May 2025

NEWS Pepper

The newsletter of *Pepper*, the public-private platform for the validation of endocrine disruptors characterisation methods

Welcome Céline Boudet, our new CEO

We are pleased to announce that Céline Boudet has officially taken office as Chief Executive Officer of Pepper as of April 1, 2025. As a specialist in environmental health and toxicology, **Céline brings over 25 years of expertise in research, risk assessment, and scientific leadership to our platform**, dedicated to the validation of methods for the characterization of endocrine disruptors. Her longstanding commitment to advancing innovative, reliable scientific methodologies will be instrumental in leading Pepper into its next chapter of excellence.

Throughout her career, notably at INERIS and ANSES, Céline has championed the integration of cutting-edge approaches such as New Approach Methodologies (NAMs) into health and environmental assessments. She has coordinated or participated to major national and European research initiatives, contributed to shaping public policies on emerging risks, and actively engaged in fostering dialogue between science, society, and regulatory bodies. Her experience and deep knowledge of both technical and societal challenges in our field position her uniquely to guide Pepper's strategic development in a fast-evolving landscape.

With her vision rooted in scientific rigor, collaboration, and responsible innovation, Céline aims to strengthen Pepper's impact at the French, European, and international levels. We are excited to embark on this new phase under her leadership and look forward to achieving new milestones together in our mission to support public health and environmental protection through validated, trusted methods.
➡ read the full communiqué here

Society of Toxicology 64th Annual Meeting

The SOT, with 8 000 members from 60 countries is quite representative of tendencies inToxicology. The SOT2025 Orlando meeting on March 16-20 underscored the necessity of developing and validating scientifically robust, globally accepted NAMs. Among the domains, the importance of sessions on Developmental and Reproductive Toxicity (DART), on Developmental Neurotoxicity (DNT), Metabolic Disorders and Endocrine Disruption is to be noticed.

Several of the speakers of the session '*Endocrine Disruption and Non-EATS Modalities: State of the Science for Metabolic Disorders and Next Steps*', were members of Pepper's Scientific Council (Dr. Patience Browne, Helen Tinwell, and Ella Atlas). Pepper's director, Philippe Hubert, presented on Assay Readiness Assessment and its implications for method development in the Continuing Education Session focused on the regulatory harmonization of NAMs.

➡ read the full communiqué here

S*T MARCH 16-20 ORLANDO
Pepper
re moments become memories
Philippe Hubert, our Director, was at SOT Orlando last week.
Discover his impressions and take-home messages
#EVENTS

Pepper's First Project Management Training for Method Validation

On March 4-7, 2025, Pepper held the **first edition of its training course on "Project management for the validation ofcell based *in vitro* methods"**. The four-day session combined theoretical content with practical exercises, including case studies and document analysis. Sophie Rigal from the German Federal Institute for Risk Assessment (**BfR**), with whom a collaboration agreement is under discussion, participated in this inaugural session. The training covered the full validation process—from method selection and SOP preparation to data management, OECD interactions, and administrative considerations. Practical exercises focused on planning tools such as validation quantification, project charts, and data management plans. We thank Sophie for her active participation and look forward to welcoming other interested organizations or institutions to future editions of this training.

At Pepper, we believe that validation should be a professional competency, and we are dedicated to equipping experts with the knowledge they need to drive validation projects. As part of this commitment, we now offer on-demand training for professionals looking to integrate validation into their careers.
If you are interested in advancing your expertise invalidation, feel free to reach out to us. Let's take the next step together!

Validation training by Pepper
4 days training session with Sophie Rigal, BfR
March 2025

NAMWISE

The NAMWISE project **aims to drive the adoption and integration of New Approach Methodologies (NAMs) for the assessment of the safety and efficacy of chemicals and pharmaceuticals.** By providing a comprehensive set of recommendations, guidance, and training resources, NAMWISE seeks to enhance NAM validation and effective implementation. The project is focusing on *in vitro* approaches (including organoids and organ-on-chips), *in silico* methods, Adverse Outcome Pathways (AOPs), and Integrated Approaches to Testing and Assessment (IATA).

The NAMWISE project brings together 18 partners from 9 European countries over a 30-month period, with funding provided by the Horizon Europe program.

Pepper contributes to NAMWISE by leveraging its expertise in the validation of bioassays relevant to regulatory frameworks. As a public-private platform, Pepper helps bridge the gap between academic innovation and regulatory needs by selecting promising methods, ensuring reproducibility and transferability, and supporting their transition into internationally recognized guidelines such as those of the OECD.

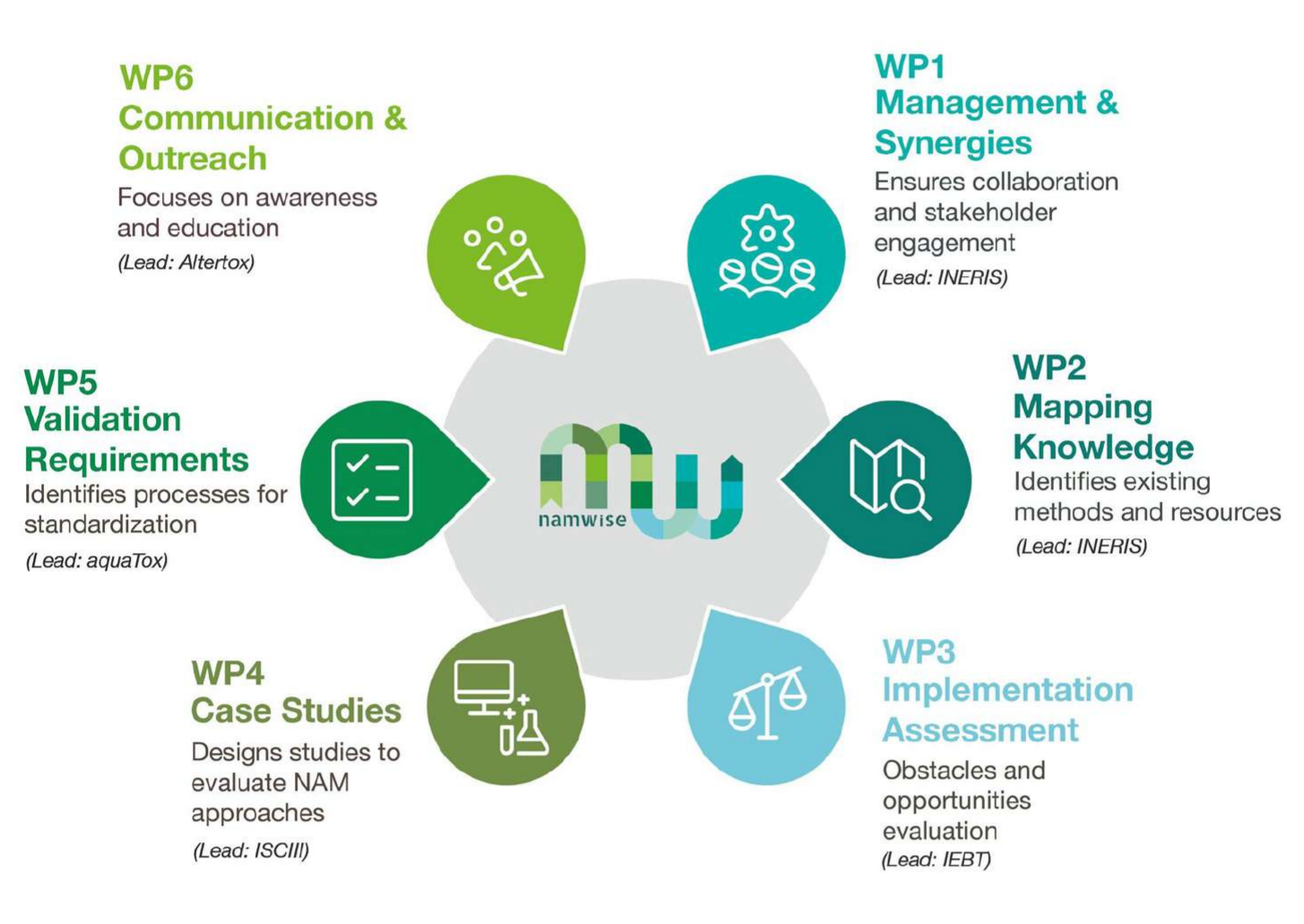
➡ to learn more about the project, read the first NAMWISE newsletter here

Pepper is contributing to two of the six Work Packages: WP2 and WP5.
Work Package 2 focuses on mapping existing knowledge, frameworks, and training resources related to NAMs, identifying data-rich substances and regulatory gaps to support case studies and future implementation.

Within WP2, PEPPER provides expertise on:
- NAM readiness and applicability
- Identification of promising NAM-based methods
- Assessment of training needs
- Endocrine disruptor testing methodologies

Work Package 5 aims to define criteria and propose solutions for the validation and standardization of NAMs, ensuring their regulatory acceptance by aligning processes across international bodies and supporting the "One Substance, One Assessment" strategy.

Within WP5, PEPPER is responsible for analyzing current business models for method validation and also contributes to:
- Comparing standardization processes across regulatory organizations
- Developing readiness criteria for regulatory implementation
- Creating harmonization recommendations aligned with the OSOA strategy


WP6
Communication & Outreach
Focuses on awareness and education
(Lead: Altertox)
WP1
Management & Synergies
Ensures collaboration and stakeholder engagement
(Lead: INERIS)
WP5
Validation Requirements
Identifies processes for standardization
(Lead: aquaTox)
namwise
WP2
Mapping Knowledge
Identifies existing methods and resources
(Lead: INERIS)
WP4
Case Studies
Designs studies to evaluate NAM approaches
(Lead: ISCIII)
WP3
Implementation Assessment
Obstacles and opportunities evaluation
(Lead: IEBT)

The ValNAM initiative

ValNAM is a joint initiative from BMBF (German Federal Ministry of Education and Research) and ZonMw (The Dutch organisation for knowledge and innovation in health, healthcare and well-being) that aim to support validation of NAMs for regulatory purposes or pharmaceutical development. The launch of ValNAM is consistent with the Dutch-German proposal to the EU to boost development and validation of methods. ValNAM will be supporting projects that are focused on validation of non-animal test methods for transfer between labs and test chemical validation efforts. ValNAM is able to finance a selection of projects for a 2-3 year period but will only directly support Dutch and German institutions and companies. The aim is to elevate the readiness of NAMs toward acceptance as OECD test guidelines or for pharmaceutical submissions. Institutions and companies outside the Netherlands and Germany can participate in kind or as sub-contractors for specific purposes that is not covered by other participants. Pepper welcomes this initiative and sees this as confirmation that method validation as a discipline needs support and structures that can facilitate validation and regulatory acceptance of NAMs. Based on the accumulated experience at Pepper we are also happy to support the initiative or if needed specific projects under ValNAM.

ZonMw COMMISSIONED BY Federal Ministry of Education and Research ptj projektträger jülich

Advancing Test Methods in Europe: Strategic Initiatives and Pepper's Engagement

Two major European initiatives are currently driving significant progress in the development, validation, and regulatory integration of testing methods for chemical safety assessment. These efforts are closely **aligned with the ongoing revision of OECD's Guidance Document No. 34 on the validation and international acceptance of new test methods.** Both initiatives, while distinct in their structure and origin, converge on the objective of **facilitating a paradigm shift in toxicological evaluation, aiming to reduce and ultimately replace the use of animal testing across regulatory frameworks.**

The EU Roadmap for the Phasing Out of Animal Testing

The first initiative, known as the EU Roadmap for the phasing out of animal experiments, was launched following the adoption of the European Commission Communication C(2023)5041. This communication served as a response to the European Citizens' Initiative, which called for stronger measures to end the use of animals in scientific procedures. The roadmap defines a structured framework to guide the transition towards the broader adoption of New Approach Methodologies (NAMs) in regulatory contexts.

Its development is supported by a series of high-level seminars and the creation of three dedicated working groups:
- Human Health
- Environmental Safety Assessment
- Change Management

The latter encompasses organizational and regulatory aspects, financial incentives, and institutional conditions necessary to enable the uptake of validated non-animal methods. A key focus lies in identifying enablers across all stages of test method development, from early research through validation to regulatory acceptance.

In this context, **Pepper was present at the inaugural seminar in late 2023 and is scheduled to participate in the third seminar, to be held on 16–17 June 2025 in Helsinki**, under the auspices of the European Chemicals Agency (ECHA) and the European Commission.

The European Test Method and Validation Strategy

Running in parallel to the roadmap, but with a complementary scope, the **European Test Method and Validation Strategy was initiated by the Netherlands and Germany and first presented at the CARACAL52 meeting in July 2024**. It was conceived to address the regulatory inertia that often prevents newly developed test methods from being integrated into legislative frameworks, despite significant public and private investments in their development.

A key moment for this initiative was the **policy conference held in Amsterdam on 22–23 January 2025**. Hosted by the Dutch Ministry of Infrastructure and Water Management, the event brought together seventy participants from fifteen countries, including regulators, scientists, and industry representatives. The discussions focused on the slow uptake of innovative methods, despite an estimated €1 billion invested over the past two decades. Participants reached consensus on the need for a coordinated European strategy supported by appropriate governance structures.

The conference highlighted four essential components for the future of test method innovation:

- alignment of test method development with regulatory requirements from the outset.
- improved coordination and funding for validation activities.
- clearer pathways for regulatory integration.
- sustained, well-governed financial mechanisms, including public-private partnerships such as the Pepper platform.

During the conference, Pepper presented a pitch outlining its contributions and perspective on the validation landscape. The full minutes of the conference and the presentation are publicly available online. Pepper will also contribute to the **enlarged pre-task force** established to draft a European governance model for method development and validation. The task-force, which includes representatives from the French regulatory authorities, is scheduled to begin its work in June 2025, with a final proposal expected by the end of the year.

Convergence and Shared Objectives

While these two initiatives differ in scope and origin, they share many of the same challenges and objectives. Both seek to foster the validation and regulatory uptake of robust, science-based test methods, aiming towards the switch to NAMs. They emphasize the importance of early regulatory engagement, the need for better coordination across Member States and the OECD, and the critical role of industry and academic stakeholders in ensuring that method development is aligned with real-world regulatory requirements.

Together, the EU Roadmap and the European Validation Strategy represent a pivotal moment in Europe's commitment to innovation, scientific rigor, and ethical responsibility in chemical safety. **Pepper remains fully engaged in both processes and will continue to contribute expertise and leadership to ensure that NAMs reach their full potential in regulatory science.**

Up-coming events

Journées Internationales d'Endocrinologie Clinique (Journées Klotz 2025)

The 67th Journées Klotz will take place on June 12-13, 2025, focusing on the theme "Hormones et Environnement." This annual conference, organized by the Société Française d'Endocrinologie, will feature sessions on topics such as the "Forever Pollution Project " highlighting the intersection of hormonal health and environmental factors. The event serves as a platform for clinicians and researchers to discuss advancements in endocrinology and their implications for public health.

SUEZ Health & Environment 2025 Workshop

SUEZ is organizing the "Health &Environment 2025" workshop, scheduled for **June 23-25, 2025**, in Cannes, France. This event will convene 15 selected PhD students alongside leading experts to explore advancements in **environmental health,** focusing on areas such as microbiology, analytical chemistry, and toxicology. Participants will have the opportunity to present their research, with a €1,500 prize awarded for the best submission, highlighting SUEZ's commitment to fosteringinnovation in environmental health.
Pepper is pleased to share that Dr. Andrea Rivero Arze, Ecotoxicologist at Pepper, will serve as a member of the Scientific Committee of the event

New national action plan on Endocrine Disruptors

Pepper is invited to make a proposal, together with Anses and Ineris, in the context of the follow-up of the French strategy on endocrine disruptors. The proposal will emphasize the need for translational research, bridging the gaps between research and validation oftest methods. It also aims to help build a national position in the context of the European test method and validation strategy.

https://sante.gouv.fr/sante-et-environnement/risques-microbiologiques-physiques-et-chimiques/article/perturbateurs-endocriniens

https://www.ecologie.gouv.fr/politiques-publiques/strategie-nationale-perturbateurs-endocriniens

Inside Pepper

Method call pre-announcement
Pepper expects to soon open the "call for methods" for validation with us.
This is an annual process, followed by a selection meeting with our Relevance Committee in the autumn.
Stay tuned for the announcement on our homepage and on LinkedIn.

Pepper in Info Chimie Magazine

Having validated methods to characterize Endocrine Disruptors is a common good that benefits everyone, particularly industrial development. The pooling of public and private contributions on the platform, supported by the French 'Programme des Investissements d'Avenir et inscrite par les autorités dans Stratégie Nationale Perturbateur Endocriniens', has led to a European success described in the Magazine article. The sustainability of this contribution pooling is essential for a secure industrial policy.

Follow the link to read the full article and learn more:

➡ PDF

➡ Online

INFO CHIMIE
Quel chemin vers l'industrialisation ?
Pepper avance sur le chemin de la validation de méthodes de caractérisation

Kevin Schlüppmann has joined Pepper as the new **Validation Project Manager**, where he will lead and support the validation of innovative test methods to ensure high scientific standards.

With a background in biology and toxicology, and a PhD focused on endocrine disruption and developmental neurotoxicity, Kevin brings substantial expertise in developing and validating *in vitro* test methods.
His knowledge will be key in enhancing the accuracy and reliability of Pepper's project processes, making him a valuable addition to the team.

➡ Kevin has successful presented his thesis at end of April 'Test method development for the identification of endocrine disruption-mediated developmental neurotoxicity'. In his thesis, Kevin used a cell system based on fetal neural progenitor cells to investigate how selected endocrine signaling pathways affect key processes of human brain development. Moreover, he compared the effects of these endocrine pathways in a species-specific context between human and rodent based test systems. Based on these results, he developed an *in vitro* assay detecting disruption of retinoic acid receptor and glucocorticoid receptor in proliferating human neural progenitor cells.

Emilio Urazmetov has joined Pepper as the new **Executive Assistant**, succeeding Louisette Kaisermann. In this role, he will support the management team by coordinating internal processes and enhancing operational efficiency.

With a strong background in project management, process optimization, and strategic support, Emilio brings valuable experience from high-pressure environments where he honed his adaptability and organizational skills. His expertise and dedication will be great assets to the Pepper team.

Pepper
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