**REVIEW**

# PROBIOTICS – THE FRIENDLY BACTERIA WITH MARKET POTENTIAL IN GLOBAL MARKET

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**ABSTRACT**
With the growing interest in self-care and integrative medicine coupled with our health-embracing increasing population, recognition of the link between diet and health has never been stronger. As a result, the market for functional foods, or foods that promote health beyond providing basic nutrition, is flourishing. Within the functional foods movement is the small but rapidly expanding arena of probiotics – live microbial food supplements that beneficially affect an individual by improving intestinal microbial balance. The consumers' overwhelming interest in and demand for functional foods, including probiotics, make it imperative that health professionals stay abreast of the latest research findings and available products. The global market for functional foods in the coming years is predicted to grow rapidly. Although Japan currently accounts for about one-half of this market, the fastest rate of growth is expected to be in the United States. Probiotic products represent a strong growth area within the functional foods group and intense research efforts are under way to develop dairy products into which probiotic organisms such as *Lactobacillus* and *Bifidobacterium* species are incorporated. Such probiotic foods may modulate gut microbial composition, thereby leading to improved gut health, for example, through improved tolerance to lactose in lactose-intolerant individuals or improved resistance to pathogenic bacteria. The fast-growing probiotics market holds a wealth of opportunities, especially for those companies that understand and cater for the final consumer. This monograph provides a summary of research on the health benefits of probiotics and offers information regarding the global market potential of probiotics.

**Keywords:** Probiotics, *lactobacillus, bifidobacterium*, functional foods.

## INTRODUCTION

Microbial balance is an important factor in the maintenance of intestinal homeostasis, and probiotics have been proposed to control diarrheal diseases (Heyman, 2000). Probiotics are viable bacterial cell preparations or foods containing viable bacterial cultures or components of bacterial cells that have beneficial effects on the health of the host (Fuller, 1989; Salminen *et al.*, 1998b). In recent times, there has been renewal of interest in the use of probiotics (as distinct from antibiotics) also termed bio-therapeutic agents, driven in large part by consumers. Well-documented probiotic strains (table 1) are clinically proven. Such probiotic microorganisms appear to be promising candidates for the treatment of clinical condition both in humans and animals. Probiotics have been used therapeutically to modulate immunity, lower serum cholesterol, treat rheumatoid arthritis, prevent cancer, improve lactose intolerance, and prevent or reduce the effects of atopic dermatitis, diarrhea, and constipation as well as candidiasis and urinary tract infections (Reid, 1999).

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The definition of the term 'Probiotic' has evolved through years by Parker (1974), Fuller (1989), Havenaar and Huis In't Veld (1992), Schaafsma (1996), Naidu *et al.* (1999), Schrezenmeir and de Vrese (2001). Fuller (1989) improved the definition of 'probiotics' as "A live microbial feed supplement, which beneficially affects the host animal, by improving its intestinal microbial balance". Perhaps the most appropriate definition, published by an Expert Consultation at a meeting convened by the FAO/WHO in October, 2001, is "Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit

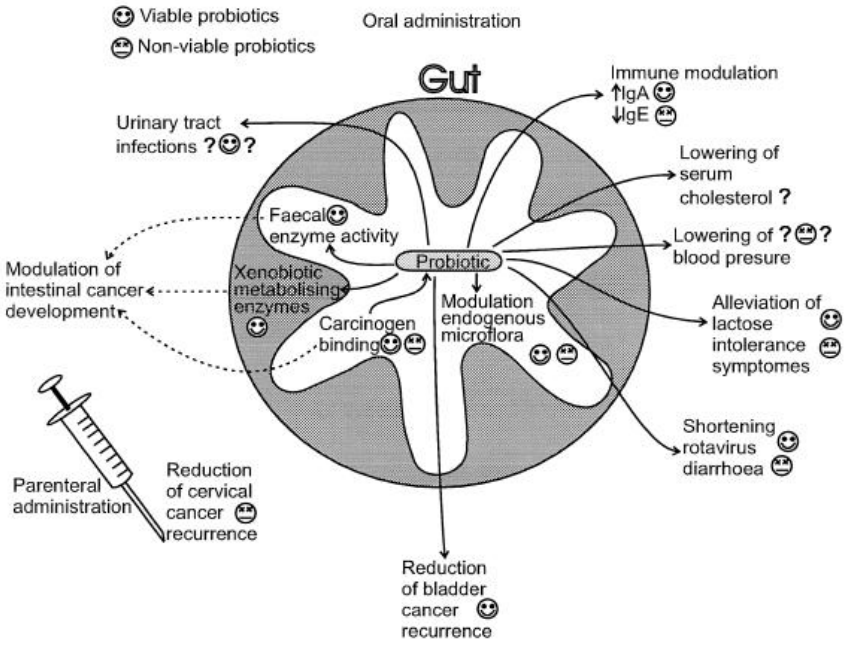


**Fig. 1**: Proposed mechanisms of viable and non-viable probiotic health effects (Salminen *et al.* 1999).

**Table 1**: Commercially used probiotic species.

**Lactobacillus species**

*L. acidophilus*
*L. casei*
*L. fermentum*
*L. gasseri*
*L. johnsonii*
*L. lactis*
*L. paracasei*
*L. plantarum*
*L. reuteri*
*L. rhamnosus*
*L. salivarius*

**Bifidobacterium species**

*B. bifidum*
*B. breve*
*B. lactis*
*B. longum*

**Streptococcus species**

*S. thermophilus*

**Table 2**: 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 $B_1$ & $B_{12}$)
- ✓ Increase nutrient bioavailability
- ✓ Improve urogenital health
- ✓ Optimize effects of vaccines (e.g. rotavirus vaccine, typhoid fever vaccine)

on the host".

This definition has the following characteristics:

- Probiotics must be alive.
- Probiotics must deliver a measured physiological benefit.
- Probiotics needn't be restricted to food applications or oral delivery.
- A definition of probiotics shouldn't limit the mechanism of action.

## MECHANISM OF ACTION OF PROBIOTICS

Probiotics have been proposed to exert their beneficial effects (figure 1 and table 2) by maintaining a normal intestinal milieu, by stimulating the immune system, by detoxifying colonic contents, by lowering serum cholesterol levels and promoting lactose tolerance, and by producing metabolites that are essential to maintain intestinal health (Gionchetti *et al*., 2000, Hooper *et al*., 2001, Resta-Lenert and Barrett, 2003).

It is now well established that there is a clear relation between diet and health. Although the primary role of diet is to provide enough nutrients to fulfill metabolic requirements, more recent discoveries support the hypothesis that, beyond nutrition in the conventional sense, diet may modulate various functions in the body. Functional foods, of which probiotic containing foods are a subset, have recently justified the efforts of health authorities in many countries, especially Japan and the United States, to stimulate and support research on the physiologic effects of food components and their health benefits and to authorize health claims (Stanton *et al*. 2001).

Europeans and Asians, in particular, have long known about the health benefits of probiotics. Now, manufacturers are eyeing the fertile North American market for product penetration.

## FUNCTIONAL FOODS

*Functional foods* as a marketing term was initiated in Japan in the late 1980s and is used to describe foods fortified with ingredients capable of producing health benefits. Functional food ingredients include probiotics, prebiotics, vitamins, and minerals and are found in such diverse products as fermented milk and yogurt, sports drinks, baby foods, sugar-free confectionery, and chewing gum. This concept is becoming increasingly popular with consumers because of a heightened awareness of the link between health, nutrition, and diet. Food manufacturers are enthusiastic about developing such products because the added ingredients give increased value to food. In Japan functional foods are considered a major product opportunity and > 80 recognized functional foods are available (Sanders, 1998).

Functional foods as a category have enjoyed considerable growth and are now firmly established, with > 300 firms operating in Japan. In Europe, interest in functional foods has increased over the past several years as the market outside of Japan has developed. In particular, probiotic foods are now relatively well established in Europe and product activity during 1997 consisted of a more concentrated launch of prebiotic foods, particularly in the dairy sector. Although probiotic foods seem to be reasonably well established in Europe and Japan, they are typically considered niche products in the United States (Young, 1996). It is expected that product development in functional foods could outstrip development in low-energy and "light" foods, which was a key area of growth in the early 1990s.

## PROBIOTICS AS INGREDIENTS FOR FUNCTIONAL FOODS OR BIOTHERAPEUTIC AGENTS?

As proposed in the functional food science in Europe project (Diplock *et al.*, 1999) it is important that all research on health effects is science, hypothesis and evidence based, and documented in well-planned nutritional and clinical studies in humans. Knowledge of the mechanism(s) by which probiotics can modulate target function(s) and their relevance to the state of well-being and health and/or reduction of a disease will originate from basic knowledge in the biological sciences. It may also be supported by epidemiological data, which could demonstrate a statistically validated relationship between the intake of individually specified probiotics (viable, nonviable or component of the microbe) and the specific benefit. It will be of particular value to have good prospective evidence that links the habitual intake of a specified probiotic component with subsequent disease risk.

## SIGNIFICANT AREAS

With respect to product contents, it is significant that probiotics be living at the time of use, and the viable colony-forming unit count must be at the level proven to confer a health benefit in humans or animals. It is no longer sufficient to state a viable count at the time of manufacture. The consumer needs to know the count at time of use. Consumers have no means of knowing how a product is handled prior to its purchase or how many organisms are alive when they use it. In a yoghurt format, likely $10^7$ to $10^8$ probiotic organisms (added after the yoghurt is made) could be delivered per dose (Reid and Bruce, 2001), although in capsule or other freeze-dried format more than $10^9$ can be delivered per dose. In terms of gut health, at least $10^9$ of *L. rhamnosus* GG or *L. reuteri* appear to be required to reduce the duration of rotaviral diarrhoea in children, yet even at this dose the

effect against bacterial gastroenteritis is questionable (Shornikova *et al.*, 1997).

Probiotics have long been promoted as improving the host intestinal microbial balance, thereby leading to improved general health. However, no study has actually tested this theory, and indeed, general health is difficult to measure. Companies such as Yakult, whose probiotic beverage product reaches 24 million people per day, would be well placed to undertake a large study to determine benefits of their product in healthy people vs. nonusers of probiotics. For this reason, in part, current conceptions of probiotic benefits must be based on target- and site-specific effects of clearly defined strains. Although this may be due to differences in adhesion and immunological effects, no clinical studies have proven the precise mode of action. Nevertheless, just as *E. coli* 0157: H7 causes gastroenteritis and not urinary tract infection, and type 1 and P fimbriated *E. coli* cause the latter and not the former, so too Lactobacilli strains differ in the effects on the gut and urogenital tract even when they belong to the same species (Reid *et al.*, 2002).

## TECHNOLOGICAL DEVELOPMENTS

Exposure to oxygen, light, temperature changes and humidity, as well as stomach acidity, can easily degrade and destroy probiotic microorganisms. The biggest challenge is delivering the promised number of cells to the intestine. A number of innovations address this issue.

- Shelf Stability essentially means that dried organisms must be blocked from exposure to water molecules and extreme heat. Microencapsulation techniques, for example the technique used by Montreal's Institute Rosell-Lallemand, provide a means to isolate clumps of bacteria, thereby providing greater protection from extreme conditions. Preparing bacteria is a critical process and producers should use good manufacturing practices (GMP) and Food and Drug Administration (FDA)-approved plants and minimize the drop-off in viability after drying bacteria.

- Coating Techniques make it possible to protect the organisms by binding the sugars (for example, Chr. Hansen's technology) that do not allow hydration until the probiotics reach the alkaline pH of the colon. Enteric coating of capsules can protect products against stomach acidity and bile salts, or be designed to take advantage of acidity so that the product dissolves in acid (Leopold and Eikeler, 2000), a technique that might be useful for treating *H. pylori* infections in the stomach.

  It is important to note that room temperature in northern Sweden in February is not the same as in Italy in July. Thus, manufacturers should consider climactic variations across regions when establishing a product's shelf life. Tests for bacterial survival, while useful in accelerated lab tests that reach 40°C (104°F) or higher, are best determined following one to two years in use.

- Encapsulation And Preservation Techniques (figure 2), such as those being developed by Canacure in Montreal and Universal Preservation Technologies Inc in California, will soon make products capable of being directed to specific sites in the body. This should make it possible to preserve and protect microorganisms for specific treatment of diseases such as *H. pylori* infections in the stomach, and for targeting inflammatory bowel disorders, pouchitis, vaginitis and throat infections. It should be noted that calcium alginate, used for micro encapsulation in conjunction with Hi-Maize starch as a prebiotic, and glycerol, used as a cryo-protectant, can improve survival of bacteria in the capsule, yet have no effect on survival in acid or bile (Sultana *et al*, 2000). This illustrates the complexity of these processes and the need to authenticate each outcome.

## RESEARCH NEEDS FOR PROBIOTICS

**Table 3**: Urgent research needs for probiotics (Diplock *et al.,* 1999; Salminen and Wright, 1998a)

| Research need | Importance of viability |
|---|---|
| Effects of probiotics on normal intestinal micro flora | Do non-viable probiotics have effects on intestinal flora |
| Immune effects of probiotics in normal subjects and subjects with gastrointestinal disease | Do non-viable probiotics have immune effects in humans |
| Probiotic effects on intestinal metabolism | Effect of non-viable probiotics on intestinal metabolism |
| Demonstration of health effects in human studies | Effect of viability on health effects |

## RECENT REPORTS' HIGHLIGHTS

In a recent study undertaken by Leatherhead Food RA, the market for functional foods in the United Kingdom, France, Germany, Spain, Belgium, Netherlands, Denmark, Finland, and Sweden was reviewed. The results of the study showed that the probiotic yogurt market in these 9 countries totaled >250 million kg in 1997, with France representing the largest market, having sales of ~90 million kg, valued at US$219 million (Hilliam, 1998).

U.S. sales of probiotics are estimated at $764 million in 2005 and are expected to rise at an average annual growth rate (AAGR) of 7.1% to $1.1 billion in 2010. Whereas,

**Table 4**: Key players in Probiotic Industry (Global Industry Analysis Report, 2004)

| | | |
|---|---|---|
| 1. A & Z Food Additives Co., Ltd. (China) | 46. Group Danone (France) | 91. Pharmabul, Inc. (USA) |
| 2. Acatris Belgium N.V (Belgium) | 47. Hansen's Natural Corporation (USA) | 92. Pharming Group N.V. (USA) |
| 3. Action Labs, Inc. (USA) | 48. Harmony Foods Corp. (USA) | 93. PL Thomas & Co., Inc. (USA) |
| 4. All One Nutritech Corp. (USA) | 49. Immudyne, Inc. (USA) | 94. Probiotics International Ltd. (UK) |
| 5. Alltech, Inc. (USA) | 50. Inter-Cal Nutraceuticals (USA) | 95. Proliant, Inc. (USA) |
| 6. American Biologics (USA) | 51. Interhealth Nutraceuticals (USA) | 96. Provita Eurotech Limited (UK) |
| 7. Amnol Chimica Biologica SRL (Italy) | 52. Interprise Limited (UK) | 97. Quality Botanical Ingredients, Inc. (USA) |
| 8. Atkins Nutritionals, Inc. (USA) | 53. Jarrow Formulas, Inc. (USA) | 98. Rainbow Light Nutritional Systems, Inc. (USA) |
| 9. Balchem Corporation (USA) | 54. Kerry Group Plc (Ireland) | 99. Reliance Private Label Supplements (USA) |
| 10. BCCM/LMG Bacteria Collection (Belgium) | 55. KGK Synergize, Inc. (UK) | 100. RFI Ingredients (USA) |
| 11. Beldem NV (Belgium) | 56. Klamath Valley Botanicals, Inc. (USA) | 101. Rhino Naturals, Inc. (USA) |
| 12. Bio-Botanica (USA) | 57. Kraft Foods Inc. (USA) | 102. Rhodia SA (France) |
| 13. BioEurope (France) | 58. Lallemand Inc (Canada) | 103. Sancor (Argentina) |
| 14. Biogaia Biologics AB (Sweden) | 59. Lawson Health Research Institute (LHRI) (Canada) | 104. Scolr Inc (USA) |
| 15. Bio-K+ International, Inc. (Canada) | 60. Lewis Laboratories International, Ltd. (USA) | 105. Seven Seas Ltd. (UK) |
| 16. Britmilk (UK) | 61. Lifeway Foods, Inc. (USA) | 106. Seven Seas Ltd. (Ireland) |
| 17. Cancer Wellness Institute, Inc. (USA) | 62. Maplehurst Genetics International, Inc. (USA) | 107. Skeet & Ike's (Canada) |
| 18. Carrington Laboratories, Inc. (USA) | 63. Martek Biosciences Corp., (USA) | 108. Solgar Vitamin & Herb (USA) |
| 19. Cascade Fresh (USA) | 64. Microbax Limited. (India) | 109. Speciality Ingredients Group (New Zealand) |
| 20. Chr. Hansen A/S (Denmark) / Chr. Hansen Biosystems (USA) | 65. Microbial Developments Limited (UK) | 110. Specialty Enzymes and Biochemicals Co. (USA) |
| 21. Conagra Functional Foods (USA) | 66. Morinaga Nutritional Foods Deutschland Gmbh (Germany) | 111. Spectrum Organic Products, Inc. (USA) |
| 22. CSK Food Enrichment (Netherlands) | 67. MTC, Industries Inc. (USA) | 112. Springfield Creamery, Inc. (USA) |
| 23. Custom Probiotics (USA) | 68. National Enzyme Company (USA) | 113. Standard Homeopathic Company &, Hyland's Inc. (USA) |
| 24. Cyanotech Corporation (USA) | 69. Native American Botanics Corporation (USA) | 114. Stauber Performance Ingredients, Inc. (USA) |
| 25. Danisco A/S (Denmark) | 70. Natren, Inc. (USA) | 115. Stonyfield Farm Inc. (USA) |
| 26. Degussa Bioactives (Germany) | 71. Natural Balance, Inc. (USA) | 116. Sun Ten Laboratories, Inc. (USA) |
| 27. Designed Nutritional Products (USA) | 72. Natura Pet Products, Inc. (USA) | 117. Sweet Wheat, Inc. (USA) |
| 28. Douglas Laboratories (USA) | 73. Naturally Vitamins (USA) | 118. Tishcon Corp. (USA) |
| 29. Down and Rogers, Inc. (USA) | 74. Nature's Life (USA) | 119. Traditional Medicinals (USA) |
| 30. Dynamic Health Labs, Inc. (USA) | 75. Nature's Way Products, Inc. (USA) | 120. Twin Labs, Inc. (USA) |
| 31. Earth Friendly Baby (USA) | 76. Naturex (UK) | 121. UAS Labs (USA) |
| 32. Ecco Bella Botanicals (USA) | 77. Nestle S.A. (Switzerland) | 122. Ultra Botanicals, Inc. (USA) |
| 33. Ecopia Biosciences, Inc. (Canada) | 78. New Chapter, Inc. (USA) | 123. USA Nutrasource, Inc. (USA) |
| 34. Eden Foods, Inc. (USA) | 79. Now Foods (USA) | 124. Valio Ltd. (Finland) |
| 35. Enzymatic Therapy (USA) | 80. Nupharma Nutraceuticals (USA) | 125. VDF FutureCeuticals, Inc. (USA) |
| 36. Evergreen Juices, Inc. (Canada) | 81. Nutriscience Innovations, LLC (USA) | 126. Vibrant Health (USA) |
| 37. Fantastic Foods (USA) | 82. Nutrition 21 (USA) | 127. Vitapharmica, Inc. (USA) |
| 38. Figuerola Laboratories (USA) | 83. Nutrition Now(r), Inc. (USA) | 128. Vitamins 2020 (USA) |
| 39. Fillo Factory (USA) | 84. Nutritional Supply Corp. (USA) | 129. Vitanica (USA) |
| 40. Frontera Foods Inc. (USA) | 85. Olympian Labs (USA) | 130. Vitapharmica Inc. (USA) |
| 41. Frutstix Co. (USA) | 86. Optio Health Products (USA) | 131. Volac International (UK) |
| 42. General Mills, Inc. (USA) | 87. Osmo (USA) | 132. Wakunaga of America Co., Ltd. (USA) |
| 43. Gilroy Foods (USA) | 88. Pacific Health Laboratories, Inc. (USA) | 133. White Wave, Inc. (USA) |
| | | 134. Wholesoy Co. (USA) |
| 44. Good Natured Products, Inc. (USA) | 89. Pal Laboratories, Inc. (USA) | 135. World Nutrition, Inc. (USA) |
| 45. Graminex (USA) | 90. Penta Manufacturing Co. (USA) | 136. Yakult Honsha Co., Ltd. (Japan) |

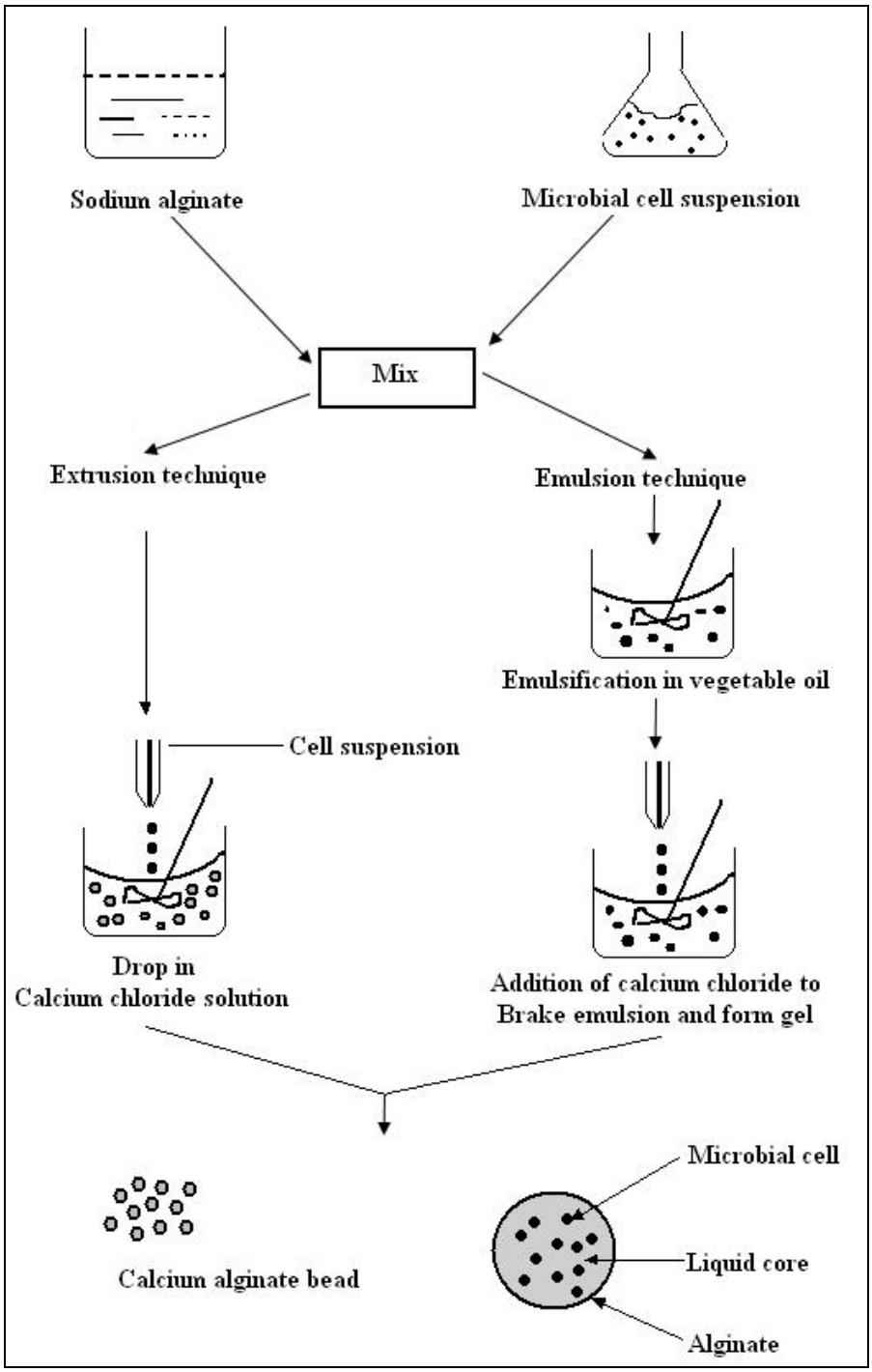


**Fig. 2**: Flow diagram of encapsulation of bacteria by the extrusion and emulsion techniques.

probiotics used in the manufacture of supplements are projected to reach $291.4 million in 2010, representing an AAGR of 6.7% (Agheyisi, 2005).

According to market research report by Global Industry Analysts, published in 2004, there are 136 major manufacturers in probiotic industry worldwide (table 4).

## REGULATORY ASPECTS

The Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food held in Córdoba, Argentina from 1-4 October 2001 recognized that there is a need for guidelines to set out a systematic approach for the evaluation of probiotics in food leading to the substantiation of health claims.

Consequently, a Working Group was convened by FAO/WHO to generate guidelines and recommend criteria and methodology for the evaluation of probiotics, and to identify and define what data need to be available to accurately substantiate health claims. The aims of the Working Group were to identify and outline the minimum requirements needed for probiotic status. Consequently, guidelines were prepared to meet this objective.

In the past five years, there have been more than 800 peer-reviewed articles on probiotics, in contrast to 85 papers the previous 25 years. Scientific excellence, quality manufacturing, honest marketing, vision and flexibility in funding and regulatory agencies, and progressive consumer education will ensure that pre-and probiotics flourish and find their appropriate place in health restoration and maintenance.

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