ASPIS

Open Symposium 2-3 July 2026 Maastricht The Netherlands

Outlook for NAM-based NGRA

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No. 963845 (ONTOX),
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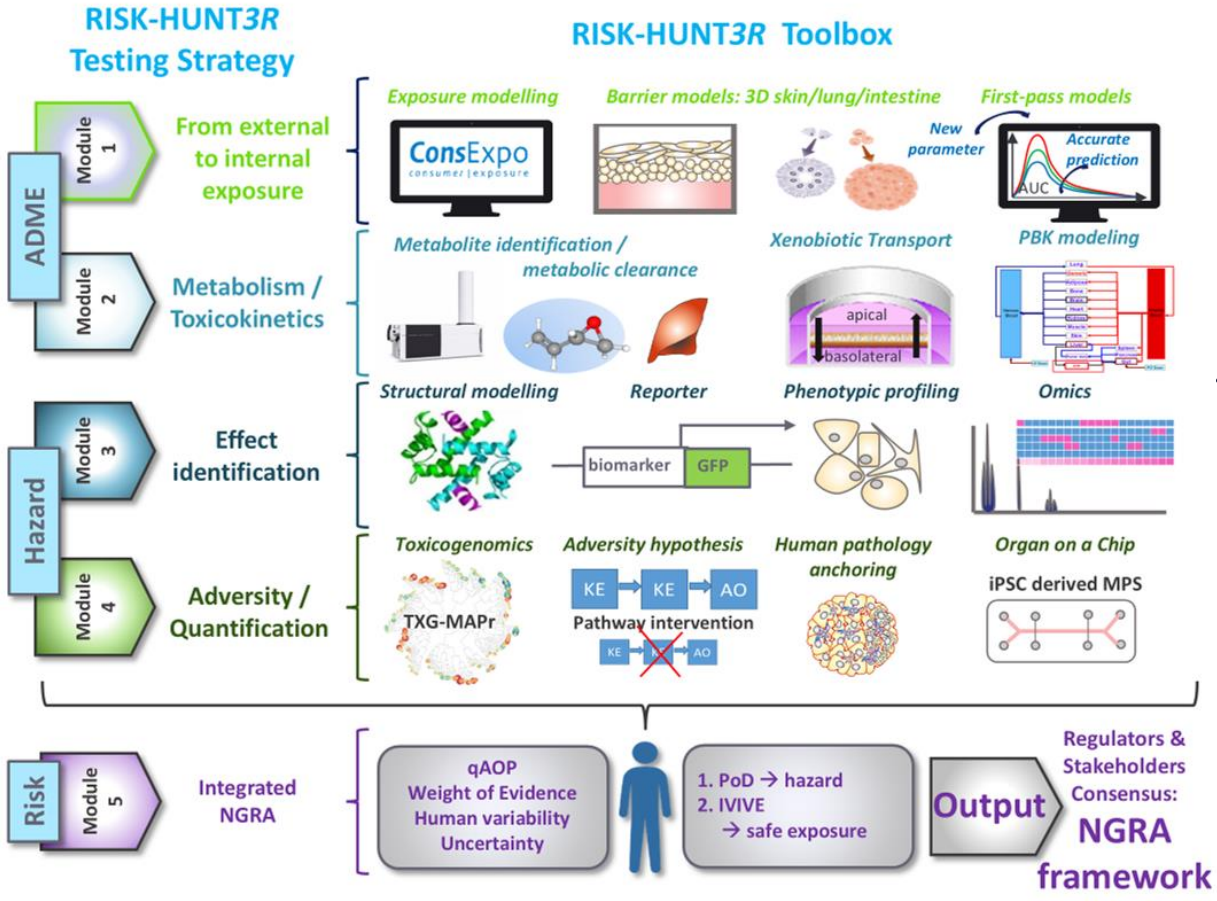
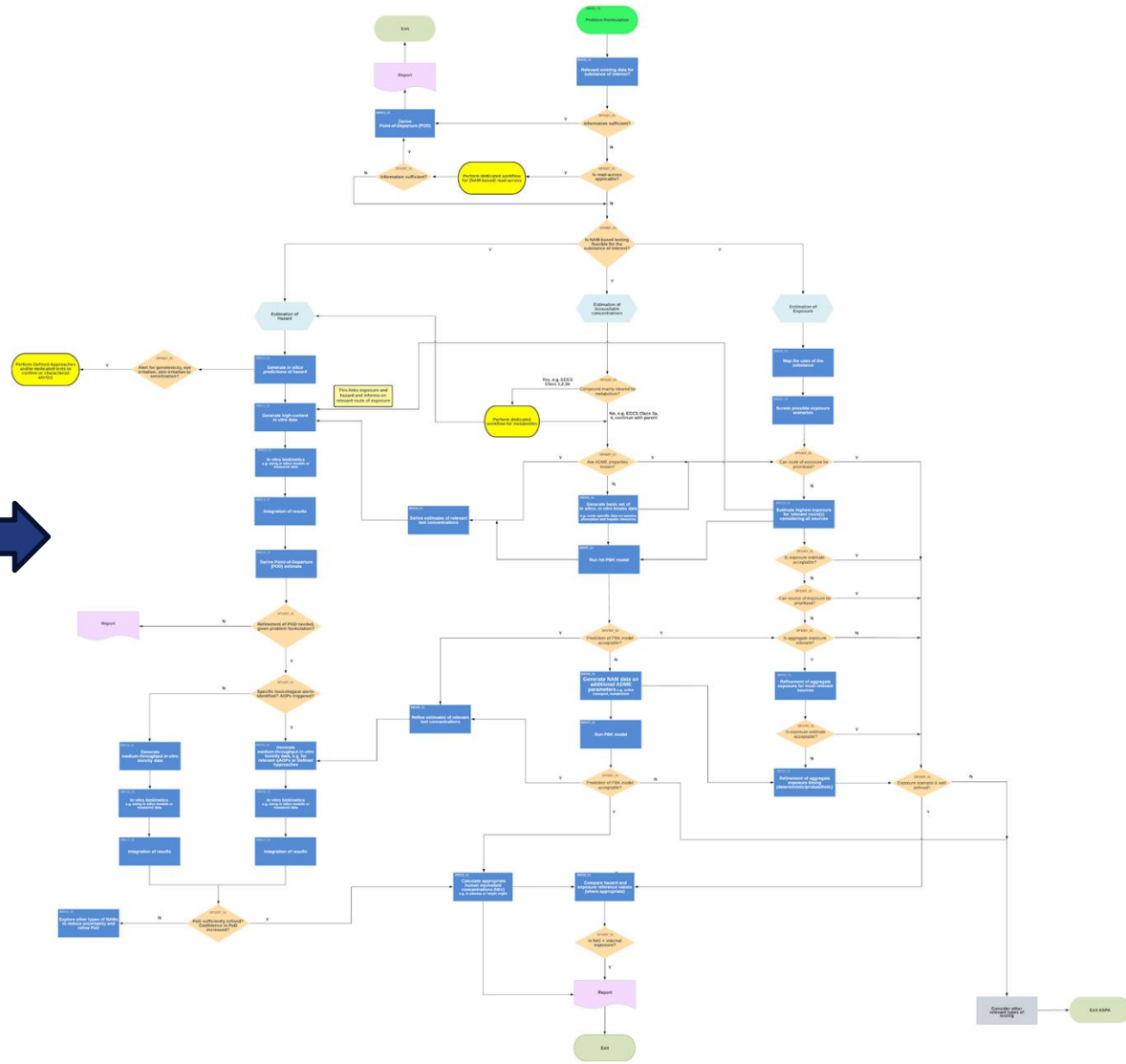
NGRA toolbox for ASPA



RISK HUNT3R

ASPA Workflow v2.0

ASPIS



From toolbox → Case studies → Learnings → Gaps

ASPIS learnings and remaining gaps

Knowledge gaps (1)

- Increase the **volume and diversity of omics data coverage of bioactivity profiles** for improved modes of action and points of departure determinations from chemical-to-biology-to-disease outcomes
- Increase the **biological coverage of systems toxicology assessment** (cells, organs, systems, populations, species, ecosystems) to improve extrapolation and confidence in determining overall safety
- Understand and integrate **inter-individual and population genetic variability** and susceptibility in NAM-based NGRA
- Understand the qualitative and quantitative aspects of **adaptive and adverse responses** to toxicity
- Understand the toxicity of **environmentally relevant chemical mixtures** (real-world exposure scenarios)

ASPIS learnings and remaining gaps

Knowledge gaps (2)

- **Exposure and hazard biomarkers of toxicity** based on knowledge of the chemical modes of action
- Explore **human-centred NAMs and NGRA frameworks** for the **protection of wildlife** (human and ecological protection under **One Health Toxicology**) that simplifies REACH
- **Re-invent sentinel species** for identifying environmental and human health hazards by monitoring their biomolecular pathways
- Improve **biological model species** to achieve protection goals
- Establish a robust **uncertainty framework for NAM-based safety assessment**, including AI-driven probabilistic risk assessment

ASPIS learnings and remaining gaps

Technology gaps

- Improve **organotypic models** representing **human (patho)physiology** for higher tier adversity assessment
- Improve **AI-enabled methodologies for *in vitro* / *in vivo***, species and toxicity read-across
- Improve the ability to **quantify biodiversity** and its associations to ecosystem services
- **Next generation validation of complex NAMs**, including *in vitro* test batteries and AI-based methods
- Effective **qualification as well as industrial and regulatory implementation** of advanced models and approaches for NAM-based NGRA

Future of NAM research?

- EC RTD workshop on future priority research areas for NAMs
- 2 day workshop April 2025 Brussels
- Stakeholders: Academia, Industry (pharma, cosmetics, chemical), Regulatory (EMA, EFSA, ECHA), ongoing EC funded NAM projects, in total~40 participants

- **Topics breakout groups:**

  - Advancing NAMs for regulatory testing: toxicology, ecotoxicology, efficacy, and quality assessment
  - Innovating NAMs for biomedical research and therapeutic development
  - Translating NAMs into practice: knowledge valorisation through standards, data sharing, and regulatory uptake

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Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing

HORIZON-HLTH-2026-01-TOOL-03

Topic **Call for proposal**

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- Topic description
- Topic updates
- Destination
- Conditions and documents
- Budget overview

General information

Programme
Horizon Europe (HORIZON)

Call
Cluster 1 - Health (Single stage - 2026) (HORIZON-HLTH-2026-01)

Type of action
HORIZON-RIA HORIZON Research and Innovation Actions

Type of MGA
HORIZON Lump Sum Grant [HORIZON-AG-LS]

Closed

Deadline model
single-stage

Opening date
10 February 2026

Deadline date
16 April 2026 17:00:00 Brussels time

Requested outcome

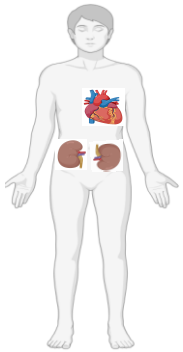
- Researchers are in possession of improved **human-relevant New Approach Methodologies (NAMs) platforms** that capture the genetic, phenotypic, age-related, immune, microbiome, and environmental exposure variability of the human population.
- **Industry gets access to platforms** that allow a faster pace of innovation for the development of more cost-effective targeted therapeutic interventions and improvement of the safety assessment of chemicals, other medicinal products, and medical devices.
- **Patients benefit from innovative platforms** and strategies that improve prediction, prevention and treatment of diseases, in particular through enhanced understanding of disease pathways and mechanisms.
- The **general population is better protected through a safer environment**, as these platforms enhance the detection and mitigation of risks posed by chemicals and other potentially harmful substances.
- **Regulatory bodies gain confidence and trust in NAMs**, supporting their integration into product development, risk assessment, and approval processes.
- **Fewer live animals** are used in biomedical research and regulatory testing.

Cluster requirements

- Attendance of **regular joint meetings** (e.g. common kick-off meeting and annual meetings).
- **Periodic report** of joint activities (delivered at each reporting period).
- **Common dissemination and communication activities** (which may include, for example: a common dissemination and communication strategy, web portal and visual identity, brochure, newsletters).
- **Common Data Management Strategy and Common Policy Strategy** (including joint policy briefs).
- **Thematic workshops/trainings** on issues of common interest.
- **Working groups** on topics of common interest (e.g. data management and exchange, communication and dissemination, science-policy link, scientific synergies).

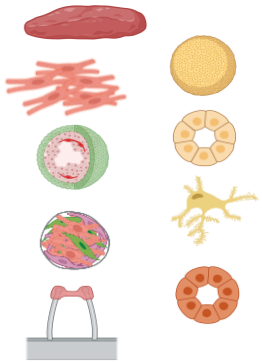
➢ **ASPIS has exemplified an active cluster interaction and collaboration.**

A vision for future NAM research: bridging biomedical and safety sciences



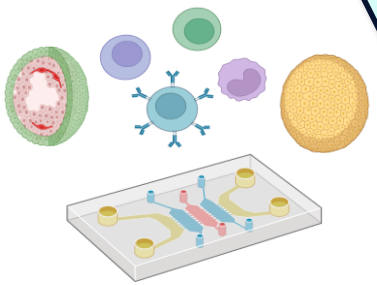
Human (patho)-physiology anchoring of NAMs and AOP mapping

Comparison of target organ NAM test batteries for robustness and human relevance



Population variability and genetic susceptibility of disease and adversity responses

Multicellular test system innovations and fit-for-purpose assessment



CoU

Case studies for the assessment of the fit-for-purpose and context of use

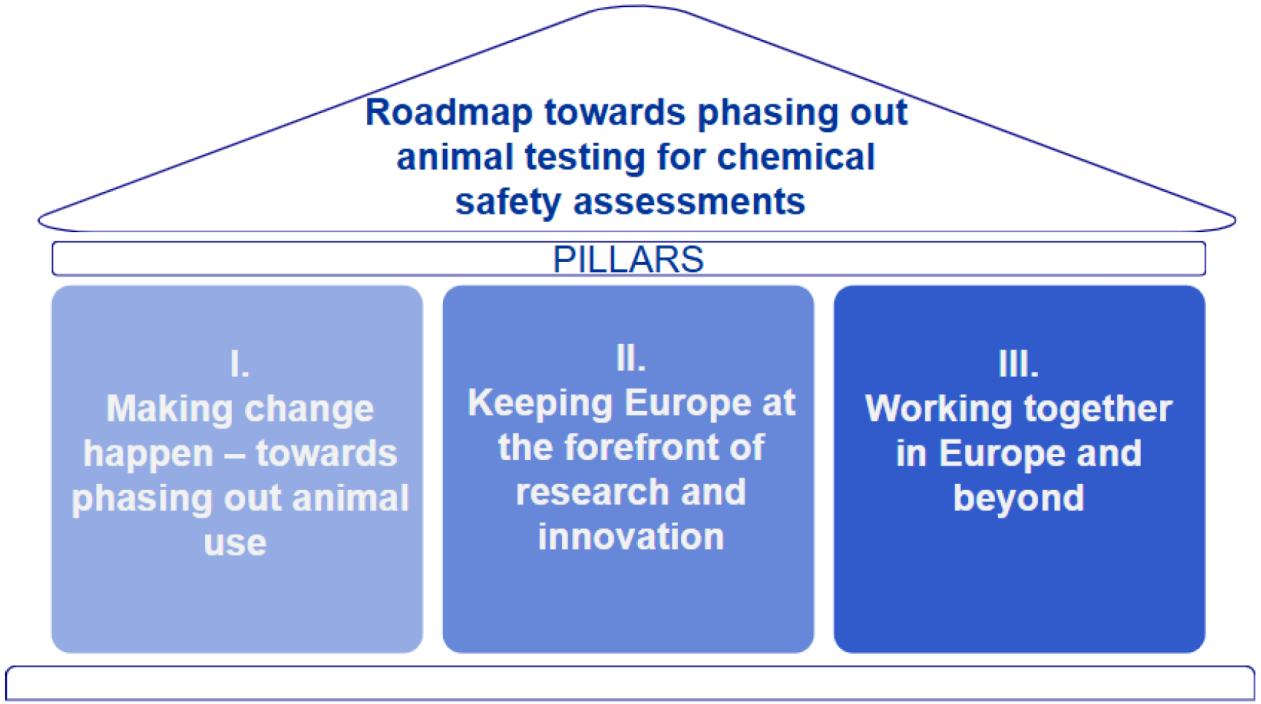
Transferability and implementation of NAMs for efficacy and safety testing

Strong cluster jointly impacting on NAM research

- Coverage of **all critical target organs** for systemic toxicity
- Cross **fertilization between biomedical sciences** and **safety sciences**
- Most **advanced test methods** and the forefront of science
- **Human and clinical relevance translation** involving pathologist and clinicians
- **Cross sector stakeholder** involvement from industry, regulators and CROs
- **Pre-validation of NAMs** and ready for industry and regulatory uptake

Impact on the EC Roadmap

- Supporting **complex endpoints**, such as repeated dose toxicity and reproductive toxicity.
- Transition to a **new scientific framework** for integrating data (e.g. ASPA)
- Support non-animal chemical safety assessments through **mechanistic understanding of toxicity**
- **'adequate level of protection'** for human health and the environment is attained
- Importance of **human-relevant data** for the development of non-animal approaches.
- Cultivating an industrial ecosystem to **bring non-animal approaches to the market**



Next steps of ASPIS contribution to Roadmap

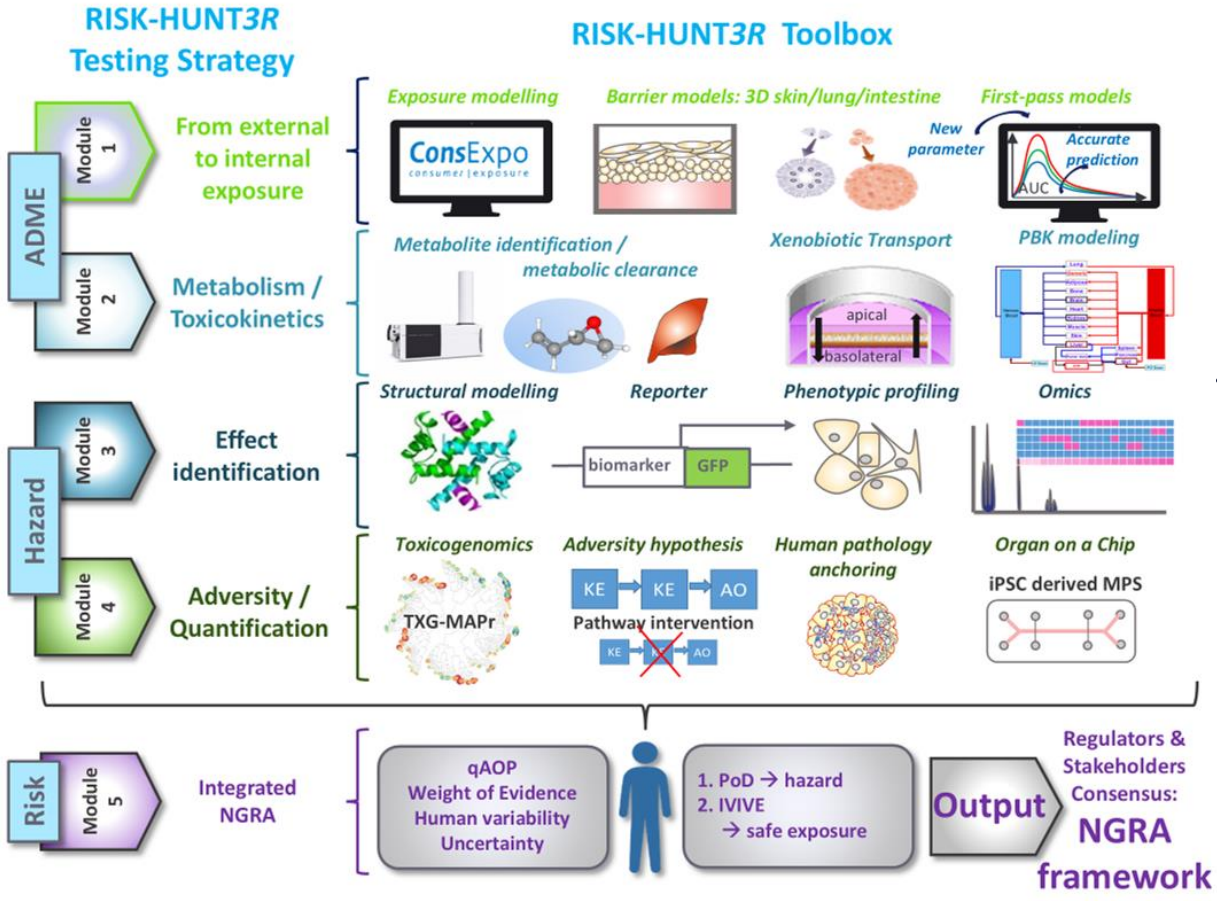
The Commission has invited EFSA and ECHA to organise a workshop in 2026 on the implementation of roadmap actions for the pesticides and biocides area.

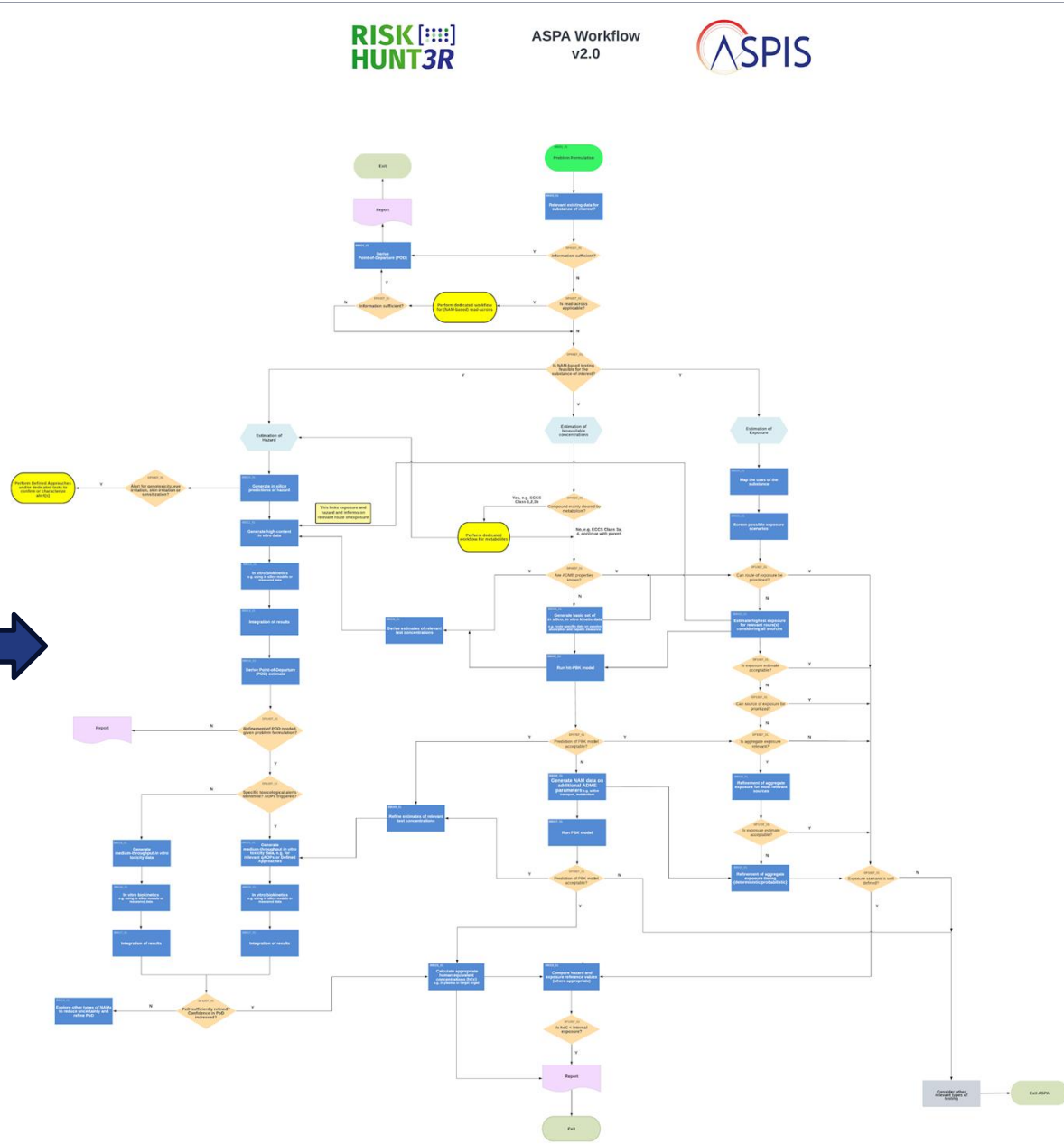
- 21-22 Oct 2026 EFSA – Parma

- 19-20 Oct 2026 - EFSA TXG-MAP project & RISK-HUNT3R joint workshop on omics interpretation tools for chemical safety assessment
- 22-23 Oct 2026 - Final RISK-HUNT3R – ASPIS Stakeholder Open Symposium on implementation of NAMs in NGRA using ASPA framework

- 9th July ECHA – Helsinki – ONTOX IA tools workshop and training

NGRA toolbox for ASPA





From toolbox → Case studies → CoU → Regulatory implementation

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ONTOX

PRECISION TOX

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This output reflects only the author's view and the Directorate-General for Research and Innovation (DG RTD) cannot be held responsible for any use that may be made of the information contained therein.

Open Symposium

2-3 July 2026

Maastricht
The Netherlands

Thank you!

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