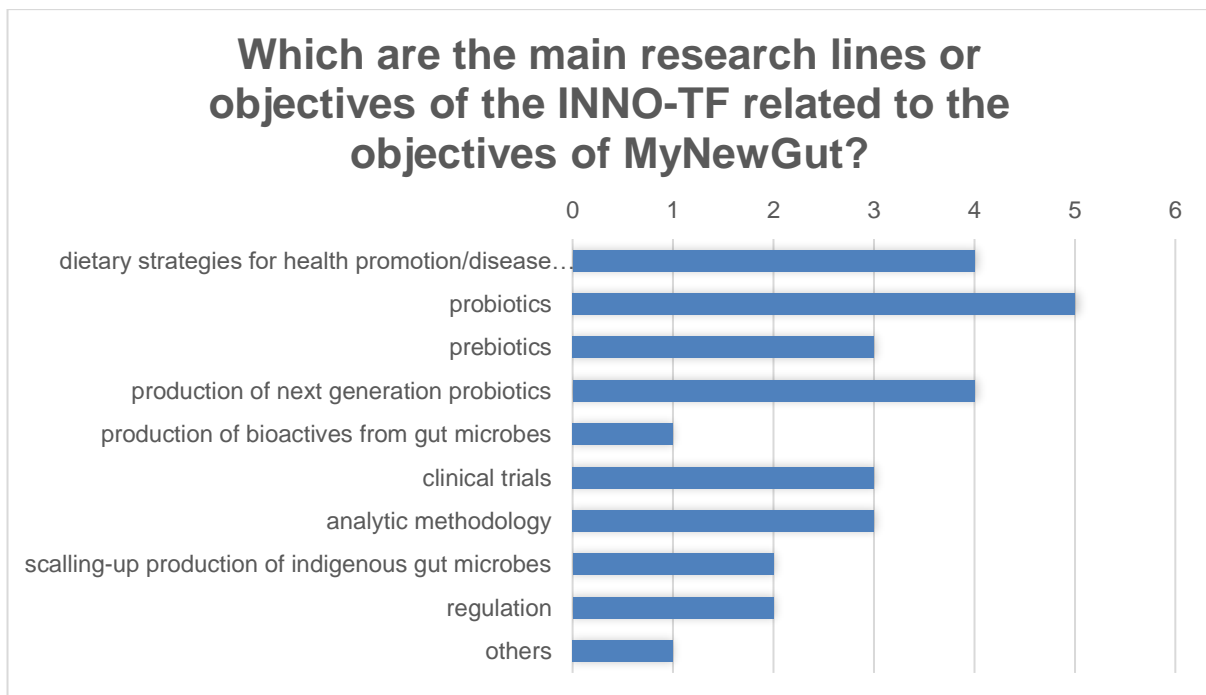




## Q&A with MyNewGut's Industrial Innovation Task Force (INNO-TF)

21 global leading health organizations make up the MyNewGut Industrial Innovation Task Force (INNO-TF). We interviewed various members to discover the current industry view on topics relevant to the MyNewGut project's objectives. Click on each question to see what the industry has to say on current and future topics regarding the gut microbiome.



### Which type of dietary, pre- or pro-biotic applications are of interest, and in which population groups?

- Dietary interventions involving both pro-/pre-biotics.
- Applications that contribute to enhancing health benefits of grain based products.



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- Developing Live Biotherapeutics Product (LBP) for overweight and obese adults and teenagers suffering from metabolic syndrome.
- Interested in probiotic isolated from human breast milk and their applications on modulating human immune defenses, reducing the risk of infections and alleviating inflammatory responses in several chronic inflammatory diseases, including mastitis.
- Interested in both traditional and more original applications of probiotics, using the best known bifidobacteria and lactobacilli but also deepening our knowledge about possible innovative applications of more alternative genera.
- Interested in probiotic applications, directed to any population group, focused on specific diseases such as obesity.
- Prebiotics, interested in human milk oligosaccharides (HMOs) as they have been studied in the past but other fibers are also interesting, depending on the applications requested by the customer.
- Would like to explore multispecies food supplements and food for special medical purpose.
- All population groups and life periods can be the target of our investigation. Such population groups include young infants, the elderly, lactating baby, women, children adults and patients.
- Health conditions such as obesity, malnutrition, diabetes, IBD, mood disorders and cognitive impairment, diseases such as infections, insulin resistance, metabolic syndrome, gastrointestinal disorders, allergic disorders, neurodegenerative diseases, stress, and type 2 diabetes.

**What is needed to better document the health benefits of the specific dietary components, pre- and pro-biotics? What are the priorities? What are the endpoints that we should be looking at?**

- The ability to define a 'healthy' gut microbiome, biomarkers needs to be explored further.
- 'Healthy vs. non-healthy' gut microbial ecosystems need to be identified.
- Accurate recording of dietary intake in intervention and cohort studies of epidemiological studies.
- Demonstrate activities of Live Biotherapeutics Product (LBP) and bacteria on weight in mice and human models.
- Conduct clinical trials in the US and Europe, 1-year duration, with weight loss as primary outcome aligned with FDA guidance.



- Conduct rigorous clinical studies with strong level of evidence (level I) that undoubtedly demonstrate the benefits of each specific dietary component as well as the mechanisms responsible for the activities.
- Identify the specific component in an ingredient which is responsible for the activity and identify the specific target in the human organism.
- Define the characteristics of the population likely to benefit from the activity of those components (gender, age, specific period of life but also genotype, context of microbiota).
- Bioinformatics tools must be taken into account in order to highlight the mechanisms of action of probiotic strains.
- Well-designed randomized clinical trials are needed, with clearly defined endpoints. The endpoint will be very different depending on the disease/condition being studied.
- Clinical relevant endpoints, with secondary mechanistic markers to explain the mechanism.
- Endpoints of interest include stability, resilience, diversity of the intestinal microbiota, nutrient absorption, immune function, modulation of mood, cognition, and energy balance.

**Do you think we need to standardise the methodologies applied in microbiome research to speed-up the translation of science into applications and authorisation of microbiome-based foods/ingredients/medicinal foods/drugs? Which area (analytic procedures, study models, intervention trials, etc.) needs standardisation?**

- The standardisation of analytical procedures that are used in the collection, storage and analysis of samples would provide an immediate and measurable benefit in spurring translation of the microbiome field from both scientific and regulatory viewpoints.
- Studies should consider EFSA criteria for confirmation of health claims and should follow the recommendations made in the [MyNewGut special issue of Trends in Food Science & Technology](#) to use insulin resistance as key factor for modulation of gut microbiome for obesity related health claims.
- Harmonisation in sequencing methodologies is needed (PCR, 16s rRNA, metagenomics) and standardisation of analysis (bio informatic).
- In order to verify results or compare efficacy, different methodologies should be standardised and well controlled. Methods in intervention trials, population studies, and analytical procedures should be well characterised. Important differences in methods to detect and quantify microbial population could have an important impact in the conclusions of the studies.
- Standardisation of the procedures would be of great help, particularly in the interpretation of the results coming from existing and future research. All the fields mentioned are worthy of efforts toward standardisation as techniques are continuously being updated, enabling deeper study of complex environments and allowing access to huge amounts of information.



- Standardisation is needed; there is an increasing number of publications which need to be carefully interpreted and are often not consistent with each other.
- Standardisation is a key tool to compare and evaluate different microbiome-based ingredients. It would be easier if all authorities/companies speak the same “language”. At least in vivo models and intervention trials should be standardised.
- Microbiota measurements needs standardisation to compare different research.
- Yes, it should be carried out in the first place, standardisation of analytic procedures and intervention trails.

**Do you think that microbiome-based predictive biomarkers of disease risk could help in developing dietary preventive strategies?**

- Yes, it is important to focus on the level of specific bacteria at baseline and evaluate the increase of these specific bacteria during the treatment.
- Microbiome based predictive biomarkers are the most promising benefits of microbiome research. Relationships should be better defined in preclinical and clinical trials.
- Understanding how the microbiome can determine the risk of developing a disease is crucial for designing a dietary strategy, to influence relevant biomarkers, and prevent the disorder.
- Microbiome based predictive biomarkers could be of real help, despite the difficulty of identifying a general predictive marker when diet and lifestyle are both individual/personal fields.
- We think that more research is needed in this field.

**How could we better predict health-related outcomes mediated by the microbiome resulting from dietary interventions? Could it be worthwhile to develop predictive tools and models?**

- A greater understanding of the physiology and ecology of microbes that inhabit the gut and of the two-way communication that occurs between microbes and the host needs to be developed.
- A systematic way of developing predictive capability would involve developing mathematical models based on existing data which would allow for the identification of knowledge and research gaps allowing for the prediction of host health outcomes.
- There is an identified need for real and demonstrated biomarkers resulting from the diet, but there still remains the genetic problem between the host and the microbiota, also affecting the interactions of both.
- Predictive tools integrating genetic data, metagenomic and dietary habits, will be key for the design the best interventions.



- A possibility could be to study metabolite production due to different treatments and to try to draw correlations among metabolites and symptoms, if any, or lacks detected in particular diseases or populations.
- Based on literature, a model could be developed to correlate different dietary interventions with health improvements. However, the differences between the dietary interventions should be considered and incorporated into the model, and this may be challenging.

**What options do you see for more open and collaborative approaches to develop and commercialise microbiome-based products that have a positive impact on the health of individuals?**

- New model set up, development and evaluation of nutritional technologies (nutrition/prebiotic/probiotic).
- European guidance to develop and register drugs and a clear definition to obtain claims by EFSA.
- Education: Consumer should know the impact of their microbiome on their health. The maintenance of a balanced microbiota is a bet of future health and consumers should be sensitised to the fact that the microbiota is not only affected by their lifestyle but will also depend on their own genetics. The future is to know which is the most suitable microbiota for each specific case and how it can be modulated to reach it. The total understanding of the microbiome, its relationship with the individual and the influential factors is a task of huge dimensions that requires a great economic effort. Hence, to accelerate the market entry of products based on microbiome studies, joint action of researchers, institutions and companies is important.
- The relationship between universities, research centers and private companies is needed. It would be interesting to have a website where research groups could offer their main research lines related to the microbiome, so that interested companies could contact them.
- People in academia are often afraid to collaborate with industry, resulting in trials with interventions that are not commercially available on the market. People also do not always conduct interventions with a microbiologist involved, which can help in choosing the most promising probiotic strain(s) and/or prebiotic product.

**Do you think microbiome science could contribute to improved dietary recommendations? How?**

- Yes, it is a critical tool in establishing nutritional recommendations, e.g. microbiome research data, used to refine dietary fibre requirements based on their effects on host physiology rather than analytical methods.
- Yes, it could reinforce negative recommendations (e.g. less fat) and increase recommendations on fibres.



- Of course, we know that dietary habits impact the microbiota but more studies are needed to explain this modulation and how is it dependent on the composition of microbiota and the genetics of the individual.
- Some recent research seems to indicate that individuals respond differently to foods, based on the different microbiota the gut hosts. Therefore, microbiome science could contribute, but the dietary recommendations should be personalised, and based on the an individual's microbiome.
- Yes, for this easy and affordable methods should be available, e.g. to test your own enterotype.

### **To what extent will the microbiome play a role in personalised nutrition?**

- As every microbiome is unique to an individual's life stage, consideration of each individual's microbiome will be a key feature of personalised nutrition.
- The microbiome is strictly personal therefore recommendations will be related.
- It is where we need to achieve. First of all, we need epidemiology studies in healthy and sick populations to build a gold standard. And then, we can imagine a routine procedure by collecting patients' stools at low cost (less than 25€) in order to have a mapping of the microbiome of the patient before the treatment and choose the best treatment for this patient.
- There is no doubt that microbiome will play an important role in personalised nutrition. Different people respond differently to food. Therefore, food choices that are good for one person may not be good for another.
- One source of such variability is our microbiome - the collection of 100 trillion germs and microbes that we carry around with us. Each of us has a unique microbiome, which is affected by what we eat, and in turn, affects our response to food.
- Microbiome and related sciences could play a fundamental role in personalised nutrition, as it has been shown by the increasing interest toward personalised clinical therapies: even more microbiome could influence the intake and absorption of nutrients. Of course, a careful approach applying metabolomic sciences would be important.
- We think that it could play an important role in the near future.

### **How could researchers contribute to evidence-based public health recommendations and policies based on microbiome science? Do you think there are enough mechanisms to strengthen this collaboration?**

- Engage with governmental agencies – provide regular updates, so that governmental representatives are kept up to date on scientific developments.



- Agencies involved in establishing recommendations, food supply, food assistance and disease control should be included.
- This collaboration should happen when clear health benefits are proven.
- The collaboration could be improved with more comprehensive, easy to understand language from scientific researchers.
- The most frequent way to communicate new results is through scientific papers, which are not familiar and accessible for consumers and public health bodies, who are not able to understand the real meaning of scientific advances. Due to this it could be worthy to increase the public and didactic meetings by making studies and results more available even for unfamiliar people.
- Books and leaflets could be prepared so to be perceived as scientifically supported and not advertisement, with some kind of small courses held for common people.
- They could contribute by performing randomized clinical trials based on microbiome science and then publish the results in literature. In most cases evidence-based public health recommendations are based on available papers, systematic reviews and meta-analysis.

**Which communication strategies can help to inform health care professionals/dietitians/public about progress in microbiome research?**

- The main issue that research is not focused enough on health and clinical data. There is too much animal data and not enough human transposition.
- International congress, workshops, conferences, seminars
- Specialised magazines and websites can be pursued but to reach the final consumer, it is currently important to use social networks.

**What is the role of consumers in succeeding in the development of microbiome-based products/applications?**

- They would be the driver of the expansion of microbiome product but the claims have to be clear and precise.
- Consumers should be opened to try natural alternative solutions to prevent and treat certain diseases different from conventional drugs therapies. It is really important that health professionals have enough information about the benefits of microbiome-based products and to communicate this to patients, consumers, etc.
- Consumers are vital, as they are the target of the microbiome-based products and studies. But they have to understand the importance of what these applications are dealing with.
- Market studies can be carried out to predict in advance which applications could be successful among consumers.



### **Which role do you think research institutions should have in the maintenance of the food industry competitiveness?**

- They should play a role in improving the connections between scientific and medical research and institutions.
- Industry and researchers must work together so that advances in food design or diets can be transferred quickly and efficiently to products for the market that offer effective solutions to the population.
- I think that research institutions should focus their studies on new developing techniques and on new discoveries about important issues. They should also consider which kind of concrete application could rise for food industry. Many efforts are done in finding causes and therapies for disease and syndromes or, regarding probiotics, about new potential genera harboring interesting characteristics but it seems that the applicability of these discoveries are forgotten, because findings are in bacteria which will never be industrialised for plenty of current technological issues. So, it could be of great help if, besides studying the properties of the new potential probiotics, research institutions could provide also techniques for the technological solving of the pending issues, so to increase industry competitiveness.
- The main role should be providing enough knowledge to the industry so that they are able to produce innovative food products.

### **Do you think the EU's funding scheme is contributing to boosting competitiveness/innovation of the European food industry? What could be improved?**

- Yes, but not effectively, too many diverting interests.
- The EU funding processes are too long for this quick advancing science.
- In spite of the fact that the microbiome has been considered as an aspect to study in some H2020 topics, the role of the microbiome in health issues should win more relevance in EU Financing programmes.
- I think that the current scheme is still too much focused on research and not on industry as much as it would be needed.
- Yes, EU's Framework Programme for Research is a good initiative to boosting innovation of the food industry.

### **Which are the most important innovation drivers for the industry in the microbiome field?**

- Private investment of financial found in order to precise the project and institutional research on epidemiology.
- There are several important innovations in the microbiome field, such as selectively eliminating harmful members of the microbiota, using combinations of commensal bacteria





as therapeutics to modulate host microbiota, protecting the gut microbiome to prevent infection (typically by opportunistic pathogens after antibiotic treatment), or modulating the composition of the endogenous host microbiota with recombinant bacteria.

### **Which are the most important barriers for the industry in the microbiome field?**

- Lack of definition for what constitutes a 'healthy' gut microbiome.
- Reduced cost of whole genome sequencing/shotgun DNA sequencing – allow researchers in the future to examine the effects of dietary manipulation on functional changes within the gut microbial community rather than changes in community composition.
- Not understanding and covering the whole picture of microbiome and human health.
- Barriers lie in the complexity of the development process, whether from a technical or regulatory point of view.
- In Europe, an important barrier is regulatory.
  - How are companies going to invest in new products based in microbiome when the beneficial effects of probiotics are questioned?
  - Who is going to educate people about the key role of their microbiome in their health?
  - How can people make food choices if beneficial effects cannot be communicated?
- That is the great challenge that the authorities together with researchers and industry must face if they want populations to have access to better products that favor health.
- The main barrier could be translating basic research into commercially and clinically viable products.

### **How could our project help consumers in making informed food choices?**

- Shaping clarity.
- Helping with diet recommendations. Obesity management, education of the patient on food and activity is most important.
- Consumers are generally unaware of the importance of the gut microbiome's role in health. The project should help to change this fact, making more dissemination of the problematic, studies and their results directed also to final consumers (not only academics).

