

THE PROBIOTICS MARKET: INGREDIENTS, SUPPLEMENTS, FOODS



FOD035D
April 2014

Rachel Agheyisi
Project Analyst

ISBN: 1-56965-796-3

bcc | Research
Market Forecasting

BCC Research
49 Walnut Park, Building 2
Wellesley, MA 02481 USA
866-285-7215 (toll-free within the USA),
or (+1) 781-489-7301
www.bccresearch.com
information@bccresearch.com

TABLE OF CONTENTS

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------------------------------------------------------------|-----------------|
| CHAPTER 1 INTRODUCTION | 2 |
| STUDY GOALS AND OBJECTIVES | 2 |
| REASONS FOR DOING THE STUDY | 2 |
| SCOPE OF REPORT | 2 |
| INTENDED AUDIENCE | 3 |
| METHODOLOGY AND INFORMATION SOURCES | 3 |
| ANALYST'S CREDENTIALS | 3 |
| RELATED BCC RESEARCH REPORTS | 3 |
| BCC RESEARCH WEBSITE | 4 |
| DISCLAIMER | 4 |
| CHAPTER 2 SUMMARY | 6 |
| <i>SUMMARY TABLE GLOBAL SALES OF PROBIOTIC INGREDIENTS, SUPPLEMENTS AND FOODS, THROUGH 2018 (\$ MILLIONS)</i> | 7 |
| <i>SUMMARY FIGURE PROJECTED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS, SUPPLEMENTS, AND FOODS, 2013 AND 2018 (%)</i> | 7 |
| CHAPTER 3 OVERVIEW | 9 |
| BACKGROUND | 9 |
| INDUSTRY CONCEPTS | 10 |
| PROBIOTICS AND HEALTHY MICROBIOTA | 10 |
| RESIDENT AND TRANSIENT PROBIOTICS | 11 |
| PROBIOTIC CLASSIFICATION AND LABELING | 11 |
| PREBIOTICS | 11 |
| SYNBIOTICS | 12 |
| PROBIOTIC DELIVERY SYSTEM | 12 |
| IMPORTANCE OF PROBIOTICS | 12 |
| FORESEEABLE DEVELOPMENTS | 13 |
| CHAPTER 4 THE GLOBAL PROBIOTIC INGREDIENTS INDUSTRY | 15 |
| INTRODUCTION | 15 |
| KEY FEATURES OF THE GLOBAL PROBIOTIC INGREDIENTS INDUSTRY | 15 |
| LEADERS IN THE GLOBAL PROBIOTICS INDUSTRY | 16 |
| BioGaia-Recent Activity | 16 |
| BioGaia Acquires Remaining 50% of TwoPac AB | 17 |
| BioGaia and Nestle | 17 |
| Promoting Oral Health Products | 17 |
| Agreements to Promote Specific Formulary | 18 |
| BioGaia's Research Affiliates | 19 |
| Chr. Hansen-Recent Activity | 19 |
| Chr. Hansen's New Attitude-Nature's No. 1 | 19 |
| Chr. Hansen, University of Copenhagen, and the West African Project | 20 |
| Chr. Hansen and FMC Corp. | 20 |
| Chr. Hansen and Sigma-Tau | 20 |
| Chr. Hansen and Jamieson Laboratories | 20 |

| TOPIC | PAGE NO. |
|-------------------------------------------------------------------|-----------------|
| Chr. Hansen and Sagitus, Ltd. | 21 |
| Chr. Hansen and Jarrow Formulas | 21 |
| Chr. Hansen, University of Aarhus and Animal Health | 21 |
| DuPont-Danisco-Recent Activity | 21 |
| DuPont and FDA GRAS Affirmation | 22 |
| DuPont and Protective Dairy Cultures | 22 |
| DuPont Opens a Probiotics Facility in China | 22 |
| Expanding HOWARU Brand | 22 |
| Groupe Danone-Recent Activity | 23 |
| Danone and Starbucks | 23 |
| Danone and Greek Yogurt in Canada | 23 |
| Danone, COFCO, and Mengniu in China | 23 |
| Danone and Yakult-New Cooperation Framework | 24 |
| Danone Institute International (DII) | 24 |
| Lallemand Health Solutions-Recent Activity | 25 |
| Large Clinical Study | 25 |
| Authorized Condition-Specific Health Claims by Health Canada | 25 |
| Certified Halal | 26 |
| Lallemand's Research Collaborators | 26 |
| Nebraska Cultures and the University of Nebraska | 26 |
| Probi-Recent Activity | 27 |
| Probi in North America | 27 |
| Probi Products in New Markets | 27 |
| Probi's Partners | 28 |
| PROBIOTIC INGREDIENTS BY TYPE | 28 |
| INTRODUCTION | 28 |
| PROBIOTICS OF THE LACTOBACILLUS GENUS | 29 |
| L. acidophilus | 29 |
| <i>TABLE 1 SELECTION OF PROPRIETARY STRAINS OF L. ACIDOPHILUS</i> | 30 |
| L. acidophilus DDS-1 | 30 |
| L. acidophilus LA-1 (L. acidophilus LA-5) | 30 |
| L. acidophilus LB | 31 |
| L. acidophilus LAFTI L10 | 31 |
| L. acidophilus Rosell-52 | 31 |
| L. acidophilus NCFM | 31 |
| L. acidophilus SBT-2062, SBT-2071, SBT-2074 | 32 |
| L. bulgaricus | 32 |
| L. casei | 32 |
| <i>TABLE 2 SELECTION OF PROPRIETARY STRAINS OF L. CASEI</i> | 33 |
| L. casei DN114001 and L. casei immunitas | 33 |
| L. casei F19 | 33 |
| L. casei 431 | 33 |
| L. casei LAFTI L26 | 34 |
| L. casei Shirota | 34 |
| L. helveticus | 34 |
| L. johnsonii | 34 |
| L. plantarum | 34 |

| TOPIC | PAGE NO. |
|--------------------------------------------------------------------------|-----------------|
| <i>TABLE 3 SELECTION OF PROPRIETARY STRAINS OF L. PLANTARUM</i> | 35 |
| L. reuteri | 35 |
| <i>TABLE 4 SELECTION OF PROPRIETARY STRAINS OF L. REUTERI</i> | 35 |
| L. rhamnosus | 35 |
| <i>TABLE 5 SELECTION OF PROPRIETARY STRAINS OF L. RHAMNOSUS</i> | 36 |
| L. rhamnosus GG (LGG) | 36 |
| L. rhamnosus GR-1 | 36 |
| L. rhamnosus HN001 | 37 |
| L. rhamnosus Rosell-11 | 37 |
| L. salivarius | 37 |
| PROBIOTICS OF THE BIFIDOBACTERIUM GENUS | 37 |
| B. animalis | 38 |
| <i>TABLE 6 SELECTION OF PROPRIETARY STRAINS OF B. ANIMALIS</i> | 38 |
| BB-12 | 38 |
| B. animalis DN 173 010 (also known as Bifidum regularis) | 38 |
| B. lactis HN019 (also known as HOWARU bifido) | 39 |
| B. bifidum | 39 |
| B. LAFTI B94 | 39 |
| B. breve | 39 |
| <i>TABLE 7 SELECTION OF PROPRIETARY STRAINS OF B. BREVE</i> | 39 |
| B. infantis | 40 |
| <i>TABLE 8 SELECTION OF PROPRIETARY STRAINS OF B. INFANTIS</i> | 40 |
| B. longum | 40 |
| <i>TABLE 9 SELECTION OF PROPRIETARY STRAINS OF B. LONGUM</i> | 41 |
| PROBIOTICS OF THE STREPTOCOCCUS GENUS | 41 |
| S. thermophilus | 41 |
| S. thermophilus TH-4 | 41 |
| PROBIOTICS OF THE BACILLUS GENUS | 41 |
| Bacillus Coagulans (B. coagulans) | 42 |
| <i>TABLE 10 SELECTION OF PROPRIETARY STRAINS OF BACILLUS</i> | 42 |
| B. coagulans GBI-30, 6086 (GanedenBC30) | 42 |
| B. coagulans ProDURA | 43 |
| B. subtilis GalliPro | 43 |
| B. licheniformis | 43 |
| OTHER COMMERCIALY SIGNIFICANT PROBIOTIC BACTERIA | 43 |
| Enterococcus | 43 |
| Lactococcus | 44 |
| Pediococcus | 44 |
| L. fermentum | 45 |
| L. fermentum PCC | 45 |
| L. fermentum ME-3 | 45 |
| Saccharomyces boulardii (S. boulardii) | 46 |
| SELECTION CRITERIA FOR PROBIOTICS | 46 |
| SELECTION CRITERIA FOR PROBIOTIC STRAINS | 46 |
| <i>TABLE 11 SELECTION CRITERIA FOR PROBIOTIC STRAINS</i> | 47 |
| SPECIES-SPECIFIC BENEFICIAL EFFECTS OF PROBIOTICS | 47 |
| <i>TABLE 12 HEALTH BENEFITS ASSOCIATED WITH LACTOBACILLUS PROBIOTICS</i> | 48 |

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------------------------------------------------------------|-----------------|
| <i>TABLE 13 HEALTH BENEFITS ASSOCIATED WITH BIFIDOBACTERIUM PROBIOTICS</i> | 48 |
| <i>TABLE 14 HEALTH BENEFITS ASSOCIATED WITH STREPTOCOCCUS PROBIOTICS</i> | 49 |
| MECHANISMS OF PROBIOTIC ACTION | 49 |
| <i>TABLE 15 PROPOSED MECHANISMS OF PROBIOTIC ACTION</i> | 50 |
| RECENT AND PROJECTED GLOBAL SALES OF PROBIOTIC INGREDIENTS | 50 |
| INDUSTRY DATA | 50 |
| RECENT GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE | 51 |
| RECENT GLOBAL SALES OF LACTOBACILLUS PROBIOTIC INGREDIENTS | 51 |
| <i>FIGURE 1 SALES OF LACTOBACILLUS PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %)</i> | 51 |
| RECENT GLOBAL SALES OF BIFIDOBACTERIUM PROBIOTIC INGREDIENTS | 52 |
| <i>FIGURE 2 SALES OF BIFIDOBACTERIUM PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %)</i> | 52 |
| RECENT GLOBAL SALES OF STREPTOCOCCUS PROBIOTIC INGREDIENTS | 53 |
| <i>FIGURE 3 SALES OF STREPTOCOCCUS PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %)</i> | 53 |
| RECENT GLOBAL SALES OF BACILLUS PROBIOTIC INGREDIENTS | 54 |
| <i>FIGURE 4 SALES OF BACILLUS PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %)</i> | 54 |
| TOTAL RECENT GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE | 55 |
| <i>TABLE 16 TOTAL GLOBAL SALES OF PROBIOTIC INGREDIENT BY TYPE, 2012 (\$ MILLIONS, %)</i> | 56 |
| TOTAL RECENT GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION | 56 |
| <i>FIGURE 5 ESTIMATED MARKET SHARES OF TOTAL GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION, 2012 (\$ MILLIONS, %)</i> | 56 |
| MAJOR MANUFACTURERS OF PROBIOTIC INGREDIENTS | 57 |
| <i>TABLE 17 MAJOR MANUFACTURERS OF PROBIOTIC INGREDIENTS</i> | 57 |
| <i>FIGURE 6 ESTIMATED MARKET SHARES OF TOP MANUFACTURERS OF PROBIOTIC INGREDIENTS, 2012 (\$ MILLIONS, %)</i> | 58 |
| MARKET DRIVERS AND DRAWBACKS | 59 |
| Better Understanding of Probiotics through Sustained Research | 59 |
| New Entrants to the Industry | 59 |
| The Regulatory Environment | 59 |
| GLOBAL SALES AND MARKET SIZE PROJECTIONS | 59 |
| PROJECTED GLOBAL SALES OF LACTOBACILLUS PROBIOTIC INGREDIENTS | 60 |
| <i>TABLE 18 GLOBAL SALES OF LACTOBACILLUS PROBIOTICS, THROUGH 2018 (\$ MILLIONS)</i> | 60 |
| PROJECTED GLOBAL SALES OF BIFIDOBACTERIUM PROBIOTICS | 60 |
| <i>TABLE 19 GLOBAL SALES OF BIFIDOBACTERIUM PROBIOTICS, THROUGH 2018 (\$ MILLIONS)</i> | 61 |
| PROJECTED GLOBAL SALES OF STREPTOCOCCUS PROBIOTICS | 61 |
| <i>TABLE 20 GLOBAL SALES OF STREPTOCOCCUS PROBIOTICS, THROUGH 2018 (\$ MILLIONS)</i> | 61 |
| PROJECTED GLOBAL SALES OF BACILLUS PROBIOTICS | 61 |
| <i>TABLE 21 GLOBAL SALES OF BACILLUS PROBIOTICS, THROUGH 2018 (\$ MILLIONS)</i> | 61 |
| PROJECTED TOTAL GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE | 62 |
| <i>TABLE 22 GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE, 2013 AND 2018 (\$ MILLIONS)</i> | 62 |
| <i>FIGURE 7 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE, 2013 AND 2018 (%)</i> | 62 |

| TOPIC | PAGE NO. |
|--------------------------------------------------------------------------------------------------------|-----------------|
| REGIONAL SALES OF PROBIOTIC INGREDIENTS THROUGH 2018 | 63 |
| <i>TABLE 23 GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION, THROUGH 2018 (\$ MILLIONS)</i> | 64 |
| <i>FIGURE 8 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION, 2013 AND 2018 (%)</i> | 64 |
| CHAPTER 5 THE GLOBAL PROBIOTIC SUPPLEMENTS INDUSTRY | 67 |
| INTRODUCTION | 67 |
| FEATURES OF THE GLOBAL PROBIOTIC SUPPLEMENTS INDUSTRY | 68 |
| ACCESS TO PROPRIETARY PROBIOTIC INGREDIENTS | 68 |
| Full In-house Processing Capabilities | 68 |
| Bulk Ingredient Suppliers | 69 |
| Contract Manufacturing | 69 |
| Product Licensing and Collaboration Agreements | 69 |
| OWNERSHIP OF APPROPRIATE PROCESSING TECHNOLOGIES | 70 |
| <i>TABLE 24 OWNERSHIP OF SUPPLEMENT PROCESSING TECHNOLOGIES</i> | 71 |
| BIO-tract Delivery System | 71 |
| LiveBac Processing Technology | 71 |
| MAKTrek Bypass Technology | 72 |
| Probiocap Microencapsulation Technology | 72 |
| Probio-Tec | 72 |
| ProTarget Technology | 72 |
| STAR Technology | 73 |
| Triple-shell Technology | 73 |
| True Delivery Technology | 73 |
| PRODUCT DIFFERENTIATION | 73 |
| Product Differentiation Based on Brand Name | 73 |
| <i>TABLE 25 SAMPLE OF PROBIOTIC SUPPLEMENT BRANDS</i> | 74 |
| Product Differentiation Based on Format | 75 |
| Capsule Format | 75 |
| Tablet Format | 75 |
| Powder Format | 76 |
| Drops, Gum, Liquids and Shots | 76 |
| Product Differentiation Based on Formulary | 76 |
| Single-species Probiotic Supplement Products | 77 |
| <i>TABLE 26 COMPOSITION OF SINGLE-SPECIES PROBIOTIC SUPPLEMENTS FOR ADULTS</i> | 77 |
| Single-species Supplement for Biocodex USA | 77 |
| Single-species Supplement from Bio-Energy Systems | 78 |
| Single-species Supplement from DSM | 78 |
| Single-species Supplement from Geneden Biotech | 78 |
| Single-species Supplement from Jarrow Formulas | 78 |
| Single-species Supplement from Natren | 79 |
| Single-species Supplement from Nebraska Cultures | 79 |
| Single-species Supplement from NOW Foods | 79 |
| Single-species Supplement from Procter & Gamble (P&G) | 79 |
| Single-species Supplement from Solgar | 79 |
| Multi-species Probiotic Supplement Products | 80 |

| TOPIC | PAGE NO. |
|-------------------------------------------------------------------------------------------------------------------|-----------------|
| Multi-species Probiotic Supplement Products for Adults | 81 |
| Multi-species Adult Probiotic Supplement from American Biologics | 81 |
| <i>TABLE 27 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM AMERICAN BIOLOGICS (BILLIONS/%)</i> | 81 |
| Multi-species Adult Probiotic Supplement from Jarrow Formulas | 81 |
| <i>TABLE 28 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM JARROW FORMULAS (MILLIONS/%)</i> | 82 |
| Multi-species Adult Probiotic Supplement from Kirkman Laboratories | 82 |
| <i>TABLE 29 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM KIRKMAN LABORATORIES (MILLIONS/%)</i> | 83 |
| Multi-species Adult Probiotic Supplement from Natren | 83 |
| <i>TABLE 30 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM NATREN (BILLIONS/%)</i> | 83 |
| Multi-species Adult Probiotic Supplement from NOW Foods | 84 |
| <i>TABLE 31 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM NOW FOODS (BILLIONS/%)</i> | 84 |
| Multi-species Probiotic Supplement Lozenge from Udo's Choice | 84 |
| <i>TABLE 32 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM UDO'S CHOICE (BILLIONS/%)</i> | 85 |
| Multi-species Probiotic Supplement Products for Infants and Children | 85 |
| Multi-species Probiotic Supplement for Infants and Children from American Biologics | 85 |
| <i>TABLE 33 MULTI-SPECIES PROBIOTIC SUPPLEMENTS FOR INFANTS AND CHILDREN FROM AMERICAN BIOLOGICS (BILLIONS/%)</i> | 85 |
| Multi-species Probiotic Supplement for Infants and Children from Country Life | 86 |
| <i>TABLE 34 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR INFANTS AND CHILDREN FROM COUNTRY LIFE (MILLIONS/%)</i> | 86 |
| Multi-species Probiotic Supplement for Infants and Children from Jarrow Formulas | 87 |
| <i>TABLE 35 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR INFANTS AND CHILDREN FROM JARROW FORMULAS (MILLIONS/%)</i> | 87 |
| Multi-species Probiotic Supplement for Infants and Children from Nature's Plus | 87 |
| <i>TABLE 36 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR INFANTS AND CHILDREN FROM NATURE'S PLUS (MILLIONS/%)</i> | 88 |
| Multi-species Probiotic Supplement for Infants and Children from Udo's Choice | 88 |
| <i>TABLE 37 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR CHILDREN FROM UDO'S CHOICE (BILLIONS/%)</i> | 88 |
| Multi-species Probiotic Supplement Products for Specific Health Conditions | 88 |
| Multi-strain Probiotic Supplement for Female Health Needs from Jarrow Formulas | 89 |
| Multi-species Probiotic Supplement for Yeast Imbalance from Udo's Choice | 89 |

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------------------------------------------------------------|-----------------|
| Product Differentiation Based on Probiotic Dosage | 89 |
| HEALTH CONDITIONS AND DEMAND FOR PROBIOTIC SUPPLEMENTS | 90 |
| Allergies | 91 |
| Cardiovascular Diseases (CVDs) | 91 |
| Chronic Constipation | 92 |
| Colorectal Cancer | 92 |
| Halitosis | 93 |
| Inflammatory Bowel Disease (IBD) | 93 |
| Traveler's Diarrhea | 94 |
| Vaginal Infections (Vaginitis) | 94 |
| PROBIOTIC SUPPLEMENTS FOR ANIMAL USE | 95 |
| Addressing the Problem of Antibiotic Resistance in Livestock | 95 |
| Sample of Currently Available Probiotic Supplements for Animal Use | 96 |
| <i>TABLE 38 SAMPLE OF PROBIOTIC SUPPLEMENTS FOR ANIMAL USE</i> | 96 |
| Multi-species Probiotic Supplement for Horses from Jarrow Formulas | 97 |
| <i>TABLE 39 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR HORSES FROM JARROW FORMULAS (BILLIONS/%)</i> | 97 |
| DISTRIBUTION CHANNELS FOR PROBIOTIC SUPPLEMENTS | 97 |
| The Internet as a Distribution Channel | 98 |
| RECENT AND PROJECTED GLOBAL SALES OF PROBIOTIC SUPPLEMENTS | 98 |
| INDUSTRY DATA | 98 |
| RECENT GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, BY TYPE | 99 |
| Recent Global Sales of Probiotic Supplements in Capsule Form | 99 |
| <i>FIGURE 9 ESTIMATED CAPSULE SALES AS A SHARE OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, 2012 (\$ MILLIONS, %)</i> | 99 |
| Recent Global Sales of Probiotic Supplements in Tablet Form | 100 |
| <i>FIGURE 10 ESTIMATED TABLET SALES AS A SHARE OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, 2012 (\$ MILLIONS, %)</i> | 100 |
| Recent Global Sales of Probiotic Supplements in Powder Form | 101 |
| <i>FIGURE 11 ESTIMATED PROBIOTIC POWDER SALES AS A SHARE OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, 2012 (\$ MILLIONS, %)</i> | 101 |
| Total Recent Global Sales of Probiotic Supplements by Type | 102 |
| <i>FIGURE 12 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE BY TYPE, 2012 (\$ MILLIONS, %)</i> | 102 |
| Recent Global Sales of Probiotic Supplements for Animal Feed | 103 |
| <i>FIGURE 13 ESTIMATED GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE AND ANIMAL FEED, 2012 (\$ MILLIONS, %)</i> | 103 |
| Total Recent Global Sales of Probiotic Supplements by Region | 104 |
| <i>FIGURE 14 ESTIMATED MARKET SHARES OF TOTAL GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY REGION, 2012 (\$ MILLIONS, %)</i> | 104 |
| MAJOR MANUFACTURERS OF PROBIOTIC SUPPLEMENTS | 105 |
| <i>TABLE 40 MAJOR MANUFACTURERS OF PROBIOTIC SUPPLEMENTS</i> | 106 |
| MARKET DRIVERS AND DRAWBACKS | 106 |
| Favorable Demographics | 106 |
| Science-based Substantiation of Beneficial Claims | 107 |
| Continuing Consumer Education | 107 |
| Continuing Improvement in Processing Technologies | 108 |

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------------------------------------------------------------|-----------------|
| Market Potential for Probiotic Supplements for Animal Use | 108 |
| Potential Demand for Supplements in Veterinary Care | 108 |
| Potential Demand for Supplements in Pet Care | 108 |
| Push Factors for Alternative (Probiotic) Supplementation | 109 |
| Growing Novel Applications | 110 |
| Bonigel-Ganeden Biotech's Cosmetic and Topical Applications | 110 |
| Natren's Probiotic Cosmetics | 110 |
| Nestle and L'Oreal | 110 |
| Regulatory Changes and Industry Reform | 111 |
| SALE PROJECTIONS AND MARKET SIZE | 111 |
| Projected Global Sales of Probiotic Supplements for Human Use in Capsule Form | 111 |
| <i>TABLE 41 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE IN CAPSULE FORM, 2013 AND 2018 (\$ MILLIONS)</i> | 112 |
| Projected Global Sales of Probiotic Supplements for Human Use in Tablet Form | 112 |
| <i>TABLE 42 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE IN TABLET FORM, 2013 AND 2018 (\$ MILLIONS)</i> | 112 |
| Projected Global Sales of Probiotic Supplements for Human Use in Powder Form | 112 |
| <i>TABLE 43 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE IN POWDER FORM, 2013 AND 2018 (\$ MILLIONS)</i> | 113 |
| Projected Total Global Sales of Probiotic Supplements for Human Use by Type | 113 |
| <i>FIGURE 15 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE BY TYPE, 2013 AND 2018 (%)</i> | 113 |
| Projected Global Sales of Probiotic Supplements for Animal Feed | 114 |
| Projected Total Global Sales of Probiotic Supplements Through 2018 | 114 |
| <i>TABLE 44 ESTIMATED GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE AND ANIMAL FEED, 2013 AND 2018 (\$ MILLIONS)</i> | 114 |
| <i>FIGURE 16 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY INTENDED USE, 2013 AND 2018 (%)</i> | 114 |
| Projected Regional Sales of Probiotic Supplements Through 2018 | 115 |
| <i>TABLE 45 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY REGION, 2013 AND 2018 (\$ MILLIONS)</i> | 116 |
| <i>FIGURE 17 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY REGION, 2013 AND 2018 (%)</i> | 116 |
| CHAPTER 6 THE GLOBAL PROBIOTIC FOODS INDUSTRY | 118 |
| BACKGROUND | 118 |
| FEATURES OF THE GLOBAL PROBIOTIC FOODS INDUSTRY | 118 |
| THE ROLE OF THE DAIRY INDUSTRY | 118 |
| Fonterra Cooperative Group | 119 |
| Arla Foods | 119 |
| Dairy Crest Group | 120 |
| Dairy Farmers of America | 120 |
| FrieslandCampina | 120 |
| Groupe Danone | 121 |
| JBS | 121 |
| Land O'Lakes | 121 |

| TOPIC | PAGE NO. |
|---------------------------------------------------------------------------------------|-----------------|
| Nestle | 121 |
| PRIVATE LABELS AND CONTRACT MANUFACTURING | 122 |
| PROBIOTIC FOODS BY TYPE | 122 |
| STARTER CULTURE | 122 |
| Legal Definition of Starter Cultures | 123 |
| Codex Standard for Fermented Milk Products | 123 |
| <i>TABLE 46 CODEX STANDARDS FOR DAIRY-BASED FOOD PRODUCTS</i> | 123 |
| <i>TABLE 47 COMMERCIAL STARTER CULTURES BY SUPPLIER AND APPLICATION</i> | 124 |
| YOGURT | 124 |
| Legal Definition of a Yogurt Product | 125 |
| Legal Requirements for Yogurt Products in the U.S. | 125 |
| Types of Yogurt Products | 126 |
| <i>TABLE 48 YOGURT CLASSIFICATION</i> | 126 |
| Natural-set Yogurt | 126 |
| Stirred Yogurt | 126 |
| Drinkable Yogurt | 126 |
| Greek Style Yogurt | 127 |
| What is "Greek"? | 127 |
| What about Whey Disposal? | 127 |
| New Uses for Whey | 128 |
| Frozen Yogurt | 128 |
| The Probiotic Content of Yogurt | 128 |
| NYA Seal | 129 |
| Marketing Probiotic Yogurts | 129 |
| <i>TABLE 49 PROBIOTIC COMPOSITION OF SELECT YOGURT PRODUCTS AVAILABLE IN THE U.S.</i> | 130 |
| DAIRY-BASED CULTURED PROBIOTIC DRINKS | 130 |
| Danone's Actimel/DanActive/Danimals | 131 |
| Arla Foods' Cultura Balance | 131 |
| Nestle's Svelty Gastro Protect | 131 |
| Stonyfield Farm's Smoothie/YoKids Smoothie | 131 |
| Yakult's Dairy Drink | 132 |
| KEFIR | 132 |
| Standards for Kefir Products | 132 |
| The National Kefir Association (NKA) | 133 |
| Currently Available Kefir Products in the U.S. | 133 |
| Lifeway Foods | 133 |
| Springfield Creamery | 134 |
| <i>TABLE 50 PROBIOTIC COMPOSITION OF SELECT KEFIR PRODUCTS AVAILABLE IN THE U.S.</i> | 134 |
| Bio-Kefir | 134 |
| Lassi-Potential Competitor to Kefir | 135 |
| Marketing of Kefir Products in the U.S. | 135 |
| PROBIOTIC CHEESE PRODUCTS | 135 |
| Overcoming the Cheese-Processing Challenge | 136 |
| Variants of Probiotic Cheese Products | 136 |
| Probiotic Cottage Cheese | 136 |
| Kefir Cheese | 136 |

| TOPIC | PAGE NO. |
|--------------------------------------------------------------------------------------------------------------------------|-----------------|
| <i>TABLE 51 CURRENTLY AVAILABLE PROBIOTIC CHEESE PRODUCTS</i> | 137 |
| NON-DAIRY PROBIOTIC DRINKS AND JUICES | 137 |
| <i>TABLE 52 SAMPLE OF AVAILABLE PROBIOTIC DRINKS AND JUICES</i> | 138 |
| Soy-based Probiotic Drinks | 138 |
| Whey-based Probiotic Drinks | 138 |
| PROBIOTIC INFANT FORMULAS | 139 |
| OTHER PROBIOTIC FOODS-BREAKFAST, SNACK, BAKED, TEA, COFFEE | 139 |
| <i>TABLE 53 SAMPLE OF CURRENTLY AVAILABLE PROBIOTIC BREAKFAST, DESSERT AND SNACK FOODS</i> | 140 |
| RECENT AND PROJECTED GLOBAL SALES OF PROBIOTIC FOODS | 140 |
| INDUSTRY DATA | 140 |
| RECENT GLOBAL SALES OF PROBIOTIC FOODS BY TYPE | 141 |
| Recent Global Sales of Probiotic Yogurt | 141 |
| <i>FIGURE 18 SALES OF PROBIOTIC YOGURT AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %)</i> | 141 |
| <i>FIGURE 19 SALES OF PROBIOTIC YOGURT BY TYPE, 2012 (\$ MILLIONS, %)</i> | 142 |
| Recent Global Sales of Probiotic Cultured Drinks | 143 |
| <i>FIGURE 20 SALES OF PROBIOTIC CULTURED DRINKS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %)</i> | 143 |
| Recent Global Sales of Probiotic Kefir | 144 |
| <i>FIGURE 21 SALES OF PROBIOTIC KEFIR AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %)</i> | 144 |
| Recent Global Sales of Probiotic Cheese | 145 |
| <i>FIGURE 22 SALES OF PROBIOTIC CHEESE PRODUCTS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %)</i> | 145 |
| Recent Global Sales of Probiotic Juices | 146 |
| <i>FIGURE 23 SALES OF PROBIOTIC JUICES AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %)</i> | 146 |
| Recent Global Sales of Probiotic Infant Formulas | 147 |
| <i>FIGURE 24 SALES OF PROBIOTIC INFANT FORMULAS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %)</i> | 147 |
| Total Recent Global Sales of Probiotic Foods by Type | 148 |
| <i>TABLE 54 TOTAL GLOBAL SALES OF PROBIOTIC FOODS BY TYPE, 2012 (\$ MILLIONS, %)</i> | 149 |
| Total Recent Global Sales of Probiotic Foods by Region | 149 |
| <i>FIGURE 25 ESTIMATED MARKET SHARES OF TOTAL GLOBAL SALES OF PROBIOTIC FOODS BY REGION, 2012 (\$ MILLIONS, %)</i> | 150 |
| MAJOR MANUFACTURERS OF PROBIOTIC FOODS | 150 |
| <i>TABLE 55 MAJOR PROBIOTIC FOOD MANUFACTURERS</i> | 151 |
| MARKET DRIVERS AND DRAWBACKS | 151 |
| Untapped Market Potential | 151 |
| Personalized Nutrition and Convenience | 152 |
| Consumer Education | 152 |
| The Regulatory Crackdown | 152 |
| SALE PROJECTIONS AND MARKET SIZE | 153 |
| Projected Global Sales of Probiotic Yogurt | 153 |
| <i>TABLE 56 ESTIMATED GLOBAL SALES OF PROBIOTIC YOGURT, 2013 AND 2018 (\$ MILLIONS)</i> | 153 |
| <i>FIGURE 26 SALES OF PROBIOTIC YOGURT AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%)</i> | 153 |

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------------------------------------------------------|-----------------|
| <i>FIGURE 27 ESTIMATED SHARE OF GLOBAL PROBIOTIC YOGURT SALES BY TYPE, 2013 AND 2018 (%)</i> | 154 |
| Projected Global Sales of Probiotic Cultured Drinks | 155 |
| <i>TABLE 57 GLOBAL SALES OF PROBIOTIC CULTURED DRINKS, THROUGH 2018 (\$ MILLIONS)</i> | 155 |
| <i>FIGURE 28 SALES OF PROBIOTIC CULTURED DRINKS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%)</i> | 156 |
| Projected Global Sales of Probiotic Kefir | 157 |
| <i>TABLE 58 GLOBAL SALES OF PROBIOTIC KEFIR, THROUGH 2018 (\$ MILLIONS)</i> | 157 |
| <i>FIGURE 29 SALES OF PROBIOTIC KEFIR AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%)</i> | 157 |
| Projected Global Sales of Probiotic Cheese | 158 |
| <i>TABLE 59 GLOBAL SALES OF PROBIOTIC CHEESE, THROUGH 2018 (\$ MILLIONS)</i> | 158 |
| <i>FIGURE 30 SALES OF PROBIOTIC CHEESE AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%)</i> | 158 |
| Projected Global Sales of Probiotic Juices | 159 |
| <i>TABLE 60 GLOBAL SALES OF PROBIOTIC JUICES, THROUGH 2018 (\$ MILLIONS)</i> | 160 |
| <i>FIGURE 31 SALES OF PROBIOTIC JUICES AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%)</i> | 160 |
| Projected Global Sales of Probiotic Infant Formulas | 161 |
| <i>TABLE 61 GLOBAL SALES OF PROBIOTIC INFANT FORMULAS, THROUGH 2018 (\$ MILLIONS)</i> | 161 |
| <i>FIGURE 32 SALES OF PROBIOTIC INFANT FORMULAS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%)</i> | 161 |
| Projected Total Global Sales of Probiotic Foods by Type | 162 |
| <i>TABLE 62 GLOBAL SALES OF PROBIOTIC FOODS BY TYPE, THROUGH 2018 (\$ MILLIONS)</i> | 162 |
| <i>FIGURE 33 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC FOODS BY TYPE, 2013 AND 2018 (%)</i> | 162 |
| Projected Regional Sales of Probiotic Foods Through 2018 | 163 |
| <i>TABLE 63 GLOBAL SALES OF PROBIOTIC FOODS BY REGION, THROUGH 2018 (\$ MILLIONS)</i> | 164 |
| <i>FIGURE 34 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC FOODS BY REGION, 2013 AND 2018 (%)</i> | 164 |
| CHAPTER 7 REGULATORY GUIDELINES FOR THE PROBIOTICS INDUSTRY | 166 |
| INTRODUCTION | 166 |
| THE CODEX ALIMENTARIUS | 166 |
| A BRIEF HISTORY OF THE CODEX: THE JOINT FAO-WHO FOOD PROGRAM | 166 |
| CODEX GUIDELINES FOR THE EVALUATION AND USE OF PROBIOTICS | 167 |
| Genus-Species-Strain | 167 |
| Screening of Potential Probiotics | 167 |
| Probiotic Safety Considerations | 168 |
| Probiotic Health Claims | 168 |
| Scientific Substantiation of Health Claims | 169 |
| Process for the Substantiation of Health Claims | 170 |
| Criteria for the Substantiation of Health Claims | 170 |
| Codex Guidelines on Nutrition Claims | 170 |
| Codex Standard for Food Additives | 171 |
| Probiotic Product Labeling | 172 |

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------|-----------------|
| U.S. REGULATORY PROVISIONS RELATING TO PROBIOTICS | 172 |
| U.S. FDA REGULATORY OVERSIGHT | 172 |
| U.S. REGULATIONS RELATING TO PRODUCT INGREDIENTS | 172 |
| Legal Definition of Ingredient Products | 172 |
| Definition of a Food Additive | 173 |
| Determining the Regulatory Status of a Food Ingredient in the U.S. | 174 |
| GRAS Provisions | 174 |
| The Food Additive Petition Process | 175 |
| U.S. REGULATIONS RELATING TO DIETARY SUPPLEMENTS | 175 |
| Overview of the Regulatory Framework | 175 |
| Legal Definition of a Dietary Supplement Product | 176 |
| Premarket Review Requirements for New Dietary Ingredient | 176 |
| Approved Product Claims for Dietary Supplements | 177 |
| Health Claims | 177 |
| Health Claims Authorized Under NLEA of 1990 | 178 |
| Qualified Health Claims | 178 |
| Product Nutrient Content Claims | 178 |
| Structural-Function Claims for Supplement Products | 178 |
| RECENT AND FORESEEABLE CHANGES IN U.S. REGULATORY PROCESS | 179 |
| FDA 2013 Guidance on Investigational New Drugs (IND) Applications | 179 |
| Implications for Dietary Supplements | 180 |
| Implications for Conventional Foods | 180 |
| Implications for Food Ingredients | 181 |
| Implications for Substantiation of Health Claims | 181 |
| Scientific Evaluation of Health Claims | 181 |
| Enforcement of Current Good Manufacturing Practices | 182 |
| GUIDANCE RELATING TO COMPLEMENTARY AND ALTERNATIVE MEDICINE PRODUCTS | 183 |
| CANADIAN REGULATORY PROVISIONS RELATING TO PROBIOTICS | 185 |
| HEALTH CANADA OVERSIGHT | 185 |
| Regulation of Natural Health Products and Foods | 185 |
| CANADIAN FOOD DIRECTORATE | 185 |
| The Use of the Term "Probiotic" | 185 |
| Safety of Probiotic Microorganisms Used in Foods | 186 |
| Acceptable Use of Function Claims | 186 |
| Labeling of Probiotic Foods | 187 |
| CANADA'S NATURAL HEALTH PRODUCTS DIRECTORATE | 187 |
| Definition of a Natural Health Product | 187 |
| Clarification of Product Classification | 188 |
| Regulations Relating to Natural Health Product Manufacturing | 188 |
| Canadian Product and Site Licensing Requirements | 188 |
| Good Manufacturing Practices (GMPs) | 189 |
| Health Canada's Compliance Policy | 189 |
| EUROPEAN REGULATORY PROVISIONS RELATING TO PROBIOTICS | 190 |
| REGULATORY AUTHORITY IN THE EU | 190 |
| EFSA ROLE IN REGULATORY PROVISIONS RELATING TO PROBIOTICS | 190 |
| PRODUCT HEALTH CLAIMS IN THE EU (A.K.A. NHCR) | 191 |
| Scope of Regulation 1924/2006 | 191 |

| TOPIC | PAGE NO. |
|--------------------------------------------------------------------------------------------------------|-----------------|
| General Conditions for Health Claims under Regulation 1924/2006 | 192 |
| Prohibited Health Claims | 192 |
| IMPLEMENTATION OF THE REGULATORY REQUIREMENTS | 193 |
| Claims Listed in Article 13 | 193 |
| Authorization Application Process | 193 |
| The Required Application Documentation | 194 |
| EFSA and Verification of Scientific Substantiation of Claims | 195 |
| EFSA-NDA Panel Guidance on Gut and Immune Health Claims | 195 |
| Verification of Beneficial Physiological Effects | 195 |
| Studies/Outcome Measures Appropriate for Substantiation of Claims | 196 |
| EFSA Review of Probiotic Nutrition and Health Claims | 197 |
| <i>TABLE 64 SELECTION OF EFSA FEEDBACK ON RECENT PROBIOTIC HEALTH CLAIM APPLICATIONS UNDER EU NHCR</i> | 198 |
| Effective Ban on the Descriptor "Probiotic" | 200 |
| EFSA Report on Fortified Infant Formulas | 201 |
| Live Yogurt Cultures-An Exception in an Ocean of Rejections | 201 |
| INDUSTRY AND PROFESSIONAL REACTIONS TO EFSA ACTIVITY | 202 |
| REGULATORY PROVISIONS IN JAPAN RELATING TO PROBIOTICS | 202 |
| MINISTRY OF HEALTH, LABOR, AND WELFARE OVERSIGHT | 202 |
| FOOD WITH HEALTH CLAIMS | 203 |
| Foods with Nutrient Function Claims (FNFC) | 203 |
| Food for Specified Health Uses (FOSHU) | 203 |
| Requirements for FOSHU Approval | 204 |
| Qualified FOSHU | 204 |
| Standardized FOSHU | 204 |
| Reduction of Disease Risk FOSHU | 204 |
| FOODS FOR SPECIAL DIETARY USES (FOSDU) | 204 |
| Requirements for FOSDU Labeling | 205 |
| Prohibition of Exaggerated and Misleading Claims | 205 |
| REGULATORY PROVISIONS IN AUSTRALIA AND NEW ZEALAND RELATING TO PROBIOTICS | 206 |
| REGULATION OF THERAPEUTIC GOODS IN AUSTRALIA | 206 |
| Therapeutic Goods Administration (TGA) | 206 |
| Definition of Therapeutic Goods | 206 |
| Australian Register of therapeutic Goods (ARTG) | 207 |
| TGA Regulation of Product Labeling and Packaging | 207 |
| TGA Pre-market Regulatory Processes | 207 |
| TGA Post-market Regulatory Processes | 207 |
| OVERVIEW OF THE FOOD REGULATORY SYSTEM | 208 |
| FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) | 208 |
| Nutrition and Health Claims | 208 |
| Front-of-Pack Labeling | 209 |
| THE ROLE OF EXPERT GROUPS AND PROFESSIONAL ASSOCIATIONS IN THE GLOBAL PROBIOTIC INDUSTRY | 210 |
| The International Scientific Association for Probiotics and Prebiotics (ISAPP) | 210 |
| The U.S. Pharmacopeial Convention (USP) | 211 |

| TOPIC | PAGE NO. |
|----------------------------------------------------------------------------------------------------------------------------|-----------------|
| FCC Monograph for a Probiotic Culture | 211 |
| The Global Alliance for Probiotics (GAP) | 211 |
| The International Probiotics Association (IPA) | 212 |
| The University of Maryland Project | 213 |
| A Likely Path of Future U.S. Regulation of Probiotics | 213 |
| The U.S. Council for Responsible Nutrition (CRN) | 214 |
| CHAPTER 8 TECHNOLOGY AND PATENT ANALYSIS | 216 |
| BACKGROUND | 216 |
| CURRENT PROBIOTIC PROCESSING TECHNOLOGIES | 216 |
| FERMENTATION | 216 |
| Lactic Acid Bacteria | 217 |
| Types of Fermentation | 217 |
| Batch Fermentation Process | 217 |
| Continuous Fermentation Process | 218 |
| Aerobic versus Anaerobic Fermentation Process | 218 |
| Limitations of the Fermentation Process | 218 |
| CENTRIFUGATION | 219 |
| Differential Centrifugation | 219 |
| Density Gradient Centrifugation | 219 |
| ULTRA FILTRATION | 220 |
| Nano Filtration | 220 |
| LYOPHILIZATION (FREEZE-DRYING) | 220 |
| ENCAPSULATION AND TABLETING | 221 |
| Vesale Pharma and IntelCaps | 222 |
| Cell Biotech and Dual-coating | 222 |
| EnCoate and Bioshield | 222 |
| Riddet Institute and Pro Bio Life | 223 |
| Novel Coating Materials-Whey Protein Isolate | 223 |
| PATENT ANALYSIS | 223 |
| PATENTS RELATING TO EXISTING AND NEW PROBIOTIC STRAINS | 224 |
| <i>TABLE 65 PATENT AWARDS FOR PROBIOTIC SPECIES BY TYPE, 2012 AND 2013 (NUMBER/%)</i> | 224 |
| <i>TABLE 66 PATENT AWARDS FOR PROBIOTIC SPECIES BY REGION, 2012 AND 2013 (NUMBER/%)</i> | 225 |
| Sample of Patents for Existing and New Probiotic Strains | 225 |
| Probiotic Bifidobacterium Strains | 225 |
| Compositions Comprising Lactobacillus plantarum Strains in Combination with Tannin and New Lactobacillus plantarum Strains | 226 |
| Use of Lactic Acid Bacteria for Improving Food Lysine Absorption of Pet Animals | 226 |
| Lactobacillus sub-species JNU2116 with Anti-mutagenic Activity | 227 |
| Lactobacillus Strains | 227 |
| Antibiotic-sensitive Lactic Acid Bacteria Strains | 228 |
| Stress Tolerant Bifidobacteria | 228 |
| Detection and Typing of Bacterial Strains | 229 |
| Lactobacillus fermentum SG-A95 for Improving Oral Bacterial Groups and Health Care Compositions Thereof | 230 |

| TOPIC | PAGE NO. |
|------------------------------------------------------------------------------------------------------|-----------------|
| Probiotic Spore-forming Lactic Acid Bacteria of Sporolactobacillus vineae Strain KCTC 11493BP | 230 |
| Bile Resistant Bacillus Composition Secreting High Levels of Phytase | 231 |
| Strains of Lactobacillus helveticus which do not ferment Lactose | 231 |
| Combination of Probiotics | 232 |
| Inhibition of Pathogens by Probiotic Bacteria | 233 |
| Bacteriocins and Novel Bacterial Strains | 233 |
| Biologically Pure Strain of Lactobacillus fermentum, strain Ess-1 | 234 |
| Probiotics for Pet Food Applications | 234 |
| PATENTS RELATING TO PROBIOTIC APPLICATIONS | 235 |
| <i>TABLE 67 PATENT AWARDS FOR PROBIOTIC APPLICATIONS BY TYPE, 2012 AND 2013 (NUMBER/%)</i> | 236 |
| Sample of Patents for Probiotic Starter Cultures | 236 |
| Metabolically Active Microorganisms and Methods for Their Production | 236 |
| Shelf-stable Product with Living Micro-organisms | 237 |
| Fermented Milk or Vegetable Proteins Comprising Receptor Ligand and Uses Thereof | 238 |
| Dairy Composition with Probiotics and Anti-microbial System | 238 |
| Antimicrobial Peptides and Methods of Their Use | 239 |
| Patent Title: Bacteriophage Resistant Lactic Acid Bacteria | 239 |
| Sample of Patents for Probiotic Fermented Foods and Beverages | 240 |
| Complete Liquid Nutrition for Children at the Age of 1-10 years Comprising Probiotics | 240 |
| Lactic Acid Bacteria and Their Use in Swine Direct-fed Microbials | 241 |
| Yogurt-cheese Compositions | 241 |
| Dry Food Product Containing Live Probiotic | 242 |
| Growth of Bifidobacteria in Fermented Milk Products | 243 |
| Combination of Probiotics | 243 |
| Consumable Product Containing Probiotics | 244 |
| Fermented Tea Beverage and Tea Beverage | 245 |
| Fermented Food Products Containing Probiotics Strains and Method for Preparing Same | 245 |
| Probiotic Infant Products | 246 |
| Fermented Food Product | 246 |
| Probiotics for Pet Food Applications | 247 |
| Sample of Patents for Therapeutic Use of Probiotics | 247 |
| Use of Probiotics | 247 |
| Probiotic Composition Suitable for Animals | 248 |
| Treatment of Immune Disease by Mucosal Delivery of Antigens using Genetically Modified Lactobacillus | 248 |
| Bacillus Strains Useful Against Calf Pathogens and Scours | 249 |
| Use and Methods for Preventing and/or Treating Oral Malodor | 250 |
| Microorganisms for Improving the Health of Individuals with Disorders Related to Gluten Ingestion | 250 |
| Probiotic Yeast compositions and Methods for Inflammatory Diseases | 251 |
| Lactobacillus helveticus CNCM I-4095 and Weight Control | 251 |

| TOPIC | PAGE NO. |
|-------------------------------------------------------------------------------------------------------------------|-----------------|
| Use of Lactobacillus for Treatment of Virus Infections | 252 |
| Bifidobacterium longum and Hippocampal BDNF Expression | 252 |
| Lactobacillus rhamnosus NCC4007, A Probiotic Mixture and Weight Control | 253 |
| Lactobacillus Strain, Composition and Use Thereof for Improving the Syndrome of Diabetes and Complication Thereof | 253 |
| Method for Increasing Fructose Digestion with Strains of Bacillus coagulans and Fructase | 254 |
| Method for Modulating Satiety Signaling with Specific Strains of Lactobacillus Acidophilus and Bacillus | 254 |
| Compositions and Methods for Controlling Diseases in Animals | 255 |
| Probiotic Lactic Acid-producing Bacteria and Uses Thereof | 255 |
| Treating Inflammatory Bowel Disease with Live Bacteria | 256 |
| CHAPTER 9 COMPANY PROFILES | 258 |
| BACKGROUND | 258 |
| GLOBAL MANUFACTURERS OF PROBIOTIC INGREDIENTS | 258 |
| BIO-ENERGY SYSTEMS INC. | 258 |
| BIOGAIA | 258 |
| BioGaia Biologics Inc. | 258 |
| CHR. HANSEN A-S | 259 |
| Chr. Hansen Inc. | 259 |
| DSM FOOD SPECIALTIES (ROYAL DSM N.V.) | 259 |
| DUPONT DANISCO | 260 |
| Danisco Madison Center | 260 |
| GANEDEN BIOTECH | 260 |
| GROUPE DANONE | 261 |
| The Dannon Company Inc. | 261 |
| LALLEMAND HEALTH SOLUTIONS (FORMERLY INSTITUT ROSELL-LALLEMAND) | 262 |
| MEGMILK SNOW BRAND CO., LTD | 262 |
| MORINAGA MILK INDUSTRY | 263 |
| NEBRASKA CULTURES | 263 |
| NESTLE, S.A. | 263 |
| Nestle USA Inc. | 264 |
| PROBI AB | 264 |
| YAKULT HONSHA COMPANY, LTD. | 264 |
| Yakult U.S.A. Inc. | 265 |
| MAJOR MANUFACTURERS OF PROBIOTIC SUPPLEMENTS | 265 |
| AMERICAN BIOLOGICS | 265 |
| BIO-K+ INTERNATIONAL INC. | 265 |
| CALPIS CO. LTD | 266 |
| Calpis America Inc. | 266 |
| COUNTRY LIFE | 266 |
| ENZYMATIC THERAPY | 267 |
| GARDEN OF LIFE INC. | 267 |
| JARROW FORMULAS | 268 |
| KIRKMAN | 268 |

| TOPIC | PAGE NO. |
|---------------------------------------|-----------------|
| NATREN | 268 |
| NATURE'S PLUS (NATURAL ORGANICS INC.) | 269 |
| NATURE'S WAY | 269 |
| NOW FOODS | 270 |
| NUTRACEUTIX INC. | 270 |
| SOLGAR VITAMIN & HERB CO. | 270 |
| UAS LABORATORIES | 271 |
| MAJOR PROBIOTIC FOOD MANUFACTURERS | 271 |
| ARLA FOODS AMBA | 271 |
| BEL GROUP (FROMAGERIES BEL) | 272 |
| BONGRAIN SA | 272 |
| CASCADE FRESH | 272 |
| CHOBANI | 273 |
| DAIRY CREST GROUP, PLC | 273 |
| DEAN FOODS | 274 |
| FAGE | 274 |
| FONTERRA COOPERATIVE GROUP | 275 |
| FRIESLANDCAMPINA | 275 |
| GENERAL MILLS | 275 |
| JOHANNA FOODS INC. | 276 |
| LIFEWAY FOODS | 276 |
| MEIJI DAIRIES CORP. | 277 |
| PARMALAT S.P.A | 277 |
| SAPUTO | 277 |
| SODIAAL S.A. | 278 |
| SPRINGFIELD CREAMERY INC. | 278 |
| STONYFIELD FARM/GROUPE DANONE | 279 |
| TILLAMOOK COUNTY CREAMERY ASSOCIATION | 279 |
| VALIO GROUP | 279 |
| Valio U.S.A. | 280 |
| WALLABY ORGANIC YOGURT | 280 |
| WELLS' DAIRY INC. | 280 |

LIST OF TABLES

| TABLE HEADING | PAGE NO. |
|------------------------------------------------------------------------------------------------------------|-----------------|
| SUMMARY TABLE GLOBAL SALES OF PROBIOTIC INGREDIENTS, SUPPLEMENTS AND FOODS, THROUGH 2018 (\$ MILLIONS) | 7 |
| TABLE 1 SELECTION OF PROPRIETARY STRAINS OF L. ACIDOPHILUS | 30 |
| TABLE 2 SELECTION OF PROPRIETARY STRAINS OF L. CASEI | 33 |
| TABLE 3 SELECTION OF PROPRIETARY STRAINS OF L. PLANTARUM | 35 |
| TABLE 4 SELECTION OF PROPRIETARY STRAINS OF L. REUTERI | 35 |
| TABLE 5 SELECTION OF PROPRIETARY STRAINS OF L. RHAMNOSUS | 36 |
| TABLE 6 SELECTION OF PROPRIETARY STRAINS OF B. ANIMALIS | 38 |
| TABLE 7 SELECTION OF PROPRIETARY STRAINS OF B. BREVE | 39 |
| TABLE 8 SELECTION OF PROPRIETARY STRAINS OF B. INFANTIS | 40 |
| TABLE 9 SELECTION OF PROPRIETARY STRAINS OF B. LONGUM | 41 |
| TABLE 10 SELECTION OF PROPRIETARY STRAINS OF BACILLUS | 42 |
| TABLE 11 SELECTION CRITERIA FOR PROBIOTIC STRAINS | 47 |
| TABLE 12 HEALTH BENEFITS ASSOCIATED WITH LACTOBACILLUS PROBIOTICS | 48 |
| TABLE 13 HEALTH BENEFITS ASSOCIATED WITH BIFIDOBACTERIUM PROBIOTICS | 48 |
| TABLE 14 HEALTH BENEFITS ASSOCIATED WITH STREPTOCOCCUS PROBIOTICS | 49 |
| TABLE 15 PROPOSED MECHANISMS OF PROBIOTIC ACTION | 50 |
| TABLE 16 TOTAL GLOBAL SALES OF PROBIOTIC INGREDIENT BY TYPE, 2012 (\$ MILLIONS, %) | 56 |
| TABLE 17 MAJOR MANUFACTURERS OF PROBIOTIC INGREDIENTS | 57 |
| TABLE 18 GLOBAL SALES OF LACTOBACILLUS PROBIOTICS, THROUGH 2018 (\$ MILLIONS) | 60 |
| TABLE 19 GLOBAL SALES OF BIFIDOBACTERIUM PROBIOTICS, THROUGH 2018 (\$ MILLIONS) | 61 |
| TABLE 20 GLOBAL SALES OF STREPTOCOCCUS PROBIOTICS, THROUGH 2018 (\$ MILLIONS) | 61 |
| TABLE 21 GLOBAL SALES OF BACILLUS PROBIOTICS, THROUGH 2018 (\$ MILLIONS) | 61 |
| TABLE 22 GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE, 2013 AND 2018 (\$ MILLIONS) | 62 |
| TABLE 23 GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION, THROUGH 2018 (\$ MILLIONS) | 64 |
| TABLE 24 OWNERSHIP OF SUPPLEMENT PROCESSING TECHNOLOGIES | 71 |
| TABLE 25 SAMPLE OF PROBIOTIC SUPPLEMENT BRANDS | 74 |
| TABLE 26 COMPOSITION OF SINGLE-SPECIES PROBIOTIC SUPPLEMENTS FOR ADULTS | 77 |
| TABLE 27 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM AMERICAN BIOLOGICS (BILLIONS/%) | 81 |
| TABLE 28 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM JARROW FORMULAS (MILLIONS/%) | 82 |
| TABLE 29 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM KIRKMAN LABORATORIES (MILLIONS/%) | 83 |
| TABLE 30 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM NATREN (BILLIONS/%) | 83 |
| TABLE 31 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM NOW FOODS (BILLIONS/%) | 84 |
| TABLE 32 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR ADULTS FROM UDO'S CHOICE (BILLIONS/%) | 85 |
| TABLE 33 MULTI-SPECIES PROBIOTIC SUPPLEMENTS FOR INFANTS AND CHILDREN FROM AMERICAN BIOLOGICS (BILLIONS/%) | 85 |

| TABLE HEADING | PAGE NO. |
|---------------------------------------------------------------------------------------------------------------------|-----------------|
| TABLE 34 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR INFANTS AND CHILDREN FROM COUNTRY LIFE (MILLIONS/%) | 86 |
| TABLE 35 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR INFANTS AND CHILDREN FROM JARROW FORMULAS (MILLIONS/%) | 87 |
| TABLE 36 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR INFANTS AND CHILDREN FROM NATURE'S PLUS (MILLIONS/%) | 88 |
| TABLE 37 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR CHILDREN FROM UDO'S CHOICE (BILLIONS/%) | 88 |
| TABLE 38 SAMPLE OF PROBIOTIC SUPPLEMENTS FOR ANIMAL USE | 96 |
| TABLE 39 MULTI-SPECIES PROBIOTIC SUPPLEMENT FOR HORSES FROM JARROW FORMULAS (BILLIONS/%) | 97 |
| TABLE 40 MAJOR MANUFACTURERS OF PROBIOTIC SUPPLEMENTS | 106 |
| TABLE 41 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE IN CAPSULE FORM, 2013 AND 2018 (\$ MILLIONS) | 112 |
| TABLE 42 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE IN TABLET FORM, 2013 AND 2018 (\$ MILLIONS) | 112 |
| TABLE 43 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE IN POWDER FORM, 2013 AND 2018 (\$ MILLIONS) | 113 |
| TABLE 44 ESTIMATED GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE AND ANIMAL FEED, 2013 AND 2018 (\$ MILLIONS) | 114 |
| TABLE 45 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY REGION, 2013 AND 2018 (\$ MILLIONS) | 116 |
| TABLE 46 CODEX STANDARDS FOR DAIRY-BASED FOOD PRODUCTS | 123 |
| TABLE 47 COMMERCIAL STARTER CULTURES BY SUPPLIER AND APPLICATION | 124 |
| TABLE 48 YOGURT CLASSIFICATION | 126 |
| TABLE 49 PROBIOTIC COMPOSITION OF SELECT YOGURT PRODUCTS AVAILABLE IN THE U.S. | 130 |
| TABLE 50 PROBIOTIC COMPOSITION OF SELECT KEFIR PRODUCTS AVAILABLE IN THE U.S. | 134 |
| TABLE 51 CURRENTLY AVAILABLE PROBIOTIC CHEESE PRODUCTS | 137 |
| TABLE 52 SAMPLE OF AVAILABLE PROBIOTIC DRINKS AND JUICES | 138 |
| TABLE 53 SAMPLE OF CURRENTLY AVAILABLE PROBIOTIC BREAKFAST, DESSERT AND SNACK FOODS | 140 |
| TABLE 54 TOTAL GLOBAL SALES OF PROBIOTIC FOODS BY TYPE, 2012 (\$ MILLIONS, %) | 149 |
| TABLE 55 MAJOR PROBIOTIC FOOD MANUFACTURERS | 151 |
| TABLE 56 ESTIMATED GLOBAL SALES OF PROBIOTIC YOGURT, 2013 AND 2018 (\$ MILLIONS) | 153 |
| TABLE 57 GLOBAL SALES OF PROBIOTIC CULTURED DRINKS, THROUGH 2018 (\$ MILLIONS) | 155 |
| TABLE 58 GLOBAL SALES OF PROBIOTIC KEFIR, THROUGH 2018 (\$ MILLIONS) | 157 |
| TABLE 59 GLOBAL SALES OF PROBIOTIC CHEESE, THROUGH 2018 (\$ MILLIONS) | 158 |
| TABLE 60 GLOBAL SALES OF PROBIOTIC JUICES, THROUGH 2018 (\$ MILLIONS) | 160 |
| TABLE 61 GLOBAL SALES OF PROBIOTIC INFANT FORMULAS, THROUGH 2018 (\$ MILLIONS) | 161 |
| TABLE 62 GLOBAL SALES OF PROBIOTIC FOODS BY TYPE, THROUGH 2018 (\$ MILLIONS) | 162 |
| TABLE 63 GLOBAL SALES OF PROBIOTIC FOODS BY REGION, THROUGH 2018 (\$ MILLIONS) | 164 |
| TABLE 64 SELECTION OF EFSA FEEDBACK ON RECENT PROBIOTIC HEALTH CLAIM APPLICATIONS UNDER EU NHCR | 198 |

| TABLE HEADING | PAGE NO. |
|----------------------------------------------------------------------------------------|-----------------|
| TABLE 65 PATENT AWARDS FOR PROBIOTIC SPECIES BY TYPE, 2012 AND 2013 (NUMBER/%) | 224 |
| TABLE 66 PATENT AWARDS FOR PROBIOTIC SPECIES BY REGION, 2012 AND 2013 (NUMBER/%) | 225 |
| TABLE 67 PATENT AWARDS FOR PROBIOTIC APPLICATIONS BY TYPE, 2012 AND 2013 (NUMBER/%) | 236 |

LIST OF FIGURES

| FIGURE TITLE | PAGE NO. |
|---------------------------------------------------------------------------------------------------------------------|-----------------|
| SUMMARY FIGURE PROJECTED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS, SUPPLEMENTS, AND FOODS, 2013 AND 2018 (%) | 7 |
| FIGURE 1 SALES OF LACTOBACILLUS PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %) | 51 |
| FIGURE 2 SALES OF BIFIDOBACTERIUM PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %) | 52 |
| FIGURE 3 SALES OF STREPTOCOCCUS PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %) | 53 |
| FIGURE 4 SALES OF BACILLUS PROBIOTICS AS A SHARE OF GLOBAL PROBIOTIC INGREDIENT SALES, 2012 (\$ MILLIONS, %) | 54 |
| FIGURE 5 ESTIMATED MARKET SHARES OF TOTAL GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION, 2012 (\$ MILLIONS, %) | 56 |
| FIGURE 6 ESTIMATED MARKET SHARES OF TOP MANUFACTURERS OF PROBIOTIC INGREDIENTS, 2012 (\$ MILLIONS, %) | 58 |
| FIGURE 7 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS BY TYPE, 2013 AND 2018 (%) | 62 |
| FIGURE 8 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS BY REGION, 2013 AND 2018 (%) | 64 |
| FIGURE 9 ESTIMATED CAPSULE SALES AS A SHARE OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, 2012 (\$ MILLIONS, %) | 99 |
| FIGURE 10 ESTIMATED TABLET SALES AS A SHARE OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, 2012 (\$ MILLIONS, %) | 100 |
| FIGURE 11 ESTIMATED PROBIOTIC POWDER SALES AS A SHARE OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE, 2012 (\$ MILLIONS, %) | 101 |
| FIGURE 12 GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE BY TYPE, 2012 (\$ MILLIONS, %) | 102 |
| FIGURE 13 ESTIMATED GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE AND ANIMAL FEED, 2012 (\$ MILLIONS, %) | 103 |
| FIGURE 14 ESTIMATED MARKET SHARES OF TOTAL GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY REGION, 2012 (\$ MILLIONS, %) | 104 |
| FIGURE 15 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC SUPPLEMENTS FOR HUMAN USE BY TYPE, 2013 AND 2018 (%) | 113 |
| FIGURE 16 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY INTENDED USE, 2013 AND 2018 (%) | 114 |
| FIGURE 17 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC SUPPLEMENTS BY REGION, 2013 AND 2018 (%) | 116 |
| FIGURE 18 SALES OF PROBIOTIC YOGURT AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %) | 141 |
| FIGURE 19 SALES OF PROBIOTIC YOGURT BY TYPE, 2012 (\$ MILLIONS, %) | 142 |
| FIGURE 20 SALES OF PROBIOTIC CULTURED DRINKS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %) | 143 |
| FIGURE 21 SALES OF PROBIOTIC KEFIR AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %) | 144 |
| FIGURE 22 SALES OF PROBIOTIC CHEESE PRODUCTS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %) | 145 |
| FIGURE 23 SALES OF PROBIOTIC JUICES AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %) | 146 |
| FIGURE 24 SALES OF PROBIOTIC INFANT FORMULAS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2012 (\$ MILLIONS, %) | 147 |
| FIGURE 25 ESTIMATED MARKET SHARES OF TOTAL GLOBAL SALES OF PROBIOTIC FOODS BY REGION, 2012 (\$ MILLIONS, %) | 150 |

| FIGURE TITLE | PAGE NO. |
|---------------------------------------------------------------------------------------------------------------|-----------------|
| FIGURE 26 SALES OF PROBIOTIC YOGURT AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%) | 153 |
| FIGURE 27 ESTIMATED SHARE OF GLOBAL PROBIOTIC YOGURT SALES BY TYPE, 2013 AND 2018 (%) | 154 |
| FIGURE 28 SALES OF PROBIOTIC CULTURED DRINKS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%) | 156 |
| FIGURE 29 SALES OF PROBIOTIC KEFIR AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%) | 157 |
| FIGURE 30 SALES OF PROBIOTIC CHEESE AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%) | 158 |
| FIGURE 31 SALES OF PROBIOTIC JUICES AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%) | 160 |
| FIGURE 32 SALES OF PROBIOTIC INFANT FORMULAS AS A SHARE OF GLOBAL SALES OF PROBIOTIC FOODS, 2013 AND 2018 (%) | 161 |
| FIGURE 33 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC FOODS BY TYPE, 2013 AND 2018 (%) | 162 |
| FIGURE 34 ESTIMATED SHARES OF GLOBAL SALES OF PROBIOTIC FOODS BY REGION, 2013 AND 2018 (%) | 164 |