



Trans-sectorial Workshop

Connecting microbiome research and innovation strategies with policy and regulation

1. Introduction

Microbiomes are biological machineries affecting the functioning of macro-organisms in all ecosystems. Key concepts about microbiome services originate from studies related to the gut microbiome and human health. Gut microbes evolve symbiotic associations with the host and dynamically interact with the environment, helping to circumvent hazards and improving the host's biological competence. The human gut microbiome influences an array of physiological functions, ranging from metabolism to neural and immune functions, affecting all aspects of health and disease. This notion is now extending to other ecosystems. Similarly, microbiomes associated with terrestrial or marine animals, as well as with soils and plants, are thought to influence their health status. We have also started thinking of the systems-level effects of microbiomes on interlinked ecosystems from humans to animals, foods, and the environment. Upon this principle, the use of microbiome modulation strategies to prevent or restore alterations in natural symbioses between micro- and macro-organisms of different origins (namely disease, poor diets, climate change, exposure to chemicals, etc.) holds promise to improve human and animal health, as well as the whole agro-food production system, with potentially positive impacts on productivity, food safety, nutritional quality and sustainability.

The translation of microbiome knowledge to applications is complex. Microbiome-related claims are the result of brand new scientific evidence, generated in the absence of standards and often with insufficient large-scale testing. The arrival of these products to the market is often hampered by the risk involved (cost and time-to-market) and the lack of experience in the regulatory environment and the absence of a clear path for applications lying in grey or as yet undeveloped areas.

Therefore, the role of microbiomes in human, animal and environmental health, directly or indirectly through actions in the whole production system, requires parallel investigations related to their possible implications in regulatory science. These could affect both the way risk assessment (e.g. chemicals, pesticides, etc.) is conducted as well as the way regulated microbiome-based products are evaluated (e.g. probiotics, prebiotics, plant protection products or bio-stimulants etc.). Nonetheless, there is no guidance or methodology in place to



systematically assess their potential effects on microbiomes or indeed by microbiomes on human, animal or plant health yet (Merten et al., 2020).

This workshop will discuss how exploitation of microbiomes functional capacities in different ecosystems and at systems level could aid in addressing the global challenges faced by society, industry and the planet, such as preserving human and environmental health, secure nutrition, safer and sustainable foods and tackling climate change. It will also identify gaps and needs in future research agendas in order to be aligned with regulations and policies. Altogether this is considered essential to foster innovation and facilitate the roadmap towards product development and commercialization and to ensure that results from research projects generate a real impact on the society and the economy.

2.Purpose

Engage different actors and stakeholders during the preparatory work and the workshop to:

- Visualize the potential of microbiome-based applications to address our global challenges and reinforce European industrial competitiveness in the next 10 years, presenting case-studies.
- Identify bottlenecks and major hurdles to these innovations
- Define actions and strategies that allow the alignment of future research agendas with advances in regulation and policies and, thus, speed up the translation of microbiome knowledge into positive impact in different sectors, from civil society to industry and regulatory bodies.

This workshop is part of EU Support and Coordination Action which works “Towards coordinated microbiome R&I activities in the food system to support (EU and) international bioeconomy goals” (2018-2022). Within this action, the workshop is one of the activities (Task 3.3) in Work Package 3.

The specific aims of WP3 and, specifically, Task 3.3 are as follows:

- Foster multidisciplinary and trans-sectorial networking to generate a systems vision of the microbiome potential for building a robust bioeconomy.
- Generate a realistic context for implementing microbiome research agendas, enabling innovation, and align future actions in the EU and beyond.

- Determine how we should integrate regulatory aspects in the MicrobiomeSupport Strategic Research and Innovation Agenda (SRIA) to implement the FOOD 2030 strategy and contribute to achieving the major sustainable and developmental goals (SDG).

3. Expectations from attendees and speakers

The MicrobiomeSupport consortium expects to engage and mobilize a large interdisciplinary and inter-sectorial community of scientists, industry and other stakeholders in networking activities and contribute to achieving the specific objectives of this action, as well as going beyond, providing a wide vision of the microbiome future from different angles. It is expected that attendees and speakers contribute to anticipating opportunities and paths for promoting microbiome innovation actions, aligned with the new Framework Program Horizon Europe as well as with policies and regulation.

Attendees will include:

- European regulatory agency/experts and policy bodies
- Members of the three advisory groups of MicrobiomeSupport: scientific experts, industrials & policy-makers
- IBF Microbiome Working Groups
- Experts in innovation and research policy and financing agencies

Discussion groups and moderators for the preparatory work have been identified to facilitate the collection of inputs via an *ad hoc* survey and organize telematic discussions when deemed appropriate, as follows:

- Microbiome and human nutrition and health (Yolanda Sanz, CSIC, Spain)
- Food microbiomes (Emmanuelle Maguin, INRA, France)
- Terrestrial animal microbiomes (Martin Wagner, FFoQSI, Austria)
- Soil and plant microbiomes (Angela Sessitsch, AIT, Austria)
- Marine, fish and environmental microbiomes (Lene Lange, BRA)
- Transversal regulatory and policy aspects (Kathleen D'Hondt, VLO, Belgium)

A specific survey, together with this introductory document plus the agenda and annexes providing information relevant to the topic of the workshop, will be distributed in advance to attendees and other parties identified as potentially interested in the workshop. All participants will also be encouraged to join one or several discussion groups in advance. All groups will have

clear guidance on how people can interact with each other and what type of information they can share from the group moderators. Participants will be invited to keep in touch with one another individually and in groups in order to share publications, surveys and other information that could help to address the key questions, before and during the workshop, and contribute ideas to build realistic research agendas and other strategies that serve the whole microbiome community, as well as industry, society and policy and regulatory bodies.

Speakers will be invited to provide a short bio (1,000 characters), prepare a power point presentation (15 minutes) and a summary (2 pages) outlining the content of the presentation, addressing the key aspects of the workshop mission according to their expertise, which include:

- Define the innovation potential of microbiomes in different areas and as interconnected systems and provide case-studies of (potential) success.
- Bottlenecks/hurdles to advance innovation in the field
- Specific research instruments and policies that may help to address needs
- Regulatory and legislative gaps and mechanisms required to facilitate the path towards safe and innovative microbiome solutions for society and the bioeconomy.

4. Outcomes of the workshop and impact

MicrobiomeSupport will report on the outcomes of the preparatory work during the meeting as well as on the final outcomes to all participants, coordinators of microbiome related initiatives and platforms, advisory boards, IBF group and wider society to make this workshop inclusive and transparent and to maximize its impact.

The dissemination actions related to the Workshop will be coordinated by EUIC (Hanna Winkler, Dafni Acedo and Bettina Schelkle) and with the active participation of the organizers and speakers, and will include:

- An *ad hoc* survey accessible through the web platform and directly through email during/after the workshop
- The MicrobiomeSupport online channels: news items via the website and the newsletters, the @MicrobiomeEU Twitter channel
- Input into the MicrobiomeSupport Strategic Research and Innovation Agenda (SRIA)

- A white paper linking innovation in the microbiome research field to policy and regulatory aspects to inform future actions within Horizon Europe and other funding initiatives (generated after the workshop).

5. Survey to widen participation of multi-sectorial stakeholders

To ensure the collection of inputs from all relevant actors and to adequately respond to the workshop mission with a view to boosting microbiome innovation, a questionnaire will be distributed one month in advance and discussed in sub-groups with leaders in the field and moderators. This intends to be concise in the number of questions and precise in the responses to get directly to the key points.

Questions:

1. Could you define at least one specific microbiome application that could help to solve a societal or environmental challenge? The more examples and the more detail per example the better.

For example: a microbiome replacement strategy (faecal microbiota transplant or live intestinal bacteria) for prevention/treatment of non-communicable diseases (e.g. IBD, obesity, etc.) OR for increasing crop productivity (specify which crop) by protecting against dryness, salinity, etc.

2. Which are the major scientific or technological barriers to accelerate translation of knowledge to applications/use in health/food systems? Which measures could help to overcome the limitations?

For example: lack of standards to monitor safety, difficulties to growth or upscale the growth of complex synthetic microbiotas outside their natural ecosystem, etc.

3. What policies could help to reinforce innovation and the uptake of new solutions? Think of educational, health, research policies, etc.

For example: educational policies to raise awareness of microbiomes services for health and the society; research actions for demonstration and proof-of concept trials, train academic actors in regulatory aspects, etc.

4. Which legislative measures are needed to speed up the translation of knowledge and technology into products and services?

For example: Speed the evaluation process of applications by regulatory bodies; Establish a clearer regulation for microbiome-based services to consumers, etc.

5. What is required to integrate the microbiome in risk and scientific assessments by regulatory bodies in Europe (EFSA) and beyond?

For example: validation of study models, generation of standards, etc.

6. Annex

Documents and References

Reference papers and work documents generated by MicrobiomeSupport

- 1) Microbiome definition
- 2) Biobanking paper
- 3) Infographic: 'Microbes are everywhere in the food system'
- 4) Video: 'The microbiome in the food system'
<https://www.microbiomesupport.eu/videos/>
- 5) Factsheet: 'Seven things you need to know about MicrobiomeSupport'

References and documents from other bodies

- 6) Merten, C., Schoonjans, R., Di Gioia, D., Peláez, C., Sanz, Y., Maurici, D., & Robinson, T. (2020). Editorial: Exploring the need to include microbiomes into EFSA's scientific assessments. EFSA journal. European Food Safety Authority, 18(6), e18061.
- 7) Amos GCA, Logan A, Anwar S, Fritzsche M, Mate R, Bleazard T, Rijpkema S. Developing standards for the microbiome field. Microbiome. 2020. 26;8(1):98.

FOOD2030 priorities

The FOOD 2030 initiative is a policy response by DG Research and Innovation to the recent international policy developments. Including, Sustainable Development Goals (SDGs) and COP21 commitments and builds the European 'Food and Nutrition Security priorities':

- NUTRITION: Sustainable and healthy diets
- CLIMATE: Smart and environmentally sustainable food systems
- CIRCULARITY: Circularity and resource efficiency of food systems
- INNOVATION: Empowerment of communities

MicrobiomeSupport aims to support the EC to meet its FOOD2030 priorities.

Horizon Europe priorities

This is the new Framework Program of the EU running from 2021 to 2027. See the main pillars of this research and innovation program (https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme_en). MicrobiomeSupport will amongst others provide input to Horizon Europe via a Strategic Research Agenda that focuses on food systems microbiomes.

