# Regulatory challenges in the drug-food continuum

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# Outline

Regulation of health claims on foods EU No 1924/2006

Reconciling science and regulation: EFSA role in health claims

Microbiome promises in the drug-food continuum

Facing new challenges related to microbiome-based products

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# EU Regulation on claims: key purposes

*A health claim is any representation that states, suggests, or implies a relationship between a food/constituent and health*

efsa
European Food Safety Authority


Consumer protection

Harmonization of legislation

Ensuring fair competition

Innovation (5 year protection)

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# Main principles of health claims regulation

Foodstuff **cannot** be attributed the property of **preventing, treating** or **curing disease** (Art 7(3) Regulation (EU) No 1169/2011).

*Classification of claims*

**Function Claims** related to maintenance of a function of the body or improvement in case of physiological decline (Art. 13.1, 13.5, 14-children)

*Foods versus drugs*

**Disease Risk Claims** related to the reduction of a risk factor contributing to the disease onset (Art. 14)

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# Main principles of health claims regulation

*For the purpose of communicating the health properties of a food/constituent to consumers:*

- Subjects with a disease cannot be the target population for health claims. In principle, the **target population** should be the **general (healthy) population** or specific **subgroups** thereof.

- Function **claims cannot refer to a disease**.

- Disease risk reduction claims cannot refer to the reduction of the risk of a disease, but should **refer to the reduction of a risk factor** for disease.

General scientific guidance on health claim application EFSA Journal 2016;14(1):4367

# Reconciling science and regulation

*Regulatory framework may be in contradiction to scientific principles*

TARGET POPULATION=GENERAL POPULATION

STUDY POPULATION

- **Disease subjects** as study groups to prove efficacy of foods
- Subjects with **diet-related disorders** considered as appropriate study groups since they **could benefit the most** from health claims made on foods.
- The relationship between a food/constituent and a **function** can be best measured by **using disease outcomes**
- **Disease outcomes provide stronger evidence than risk factors** for the ability of a food to reduce the disease risk.

General scientific guidance on health claim application. EFSA Journal 2016;14(1):4367

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# Reconciling science and regulation

*The problem of the case-by-case scientific judgement*

**STUDY GROUP:**

IBS patients to prove an effect on GI discomfort

**TARGET POPULATION:**

General adult population

**STUDY GROUP:**

Mildly hypercholesteraemic subjects to prove reductions in LDL-cholesterol

**TARGET POPULATION:**

Adults who want to lower their blood cholesterol concentrations.

**CLINICAL OUTCOMES:**

Symptoms of infections, incidence of infections

**CLAIM:** Defence against pathogens or reduction of the risk of infections

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# Probiotics in (some) professional guidelines

*Versus health claims approval*

World Gastroenterology Organisation

Global Guardian of Digestive Health. Serving the World.

**October 2011**

## WGO Practice Guideline – Probiotics and Prebiotics

- **Treatment of acute diarrhea**
- **Hepatic encephalopathy**
- **Pouchitis**
- **Allergy Treatment of atopic eczema**
- **Inflammatory bowel disease (IBD)**
- **Ulcerative colitis**
- **Necrotizing enterocolitis**
- **Radiation-induced diarrhoea**

Whether a claim is a food or medicinal claim and the admissibility of the target population for a claim depends on risk managers

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# Microbiome promises in the drug-food area

*37% microbiome research*

## MICROBIAL SPECIES AND GENES IN BODILY AREAS

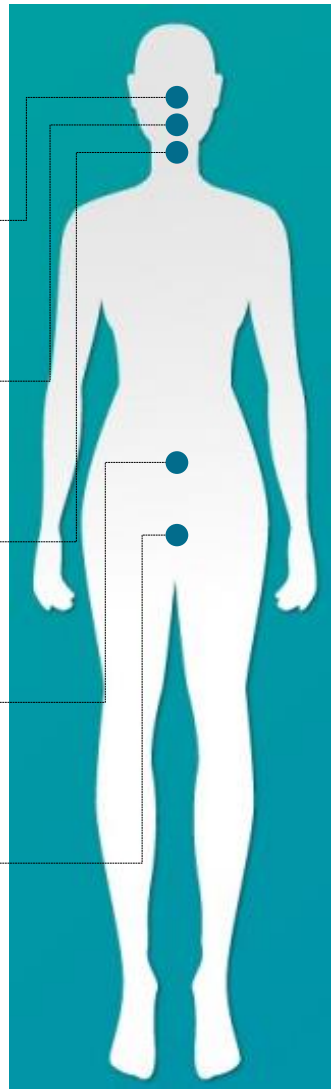
**Nostrils**
900 species
30.000 genes

**Mouth**
800 species
70.000 genes

**Teeth**
1.300 species
20.000 genes

**Feces**
4.000 species
800.000 genes

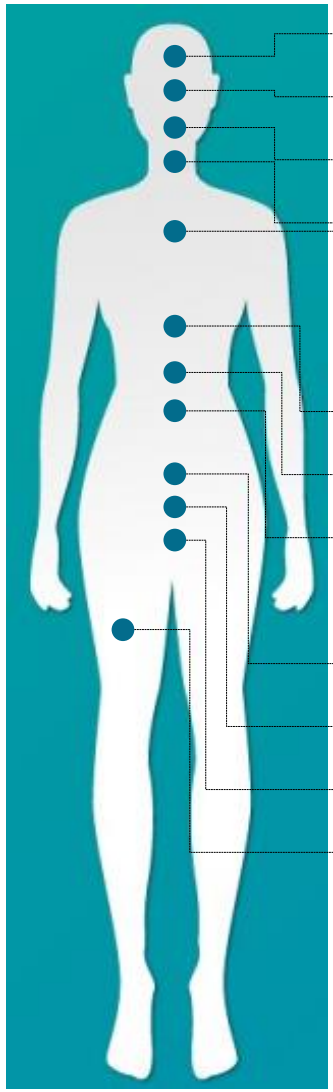
**Vagina**
300 species
10.000 genes



SOURCE: Human Microbiome Project

**Microbial Balance**

**Microbial Dysbiosis**



- Cognitive dysfunction
- Autism
- Periodontitis
- Stress
- Asthma
- Metabolic syndrome
- Heart disease
- Allergies
- Obesity/diabetes
- Colon cancer
- Liver disease
- Colorectal cancer
- Crohn's disease
- Osteoporosis

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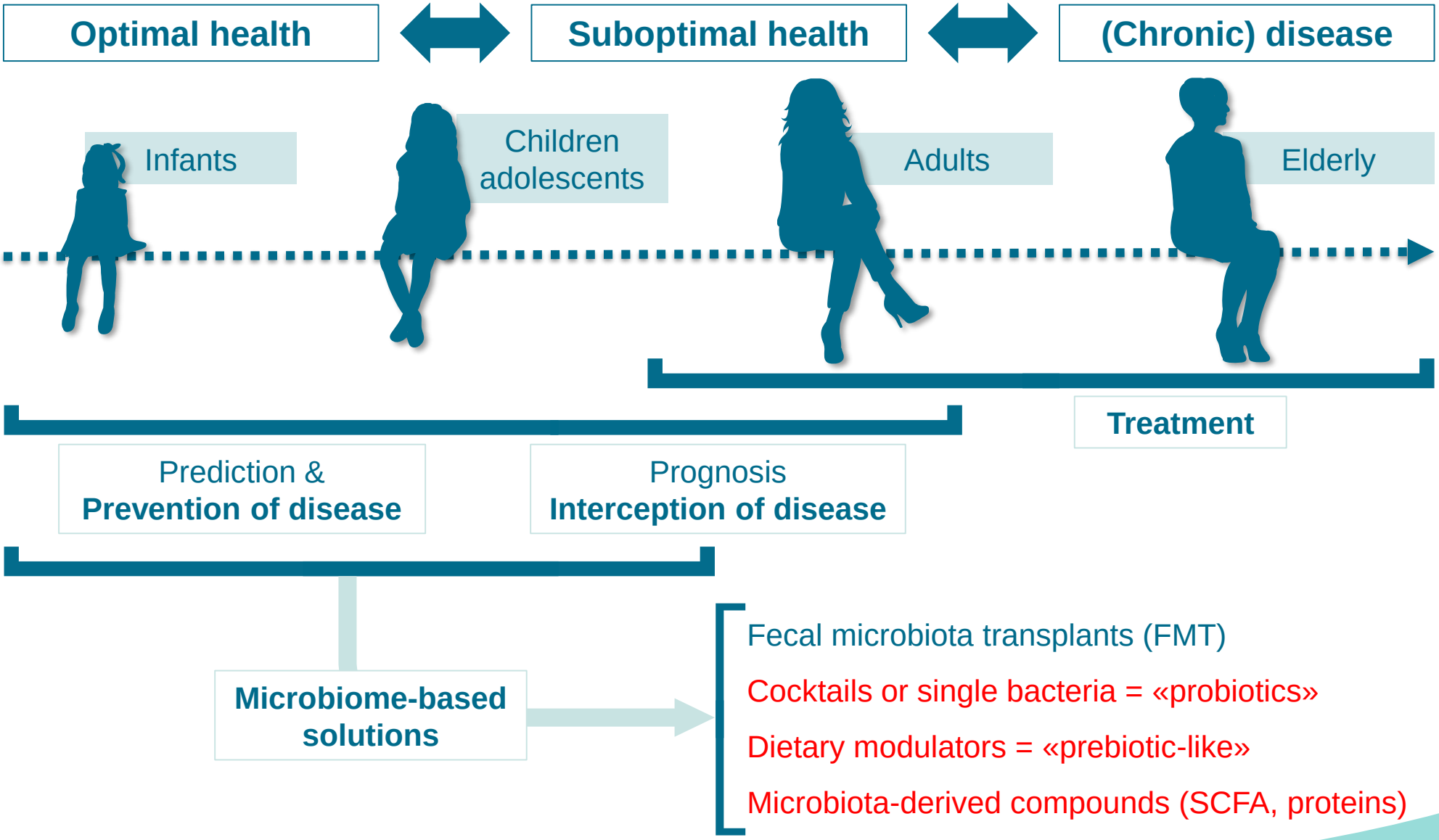
# Microbiome promises in the drug-food area

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Romaní-Pérez M, Agusti A, Sanz Y. Curr Opin Clin Nutr Metab Care. 2017;20:484-491.

# Facing new challenges: microbiome products

- **EFSA guidance on novel food applications**: Section 9- relates to foods consisting of, isolated from or produced from microorganisms
  - Indigenous human gut bacteria
  - Unambiguous taxonomic classification, whole-genome characterization, antibiotic resistance assessment and other safety issues.
  - Examples of novel foods/ingredients approved:
    - *Clostridium butyricum CBM 588*
    - Milk products fermented with *Bacteroides xylanisolvens*

      (EFSA Journal 2016;14(11):4594)

- **EFSA guidance on the characterisation of microorganisms used as feed additives or as production organisms**. Under public consultation until 15 September 2017

# Facing new challenges: personalization

- **Priority topics for the development of risk assessment guidance by EFSA's Scientific Committee in 2016–2018**: Individual susceptibility and uncertainty factors should be considered for future assessments, including variables such as the individual's microbiota (influencing glycaemic responses to a given diet/food, nutrient absorption and metabolism, xenobiotic metabolism, maturation of the immune and nervous systems, etc.), etc. (*EFSA Journal 2016;14(6):4502*).

- **Classification of personalized foods**
  - Conventional foods? Narrowing down the groups of the general population?
  - Foods for Special Groups or Medical Purposes (FSMPs)? When are intended for patients to meet specific nutritional needs (*Regulation (EU) No 609/2013, EFSA Journal, 13: 4300)*.

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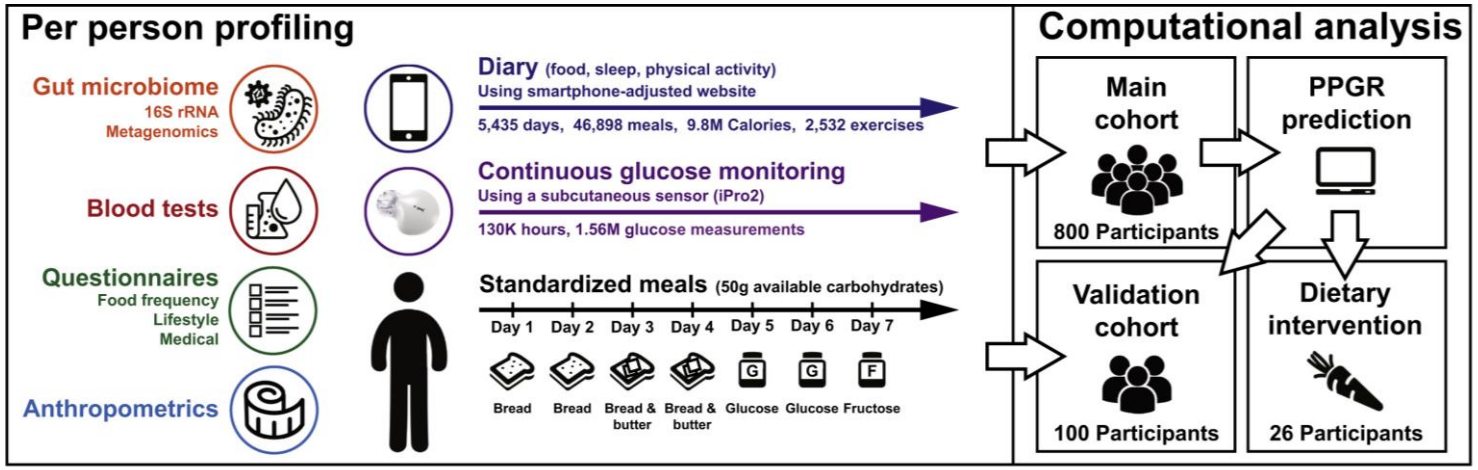
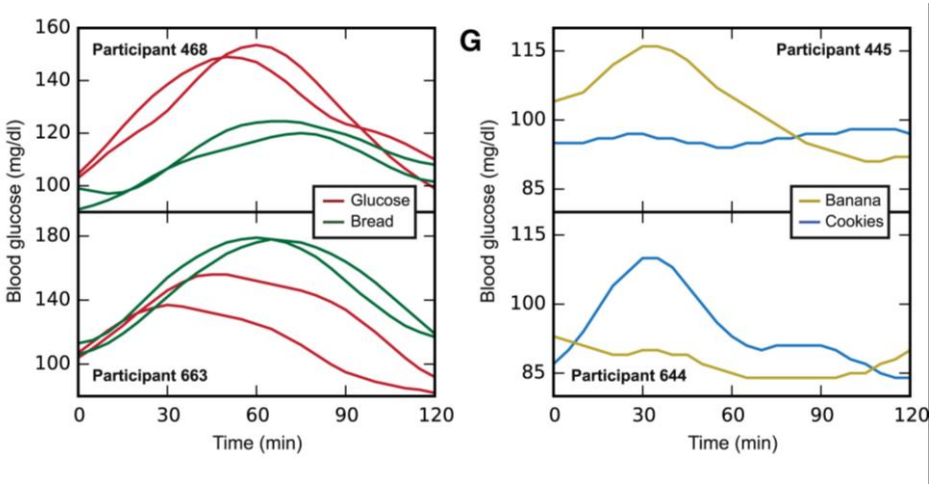
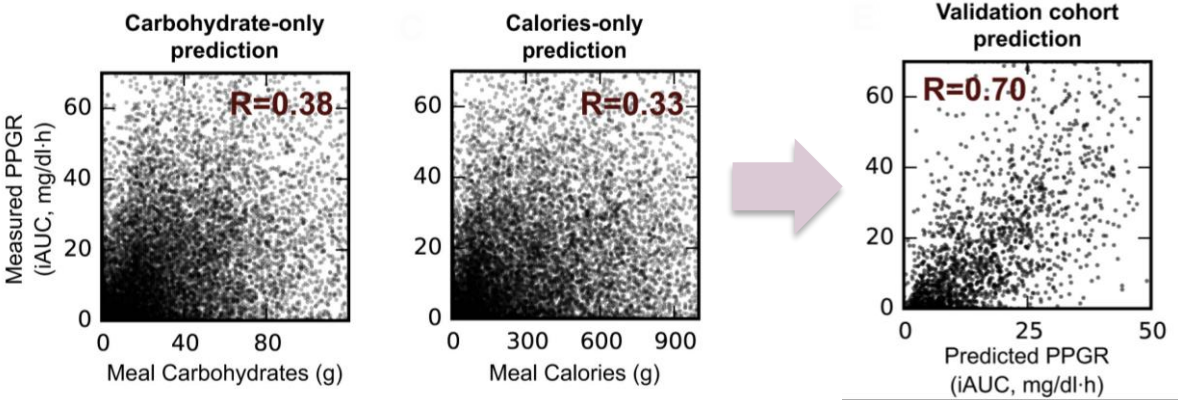
# Towards holistic and more personalized nutrition and health approaches




## Microbiome improves prediction of glycemic response




Zeevi et al. Cell. 2015 Nov 19;163(5):1079-1094.

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# Microbiota-based (directed) foods as conventional or medical foods?

- They can have a place as conventional and medical foods, depending on their purpose.

- As **conventional foods**:

  (i) they should be intended for **general healthy population** and affect **risk factors** for disease

  (ii) functions of the **microbiota** are **not** considered as **part of the functions of the human body**, but as mechanisms.

- As **medical foods** (FSMPs): they are intended for managing disease but for meeting **specific nutritional needs only.**

*Alliances between the food and health area are key to respond to the demographic change and develop a sustainable health care system*

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# Thank you

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