# Looking back at Pepper 5th anniversary symposium and what's coming next. **Endocrine disruptors: accelerating method validation to protect us**

Pepper wishes you a Happy New Year 2025, and warmly thanks all speakers of December 6<sup>th</sup> symposium for their investment in the event preparation, and the quality of their interventions throughout the day. More than 150 participants attended our 5<sup>th</sup> anniversary-symposium on site, and over 250 joined online, proving the significant interest in the validation of methods for characterization of endocrine disruptors. The symposium was a great opportunity for us to celebrate the milestone of 5 years of achievements, and to exchange and explore perspectives on validation with all participants, in a context of ongoing initiatives and developments at European and international levels. This events is part of a very fruitfull year for validation, in which we actively participated (cf. events p.3).

«When we started Pepper, we started from the observation there is a huge gap between research and regulatory science people. The first objective of Pepper was to bridge this gap. Our second approach was to be pragmatic, and not to dream of something perfect before starting to act.»

Philippe Hubert, director of Pepper

Can you imagine measuring a distance without a standard meter? No. In turn, can you imagine characterizing EDs without a series of methods validated and accepted by all? I think we have the answer... We absolutely need it. »

Philippe Prudhon, president of Pepper

# Validation: Expectations, recognition of Pepper contribution, and need to accelerate

## 5 years of Pepper - in figures

9

Collaborations with 9 countries (partnerships, funding, etc.),

11

11 and soon 13 methods included in the work program

**25** 

25 laboratories working with Pepper

**70** 

Over 70 experts participating in Pepper's activities

4

4 scientific articles published

December 6<sup>th</sup> symposium demonstrated the need for validation and explored solutions to accelerate it. Three keynote speakers introduced the sessions, Jordane Wodli (European Commission), Dr Ella Atlas (Health Canada, president of Peppers Scientific council), and Hans Meijer (Dutch Ministry of Infrastructure and Water Management). The discussion panels included representatives of public authorities, risk assessment agencies, private laboratories, French and European academics, industry representatives and other stakeholders (NGOs and trade unions).

The first session, facilitated by Cecile Michel-Caillet (Anses), showed how method validation is a tool for risk management policies of substances and endocrine disruptors. The second one, facilitated by Sebastian Hoffmann (seh consulting) dealt with the practice of method validation and developers and addressed operators' needs. The last session, facilitated by Nathalie Homobono (French Ministry of Economy), focused on how to build a common good of validation.

All panelists agreed on the need for method validation and availability of method validation of quality, to address the endocrine disruptors challenge, while strengthening innovation and trust, and also answering societal expectations for protection of human health and ecosystems. The validation framework is both European (EU) and international, with OECD "guidance documents on assays" allowing Mutual Acceptance of Data between countries and the different interested parties – industry, regulators, public authorities, and other stakeholders. Several speakers acknowledged the innovative approach of Pepper, namely its pragmatic and action–oriented approach coupled with its unique public–private governance. An important discussion point was how to build a robust test method development protocol, anchored in a multidisciplinary approach. Several topics raised significant debate among panelists, such as the integration of validation in research programs or validation funding by public and private stakeholders.

«We discovered the existence of two levels of trust: technical trust, and the trust in people telling you that you can trust. I'm not joking, that's real life.

[...] we are carrying out 3 types of action: [...] selecting and identifying relevant methods to enter the validation stage [...] "operational technical validation" [...] building confidence in Pepper's work, through peer reviews, a validation report submitted to the outside. »

«Time to act has come: we absolutely need a panel of methods to characterize Endocrine disruptors (ED) because industry has the obligation to answer public authorities on the properties of their substances, in particular ED properties, and it is now time to bring a pragmatic and rapid response to interested parties.»

### Philippe Prudhon, president of Pepper

## Philippe Hubert, director of Pepper











































## Ressources

Interviews:

Philippe Prudhon Ella Atlas Philippe Hubert **Posters:** 

**Methodes** 

5 years

Presentations

> read online

access all the ressources > HERE

# A record year of international initiatives on validation

2024 has been a year exceptionally busy in terms of (methods) validation, with Pepper participating in the many events organized.

## Towards a more operational validation and revision of OECD GD 34

Almost one year exactly before the Pepper symposium, in December 2023, OECD launched the initiative, by organizing a workshop on "Operational and financial aspects of validation", which report mentions interest for "Establishing a validation management team". The creation of further national activities, such as public-private partnerships, for the funding of validation studies, is one of the points stressed in the report, in which Pepper is mentioned among competent groups on validation. Besides, OECD launches the update of its guidance document on validation (OECD GD 34), on the agenda of several meetings ever since.



More information: OECD (2024), Workshop report on operational and financial aspects of validation, OECD Series on Testing and Assessment, No. 399, OECD Publishing, Paris, <a href="https://doi.org/10.1787/db9979eb-en">https://doi.org/10.1787/db9979eb-en</a>.

## European Union: methods validation recognized as a political objective by the Council

In 2024, method validation has been twice at the agenda of the Council, first during the Environment Council in June, and then at the Competitiveness Council in November. In point 32 on its conclusions, the Environment Council stresses "the necessity of sound testing methods to identify possible negative impacts of exposure to chemical substances [...], encourages the development of testing guidelines, cooperation and exchange of information between all actors to promote reproducibility and transferability of results; invites the Commission to develop a European Test Method and Validation Strategy [...].".



 $\label{lem:more information: Environment Council conclusions, June 2024, $$ \underline{https://data.consilium.europa.eu/doc/document/ST-1]326-2024-INIT/en/pdf$$ 

## New alternative methods (NAMs) at the core of EPAA discussions

The European Partnership for Alternative Approaches to Animal Testing (EPAA) had NAMs in regulatory adaptations as main topic for its Annual Forum, which took place on November 13th and entitled: "Maximizing the adoption of NAMs in existing European regulations". The event was followed by a 2-day EPAA Partners' forum focusing on "Use of NAMs for the assessment of Endocrine Disruption (ED) within EU regulatory frameworks (human health and environment)".



More information: Annual forum: <a href="https://single-market-economy.ec.europa.eu/events/2024-epaa-annual-conference-maximising-nam-uptake-under-existing-eu-regulations-2024-11-13\_en">https://single-market-economy.ec.europa.eu/events/2024-epaa-annual-conference-maximising-nam-uptake-under-existing-eu-regulations-2024-11-13\_en</a>

EPAA partners' forum: https://ec.europa.eu/newsroom/jrcispra/newsletter-archives/58612 et https://www.linkedin.com/in/epaa-european-partnership-for-alternatives/recent-activity/all/

# **Upcoming Events**

2025 starts with new initiatives towards achieving a EU Strategy on validation Policy conference 'European Test Method & Validation Strategy' January 22-23, Amsterdam



2025 starts with a 2-day event organized by Dutch authorities, which aims at gathering interested parties, including Pepper, to discuss how to speed up the availability of regulatory accepted test methods for European chemicals risk assessment. The event is structured around the building blocks of the European Test Method & Validation Strategy, currently under construction, and will address essential test method development aspects including prioritization, coordination & structural funding.

More information: Policy conference 'European Test Method & Validation Strategy', 22-23rd of January 2025, Amsterdam <a href="https://chemischestoffengoedgeregeld.nl/nieuws/policy-conference-european-test-method-validation-strategy">https://chemischestoffengoedgeregeld.nl/nieuws/policy-conference-european-test-method-validation-strategy</a>





