99TH ADVISORY FORUM
PAPHOS, 04-05 MARCH 2026

Sofia Batista Leite

(PREV, mamtox team)

efsa
EUROPEAN FOOD SAFETY AUTHORITY

WHY?

or How it started....

ENGAGEMENT

1,217,916 signatories from 27 EU Member States.

COMMISSION'S RESPONSE TO THE CITIZENS' INITIATIVE

The Commission is proposing the following actions in response to the objectives of the citizens' initiative:

- continue to **apply and enforce the animal testing ban** in the framework of the EU Cosmetics Regulation;
- consider the need for legislative changes to further **clarify the interface between the EU Cosmetics and REACH Regulations** based on the outcome of an ongoing judicial review;
- kick off work on a roadmap **towards replacing animal testing in chemical safety assessments**, with multiple actions and a step-by-step path to replacing animal testing, involving all relevant stakeholders;
- initiate a series of actions to accelerate the reduction of **animal testing in research, education and training**, including exploratory workshops, and sustaining new training initiatives for early career scientists;
- continue to support research on alternatives to animal testing with **EU funding.**

More info in: https://citizens-initiative.europa.eu/save-cruelty-free-cosmetics-commit-europe-without-animal-testing_en

STRUCTURE OF THE WORK

European Commission
(DG Grow and DG ENV)

Interservice group
ECHA, **EFSA**, EMA, JRC, RTD, SANTE, SG, ENV, GROW

EPAA
PARC
ASPIS
Industry
MS
NGOs

WG Human Health safety assessment

WG Environmental safety assessment

WG Change management

EFSA

EFSA

EFSA

Milestone

Milestone

Stakeholder consultation process

Draft roadmap

Roadmap Towards Phasing Out Animal Testing

AIM

*to provide a **plan/schedule** to accelerate reaching the **ultimate** goal of phasing out animal testing*

- Applicable to **all relevant pieces of EU chemical legislation** that might lead to animal testing for **chemical safety assessments**
  – 15 legislative areas

Backup slide

Commission Communication
(~15 pages)

Policy background & high-level EC actions

+ Staff working document (SWD)

Scientific Recommendations from WGs

expected publication: March 2026

PRINCIPLES OF THE ROADMAP – TOWARDS A NEXT GENERATION RISK ASSESSMENT (NGRA)

Non-Animal Safety Assessments

NGRA promotes chemical safety assessments without animal testing, focusing on alternative scientific methods.

Mechanistic Toxicity Understanding

The approach relies on understanding molecular mechanisms to predict toxic effects accurately.

Integrated Risk Assessment

NGRA aims to develop integrated methods assessing both human health and environmental risks holistically.

The future of risk assessment focuses on ethical, effective, and innovative scientific approaches replacing animal tests.

STAFF WORKING DOCUMENT (SWD)

*to provide a **plan/schedule** to accelerate reaching the **ultimate** goal of phasing out animal testing*

- It reflects a transition: where NAMs can be add of value | where to reduce animals
- Where possible, steps are organised in short-, medium- and long-term,

Examples areas covered in the scientific recommendations

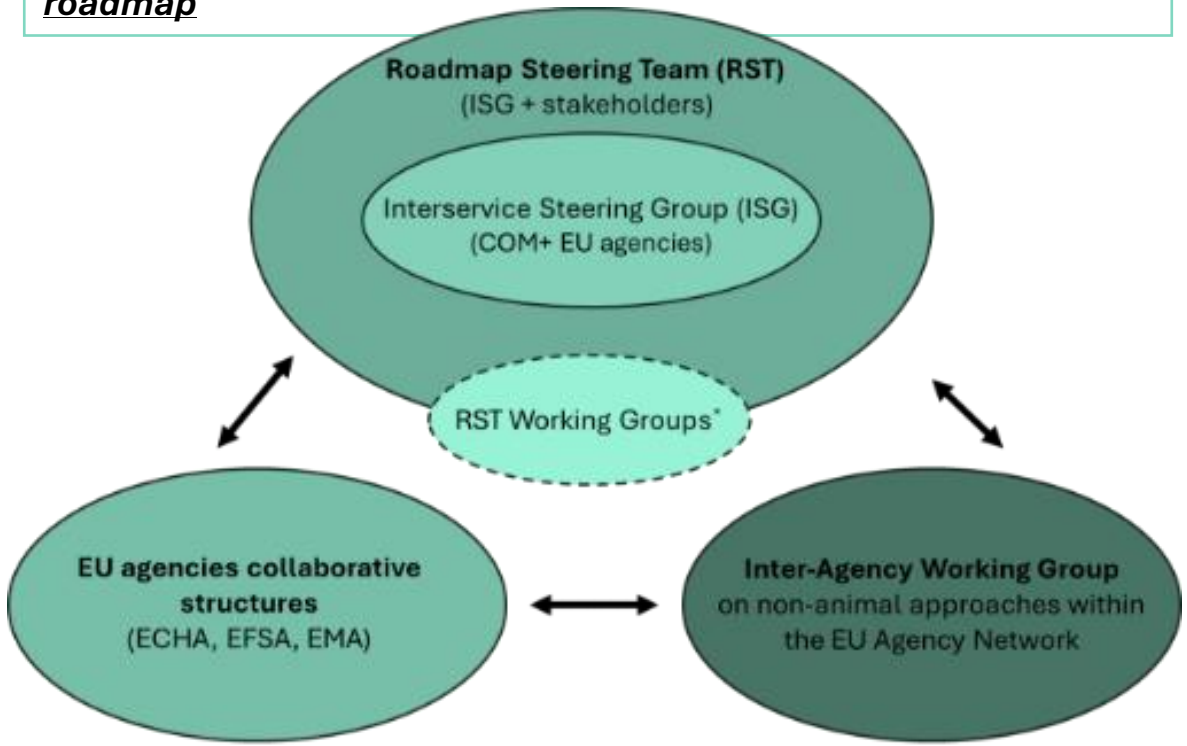
- Next generation risk Assessment (NGRA)
- Acute fish tox
- long-term toxicity
- ADME
- Acute toxicity
- Omics
- Toxicokinetics (TK)
- Aquatic and terrestrial bioaccumulation
- Endocrine Disruption (ED)
- Reducing the number of animals & species
- Genotoxicity
- Carcinogenicity
- Developmental neurotoxicity (DNT)
- species sensitivity
- Nanomaterials
- Fish chronic toxicity
- Developmental & reproductive tox (DART)

EC COMMUNICATION – MAIN RELEVANCE TO EFSA WORK

Puts the Roadmap in context of EU policy agenda, including

- OSOA & the European Strategy for Test Method development and validation and the Common Data Platform,
- The Biotech Act,
- AI Strategy
- Revision of PP data requirements

EC Proposed governance model for the implementation of the roadmap

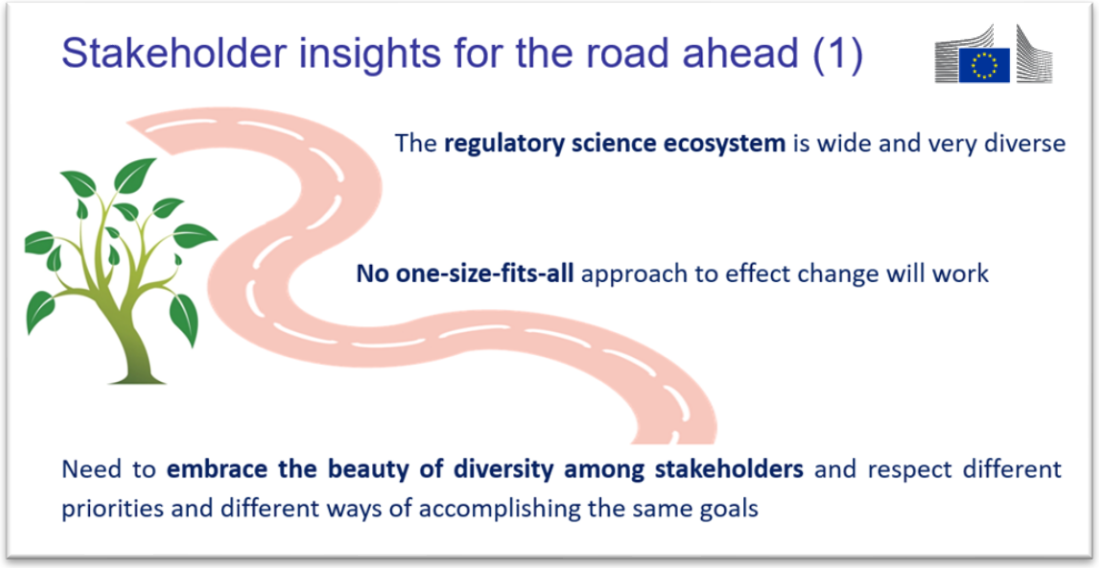


*Working Groups will be set up if needed with the option of stakeholder participation

List of Action points by the EC, including

- Push staff working doc. recommendations
- Maintenance of catalogue of transitional initiatives
- Explore the use of **AI** in regulatory toxicology
- ← New **Collaborative structures** & stakeholder engagement
- Map Training (existing training but also existing needs)
- Provide funding for NAMs
- **EU report** on Key Areas of Regulatory needs (**KARN**) for Non-animal **every 3 years**
- Foster & Support **validation** and **qualification**
- Support agencies on exploring **Safe Spaces**
- Implement indicators of success

TO FINISH



Collaboration is essential!

EFSA would like to align and count with MSs support

Ongoing and next steps at EFSA

- Reinforce alignment and collaborations – ECHA & EMA; discussion with stakeholders
- Reflection on the existing EFSA NAMs structures, harmonisation and way of working! Examples from other agencies:
  - EMA has the Innovation Task force and the 3Rs Working Party
  - ECHA is implementing the Collaborative Platform on Alternatives to Animal Testing
- Discussion on the ongoing NAMs projects and alignment with Roadmap recommendations and ongoing EU-funded projects

➢ October 2026: EFSA-ECHA workshop on the implementation of the EC roadmap the area of Pesticides & Biocides

A HUGE TEA

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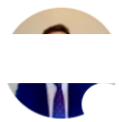

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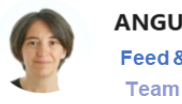

ANGUITA FRE
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VAGENENDE Bén
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THANK Y

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Paphos-4-5th March 2026

USE OF NAMs IN BAU ACTIVITIES @ EFSA

Chantra Eskes (FEEDCO) & core KIC-NAMs

4 March 2026

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NAMs AND NGRA

New Approach Methodologies (NAMs)

- NAMs are considered to be **any non-animal technology, methodology, approach, or combination of these that prevents the use of animals for experimental purposes**.
- NAMs refers to **any new approach** which can be used to provide information in the context of hazard and risk assessments.
- These new approaches include: **in silico approaches, in chemico and in vitro assays, integrated approaches** that combine different sources of information, as well as a variety of **new testing tools**, such as high-throughput screening and high-content methods (e.g. transcriptomics, proteomics and metabolomics).

Next Generation Risk Assessment (NGRA)

Refers to the adoption and integration of NAMs into risk assessment (2022 EFSA External scientific report).

NAMs IN SCIENTIFIC ASSESSMENTS @EFSA (1/2)

	CONTAM	FEED	FIP	GMO	Novel foods	PLANTS	PREV
Regulation waiver / provision to use NAMs	n.a.	✓ (extrapolation, waiver)	✓ (*new) (NAMs, tiered approach, waiver)	✓ (history of safe use)	✓ (*new) (ADME, NAMs, tiered strategy)	✓ (NAMs)	✓ (NAMs, waivers)
Non-testing (e.g., exposure, Read-across (Rax), TTC, AI, existing info)	✓ (AI, existing info, RAx, TTC)	✓ (existing info, RAx, TTC)	✓ (existing info, RAx, TTC)	✓ (existing info, RAx)	✓ (existing info)	✓ (existing info, waivers)	✓ (existing info, historical control data, RAx)
In silico (e.g., ADME, BMD, PBK, (Q)SARs)	✓ (BMD, PBK, (Q)SARs)	✓ (PBK, (Q)SARs)	✓ (ADME, bioinformatics, BMD, PBK, (Q)SARs)	✓ (protein safety)	✓ (allergenicity, (Q)SARs)	✓ (population models, TKTD)	✓ (BMD, Metapath, PBK, (Q)SARs)
In vitro (e.g., genotox, ADME, DNT, ED)	✓ (genotox)	✓ (ADME, genotox)	✓ (genotox)	✓ (protein safety)	✓ (ADME, genotox)	✓ (ED ecotox)	✓ (ADME, DNT, ED, genotox, neurotox)
Mechanistic (e.g., AOP, MoA)	✓	✓	✓	✓	✓	✓	✓
Others (e.g., WoE, IATA, DNT, omics, waiving 2nd species)	✓ (omics, WoE)	✓ (extrapolation animal species)	✓ (allergenicity, WGS)	✓ (protein safety)	✓ (omics)	✓ (WoE)	✓ (DNT, IATA, waiving 2nd species, WoE)

NAMs IN SCIENTIFIC ASSESSMENTS @EFSA (2/2)

	MESE	iDATA	CSO	KNOW
Regulation waiver / provision to use NAMs	n.a.	n.a.	n.a.	n.a.
Non-testing (e.g., exposure, RAx, TTC, AI, existing info)	✓ (existing info, extrapolation, RAx)	✓ (RAx)	✓ (existing info)	✓ (AI)
In silico (e.g., (Q)SARs, ADME, PBK)	✓ (BMD, (Q)SARs, PBK)	✓ ((Q)SARs)	✓ (PBK, (Q)SARs, TKPlate)	n.a.
In vitro (e.g., genotox, ADME, DNT, ED)	✓ (ADME, genotox, nano)	n.a.	✓ (ADME)	n.a.
Mechanistic (e.g., AOP, Biomarkers, MoA)	✓	n.a.	✓	n.a.
Others (e.g., WoE, IATA, DNT, omics, waiving 2nd species)	✓ (WoE)	n.a.	n.a.	n.a.

EXAMPLE WORKING GROUPS RELATED TO NAMs

- **Standing WGs**
  - Benchmark dose modelling (MESE)
  - Endocrine disruptors (PREV)
  - Genotoxicity (MESE)
  - GLP (FDP)
  - NAMs WG (MESE)
  - Neurotoxicity (PREV)
  - Read-across (MESE)

- **Other WGs**
  - ADME and PBK modelling (upcoming –MESE)
  - Biomarkers of effects (MESE)
  - Evidence appraisal (MESE)
  - Phasing out dog studies (PREV)

EXAMPLE OF GUIDANCES & TOOLS RELATED TO NAMs

Cross-cutting Guidances from EFSA's Scientific Committee

- **2025** EFSA Guidance on the use of read-across for chemical safety assessment in food and feed
- **2024** Conceptual basis for the development of guidance for the use of biomarkers of effect in regulatory risk assessment of chemicals
- **2021** EFSA Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals
- **2019** EFSA Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment
- **2017** EFSA Guidance on the use of the weight of evidence approach in scientific assessments

Cross-cutting EFSA tools

- TKPlate 1.0: An Open-access platform for toxicokinetic and toxicodynamic modelling of chemicals to implement new approach methodologies in chemical risk assessment
- OpenFoodtox 3.0 Chemical hazards database

1S1A Subgroup on EU strategy for test method development and validation

- **Background**
  - Lack of validated methods to address some areas of regulatory relevance & demand for animal-free methods
  - Need to accelerate availability of validated and regulatory accepted test methods for safety assessment. Current process long, lack overarching coordination, not sufficiently aligned with wider regulatory needs. Insufficient financial mechanisms for validation

- **Approved @ 1S1A Expert Group Meeting on Dec. 17-18, 2025**, based on:
  - 2023 proposal by NL and DE at CARACAL meeting
  - Dec. 2024 workshop and Jan. 2025 policy conference organised by NL, DE and ECHA
  - 2025 writing team composed of NL, FR, ECHA, EFSA, OECD
  - Consultation with DG ENV and DG GROW

- **Mission**
  - **Prioritise regulatory needs** for new validated test methods based on regulatory and societal needs (aligned with EU Roadmap for phasing out animal testing)
  - **Foster validation** of priority test methods through overarching coordination and financial mechanisms

- **First meeting: Q2 2026**

TAKE HOME MESSAGES

- EFSA has a number of Guidance Documents and WGs that contribute to the implementation of NAMs in its risk assessments.
- Although animal methods are still the main method used, various NAMs are used across different areas of EFSA's risk assessment.
- Consistency in the use of NAMs (internally and externally) is important.
- EFSA contributes to the 1S1A subgroup on an EU strategy for test method development and validation, to help prioritise regulatory needs and foster method validation.
- Input from MSs on the use of NAMs for risk assessment of the food chain are welcome.


QUESTIONS?

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Paphos-4-5th March 2026

THE FUTURE OF EFSA'S NAM ACTIVITIES :

IMPLEMENTATION IN EFSA RISK ASSESSMENT AND BEYOND

Jean Lou Dorne
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NAMS: WHAT FOR AND CHALLENGES ?

Paradigm Shift: **Next Generation Risk Assessment (NGRA)**

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

- **Mechanistic-based NGRA** for chemicals in food and feed
- **Support RAs** in appraisal/integration results using NAMs and **address data gaps** to reduce/phase out animal testing
- **Design/validation** OECD NAM-based: Integrated Approaches to Testing and Assessment (**IATAs**)

HOW AND WHERE CAN NAMS BE INTEGRATED IN NEXT GENERATION CHEMICAL RISK ASSESSMENT ?

Step 1
Hazard Identification

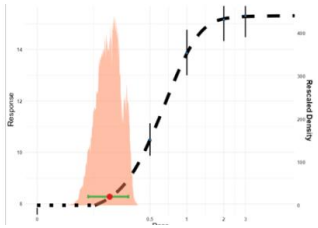
Step 2
Hazard Characterisation

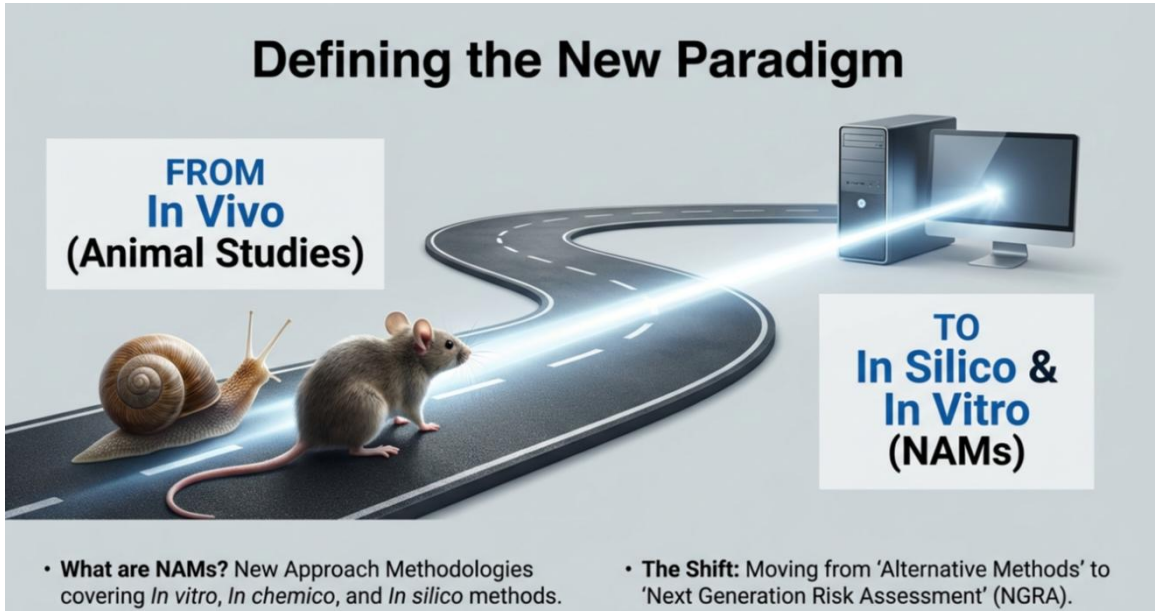
Step 3
Exposure Assessment

Step 4
Risk Characterisation

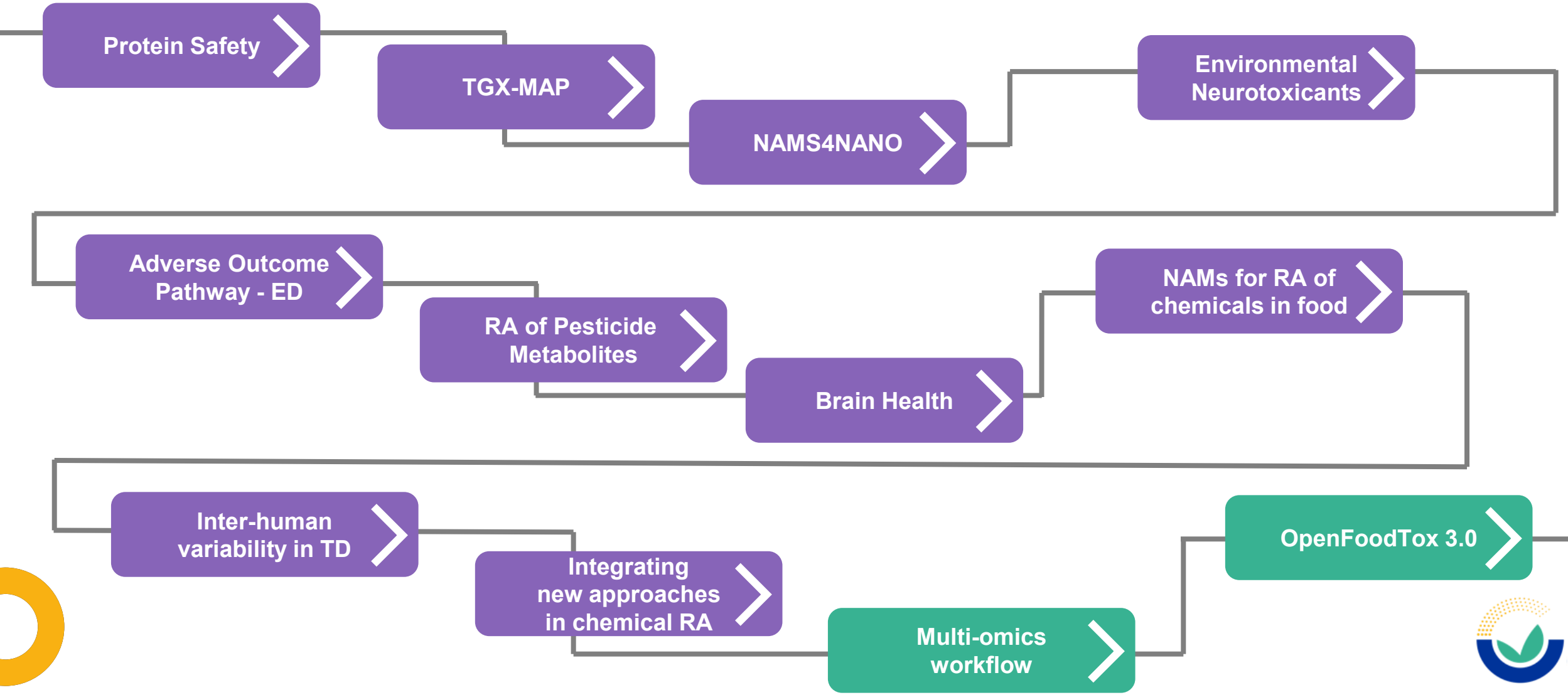
Classify chemicals for specific properties
e.g. Genotoxicity

Dose response Modelling:
Derive Reference Point





NAMS PROJECTS UNDER THE IRMA & DEEP PROGRAMMES

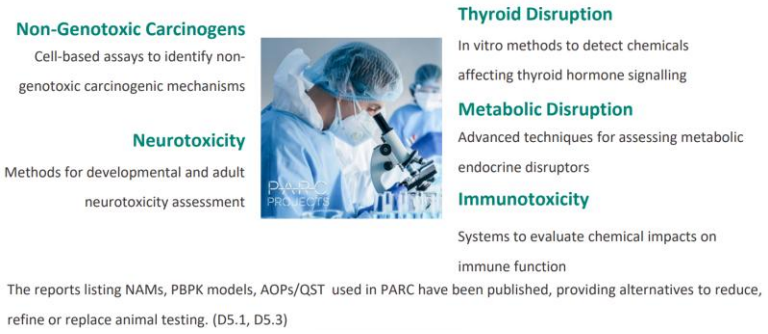


KEY NAM OUTPUTS, DATAGAPS AND PROPOSE STEPS FROM IRMA AND DEEP PROJECTS

PROJECT: IRMA, DEEP	DELIVERABLE	IMPACTED UNITS	DIRECT USE IN EFSA BAU	DATA AND SCIENCE GAPS FOR FURTHER ACTION
Protein Safety	In silico models	GMO, NIF, FEEDCO	YES (RA, GD/Opinions)	DBs, Validation, Data Req
TGX-MAP	OMICs, Vitro, Silico	All Chemical units	NOT YET (Prototype tool)	Case studies, WoE , Data Req
NAMS4NANO	Frameworks, In vitro Battery	MESE, FIP, FEEDCO, NIF, PREV	YES (Case studies, Future GD)	Update GD, Qualify, Data Req
Environmental Neurotoxicants	In vitro Battery	PREV, FIP, FEEDCO	YES (PPP dossier, Proposal data Req, OECD GD, pre-validation ongoing)	Validation, Integrate models TKPlate
Adverse Outcome Pathway – ED	New ED AOP and method for AOP DEV	PREV, FIP, FEEDCO, MESE	YES any ED Assessment (PPP dossier, AOP Wiki)	OECD endorsement ongoing, DEV qAOPs, in vitro batteries,Training
RA of Pesticide Metabolites	QSAR Tools	All Chemical units	YES (soon PPP dossier, Tool)	Chrom aberration and repeat tox
Brain Health	In Vitro Battery	PREV, FIP, FEEDCO	NOT YET (AOP DEV + Test GD)	OECD GD, QIVIVE ADME
NAMs for RA of chemicals	In vitro/ Silico	All Chemical units	YES (cases PREV, NIF, FEEDCO)	OECD GD, Data Req, SC GD TK
Inter-human variability TD	OMICs, Vitro, Silico	All Chemical units	NOT YET (AOP DEV + Test GD)	GD, Integration TK variability
New approaches chemical RA	TK TD, Vitro Silico	All Chemical units	YES (cases FEEDCO, FIP, NIF)	Data Req, SC GD TK, OMICs
Multi-OMICs workflow	Vitro Silico	All Chemical units	NOT YET (Prototype tool)	BMD, WoE, GD, TK, multiOMICs
OpenFoodTox 3.0	DB, Silico	All Chemical units	YES (most panels, QSAR DEV)	Data Collection, EU platform

PARC – PARTNERSHIP FOR THE ASSESSMENT OF RISKS FROM CHEMICALS

Y4: 1st report on NAMs (D5.1)



The reports listing NAMs, PBPK models, AOPs/QST used in PARC have been published, providing alternatives to reduce, refine or replace animal testing. (D5.1, D5.3)

Key endpoints selected by PARC

Human RA

- Developmental neurotoxicity
- Metabolic endocrine disruption
- Endocrine thyroid disruption
- Non-genotoxic carcinogenicity
- Immunotoxicity

ERA

- Apical endpoints (e.g mortality, endocrine, reproduction
- Grouping/read-across
- In silico models invertebrates, aquatic vertebrates

Key chemicals selected by PARC

- BPA and BPA alternatives, PFAS, Flame retardants, Mycotoxins

In vitro methods

Advanced human cell systems, OMICs, AOPs, IATAs, High-content analysis microscopy, high-resolution mass spectrometry, human inducible pluripotent stem cell technology, qAOPs

In silico models

QSARs, QIVIVE, PBK, landscape models, Large Language models,TKTD for Ecotoxicology

STRUCTURE HAZARD DATA AND MODEL CODES IN PARC: TOXCODE4ONEGRA

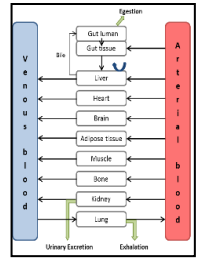
- **Structured NAM-based Hazard Database using OECD harmonised Templates (OHTs)**

OECD Harmonised Templates(OHTs)

OpenFoodTox

- **Structured Model Codes (FAIR)**

MOUSE !!

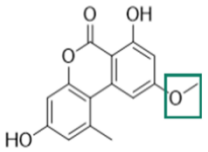


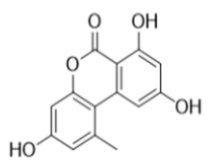
- **Optimise Direct use of PARC NAM/in vivo data in EFSA/ECHA RA**

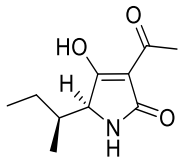
- **Kick-off 15 May 2026 managed by ANSES and BfR: PARC WP 5 10 partners incl EFSA and ECHA**
- **Structure/Share NAM data + implement in PARC, EFSA's OFT/TKPlate, OECD QSAR Toolbox**
- **Support ontology DEV (HBM, qAOPs, TK/TD) and implementation EC roadmap**
- **Specific EFSA and ECHA–relevant case studies** (DNT, emerging chemicals, mycotoxins etc..)

CONTAM ALTERNARIA RISK ASSESSMENT 2025-2026 : RELATIONSHIP WITH PARC

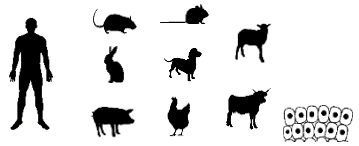
Alternaria mycotoxins







Multiple species



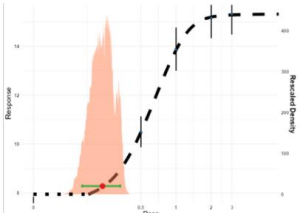
No or Little in vivo data

PARC Filling gaps: Rapid Response mechanism

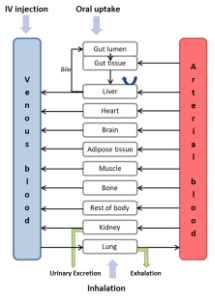
Use of NAMs

Opinion Summer 2026

In vitro BMD modelling

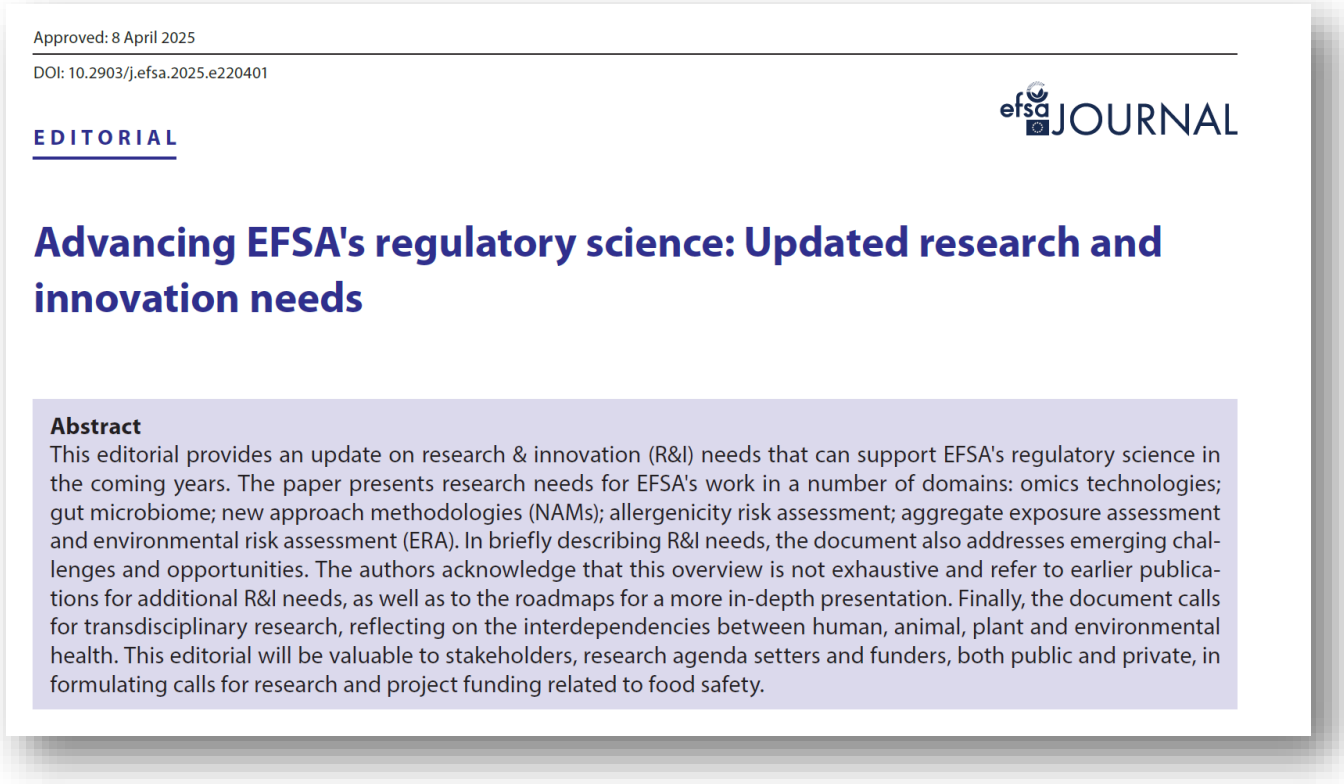


PBK Modelling: Interspecies differences



Use of Internal TTC

-RESEARCH AND INNOVATION NEEDS-



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EDITORIAL

Advancing EFSA's regulatory science: Updated research and innovation needs

Abstract

This editorial provides an update on research & innovation (R&I) needs that can support EFSA's regulatory science in the coming years. The paper presents research needs for EFSA's work in a number of domains: omics technologies; gut microbiome; new approach methodologies (NAMs); allergenicity risk assessment; aggregate exposure assessment and environmental risk assessment (ERA). In briefly describing R&I needs, the document also addresses emerging challenges and opportunities. The authors acknowledge that this overview is not exhaustive and refer to earlier publications for additional R&I needs, as well as to the roadmaps for a more in-depth presentation. Finally, the document calls for transdisciplinary research, reflecting on the interdependencies between human, animal, plant and environmental health. This editorial will be valuable to stakeholders, research agenda setters and funders, both public and private, in formulating calls for research and project funding related to food safety.

https://www.efsa.europa.eu/en/efsajournal/pub/e220401

EFSA Editorial

- ✓ **OMICs**
- ✓ **NAMs**
- ✓ Allergenicity RA
- ✓ Aggregate Exposure Assessment
- ✓ Environmental RA

NAMs

- ✓ **In vitro models**: NAM-based safe levels of chemicals
- ✓ **In silico models** for safe levels of chemicals
- ✓ **WoE workflow to integrate NAMs in vitro/in silico and practical case studies**

CURRENT GENERAL NAM GAPS FOR HUMAN, ANIMAL AND ENVIRONMENTAL HEALTH RISK ASSESSMENTS

HARMONISATION

Assessing Quality of NAM data (i.e. in silico models, in vitro methods, AOPs, IATAs)

Structuring NAM-based Data and model codes and Integration in RA workflows

GUIDANCE DEVELOPMENT

Harmonised guidance for NAM integration in RA for food and feed chemicals

FURTHER DEVELOPMENT, QUALIFICATION AND VALIDATION

QSAR models for missing test species and specific endpoints

QIVIVE Tools for handling in vitro data and qAOPs

Derivation of Reference of point/Points of departure from NAM data

TRAINING EFSA STAFF AND EXPERTS

THANKS TO ALL@ EFSA !

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- **COMM :** Tony, Patrick,
- **Procurement** : Cristina, Muriel, Laura

STRONGER TOGETHER TO IMPLEMENT NAMS

EU MS Food Safety Agencies

European Commission

PARC

食品安全委員会
Food Safety Commission of Japan
内閣府
Cabinet Office

EFSA Stakeholders

Global Coalition for Regulatory Science Research

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

epaa
The European Partnership for Alternative Approaches to Animal Testing

World Health Organization

efsa
EUROPEAN FOOD SAFETY AUTHORITY

ECHA
EUROPEAN CHEMICALS AGENCY

FDA

ASPIS

EUTOXRISK

OECD
BETTER POLICIES FOR BETTER LIVES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CFSA 国家食品安全风险评估中心
China National Center for Food Safety Risk Assessment

ILMERAC

APCRA
ACCELERATING THE PACE OF CHEMICAL RISK ASSESSMENT

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EUROPEAN FOOD SAFETY AUTHORITY

Backup slides

EC ROADMAP OVERVIEW: REGULATIONS UNDER SCOPE OF THE ROADMAP

1. Chemicals registered under the REACH Regulation (ECHA)
2. Biocides (ECHA)
3. Pesticides (EFSA)
4. Food improvement agents (food additives, food enzymes and food flavourings) (EFSA)
5. Chemicals used in food contact materials (EFSA)
6. Feed additives (EFSA)
7. Human medicinal products (EMA)
8. Veterinary medicinal products and MRLs for active substances in veterinary medicinal products for food-producing animals (EMA)
9. Medical devices
10. Chemicals used in materials/products in contact with drinking water (ECHA)
11. Chemicals covered by the CAD and CMRD (ECHA)
12. Chemicals used in human nutrition (EFSA)
13. Detergents
14. Classification, labelling and packaging of chemicals (ECHA)
15. Water and Waste legislation (identification of priority substances)

DISCLAIMERS FROM EC

Commission roadmap towards **phasing out animal testing** for chemical safety assessments.

- The Roadmap (Commission Communication + Staff Working Document) will contain recommendations (action points) on specific human health or ecotoxicological areas of concern or organisational structures
  - → This **does not pre-empt or indicate any changes in legislation**
  - → Legislative changes follow the procedure foreseen in the specific piece of legislation and the Treaties

- All recommendations in this presentation are **preliminary** and might be changed based on feedback received

- Phasing out animal testing will make it necessary to develop further animal-free methods or approaches. → will require discussions with experts and Member State representatives during the **implementation phase** of the Roadmap

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2. ROADMAP IN CONTEXT OF THE EU POLICY AGENDA

- Life Sciences Strategy[1]
- European Biotech Act [2]
- EU Startup and Scaleup Strategy[3, 4]
- European Innovation Act [5]
- One Health governance in the EU [6]
- Chemicals Industry Action Plan[7] ,
  - Common Data Platform for Chemicals (CDPC)
- One Substance, One Assessment
  - The European Strategy for Test Method development and validation [8]
- Safe and Sustainable by Design (SSbD) framework [9]
- EU Apply AI Strategy [10]
  - AI in Science Strategy . [11]
- European Health Data Space Regulation [12]
- European Virtual Human Twins Initiative [13]
- New Human Pharmaceutical Legislation [14]
- European Research Area (ERA) Policy Action on New Approach Methodologies [15]
- Plant Protection Actives Legislation- proposal for update

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