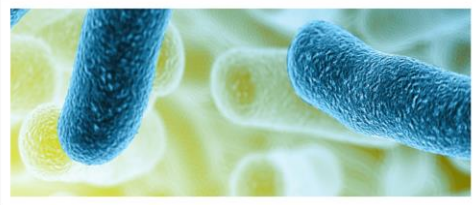


## Realising the Food Microbiome Potential

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

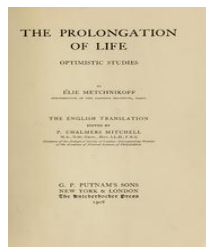


- Current European food microbiome landscape
- Current food regulatory frameworks and issues
- Learnings and opportunities to unlock potential
- Insights on realising the microbiome research potential in food sector with specific reference to approaches to advance the field

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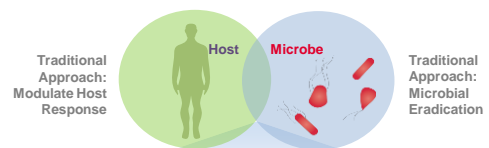
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## Microbiome modulation and health



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



A spectrum of new health enhancing foods and transformative treatments



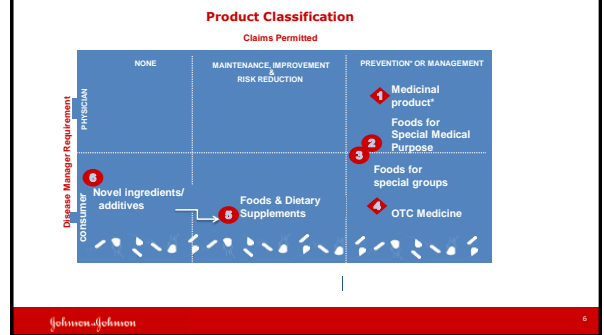
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## Microbiome can play critical roles along the wellness spectrum

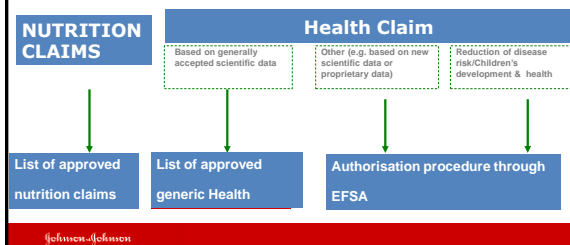


## Multiple pathways for microbiome products exist



## 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
- Crownlife
- INFABio

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## 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*).



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## 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

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## 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



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## Learnings and opportunities to unlock innovation potential



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

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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)



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## Realising the microbiome potential

### Research and collaboration

- JPI Joint Action Intestinal Microbiomics >6M €

1. EarlyMicroHealth
2. EarlyVir
3. DINAMIC
4. ArylMUNE
5. GI-MDH
6. MaPLE

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## Realising the microbiome potential

### Biomarker initiatives

- JPI
  - ERA-NET Biomarkers for Health and Nutrition
  - FOOTBALL – THE BIOMARKER ALLIANCE
  - MIRDIT
- ILSI Marker Validation initiative



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## Venturing into uncharted territory requires a laser focus



What assay systems will we need? How will we incorporate? What placebo is appropriate? How do we scale up production? How can we study microbes in living? How do we communicate health benefits of bacteria?

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

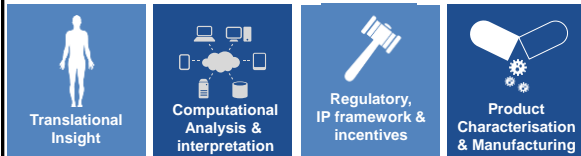
What advanced vitro models will be needed? How will we keep pace with individual computational platform? What will the clinical development program look like? Subject selection criteria? talent and collaborators?

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## Realising the microbiome potential

...challenges in translating emerging science to food products







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## The future of the food microbiome

...innovative products

-  Optimised & Novel foods and ingredients (e.g. cocktails of microbes, fibres, prebiotics)
-  Food and food supplements with authorised health claims
-  Medical foods
-  Personalised food & diet solutions



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## 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](mailto:dgevers3@its.jnj.com)



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## 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](mailto:dgevers3@its.jnj.com)



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