

RARA

Berlin 7 December 2022

Addressing knowledge gaps: New approach methodologies (NAMs)

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Team leader

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Trusted science for safe food

Addressing knowledge gaps

- **Transparency Regulation (EU) 2019/1381**

- increased scientific cooperation budget
- increased cooperation with Member States
- sustainability of the risk assessment system

- **Towards partnership** - EFSA strategy 2027

- **Safe Food Systems**

- requires enhanced risk assessment capacity with Member States and other EU agencies

Drivers of change

Aim

- **Minimise scientific divergence**/need for verification studies (Art. 32d TR) through **preparedness**

- Develop multi-annual science projects, and explore synergies with **research and Member States initiatives**

- Build a reliable multi-annual workplan

- Implement **new methodologies, tools, and data** into **regulatory science** in partnership with Member States and other EU agencies

Impact

Process

- **EU policies and risk management decisions supported** by EFSA's work;
- Provide **EU Knowledge hub**;
- Facilitated moving towards **food safety knowledge ecosystem**;

3 step process

- Select and develop a scientific theme
- Develop a "roadmap for action"
- Commission studies/projects and integrating results in risk assessment and risk communication



New Approach Methodology (NAMs)

SCIENCE-POLICY INTERFACE

The Commission will:

- foster multidisciplinary research and digital innovations for **advanced tools, methods and models, and data analysis capacities**¹⁰² to also move away from animal testing:



Brussels, 14.10.2020
COM(2020) 667 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

EC policy

EFSA strategy
2027

STRATEGIC
OBJECTIVE 2

Ensure preparedness
for future risk analysis needs

KEY ACTIONS

- ▶ Develop and integrate new approach methodologies (NAMs) and omics for regulatory risk assessment



ASPIS Consortium
(RISK-HUNT3R,
ONTOX and
PrecisionTOX)



EUTOXRISK



NAMs
landscape

Safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.

Changing the way to do risk assessment

Co-creation with all ecosystem actors



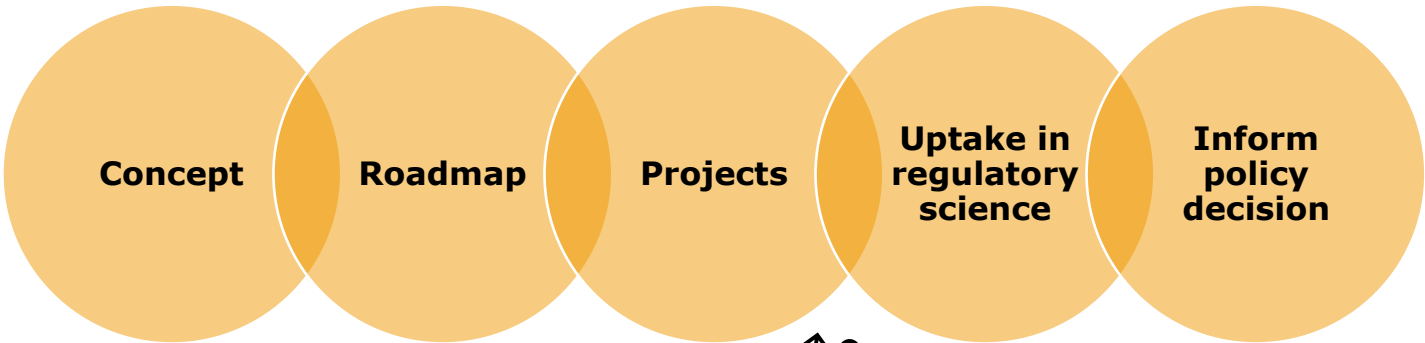
EC Services



International organisations,
Third country RA bodies



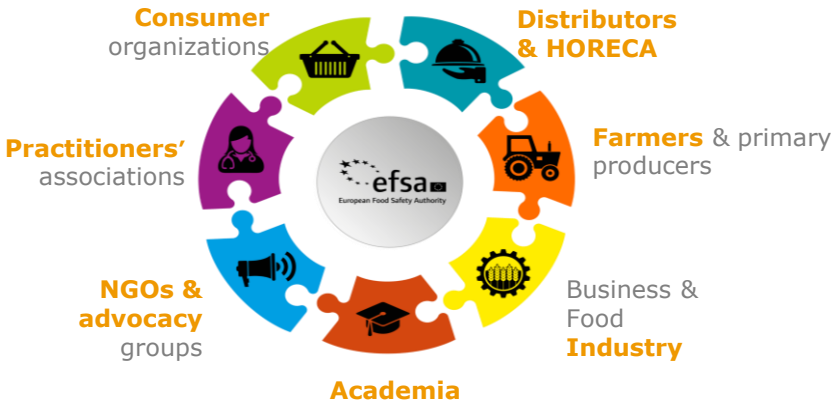
EU Agencies



National food safety
organisations



Individual experts



Input from partners to address knowledge gaps

EFSA's SPIDO workshop "Exposure science – advancing aggregated exposure assessments"

24 February 2022
Online (Zoom)

Category of participants
International Partners
Advisory Forum
Registered Stakeholders
EU Agencies
DG SANTE
JRC
EFSA Scientific Committee
EFSA experts
Others

Input in draft outline on
vision, objectives, knowledge gaps

**Concept
phase**

TECHNICAL REPORT

APPROVED: 15 October 2020
doi:10.2903/sp.efsa.2022.e200502

Theme (Concept) Paper - New Approach Methodologies

European Food Safety Authority (EFSA), Jose Tarazona, George Kass, Jean-Lou Dorne, Djien Liem, Konstantinos Paraskevopoulos, Juliane Kleiner, Claudia Heppner, Marta Hugas

Roadmap



EXTERNAL SCIENTIFIC REPORT



APPROVED: 2 May 2022

doi:10.2903/sp.efsa.2022.EN-7341

Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment

Sylvia E. Escher¹, Falko Partosch¹, Sebastian Konzok¹, Paul Jennings², Mirjam Luijten³, Anne Kienhuis³, Victoria de Leeuw³, Rosmarie Reuss⁴, Katrina-Magdalena Lindemann⁴, Susanne Hougaard Bennekou⁵

¹ Fraunhofer ITEM, ² Vrije Universiteit Amsterdam, ³ National Institute for Public Health and the Environment, ⁴ Eura AG, ⁵ The National Food Institute Denmark

Report [here](#)

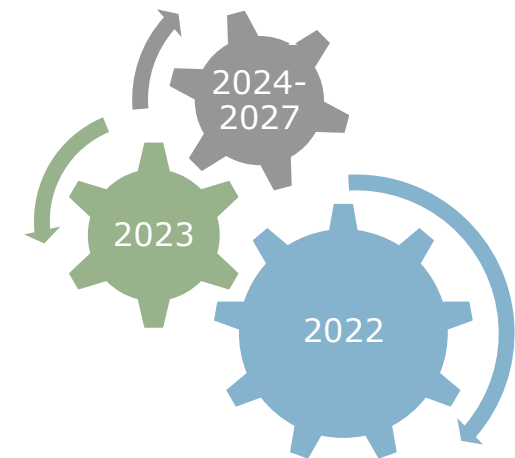
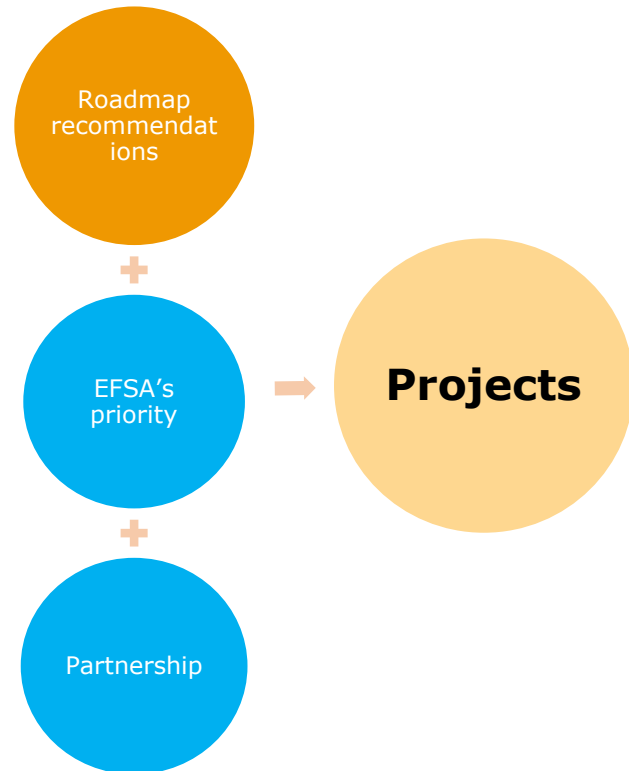
Define **priorities** and **multiannual strategy** for the incorporation of NAMs in regulatory hazard and exposure assessment of chemicals in food and feed

NAMs multi-annual plan opportunities to align

GP/EFSA/MESE/2022/01 - NAMS4NANO: Integration of New Approach Methodologies results in chemical risk assessments: Case studies addressing nanoscale considerations

Deadline: 20 September 2022

Expired



NAMs 2-step grant (pilot) opportunities to co-create

Projects

Knowledge gaps flagged in the NAMs roadmap:

New AOPs/AOP networks

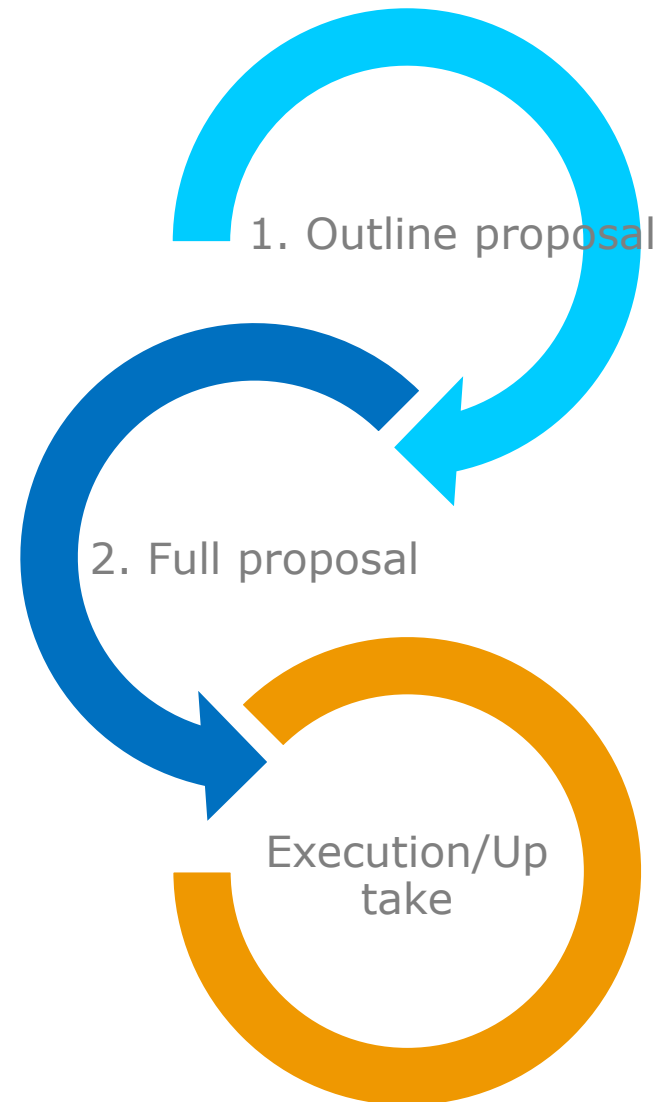
- Developmental neurotoxicity
- Endocrine disruption: metabolic syndrome, adrenal axis
- Oxidative stress-mediated neurotoxicity

In vitro transcriptomics

- To predict target organ toxicity and adversity

€10M

Grant



1. Outline proposal

Problem, solution, impact, capacity, draft budget

2. Full proposal

Co-design with beneficiary

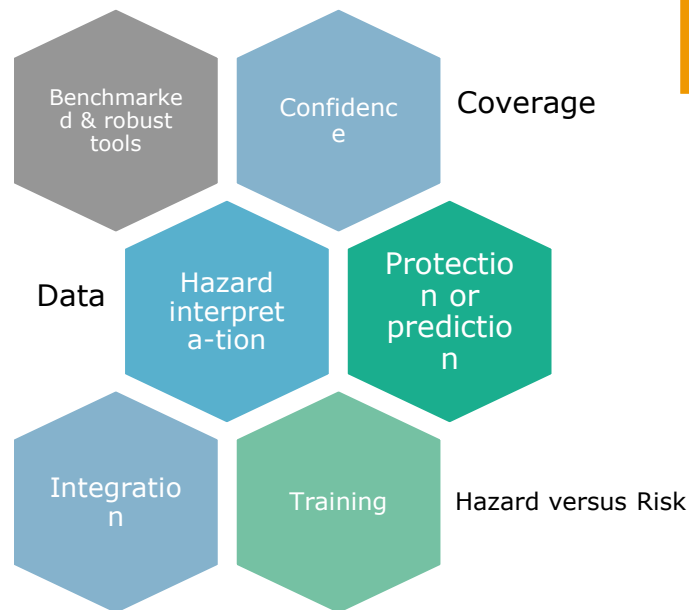
Execution/Up take

- Facilitates capacity building
- Co-design to fill knowledge gaps
- Alignment of funding opportunities
- Ready to take up outcome in regulatory science

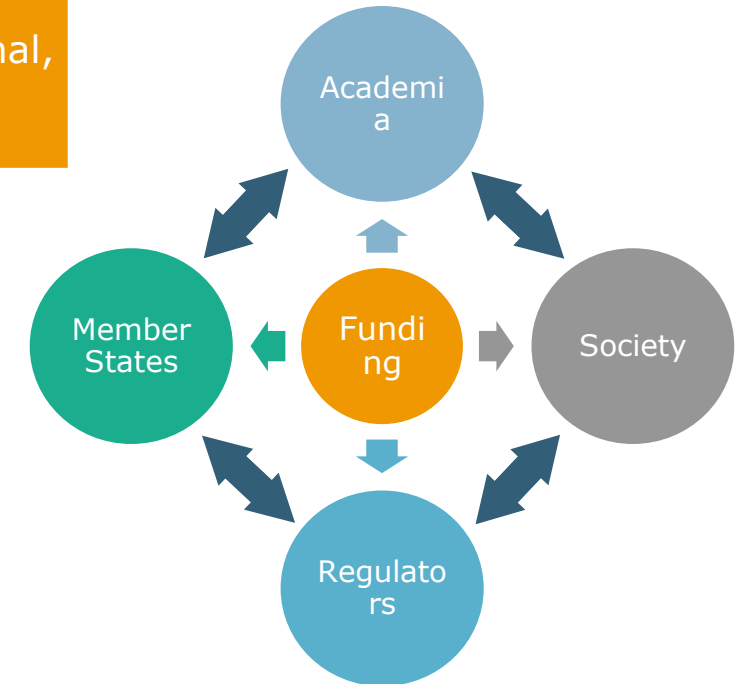
Partnership approach

Vision, expectations and opportunities

Collaboration, acceptability and sustainability

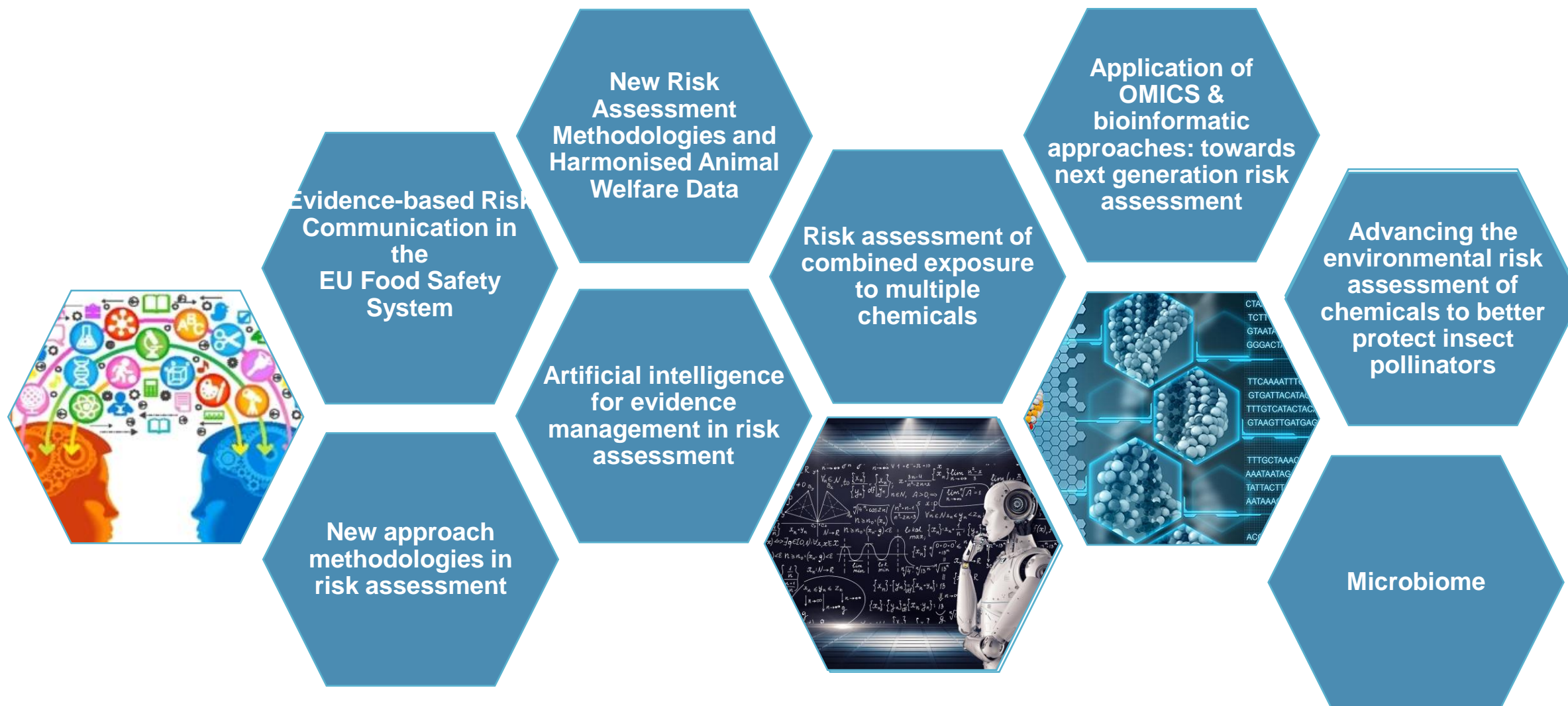


A model to optimise interactions with national, European and international partners



What can we **do more** to enhance and **strengthen** our **collaborations** and **work together**?

Innovation and preparedness at EFSA





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