lactobacillus* and *Bifidobacterium*; less is known about other probiotics. Information on the long-term safety of probiotics is limited, and safety may differ from one type of probiotic to another. For example, even though a National Center for Complementary and Integrative Health (NCCIH)-funded study showed that a particular kind of *Lactobacillus* appears safe in healthy adults age 65 and older, this does not mean that all probiotics would necessarily be safe for people in this age group.

Effectiveness of probiotics

Researchers have studied probiotics to find out whether they might help prevent or treat a variety of health problems, including: (Byrne, 2010) [3]

- Digestive disorders such as diarrhea caused by infections, antibiotic-associated diarrhea, irritable bowel syndrome, and inflammatory bowel disease
- Allergic disorders such as atopic dermatitis (eczema) and allergic rhinitis (hay fever)
- Tooth decay, periodontal disease, and other oral health problems
- Colic in infants
- Liver disease
- The common cold
- Prevention of necrotizing enterocolitis in very low birth weight infants.

There's preliminary evidence that some probiotics are helpful in preventing diarrhea caused by infections and antibiotics and in improving symptoms of irritable bowel syndrome, but more needs to be learned. We still don't know which probiotics are helpful and which are not. We also don't know how much of the probiotic people would have to take or who most likely benefit from taking probiotics would. (Lee and Salminen, 1995) [9] Even for the conditions that have been studied the most, researchers are still working toward finding the answers to these questions. Probiotics are not all alike. For example, if a specific kind of *Lactobacillus* helps prevent an illness, that doesn't necessarily mean that another kind of *Lactobacillus* would have the same effect or that any of the *Bifidobacterium* probiotics would do the same thing. Although some probiotics have shown promise in research studies, strong scientific evidence to support specific uses of probiotics for most health conditions is lacking. (Kurmann

and Rasic, 1995) [8] The U.S. Food and Drug Administration (FDA) have not approved any probiotics for preventing or treating any health problem. Some experts have cautioned that the rapid growth in marketing and use of probiotics may have outpaced scientific research for many of their proposed uses and benefits.

Alleged health effects of probiotics

Intestinal effects

- Relieve effects and promote recovery from diarrhea (rotavirus, travelers' and antibiotic-induced)
- Produce lactase, alleviate symptoms of lactose intolerance and Malabsorption.
- Relieve constipation
- Treat colitis

Immune system effects

- Enhance specific and nonspecific immune response
- Inhibit pathogen growth and translocation
- Stimulate gastrointestinal immunity
- Reduce chance of infection from common pathogens (*Salmonella*, *Shigella* etc.)

Other effects

- Reduce risk of certain cancers (colon, bladder)
- Detoxify carcinogens
- Suppress tumors
- Lower serum cholesterol concentrations
- Reduce blood pressure in hypertensives
- Treat food allergies
- Synthesize nutrients (folic acid, niacin, riboflavin, vitamins B₁ & B₁₂)
- Increase nutrient bioavailability
- Improve urogenital health
- Optimize effects of vaccines (e.g. rotavirus vaccine, typhoid fever vaccine)

Conclusion

Probiotics are gaining importance because of the numerous health benefits, for example, treating diarrhea, irritable bowel disease, cardiac diseases, lactose intolerance, asymptomatic bacterial vaginosis, hypercholesterolemia, atherosclerosis, arteriosclerosis, etc. The ability of probiotics to prevent diseases and improve health at all ages is increasing the market potential at a high rate. A probiotic product is considered successful following the proof of its effect as well as whether a high number of viable organisms survive in the food at the time of consumption and at the time it reaches the colon. In the development of probiotic foods containing these bacteria in sufficient numbers throughout shelf-life as well as stabilization in ingestion is needed to be overcome. There is always certain loss in cell viability during gastric transit. Considering this loss, the probiotic food product should be consumed regularly in adequate quantity to deliver the relevant dose of live bacteria to the gut. Probiotic market is showing continuous growth globally, which indicates a boom in the economy in near future. In India amiable investment climate with proactive government support, qualified manpower and constant supply of raw materials are some of the fundamental factors which are paving the way for the probiotic industry to make huge pace in Indian market. There are excellent growth opportunities to capitalize the prevailing situation and produce booming results for domestic and foreign companies. However there are alarming challenges in the expansion of this emerging market. The major constrain is

to generate the awareness among different socioeconomic and geographical segments of highly populous and diverse country. Price of the product, to maintain demand and supply aspect and delivery channels are also important constrains to flourish the probiotic industry in India. India is a diverse country in terms of culture and topography, which requires region-specific marketing strategy. Only a region-specific marketing strategy with local sale support will help the business development. Therefore, Marketing and distribution of the product is a great challenge for Indian probiotic industry.

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