Policy and regulations on alternatives to animal testing

In the Netherlands and the EU

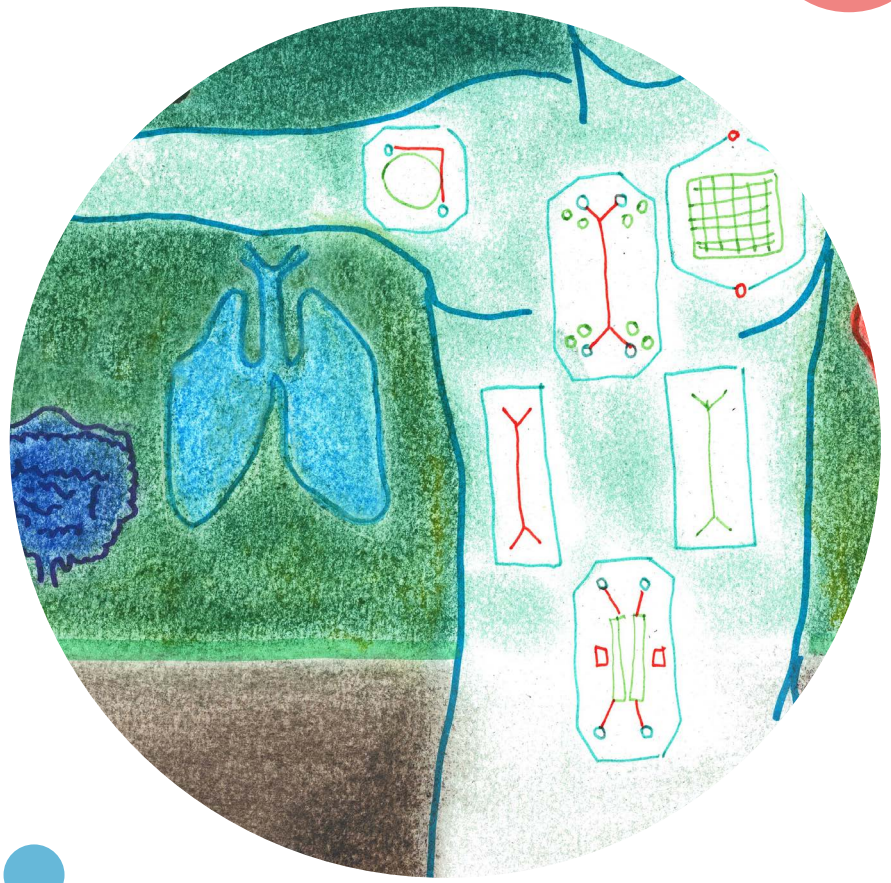
tpi.

Introduction

This document has been issued by the Dutch Interdepartmental Working Group on Alternatives to Animal Testing (IWAD) and concerns policy aimed at innovating the risk assessment of chemical substances, vaccines and medicines, which will also substantially reduce the need for animal testing. In developing, accepting, and implementing better alternatives to animal testing, the key is to remain compliant with the legal requirements to disclose information on safety. This policy is in line with the Programme to accelerate the Transition towards Innovation without the use of Animals (TPI).

This text refers to existing public documents provided by the ministries involved in the policy area of animal testing, such as reports of General Consultations in the House of Representatives and European Union regulations. The ministries involved are: Agriculture, Nature and Food Quality; Education, Culture and Science; Infrastructure and Water Management; Health, Welfare and Sport; Economic Affairs and Climate Policy; Defence; and Social Affairs and Employment.

This document does not outline a new policy, but explains the relationship between the relevant policy dossiers of the above ministries. It shows that the drivers of the transition programme for innovation without the use of animals can be found not only in animal welfare policy, but also in the pursuit of open science, advances in personalised medicine, and the development of improved tests for the safety of chemical substances.



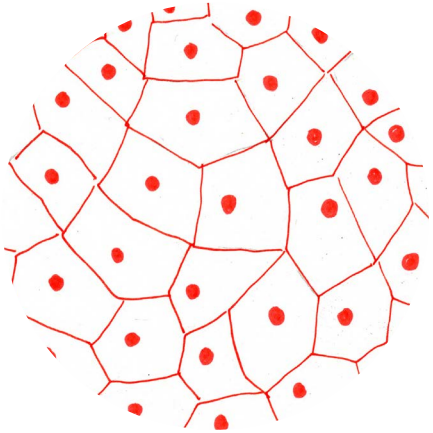
The policy on alternatives to animal testing

Together with scientific and civic organisations, and the business community, the various ministries of the central government in the Netherlands aim to accelerate the ongoing transition towards innovation without the use of animals. The Ministry of Agriculture, Nature and Food Quality is in charge of the Transition Programme toward Innovation without the use of Animals (TPI).

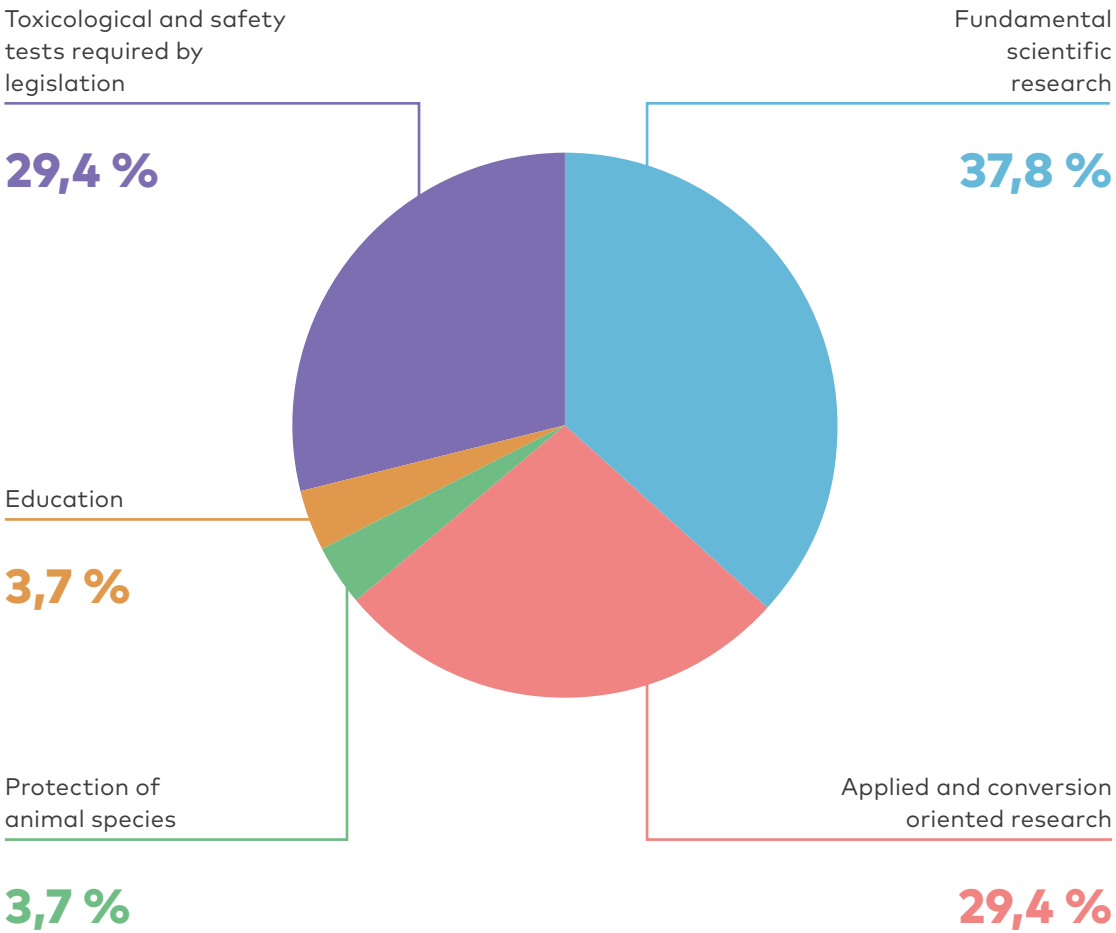
TPI, Philosophy and Approach, Ministry of Agriculture, Nature and Food Quality, 1 June 2018

The aim of the collaboration is to develop research models and assessment methods that are able to better predict the efficacy or functionality, on the one hand, and the side effects or toxic effects of medicines and chemical substances, on the other. This will reduce the need for animal testing, while providing more precise and more accurate information on medicines and chemical substances. However, the relationship between more alternatives and fewer animal tests is not linear.

Review of TPI 2018-2020, evaluation of the acceleration programme, November 2020

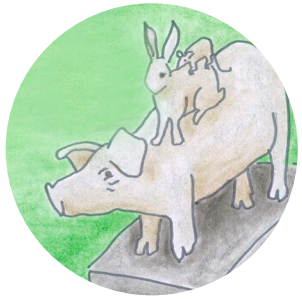


In 2019, animal tests were carried out for the following purposes:



Purpose	Number of animal tests	%
Research to unravel the cause of diseases	139.574	34,89
Toxicological research	64.048	16,01
Production of vaccines and medicines for farm animals and pets	60.274	15,07
Applied and translational research for the benefit of humans	50.006	12,50
Testing vaccines and medicines for contamination	36.154	9,04
Protection of animal species	20.118	5,03
Education	14.936	3,73
Research on the accumulation of chemical substances in the environment	5.593	1,40
Animal feed toxicity testing	3.579	0,90
Developing medicinal substances for both humans and animals	3.475	0,87
Other	2.193	0,55
Total	339.950	100

'The latest figures from Zo doende 2019, Animal testing in the Netherlands', published in Dutch newspaper De Volkskrant



In addition, the EU Directive 2010/63/on the protection of animals used for scientific purposes, the European Pharmacopoeia and the REACH Regulations, including the EU Biocidal Products Regulation, aim to replace, refine and reduce (3Rs) the use of animals in scientific procedures.
The Dutch policy on animal testing is based on the Experiments on Animals Act (Wet op de dierproeven, WOD).
European Directive 2010/63/on the protection of animals used for scientific purposes was implemented into the Act at the end of 2014. This included the introduction of a new registration system and a new licensing system.
The objectives of the directive are the protection of laboratory animals, transparency and the creation of equal conditions of competition in Europe.
The directive has aligned policy in all Member States.

Rules on animal testing and research, business.gov.nl

Directive 2010/63/EC on the protection of animals used for scientific purposes

European Pharmacopoeia, Council of Europe, DG EDQM

Animal testing under REACH, ECHA

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market

Regulation (EU) 528/2012 on the supply and use of biocidal products

If there are recognised alternatives to animal testing in the EU, they must be used.
The Dutch Central Authority for Scientific Procedures on Animals (CCD) assesses licence applications for animal testing based on this provision.
Testing the ingredients and finished products of cosmetics on animals has been completely banned in the Netherlands since 1997 and in the EU since the end of 2013.

Dutch Experiments on Animals Act

Central Authority for Scientific Procedures on Animals (CCD)

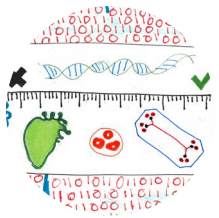
EU ban on animal testing for cosmetics purposes

It is clear that not every scientific domain already has adequate alternative methods to animal testing for safety assessments. Vice versa, however, in some fields the efficacy and/or safety for humans or the ecosystem are unable to be properly predicted on the basis of animal testing.
Therefore, the scientific aim is to approach the unique organism as closely as possible with a view to designing alternative tests that are better able to predict efficacy and safety for humans and animals.
The movement towards innovation without the use of animals is therefore in line with the mission-driven innovation policy of top sectors such as Life Sciences and Health, and Agri & Food.

Factsheet with -among other- the Health and Healthcare mission, Dutch Ministry of Economic Affairs p3

It is important therefore to find better alternatives to animal testing for efficacy research and safety assessments.
This applies to good scientific practices, the development of medicines and crop protection agents, and the assessment of substances marketed for the health and safety of consumers and workers.
Better alternatives are being sought in measurement models based on knowledge of humans using organ on chip-technology, for instance, artificial intelligence and big data, or the results of citizen science on lifestyle interventions.

Human measurement models 2.0: for health research on disease and prevention, 11 February 2020



In the field of personalised medicine, for example, there is a considerable drive to work with material from the unique human being.

Guideline on reproductive toxicology (ICH S5), EMA

In circles of assessment organisations an appeal has been made to carefully examine information that produces a test and whether in vitro methods are as effective or even better.
This happens in the medical world, for example, under the label 'fit for purpos', and in the field of toxicology with Advanced Outcome Pathways (AOPs). The best information is generally obtained from data derived from various methods.

Users' Handbook supplement to the Guidance Document for developing and assessing Adverse Outcome Pathways (AOPs), OECD, 2018

In areas where scientific developments using models based on knowledge of human beings are successful, policy efforts are being undertaken to prevent animal testing from automatically being included in guidelines. This applies to cellular and gene therapy products, for example.
The Medical Devices Obligations Taskforce (MDOT), which is examining the impact of new regulations, is also encouraging data sharing for the purpose of using alternatives to animal testing. This is aimed at preventing an unnecessary increase in the use of laboratory animals.

Guideline on designing cellular and gene therapy products without the use of animals

Information on the Regulation (EU) 2017/745 on medical devices

About the MDOT, Fraunhofer Institute, 10 September 2019

In view of the nuances in safety assessments based on animal testing, the ministries have joined forces to accelerate the transition towards innovation without the use of animals. Despite the different dynamics in the policy areas that the ministries represent – from discovering new medicines for a specific group to preventing the harmful effects of substances of concern for an unspecified group – they have a shared interest in increasing the effectiveness of the assessment system without using laboratory animals.
The ministries are therefore working together on a call for proposals and grant funding as part of the National Research Agenda on the theme 'Improved predicative models without the use of animals serving as the basis for a new safety assessment method'.

Moreover, greater transparency should prevent the unnecessary duplication of tests and the data derived from tests can be used or reused more frequently and effectively. An area where gains can be made is transparency and knowledge-sharing on functionality and toxicity research.
Good progress has been made in the context of open science in recent years. Open access publishing is possible in more and more journals and research data are increasingly and more readily being made available (FAIR data).

The results of animal studies in the International register of preclinical trial protocols, EU

Towards more transparency, information of ZonMw

Colophon

Redaction
The Transition Programme for Innovation
without the use of animals
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Research, advice and
participation agency
E:M+MA.

Dutch Ministries of:
Agriculture, Nature and Food Quality;
Defence;
Economic Affairs and Climate Policy;
Education, Culture and Science;
Health, Welfare and Sport;
Infrastructure and Water Management;
Social Affairs and Employment.

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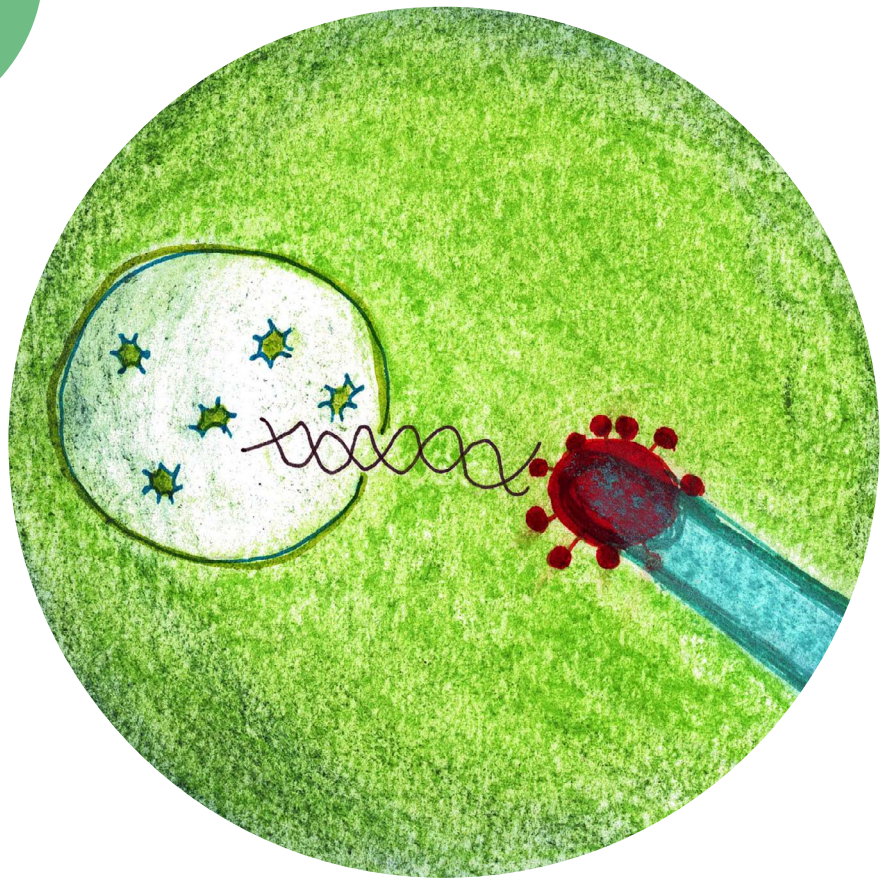


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