European Parliament

STOA online workshop

Health and economic benefits of microbiomes

Participants' booklet

EPRS | European Parliamentary Research Service

Scientific Foresight Unit (STOA)

PE 690.022 – May 2021

EN

Health and economic benefits of microbiomes

STOA (online) workshop

Tusday 11 May 2021, 14:00 - 16:30

Online by WeBex

Participants' booklet

Prepared by Gianluca Quaglio and Virgina Mahieu

Available at Health and economic benefits of microbiomes (online event)

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1. Programme

14:00-14:10 - WELCOME

Eva Kaili, MEP and STOA Chair

14:10-14:55 - HEALTH AND ENVIRONMENTAL IMPLICATIONS OF MICROBIOMES

Moderator: Nassos Typas, European Molecular Biology Laboratory, Heidelberg, Germany

Emmanuelle Maguin, INRAE, France
The microbiome-host symbiosis, a cornerstone of human health

Elisabetta Caselli, University of Ferrara, Italy
Microbial strategies to reduce pathogens and drug resistance in clinical settings

Lene Lange, LLa-BioEconomy, Denmark
Microbiomes for animal health and environmental sustainability

14:55-15:40 ECONOMIC AND REGULATORY ASPECTS OF MICROBIOMES

Moderator: Irene Verheijen, European Association for Food Law (EFLA)

Angela Sessitsch, AIT Austrian Institute of Technology (AIT)
How tiny little things run the earth and the circular economies

Martha Hugas, European Food and Safety Agency (EFSA)
Safety and regulatory challenges for microbiome innovations

Kathleen d`Hondt, Flemish Government, Belgium
Policy options for microbiome innovations: perspectives from the OECD

15:40-16:20 Q&A

16:20-16:30 CLOSING REMARKS

Othmar Karas, MEP and Vice-President of the European Parliament

2. Introduction

The microbiota is a collective term referring to the reservoirs of micro-organisms living in the human body, in animals, and in the environment. They are nearly ubiquitous both in our soils and in our gut, working behind the scenes but providing vital support to our health and well-being. Microorganisms always live in microbial communities, which are quite diverse. Although the terms are used interchangeably, there is a slight difference between microbiome and microbiota. In fact, 'microbiota' refers to the actual organisms ('bugs') within a microbial community, and 'microbiome' to the organisms of a microbial community in its "theatre of activity", i.e. taking into consideration e.g. environmental conditions.

Microbiomes should not be confused with probiotics, which are beneficial bacteria found in certain foods or supplements and are defined as "live micro-organisms that confer a health benefit to the host when administered in adequate amounts", according to United Nations Food and Agriculture Organization/World Health Organization guidelines. Commonly used probiotics include Lactobacillus, Bacillus, Escherichia or Streptococcus, however combinations of more than one are common to achieve maximal effects. Probiotic use is increasingly practised for human, veterinary and environmental applications in order to treat or beneficially affect the innate microbiome.

Perhaps due to their small size, microbiomes have been relatively unknown until now, but they are gaining fame due to recently mounting scientific evidence that shows their vital importance in our lives and the negative consequences for our health and environment due to damaging or losing them. Furthermore, microbiomes could improve our food production and quality, treat certain non-communicable diseases, and assist in mitigating antimicrobial resistance (AMR). In a larger perspective, they can also support the circular economy through waste degradation, and help mitigate pollution and climate change. Though their promising and exciting uses are becoming increasingly evident, currently there is no EU legislation to directly regulate and evaluate the safety and composition of microbiomes within the food or medical sectors.

This STOA workshop aims at informing on and highlighting the importance of microbiomes, and at discussing how they can benefit our society. It is divided into two parts: The first will focus on the clinical and environmental implications of microbiomes, while the second will focus on their economic and regulatory aspects.

2.1 Health and environmental implications of microbiomes

Microbes and human health

Microbiomes are a key aspect of human health in terms of digestion, hormone regulation and the immune system. There is even evidence that they may signal directly to our brains, influencing our development and mental health. Nutrition, physical activity, childbirth, drug treatments, and environmental factors affect our gut microbiomes, and imbalances can detrimentally affect our health. There is indication that societal changes of the last few decades in lifestyles and food production practices could be causing changes in gut microbiomes and affecting public health.

Research in this area is mounting and it is becoming increasingly clear that a large host of non-communicable diseases could be attributed to imbalances in our gut microbiome, including gastrointestinal inflammation, metabolic conditions, and even cardiovascular, respiratory, and neurological illnesses. Microbiomes also have the potential to treat a number of medical conditions such as inflammatory bowel disorders, obesity, diabetes, and more. But there is a need for new diagnostic tools to support this growing field, and a more centralised EU legislation could support European innovation in this field.

Antimicrobial resistance and healthcare-associated infections

Overuse and misuse of antibiotics forces evolution of disease-causing microbes that are resistant to treatments. This could lead to drug-resistant illnesses that are difficult to treat, and perhaps even future pandemics. Already this is becoming an issue, with 33,000 deaths in 2015 alone reported in the EU from drug-resistant infections. There is the potential to treat bacterial infections with probiotics, thereby reducing the need to use antibiotics as a standard treatment and also mitigating some of the potentially detrimental effects of antibiotics on our innate microbiomes.

Furthermore, AMR can contribute to healthcare-associated infections, which occur due to the persistent contamination of surfaces in a clinical environment that cannot be fully controlled by conventional cleaning. Recent evidence shows healthcare-associated infections could be mitigated by using probiotic cleaning hygiene systems, i.e. using beneficial bacteria to fight disease-causing pathogens and therefore prevent infections.

In 2017, the EU launched its One Health Action Plan against Antimicrobial Resistance, which is aimed at promoting best practices in the EU, boosting research, development, and innovation, and shaping the global agenda with regards to AMR. Furthermore, the European Health Union includes provisions to tackle AMR.

Environmental sustainability

Microbes are present in every corner of the natural world. They perform essential functions in breaking down organic waste and recycling nutrients both on land and at sea. They nourish the plants and marine life that we eat and that clean our air, inextricably supporting life on earth. While they are important to protect for these reasons, we can also harness the power of microbiomes to support agriculture and environmental sustainability. For example, the use of bio-pesticides is being offered as an alternative to chemical pesticides with fewer damaging effects to the ecosystem. Using microbes to degrade organic and plastic waste could support recycling, reduce landfill content and fuel agriculture. These applications would be climate-friendly, tackle pollution, and contribute to achieveing the goals of the European Green Deal.

Replacing synthetic pesticides with biopesticides is one of the goals of the Farm to Fork (F2F) strategy. Furthermore, one of the pathways under Food 2030, the EU's research and innovation policy to improve food systems, is the microbiome world. This is an opportunity for our society and our planet to manage our resources and improve our health.

2.2 Economic and regulatory aspects of microbiomes

Circular economy

The circular economy has gained increasing prominence in recent years. A circular economy is an alternative to a traditional linear economy (make, use, dispose) in which resources are kept in use for as long as possible, extracting the maximum value from them while in use, and regenerating products and materials at the end of each service life.

The aforementioned practical applications of microbes are not only beneficial in those specific areas, but could also ultimately support a circular economy by closing gaps in the production chain. Microbiomes used to break down waste, along with contributing to cleaning the environment, can fuel the agricultural systems and thereby reduce costs. They can also be used to improve livestock feed, increase crop yields, improve soil nutrition, and preserve foods (i.e. through fermentation). These microbiome activities could help achieve the goals of the revision of the Feed Additives Regulation. They could also contribute to the implementation of several of the United Nations Sustainable Development Goals (SDGs) including clean energy (SDG 7), responsible consumption and production (SDG 12), and climate action (SDG 13), as well as the Circular Economy Action Plan.

EU regulation on microbiomes

Despite the upswell in scientific insight, regulation and legislation to determine the place of microbiomes in the European society is currently lacking. There is currently no EU guidance or regulation on systematic assessment of microbiomes in the context of human, animal or plant health. They are only generally and indirectly mentioned through the Plant Protection Products Regulation and the European Medicines Agency safety requirements on veterinary drugs. EU food law also does not yet contain any provisions for microbiomes, despite the increasing evidence that they are – or should be – a very important consideration in our diet.

For the benefits of microbiome research and innovation to reach society, standardisation, protocols and a regulatory framework are needed. Especially as microbiomes can be subject to fad marketing, they can lack credibility and quality control. To this effect, EU-wide establishment of research standards, combined with funding, collaboration and pre- and post-market surveillance of microbiome-based products and applications are needed.

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3. Welcome

Eva KAILI, MEP and STOA Chair

Eva Kaili has been a Member of the European Parliament, part of the Hellenic S&D Delegation since 2014. She is the Chair of the European Parliament's Panel for the Future of Science and Technology (STOA) and STOA's Centre for Artificial Intelligence (C4AI), member of the Committee on Industry, Research and Energy (ITRE), and substitute member of the Committees on Economic and Monetary Affairs (ECON) and Budgets (BUDG), and of the Special Committee on Artificial Intelligence in a Digital Age (AIDA).

Eva is member of the delegation to the ACP-EU Joint Parliamentary Assembly (DACP), and substitute member of the delegation for relations with the Arab Peninsula (DARP), and the delegation for relations with the NATO Parliamentary Assembly (DNAT).

In her capacity, she has been working intensively on promoting innovation as a driving force of the establishment of the European Digital Single Market.

She has been the draftsperson of multiple pieces of legislation in the fields of blockchain technology, online platforms, big data, fintech, AI and cybersecurity, as well as the ITRE draftsperson on the Juncker Plan EFSI2 and more recently the InvestEU programme.

She has also been the Chair of the Delegation to the NATO Parlimenary Assembly in the European Parliament, focusing on Defence and Security of Europe. Prior to that, she has been elected as a Member of the Hellenic Parliament (2007-2012), with the PanHellenic Socialist Movement (PASOK).

She also worked as a journalist and newscaster prior to her political career. She holds a Bachelor degree in Architecture and Civil Engineering, and a Postgraduate degree in European Politics.

4. Part I: HEALTH AND ENVIRONMENTAL IMPLICATIONS OF MICROBIOMES

4.1 Moderator: Athanasios TYPAS, Group Leader & Senior Scientist, European Molecular Biology Laboratory (EMBL), Heidelberg, Germany

Nassos Typas is a trained biochemist, geneticist and systems biologist. He did his undergraduate studies in Chemistry/Biochemistry at the Aristotle University of Thessaloniki, his PhD at the Free University of Berlin with Regine Hengge, and his postdoctoral research at University of California at San Francisco with Carol Gross. Since 2011 he has been running his own group at the European Molecular Biology Laboratory (EMBL) at Heidelberg, and since 2020 he has been a Senior Scientist.

His group develops systems-based quantitative approaches and combines it with mechanistic work to study how bacteria interact with the environment, the host and with each other. The overarching goal is to identify new principles and mechanisms that govern such interfaces, and to shed light into the vast dark matter encoded in bacterial genomes. Key focal areas of the lab are on antibiotics, host-pathogen interactions and the human gut microbiome.

Nassos has received a number of awards, e.g. NIH Pathway to Independence Award (K99/R00), Sofja Kovalevskaja Award from the Humboldt Foundation, ERC Consolidator Grant, and VAAM Research Award. He is a member of the European Academy of Microbiologists.

4.2 Emmanuelle MAGUIN, Senior Researcher at INRAE, France

Dr. Maguin is a senior researcher at the French National Institute for Agriculture, Food and Environment (INRAE) with a long track expertise in microbiome research on fermented foods and then on human and animal microbiomes. She is experienced in the management of multidisciplinary research and innovation activities as head of the INRAE microbiology research division (2006-2016, 22 laboratories) and of two multidisciplinary flagship programmes on microbial ecosystems and on food system microbiomes and holobionts, assemblage of hosts and microorganisms. She is advising the INRAE scientific director on microbiome and is a member of several scientific advisory boards. She is co-coordinating the MicrobiomeSupport European Coordination Support Action (CSA) and International Human Microbiome CSA.

Key message

For several decades chronic diseases have been steadily on the rise and represent a major threat to healthy ageing. By 2025, chronic diseases will affect one person in four (WHO report). Microbiomes, which is are communities of microorganisms and their activities, bring services to their hosts, e.g. the planet, plants, animals, humans etc. Microbiome and the host-microbe interplay has been shown through numerous studies and European and international projects to be a key driver of health, notably human health.

This knowledge radically transforms the human health paradigm inherited from infectious diseases, from a linear vision of one microbial agent and its associated ability to generate a disease to a more complex situation where the interactions between numerous environmental, host and microbiome factors determine the risk of developing a disease and possibly the response to a given therapy.

In the last 60 years our industrialised societies markedly changed our lifestyles in terms of nutrition, food systems and food, physical activity, childbirth, drug treatments including antibiotics, exposure to environmental factors etc. All these recent modifications are putting the human-microbe symbiosis at risk of progressive functional alterations.

The recent concepts of One-Health and personalised medicine are integrating this complexity considering the specific history of the host, environmental exposure, and sometimes microbiome specificities and modifications over a human lifespan. However, there is still a need to advance knowledge on these multifactorial interactions. A key prerequisite to producing robust data and providing meaningful analyses is the availability and large-scale use of harmonised standards and operating procedures, as well as access to unified repositories.

These recent concepts are integrating healthy diets which are also more sustainable, as a means to promote health and well-being, thereby helping to reduce non-communicable diseases. This new vision makes it necessary to reconsider current health systems mostly focused on the human body in order to integrate environment-microbiome-host as key elements for prevention and maintenance of a healthy state, to re-examine and to invent new diagnostic and prognostic tools, new clinical validation schemes and new therapeutics development schemes, as well as to implement the required regulatory framework for microbiome-based innovations and increase awareness, information and training on this paradigm.

4.3 Elisabetta CASELLI, Professor and Chair of Clinical Microbiology, University of Ferrara, Italy

As well as being Associate Professor and Chair of Clinical Microbiology at the University of Ferrara (Italy), at the Department of Chemical and Pharmaceutical Sciences, in the Section of Microbiology, Elisabetta Caselli is also the scientific manager of the CIAS Interdepartmental Research Center of the University of Ferrara, and member of the PhD Doctorate in Advanced Therapy and Experimental Pharmacology (University of Ferrara). Recipient of national and international grants as Principal Investigator, her main research fields include clinical microbiology, infectious diseases and healthcare-associated infections, antimicrobial resistance, immunology, autoimmunity, microbiome in health and disease, built-environment microbiome, and biological and sustainable strategies to balance the microbiome as a tool in infection prevention and control.

Her research activity has produced over 100 original papers published in international peer-reviewed scientific journals, 4 chapters in scientific books, 4 patents, and over 200 communications at national and international meetings, often as invited speaker.

Key message

Recent research shows that the built environments can be considered as super-organisms with their own microbiome, like living organisms and the human body. Interestingly, more confined environments have microbiomes displaying less biodiversity compared to natural unrestricted environments. Furthermore, more confined built environments (such as hospitals) have more 'anthropic' microbiomes, essentially derived from humans, and more resistant microbiomes, due to the selective pressure exerted by disinfectants and antimicrobial drugs.

Concerning the hospital environment, these features are of importance, as the hospital microbiome represents a reservoir for microbes capable of transmitting the so-called healthcare-associated infections (HAIs). HAIs are a global concern, each year affecting over 4 million patients in the EU, with about 90,000 avoidable deaths and 1.1 bn euro of extra sanitary costs. Major causes are indeed the persistent microbial contamination of the hospital environment and the antimicrobial resistance (AMR) of HAI-associated microbes, which are often multi-drug or even pan-drug resistant, as reported by the WHO in the ESKAPE and DIRTY DOZEN lists of pathogens responsible for HAI onset.

Hospital decontamination has been so far addressed by conventional chemical-based sanitation, however this does not prevent recontamination, has a high environmental impact, and might contribute to the increase of AMR of the hospital microbiome. In this regard, the current high use of disinfectants/antibiotics due to the COVID-19 pandemic might contribute to worsening the AMR concern and environmental pollution.

In the search for new methods, effectively providing stable decontamination without undesirable "side effects", probiotic-based sanitation (PBS) was shown to modulate the hospital microbiome by replacing dangerous resistant pathogens with beneficial microbes, and the use of this method was associated with a 99.9% decrease of AMR pathogens and associated HAIs (-52%), accompanied by reduction of antibiotic consumption and related costs. In addition, recent yet-unpublished results show that PBS may be efficient also against viruses, including SARS-CoV-2. These new approaches could open new perspectives in the fight against infections of bacterial, fungal and viral origin. This may be crucial especially now, while we are fighting the spread of the pandemic virus, to avoid possible risks of eventual future pandemics due to resistant bacteria ecologically and sustainably.

4.5 Lene LANGE, LLa-BioEconomy, Denmark

The professional career of Lena Lange includes experience from leading R&D positions in both private sector and academia. After PhD and Postdoc positions at University of Copenhagen, she joined the Danish Ministry of Foreign Affairs, DANIDA, Seed Pathology Institute (1978-1986). A major part of her career, from 1987 to 2007, was holding R&D positions in private industry, Novo, Novo Nordisk and Novozymes A/S, finishing in a top research career position (Director of Research in Molecular Biotechnology). From 01.02.07 she was recruited back to academia, first as Head of Institute of Biology, University of Copenhagen, and from 01.09.08 as Dean of Research (and Professor in Biotechnology) at Aalborg University, Denmark (2009-2013); Director of Research for Aalborg University (2012-2015). She was then Professor and Research Leader, Technical University of Denmark (2015-2018). In 2018, she became the founder & owner of the startup company BioEconomy, Research & Advisory. Lene Lange has published over 270 peer-reviewed papers, books, monographs and patents, which as of today have together resulted in over 3700 citations.

Key message

One of the most radically game-changing innovations is the sequencing of gut microbiomes. It is much in focus for man, but of no less importance for animals, and especially relevant for improvements within industrial production of pigs, chicken and fish. Gut health is of crucial importance for animal welfare; most importantly, improved gut health (less inflammation) may reduce the amount of antibiotics needed, especially decreasing the need for large-scale prophylactic treatments. Reducing the use of antibiotics is the strongest measure for reducing the risk of the developing threat of a new antibiotics-resistance pandemic, making infectious diseases non-curable. Microbiome research within the last few years has documented that the animal gut microbiome can be modified and improved by the feed intake. By a combination of molecular and bioinformatic research studies of microbiome composition and function we now know which types of animal feed can have such beneficial effect on gut health. Probiotics (beneficial microbes) and prebiotics (produced by enzyme-processing of plant cell wall materials); these are anti-inflammatory components in the feed-biomass or released by fermenting the feed. *Recommendation: Contribute to reducing the threat of an antibiotic-resistance pandemic by making gut health-improving animal feed additives a part of dietary requirements for industrial animal production*.

Microbiome research is very important for understanding environmental sustainability. The biodiversity-rich microbiomes - of soil, leaves roots - are a characteristic of undisturbed nature. By studying the microbiome composition and function of such natural microbiome systems, we gain insight into balances and microbial interactions of a healthy environment. However, microbiome research is also highly important for a range of applications: planned re-wilding of low-and-humid agricultural soils for decreasing emissions should be followed by microbiome analysis to monitor intended impact. Climate change impacts thawing of permafrost soils. Estimates of emissions during transition from frozen to non-frozen can be monitored by analysing changes taking place in the soil microbiome. Studies of the microbiome of anaerobic digestion in waste-water treatment plants have shown very rich biodiversity in organisms and enzyme functions; the bacteria up-concentrates phosphorous, enabling us to produce more sustainable soil-improvement products using this biogenic phosphorous. Furthermore, studying the microbiome of waste-water can be an important tool for tracking the spread and development of antibiotic-resistance genes, thus providing us with a tool for early warning. *Recommendation: Give priority to microbiome research across all sectors, human health, animal health, for developing early warning systems, following the threat of an antibiotic-resistance pandemic, and early warning of increased emissions; thus, of importance for improved sustainability at large.*

5. Part II: ECONOMIC AND REGULATORY ASPECTS OF MICROBIOMES

5.1 Moderator: Irene VERHEIJEN, President of the European Food Law Association (EFLA)

Irene Verheijen is the President of the European Food Law Association (EFLA) as of 1 October 2020. The EFLA is an international non-profit making organisation that seeks to contribute to the awareness and better understanding of food law and to contribute to the development and international harmonisation of food law, with due regard to its specific character and its role in the field of consumer protection.

She works as a lawyer based in Amsterdam at the law firm Legaltree. She specialises in the field of regulated markets, where the interaction between government and industry plays an important role. Her focus is in particular on the food industry.

Irene Verheijen advises companies throughout the food chain (from animal feed companies to suppliers and producers of foodstuffs) on the (interpretation of) laws and regulations they must comply with when producing and marketing their products. Where appropriate, she assists these companies in legal proceedings, against the government but also between companies or in relation to consumers.

Irene regularly publishes and lectures on topical issues in the field of food law. She is co-author of the practice guide Roadmap Food Law and of the EU Food Law Handbook. She plays an active role in both EFLA and the Dutch Food Law Association.

5.2 Angela SESSITSCH, Head of the Bioresources Unit, Austrian Institute of Technology (AIT)

Dr Angela Sessitsch heads the Bioresources Unit of the AIT Austrian Institute of Technology. She studied biochemistry at the University of Technology in Graz, holds a PhD in Microbiology from the Wageningen University, the Netherlands, and is habilitated at the Vienna University of Natural Resources and Life Sciences. She has pioneered plant-associated microbiomes, and is interested in understanding the interactions between plants, microbiomes and the environment as well as to develop applications.

Angela Sessitsch is coordinator of the EU-funded Coordination and Support Action MicrobiomeSupport aiming at promoting and supporting food systems microbiomes and the global bioeconomy. She is also Vice-President of the Austrian Association of Molecular Life Sciences and Biotechnology, Leader of the Working Group 'Plants and Microbiomes' of EPSO (European Plant Sciences Organisation) and Member of the Board of Directors of the International Phytobiomes Alliance.

Key message

Microorganisms occupy all niches on earth, are extremely diverse and highly abundant. They generally occur within complex microbial communities, also termed microbiomes, comprising fungi, bacteria, archaea, unicellular eukaryotes and viruses. Microbiomes have crucial roles maintaining life on earth. For example, marine microbiomes produce most of the oxygen that we breathe and have indispensable roles in carbon sequestration and nutrient cycling. Soil microbiomes fix nitrogen and methane, enabling fertilization and greenhouse gas mitigation effects. The human gut microbiome has clear links with human health; similarly, plant and animal microbiomes have important roles in plant and animal health.

Our growing understanding of the role of microbiomes in environmental and food systems suggests that microbiome innovations have the potential to improve sustainable food, feed and biofuel production whilst underpinning the principles of circularity. For example, applications of natural or engineered microbiomes to degrade organic and waste materials into nutrients in food and fibre chains might enable a more sustainable fuel industry. Progress is also being made in the application of plant microbiomes for increasing crop yields and improving salt and drought tolerance of crops. Soil microbiomes can be applied as bio-fertilizers for soils and can reduce nitrogen leaching.

The role of food microbiomes in the production and preservation of fermented foods such as bread, chocolate, beer, yoghurt, kefir and kimchee is undergoing a renaissance owing to the application of genomics technologies to understand the composition and functions of food microbiomes. The use of environmental microbiomes for the bioremediation and degradation of toxic contaminants and waste products is expected to accelerate the development of a circular bioeconomy.

The potential of microbiome applications to support the development of a mature bioeconomy and the achievement of the climate mitigation goals has been acknowledged by numerous organisations like the World Economic Forum, FAO or the OECD. Microbiome technologies together with genomics, gene editing and synthetic biology were identified as being key to accelerating bio-innovation in food systems: they are one of 12 promising technologies that could transform food systems in the next decade, while fully adopting the SDGs. However, the huge potential of microbiomes to improve and support food systems and the bioeconomy is just beginning to be understood and microbiome innovations have only recently started to reach the market.

5.3 Marta HUGAS, Chief Scientist, European Food Safety Authority (EFSA)

Dr Marta Hugas is serving as Chief Scientist at the European Food Safety Authority (EFSA). EFSA is a decentralised agency of the EU with a scope on risk assessment and risk communication on food and feed safety from the farm to fork. Marta holds a BSc in biological sciences, an MSc in genetics and microbial biotechnology, and a PhD in food microbiology.

Dr Hugas had a 20-year career in applied research before joining EFSA in 2003. She has extensively published papers and book chapters. In EFSA, she has been leading the reflection on the impact of the microbiome in regulatory assessments. Recently she has been appointed by the UN Secretary General to the Scientific Group for the preparation of the 2021 UN summit on Food Systems as a co-coordinator of Action Track 2, Shifting to Sustainable Consumption Habits.

Key message

EFSA is the food and feed risk assessment body in the EU, it performs regulatory science, assessing the latest science to inform policy decisions, and operates a large network of risk assessment and communication bodies in and beyond Europe. As one of the core tasks of EFSA is to assess risks to human, animal and environmental health from substances linked to food and feed production, the increasing understanding of the role of microbiomes in health calls for a prospective mapping of these roles into regulatory scientific assessment processes with a view to understanding their potential health impact in the various hosts.

Legal requirements under the EU food law do not specify to account for microbiomes in risk assessment. There is currently also no internationally agreed guidance or methodology in place to systematically assess for possible effects on the microbiomes or by the microbiomes on human, animal, or plant health. Knowledge of how the microbiome modulates the pharmacokinetics and metabolism of chemicals is incomplete. There is a challenge in translating a decrease in microbiome diversity into a functional consequence as there are as yet no standards to define a healthy microbiome.

So far, potential effects on microbiomes are studies under various activities across EFSA: e.g. (1) During the re-evaluation of the food additives, (2) Under the health claim legislation (Regulation (EC) No 1924/2006), (3) Antimicrobial resistance including the role that microbiomes could play in the wider environment as reservoirs for antimicrobial genes; (4) The efficacy of digestibility enhancers as feed additives is evaluated for their impact on the animal gut microbiome. However, microbiomes could also become prominent in other areas of EFSA's scientific assessments: e.g. plant health, plant protection products, genetically modified organisms. Animal and human gut microbiomes could have potential relevance for all risk assessments of oral exposure to chemicals.

As microbiome assessment lies at the very heart of the intersection of chemical and biological risk assessment, it will provide ample opportunities in the future for these two disciplines to collaborate and foster mutual understanding on their respective risk evaluations. For all the above reasons, it's of great importance that research and innovation projects address the fate of microbiome in pre-market assessment of regulated products and in generic risk assessments

5.4 Kathleen D'HONDT, Department of Economy, Science and Innovation, Flemish Government

Kathleen D'Hondt, PhD, was trained as a molecular cell biologist both in academia and in industry. She earned her PhD from the University of Ghent and spent several years as a postdoc in Belgium, the Netherlands (WAU) and the Biozentrum in Basel. In 2006, she joined the Department of Economy, Science and Innovation of the Flemish government as a Policy Analyst and joined in 2013 the OECD as a policy analyst in the Working Party on Bio, Nano and Converging Tech (BNCT). Since 2016, she has been back at the Department of Economy, Science and Innovation of the Flemish government.

Key message

It is now accepted that human microbiomes have an important role in human health, especially related to non-communicable diseases. It is anticipated that through diet, the gut microbiome can provide intervention options in the protection against non-communicable diseases, and perhaps even to cure such conditions. The food and pharmaceutical industries recognise the potential for new understanding of the microbiome to translate into products.

Although the relevant actors are gaining scientific insights ever more rapidly, challenges remain in terms of developing an evidential base, standardisation of terms and protocols, and a credible and well-tailored regulatory framework. While the field genuinely holds promise, it is also subject to hype. Many health claims ascribed to food products targeting the microbiome lack sufficient scientific substantiation and are merely associative, with no established causal pathway. If such a promising scientific field is to lead to innovative applications, policies on science and innovation could be improved in five areas, mentioned here below.

Science policy. International research, sufficient funding, transcontinental microbiome research programmes, closer interaction between microbiome research communities and access to large interconnected data infrastructure will be key. Sufficient options for targeted research projects addressing hypothesis-driven science to move beyond mere tool development and cataloguing will lead to a deeper understanding: of the host-microbiome nexus; of what constitutes a healthy microbiome; and of causal relations between microbiomes and health throughout the life span.

Enabling translational science. Standard protocols are required for clinical design, marker validation and statistical interpretation. Better characterisation of a healthy gut will be important for establishing disease biomarkers.

Public-private collaboration. Public Private Partnerships may accelerate innovation by avoiding duplication of efforts and generating more complementary data.

Regulatory frameworks. The frameworks to evaluate health claims of new food products and new dietary approaches need improvements: terminology and categories need clarifying within and across regulatory systems; harmonising the terminology used in the various regulations; and designing regulatory frameworks that respond properly to new products on the food-drug continuum. Postmarketing surveillance may support the evidence base of certain products.

Skills, communication and the public. Moving from cataloguing to insights into physical processes and novel applications will require new technology development, engineering, computer modelling and bioinformatics. Healthcare professionals and the public should be informed in a clear and understandable way.

6. Closing remarks

Othmar KARAS, Vice-President of the European Parliament

Othmar Karas was born in Ybbs an der Donau in 1957. He is Vice-President of the European Parliament, President of the Austrian Aid Organisation 'Hilfswerk Österreich' and chairman of the non-partisan citizen's forum 'Bürgerforum Europa', which he founded as a think-tank and dialogue platform. Furthermore, he is non-regular lector at the Danube University Krems, the Vienna University for Economics and Business, and the University of Vienna.

Othmar Karas was Member of the Austrian Parliament and Secretary-General of the Austrian People's Party, before he was elected to the European Parliament in 1999.

After eight years as Vice-President of the EPP Group, Othmar Karas served as Vice-President of the European Parliament from 2012 to 2014 - a position he resumed in 2019.

In 2020, he was appointed deputy chairman of the Subcommittee on Taxation (FISC) promoting fiscal justice.

7. About STOA

Mission

The Panel for the Future of Science and Technology (STOA) forms an integral part of the structure of the European Parliament. Launched in 1987, STOA is tasked with identifying and independently assessing the impact of new and emerging science and technologies.

The goal of its work is to assist, with independent information, the Members of the European Parliament (MEPs) in developing options for long-term, strategic policy-making.

The STOA Panel

The STOA Panel consists of 27 MEPs nominated from eleven permanent parliamentary committees: AGRI (Agriculture & Rural Development), CULT (Culture & Education), EMPL (Employment & Social Affairs), ENVI (Environment, Public Health & Food Safety), IMCO (Internal Market & Consumer Protection), INTA (International Trade), ITRE (Industry, Research & Energy), JURI (Legal Affairs), LIBE (Civil Liberties, Justice and Home Affairs), REGI (Regional Development) and TRAN (Transport & Tourism).

Ewa KOPACZ is the European Parliament Vice-President responsible for STOA for the first half of the 9th parliamentary term. The STOA Chair for the first half of the 9th parliamentary term is Eva KAILI with Christian EHLER and Ivars IJABS elected as 1st and 2nd Vice-Chairs respectively.

The STOA approach

STOA fulfils its mission primarily by carrying out science-based projects. Whilst undertaking these projects, STOA assesses the widest possible range of options to support evidence-based policy decisions. A typical project investigates the impacts of both existing and emerging technology options and presents these in the form of studies and options briefs. These are publicly available for download via the STOA website: www.europarl.europa.eu/stoa/.

Some of STOA's projects explore the long-term impacts of future techno-scientific trends, with the aim to support MEPs in anticipating the consequences of developments in science. Alongside its production of 'hard information', STOA communicates its findings to the European Parliament by organising public events throughout the year. STOA also runs the MEP-Scientist Pairing Scheme aimed at promoting mutual understanding and facilitating the establishment of lasting links between the scientific and policy-making communities.

Focus areas

STOA activities and products are varied and are designed to cover as wide a range of scientific and technological topics as possible, such as artificial intelligence, blockchain, 5G, genetic engineering, antibiotics resistance, internet addiction, face recognition, pollution, sustainable agriculture, COVID-19 and health in general.

These activities are clustered within three main thematic areas: Artificial intelligence & other disruptive technologies, The new Green Deal, and Quality of life. In addition, STOA's work addresses four cross-cutting policy areas: Science, technology and innovation; Societal and ethical challenges; Economic challenges; and Legal challenges.

ESMH

The European Science-Media Hub (ESMH), operating under the political responsibility of the STOA Panel, is a platform to promote networking, training and knowledge sharing between the European Parliament, the scientific community and the media. The ESMH creates a network among policy-makers, scientists and media involving science, academia, educational and research entities, and professional associations of journalists and scientists.

For journalists and media representatives, the ESMH organises training sessions and workshops on current technological developments, both as subjects of their reporting and as means of facilitating their work. Via media monitoring and media intelligence tools, the ESMH follows the most popular topics in the field of science and technology on different platforms including journals, newspapers and social media.

The ESMH makes information available to journalists, other media and citizens about new scientific developments, as well as about scientific topics that attract media attention, and promotes information based on evidence.

Centre for AI (C4AI)

To intensify its activities in the field of artificial intelligence (AI), STOA has launched its Centre for AI (C4AI). C4AI was established by decision of the STOA Panel on 19 December 2019, and was announced at the high-level STOA workshop 'The Future of Artificial Intelligence for Europe', which took place on 29 January 2020 at the European Parliament in Brussels.

Within the context of STOA and based on decisions of the STOA Panel, C4AI produces studies, organises public events and acts as a platform for dialogue and information exchange on AI-relevant topics within the Parliament and beyond. In particular, it provides expertise on the possibilities and limitations of AI and its implications from an ethical, legal, economic and societal perspective. Through these activities, C4AI aims to contribute to the quality and coherence of discussion and policy-making as the EU seeks to coordinate its efforts and influence global AI standard-setting.

STOA Panel members

	Panel Member	Committee		Panel Member	Committee
	Ewa KOPACZ (EPP, PL) **EP Vice-President** **STOA Bureau member**			Francesca DONATO (ID, IT)	**AGRI**
	Eva KAILI (S&D, EL) **STOA Chair** **STOA Bureau member**	**ITRE**		Herbert DORFMANN (EPP, IT)	**AGRI**
	Christian EHLER (EPP, DE) **1st STOA Vice-Chair - STOA Bureau member**	**ITRE**		Lina GALVEZ MUÑOZ (S&D, ES)	**EMPL**
	Ivars IJABS (Renew Europe, LV) **2nd STOA Vice-Chair - STOA Bureau member**	**ITRE**		Alexandra GEESE (Greens/EFA, DE)	**IMCO**
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	Panel Member	Committee		Panel Member	Committee
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	Othmar KARAS (EPP, AT)	**ITRE**		Hermann TERTSCH (ECR, ES)	**ENVI**
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	Michèle RIVASI (Greens/EFA, FR)	**ENVI**	AGRI: Agriculture and Rural Development CULT: Culture and Education EMPL: Employment and Social Affairs ENVI: Environment, Public Health and Food Safety IMCO: Internal Market and Consumer Protection INTA: International Trade ITRE: Industry, Research and Energy JURI: Legal Affairs LIBE: Civil Liberties, Justice and Home Affairs REGI: Regional Development TRAN: Transport and Tourism		

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This is a publication of the Scientific Foresight Unit (STOA)
EPRS | European Parliamentary Research Service

PE 690.022