PFNDAI

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FOOD WITH ADDED PRE & PROBIOTIC INGREDIENTS

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STRUCTURE OF REGULATION

1. Definitaions
2. General Requirements
3. Product Requirements
    I. Basic Requirements/Description
    II. Labelling Requirements
    III. Additives
    IV. Specific References

FOOD WITH ADDED PROBIOTIC INGREDIENTS

means
food with **live micro-organisms** beneficial to human health,
which when ingested in **adequate numbers**
as a single strain or as a combination of cultures,
confer one or more specified or demonstrated
health benefits in human beings;

Probiotic preparations may contain added prebiotics permitted under these regulations

General Requirements

The health claim in respect of an article of food may include the following types, but not limited to

(i) ingredients (nutrient or nutritional) function claims;

(ii) enhanced function claims;

(iii) disease risk reduction claims;

(iv) health maintenance claims;

(v) immunity claims – increased resistance (excluding vaccines)

(vi) anti-ageing claims.

General principles for query or challenge.-

(i) prepare and make available the **comprehensive product information, safety and claims** support data and shall periodically get it reviewed and scrutinised by a scientist or expert with relevant qualifications and experience;

(ii) attach the **scientific view** of the reviewer on claims and its veracity along with the qualification and experience of the reviewer as an essential part of the document;

(iii) clarify, in case of a technical query from the Food Authority or on a public complaint lodged with the Food Authority, and assist the Food Authority to examine or authorise an appropriate expert group to review the case;

(iv) alter or modify or stop claim when directed by the Food Authority which shall be based on the opinion of an expert group.

10. Food with added probiotic ingredients. – (1) (i) No food business operator shall use probiotic ingredients in food except the probiotic culture of the microorganisms specified in Schedule VII or those probiotic microorganisms approved by the Food Authority from time to time. Probiotic preparations may contain added prebiotics permitted under these regulations.

Rules

1. Please keep silence
2. Make a single line
3. Keep distance
4. ……
5. ……

What do I imagine????

Rules

1. Please keep silence
2. Make a single line
3. Keep distance
4. ……..
5. ……..

Rules

- No one will Utter a word
- Do not break the line
- Any one found pushing will be punished

What do I imagine now ????

Rules

1. No one will Utter a word
2. Any one found shouting will be punished
3. ……
4. ……

No food business operator shall use probiotic ingredients in food except the probiotic culture of the microorganisms specified in Schedule VII or those probiotic microorganisms approved by the Food Authority from time to time..

The viable number of organisms in food with added probiotic ingredients shall be

$\geq 10^8$ CFU/g

Provided that a **lower viable number** may be specified with proven studies on health benefits with those numbers subject to the

prior approval of the Food Authority

The Food Authority may, from time to time, specify the probiotic microorganisms approved by it after proper scientific evaluation:

Schedule –VII
List of strains as probiotics (live micro-organisms)

1. Lactobacillus acidophilus
2. Lactobacillus plantarum
3. Lactobacillus reuteri
4. Lactobacillus rhamnosus
5. Lactobacillus salivarius
6. Lactobacillus casei
7. Lactobasillus brevis
8. Lactobacillus johnsonii
9. Lactobacillus delbrueckii sub- sp. bulgaricus
10. Bacillus coagulans
11. Lactobacillus fermentum
12. Lactobacillus caucasicus
13. Lactobacillus helveticus
14. Lactobacillus lactis
15. Lactobacillus amylovorus
16. Lactobacillus gallinarum
17. Lactobacillus delbrueckii
18. Bifidobacterium bifidum
19. Bifidobacterium lactis
20. Bifidobacterium breve
21. Bifidobacterium longum
22. Bifidbacterium animalis
23. Bifidobacterium infantis
24. **Streptococcus** thermophilus
25. Saccharomyces boulardii
26. Saccharomyces cerevisiae
27. Lactobacillus paracasei
28. Lactobacillus gasseri

Provided that the presence of the commonly used starter cultures of lactic acid producing bacteria such as Lactococcus spp., earlier known as Streptococcus spp., Lactobacillus spp. and other such microorganisms used in the preparation of fermented milk **(dahi)** and related products **shall not be considered as probiotics**, if the probiotic properties have not been substantiated.

Labelling Requirements:

(a) the words “PROBIOTIC FOOD”;

(b) genus and species including strain designation or culture collection number, where applicable, in brackets where probiotics are mentioned in the list of ingredients;

(c) viable numbers at the end of the shelf-life of probiotic strain corresponding to the level at which the efficacy is claimed;

(d) the recommended serving size which shall deliver the effective viable dose of probiotics related to health claims and recommended duration of use, proper storage temperature conditions, and time limit for ‘Best Use’ after opening the container;

(e) an advisory warning ‘NOT FOR MEDICINAL USE’ prominently written; and

(f) a warning or any other precaution to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable.

3) No food business operator shall use **additives** in probiotic preparations except those specified in **Schedule VA** to **Schedule VF**.

Note.- The guidelines issued by the **Indain Council of Medical Research and Department of Biotechnology** with respect to probiotics provide additional information on their use.

ICMR-DBT Guidelines for Evaluation of Probiotics in Food

June 13, 2011

These guidelines are not meant for probiotics which by definition would come under drugs, beneficial microorganisms not used in foods or genetically modified microorganisms (GMOs)

Ref: Indian J Med Res 134, July 2011, pp 22-25

Definition of probiotics: Probiotics are ‘live microorganisms which when administered in adequate amounts confer a health benefit on the host’ (FAO/ WHO, 2002)4 .

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Genus, species and strain identification: Effects of probiotics are strain specific. Strain identity is important to link a strain to a specific health effect as well as to enable accurate surveillance and epidemiological studies. Both phenotypic and genotypic tests should be done using validated standard methodology. Nomenclature of the bacteria must conform to the current, scientifically recognized names as per the International Committee on Systematics of Prokaryotes (ICPS)1

In vitro tests to screen potential probiotic strains:

(I) Resistance to gastric acidity,

(ii) Bile acid resistance,

(iii) Antimicrobial activity against potentially pathogenic bacteria (acid and bacteriocin production),

(iv) Ability to reduce pathogen adhesion to surfaces,

(v) Bile salt hydrolase activity.

In vivo safety studies in animal models:

Assessment of the acute, subacute and chronic toxicity of ingestion of extremely large amounts of probiotics should be carried out for all potential strains. Such assessment may not be necessary for strains with established documented use. 6. In vivo efficacy studies in animal models: To substantiate in vitro effects, appropriate, validated animal models must be used first, prior to human trials.

Evaluation of safety of probiotics for human use:

In recognition of the importance of assuring safety, even among group of bacteria that are Generally Recognized as Safe (GRAS)**, probiotics strains needs to be characterized at a minimum with the following tests:

(i) Determination of antibiotic resistance patterns. It should be ascertained that any given probiotic strain is not at significant risk with regard to transferable antibiotic resistance.

(ii) Assessment of undesirable side-effects.

(iii) If the strain under evaluation belongs to a species that is a known mammalian toxin producer or of haemolytic potential, it must be tested for toxin production and haemolytic activity respectively. Assessment of lack of infectivity by a probiotic strain in immunocompromised individuals would be an added measure.

Effective dosage of probiotic strain/strains:

The minimal effective dose or the level of viable cells of the probiotic strain in terms of cfu/ml/day in the carrier food that demonstrates general health promoting functions or well being or specific health claims in target population should be clearly indicated.

Labeling requirements:

(i) Genus, species and strain designation following the standard international nomenclature.

(ii) The minimum viable numbers of each probiotic strain should be specified at the level at which efficacy is claimed and at the end of shelf- life.

(iii)Evidence-based health claim(s) should be clearly stated.

(iv) The suggested serving size to deliver the minimum effective quantity of the probiotic related to the health claim.

(v) Proper storage conditions to be mentioned.

Manufacturing and handling procedures:

Adequate quality assurance programmes should be in place. Good Manufacturing Practices should be followed in the manufacture of probiotic foods The Codex General Principles of Food Hygiene and Guidelines for Application of Hazard Analysis and Critical Control Point (HACCP)20 should be followed

FOOD WITH ADDED PREBIOTIC INGREDIENTS

means

food that contains added prebiotic ingredients

which are **nonviable food components**

that confer

health benefits to the consumer

by

modulation of gut microbiota;

FOOD WITH ADDED PREBIOTIC INGREDIENTS

(1) (i) No food business operator shall use prebiotics in manufacturing food containing prebiotics except those specified in **Schedule VIII** or those prebiotics approved by the Food Authority from time to time.

List of Prebiotic Ingredients allowed: Schedule VIII

1. Polydextrose
2. Soybean oligosaccharides
3. Isomalto-oligosaccharides
4. Fructo-oligosaccharides
5. Gluco-oligosaccharides
6. Xylo-oligosaccharides
7. Inulin
8. Isomaltulose
9. Gentio-oligosaccharides
10. Lactulose
11. Lactoferrin
12. Sugar alcohols such as lactitol, sorbitol, maltitol, inositol, isomalt
13. Galacto-oligosaccharides

The prebiotic component shall be characterised for a given product by providing the following

1. Source,
2. Origin,
3. Purity,
4. Chemical composition and structure,
5. Vehicle,
6. Concentration and
7. Amount in which it is to be delivered to the host.

(i) Claims not allowed

- Preventing a human disease
- treating a human disease or
- curing a human disease, or
- refer to such properties.

(ii) The claim statement allowed relating to

- Structure
- Function or
- General well-being of the body

if supported by accepted scientific data.

Labelling Requirements:-

(a) the words “PREBIOTIC FOOD”;

(b) name of prebiotic;

(c) Serving size to have health benefit;

(d) warning ‘NOT FOR MEDICINAL USE’ prominently

(e) Other Declarations

- a warning or precautions while consuming,
- known side effects,
- Contraindications,
- Product-drug interactions, as applicable.

Additives:

As per Schedule VA to Schedule VF

Thank You

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