LA STRATEGIA EFSA PER L'IMPLEMENTAZIONE DEI NAMS NELLA VALUTAZIONE DEL RISCHIO

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Scientific Officer - Toxicology

EFSA Methodology and Scientific Support Unit

Congresso SITOX, 22.02.2023

EUROPEAN FOOD SAFETY AUTHORITY

EFSA STRATEGY 2027

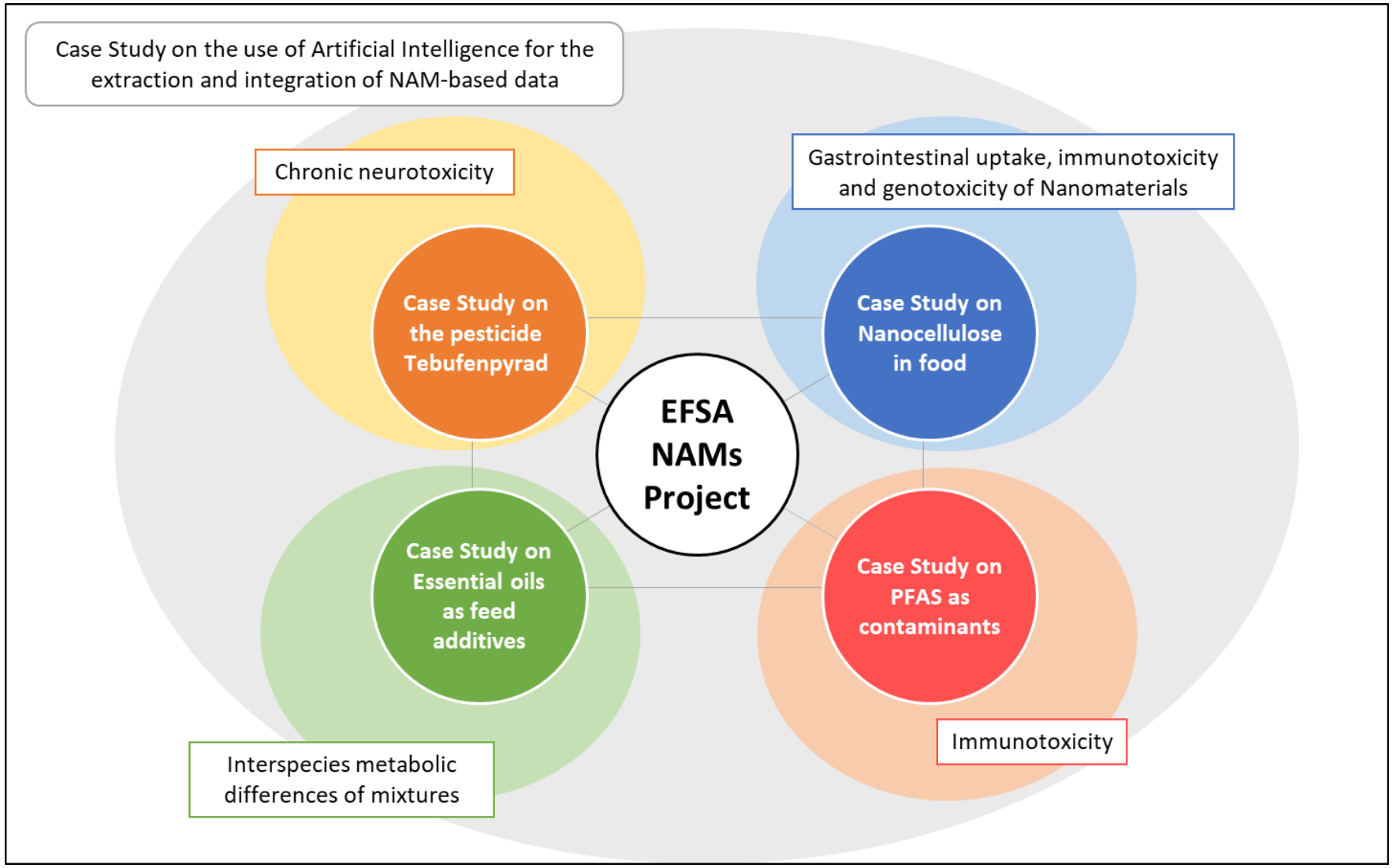
Goals:

- Improve the **quality** of scientific guidance and methodologies
- Develop and integrate **NAM-based approaches** for regulatory risk assessment
- Minimisation of **animal testing**
- Ensure more **informative** risk assessments
- Make use of wider, improved and new **data streams**

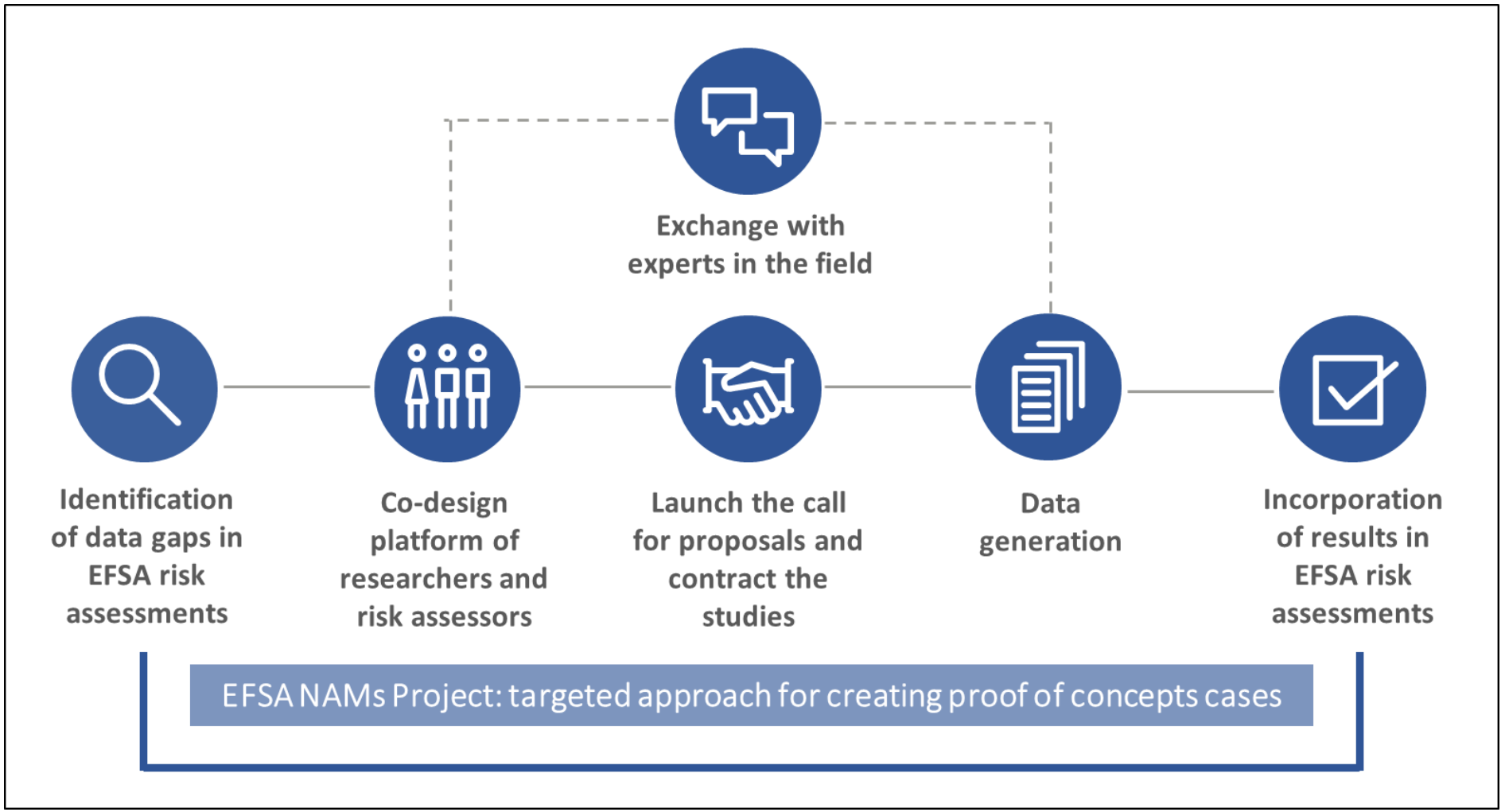
Actions:

- Launch **experimental case studies** for filling data gaps identified in EFSA risk assessments using NAMs
- Define in parallel the **mid-term strategy** (i.e. development of a Roadmap for action)
- Explore the use of **AI for integrating NAMs data** in risk assessments
- **Increase international cooperation** (i.e. via NanoNetwork, APCRA, and ILMERAC Working Group on NAMs)

EFSA NAMS PROJECT ONGOING CASE STUDIES, SECTORS AND TOXICOLOGICAL ENDPOINTS COVERED



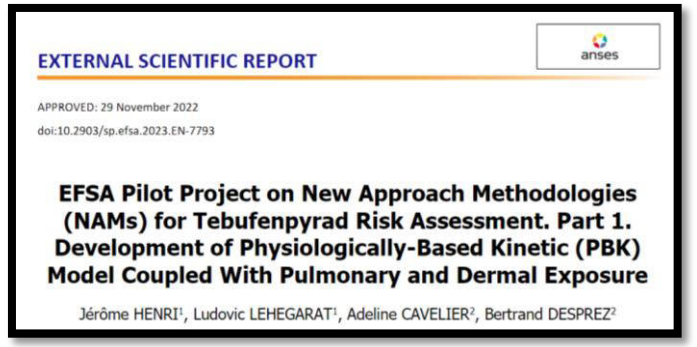
EFSA NAMS PROJECT TARGETED APPROACH FOR CREATING PROOF OF CONCEPTS CASE STUDIES



EFSA NAMS CASE STUDY ON TEBUFENPYRAD

Aim: explore the use of NAMs to investigate the neurotoxicity potential of the pesticide Tebufenpyrad

- **Part 1**: 'Development of physiologically-based kinetic (PBK) model coupled with pulmonary and dermal exposure'
- **Part 2**: 'Hazard characterisation and identification of the Reference Point'


EXTERNAL SCIENTIFIC REPORT

anses

APPROVED: 29 November 2022

doi:10.2903/sp.efsa.2023.EN-7793

EFSA Pilot Project on New Approach Methodologies (NAMs) for Tebufenpyrad Risk Assessment. Part 1. Development of Physiologically-Based Kinetic (PBK) Model Coupled With Pulmonary and Dermal Exposure

Jérôme HENRI[1], Ludovic LEHEGARAT[1], Adeline CAVELIER[2], Bertrand DESPREZ[2]


EXTERNAL SCIENTIFIC REPORT

Universität Konstanz

APPROVED: 23 November 2022

doi:10.2903/sp.efsa.2023.EN-7794

EFSA Pilot Project on New Approach Methodologies (NAMs) for Tebufenpyrad Risk Assessment. Part 2. Hazard characterisation and identification of the Reference Point

Mahshid Alimohammadi, Birthe Meyburg, Anna-Katharina Ückert, Anna-Katharina Holzer, Marcel Leist

Q3 2020 – Q3 2022

A Workshop on the results of the project and follow up activities was organised in September 2022


European Food Safety Authority (EFSA)

160.621 follower

1m •

OC/EFSA/PREV/2023/01 - Prior Information Notice (PIN)

#EFSAprocurement | EFSA is planning to launch a call for tender on 'Environmental Neurotoxicants – Advancing Understanding on the Impact of Chemical Exposure on Brain Health and Disease'.

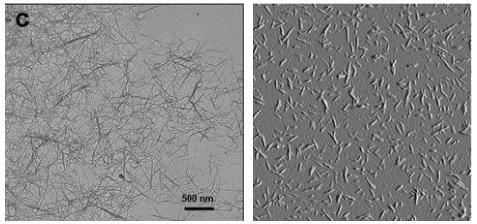
If you work in the field and you are interested, additional information may be found at the following link:

https://lnkd.in/dA5Drc6s

EFSA NAMS CASE STUDY ON NANOCELLULOSE

APCRA Case Study

Aim: explore potential effects of nanocellulose as a model for **dietary nanofibres** relevant to EFSA



Cellulose nanofibrillated and nanocrystals (Catalan et al., 2015-2017)

- **Lot 1**: 'Nanocellulose oral exposure: gastrointestinal digestion, nanofibers uptake and local effects'
- **Lot 2**: 'Exploring the use of gut-on-a-chip models for risk assessments of nanofibers'

Lot 1

ISTITUTO SUPERIORE DI SANITÀ · anses · JRC EUROPEAN COMMISSION · INRAE science for people, life & earth · sciensano

Lot 2

IBBC Istituto di Biochimica e Biologia Cellulare / Institute of Biochemistry and Cell Biology · Consiglio Nazionale delle Ricerche · IRGB Istituto di Ricerca Genetica e Biomedica


GUIDANCE

EFSA Journal

ADOPTED: 30 June 2021

doi: 10.2903/j.efsa.2021.6768

Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health

EFSA Scientific Committee, Simon More, Vasileios Bampidis, Diane Benford, Claude Bragard, Thorhallur Halldorsson, Antonio Hernández-Jerez, Susanne Hougaard Bennekou, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Hanspeter Naegeli, Søren Nielsen, Josef Schlatter, Dieter Schrenk, Vittorio Silano (deceased), Dominique Turck, Maged Younes, Jacqueline Castenmiller, Qasim Chaudhry, Francesco Cubadda, Roland Franz, David Gott, Jan Mast, Alicja Mortensen, Agnes G. Oomen, Stefan Weigel, Eric Barthelemy, Ana Rincon, José Tarazona and Reinhilde Schoonjans

Q1 2022 – Q2 2023

EFSA NAMS CASE STUDY ON PFAS

APCRA Case Study

Aim: to develop and implement **NAM-based IATA** for exploring the mode of action (MoA) for the observed **immunosuppression effects** (i.e. reduction in the vaccination efficacy and possible increase in susceptibility to infectious diseases) and for addressing **immunotoxicity of PFAS other than PFOS and PFOA**, including the assessment of a **common MoA** and potency differences.

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SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 9 July 2020

doi: 10.2903/j.efsa.2020.6223

Risk to human health related to the presence of perfluoroalkyl substances in food

EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel), Dieter Schrenk, Margherita Bignami, Laurent Bodin, James Kevin Chipman, Jesús del Mazo, Bettina Grasl-Kraupp, Christer Hogstrand, Laurentius (Ron) Hoogenboom, Jean-Charles Leblanc, Carlo Stefano Nebbia, Elsa Nielsen, Evangelia Ntzani, Annette Petersen, Salomon Sand, Christiane Vleminckx, Heather Wallace, Lars Barregård, Sandra Ceccatelli*, Jean-Pierre Cravedi, Thorhallur Ingi Halldorsson, Line Småstuen Haug, Niklas Johansson, Helle Katrine Knutsen, Martin Rose, Alain-Claude Roudot, Henk Van Loveren, Günter Vollmer, Karen Mackay, Francesca Riolo and Tanja Schwerdtle

Q1 2022 – Q1 2024

EFSA NAMS CASE STUDY ON ESSENTIAL OILS

Aim: to design and conduct a series of NAM-based experimental studies for assessing qualitative and quantitative **differences and similarities in metabolic competences across different target species** for essential oils components and to conduct a QIVIVE and comparison among species.

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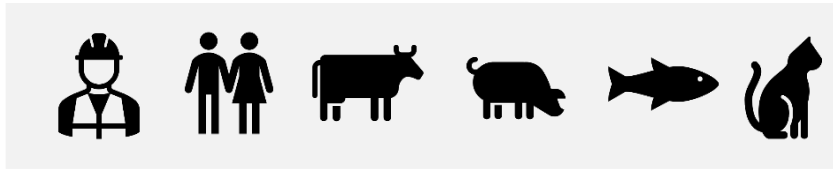
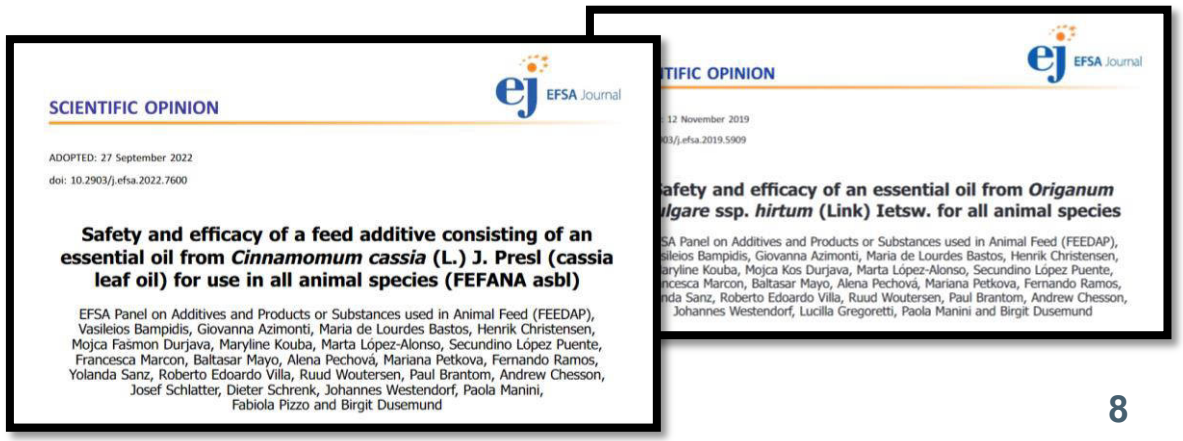


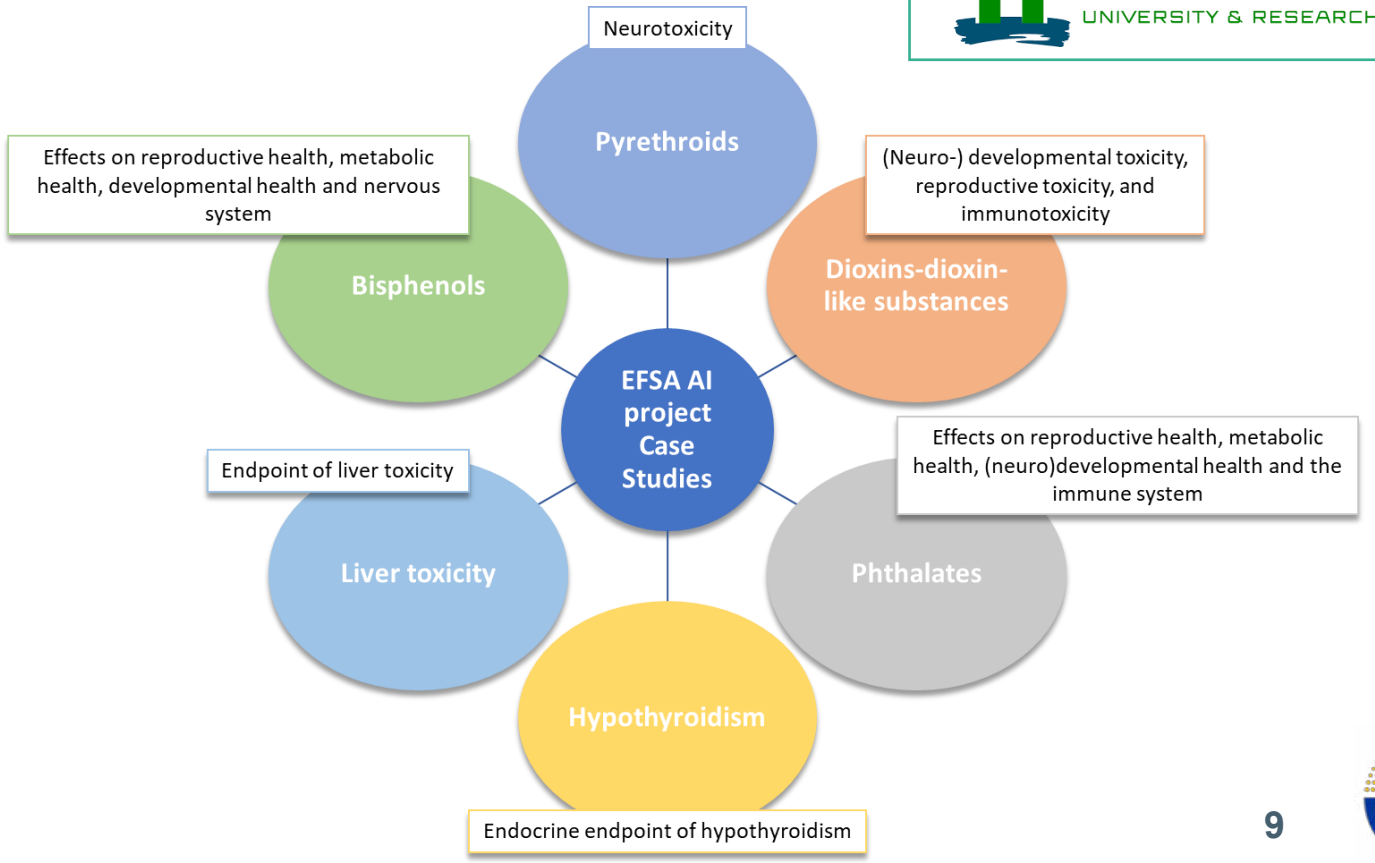


Q1 2022 – Q1 2024

EFSA AI4NAMS PROJECT

Aim: to explore the use of artificial intelligence **(AI)-based tools for searching, extracting and integrating NAMs-based data** into chemical risk assessment. As real proof-of-concept, the approach developed will be applied to **selected chemicals and endpoints** relevant to EFSA and finally integrated into (refined) EFSA risk assessments.

Q3 2021 – Q2 2023



EFSA ROADMAP FOR ACTION ON NAMS

EXTERNAL SCIENTIFIC REPORT

APPROVED: 2 May 2022

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

Development of a Roadmap for Action on

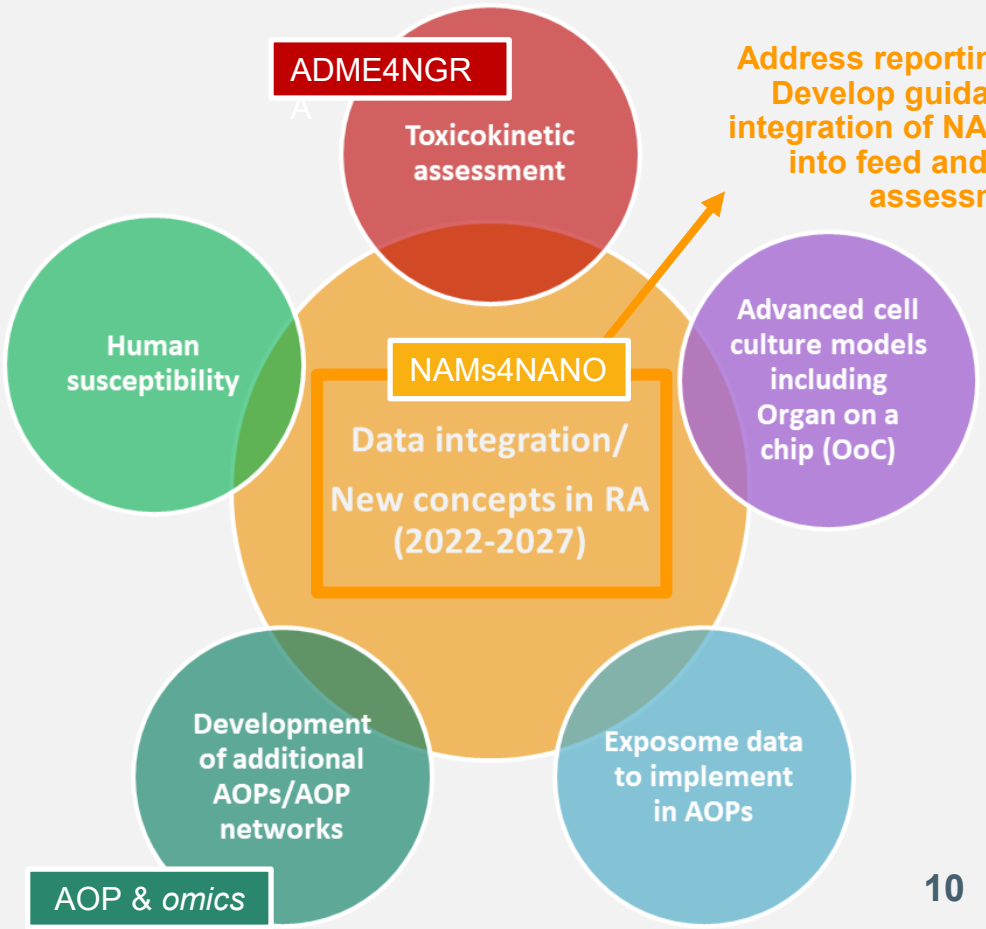
New Approach Methodologies in Risk Assessment

Sylvia E. Escher[1], Falko Partosch[1], Sebastian Konzok[1], Paul Jennings[2], Mirjam Luijten[3], Anne Kienhuis[3], Victoria de Leeuw[3], Rosmarie Reuss[4], Katrina-Magdalena Lindemann[4], Susanne Hougaard Bennekou[5]

[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

Aim: to propose potential **EFSA priorities regarding the incorporation of NAMs** into regulatory hazard and risk characterisations of chemicals in food and feed

Result: six prioritised areas



NEW EFSA PROJECT ‘NAMS4NANO’

Title: **NAMS4NANO** (GP/EFSA/MESE/2022/01)

Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations


efsa
European Food Safety Authority

CALL FOR PROPOSALS

SIMPLIFIED FORM OF GRANT - FINANCING BASED ON ACHIEVEMENT OF RESULTS

Call reference: GP/EFSA/MESE/2022/01
Call title: NAMS4NANO: Integration of New Approach Methodologies results in chemical risk assessments: Case studies addressing nanoscale considerations.
[LOT 1: Review of tools and developing a 'Qualification System for NAMs']
[LOT 2: Risk assessment case studies]
[LOT 3: Methodological and generic case studies]

Project/Process code: EPA13.02-ENV22-MESE-01
Budget line: 3210

Restricted to **the list of competent organisations** established by the Authority's Management Board in application of article 2 the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the Authority's remit.

First phase: (3 LOTs, ongoing)

- Design EFSA relevant case studies in the area of **nanomaterials** integrating NAMs and existing data
- Development of **methodologies** to promote the use of NAMs data and its **integration** in EFSA risk assessments

Second phase: (to be launched in 2024)

- Design case studies on **nanoplastics**
- Develop a risk assessment guidance for nanocontaminants and promote an **international** risk assessment for nanoplastics

Q1 2023 - Q2 2026

FIRST PHASE (ONGOING)

- **Objective 1:** Reviewing the available NAM-based tools and methods for assessing the toxicity of nanoparticles, in particular those developed by recent EU Research projects.
- **Objective 2:** Developing a qualification system for facilitating the regulatory use of NAM tools and methods, using the experience from EU and international agencies (EMA, US FDA).
- **Objective 3:** Designing and conducting a first set of proof-of-concept case studies to demonstrate that the combination of existing *in vivo* information and NAM-based data can provide better information for safety assessments than new *in vivo* studies.

3 Objectives in 3 LOTs

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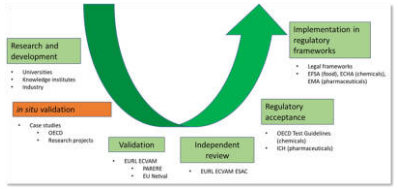
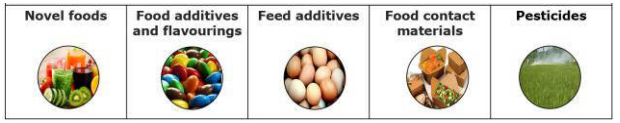


LOT 1: Review of tools and developing a 'Qualification System for NAMs'

LOT 2: Risk assessment case studies



LOT 3: Methodological and generic case studies

NAMS: TANGIBLE OUTCOMES

- Fill **data gaps** in chemical risk assessment without generating new *in vivo* data
- Move towards a **mechanistic-based risk assessment**
- Enhanced **acceptance/confidence to use NAMs** data, IATA and biomarker data in the derivation of Health Based Guidance Values
- Promote internationally **harmonised guidance**

Thank you for your attention!

Questions?

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