



Meeting report NCad Stakeholder Meeting on 'Accelerating the Transition to regulatory research without animal testing - Opportunities and challenges'

On 9 October 2025 a diverse group of stakeholders attended the online NCad Stakeholder Meeting on 'Accelerating the Transition to regulatory research without animal testing - Opportunities and challenges'. This was the second meeting in a series of five meetings held to gather input for the Transition Policy Advice 2.0 that the NCad is working towards.

Introduction and welcome

During the introduction moderators Kees Le Blansch (bureau KLB) and Daan Schuurbijs (De Proeffabriek) outlined the session's focus on the Netherlands' role in Europe's transition towards animal-free regulatory research. Building on NCad's evaluation of its earlier Transition Policy Advice 1.0, they explained that the aim of this meeting was to reflect on how to align national strengths with European developments and to help guide strategic choices.

Introductory presentation by DG ENV (European activities in the field non-animal regulatory research)

Katrin Schutte from DG ENV presented a major EU policy development: the forthcoming roadmap to phase out animal testing in chemical safety assessments.¹ The roadmap aims to harmonise approaches across around 15 EU legislative areas and sets out coordinated short-, medium-, and long-term actions to accelerate the uptake of non-animal methods in regulatory practice. Successful implementation will require strong collaboration among EU agencies, Member States, and stakeholders through structured networks and expert groups to ensure coherence and progress across the EU regulatory system. Adoption is expected in early 2026.

Two complementary initiatives were also highlighted: the EU Test Method Development and Validation Strategy, which aims to accelerate and fund test method development and their regulatory acceptance, including non-animal methods, and the ERA NAMs Action (2025–2028), focused on increasing the availability and use of non-animal methods in research and regulation.

In response to questions after the presentation, it was explained that additional funding options for method development and validation are being explored by the European Commission. Regarding the planned regulatory science network, the Commission envisions an organised community of practice with institutional support, though its exact form is still under consideration. It was also pointed out that the Roadmap not only focuses on phasing in new approach methodologies (NAMs), but also on phasing out animal testing and addressing (non-) scientific hurdles that need to change, in which collaboration is key.

Introductory presentation by Mimetas (human 3D disease models)

Henriëtte Lanz (Mimetas) presented current barriers and opportunities in the transition towards animal-free research. Mimetas develops in vitro 3D organ-on-chip models for applications in medicines, chemicals and food. Mimetas aims to model disease complexity from an organ niche in

¹ https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/roadmap-towards-phasing-out-animal-testing_en

3D systems, with the potential to deliver more effective medication and reduce the need for animal testing.

In this presentation, the focus was on drug development, where these 3D systems enable real-time monitoring of immune responses and cellular interactions, offering higher target specificity, improved stability and access to previously 'undruggable' targets and leverage new mechanisms of action. Henriëtte highlighted opportunities linked to new drug modalities such as gene and cell therapies and antibody-drug conjugates, which require human-relevant models for efficacy and toxicity testing, thereby accelerating the shift away from animal use. Remaining barriers include evolving regulatory and validation frameworks and the resource burden of participating in multiple stakeholder initiatives.

Policy developments, including the FDA and NIH roadmaps in the US and the Dutch Growth Fund for animal-free biomedical translation, further support this transition. The key challenge, as was noted, is navigating multiple roadmaps, especially since they're still in flux. Ultimately, the transition is as much a social process as a technical one, requiring the active involvement of all stakeholders.

The presentation prompted a constructive discussion. Points were raised that the FDA roadmap largely mirrors the EU approach. Closer coordination between agencies could help to increase the likelihood of agreement between the two roadmaps.. Greater focus is needed on OECD test acceptance as a key prerequisite for progress, while continued attention will still be required once this first barrier is overcome.

Plenary inventory of developments, opportunities, and barriers is needed for the reduction of animal tests. After the presentations, participants together explored through a Mentimeter session on how current European initiatives and broader system changes could together accelerate the transition to animal-free testing.

Focus on existing initiatives

Participants first reflected on which ongoing efforts are currently most effective within the European framework. The EU Strategy for Test Method Development and Validation and the Roadmap for phasing out animal testing in chemical safety assessments received most attention, indicating that validation and regulatory acceptance remain central challenges. In discussing these results, participants noted that these initiatives serve as an overarching framework linking related initiatives rather than a separate activity, which may explain why these two initiatives received the highest priority.

Needs for broader change

Subsequent questions invited participants to look beyond the current system and identify what is still needed for broader change. Long-term funding, reform of validation criteria and risk-assessment culture, open data sharing, interdisciplinary training and "learning-by-doing" approaches were all seen as important enablers. The latter was further discussed as a way to build regulatory experience with NAMs, for example through pilot "sandbox" settings.

In the discussion, participants pointed out that progress depends on a regulatory system that is coherent, while also allowing for opportunities to evaluate and adopt innovative methods where appropriate. Once accepted, methods should be transferable across frameworks such as REACH, cosmetics and pesticides, supported by validation that reflects diverse substances and regulatory purposes. Better use of FAIR and connected data was seen as part of the same challenge, linking knowledge across domains to speed up acceptance and avoid unnecessary repetition.

Opportunities and barriers

Participants identified opportunities both in scientific innovation, such as Next Generation Risk Assessment and systematic review methods, and in stronger collaboration and shared responsibility across sectors. The main barriers were seen as cultural and institutional: persistent preference for

animal methods, limited training and awareness, and hesitation to accept negative results. Global regulatory alignment was also mentioned as an ongoing challenge.

In the discussion, some participants noted that new methods should be presented with realistic expectations, as overstating their potential can slow down acceptance. Barriers were seen not only as cultural and institutional, such as bias towards animal methods and limited training, but also as global, with stronger international alignment beyond Europe still needed.

Breakout groups, plenary feedback and further discussion

After a short break all participants were divided into four groups lead by NCad (former) members, to discuss the following questions:

1. How can the Netherlands support the transition at EU-level, for instance by leadership, policy alignment or international diplomacy?
2. What support systems (e.g. education, infrastructure, validation) are currently underdeveloped and what strategic investments are needed from Member States (and The Netherlands) to enable regulatory science without animal testing?

After 30 minutes all participants came back from the breakout groups and the outcome was discussed in plenary.

International and Multi-Level Coordination and Policy Leadership

Across groups, participants discussed the role the Netherlands can play in EU and global coordination, including the importance of clear internal alignment so that coherent positions can be presented within EU discussions, and the value of sharing Dutch experience with transition management. The Netherlands' strong scientific and regulatory environment was viewed as an opportunity to strengthen harmonisation across Member States, especially given differing levels of motivation and progress.

Regulatory Frameworks, Barriers and Transparency

Outdated legislation, strict data-requirement structures and the continued bias towards animal-based endpoints were widely identified as major barriers to NAM uptake. Participants noted that regulatory acceptance remains slow due to unclear validation expectations², limited integration of NAMs into existing frameworks and inconsistencies between regulatory sectors such as chemicals, pharmaceuticals, medical devices and environmental protection. Better transparency on regulatory processes, licensing systems and the handling of NAM data was considered important for building confidence and enabling wider use.

Technical and Scientific Challenges

Groups highlighted overarching technical challenges, including difficulties translating NAM outputs to traditional regulatory endpoints and method-specific constraints (e.g. solubility limits in skin sensitisation or skin/eye irritation tests). Broader systemic factors were also discussed, such as cultural and institutional reliance on animal testing and the need for clearer expectation management about the capabilities and limitations of NAMs.

² Revision of OECD Guidance document on validation and international acceptance (no. 34) addresses the issue of unclear validation expectations.

Validation, Infrastructure and Data Systems

Participants highlighted long validation timelines, fragmented or insufficient funding and the need for accessible infrastructure, such as laboratories, equipment, test chemicals, networks and specialised expertise. Public-private partnerships were seen as useful models for sharing costs and capacity. There were also concerns about fragmented data systems, inconsistent terminology and difficulties integrating or interpreting NAM data. The Netherlands' existing strengths in FAIR data and open science were mentioned alongside suggestions to develop more coherent data infrastructures and to reduce fragmentation in national and EU funding initiatives.

Education, Skills and Cross-Community Collaboration

Education and training emerged as major cross-cutting themes. Groups stressed the need for early and continuous learning for regulators, assessors, scientists and students, and for NAM-related content to be embedded in relevant academic and professional programmes. Knowledge gaps within regulatory authorities and the limited ability of trained professionals to apply NAMs in practice were noted. Strengthening collaboration and information exchange between academia, regulators and industry was seen as essential, as many NAMs developed in research are not easily translated into regulatory use.

Plenary inventory: who needs to do what?

Following the plenary feedback and discussion, Mentimeter was again used to explore the roles and responsibilities of different actors in accelerating the transition. Participants considered industry as having the most direct role, followed by the EU and Member States, finally with researchers and educational institutes also playing an important part. NGOs and civil society were generally ranked lower in terms of direct responsibility in this poll.

For industry, participants emphasised the need for concrete action and openness, including data sharing through safe harbours and the exchange of case studies and lessons learned.³ Industry was encouraged to invest in NAMs, submit parallel NAM data to support acceptance, and co-fund validation studies. Agreement on criteria for NAM maturity, licensing validated methods to other companies, and incorporating ethical considerations into corporate responsibility were also mentioned. Cooperation and dialogue with regulators were seen as crucial, as industry's progress depends on regulatory openness and trust. Several participants noted however that if regulations are updated, industry will follow.

Participants also underlined the role of governments, including the EU and Member States, in updating and aligning regulations across frameworks, ensuring transparency in procedures and decisions, and setting clear priorities, timelines and goals. The transition requires us to encourage developments that are considered supportive and discourage activities that are considered not supportive. Sustainable funding for validation, coordinated education on NAMs for regulators and assessors, and global harmonisation through collaboration with non-EU countries, were all considered essential. Participants also stressed that the transition requires attention to social and ethical barriers, and that engaging the public is essential but often undervalued.

In the broader discussion, participants noted that industry remains cautious about sharing data, which reinforces the need for the EU to facilitate trusted platforms where companies, regulators and other stakeholders can exchange data and experience without competitive risk. Such safe spaces would support collaboration, ethical reflection and societal engagement. Overall, the discussion highlighted the mutual dependence between industry and government: effective regulation should facilitate innovation, while transparent industry practices are needed to build trust.

³ An example of animal-free implementation of Safe and Sustainable by Design (SSbD), was provided by Unilever's approach to developing a novel biosurfactant for home care products
<https://sers.unilever.com/files/92ui5egz/production/6814727012110f78df6380f9d5d0f28c029218b4.pdf>

Closing words

Reineke Hamelers from the NCad thanked all participants for their time and valuable contributions to this stakeholder meeting, which is one of five sessions organised as part of NCad's preparation of the Policy Transition Advice 2.0. The discussion provided valuable input for shaping this advice and for identifying where the Netherlands can make a strategic contribution at the European level.