



Transition Programme for Innovation without the use of animals (TPI)

Philosophy and approach

Action plan for the Transition Programme for Innovation without the use of animals (TPI)

The philosophy and approach for the Transition Programme for Innovation without the use of animals (TPI) specifies the basic principles of the transition process, its governance, the ambitions and the solution strategies. It was created in collaboration with the TPI partners: the Royal Netherlands Academy of Arts and Sciences (KNAW), the Netherlands Organisation for Health Research and Development (ZonMw), the Netherlands National Committee for the protection of animals used for scientific purposes (NCad), the Dutch top sectors Life Sciences & Health and Chemistry, the Association of Health Funds (SGF) and the Dutch Society for the Replacement of Animal Testing. The government's involvement is coordinated by the Ministry of Agriculture, Nature and Food Quality (LNV) in collaboration with the Ministries of Education, Culture and Science (OCW), Health, Welfare and Sport (VWS), Economic Affairs and Climate Policy (EZK) and Infrastructure and Water Management (I&W).

The Think Tank¹ and the NCad² have already recommended that the Netherlands should strive to be a frontrunner in this transition process. The collective ambitions of TPI go much further than just animal welfare and the replacement of animal studies: a critical success factor of TPI is the acceleration of developments within the fields of science, health and safety. A wide variety of universities and businesses have already indicated their willingness to participate actively in the TPI process.

1. Basic principles of TPI

TPI identifies drivers, connects parties and promotes ideas and concepts that strive for:

- better applicability and reliability
- better predictability and reproducibility within science
- better treatment methods and efficacy of medicines
- better quality and openness of research data
- the application of promising technologies
- solutions to problems within the chain, e.g. avoiding the 'valley of death'
- the creation of a platform for social debate
- decrease dependence on laboratory animals

1.1 Transitional strategy

Both in the Netherlands and abroad, great progress is being made in the fields of science, health, and risk and safety assessment. There are opportunities in multiple sectors for people, animals and the environment whilst minimising the number of laboratory animals used. At the same time, social and political concern over the use of laboratory animals for scientific and other research is growing. We find ourselves in a transitional phase and we need to benefit from the vast range of innovative methods, processes and technologies that can provide solution strategies and accelerate this transition.

This goes beyond the boundaries of the current 3R policy, which focuses on replacing, reducing and refining animal studies within the current frameworks and systems (legislative or otherwise).

Transitions are not policy decisions, they reflect feelings in society. However, the decision to actively facilitate a transitional strategy is a policy decision. The Transition Programme for Innovation without the use of animals (TPI) explores and accelerates the transition to animal-free research and testing.

¹ Think Tank on Supplementary Financing for Alternatives to Animal Testing, titled '*In Transition! The Netherlands leads the way in laboratory animal-free innovations*' (2015)

² NCad opinion Transition to non-animal research (2016)

1.2 Multi-stakeholder process

When the Think Tank and the NCad were formulating their recommendations, stakeholders with a wide range of roles and interests were already involved in the design of the transition process. This collaboration between government bodies, the business sector, knowledge institutes and NGOs results in new insights and networks, including innovation networks.

1.3 Multidisciplinary approach

TPI brings together a wide range of sectors and fields. It identifies drivers, connects parties and promotes ideas and concepts. By thinking from a multidisciplinary perspective, we encourage researchers, regulators and other stakeholders push their boundaries. TPI offers a platform for ministries and other stakeholders to identify new disruptive activities within their field.

Subsequently they work together to explore the potential of these activities and/or innovations, either at the technical level (e.g. development of humane models and algorithms) or at the process level (e.g. new funding/regulation methods). TPI partners will then select the best ideas, elaborate them into innovation networks and – if possible – translate them into specific projects.

1.4 International strategy

International legal frameworks and decision-making bodies give TPI a strong international dimension. It is vital that TPI expands into these areas as soon as possible and further increases and deepens its international impact. For this reason, we also operate outside the Netherlands and we reach out to international players. They will meet each other at conferences and workshops.

2. Governance of TPI

2.1 Responsive, networking government

Science, consumer safety and medical research are fields that particularly transcend national borders. The government plays a facilitating and coordinating role while all TPI partners actively shape the transition. They gain insight into activities and developments, connects parties both within and outside the traditional frameworks and communicate with all parties regarding progress and results.

2.2 Collaboration between ministries

The TPI partners consider interdepartmental collaboration on content, processes and funding to be a key success factor in this transition process:

- to combine knowledge in terms of relevant policy areas
- to facilitate access to each other's partners and decision-making bodies at both the national and international level
- to benefit from the competences, powers and mandates of all partners
- to integrate policy and funding opportunities
- to engage in shared objectives and activities

The following ministries participate in TPI activities relevant to them:

- Ministry of Agriculture, Nature and Food Quality (coordinating ministry)
- Ministry of Economic Affairs and Climate Policy
- Ministry of Education, Culture and Science
- Ministry of Health, Welfare and Sport
- Ministry of Infrastructure and Water Management

2.3 TPI core committee

The TPI core committee consists of directors of each of the TPI partners. Together, they establish ambitions, goals, strategies and the action plan, which gives clear direction to the transition process. The core committee actively keeps its network involved and monitors developments, initiatives and activities relating to animal-free innovation.

2.4 TPI transition group

All members of the core committee allocate one policy officer to the TPI transition group for the preparation, supervision and execution of activities. The transition group monitors and discusses the progress of the transition. They serve as the 'linking pin' between TPI and the various activities.

2.5 TPI transition office

To fulfil its governing role, the Ministry of Agriculture, Nature and Food Quality has set up a transition office consisting of the director, the secretary, the communications officer and the TPI organiser, among others. The transition office monitors and gains insight into relevant national and international activities and developments and facilitates the set-up of new activities. The transition office is represented in the core committee, the transition group and other departments.

3. Joint ambition

The ambition of the TPI partners is to **establish the Netherlands as a frontrunner in the international transition to animal-free innovation.**

The frontrunner role is based on **accelerating** the transition:

- knowledge development in all fields, from biotechnology to big data
- relevance to humans, animals and the ecosystem
- innovation of content, processes and systems
- animal-free research and testing.

The TPI partners are working within a broad range of sectors and disciplines to prevent unnecessary animal studies and to minimise the use of laboratory animals.

TPI provides a platform for innovative businesses and scientists. TPI steps in when development is being hampered, e.g. by funding difficulties, slow validation processes or limited acceptance in legal frameworks.

4. Solution strategies

4.1 Encourage disruptive change

TPI's ambition is to accelerate the transition process by effectuating a wave of changes.

We define solution strategies and long-term visions for research. Transitions are shaped by disruptive change, i.e. activities that challenge the current system ('fracking and cracking') and can help bring about major transformations. TPI shares the same focus: to encourage activities and innovations that do not fit within the current frameworks and regulations. The transition process is non-institutional: operating outside the current system creates the freedom and opportunity required to develop new systems. In practice, this means that TPI helps set up and facilitate activities that can then be adopted and further expanded by the sectors themselves.

Policy optimization (3R policy)



TPI: acceleration, experimentation and implementation

4.2 Set up and facilitate innovation networks

Activities take place within innovation networks and specific projects. Innovation networks connect and support pioneers, enabling them to explore and expand their horizons within a safe environment. Pioneers of all relevant stakeholders are invited to develop and experiment with disruptive change. They work together on specific steps towards new and more effective standards. TPI facilitates these pioneers by appointing a transition expert, a content expert, and a 'linking pin' to the transition group. The innovation network will then explore the available courses of action. If an idea proves unviable, the innovation network will be disbanded and the lessons learned will be shared.

4.3 Innovation networks in development

Three innovation networks are currently being developed within the scope of TPI:

1. Innovative health care research

Status: ongoing. Linking pin: the Association of Health Funds

The objective of this innovation network is to encourage research funders to shift their focus from research with laboratory animals to research with humane measurement models. The network will investigate how research funders can encourage and facilitate animal-free research or issue instructions in the form of requirements and conditions.

The network consists of creative thinkers and actors within organisations that fund research both with and without laboratory animals: health funds, the Netherlands Organisation for Scientific Research (NWO), the Dutch top sectors, ZonMw, dsRAT, universities, ministries and businesses.

2. Start-up, scale-up

Status: ongoing. Linking pin: top sector Life Sciences & Health

This innovation network ensures that start-ups and scale-ups that use animal-free innovation will be supported by facilitating access to the right regulators, consumers (users of their technology), financial backers, experts and advisors.

3. Conceptual safety assessment

Status: in development. Linking pin: RIVM.

In 2017, the RIVM formulated a roadmap for animal-free innovations in regulatory safety assessment (PIRV) based firmly on the aspects of innovation, safety and animal welfare. In 2018, the RIVM is setting up an innovation network focusing on the development of a new conceptual framework for safety assessment based on animal-free innovation. This innovation network should involve ongoing initiatives such as the EU H2020 projects EUToxRisk, Euromix and HBM4EU. In addition, the innovation network should be complemented by policy makers from the various regulatory bodies and ministries concerned.

4.4 Innovation networks on the drawing board

A number of innovation networks are also 'on the drawing board', waiting to be elaborated by the parties involved:

- Idea for an innovation network that will establish human-oriented techniques as the standard for human research purposes, e.g. for efficient humane concepts for medicines.
- Idea for an innovation network focusing on 'safe harbours' for the admission of certain substances, initially for plant protection products. This could be done by exploring possible decisions on measures and consequences based on a number of animal-free innovations, while the regular process carries on in the background.
- Ideas for an innovation network in the field of gene and cell therapy products (ATMPs) and an innovation network in the field of biotech-derived products.

A strategy for initiating, elaborating, funding and launching additional innovation networks will be elaborated in further detail over the coming months. For more information, please send an email to tpi@minez.nl.

4.5 Projects

As mentioned above, viable and promising ideas from innovation networks can be converted into specific projects at any given moment. These projects have a specific objective or outcome and a plan to achieve it, and they can be adopted and developed by parties in the sectors concerned. They are financed through investment funds, private finance or government funding. The more we explore ideas, the more promising ideas and concrete projects we will discover. New activities and insights will ensure constant adjustment and development of TPI and its joint designers. Five projects relating to TPI are currently ongoing:

1. Foundation of the Humane4Animals Fund (*Dutch Society for the Replacement of Animal Testing*)

The initiators of the Humane4Animals Fund are seeking donor-advised or private funding to support animal-free research. The goal of the fund is to encourage animal-free innovation in the Netherlands by providing adequate funding to the entire knowledge and innovation chain. The fund's further development will depend on the progress and outcomes of the TPI process. The identification of specific drivers – such as animal-free models that are ready to be launched on the market – and the interconnection of researchers, organisations and funds will help to establish the fund as an important new source of financial backing.

2. Development of a Question Based Validation Sheet (*Medicines Evaluation Board*)

As part of the research project 'Next step to animal-free medicine research', an instrument will be developed to establish the predictive value of animal studies. This instrument, known as the Question Based Validation Sheet, can lay the foundations for a register of certified laboratory animal models (models that have a sufficient level of predictive value).

3. Set-up of a 'data warehouse' (information portal) on animal-free innovation (Ministry of LNV)

The goal of this initiative is to establish an information portal on animal-free innovation and set up platforms and network organisations. These will help boost networks at the regional, national and international levels and accelerate the development of animal-free innovation from concept to implementation. In addition, new innovation networks will be developed to help set up the information portal and create networks.

4. Formulation of a long-term vision for the central nervous system (KNAW/NCad)

At the request of the then State Secretary for Economic Affairs and the Minister of Education, Culture and Science, the KNAW set up a committee of experts to conduct a pilot to establish a long-term vision for the transition to animal-free research. The NCad was also involved in this process. Within the scope of this pilot, a long-term vision will be formulated for the field of neuroscience (more specifically, for the central nervous system) on the basis of equal or better research quality. The committee will also establish a format and guidelines for future long-term visions within other scientific fields. The committee was established in March 2018 and expects to deliver the elaborated long-term vision by the second half of 2018.

5. Research programme 'More Knowledge with Fewer Animals 2018-2020' (ZonMw)

- More Knowledge with Fewer Animals 2018-2020 is an umbrella programme consisting of multiple modules with different objectives, conditions and collaboration partners:
- **The Life Sciences & Health (LSH) module:** This module will probably involve two initiatives. The first initiative – Create2Solve – aims to achieve accelerated development, application and commercialisation (wherever possible/relevant) of animal-free innovation. It has a wide target audience, with parties from the pharmaceutical (including contract research organisations involved in clinical trials), foodstuff, cosmetic and chemical industries all eligible to submit problems. The second initiative within the LSH module is chain financing, the goal of which is to advance successful and promising animal-free innovation projects to the next level.
- **The Knowledge Infrastructure module:** This module focuses on Open Science and safeguarding the quality and transparency of laboratory animal research. Examples of its goals include open-access publication of all results and more comprehensive reporting of data on animal studies, using reporting guidelines and applying syntheses of evidence (systematic literature studies).
- **The Internationalisation module (InnoSysTox 2019 initiative):** Within this module, ZonMw will once again make an international appeal concerning animal-free innovation and toxicology as a follow-up to a successful initiative conducted in 2014. This time, ZonMw will seek one or more extra financial backers for this initiative in addition to the German Federal Ministry of Education and Research (BMBF) and Projektträger Jülich.

5. In conclusion

By formulating this philosophy and approach, we have taken important steps in the process of accelerating the transition. Although we are still in the initial phase, all parties involved are committed to achieving our joint ambition in close collaboration and with clear governance: to establish the Netherlands as a frontrunner in the international transition to animal-free innovation.

TPI is coordinated by the Ministry of Agriculture, Nature and Food Quality (LNV): tpi@minez.nl

TPI partners are organisations that want to help realise the joint ambition of establishing the Netherlands as a frontrunner in the international transition to animal-free innovation:



Association of Health Funds (SGF)



Top sector Life Sciences & Health



Top sector Chemistry



The Netherlands Organisation for Health Research and Development



Royal Netherlands Academy of Arts and Sciences

Dutch Society for the Replacement of Animal Testing (dsRAT)

The Netherlands National Committee for the protection of animals used for scientific purposes (NCad)



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



National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport



Ministry of Agriculture, Nature and Food Quality



Ministry of Health, Welfare and Sport



Ministry of Education, Culture and Science



Ministry of Economic Affairs and Climate Policy



Ministry of Infrastructure and Water Management