

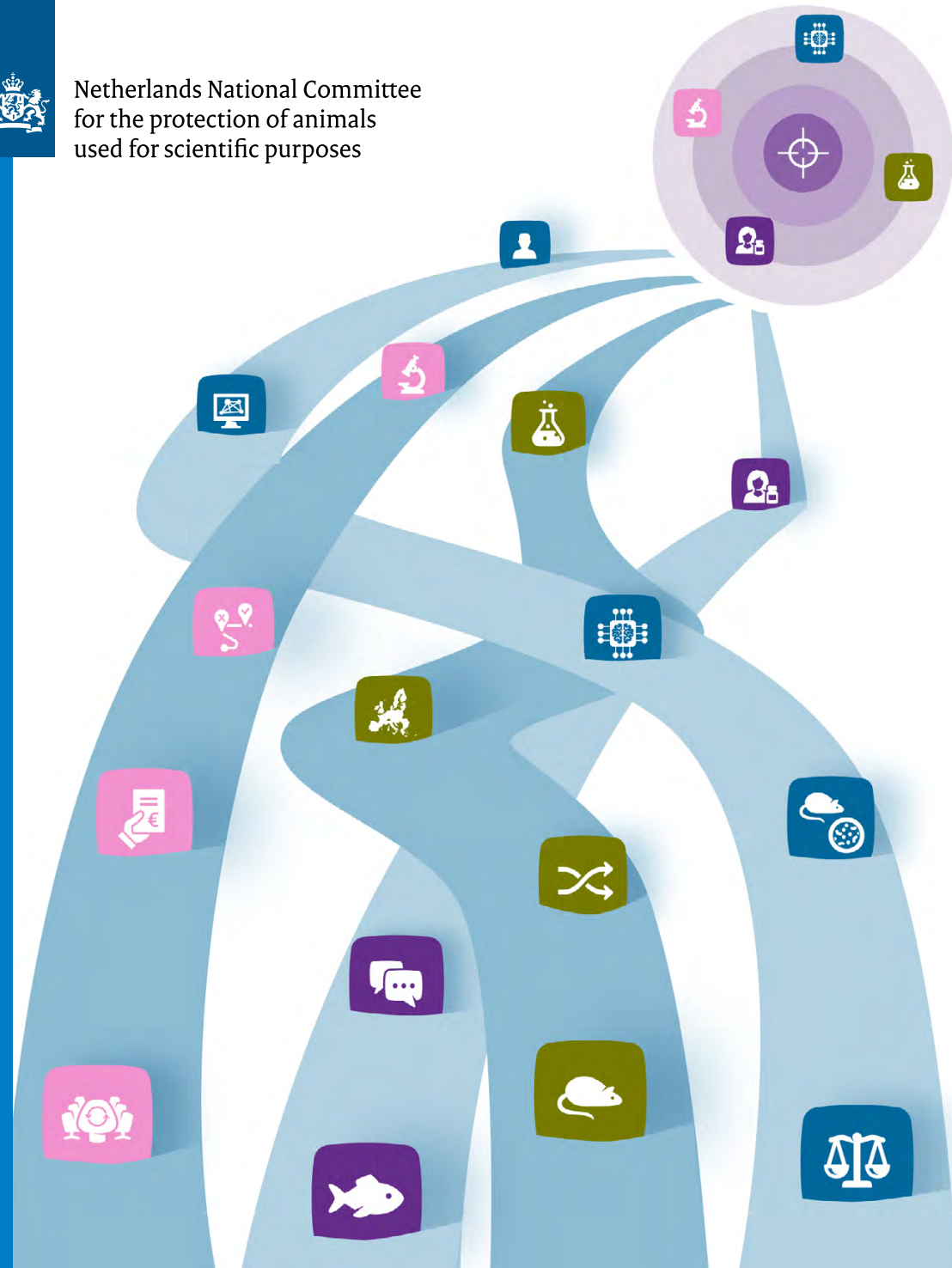


Netherlands National Committee
for the protection of animals
used for scientific purposes

Summary

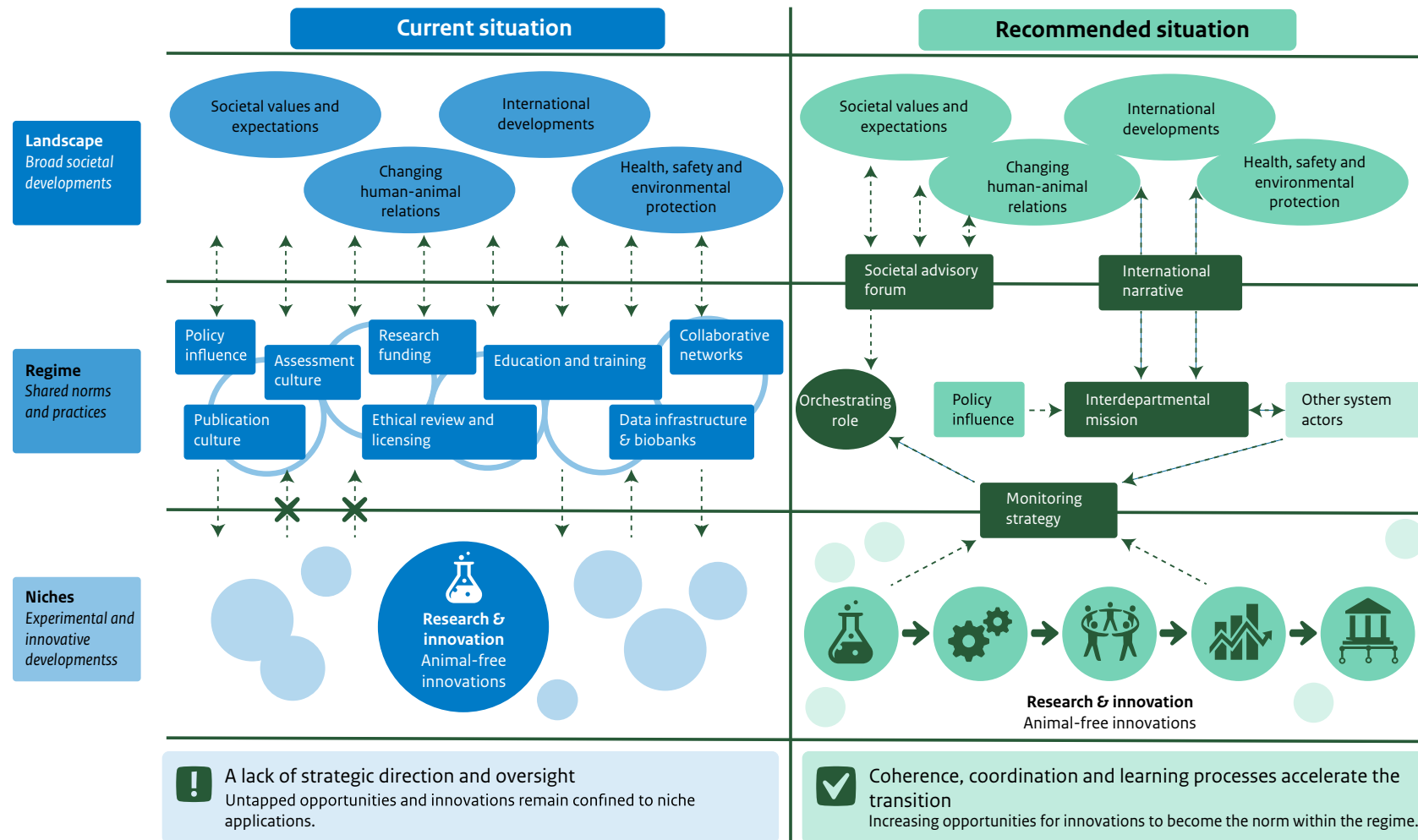
From niche to norm

Transition Policy Advice: working together
towards a society without animal
experiments



The transition towards a society without animal experiments

Towards integrated and orchestrated collaboration for systems change



In this figure the left-hand side illustrates how the actors and conditions within the regime are insufficiently connected. As a result, innovations emerging from niches face difficulties in scaling up into mainstream practice. The right-hand side shows the recommended situation: an interministerial mission and a shared international narrative provide direction, the orchestrating role connects and monitors, the societal sounding board contributes normative and societal input, and policy agendas specific to each domain translate this shared ambition into implementation. In this way, successful innovations are incorporated into policy, research, education and practice.

About this Transition Policy Advice

The NCad issues this Transition Policy Advice on its own initiative as a follow-up to its 2016 Transition Policy Advice and the subsequent evaluation. While the advice is primarily addressed to the Minister for Food Security, Fisheries and Horticulture, the policy advice concerns responsibilities shared across multiple ministries and actors in science, industry and wider society.

Background and core message

The development, funding and applicability of animal-free research methods have increased substantially in recent years. As a result, the Netherlands has built a strong knowledge and innovation position during the initial phase of the transition. However, this progress does not automatically lead to fewer experiments using animals. New methods may continue to exist alongside established research practices without replacing them, while the potential and pace of change vary considerably between different research fields. Without targeted next steps, a significant part of the innovation capacity that has been built up will therefore not be, or will be insufficiently, harnessed for the transition towards a society without animal experiments. Transition studies help explain why this occurs. Innovation often emerges first in protected environments where new methods and forms of collaboration can be developed. Such innovations only change established practice when the existing system also begins to move. In the context of the animal experimentation policy, this means that it is not sufficient to strengthen animal-free methods alone; the structures underpinning existing research practices must also be adapted. Animal experiments often have an advantage in this respect, because knowledge, routines and assessment are already organised around them. The next phase of the transition therefore requires a deliberate interplay between innovation and change in established research practice.

At the same time, scientific capabilities are expanding and knowledge about animals' interests and capacities is growing. This makes the question of whether, and under what conditions, the use of animals can still be justified increasingly urgent. This question should not only be asked once the decision to conduct an animal experiment has already been made, but should guide the design of research,

the development of research strategies and the identification of the research outcomes needed to answer research questions. Scientific and technological developments are also enabling new research strategies. This creates a responsibility to shape the research and innovation ecosystem in such a way that animal-free methods become the default starting point and other research strategies are genuinely given the space to develop and become embedded in practice.

The NCad therefore calls for a fundamental restructuring of the transition approach. The development of animal-free methods must evolve from a collection of separate innovations into a coordinated change of research, policy and practice. This requires a clear guiding objective, coherent public governance and, based on this, a clear allocation of responsibilities among all relevant actors. These responsibilities therefore cannot be assigned solely to individual researchers or the scientific community. After all, the transition is shaped in part by the way the research and innovation system is organised. Within this system, national and international regulation, funding, education, economic interests and societal values also determine the direction and pace of change.

The NCad deliberately refers to a society without animal experiments. This ultimate goal is not a prediction with a fixed end date, but a compass guiding policy, research and practice. Since possibilities differ across policy, research and practice domains, each domain requires concrete intermediate objectives linked to clear responsibilities and visible progress. At the same time, the protection of animals currently in use and the structural phase-out of animal experiments must be pursued with equal commitment and in conjunction with one another.

Recommendations

The recommendations together form a single change strategy built on five pillars:

- I. Governance & ownership
- II. Reassessment of the ethical framework
- III. Innovation and ecosystem policy
- IV. International strategy
- V. Monitoring.

Each pillar fulfils a necessary condition on which the effectiveness of the other pillars depend. The strength of the advice therefore lies in the coherence between the pillars as a prerequisite for system change.

Recommendation I. Embed the transition towards a society without animal experiments as an interministerial mission, with shared ownership and clear responsibilities

Brief rationale. The transition towards a society without animal experiments has been placed on the agenda by multiple stakeholder groups from different sectors, but within government currently lacks shared responsibility for the transition as a whole. Several ministries influence the use of animals in research through their respective policy areas, while a shared objective, clear allocation of responsibilities and a designated system-level actor are lacking. As a result, measures remain fragmented across different policy areas and policy instruments are not deployed in a sufficiently coordinated manner. The transition therefore cannot be treated as a separate policy dossier of the ministry responsible for animal welfare, but requires a single interministerial mission with clearly defined responsibilities assigned to each policy domain and a designated system-level actor.

At the same time, government does not need to, and should not, determine change entirely from the top down. The transition emerges from the interaction between policy, science, industry and societal initiatives. Within this context, a crucial function is missing: an actor that develops an integrated overview, identifies connections and determines where the system is becoming blocked, and from that bases places the necessary system interventions on the agenda and promotes their implementation. Existing organisations do not fully perform this role, because they either see only part of the transition or are themselves involved in implementation, which prevents them from independently safeguarding the coherence of the system. An independent orchestrating role is therefore needed to transform the currently fragmented efforts into a manageable transition by identifying system-wide blockages at an early stage and ensuring that they are addressed at the appropriate level.

Sub-recommendations

I.1 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to establish the transition towards a society without animal experiments as an interministerial mission of central government, within formal and preferably existing structures bringing together the responsible ministers of the Ministry of Defence, Ministry of Economic Affairs and Climate, Ministry of Infrastructure and Water Management, Ministry of Education, Culture and Science, Ministry of Social Affairs and Employment, Ministry of Health, Welfare and Sport. For each policy domain, the responsible minister should establish a dedicated transition policy agenda setting out:

- which specific interim goals are to be pursued in each policy domain and the timeframe for achieving them;
- the policy instruments to be deployed;
- the route and moments through which the minister will report on progress;
- the public and private actors responsible for, and/or accountable for, specific aspects of the transition.

The interim goals are adaptive reference points that are periodically reassessed on the basis of progress and new insights. Each transition policy agenda should specify which financial resources are available or will become available. The responsible minister is accountable for implementing the agenda and for progress within their respective policy domain. The Minister for Food Security, Fisheries and Horticulture, with overall system responsibility, safeguards coherence between the transition policy agendas, coordinates their collective progress and reports periodically to the House of Representatives.

I.2 The NCad recommends the Minister for Food Security, Fisheries and Horticulture, together with the ministers responsible for the relevant domains, to assign and structurally embed an orchestrating role for the transition towards a society without animal experiments, supported by a small, structurally funded team.

This orchestrating role:

- monitors and interprets progress in the transition from an independent position, and identifies deviations from the transition policy agendas;

- identifies and brings to the agenda bottlenecks that transcend policy domains, research categories and actors, framing them as system-level challenges;
- connects learning processes across policy domains, research categories and actors enabling the system as a whole to learn.

Based on the three tasks outlined above, the body performing this orchestrating role reports periodically and publicly on progress in the transition. This role should preferably be organisationally embedded within an existing executive agency, with close links to substantive expertise in transition studies, thereby building on existing infrastructure. Its mandate, interministerial scope, access to information and authority to report independently and publicly should be formalised through an establishment decision.

1.3 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to establish a permanent societal advisory forum that provides the orchestrating role with societal signals and priorities.

The forum should ensure structured participation by organisations representing perspectives on normative questions in the transition that are otherwise not structurally represented in governance, including patient organisations, animal interest organisations, nature and environmental organisations, and consumer organisations.

The forum should have a clear mandate: it should independently determine which societal priorities, bottlenecks, conflicts of values and concerns about societal support it brings forward, and should raise these issues both upon request and proactively. In its public reports, the orchestrating role must account for how the signals raised have been weighed and what action has been taken in response.

Recommendation II. Reassess the ethical basis of research involving animals

Brief rationale. The current harms-benefit analysis provides insufficient guidance in practice for a robust and traceable justification of research using animals. The assessment focuses primarily on visible distress, while other ways in which animal interests may be compromised are difficult to incorporate because it is unclear how they should be assessed. At the same time, expected benefits are often formulated in general terms, and it remains insufficiently clear how likely, meaningful and applicable they actually are. The issue does not lie in a lack of diligence among those involved, but in a framework that provides too little practical direction. Reassessment is therefore needed to ensure that animal interests and uncertain benefits are weighed more in a more explicit, consistent and transparent manner.

Moreover, formal ethical weighing carries particular weight in the licensing process. As a result, ethical assessment takes place relatively late in the process, even though ethical considerations in research practice arise earlier and often informally, when the opportunity to choose a different approach may already be limited. Ethical reflection should therefore be integrated earlier in the process and embedded visibly throughout the entire research chain, with a more formal role, so that it not only assesses the implementation of a planned animal experiment but also influences the choices that precede it. Reassessment is therefore important not only for the quality of individual decisions, but also for the wider transition.

Sub-recommendation

II.1 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to take the lead in updating the ethical assessment framework for research involving animals and to ensure that the outcomes are embedded throughout the research chain: in research strategies, model selection, funding decisions, Animal Welfare Bodies advice, Animal Ethics Committees advice and Central Authority for Scientific Procedures on Animals decision-making.

Establish an independent working group for this purpose, with a strong and independent foundation of ethical expertise, including expertise in animal ethics, animal behaviour and animal welfare. In addition, involve practical knowledge and societal perspectives to determine which research, assessment and funding

practices need to change to enable the framework to take effect throughout the research chain. The working group should be tasked with delivering, within a specified timeframe, a concrete proposal for an updated framework and an implementation plan for embedding it in existing formats and assessment practices. The update should focus on four areas that are insufficiently developed in the current framework:

- Operationalising broader welfare concepts and other ethically relevant concepts, ensuring that the interests of animals extend beyond distress alone and can be weighed in a transparent and traceable way as part of the proportionality assessment.
- Giving uncertainty on the benefits side an explicit place in the assessment, so that uncertainty about the nature, scale, timeframe and translatability of expected benefits is made visible rather than being subsumed under general references to scientific, societal or economic relevance.
- Including an explicit forward oriented question as an integral part of the assessment: what changes in research strategy, knowledge, funding, collaboration or infrastructure are needed to answer the relevant research question without animals in the future?
- Establishing the practical conditions required to ensure that the framework to have an effect throughout the research chain.

The Minister for Food Security, Fisheries and Horticulture should designate a responsible party for the further development, implementation and periodic updating of the ethical framework. Following its implementation, an evaluation should assess whether the framework is in fact being applied throughout the entire chain, from the development and support of research through to assessment, licensing and funding of research involving animals, and whether this leads into more rigorous and transparent ethical assessments.

Recommendation III. Create the conditions within the research and innovation ecosystem that enable animal-free innovations to scale up from niche applications to mainstream practice.

Brief rationale. The Netherlands risks failing to capitalize on its scientific lead in animal-free innovation. New methods are being developed, but often do not reach the research practice because the pathway from development to evidence generation, acceptance, adoption, scale up and use is not organised in a coherent way. As a result, public and private investments are not fully utilized, and The Netherlands risks losing ground in technological fields that are important for health, innovation and competitiveness.

The transition is still too often treated as a separate research or ethical issue, whereas it requires change across the entire research and innovation system. Research models are not selected solely on the basis of their suitability for the research question; choices are also shaped by education, available expertise, infrastructure and established and - often mandatory - assessment practices, making it more difficult for new methods to gain uptake. New methods should therefore not be assessed primarily on whether they reproduce the outcomes of an animal experiment, but on their ability to answer the research question reliably. The transition towards a society without animal experiments requires research to be designed around the knowledge question. This enables human-derived models, existing data, computational analyses and other evidence-based sources to be combined in order to generate more relevant information collectively than any single model could provide on its own.

Sub-recommendations

III.1 The NCad recommends the Minister for Food Security, Fisheries and Horticulture, together with the ministers responsible for the relevant domains, to embed the transition in broader science and innovation policy as part of future-agile science. Animal-free innovation must be aligned with the transition goal in policy agendas and funding programmes.

Use *target images* as a tool to provide direction and ensure implementation within each research domain. The interministerial working group, informed in part by signals from the orchestrating role, determines which domains require new or updated *target images* and how their implementation can be strengthened. The NCad safeguards coherence and quality across the *target images* and ensures that lessons learned are carried across from one *target image* to another.

III.2 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to establish long-term, ecosystem-oriented funding streams for animal-free innovation, in which public, private and public-private investment complement one another and support the full pathway from method development to structural use. Funding programmes should explicitly set out the steps expected to lead to application.

Focus support on structured engagement with end users and market actors from the early development phase, without prematurely forcing new evidence pathways into existing assessment paradigms. This should follow a technology-readiness model and a phased approach in which scientific, technical, regulatory, user and market readiness are assessed together. Funding should be linked to *target images* and phase-out pathways once these have been sufficiently developed, assessed and assigned to responsible parties.

III.3 The NCad recommends the Minister for Food Security, Fisheries and Horticulture, together with the responsible members of the government and relevant infrastructure stakeholders, to explicitly adapt existing data, material and research infrastructures to support animal-free innovation. This should include safeguarding quality standards, interoperability, sustainable access to human-derived material, the reuse of both human data and historical animal data, shared core facilities, and secure forms of data visiting.

The orchestrating role, in collaboration with relevant infrastructure stakeholders, funders and subject-matter experts, should develop a proposal for the infrastructure required, both nationally and at European level. This proposal should identify which components require public-private partnerships. It should then be used to inform the design and adjustment of policy and funding programmes.

III.4 The NCad recommends the Minister for Food Security, Fisheries and Horticulture, together with the Minister of Education, Culture and Science (OCW), to structurally orient education, vocational education and professional development in the life sciences are structurally towards *future-agile science*.

Curricula and lifelong learning programmes should embed knowledge of the full range of available methods, critical assessment of research strategies and model selection, ethical reflection, data science, regulatory science, and the development and application of animal-free approaches. Attention should also

be given to internationally trained researchers with diverse prior knowledge and established ways of working.

Recommendation IV. Coordinate Dutch efforts through a coherent international strategy for multilateral and bilateral cooperation.

Brief rationale. The Netherlands has strong scientific and transition studies expertise, innovative infrastructure and international networks, but has not yet sufficiently translated these strengths into a coherent and recognisable international strategy. Initiatives remain fragmented, sectors pursue different priorities, and it is not always clear what changes The Netherlands seeks to achieve internationally. As a result, Dutch influence remains below what could be expected based on its knowledge and innovation position, and national investments generate less international recognition and uptake as they could.

This is problematic because many of the conditions for widespread application are determined outside The Netherlands, including what constitutes convincing evidence, which research is funded and which methods gain scientific and policy legitimacy. The Netherlands should therefore define nationally which changes it seeks to advance internationally. This should also include challenging the assumption that the transition consists of replacing animal experiments on a one-to-one basis. By combining multilateral engagement with bilateral cooperation, the Netherlands can deploy its expertise more strategically and avoid international dependencies becoming a reason to refrain from making national choices and/or progress.

Sub-recommendations

IV.1 The NCad recommends the Minister for Food Security, Fisheries and Horticulture, together with the other responsible ministers, to consistently communicate a single shared core narrative: animal-free innovation achieves replacement not primarily by reproducing existing animal experiments one-to-one, but by transforming research questions, evidence strategies and science itself.

Methods should be assessed on their relevance, reliability, societal significance and ethical justification, rather than against the animal model as an assumed standard.

IV.2 The NCad recommends the Minister for Food Security, Fisheries and Horticulture, together with fellow ministers, to formulate a coherent international strategy that translates the core narrative on the transition towards a society without animal experiments set out in IV.1 into clear priorities for Dutch action in multilateral forums, bilateral partnerships, and international research and innovation collaboration.

The strategy should make explicit what changes the Netherlands seeks to achieve in international norms, frameworks and assessment practices, and where Dutch expertise and international developments can most effectively reinforce one another.

IV.3 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to work with like-minded countries on targeted bilateral initiatives that build practical experience and evidence and strengthen international coalitions.

These initiatives should be used to advance reforms that create a level playing field for animal-free innovations, both within regulatory frameworks and validation standards and in the criteria governing how scientific research is funded, assessed and published.

Recommendation V. Monitor the transition in an integrated and coherent manner.

Brief rationale. Progress in the transition cannot be reliably assessed on the basis of the number of animal experiments alone. A decline may indicate replacement, but may also reflect the displacement of research; an increase can have various causes, including growth in research areas or changes in legislation. Moreover, an increase in animal-free methods does not automatically lead to fewer animal experiments. Without insight into the causes underlying the figures, it remains unclear whether policy is effective and where intervention is required.

The transition consists of changes that are interdependent. A new method will not lead to application if acceptance, infrastructure or expertise are lacking, while additional funding alone does not demonstrate that research practice is changing. Monitoring should therefore track both outcomes and the conditions that enable change. A shared Theory of Change or roadmap towards impact makes explicit what changes are being pursued, how interventions contribute to these changes and under which conditions they are expected to collectively result in more animal-free research and reduced animal use.

Sub-recommendations

V.1 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to commission the development of a Theory of Change for the transition towards a society without animal experiments, based on the core logic of this Transition Policy Advice.

The orchestrating role should take ownership of the process of developing and periodically reassessing the Theory of Change. It should ensure that the Theory of Change is developed with independent methodological support and through co-creation with relevant actors. Adoption and any subsequent revisions should take place within the interministerial structure set out in Recommendation I, ensuring that the Theory of Change is embedded in government decision-making and serves as the foundation for monitoring, evaluation and adaptive learning. The Theory of Change should explicitly map which combinations of interventions can create positive feedback loops and potential tipping points, which interventions are enabling conditions, and where unintended consequences or rebound effects may occur.

V.2 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to develop, on the basis of the Theory of Change, a focused set of indicators structured around two interrelated layers.

Outcome indicators should track and interpret changes in animal use and in the application of animal-free research strategies. System indicators should track whether the conditions for change are shifting, including ownership, funding, infrastructure, training, assessment practices, regulatory acceptance, market development, and whether routines that impede progress are being phased out.

V.3 The NCad recommends the Minister for Food Security, Fisheries and Horticulture to assign for monitoring with an independent body that is institutionally separate from the commissioning ministries.

Establish a fixed evaluation cycle, preferably every three years. Monitoring is effective when, in each cycle, the assumptions underpinning the Theory of Change are tested, trends and areas of stagnation are interpreted, and it is identified where course correction is required. The orchestrating role coordinates the process, interprets the findings and brings conclusions and required actions onto the agenda within the interministerial structure.