Realising the Food Microbiome Potential
The Microbiome, Diet and Health: Assessing Gaps in Science & Innovation

C. Shortt, J&J Consumer
Thematic Session 1: Potential for Healthier Foods and Health Innovation

Outline
- Current European food microbiome landscape
- Current food regulatory frameworks and issues
- Learnings and opportunities to unlock potential
- Insights on realising the microbiome research potential in food sector with specific reference to approaches to advance the field

Microbiome modulation and health

Host-microbe nexus is key to unlocking the microbiome’s potential

A spectrum of new health enhancing foods and transformative treatments

Traditional Approach:
- Modulate Host Response
- Microbial Eradication

Host-microbe nexus is key to unlocking the microbiome’s potential

C. Shortt, J&J Consumer
Microbiome can play critical roles along the wellness spectrum

Observable Symptoms of Disease

- MB PROFILING
- OPTIMIZED FOODS/NUTRITION
- PERSONALIZED MEDICINES
- PERSONALIZED NUTRITION PRESCRIPTIONS
- FOODS FOR SPECIAL MEDICAL PURPOSES

Additional opportunities for interception and prevention

Microbiome Solutions Along An Individual’s Health Journey

Multiple pathways for microbiome products exist

Product Classification

<table>
<thead>
<tr>
<th>Disease Manager Requirement</th>
<th>Claims Permitted</th>
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</thead>
<tbody>
<tr>
<td>PREVENTION* OR MANAGEMENT</td>
<td>Foods &amp; Dietary Supplements</td>
</tr>
<tr>
<td>NONE</td>
<td>Novel ingredients/medications</td>
</tr>
<tr>
<td>MAINTENANCE, IMPROVEMENT &amp; RISK REDUCTION</td>
<td>Foods for special groups</td>
</tr>
<tr>
<td>NONE</td>
<td>OTC Medicine</td>
</tr>
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EC health claim framework

- EC 1924 2006, determines the claims that can be made
- Establishes the lists of nutrition & generally accepted claims
- Establishes the procedure for the authorisation of new claims

Investment in science

- The good, GI-tract Functionality & Human health Cluster
  - Crownalife
  - INFABio
EC authorised health claim

improved lactose digestion

Live cultures in yoghurt or fermented milk improve lactose digestion of the product in individuals who have difficulty digesting lactose.

In order to bear the claim, yoghurt or fermented milk should contain at least $10^{8}$ CFUs/g of live starter microorganisms (Lactobacillus delbrueckii subsp. bulgaricus and Streptococcus thermophilus).

EC health claim requirements

Demonstrate

- Characterisation of ingredient
- The effect is relevant to health
- The quantity of food for the effect is reasonably achieved as part of a balanced diet
- The study group is representative of the target population
- A cause and effect relationship exists

EC view of the term probiotic

‘live microorganisms which when administered in adequate amounts confer a health benefit on the host’
FAO/WHO, 2001

- Considered a health claim
- Required prior approval
- Taken off labels

Learnings and opportunities to unlock innovation potential

<table>
<thead>
<tr>
<th>Learnings</th>
<th>Opportunities</th>
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<tbody>
<tr>
<td>Scientific guidance</td>
<td>Characterisation requirements</td>
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<tr>
<td></td>
<td>Determination of health benefits</td>
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<td></td>
<td>Association/Causation</td>
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<tr>
<td>Clinical trial guidance</td>
<td>Design</td>
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<td>Statistical analysis</td>
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<td></td>
<td>Best practice</td>
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<tr>
<td>Robust human studies</td>
<td>Investment</td>
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<tr>
<td>Marker validation research</td>
<td>Investment</td>
</tr>
<tr>
<td>Regulatory dossier development guidance</td>
<td>Recognition of unique requirements and skills</td>
</tr>
<tr>
<td>Engage Authorities</td>
<td>Increase dialogue to address regulations particularly in relation to innovative space/ borderline topics</td>
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<tr>
<td>Consumer/Meaning engagement</td>
<td>Understand products/science/benefits/use</td>
</tr>
<tr>
<td>Cross-discipline research stimulus</td>
<td>Multi-stakeholder engagement, co-ordination, training</td>
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Realising the microbiome potential

Research and collaboration
- EC Research and Innovation Agenda
- Food Research Area
- HORIZON 2020
- Joint Programme Initiative
- NutriTECH
- Pathway-27
- Ongoing stakeholder dialogue (eg, EFSA webinars, Probiotic term)

Realising the microbiome potential

Research and collaboration
- JPI Joint Action Intestinal Microbiomics >6M €
  1. EarlyMicroHealth
  2. EarlyVir
  3. DINAMIC
  4. AryIMUNE
  5. GI-MDH
  6. MaPLE

Realising the microbiome potential

Biomarker initiatives
- JPI
- ERA-NET Biomarkers for Health and Nutrition
- FOODBALL – THE BIOMARKER ALLIANCE
- MIRDIET
- ILSI Marker Validation initiative

Venturing into unchartered territory requires a laser focus

And an end to end assessment of challenges to enable delivery of foods with health claims and dietary disease management potential
Realising the microbiome potential

...challenges in translating emerging science to food products

The future of the food microbiome

...innovative products

Janssen Human-Microbiome Institute

Vision
Accelerate the translation of microbiome research into breakthrough solutions that promote health

Mission
Shape the field and establish a leadership position for Janssen to become the partner of choice for top microbiome science

Global Head
Dirk Gevers, dgevers3@its.jnj.com

JHMI brings focus to 5+ years of microbiome efforts across Janssen/J&J

Teams exploring the microbiome today:
• Consumer – Dermatology & Gut Health
• IBD – VE202, APC, Enterome
• Disease Interception Accelerator – Gestational Diabetes
• T2D, Obesity, Metabolic Disorder – Intrexon
• Plus various efforts by Oncology, Infectious Diseases, Janssen Prevention Center and JLINX
• dgevers3@its.jnj.com
THANK YOU