

1 April 2020, Webinar DK-SE Medicon Valley Alliance

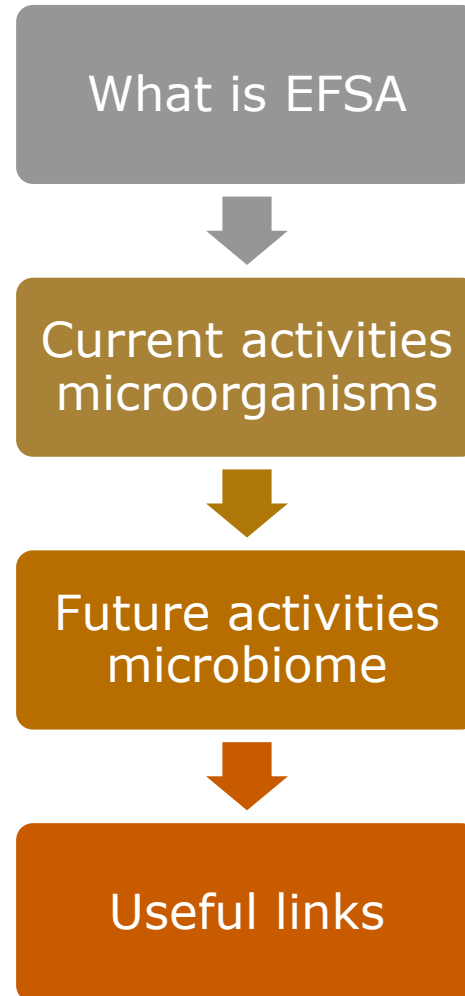


EFSA regulatory perspectives on Risk Assessment and microbiomes

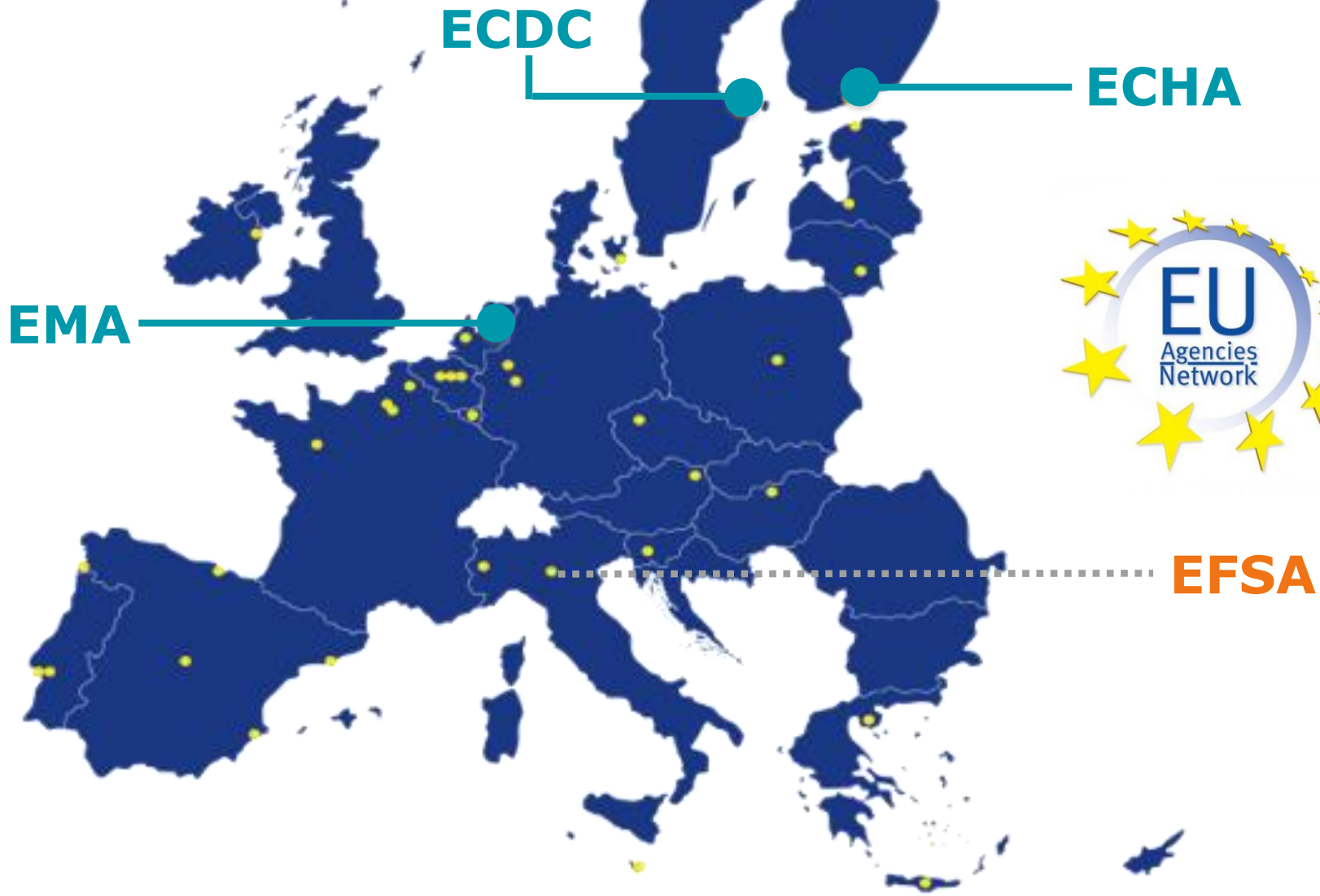
Reinhilde Schoonjans

Senior Officer, Scientific Committee and
Emerging Risks Unit

Trusted science for safe food



The EU Agencies





HEADQUARTERS
in the **heart of Parma**

ESTABLISHED
2002



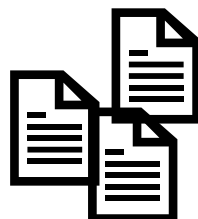
> 450 staff



< 1,350 experts



1,000 meetings/year



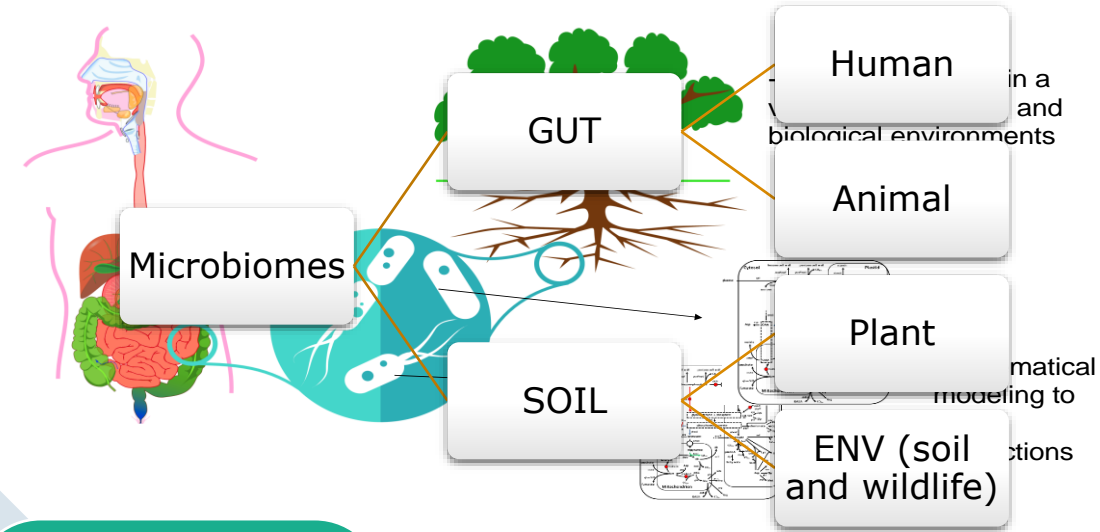
5,000 outputs /
500 a year

The Scientific Panels



- GMO (GMM, GMP, Synbio, omics colloquium)
- PPP (virus, fungus, bacterium)
- BIOHAZ (QPS, Antimicrobial properties)
- NDA (novel foods)
- NDA (health claims on probiotics)
- CEF (enzymes)
- FAF (enzymes, emulsifiers, artificial sweeteners)
- FEED (enzymes)
- SCER (nanoparticles)
- ED: outreach/research
- ALPHA, PLH: animal and plant resilience
- [For acronyms: http://www.efsa.europa.eu/en/science/scientific-committee-and-panels](http://www.efsa.europa.eu/en/science/scientific-committee-and-panels)

- **EFSA wide capacity building on “microbiomes in risk assessment”**



Workshop with the EFSA Scientific Committee

19 Feb

Thematic Grant (writing specifications for cooperation with EU MS)

March

State of the art on methodologies, Road map for risk assessment

Influencing EU research agenda (nothing focused on RA yet)

Workshop with the
EFSA Scientific
Committee

19 Feb

- **EXAMPLES:**

- Interpretation of toxicological studies: What are the metabolic functions of GUT microbiomes of test animals and how do they compare to those of humans?
- Computational models could be a start for DIRECT impacts (through metabolism) or INDIRECT (through compositional changes)

- Studies in variation of the background and the impact of modulators
 - What can we learn from work done in ruminants for Feed additives?
- When does an effect becomes adverse?
 - Focus on functionality, causality
 - Establish criteria between modulation and adversity
 - Map/database of what is seen in Tox studies
- Disease is the cause or the effect?
 - Causality
 - To not start from the disease, link the metabolic pathways to families/subpopulations of microbiota.

- Minutes of the plenary meeting:

<https://www.efsa.europa.eu/sites/default/files/event/2020/97th-plenary-meeting-scientific-committee-minutes.pdf>

- Knowledge used for the writing of the technical specifications of the Thematic Grant call (see next slides)
- Editorial in the EFSA Journal: to be expected later 2020

6.2. Thematic discussion on microbiome

This half-day workshop was organised to provide the participants with an overview of the role of the microbiome in the gut and in the soil. The contribution of the microbiome in nutrition and health is subject of ongoing research and is one of the topics considered for the EFSA Science strategy.

Yolanda Sanz introduced how the gut microbiome establishes a mutualistic relationship with its host. The breakdown of this mutualistic symbiosis leads to a number of adverse effects and diseases. For example: the gut microbiome has been shown to be associated with a healthy growth while its alteration leads to malnutrition. The microbiome also strongly interacts with the environment, increasing for example the resilience of the host to diseases, or increasing the flexibility of the host to changing environments. The microbiome not only interacts with foods but also with xenobiotics, leading to health/toxic effects of foods and chemicals; it also contributes to inter-individual variability and should therefore be considered in risk assessment.

A number of research activities are currently looking at the use of microbiomes to increase the sustainability, productivity and safety of food production. Possible implications for risk assessment could be the establishment of a microbiological acceptable daily intake, which implies the definition of a healthy microbiome, and the definition of reference strains representative of the human or animal microbiota. The possible integration of microbiome data in toxicokinetics and predictive risk models should then be explored.

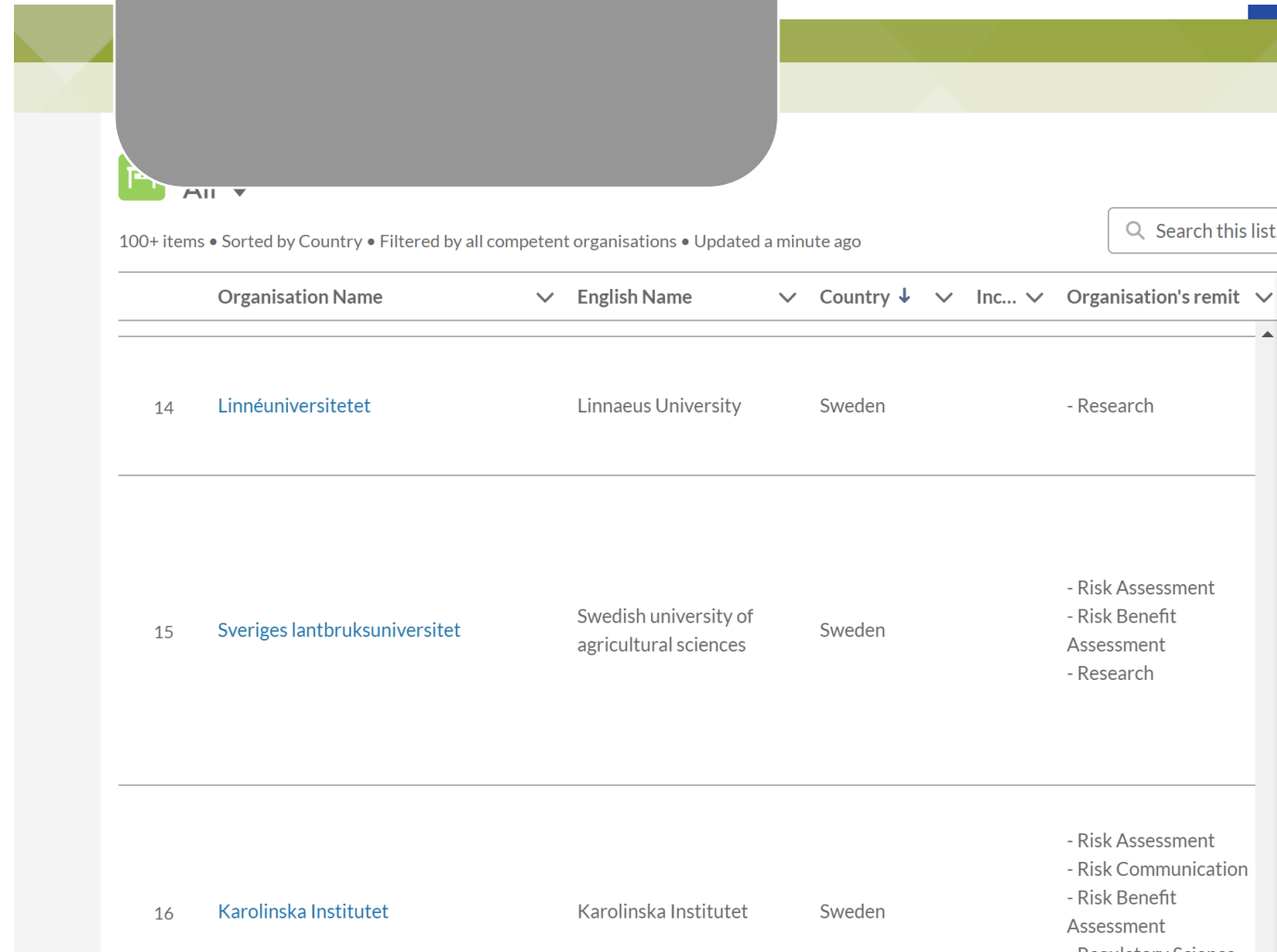
Influencing (EU) research agenda (nothing on RA yet)

■ INDICATIVE EXAMPLES:

- Criteria for link between microbiome and diet/toxicology
- Map of microbiomes focussing on functions and metabolisms and host interactions (rather than composition)
- How relevant is the gut microbiome compared to higher up GIT microbiomes (gut vs small intestine)? Colon more important since more abundance, carbohydrates needed for integrity of the barrier?
- Is the current model for testing still OK? Absorption may not be needed to cause adversity – but changed composition might
- Reaching to AOP/OMICS/statistics community -Which expertise is needed?

Thematic Grant March

- Cooperation with EU Member States
- EFSA focal point contacts to help project/consortium formation
- Deadline for application: 30 June 2020
- Project: max 2,5 years
- Co-financing: max 50% from EFSA, max 500K per lot



100+ items • Sorted by Country • Filtered by all competent organisations • Updated a minute ago

Search this list.

	Organisation Name	English Name	Country	Inc...	Organisation's remit
14	Linnéuniversitetet	Linnaeus University	Sweden		- Research
15	Sveriges lantbruksuniversitet	Swedish university of agricultural sciences	Sweden		- Risk Assessment - Risk Benefit Assessment - Research
16	Karolinska Institutet	Karolinska Institutet	Sweden		- Risk Assessment - Risk Communication - Risk Benefit Assessment - Regulatory Science

Stakeholders

Consultations

Calls for data

Observers

Careers

Procurement

Grants









Closed Article 36 grants

Research Platform

Fellowship programme

GP/EFSA/ENCO/2020/02 - Thematic grants: Preparedness for future challenges in specific areas of EFSA's work


Deadline: 30 June 2020

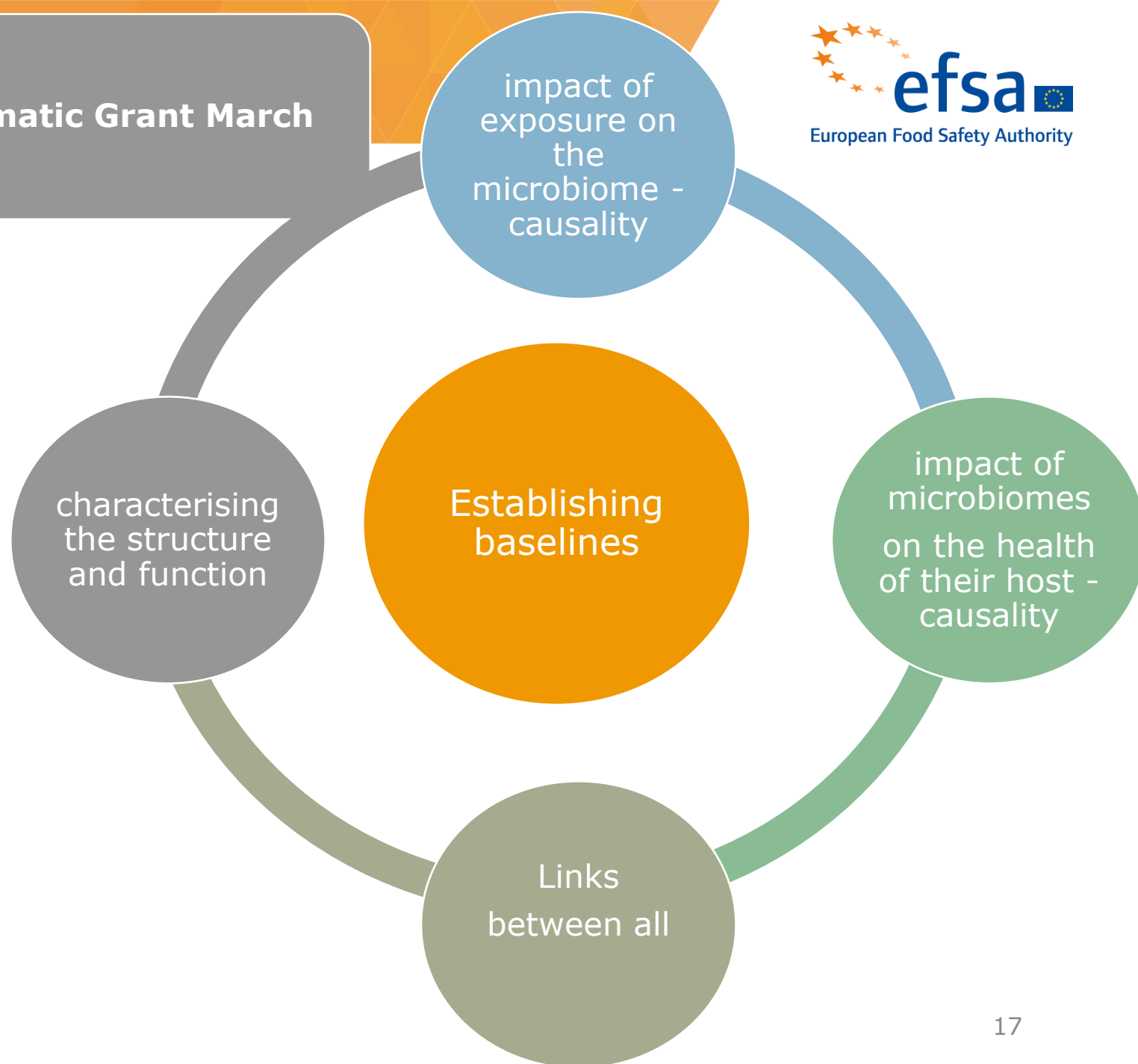
- [Call for proposals and guide for applicants](#) 
- [Annex 1: Rules on eligibility of costs](#) 
- [Annex 2: Draft grant agreement](#) 
- [Annex 3: Estimated budget template](#) 
- [Annex 4: Application form](#) 
- Annex 5: Legal entity form (download template [here](#))
- Annex 6: Financial identification form (download template [here](#))
- [Annex 7: Declaration on honour for exclusion criteria](#) 
- [Annex 8: Declaration on honour for selection criteria](#) 
- [Annex 9: Simplified financial statement](#) 
- Annex 10: Institutional and Individual declarations of interests (download template [here](#))

- Technical specifications: background, main objectives and specific objectives
- Lot 1: **gastro-intestinal (GI) tract microbiomes (human and domestic animal)**
- Lot 2: **environmental microbiomes (plants, wildlife, soil)**

- The main objective is to build capacity for
- (1) evaluating the impact on microbiomes by various modulators under EFSA's assessments, and
- (2) evaluating the impact of microbiomes on human, animal and plant health, in order to determine whether microbiomes can be included in risk assessments under EFSA's remit or not.

Thematic Grant March

- Reviewing the state of the art and appraising critically the evidence, technologies and models (in vitro/in silico/in vivo) for: 
- Drafting a roadmap to advance research to address risk assessment needs to account for environmental microbiomes

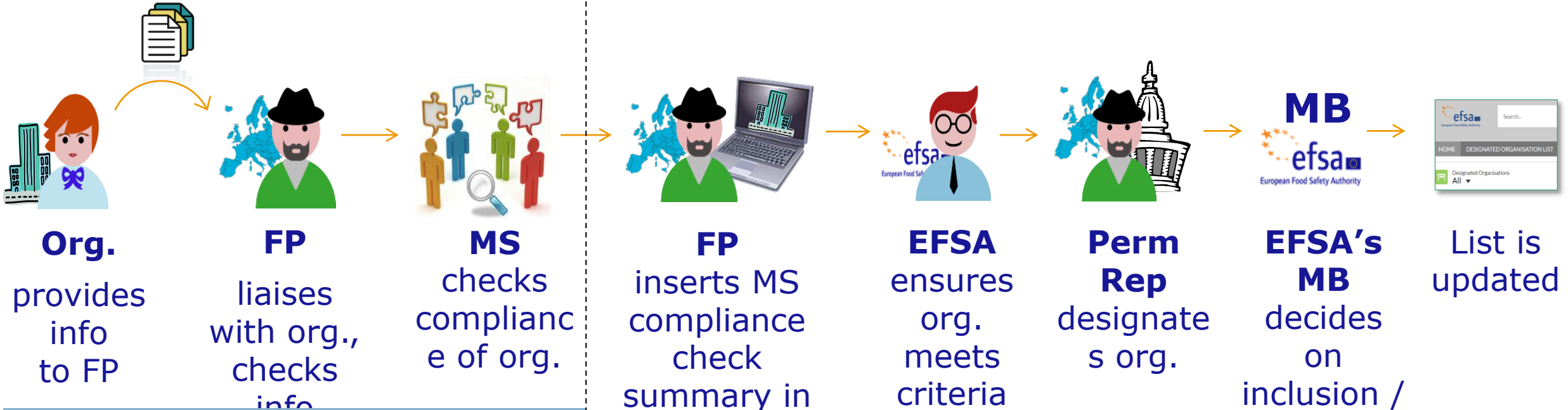


deadline

Step 1 →

Step 2

To-be-completed / List inclusion before signature of grant



Steps at national level out of the tool

Steps supported by / tracked in the tool

- Call dossier at EFSA`s grant page - <http://www.efsa.europa.eu/en/calls/art36grants>
- Competent organisations page - <http://www.efsa.europa.eu/en/partnersnetworks/scorg>
- EFSA national Focal Points contacts - <http://www.efsa.europa.eu/en/people/fpmembers>

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[Swedish National Food Agency](#)

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- Marco Pautasso (PLH)

- Procurement team, ENCO team,
KIC Biotech





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