

# Pharma & Healthcare Update

December 26, 2009

## PROBIOTIC FOODS MARKET IN INDIA SOON TO BE REGULATED

Probiotic foods, currently classified as general food with little regulation, are soon likely to be regulated by a set of stringent guidelines. The Indian Council of Medical Research ("ICMR"), the apex body for the formulation, coordination and promotion of biomedical research, alongwith the Department of Biotechnology of the Ministry of Science and Technology have proposed '*Guidelines for Evaluation of Probiotics in Food in India*<sup>4</sup>' ("**Draft Guidelines**"), which articulates the base for the law to govern probiotics.

The ICMR has invited comments and suggestions from public on the Draft Guidelines<sup>2</sup>.

## WHAT ARE PROBIOTICS?

The health advantages of probiotics were discovered a century ago by Dr. Elie Metchnikoff<sup>3</sup>. Probiotics, also known as 'friendly bacteria' in lay terms, are live, non-pathogenic<sup>4</sup> microorganisms that benefit the consumer's digestive system by restoring the naturally existing gastrointestinal microflora, preventing the colonization of the intestine by pathogens, and, consequently, improving the immune system<sup>5</sup>. Clinical studies in the past have demonstrated benefits of probiotics in multiple diseases, such as intestinal infections and inflammations, colon cancer, gynaecological infections and allergies. Probiotics are available in the marketplace in the form of health foods (like yoghurt, icecreams and milk beverages) and dietary supplements (like capsules, tablets, and powders). The most commonly used probiotics in these commercially available products belong to *Lactobacillus* and *Bifidobacterium* genera, which are found naturally in dairy products.

## THE EXISTING LEGAL FRAMEWORK GOVERNING PROBIOTICS IN INDIA

The Indian probiotic market is worth INR 1.2 billion and growing annually at the rate of about 40 percent<sup>6</sup>. However, it is currently regulated by extant food laws that regulate general food items that include:

- The Prevention of Food Adulteration Act, 1952 ("**PFA Act**") and corresponding Rules of 1955 ("**PFA Rules**"),
- Certain food product specific orders under the Essential Commodities Act, 1955 and
- The Standards of Weights and Measures Act, 1976 and corresponding Rules of 1977.

The various authorities concerned include:

- The Ministry of Health and Family Welfare,
- The Ministry of Food Processing Industries,
- The Ministry of Consumer Affairs, Food and Public Distribution, and
- The Ministry of Agriculture.

The Food Safety and Standards Act, 2006 was enacted out of the need for a single regulatory body and consolidated food law. This Act, when implemented in full, will replace the PFA Act and Rules and the abovementioned food specific legislations. It also envisages creation of an apex regulatory authority- the Food Safety and Standards Authority of India (FSSAI) alongwith other subordinate bodies- to regulate all food related issues.

The PFA Rules, presently in force, set down the minimum standards of quality and content for food products. The PFA Rules also regulate labeling and packaging of food products in order that maximum information about the food product should be disclosed to the consumer which *inter alia* includes ingredients, nutritional information, date of expiry, manufacturer and manufacturing unit details and country of origin and importer (for imported food).

## THE NECESSITY TO REGULATE PROBIOTICS

Probiotics food products are sold as food but the therapeutic effect that they intend to have or claim to have takes such products beyond the ambit of ordinary food articles as envisaged under extant food legislation<sup>7</sup>. While they are not generally perceived as substitutes of drugs, the claims by various manufacturers about the ability of probiotics to cure a variety of diseases has made the Food & Drug Administration authorities in several countries to define parameters and guidelines at par with drugs in order to regulate their quality and claims. In India, probiotics are also occasionally recommended by doctors by way of treatment. These factors, combined with the recent augment in the probiotics food market in India and the absence of separate regulations to address the use of probiotics in food products, have prompted the regulators to set the ball rolling towards prescribing a full-fledged set of guidelines to govern use of probiotics in food.

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### Analysing SEBI's Consultation Paper

The Draft Guidelines have been formulated on the following premises:

- \* Probiotic cultures of foreign origin are being used in currently available food products. As there are inherent differences in gut microflora of the Indian population as compared to the Western population, the effects of such cultures on the Indian population may not be the same as that on the Western population.
- \* The effects of probiotic cultures on immunocompromised individuals need to be tested as the likelihood of opportunistic infections is high.
- \* The possibility of ineffective products marketed under false claims is higher in an unregulated market; hence the need to lay down criteria for terming a product as a “probiotic” product. Further, any health claims made in relation to a product must be substantiated by clinical trial data.
- \* Consumers must be fully aware of the contents and effects of a “probiotic” product before purchasing the same.
- \* Probiotics have been defined as *“live microorganisms which, when ingested in adequate amounts as a single strain or as a combination of strains, confer one or more specified health benefits to the consumers”*.

Based on the above considerations, the Draft Guidelines lay down the following conditions a “probiotic” food product would be subject to before it reaches the marketplace:

- \* The nomenclature of the strain of the probiotic must conform to current internationally recognized names<sup>8</sup>.
- \* *In vitro* tests that include tests mimicking the hostile gut environment as well as animal studies for screening potential probiotic strains
- \* *In vivo* tests in appropriate validated animal models
- \* *In vivo* tests on humans in following four phases:
  - Phase I (to determine safety)
  - Phase II (to determine efficacy)
  - Phase III (to determine effectiveness)
  - Phase IV (post marketing surveillance)
- \* The Draft Guidelines suggest that certain tests shall be conducted even on Generally Recognised as Safe (termed as “GRAS”) probiotic strains, although United States Food and Drug Administration (USFDA) permits the marketing of products using GRAS strains without them being subject to premarket review and other approval requirements set down by USFDA<sup>9</sup>.
- \* Information on products labels to *inter alia* mention:
  - Genus, Species as well as Strain of probiotic
  - Only evidence based health claim(s)
  - Serving size for efficacy claimed
  - Storage conditions

These labelling requirements are stipulated over and above those prescribed by the food laws mentioned above.

\* Probiotic foods should be manufactured using Good Manufacturing Practices (GMP) and the Codex General Principles of Food Hygiene and Guidelines for Application of Hazard Analysis and Critical Control Point (HACCP) should be followed.

The set of final guidelines, which shall lay down the precise clinical study requirements that would need to be conducted to substantiate health claims of probiotic foods, is awaited. Such guidelines would not only boost consumers' faith in probiotics but also alleviate risks in their consumption.

**- Aditi Nadkarri & Gowree Gokhale**

1 Available at <http://www.icmr.nic.in/guide/Enclosure-%20VERSION%202%20draft.pdf>

2 News source: <http://www.financialexpress.com/news/...../549151/0>

3 Dr. Metchnikoff's book *The Prolongation of Life: Optimistic Studies* is credited with being the first to theorize that lactic-acid bacteria could prolong life.

4 Non disease producing microorganisms

5 J Appl Bacteriol. 1989 May;66(5):365-78. available at <http://www.ncbi.nlm.nih.gov/pubmed/2666378>

6 Statistics courtesy: <http://www.expresspharmaonline.com/20080430/research01.shtml>

7 Under PFA Act: Section 2(v) "Food" means any article used as food or drink for human consumption other than drugs and water and includes :-

- (a) any article which ordinarily enters into, or is used in the composition or preparation of, human food,
- (b) any flavouring matter or condiments, and

- (c) any other article which the Central Government may having regard to its use, nature, substance or quality, declare by notification in the official Gazette, as food for the purposes of this Act.

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## Scope of judicial interference and inquiry in an application for appointment of arbitrator under the (Indian) Arbitration and Conciliation Act, 1996

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8 Nomenclature of the bacteria must conform to the taxonomic categories given under following references:

· Approved Lists of Bacterial Names (Int. J. Syst. Bacteriol, 1980,30:225-420), also available in <http://www.bacterio.cict.fr/>

· Validation Lists, published in the International Journal of Systematic and Evolutionary Microbiology (or International Journal of Systematic Bacteriology, prior to 2000)

9 Source: <http://www.fda.gov/Food/...../FoodIngredientsandPackaging/ucm061846.htm>

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