Extending Your Reach in the Probiotics Space

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Probiotic Market Overview

SupplySide West 2019

Claire Morton Reynolds
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Consumers are more engaged and proactive.

Increasingly, consumers think about their health daily and are always looking for ways to be healthier.

<table>
<thead>
<tr>
<th></th>
<th>Millennials</th>
<th>Gen X</th>
<th>Boomers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Think About Health Daily</td>
<td>69%</td>
<td>62%</td>
<td>54%</td>
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<table>
<thead>
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<th>Millennials</th>
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<tbody>
<tr>
<td>Always Looking for Ways to be Healthier</td>
<td>68%</td>
<td>59%</td>
<td>48%</td>
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Source: Top 2 Box Agreement; NEXT Data & Insights Values and Generational Health Survey; Gen Pop Samples of N=1,000 each
Consumers eat with more nuanced goals.

With growing self awareness of the role of food and nutrition in one’s health consumers are beginning to look to their diets to help them achieve their health goals and to achieve specific and nuanced outcomes.

**I eat a diet with the goal of improving my general health though better digestion**

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<tr>
<td><strong>69%</strong></td>
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<tr>
<td><strong>61%</strong></td>
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<tr>
<td><strong>56%</strong></td>
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**I eat to help detoxify**

<table>
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<th>Millennials</th>
<th>Gen X</th>
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<tbody>
<tr>
<td><strong>50%</strong></td>
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</tr>
<tr>
<td><strong>37%</strong></td>
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<td></td>
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<tr>
<td><strong>17%</strong></td>
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</tbody>
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Source: Top 2 Box Agreement; NEXT Data & Insights Values and Generational Health Survey; Gen Pop Samples of N=1,000 each
U.S. nutrition industry reaches $219B in ‘18

U.S. natural and organic products industry grew 6.5% to $219B in 2018

Sales Growth

Sales
Growth

12%
10%
8%
6%
4%
2%
0%

Natural & Organic F&B 39%
Functional F&B 31%
Natural Living 9%
Supplements 21%
Supplement growth rebounds slightly to 6.0%

Dietary supplement sales grow 6.0% to $46B in 2018
Functional food & beverage sales grew 7.5% to $68B in ‘18

Highest growth categories:
- Beverages
- Snacks

Hot functional ingredients:
- Hemp CBD
- Mushrooms
- Adaptogens
- Probiotics
Alternative and novel delivery formats

- **2013**
  - Pill: 63%
  - Gummy: 6%
  - Other Non-Pill: 31%

- **2018**
  - Pill: 51%
  - Gummy: 12%
  - Other Non-Pill: 37%

**Non-pill +12%**

*Nutrition Business Journal estimates ($mil, consumer sales)*
Probiotic growth dips below 10% in 2017 and continues to slow – now a $2.2B market
Synbiotic market now at $658M, stealing market share from single probiotics
Synbiotics continue to capture market share in pre/pro/synbiotic market
Prebiotics/synbiotics grow from 26% of market in 2016 to est. 36% in 2019.
Probiotic Raw Material sales growth drops off as growth for finished products shrinks.
Condition-Specific Opportunities
Probiotics currently capture 27% of Gut Health market

Sales and Growth, 2015-2021e

Market Breakdown by Ingredient

- Probiotics: 27%
- Other: 32%
- Synbiotics: 16%
- Digestive Enzymes: 15%
- Psyllium: 5%
- Combination Herbs: 3%
- Prebiotics: 2%

Growth and Revenue ($mil) from 2015 to 2021e
Cold, flu & immunity supplements spike to 10% in 2017 due to severe flu season.
Children's Health Supplements by Ingredient, 2018

- Multivitamins: 71%
- Probiotics: 10%
- Calcium: 5%
- B Vitamins: 5%
- Fish/Animal Oils: 4%
- Other: 4%
- Probiotics: 10%
- Other: 4%

Children's Health Sales and Growth 2014-2022e
Market Manifestations across conditions
Personalized nutrition represents strong area of opportunity for gut health

Minimal Personalization =
Lower cost
Off-the-shelf solutions

Maximum Personalization =
Higher cost
Individualized solutions

- Survey-Based Nutrition
- Biomarker Tests
- Condition Specific Supplements
- Tracking Devices
- Genetic and Microbiome Testing
Product Format Opportunities
Probiotics appear most in food and bev vs. supplements at Expo West 2019

Probiotics in Products at Expo West 2019 - Top Products by Incidence

- Dairy
- Drinks
- Snacks, Cookies & Candy
- Supplements
- Frozen Food
- Cosmetics
- Bakery
Strong probiotic growth in aisles outside F&B, supplements: skincare and cleaning products

Growth of Probiotics from EW '17 to EW '19 across Categories

Condiments, Oils & Salad Dressings
Home And Garden
Cosmetics
Snacks, Cookies & Candy
Pet Care
Dairy
Sauces, Spices & Seasonings
Total Probiotics
Bakery
Drinks
Grains, Pasta & Side Dishes
Frozen Food
Supplements
Pet Food
Market Manifestations -

[Images of various products]

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Thank You!

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A Historical Perspective on Taxonomy Changes

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IPA Regulatory Committee Chair

SupplySide West 2019 Workshop:  
Extending Your Reach in the Probiotic Space  

October 19, 2019
Extending Your Reach in the Probiotics Space

Jessica ter Haar, Ph.D.
Scientific Director, International Probiotics Association (IPA)

Anthony Thomas, Ph.D.
Director of Scientific Affairs, Jarrow Formulas
TAXONOMY RECLASSIFICATION OF THE LACTOBACILLUS GENUS

SCIENTIFIC OVERVIEW AND FRAMEWORK

Dr Jessica ter Haar
Director of Scientific Affairs
International Probiotics Association

Dr. Anthony Thomas
Scientific Committee
International Probiotics Association
Continuous Scientific Development

WHAT is happening?

Over 251 species within this genera that started with 35 in 1980

(*) Creation of new genera (names) from *Lactobacillus* species

Commercially important *Lactobacillus* probiotic strains span at least 7 of these phylogroups (food fermentation *Lactobacillus* strains cover more)

Salvetti et al. 2018
Description of Process
HOW will this happen?

Taxonomic names are:
• Result of research classifying genera according to genotype and phenotype
• Instruments of scientific communication (General Consideration 8 of the Code)
• Names are forever and once described never disappears (Rule 23 of the Code)
• Names should aim at stability and useless creation of names should be avoided (Principle 1 of the Code, 2008 revision)
• A name is permanently associated to the type strain of a species (Rule 15 of the Code)

This means for the new reclassification names:
• 23 NEW GENERA will be described
• The organisms WILL NOT change
• The species names WILL NOT change
• The genus name WILL change
• Genus names will preferably start with an “L” to minimize disruption
Events and Timelines
WHEN is this happening?

Pre-2012
Scientific group of Italians, Belgians, Germans working on this taxonomic group

Sept 2018
Decision to split genus, Berlin
+ Comparative genetics publication by Salvetti et al.

Oct 2018
LABIP expert workshop, Verona

July 2019
Impact of reclassification publication by Pot et al.

Oct 2019
Manuscript submitted for peer review in the International Journal of Systematic and Evolutionary Microbiology (IJSEM)
+ Name changes are official
+ Old/new names can be found on University of Bologna website

? 2019/2020 ?
Publication in the IJSEM
+ Grace period for label/commercial literature changes
+ GRAS / QPS list updated
+ Etc.

Eventual site of the new / old names:
https://site.unibo.it/subcommittee-lactobacillus-bifidobacterium/en
Scientific Advantages to Reclassification
Why is this A GOOD THING?

1. Accurate identification of organisms
   - Provides basis for safety assessment, quality assurance and non-fraudulent labeling

2. Attribution of benefits
   - Mechanisms and functions associated to specific groups (Sanders et al., 2018)

3. Scientific communication
   - *Lactobacillus* ssp. have a long history of safe/legal use in humans, but not all

---

**Diagnostic difficulties of *Lactobacillus casei* bacteraemia in immunocompetent patients: A case report**

Chiara Tommasi, Francesco Foutani, Marcello Masala, Milivoja Ballardini, Marco Favaro, Marcello Meledandri, Carla Fontana, Pasquale Narciso & Emanuele Nicotri

*Journal of Medical Case Reports* 2, Article number: 315 (2008) | [Download Citation](#)

**Safety of probiotics in patients receiving nutritional support: a systematic review of case reports, randomized controlled trials, and nonrandomized trials**

Kevin Whelan, Clio E Myers

Thank You

Questions?

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310.204.6936
The International Probiotics Association (IPA) is a global non-profit organization bringing together through its membership, the probiotic sector’s stakeholders including but not limited to academia, scientists, health care professionals, consumers, industry and regulators. The IPA’s mission is promote the safe and efficacious use of probiotics throughout the world. Holding NGO status before Codex Alimentarius, the IPA is also recognized as the unified Global Voice of Probiotics® around the world.

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COMMERCIAL IMPLICATIONS OF THE LACTOBACILLUS TAXONOMY CHANGE
- A CONCEPTUAL REVOLUTION IN THE INDUSTRY -

Nina Vinot
Area Sales Manager Probiotical
IPA Probiotic Workshop in SSW
Saturday, October 19th 2019
Las Vegas

The Global Voice of Probiotics®
www.internationalprobiotics.org
COMMERCIAL IMPLICATIONS

CHALLENGES FOR COMMUNICATION
OTHER PRAGMATIC IMPLICATIONS
OPPORTUNITIES
HOW TO BE BETTER PREPARED FOR THE CHANGE
CHALLENGE FOR COMMUNICATION

1. Internal communication to update technical/quality documentation, marketing tools, websites, questions on patents

2. Communicating to customers/brands, and prepare the impact on labelling, agreements, links to the publications

3. Communication to end-users, reassurance that the strains, effects and safety are not changed

INDICATIONS: Ladyflor® Folic, containing folic acid (Vitamin B9) and Vitamins B2, B6, B12 are suitable when a deficiency of B vitamins and Zinc may occur, due to inadequate dietary intake, in needs, especially for women. Supplemental folic acid intake increases maternal folate status. A risk factor in the development of neural tube defects. The action of the two probiotic microorganisms BA05 and Lactobacillus reuteri LRE02 is natural, effective and free from side effects, useful in microflora.

<table>
<thead>
<tr>
<th>FUNCTIONAL COMPONENTS</th>
<th>Amount per 1 stick pack</th>
</tr>
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<tbody>
<tr>
<td>Folic acid (Vitamin B9)</td>
<td>400 µg, 200% NRVs</td>
</tr>
<tr>
<td>Vitamin B2 (in coated form)</td>
<td>2.1 mg (equal to 0.7 mg of Vitamin B2), 50% NRVs</td>
</tr>
<tr>
<td>Vitamin B6 (in coated form)</td>
<td>2.1 mg (equal to 0.7 mg of Vitamin B6), 50% NRVs</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>1.25 µg, 50% NRVs</td>
</tr>
<tr>
<td>Zinc Gluconate</td>
<td>11 mg (equal to 1.5 mg of zinc ion), 13% NRVs</td>
</tr>
<tr>
<td>Tyndallized Bifidobacterium lactis Bb1 (DSM 17850)</td>
<td>50 mg*</td>
</tr>
<tr>
<td>Bifidobacterium lactis BA05 (DSM 18352)</td>
<td>≥ 2 billion* cells</td>
</tr>
<tr>
<td>Lactobacillus reuteri LRE02 (DSM 23878)</td>
<td>≥ 0.5 billion* cells</td>
</tr>
</tbody>
</table>
OTHER PRAGMATIC IMPLICATIONS

4. Academic, scientific and medical communities – ensure that new articles and patents are filed with new names, and that meta-analyses and literature searches check both.

5. Regulators and governments will need to update the positive lists (QPS, GRAS…)

6. Transportation and border control

7. Lawyers and IP professionals
OPPORTUNITIES

Better ecologic vision for better product development

Nomadic/free-living bacteria have a wider genome and more tools to survive in various environments

Host-adapted bacteria are more competitive when compared to bacteria that do not share an evolutionary history with the host (antagonization of pathogens)

Bacteria without a joined evolution are more inclined to stimulate an immune response
HOW TO BE BETTER PREPARED FOR THE CHANGE

For New launches or changes of artwork:

*Lactobacillus rhamnosus*

*L. rhamnosus GG (ATCC 53103)*

*Lactosmurf rhamnosus GG (ATCC 53103)* (previously classified as *Lactobacillus rhamnosus*)
KEEP CALM AND FOCUS ON BACTERIA