



Evaluation of Labeling Practices of Probiotic Products commercially available in Delhi Market

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ABSTRACT

Developed countries around the world have specific regulatory guidelines for probiotics, however in India; there is no regulatory regime for these products till date. In this study, the prevailing labeling practices of the probiotic products available in the Delhi market were surveyed. A cross-sectional study was conducted across 132 retail outlets and 40 chemist outlets in Delhi selling probiotics using a simple random selection process. The most popular products based on this survey were selected and their labels compared as per the existing regulations and ICMR-DBT guidelines. Majority of probiotic food products were listing the nutritional facts, best before date, probiotic organisms used along with other parameters such as net quantity and batch number. The critical parameters of number of viable probiotic microorganisms and health claims were not mentioned by most of them. The labels of probiotic food products on comparison with popular probiotic drugs sold in the market were also found to be less compliant. The probiotic drugs fared well in their overall compliance of 99% versus 84% of probiotic foods.

Keywords: ICMR-DBT guidelines for labeling, Probiotics.

INTRODUCTION

Probiotic is a new buzz in the human diet portfolio. Probiotics first became popular in Japan in 1980s and ever since the concept has spread to other parts of the world. The market for probiotics holds a very promising future as the consumers are becoming increasingly aware of the link between health, nutrition and diet. Consumption of probiotics exerts a myriad of health benefits including blood cholesterol reduction, Improving lactose intolerance, prevention and cure of bacterial and viral infections, boosting up of the immune system and anticarcinogenic and antimutagenic effects. Increasing awareness about these health benefits has led to a fast growing global market. Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit on the host. There is abundant experimental evidence to support the health benefits of probiotics, including

improvement of the intestinal microbial balance by antimicrobial activity, alleviation of lactose intolerance symptoms, prevention of food allergies, enhancement of immune potency, antitumorigenic activities, antioxidative and antiatherogenic effects and hypocholesterolemic property (1). They consist of bacteria (especially lactic acid bacteria and bifidobacteria) and yeasts (especially *Saccharomyces*), and may be present either in food (especially fermented milks), food supplements or drug (2). The key microorganisms used as probiotic are listed in Table 1.

Table 1: Key microbial species used as probiotics

Microorganisms considered as probiotics				
<i>Lactobacillus</i> species	<i>Bifidobacterium</i> species	Other lactic acid bacteria	Non-lactic bacteria	acid
<i>Lactobacillus acidophilus</i>	<i>Bifidobacterium adolescentis</i>	<i>Enterococcus faecalis</i>	<i>Bacillus cereus</i> var. <i>toyoi</i>	
<i>L. casei</i>	<i>B. animalis</i>	<i>Lactococcus lactis</i>	<i>B. coagulans</i>	
<i>L. crispatus</i>	<i>B. bifidum</i>	<i>Leuconostoc mesenteroides</i>	<i>B. clausii</i>	
<i>L. gallinarum</i>	<i>B. breve</i>	<i>Pediococcus acidilactici</i>	<i>Escherichia coli</i> strain nissle	
<i>L. gasseri</i>	<i>B. infantis</i>	<i>Sporolactobacillus inulinus</i>	<i>Propionibacterium freudenreichii</i>	
<i>L. johnsonii</i>	<i>B. lactis</i>	<i>Streptococcus thermophilus</i>	<i>Saccharomyces cerevisiae</i>	
<i>L. paracasei</i>	<i>B. longum</i>	<i>S. salivarius</i>	<i>S. boulardii</i>	
<i>L. plantarum</i>				
<i>L. reuteri</i>				
<i>L. rhamnosus</i>				
<i>L. delbrueckii</i>				
<i>L. fermentum</i>				
<i>L. brevis</i>				

Probiotics are subcategorized according to their intended use as probiotic foods, probiotic drugs, probiotics for animal use and genetically modified probiotics. Probiotics are not considered as single category rather subcategorized under different categories as per existing regulations of countries around the globe as shown in Table 2.

Table 2: Probiotic subcategories in different countries

S. No.	Country	Category
1.	Denmark/Sweden/Finland	Food Supplements
2.	Canada	Natural health products
3.	Italy	Dietary food
4.	European countries/Belgium/Germany	Biotherapeutic agent
5.	Japan/India/China/Malaysia	Functional food
6.	USA	Dietary Supplements/Drugs/Live Biotherapeutic agents/Medical food

Source: (3)

Probiotics are considered to be food supplements, not drugs. In some cases, the commercial probiotics are not regulated with respect to their efficacy and rigid quality parameters. There is a provision that these can be marketed without any demonstration of efficacy or safety provided that no specific efficacy claims are made for them. Majority of studies have found out that the contents of commercial probiotics

intended for both human and animal use are often not accurately represented on their labels; a large percentage of products did not contain the specified organisms, contained some other species of microorganisms, or did not contain the numbers of organisms as stated on their labels (4,5,6,7,8).

The Indian probiotic industry accounts for less than 1% of the total market turnover presently but it has a huge potential considering the fact that it is the world's largest milk producer. A range of probiotics are available in the Indian market. With the demand and supply of these products increasing exponentially and a steep expected increase considering the multiple health claims, there is an urgent need to put in place safeguards to protect the consumers from any adverse effects, ensure the standardization of products being marketed and their efficacy close inspection of the label, however, can raise "warning flags" when errors or deficiencies in labeling are present.

The aim was to study the current labeling practices of probiotic products available in Delhi market, as no such information is available. There is no regulatory regime for probiotic foods in India and only ICMR-DBT has laid down guidelines for evaluation of probiotics in 2011. The ICMR-DBT guidelines recommend that the probiotic organism in question be characterized to strain level and deposited with a culture repository. In order to screen the prospective probiotic strains, the guidelines suggest a series of *in vitro* tests under conditions that mimic the host gut, *in vitro* studies for studying safety and efficacy in animal models followed by similar studies in humans. In addition the guidelines list down the information that should be mentioned on the probiotic product labels. This study was performed to evaluate labeling of commercially available human probiotics -drugs and foods.

METHODOLOGY

Probiotics intended for use in humans were purchased over the counter from a variety of sources, including health food stores, pharmacies, grocery stores and retail stores. A cross-sectional study was conducted across 132 retail outlets and 40 chemist outlets in Delhi selling probiotics using a simple random selection process. In India there are no regulatory guidelines for probiotic foods. Due to absence of any such standards and guidelines, there is great scope for spurious products with false claims being marketed. It hence, becomes imperative that these products fulfill some crucial essential conditions before being labeled as a 'probiotic product'. A holistic approach is therefore needed for formulating guidelines and regulations for evaluating the safety and efficacy of probiotics in India which should be in consonance with current international standards. Keeping in view the above, a Task Force was constituted by ICMR, involving experts from diverse fields to formulate guidelines for evaluation of probiotics in food in India. According to their recommendation, the labels should be evaluated for name of organisms, accuracy of organism name and its spelling, the number of viable organisms that are usually not present. This study adapted the ICMR-DBT guidelines (9) to evaluate the labeling requirements of probiotic foods which are as follows-

- Genus, species and strain designation following the international nomenclature

- Minimum viable numbers of each probiotic strain at the level at which efficacy is claimed and at the end of shelf life
- Evidence based health claims
- Suggested serving size to deliver minimum effective quantity of probiotic related to the health claim
- Storage conditions.

RESULTS AND DISCUSSION

Major probiotic food brands (i.e. Mother Dairy, Yakult ,Nestle and Amul) and their popular product category(drink, curd, icecream etc.) were identified by the survey of 132 outlets across Delhi and their labels were studied. In case of probiotic drugs, the selection of the popular brands was based on the results of survey of 40 chemist shops. The popular brands based on the survey were selected for this study as listed in Table 3.

Table 3: List of Major Probiotic Players in Delhi market.

S. No.	Company	Probiotic Product (S) range	
1.	Food Industry	Mother Dairy	Curd, drink
2.		Yakult- Danone (I)Pvt. Ltd.	Drink
3.		Nestle India Ltd.	Curd, drink
4.		Amul	Drink, ice-cream
5.	Pharmaceutical companies	Dr. Reddy's Laboratories	Tablet
6.		Tablets India Ltd.	Tablet
7.		Polchem Hygiene Labratories	Tablet
8.		Theon Pharmaceuticals Ltd.	Tablet
9.		Unique Biotech Ltd.	Tablet
10.		USV Ltd.	Tablet
11.		Lupin Ltd	Tablet

All the popular products (foods and supplements) and their labels were studied as per the existing regulations and guidelines. Many parameters were included as listed in Table 4. The general being as best before date, product net quantity, batch no., storage instructions. license no., Specific being the name of microorganisms and their number, health claims were focused in this study.

Table 4: Labeling Parameters studied for Probiotic Foods and Drugs

S. No.	Parameter	Probiotic Foods	Probiotic Drugs
1.	Nutritional information	+	Not Applicable
2.	Best before	+	+
3.	Storage instruction (s)	+	+
4.	Name of Microbe (s)	+	+
5.	Microbial counts	+	+
6.	Batch No.	+	+
7.	License No.	+	+
8.	Product Net Quantity	+	+
9.	Health Claims	+	Not applicable

Only the probiotic foods labels were studied for their nutritional contents and health claims. As these are critical based on the guidelines issued by ICMR, DBT and whereas in case of drugs these are not that essential as most of the time, the drugs are prescribed by medical practitioners. These parameters as listed in the Table 3, were then used as criteria for the percent compliance study. In case of probiotic foods, the names of microorganisms were listed in a general manner. Only in 57% cases, genus, species and strain designation following the standard international nomenclature (genus as well as species) were mentioned. The ICMR-DBT guidelines also suggest the listing of health claims on the label but only 4 out of the 7 probiotic products were found to be mentioning the same. The probiotic efficacy is based on the number of viable probiotic microorganisms present in the dosage. This critical parameter was listed in only 29% of the labels of the popular bands (Figure 1).

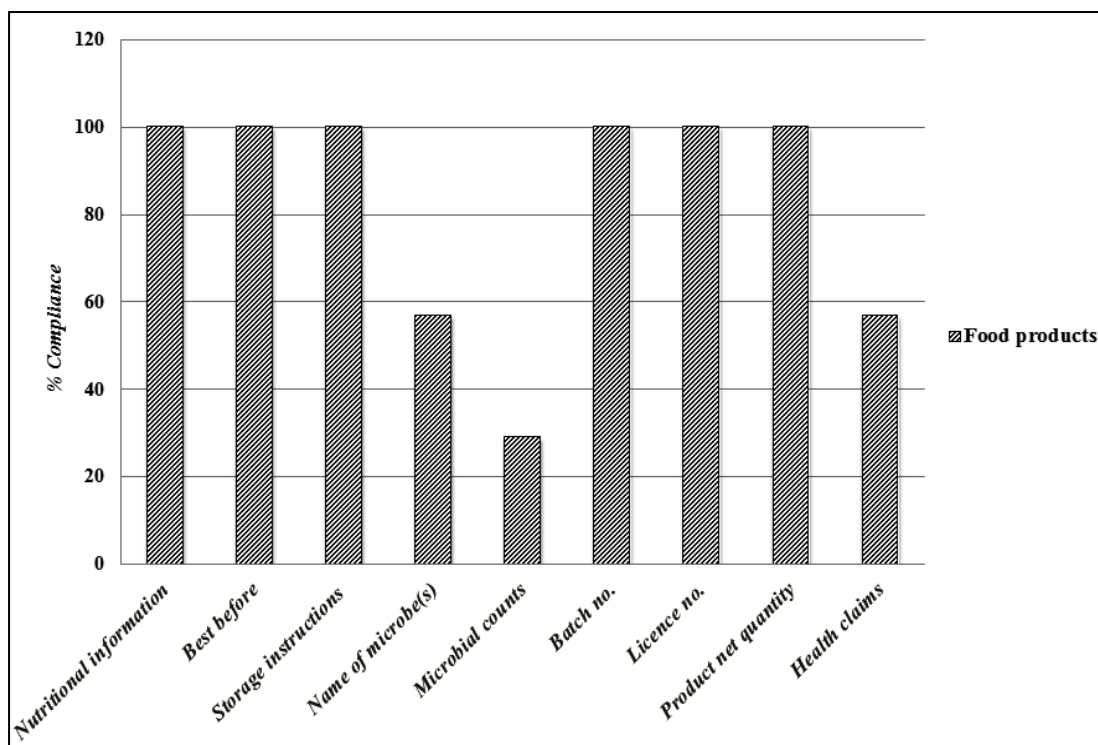


Figure 1: Percent compliance of probiotic foods.

All the products mentioned the nutritional facts, best before date, storage instructions along with other parameters like net quantity and batch number. The minimum viable numbers of each probiotic strain at the level at which efficacy is claimed and at the end of shelf- life were not stated. The functionality of a probiotic product is also dependent on serving size which was not mentioned in majority of labels. The suggested serving size helps to deliver the minimum effective quantity of the probiotic related to the health claim. The absence of such critical facts reflects mislabeling but since in India no such regulations exist only guidelines, the companies are relaxed in providing such information to the consumers.

Every country has formulated its own rules for dietary supplements. Probiotics are also termed as nutraceuticals or dietary supplements. They are classified under categories such as food supplements as well as healthcare products. Norms for regulating ingredients, labeling, claims and promotions vary from country to country, depending on the respective rules and regulations. Since nutraceuticals products do not pass through clinical trials, these products can be unsafe or have hazardous content. The Office of the Drugs Controller General of India had called on all companies selling products which contain probiotic bacteria as dietary supplements to obtain drug licenses. These are regulated as drugs. The probiotic drug labels studied during this project, met majority of criterion as shown in Figure 2. The name and numbers were mentioned on almost all labels but the scientific names of the probiotic organisms were not written in italics.

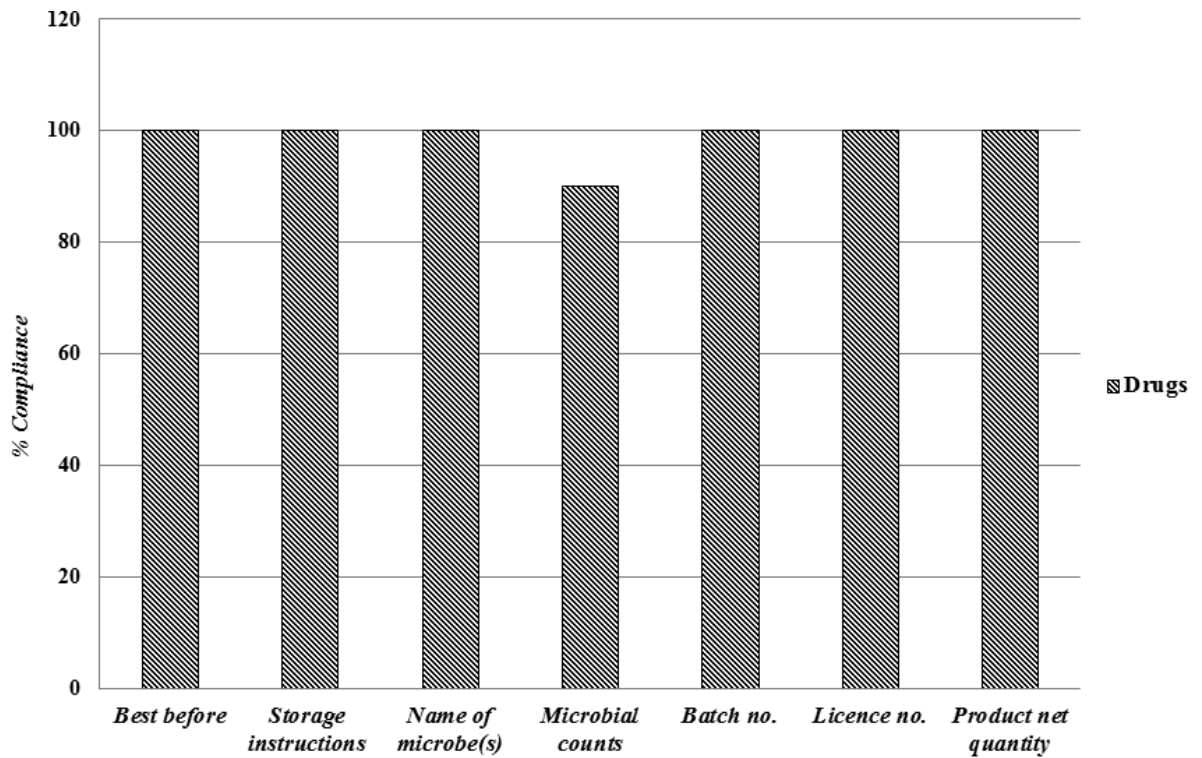


Figure 2: Percent compliance of probiotic drugs.

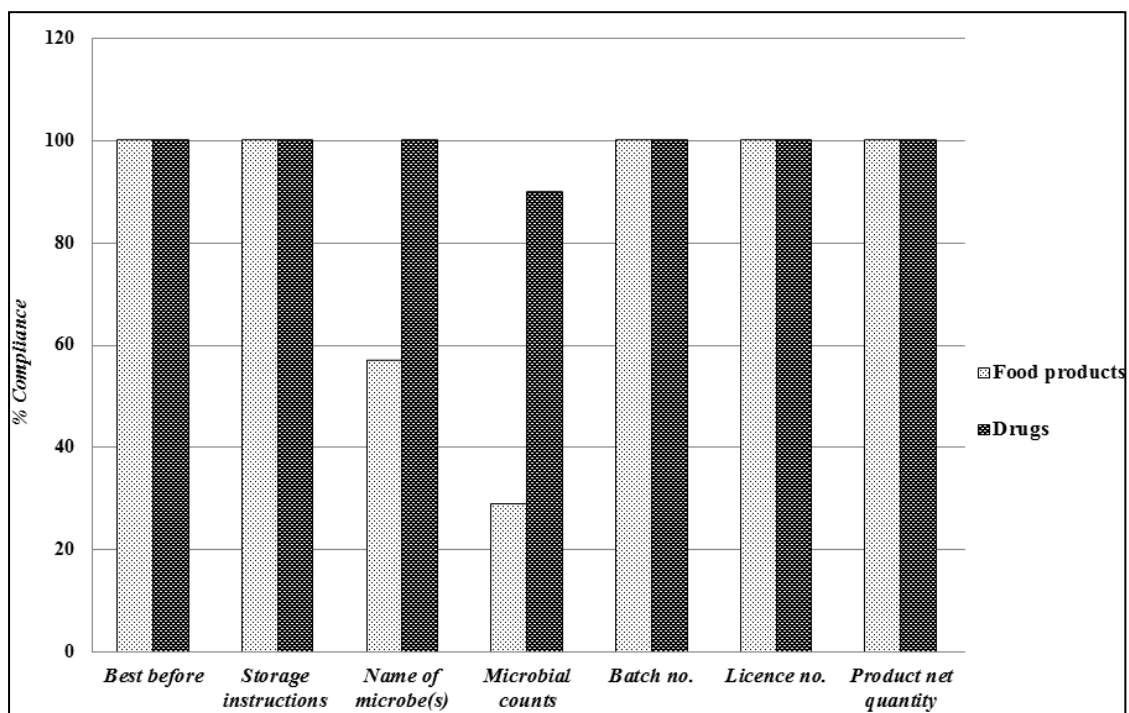


Figure 3: Comparative percent compliance of probiotic foods and drugs.

The labels of probiotic food products on comparison with popular probiotic drugs sold in the market were also found to be less compliant (Figure 3). The probiotic drugs fared well in their overall compliance of 99% versus 84% of probiotic foods

(Figure 4). Probiotic drugs and dietary supplements fared better as the microorganism(s) and their number were present on the label of majority of such products.

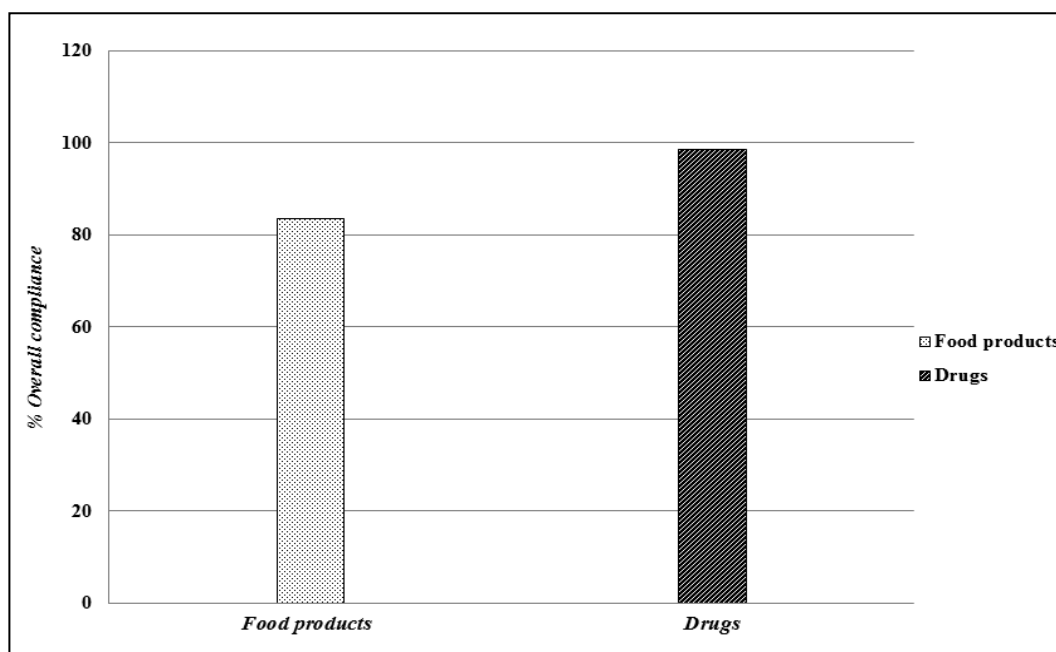


Figure 4: Percent overall compliance on probiotic foods and drugs.

CONCLUSION

Probiotics are defined as live microorganisms which when administered in adequate amounts confer a health benefit for the host. Studies show that ingestion of probiotics in any form i.e. foods, drugs (in form of tablets, capsules or powder), have a health promoting effect. Therefore, there is an increase demand of probiotics and a fast growing Indian market for them. This pilot study revealed that probiotic drugs are better compliant in comparison to probiotic foods in their labeling. As per the ICMR-DBT guidelines, majority of probiotic food products sold in the market were listing the nutritional facts, best before date, probiotic organisms used along with other parameters such as net quantity and batch number. The critical parameters of number of viable probiotic microorganisms and health claims were not mentioned by most of them. Thus in the interest of consumers, there is an urgent need to put in place a regulatory regime to evaluate the probiotics in India. The probiotic foods labels must list some basic information such as the name of the strain added in the product, the number of microorganisms present, health claims if any, best before date and storage conditions as it will help consumers to make informed choices.

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