Current Situation & Development Trend of Probiotics Food in China

Lillian Fan

中食安信（北京）信息咨询有限公司
Antion (Beijing) Information Consulting Co., Ltd.
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About Antion
Company Overview

- Antion China was established in 2013
- National high-tech enterprise with 19 IPs
- Providing food regulations consulting services for food industry all over the world.
- Our staffs have rich experience in food industry and regulation consulting services.
- Our Advisory Group is consisted of professional technicians.
- Service in Chinese, English, Japanese and Korean
Service Scope

Industry Information
- Weekly & monthly newsletter
- Food industry analysis report
- Professional translation
- AntionGlobal.com

Information-based System
- Food regulation platform
- Food label audit system
- Competitive products database

Regulation Consulting
- Daily compliance management
- Product compliance audit
- Government affairs communication
- Whole outsourcing service

Application & Registration
- “Three Novel” food approval
- IF formula registration
- Imported food without national standard
- Health food registration and filing
Our Client
What Kinds of Probiotics Can Be Used?
Supervision Authorities

- National Health Commission
  - Mass Health
  - Food Safety Standards
  - Novel Food Ingredient
  - New Variety of Food Additive

- Ministry of Agriculture and Rural Affairs
  - Agricultural Products
  - GMO

- General Administration of Customs, China
  - Import & Export
  - CBEC
  - Tariff

- State Administration for Market Regulation
  - Special Food
  - Advertising
Chinese Food Classification

Food

Special food
- Health food
- Infant formula
- FSMP

Normal food

Foods for Special Dietary Uses

Infant formula
- Infant formula
- Older infants and young children formula
- FSMP

Complementary foods
- Cereal-based complementary foods for infants and young children
- Canned complementary foods for infants and young children
- FSMP

FSMP

Other
- Complementary food supplements
- Sport nutritional food
- Other
## Normal Food vs Health Food

<table>
<thead>
<tr>
<th>Category</th>
<th>Normal Food</th>
<th>Health Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>No clear definition</td>
<td>Applicable to a specific group of people, with functions to regulate the body, and not for the purpose of treating diseases</td>
</tr>
<tr>
<td>Claims</td>
<td>Nutrient Function Claim e.g. Vitamin C is able to maintain bone and gingiva health; Vitamin C has anti-oxidation efficacy</td>
<td>Health Function Claims (Positive List of 27 approved function claims; Supplement vitamins &amp; minerals)</td>
</tr>
<tr>
<td>Format</td>
<td>Normal food format</td>
<td>Normal food format+ Capsule, Soft gel, etc.</td>
</tr>
<tr>
<td>Others</td>
<td>No Need Product Registration</td>
<td>Need Product Registration or Filing</td>
</tr>
</tbody>
</table>
## List of Stains that Can Be Used in Food (1)

<table>
<thead>
<tr>
<th>Chinese Name</th>
<th>Latin Name</th>
<th>Chinese Name</th>
<th>Latin Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>青春双歧杆菌</td>
<td>Bifidobacterium adolescenris</td>
<td>发酣乳杆菌</td>
<td>Lactobacillus fermentium</td>
</tr>
<tr>
<td>动物双歧杆菌 (乳双歧杆菌)</td>
<td>Bifidobacterium animalis (Bifidobacterium lactis)</td>
<td>格氏乳杆菌</td>
<td>Lactobacillus gasseri</td>
</tr>
<tr>
<td>两歧双歧杆菌</td>
<td>Bifidobacterium bifidum</td>
<td>瑞士乳杆菌</td>
<td>Lactobacillus helveticus</td>
</tr>
<tr>
<td>短双歧杆菌</td>
<td>Bifidobacterium breve</td>
<td>约氏乳杆菌</td>
<td>Lactobacillus johnsonii</td>
</tr>
<tr>
<td>婴儿双歧杆菌</td>
<td>Bifidobacterium infantis</td>
<td>副干酪乳杆菌</td>
<td>Lactobacillus paracasei</td>
</tr>
<tr>
<td>长双歧杆菌</td>
<td>Bifidobacterium longum</td>
<td>植物乳杆菌</td>
<td>Lactobacillus plantarum</td>
</tr>
<tr>
<td>嗜酸乳杆菌</td>
<td>Lactobacillus acidophilus</td>
<td>罗伊氏乳杆菌</td>
<td>Lactobacillus reuteri</td>
</tr>
<tr>
<td>干酪乳杆菌</td>
<td>Lactobacillus casei</td>
<td>鼠李糖乳杆菌</td>
<td>Lactobacillus rhamnosus</td>
</tr>
<tr>
<td>卷曲乳杆菌</td>
<td>Lactobacillus crispatus</td>
<td>唾液乳杆菌</td>
<td>Lactobacillus salivarius</td>
</tr>
<tr>
<td>德氏乳杆菌保加利亚亚种 (保加利亚乳杆菌)</td>
<td>Lactobacillus delbrueckii (Lactobacillus bulgaricus)</td>
<td>清酒乳杆菌</td>
<td>Lactobacillus sakei</td>
</tr>
<tr>
<td>德氏乳杆菌乳亚种</td>
<td>Lactobacillus delbrueckii</td>
<td>嗜热链球菌</td>
<td>Streptococcus thermophilus</td>
</tr>
</tbody>
</table>
## List of Stains that Can Be Used in Food (2)

<table>
<thead>
<tr>
<th>Chinese Name</th>
<th>Latin Name</th>
<th>Chinese Name</th>
<th>Latin Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>乳酸乳球菌乳酸亚种</td>
<td>Lactococcus Lactis subsp. Lactis</td>
<td>肠膜明串珠菌肠膜亚种</td>
<td>Leuconostoc mesenteroides subsp. Mesenteroides</td>
</tr>
<tr>
<td>乳酸乳球菌乳脂亚种</td>
<td>Lactococcus Lactis subsp. Cremoris</td>
<td>小牛葡萄球菌</td>
<td>Staphylococcus vitulinus</td>
</tr>
<tr>
<td>乳酸乳球菌双乙酰亚种</td>
<td>Lactococcus Lactis subsp. Diacetylactis</td>
<td>木糖葡萄球菌</td>
<td>Staphylococcus xylosus</td>
</tr>
<tr>
<td>费氏丙酸杆菌谢氏亚种</td>
<td>Propionibacterium freudenreichii subsp. Shermanii</td>
<td>肉葡萄球菌</td>
<td>Staphylococcus carnosus</td>
</tr>
<tr>
<td>产丙酸丙酸杆菌</td>
<td>Propionibacterium acidipropionici</td>
<td>马克斯克鲁维裁母</td>
<td>Kluyveromyces marxianus</td>
</tr>
<tr>
<td>乳酸片球菌</td>
<td>Pediococcus acidilactici</td>
<td>凝结芽孢杆菌</td>
<td>Bacillus coagulans</td>
</tr>
<tr>
<td>戊糖片球菌</td>
<td>Pediococcus pentosaceus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data is collected on September 18, 2019.
# List of Stains that Can Be Used in Infant Food

<table>
<thead>
<tr>
<th>Chinese Name</th>
<th>Latin Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>罗伊氏乳杆菌（菌株号: DSM17938）</td>
<td>Lactobacillus reuteri (DSM17938)</td>
</tr>
<tr>
<td>鼠李糖乳杆菌（菌株号: HN001）</td>
<td>Lactobacillus rhamnosus (HN001)</td>
</tr>
<tr>
<td>鼠李糖乳杆菌（菌株号: LGG）</td>
<td>Lactobacillus rhamnosus (LGG)</td>
</tr>
<tr>
<td>乳双歧杆菌（菌株号: Bi-07）</td>
<td>Bifidobacterium lactis (Bi-07)</td>
</tr>
<tr>
<td>乳双歧杆菌（菌株号: HN019）</td>
<td>Bifidobacterium lactis (HN019)</td>
</tr>
<tr>
<td>动物双歧杆菌（菌株号: Bb-12）</td>
<td>Bifidobacterium animalis (Bb-12)</td>
</tr>
<tr>
<td>嗜酸乳杆菌（菌株号: NCFM）</td>
<td>Lactobacillus acidophilus (NCFM)</td>
</tr>
<tr>
<td>发酵乳杆菌（菌株号: CECT5716）</td>
<td>Lactobacillus fermentum (CECT5716)</td>
</tr>
<tr>
<td>短双歧杆菌（菌株号: M-16V）</td>
<td>Bifidobacterium breve (M-16V)</td>
</tr>
</tbody>
</table>

Data is collected on September 18, 2019.
Infant Food

Foods for Special Dietary Uses

Infant formula
- Infant formula
- Older infants and young children formula
- FSMP for infant

Complementary foods
- Cereal-based complementary foods for infants and young children
- Canned complementary foods for infants and young children

FSMP

Other
- Complementary food supplements
- Sport nutritional food
- Other
List of Stains that Can Be Used in Health Food

<table>
<thead>
<tr>
<th>Chinese Name</th>
<th>Latin Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>两岐双岐杆菌</td>
<td>Bifidobacterium bifidum</td>
</tr>
<tr>
<td>婴儿双岐杆菌</td>
<td>Bifidobacterium infantis</td>
</tr>
<tr>
<td>长双岐杆菌</td>
<td>Bifidobacterium longum</td>
</tr>
<tr>
<td>短双岐杆菌</td>
<td>Bifidobacterium breve</td>
</tr>
<tr>
<td>青春双岐杆菌</td>
<td>Bifidobacterium adolescentis</td>
</tr>
<tr>
<td>德氏乳杆菌保加利亚种</td>
<td>Lactobacillus delbrueckii subsp. bulgaricus</td>
</tr>
<tr>
<td>嗜酸乳杆菌</td>
<td>Lactobacillus acidophilus</td>
</tr>
<tr>
<td>干酪乳杆菌干酪亚种</td>
<td>Lactobacillus casei subsp. Casei</td>
</tr>
<tr>
<td>嗜热链球菌</td>
<td>Streptococcus thermophilus</td>
</tr>
<tr>
<td>罗伊氏乳杆菌</td>
<td>Lactobacillus reuteri</td>
</tr>
</tbody>
</table>

Data is collected on September 18, 2019.
Overview of China's Probiotic Market
Health Food Industry Trends (2014 – 2018)

Billion RMB

2014: 390
2015: 400
2016: 459
2017: 500
2018: 530

Source: Government report and Antion analysis
Health Food Industry Trends (Import 2008 – 2018)

Source: Government report and CCCMHPIE analysis.
Market Scale of Probiotics in China (2012 – 2022)

Source: Publicly available data consolidation.
Probiotics becomes more and more popular in China.
China’s Probiotics Market

Source: Publicly available data consolidation.
Health Food Approval Situation (2013 – 2019)

The number of approved registration health food is continuous declining in the recent years

- Among the 17,500 registered health food, only less than 1% are probiotics products.
Market Products Examples

Example
Market Products Examples

Example
Problems, Challenges and Risks
Definition

Strains

Function & Format

Awareness

Quality

Compliance
Definition

- **FAO/WHO** (2002)
  live microorganisms which when administered in adequate amounts confer a health benefit on the host.

- **Probiotics Health Food Review Regulations** (2001)
  The probiotic species must be a member of the normal flora of the human body, and its live bacteria, dead bacteria and its metabolites can be utilized.

- **Probiotics Health Food Application & Review Regulations (Comments)** (2019)
  Probiotics are living microorganisms that are beneficial to the health of the host when ingested in sufficient quantities.
Function & Format

Function

- Improve immunity: 40%
- Regulation of intestinal flora: 34%
- Laxative: 14%
- Other Functions: 12%

Format

- Powder: 47%
- Capsule: 27%
- Liquid: 11%
- Milk & Yoghurt: 9%
- Tablet: 6%
Regulatory Changes and Trend Analysis
Potential Health Food Ingredients

- **2017 “保健食品原料目录研究”专项课题**
  - 沙棘（油），人参（红参），西洋参，天麻，三七；灵芝，灵芝孢子粉，枸杞子，螺旋藻；银杏叶（银杏叶提取物），红花，黄芪，石斛，红景天；鱼油，海豹油，鳕鱼肝油，大蒜油，牛初乳，蜂王浆；植物甾醇（植物甾醇酯），番茄红素，辅酶Q10，褪黑素，维生素B6，角鲨烯，肉苁蓉。

- **2018 “保健食品原料目录研究”专项课题**
  - 山楂、黄精、玉竹、阿胶；金银花、山茱萸、生地、蜂胶；苦丁茶、薏苡仁，五味子，桑叶；盐藻及提取物、松花粉、DHA及DHA藻油、共轭亚油酸、蛹虫草（蛹虫草子实体）；大豆蛋白、乳清蛋白、蚕蛹水解氨基酸、酪蛋白磷酸肽+钙；1. 益生菌：两岐双歧杆菌、长双岐杆菌、短双岐杆菌、青春双岐杆菌、动物双歧杆菌、嗜酸乳杆菌、植物乳杆菌、罗伊氏乳杆菌、鼠李糖乳杆菌。2. 益生元：异麦芽低聚糖（IMO）、低聚果糖（FOS）、低聚半乳糖（GOS）、低聚木糖（XOS）、低聚乳果糖（LACT）、大豆低聚糖（SOS）、菊粉（Inulin）。3. 益生菌+益生元组合。
Novel Food Ingredient Application Process

Applicant

NHC Acceptance Centre

Submit Required Documents

CFSA Assessment

Pass

NHC

Public Comment

Yes

NHC

Technical Review Opinions

Administrative License

Not Pass

NHC

Request Supplementary Documents

Administrative License Termination Review Notice

Source: Management Measure on Safety Review of Novel Food Ingredient NHFPC Announcement No.1, Implemented on 1 October 2013
Documents for Novel Food Ingredient

1. Application Form
2. Novel Food Ingredients Research Report
4. Production Process
5. Implementation of Relevant Standards
6. Label & Instruction
7. Domestic and foreign research and utilization and related safety assessment data
8. Other information that contributes to the review
9. Application Attorney Letter
10. One Unopened Samples of minimum package or 30g Ingredient
11. A certificate issued by imported novel food ingredient's expert country (region)'s relevant departments or organizations that allows the product to be produced or sold in the country (region)
12. A supporting material issued by imported novel food ingredient's expert country (region)'s relevant departments or organizations about the production enterprise being reviewed or authenticated.
Novel Food Ingredient

Properly Simplify the Application Documents

Amend the Management Measure on Safety Review of Novel Food Ingredient

Adjust the Application Scope of Food Ingredients

More Strict Technical Assessment

Properly Simplify the Application Documents
• Promote the probiotics into Health Food Ingredient List
• Apply new species/strains of probiotics
• Apply new health functions
• Format innovation
Q&A