FOURTH YEAR ANNUAL REPORT FOR ASPIS

(REPORTING PERIOD: NOVEMBER 2024 TO NOVEMBER 2025)

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EXECUTIVE SUMMARY

ASPIS (Animal-free Safety Assessment of Chemicals: Project Cluster for Implementation of Novel Strategies) brings together three Horizon 2020-funded projects: *PrecisionTox*, *ONTOX*, and *RISK-HUNT3R*, uniting more than 70 research organisations across Europe, the UK, and the US. Together, the cluster develops innovative scientific methods, known as new approach methodologies (NAMs), which aim to improve how we assess the safety of chemicals without relying on traditional animal testing. These methods make use of modern tools such as genomics, advanced cell models, artificial intelligence, and computer-based simulations to better understand how chemicals can affect human health and the environment.

During its fourth year, ASPIS continued to strengthen collaboration across the three consortia, advancing the scientific foundations needed for next-generation, human-relevant chemical safety assessments. Each project made significant progress:

PrecisionTox expanded its evolutionary approach to understanding toxicity across species, increased its multi-omics datasets, and continued addressing policy barriers to the uptake of NAMs.

ONTOX advanced its predictive models for liver, kidney, and developmental toxicity, developed large-scale chemical property databases, and progressed its probabilistic risk assessment approach (OPRA).

RISK-HUNT3R focused on finalising major case studies, refining the ASPA next-generation risk assessment workflow, and building tools such as the ASPA-assist dashboard to support practical regulatory use.

A key development this year was the strategic restructuring of ASPIS. To enhance impact and long-term sustainability, working groups were reorganised into three Task Forces: Impact, Sustainability, and ASPA & OPRA, alongside two continuing groups dedicated to Communication & Dissemination and to early-career training through the ASPIS Academy. This new structure ensures that ASPIS strengthens its scientific legacy, maximises regulatory relevance, and supports broader uptake of NAMs by regulators, industry, and society.

Throughout the fourth year, ASPIS also reinforced its presence in the wider NAMs community. The Cluster partnered with European and international initiatives such as PARC, VICT3R, and VHP4Safety, and hosted key events including the 5th ASPIS Open Symposium in Athens. These activities promoted dialogue between scientists, regulators, policymakers and other stakeholders, supporting Europe's transition toward modern, animal-free safety assessment.

Overall, ASPIS continues to deliver substantial progress toward the development, operationalisation and regulatory integration of next-generation risk assessment frameworks. Through shared resources, joint case studies and harmonised communication efforts, the cluster is shaping a sustainable foundation for safer, faster, and more human-relevant chemical safety evaluation.

The science and policy research within ASPIS contributes to discussions that help shape Europe's roadmap to phase out animal testing for chemical safety evaluations in response to the European Citizens' Initiative "Commit to a Europe without Animal Testing". Recommendations directly linked to our research include: *(i)* expanding the taxonomic scope of NAMs, *(ii)* proposing short-, medium-, and long-term strategies for integrating NAMs across regulatory sectors, and *(iii)* enhancing the use of relevant data and alternative model species to assess chemical risks, thereby supporting the protection of humans, animals, and ecosystems through 'One Health' governance of chemical safety.

Achievements of Year 4 include:

- Participation in high-level scientific and policy events, including the 5th ASPIS Open Symposium and major EU-level workshops on transitioning to animal-free chemical safety assessment.
- Organisation of several ASPIS Academy activities, including a summer school, mentoring programme, twinning exchanges, a joint webinar series, and networking events for early-stage researchers.
- Teaming up with related European and international initiatives such as PARC, VICT3R and VHP4Safety to leverage scientific synergies and increase cross-project impact.
- Development and refinement of next-generation risk assessment tools, including the ASPA workflow and its digital interface (ASPA-assist), advancing their operational use.
- Continued development of the OPRA probabilistic risk assessment framework, together with early-stage application in real-life regulatory case studies.
- Publication of an Action Plan (available here) on solutions to roadblocks for the usage of NAMs, delineating broad consensus for specific policy solutions, like the regulatory use of data, education and training strategies and routes towards validation.
- Publication of a report (available here) identifying key gaps and opportunities for integrating NAMs into EU regulation, detailing how NAMs remain underrecognized and face restrictive frameworks. Better alignment between the OECD Test Guidelines and Directive 2010/63 is needed, as is a clearer interpretation of the legal requirements.
- Progress on case studies applying multi-omics and comparative analysis on the grouping of substances according to their potential modes of action, feeding into OECD guidance on performing and reporting omics-based grouping of data-poor substances, including the plausible toxicological interpretation of biomolecular profiles.
- Strengthening of sustainable knowledge resources, including FAIR-aligned data infrastructures, database integration across the three projects, and the preparation of commercially exploitable NAM tools.
- Dissemination of ASPIS outputs across international scientific conferences, policy events and stakeholder meetings, supported by unified communication campaigns and strengthened social-media engagement.

PrecisionTox

- Producing guidance on reporting, sampling, and utilising omics data for regulatory applications.
- Reporting on the solutions to overcome socio-technological barriers to the uptake of NAMs in chemical regulation, and on the capacity of EU legislative tools to incorporate NAMs.
- Helping to shape EU and UK policy via its active contributions to roadmap developments, high-profile events, and ongoing parliament engagement.

ONTOX

- Delivering integrated human-based toxicity assessment frameworks, in vitro assay batteries, and mechanistic models across liver, kidney, and neurodevelopment, enabling animal-free prediction of chemical-induced adverse outcomes.
- Advancing next-generation computational tools—including large language models, QSAR/fragment-based models, HT-PBK approaches, AOP networks, and the ONTOX Hub—to improve accessibility, systems-toxicology reasoning, and cross-platform integration for regulatory use.
- Strengthening regulatory and stakeholder readiness through coordinated dissemination, open-access data collections, AI-supported probabilistic risk assessment tools, and targeted activities that accelerate the uptake and sustainability of NAMs.

RISK-HUNT3R

- The ASPA workflow for NGRA was included in the European Commission's roadmap considerations for phasing out animal testing
- The ASPA workflow has been tested in-house by external large industry partners, gauging its practical fitness for the purpose of real-world chemical safety assessment.
- Three regulatory case studies have been submitted to the OECD IATA Case Study Project group for their 2025 review cycle and have been favourably evaluated. The cases were all guided by the ASPA workflow, which, as a result, has seen positive international regulatory recognition, with the OECD seeking to draw from the NGRA workflow and its digital interface to aid future IATA reporting and reviewing.

BACKGROUND

ASPIS is a collaboration of the Horizon 2020 funded projects *ONTOX*, *PrecisionTox* and *RISK-HUNT3R*. It represents Europe's €60M effort towards the sustainable, animal-free and reliable chemical risk assessment of tomorrow. ASPIS includes more than 70 institutions across 16 countries of the European Union plus the United Kingdom and the United States. The mission of ASPIS is to establish a next-generation risk assessment framework based on new approach methodologies (NAMs), encompassing *in vivo* to *in silico* technologies.

ASPIS maintains its commitment to improving the accuracy, speed and affordability of chemical safety testing without the use of laboratory animals. Building on advances within the three consortia and close interactions with its stakeholders, it provides NAMs to accelerate and improve chemical risk assessment. Through these activities, informed decisions that safeguard human and environmental health can be made to facilitate the development of safe and sustainable products. The goals of ASPIS are being met through international cooperation, methods development and guidance documents for chemical safety testing and risk assessment.

ASPIS has initially operated through nine Working Groups (WGs), composed of investigators from all three consortia, including early-stage researchers, who specialize in research domains central to the cluster's mission: Chemical Selection, Risk Assessment, quantitative Adverse Outcome Pathway, Omics, Kinetics & Exposure, Computational Approaches, Database and Communication & Dissemination, and the ASPIS Academy (Figure 1).

The WGs were co-chaired and included members from each of the three projects, Early-Stage Researchers (ESR) forming the ASPIS Academy and the Joint Research Centre (JRC). WGs regularly scheduled monthly or bimestrial virtual meetings, as well as *ad hoc* meetings when needed. Meeting recordings and other ASPIS documentation (manuscripts, posters, PowerPoint presentations and meeting slide decks) are stored and maintained on the ASPIS MS Teams/SharePoint. Additionally, there are dedicated Slack, GitHub, LinkedIn groups facilitating internal and external communication.

In the fourth year, ASPIS underwent a strategic restructuring to enhance impact, sustainability, and alignment with long-term goals. This shift was initiated during the 4th annual ASPIS Open Symposium 2024 (Copenhagen, Denmark), where the WG chairs and the cluster coordinators evaluated the relevance and future role of the WGs. As a result, the original nine WGs transitioned into a more streamlined structure comprising three Task Forces: 1) Impact, 2) Sustainability, and 3) ASPA & OPRA, alongside two continuing WGs: Communication and Dissemination and the ASPIS Academy (Figure 2).

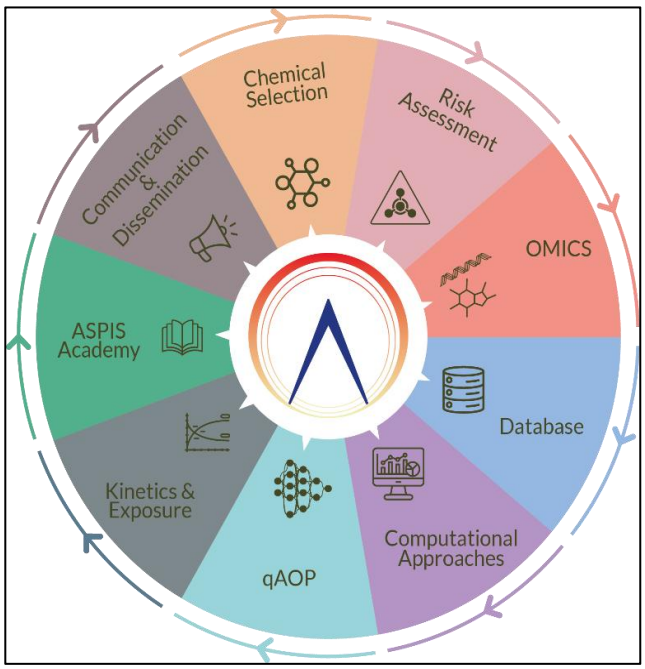

Figure 1. ASPIS Working Groups.

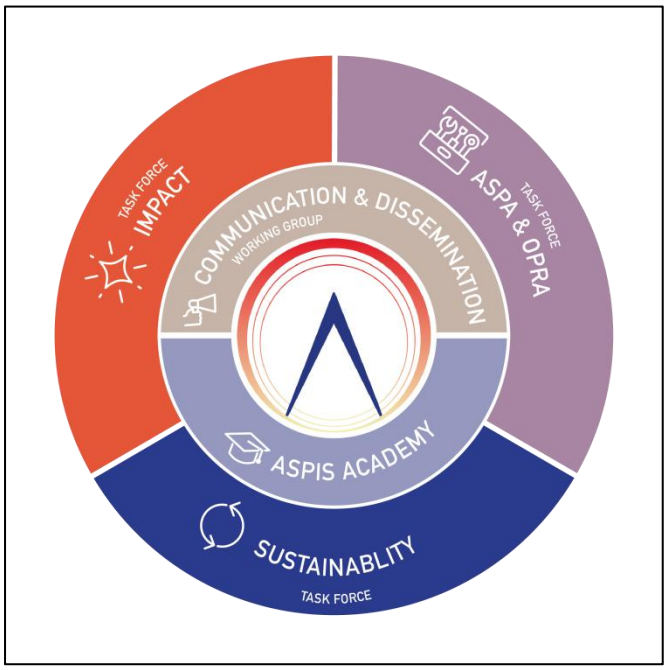

Figure 2. Structure of ASPIS after recent transition.

The ASPIS coordination team is composed of the three ASPIS project coordinators: Mathieu Vinken; Vrije Universiteit Brussel-Belgium, ONTOX; Bob van de Water; Leiden University, RISK-HUNT3R; and John Colbourne; University of Birmingham, PrecisionTox, and the three ASPIS project managers (Martijn J. Moné - RISK-HUNT3R, Agata Ormanin-Lewandowska - PrecisionTox, Julia D. Zajac - ONTOX).

The ASPIS project managers ensure smooth coordination and effective communication across the consortia. They assist the coordinators in efficiently achieving the ASPIS cluster goals and their responsibilities include organizing coordination meetings, compiling meeting reports, and facilitating cross-communication among the three ASPIS projects, and coordination team. Additionally, they are instrumental in organizing the ASPIS Open Symposia.

ASPIS ACTIVITIES - YEAR 4

ASPIS was launched in July 2021; under the leadership of Bob van de Water; Leiden University, RISK-HUNT3R coordinator. The ASPIS leadership role was then inherited by John Colbourne; University of Birmingham, PrecisionTox coordinator. Then the ASPIS leadership was transferred to Mathieu Vinken; Vrije Universiteit Brussel-Belgium, ONTOX coordinator which will continue to May 2026.

During the first year of ASPIS, formal organisational and WG structures were established. Its mission and goals were developed and areas for cross-consortium collaboration were identified. In its second and third, and fourth years ASPIS built on this foundation with each WG pursuing its individual activities, as well as several ASPIS-wide projects. The newly established Task Forces were designed to address key priorities outlined in the original H2020 call, including:

- Scientifically sound, practicable non-animal solutions for chemical safety assessment
- Engagement with regulatory bodies to translate methods into practice
- Uptake and commercial exploitation of developed approaches
- Contribution to the 3Rs principles, with a particular emphasis on 'Replacement'.

And will focus on communicating and implementing discoveries made by the cluster, implementing approaches to increase ASPIS impact and sustainability.

Governance meetings continued to be held on a regular basis including:

- Coordinators meeting (monthly) is attended by the ONTOX, PrecisionTox and RISK-HUNT3R coordinators, and project managers. Additionally, representatives from the European Commission (EC) are invited to attend.
- WG chairs and Task Force meetings includes consortia coordinators, project managers, WGC chairs, and the ASPIS Academy Core team.
- Stakeholder and Regulatory Advisory Board (SRAB meetings, ad-hoc) is attended by the members of the SRAB, project coordinators, and project managers.
- Ad hoc meetings were held at various times throughout the year. During this reporting period ASPIS coordinators and project managers met with members of PARC, EPAA, EFSA, VICT3R and the US FDA, EPA and NIEHS.

In 2025, ASPIS partnered with PARC to identify synergies, continued collaboration with the VICT3R project across five working groups, and co-hosted the ASPIS Academy webinar series with VHP4Safety. A key highlight was the 5th ASPIS Open Symposium on 17–18 September 2025 in Athens, Greece, organized by the current chairing project ONTOX, providing a platform for scientific dialogue, strategic planning, and stakeholder engagement.

In addition, the three ASPIS projects have secured a six-month extension to further strengthen the impact, and long-term sustainability of the cluster's scientific and regulatory contributions.

Impact Task Force

The Impact Task Force focuses on impact at the research, regulatory, industrial and societal level. The goal is to maximize ASPIS visibility and to leverage impact in view of generating sustainability and a

tangible legacy. This Task Force intends to generate a paper on the overall ASPIS impact as well as a visionary paper on the future of the use of NAMs for chemical safety evaluation and their impact.

Sustainability Task Force

The Sustainability Task Force oversees the legacy of ASPIS considering the cluster research contributions alongside ongoing initiatives, including the Partnership for the Assessment of Risks from Chemicals (PARC) and the EC Roadmap for phasing out animal testing in chemical safety assessments in Europe, the NIH Complement-ARIE programme in the USA and the UK's ambitions to progress NAMs as part of its nationalised Chemicals Strategy. The goal is to ensure that the ASPIS data are stably archived, publicly accessible and made useful to all NAMs stakeholders following the FAIR principles. Emphasis is placed on the completion and integration of project-specific databases. Moreover, the ASPIS NAM safety assessment tools will be made commercially available when possible. These scientific activities are being integrated with work being completed on the legislative and regulatory mapping of NAMs so that progress continues to be made at operationalising NAMs via guidance documents (e.g., OECD) and by nudging changes to regulatory statutes. The primary ambition of this Task Force is for ASPIS to lay a foundation on which the private sector may invest to accelerate NAMs development.

ASPA & OPRA Task Force

The main goal of the ASPA & OPRA Task Force is to follow up on the development, optimization and operationalization of next-generation chemical risk assessment strategies generated in ASPIS, namely the Alternative Safety Profiling Algorithm (ASPA) and the ONTOX Probabilistic Risk Assessment (OPRA) approach. Furthermore, focus is put on finding synergies between ASPA, OPRA and the discoveries on the genetic basis of susceptibility by PrecisionTox by mutual application of several AI-based tools and probabilistic approaches for both exposure and hazard modelling. Most importantly, this Task Force supports the demonstration of the relevance and reliability of both ASPA and OPRA in the ASPIS projects through several real-life case studies in collaboration with end-users in industrial and regulatory settings.

Communication and Dissemination Working Group

This WG harmonises dissemination activities and maximises the impact of ASPIS. Its objective is to effectively communicate scientific advances through a clear unified channel to regulatory stakeholders, policymakers, non-governmental organisations and the public. Taking in consideration these target audience objectives, recent highlights include:

- Strengthened stakeholder engagement and fostering dialogue among regulators, industry and academia through booths and impactful communication materials (event recaps, feature stories, video content) at the key scientific conferences 2025 SOT ToxExpo, SETAC 2025, 13th World Congress on Alternatives and Animal Use in the Life Sciences, and EUROTOX.
- Supported the organization of the 4th ASPIS Open Symposium.
- Expanded the ASPIS Academy online presence with new content—interviews, videos, and news-supporting early-stage researchers and maintaining active social media outreach.

- Enhanced the ASPIS website with a new section highlighting cluster publications and key outputs.

ASPIS Academy

The ASPIS Academy is a network of early-stage researchers (ESRs) focused on the development and use of NAMs in the safety assessment of chemicals. It promotes the careers of ESRs through specialised training, championing equal opportunity, and creating a platform devoted to the voices and aspirations of a new generation of regulatory scientists.

Recent highlights include:

- Opening to external ESRs since April 2024.
- Establishing the "Manual for the ASPIS Twinning Program" to provide opportunities for students from all three ASPIS projects to visit and collaborate with laboratories across the network.
- Organising a bimonthly webinar series with VHP4Safety project in which ESRs give scientific presentations on different topics based on the collaboration groups.
- Organising the in-person training "ASPIS Academy Summer School: Let's talk about data!" as a satellite meeting to the ONTOX annual meeting.
- Organising ASPIS Academy session at SETAC 2025 "Bridging the gaps between ESRs for collaborative environmental toxicology communities".
- Launching the ASPIS Academy: Back to School programme to bring NAMs to classrooms and inspire the next generation of scientists.
- Maintaining the mentoring activity through a 2nd edition across the three consortia.
- Organising a networking event at the ASPIS Open Symposium 2025 in Athens, Greece.
- Collaborating with other ESR communities:
    - Strengthened stakeholder engagement by hosting booths at the 2025 SOT ToxExpo, promoting ASPIS achievements to regulators and industry.
    - Co-organised the ASPIS Open Symposium 2025, fostering dialogue among regulators, industry, and academia on advancing animal-free chemical safety assessment.
    - Represented ASPIS at major policy events, including the EU Roadmaps for Animal-Free Innovations (Brussels) and the 3rd EC Workshop on Phasing Out Animal Testing (Helsinki).
    - Expanded the ASPIS Academy online presence with new content - interviews, videos, and news - supporting early-stage researchers and maintaining active social media outreach.
    - Enhanced the ASPIS website with a new section highlighting cluster publications and key outputs.
    - Produced impactful communication materials, including event recaps, feature stories, and video content from the ASPIS Open Symposium 2025.

- Further communicating and disseminating the activities of ASPIS Academy such as poster sessions, networking opportunities, interviewing of scientists, and social media management.

DISSEMINATION

Trainings

Project	Training / Topic	Date	Mode
PrecisionTox	NAMs in regulatory context and embedded translation	29 Feb 2024	External Café Scientifique
PrecisionTox	Understanding science in policy and politics	14 Jun 2024	Internal In person training
PrecisionTox	BfR Training Course: Grouping Chemicals using Omics Data	26 Jul 2024	External In person training
PrecisionTox	Biological question-based approaches for hazard and safety assessment	31 Oct 2024	External Café Scientifique
PrecisionTox	Hands on Training on PrecisionTox Data Explorer	11 Dec 2024	Internal Webinar
PrecisionTox	Key Areas of Regulatory Challenge (KARC): how researchers can contribute to the regulatory uptake of NAMs.	16 Jan 2025	External Café Scientifique
ONTOX	Research Output Management Strategies for Animal-Free Risk Assessment	14 Feb 2025	online
ONTOX	Bridging science and society: Stakeholder involvement in animal-free risk assessment	8 Apr 2025	online
ONTOX	European Commission RTD workshop on NAMS future priority research areas	10–11 Apr 2025	on site
ONTOX	Using LLMs to explore physiological maps (hackathon)	8–9 May 2025	on site
ONTOX	qAOPs: Advancing Human-	27 Jun 2025	online

	relevant toxicology through data driven models		
ONTOX	AI Tools: Introduction and Demonstration – Webinar #1	3 Jul 2025	online
ONTOX	Adverse outcome pathways: basic concepts and liver toxicity as a case study	19 Aug 2025	online
ONTOX	AI Tools: Introduction and Demonstration – Webinar #2	9 Sep 2025	online
ONTOX	AI Tools: Introduction and Demonstration – Webinar #3	2 Oct 2025	online
ONTOX	ECETOC–VHP4Safety–ONTOX: AI in toxicology and chemical safety workshop	28–29 Oct 2025	online
RISK-HUNT3R	RISK-HUNT3R Data and Protocol Organisation	6 & 20 Dec 2024	online
RISK-HUNT3R	Special guidelines to upload TempO-Seq data	9 Dec 2024	online
RISK-HUNT3R	Career paths workshop & Business cases for NAMs (setting the stage)	10 Feb 2025	in person
RISK-HUNT3R	ASPA–NGRA preparatory meeting	22–23 May 2025	online
RISK-HUNT3R	ASPA–NGRA Expert Workshop	27–28 May 2025	in person
RISK-HUNT3R	Algorithmically structured NGRA	17–18 Jun 2025	in person
RISK-HUNT3R	NAMASTOX: a computational tool supporting the use of workflows for NGRA	24 Jun 2025	online

ASPIS at major events

- SOT
  ASPIS was represented at the 65th Annual Meeting and ToxExpo of the Society of Toxicology, held 16–20 March 2025, in Orlando, Florida. At the booth, the Altertox team conducted

interviews with ASPIS Cluster members to highlight their work and showcase the three projects along with the latest developments within ASPIS.
Video interviews are available in the *SOT Stories playlist on YouTube*.
In this occasion, ASPIS also hosted a joint scientific session: C*hallenges of NAM-Based Toxicokinetic Assessment in Regulatory Risk Assessment*, featuring both RISK-HUNT3R and ONTOX representatives.

- WC13
  Held on 31 August – 4 September, 2025, the 13th World Congress on Alternatives and Animal Use in the Life Sciences (WC13 Rio) featured a booth organized by RISK-HUNT3R/ASPIS booth, where the latest updates on the ASPIS cluster of projects (ONTOX, RISK HUNT3R and PrecisionTox) were shared. The activities of the ASPIS Academy were also showcased.
  In this occasion, ASPIS also hosted three joint scientific sessions: *ASPA, the guided workflow for next-generation chemical safety assessment, Artificial Intelligence to Reduce and Replace Animal Testing, and Empowering the Next Generation of Researchers for Next Generation Risk Assessmen*t featuring representatives from RISK-HUNT3R and ONTOX.

- EUROTOX
  ASPIS hosted a joint scientific session titled *Assessing and Communicating Uncertainty in Next Generation Risk Assessment*, with contributions from RISK-HUNT3R and ONTOX representatives during EUROTOX Congress held on 14-17 September 2025 in Athens.

- EU Roadmap for Animal-Free Innovations
  Held on 4–6 March 2025, the Brussels featured ASPIS representation in discussions on how ASPIS outputs can contribute to achieving the milestones outlined in the EU Roadmap for Animal-Free Innovations.

- 3rd EC Workshop on Phasing Out Animal Testing
  Held on 16–17 June 2025, the 3rd European Commission Workshop on Phasing Out Animal Testing, organised in collaboration with ECHA, gathered stakeholders to review draft recommendations and Roadmap milestones. ASPIS was strongly represented at the event, with all three ASPIS coordinators present.

- ASPIS OS 2025
  The annual ASPIS Open Symposium 2025 was held on 17-18 September in Athens. This key event brought scientists, regulators, industry leaders and other stakeholders together to explore the latest advancements in assessing chemical safety without laboratory animals, with human health protection at the core.
  In its fifth edition, the Symposium reaffirmed Europe's role as a leader in developing New Approach Methodologies (NAMs) and Next-Generation Risk Assessment (NGRA) – helping map a pathway toward safer chemical testing that reduces and replaces animal use.
  At the heart of ASPIS are two cornerstone next-generation risk assessment frameworks: the Alternative Safety Profiling Algorithm (ASPA) and the ONTOX probabilistic risk assessment (OPRA) approach.
  During the 2025 Symposium, both ASPA and OPRA were presented with their latest refinements, demonstrating how each framework, individually and together, advances the operationalisation of next-generation risk assessment. ASPA workflow integrates diverse NAMs and related data into a transparent, science-based framework for NGRA. OPRA offers an advanced, AI-enabled

probabilistic framework that brings data-driven prediction and uncertainty analysis into the evaluation process. The presentations highlighted the essential role of NAMs and AI-powered tools in enabling practical, robust and future-ready regulatory decision-making.

Case studies on developmental neurotoxicity (DNT) provided strong examples of NAMs already being considered for regulatory decision-making. Discussions also focused on sustainability, ensuring that ASPIS results, tools, and knowledge will remain accessible beyond the projects' official end in 2026.

This year's Symposium also introduced scientific flash presentations, where nine researchers showcased their work in concise and engaging talks. In addition, nearly 20 scientists presented posters, with an expert jury recognising three Best Poster Award winners – one from each ASPIS project – for their outstanding contributions:

- Eliska Kuchovska (ONTOX; IUF – Leibniz Research Institute for Environmental Medicine) – "Regulation of key neurodevelopmental processes by disease pathways and nuclear receptors in a human Neurosphere Assay"
- Shaleen Glasgow (PrecisionTox; University of Birmingham) – "Comparative transcriptomics of Daphnia and Bio-medical models for the evolutionary conservation of a gene network for toxicant associated fatty liver disease"
- Eike Cöllen (RISK-HUNT3R; University of Konstanz) – "Rapid identification of neurotoxicity alerts for multiple compound classes by high-throughput single cell Ca^{2+} assays"

With strong engagement from regulators, academia, and industry, the ASPIS Open Symposium 2025 confirmed the growing momentum behind NAMs. The discussions will feed directly into the EU's ongoing REACH revision and the forthcoming European Commission roadmap for phasing out animal testing. The Symposium demonstrated that ASPIS is firmly on track to deliver a lasting impact: helping Europe achieve sustainable, innovative, and animal-free chemical safety testing for the future. A press release on this event is available at *www.sav.sk/index.php/index.php?l.* A series of videos recorded during ASPIS OS 2025 is available on the ASPIS YouTube channel.

ASPIS PUBLICATIONS (NOVEMBER 2024 TO NOVEMBER 2025)

Bahtiri, S., Hagens, T. M. S., van de Water, B., & Niemeijer, M. (2025). Mechanism-based drug safety testing using innovative *in vitro* liver models: from DILI prediction to idiosyncratic DILI liability assessment. *Expert Opinion on Drug Metabolism & Toxicology*, *21*(7), 769–787. *https://doi.org/10.1080/17425255.2025.2516051*

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Čavoški, A., Holden, L., Mueller, L., & Lee, R. (2025). Balancing chemical safety and animal welfare considerations in the application of new approach methodologies for chemical safety assessment. *NAM Journal*, *1*, 100013. *https://doi.org/10.1016/j.namjnl.2025.100013*

Čavoški, A., Lee, R., & Holden, L. (2025). The Role of Epistemic Communities in Formulating EU Policy: The PrecisionTox Project. *Transnational Environmental Law*, *14*(1), 198–223. *https://doi.org/10.1017/S204710252400027X*

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OUTLOOK 2026

As the ASPIS cluster approaches its final months, efforts across ONTOX, PrecisionTox and RISK-HUNT3R continue to focus on consolidating scientific outputs, strengthening regulatory engagement, and ensuring the long-term sustainability of the cluster's tools, databases and frameworks. In parallel, the cluster is preparing a comprehensive paper highlighting its most significant achievements, with particular emphasis on its impact in delivering scientifically sound and practicably implementable non-animal solutions that are ready for deployment in meaningful chemical risk assessment. The paper will also reflect the increasing recognition and engagement of regulatory bodies in translating ASPIS results, methods and tools into regulatory practice, the uptake and commercial exploitation of the developed next-generation risk assessment approaches, products and services, and the cluster's contribution to the 3R principle, with a specific focus on full replacement opportunities.In addition, the pivotal ASPA–NGRA Workshop that took place in Berlin on 27–28 May 2025 will see its workshop report publication involving all ASPIS, industry and regulatory stakeholders.

The current chairing of ASPIS by ONTOX will conclude in May 2026, after which leadership will transition to a rotating system shared between the three consortia to support continuity beyond the project's formal end. At the same time, ASPIS is preparing for several major scientific events in 2026, including SOT 2026, the ESTIV Congress 2026 where the final ASPIS Open Symposium will be organised as an official satellite meeting (2–3 July 2026 in Maastricht, the Netherlands), and the EUROTOX Congress, ensuring strong visibility and dissemination of ASPIS achievements during its concluding phase.