SCENARIOS FOR MICROBIOME R&D AND NEEDS FOR ACTION – RESULTS FROM THE PROGRESS PROJECT

Presentation at the OECD International Workshop
Personalised Nutrition for Better Health – Targeting the Microbiome –

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PROGRESS Project

Project Title	Priorities for Addressing Opportunities and Gaps of Industrial Biotechnology for an efficient use of funding resources (PROGRESS)
Type, Time frame, Contractor	H2020, Coordination and Support Action August 2016-October 2017 Fraunhofer Institute for Systems and Innovation Research ISI, Karlsruhe, Germany
Goals	To **support** the deployment of Industrial biotechnology (IB) in the **EU industry** by **identifying high-value opportunities for IB** and **proposing actions** to address them successfully ▪ Provide a comprehensive and reliable **information base** for a plausible outlook for IB in the EU in the short and medium-term ▪ Elaborate **future scenarios** for IB in Europe ▪ Provide **strategic advice** for research, industry and policy

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Key steps and methodological approach

Step	Main method
General analysis of Innovation potential of IB and demand / needs	Literature Review Stakeholder Interviews
Analysis and Scenarios for 6 Value Chains	Desk research, interviews, patent analysis, EMS survey analysis 6 VC Workshops, in total > 60 participants System Dynamics modelling for 2 VC
Elaboration of goals for IB in Europe	Stakeholder Workshop
Identification and description of recommendations	Cross-analysis of results Verification by experts
Role of EU Member States and Collaboration between EU member states	Policy Workshop

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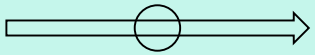
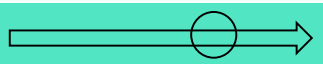
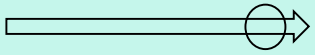
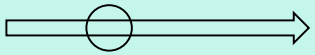
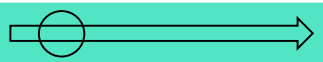
Portfolio of value chains

- covers diversity of IB
- represents different important aspects

- Emerging, S&T-driven field
- Potential for novel high value applications, products and services, but infant stage
- EU well positioned in global competition

Value Chain	Characteristics			Maturity stage	EU competitiveness (% shares of world output)	
	Potential Volume	Price	Quantity of feedstock		Patents	Pro-duction capacities
Lignocellulosic ethanol	++	-	++		32%	9 %
Bio-based plastics	+	-	+		43%	27%
Enzymes	-	+	- -		36%	40%
Production of Bio-pharmaceuticals	- -	++	- -		n.a.	31 %
Biotech Flavours and Fragrances	-	+	-		31%	30%*
Microbiomes	-	+	- -		41%	n.a.

++ Very high, + High, - Low, - - Very low

* market demand

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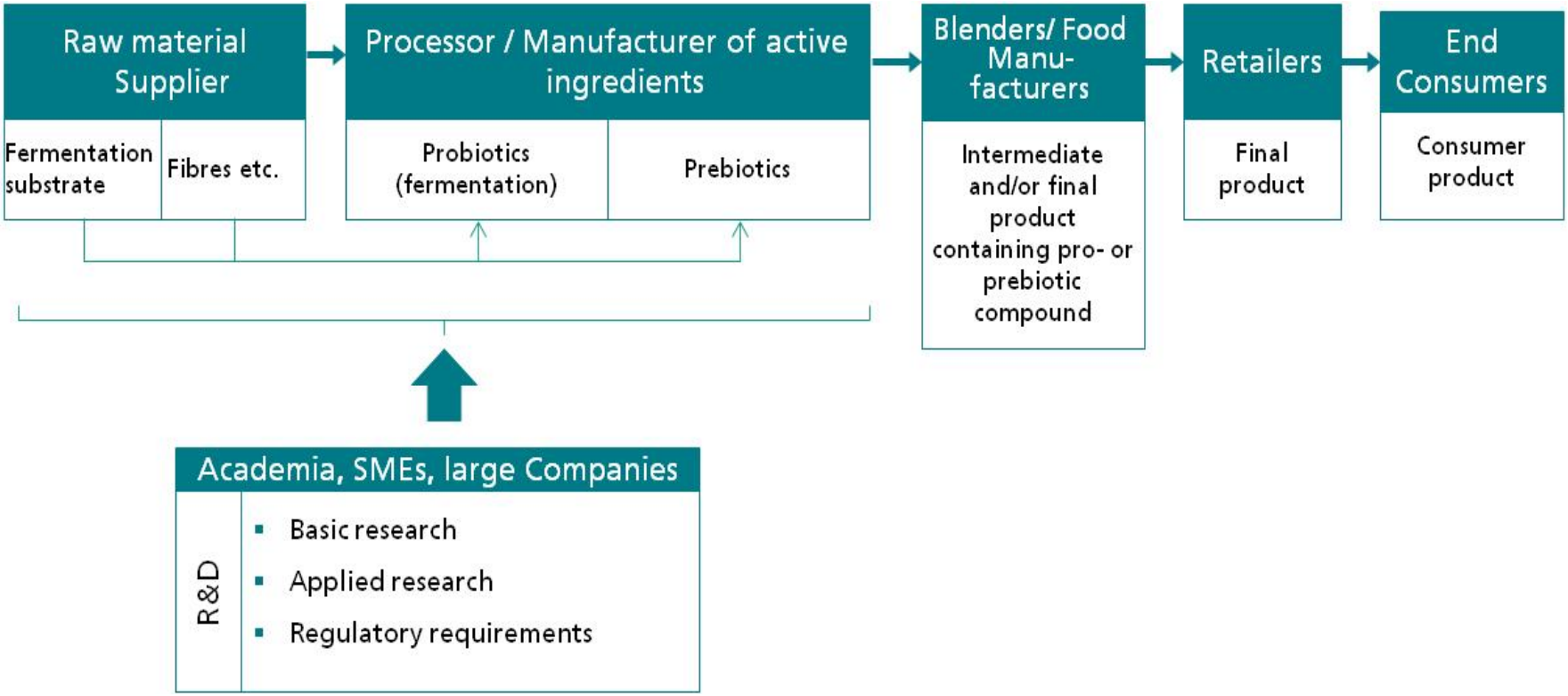
Value Chain: Microbiomes for Food and Healthy Nutrition

Definition: Engineering of human microbiota via food, food ingredients or over-the-counter “pills” (without medical prescription)



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Key developments and factors for the microbiome value chain

Technology	Business	Policy
▪ Knowledge: Understanding of healthy/unhealthy states over life span ▪ Methods: *functional* analysis by combining meta-omics technologies ▪ Broaden the spectrum of bacteria/interventions/modes of action ▪ Need for R&D resources (biobanks, cohort studies, data access, standards, interdisciplinarity of skills)	▪ Academia-industry and cross-industry collaborations and knowledge transfer ▪ SMEs as innovators, technology and service providers in high-risk fields: spin-offs/start-ups, licensing, acquisition ▪ Consumer demand: markets beyond particularly health-conscious consumers? ▪ Public perception, information and education	▪ Coherence between R&D/ economic/ health policy ▪ Regulatory framework at the interface of food/medicine: Required evidence for food with health claims ▪ Differentiation? Nutrition to stay healthy, Food for Special Medical Purposes, and microbiome therapeutics

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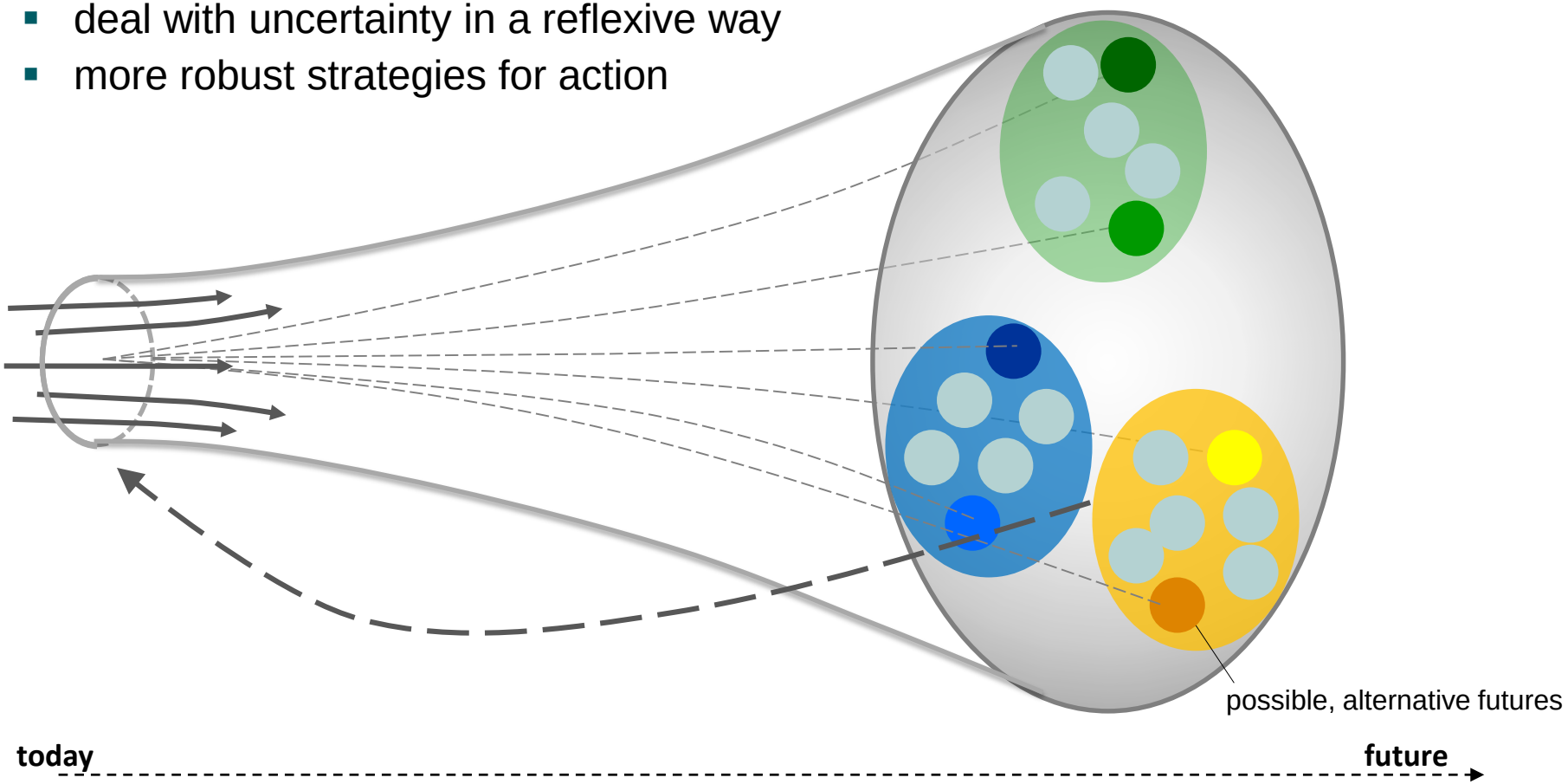
Scenario development as important element of value chain analyses

Rationale:

- widened perception, alternative futures
- deal with uncertainty in a reflexive way
- more robust strategies for action



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Scenario development for microbiome value chain

Goal

- Elaborate future scenarios in Europe in the next 10-12 years
- Identify implications for R&D policy

Workshop with 13 European experts from academia, industry, policy

Scenario 1 Dreaming of an optimal development	Scenario 2 Focus on publicly funded academic research	Scenario 3 Support and disincentives on the demand side
▪ Scientific, economic and health potentials realised	▪ Scientific, economic potentials realised ▪ Risk of consumer fraud ▪ Public health issues neglected	▪ Consumer concerns prominent ▪ Academic and industrial activities focussed

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Scenario 1: „Dream: Optimal development“

Policy

- Support of active, diverse innovation landscape
- Regulations clear, harmonised in the EU

Technology

- Deepened understanding of microbiota composition and functions in health and disease over life span
- Broad spectrum of microbiome interventions/products and of modes of action exploited
- Successful engineering of microbiota and long-term stability of engineered microbiota

Business

- Broad spectrum of microbiome interventions/products commercialised, intensive international competition
- High consumer demand in segments with and without official health claims
- Health education/competence important, but also social media, peer-to-peer advice, DIY microbiome monitoring

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Scenario 2: Focus on publicly funded, academic research

Policy

- Significantly increased, publicly funded research, research data must be made publicly available
- Regulations remain status quo
- No specific measures for consumer education and protection

Technology

- Scientific-technical progress similar to Scenario 1
- Academia dominates; companies hardly engage in research (IP situation, status quo regulation unfavourable)

Business

- Broad spectrum of microbiome interventions/products commercialized, based on publicly available knowledge
- Public perception positive, high consumer demand, celebrity marketing campaigns
- Life style/demand driven interventions with unproven health effects dominate; official health claims hardly influence purchase decisions
- Market success may be short-term fashion

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Scenario 3: Support and disincentives on the demand side

Policy/Society

- EU-wide regulation supports the development of novel products (e.g. clear definitions and procedures, broad product scope)
- Public and consumer concerns shape regulation, R&D and markets
- Strict regulatory (country-specific) requirements (e.g. evidence, data protection, protection against unsafe products or misleading claims)

Business

- Unfavourable ROI for novel products for small markets
- Focus on few well-established premium-priced products with health claims for health-conscious consumers

Technology

- R&D funding remains status quo
- Strong focus on safety/efficacy issues, high level of standardization hampers innovation

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Conclusions: Implications for policy

- R&D support a priority, but alone not sufficient
- Coherent R&D-, economic-, health policy
- Support of active, diverse innovation landscape
  - R&D infrastructure, multidisciplinarity of skills
  - International collaboration
  - Public-private cooperation, IP protection, SME support
  - Balance flexibility/openness with comparability/standardisation
- Align R&D policy with regulatory activities (time-line, areas incentivised)
  - Challenge: Regulatory framework at the interface of food/medicine
  - Establish trust and credibility by balancing the – potentially differing – interests of R&D, industry, consumers and the public
- Integration with healthy nutrition policies required to achieve public health effects

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Project web site

http://www.progress-bio.eu/progress-bio/

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