



*Accelerating the transition
to an animal-free regulatory system:
Let's make it happen together!*

*ECHA NAM workshop Helsinki
1 June 2023*

Merel Ritskes-Hoitinga

Prof in Evidence-Based Transition to Animal-Free Innovations
Institute for Risk Assessment Sciences (IRAS) TOX

Overview

- How did I get here?
- Where is the evidence?
- Can we act more upon scientific evidence / using systematic reviews?
- Accelerating the transition to animal-free innovations – transition science
- Setting goals and leadership

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ARTERY 16(1):25-50 (1988)

ATHEROSCLEROSIS IN THE RAT

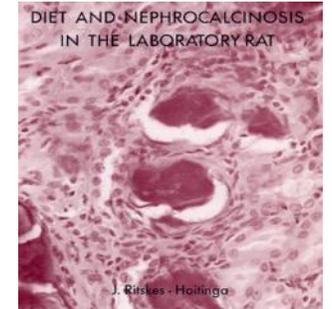
J. Ritskes-Hoitinga and A.C. Beynen

Department of Laboratory Animal Science, State University, P.O.Box 80.166,
3508 TD Utrecht (The Netherlands)

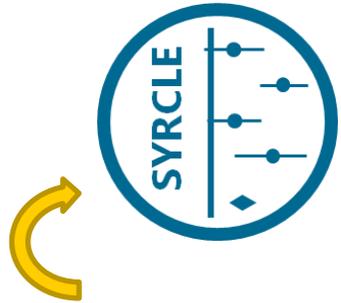


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DIET AND NEPHROCALCINOSIS
IN THE LABORATORY RAT



J. Ritskes-Hoitinga



www.ritskes-hoitinga.eu

The story of my life:
from Refinement to Replacement



Radboudumc
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Where and what is the evidence behind drug legislation?

pubmed.ncbi.nlm.nih.gov/35983829/

National Library of Medicine
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Search: Ritskes-hoitinga

Search results

A History of Regulatory Animal Testing: What Can We Learn?

Doortje Swaters¹, Anne van Veen², Wim van Meurs¹, Janette Ellen Turner³, Merel Ritskes-Hoitinga⁴✉

Affiliations + expand
PMID: 35983829 DOI: 10.1177/0261192922118001

Free article

Abstract

The contemporary pharmaceutical industry is voicing growing concerns about the translatability and reproducibility of animal models. In addition, the usefulness of certain of the required regulatory safety tests in animals is being increasingly questioned. It remains difficult, however, to make the move toward alternative testing methods, not least because of legislative demands. A historical analysis was performed, in order to study how the mandatory animal studies in legislative requirements came about. This article reflects on the role that specific public health disasters played in the creation of (moral) regulatory requirements for animal testing. It will show how the

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Flexible approaches possible

Communication

The Promises of Speeding Up: Changes in Requirements for Animal Studies and Alternatives during COVID-19 Vaccine Approval—A Case Study

Merel Ritskes-Hoitinga^{1,2,*}, Yari Barella³ and Tineke Kleinhout-Vliek⁴✉

1 Department of Population Health Sciences, Institute for Risk Assessment Sciences (IRAS), Faculty of Veterinary Medicine, Utrecht University, Postbus 80163, 3508 TD Utrecht, The Netherlands
2 Department of Clinical Medicine, Faculty of Health Sciences, Aarhus University Hospital, Palte Juul Jensens Boulevard 99, 8200 Aarhus N, Denmark
3 Faculty of Science, Radboud University, Postbus 9010, 6500 GL Nijmegen, The Netherlands; yaribarella.94@gmail.com
4 Copernicus Institute of Sustainable Development, Utrecht University, Postbus 80.115, 3508 TC Utrecht, The Netherlands; t.h.kleinhout-vliek@uu.nl
* Correspondence: j.ritskes-hoitinga@uu.nl

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Medical regulators: look beyond animal tests

Flexible approaches used to accelerate COVID-19 vaccines deserve wider uptake.

Merel Ritskes-Hoitinga ✉

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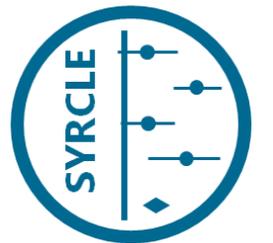
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Software beats animal tests at predicting toxicity of chemicals

Can we use evidence more?

What are systematic reviews?

**Systematic reviews bring us the most
objective and complete scientific evidence
and lead to better evidence-based decision making**



Systematic Review results:

low publication quality

and low translation of animal studies to

humans is made transparent.

Scientific need for change.

Changes coincide with resistance.

*It needs perseverance and
managing transitions:*

Transition science

Multi-level perspective transition analysis

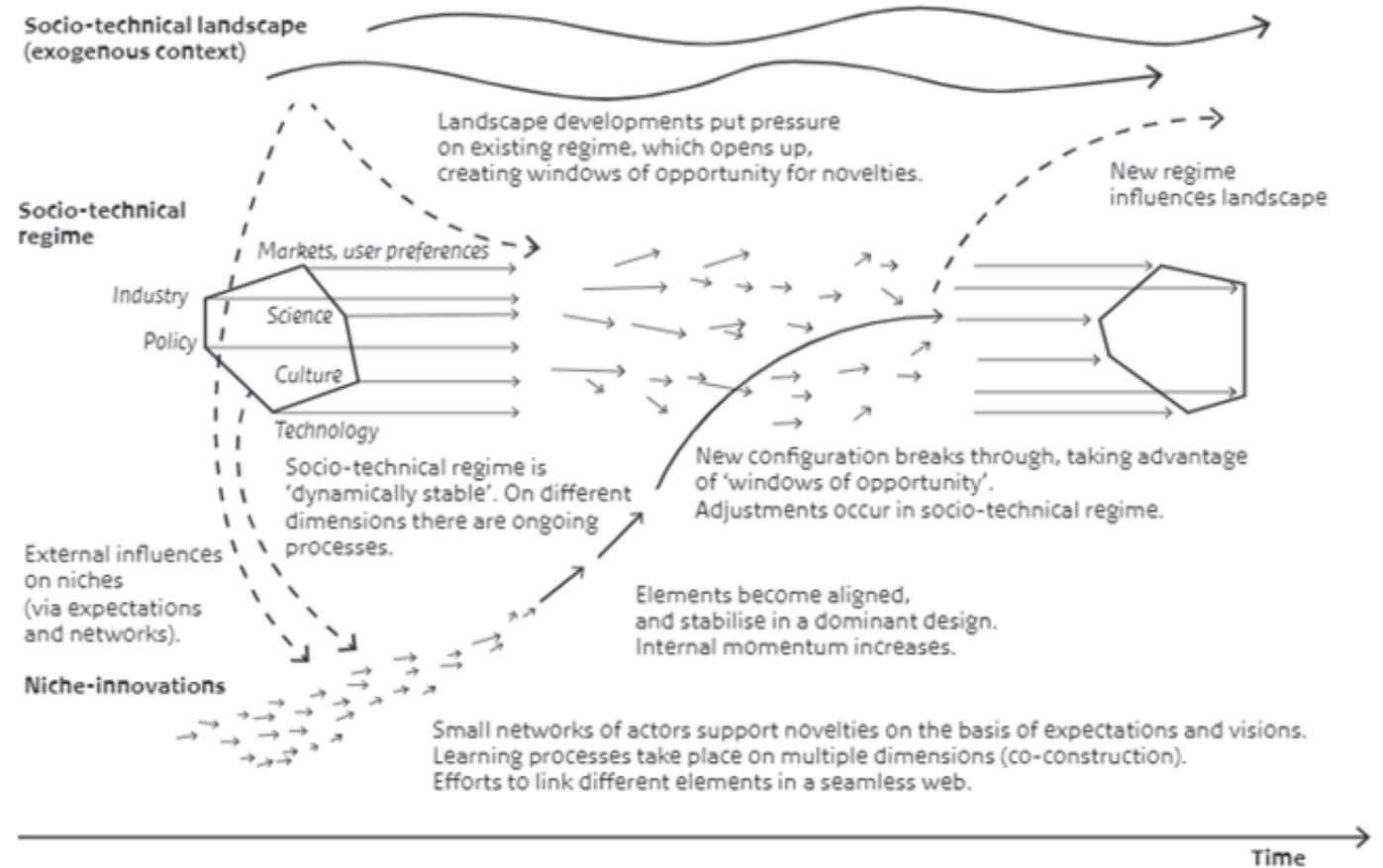
Identify:
Barriers, leverages and
opportunities

Niche: Alternative system

Regime: Dominant system

Landscape: Societal trends

Goal:
Identify
opportunities to
accelerate the
transition



tpi. The Dutch Transition Program to animal-free Innovations

Mission:

Better predictions without (lab) animals

Ambition:

The Netherlands with TPI as a catalyst of the (inter)national transition towards animal-free innovations

Partner program founded in 2018: 11 partners (including a young TPI!)

TPI-policy is in conjunction with 3Rs policy, to ensure animal-welfare as long as animals are needed.

tpi.



Universities of
The Netherlands }



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



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



Ministry of Agriculture, Nature and
Food Quality of the Netherlands

tpi. International ambition and activities

European/international approach is crucial to validate, accept and implement non-animal methods (NAMs).

TPI:

- Plans to start conversations with other EU member states about validation of NAMs;
- To find common ground on what is needed to improve validation;
- Together we can accelerate our national efforts and improve our chances to a European approach!



Interested or questions ?

Feel free to contact our program manager:

Erica van Oort, PhD
e.vanoort@minlnv.nl
Ministry of agriculture, nature and food quality

www.animalfreeinnovationtpi.nl



Education: Multi-level perspective transition analysis



Co-creation

Interdisciplinary learning



Commentary

Identifying Key Factors for Accelerating the Transition to Animal-Testing-Free Medical Science through Co-Creative, Interdisciplinary Learning between Students and Teachers

Fatima Zohra Abarkan ¹, Anna M. A. Wijen ², Rebecca M. G. van Eijden ³, Frédérique Struijs ¹, Phoebe Dennis ³, Merel Ritskes-Hoitinga ^{4,5,*} and Ingrid Visseren-Hamakers ⁶

- ¹ Faculty of Science, Radboud University, Radboud Honours Academy, 6525 AJ Nijmegen, The Netherlands
 - ² Faculty of Medical Science, Radboud University, Radboud Honours Academy, 6525 AJ Nijmegen, The Netherlands
 - ³ Institute for Management Research, Radboud University, Radboud Honours Academy, 6525 AJ Nijmegen, The Netherlands
 - ⁴ Faculty of Veterinary Medicine, Utrecht University, 3584 CL Utrecht, The Netherlands
 - ⁵ Department of Clinical Medicine, Aarhus University, 8000 Aarhus C, Denmark
 - ⁶ Institute for Management Research, Radboud University, 6525 AJ Nijmegen, The Netherlands
- * Correspondence: j.ritskes-hoitinga@uu.nl



News & events News Three consortia awarded funding for acceptance and implementation of animal-free models in safety assessment

Three consortia awarded funding for acceptance and implementation of animal-free models in safety assessment

25 August 2022

Within the Dutch Research Agenda (NWA) 'Non-animal models: acceptance and implementation', three consortia will research on the acceptance and implementation of existing animal-free models. A total of about € 2.9mln has been awarded for this research. This programme is a collaboration between the Dutch Ministries of Infrastructure and Water Management (I&W), Public Health,



Characteristics

Research programme

[Animal-free assessment models: acceptance and implementation](#)

Themes

[Knowledge Utilisation](#)

[Health](#)

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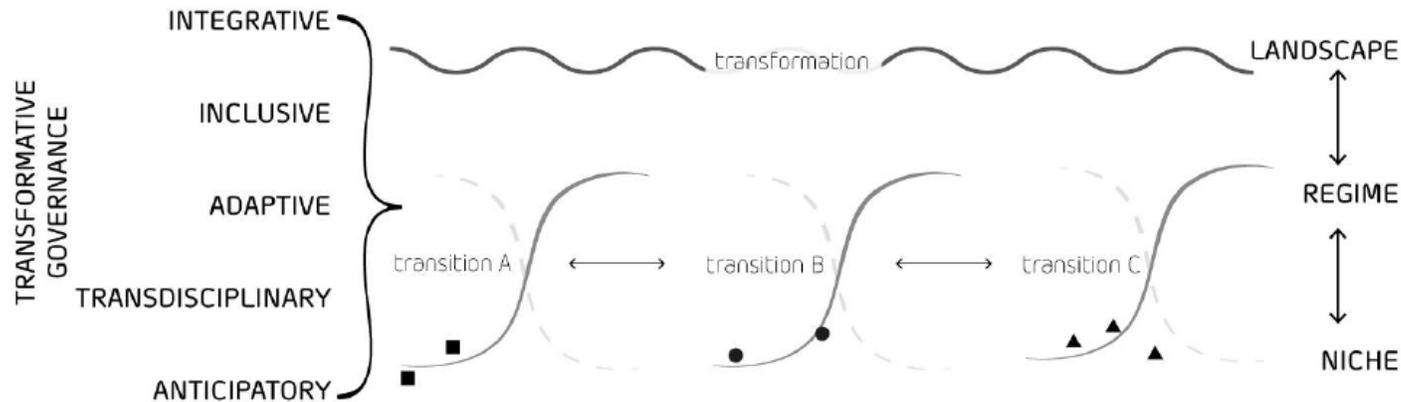
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INTEGRATING TRANSFORMATIONS AND TRANSITIONS THROUGH TRANSFORMATIVE GOVERNANCE



Visseren-Hamakers, I.J. et al. 2022. How to save a million species? Transformative governance through prioritization. In: Visseren-Hamakers, I.J. and Kok, M. (Eds.) 2022. *Transforming Biodiversity Governance*. Cambridge University Press.

- Climate crisis
- Energy crisis
- Biodiversity crisis
- Covid pandemic crisis

Transitions inform and influence one another. Study the underlying causes.

We need mixed methods research and flexible approaches: combining quantitative and qualitative research

We need inter- and transdisciplinary research

Providing scientific evidence is clearly not sufficient to make real changes

Promising recent developments – transition *is* happening

Multi stakeholder article on building scientific confidence in New Approach Methods – van der Zalm A et al. Archives Toxicology 2022

European Citizen's initiative

European Parliament asking for a roadmap

Food and Drug Administration modernisation act

European Medicines Agency 3R working party

European Food Safety Authority roadmap

This European Chemicals Agency New Approach Methods workshop

THE CHALLENGE

HUMAN-RELEVANT SCENARIOS

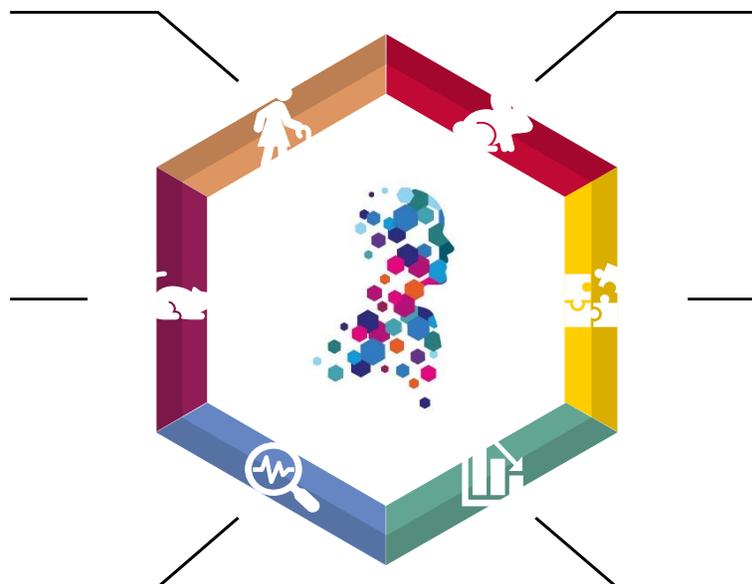
Current animal tox testing regimes do not reflect human-relevant scenarios, such as differences in susceptibility due to age, gender, timing of exposure, or disease state.

REPRODUCIBILITY

Only 25% of published results obtained with animal data can be reproduced.

PREDICTIVE VALUE

The results of a laboratory animal can only predict the results in reproductive toxicity of another species by 60%.



9,338,162 ANIMALS

Were still being used for research and testing in the EU in 2017 (**about one third for toxicity testing**).

INTERDISCIPLINARY APPROACH

Integrating data from new in vitro and in silico methods, data sciences and social sciences

SLOW DECREASE

In 10-years time, the use of animals is only decreased by 22% with the current approach to gradually refine, reduce and replace animal testing.

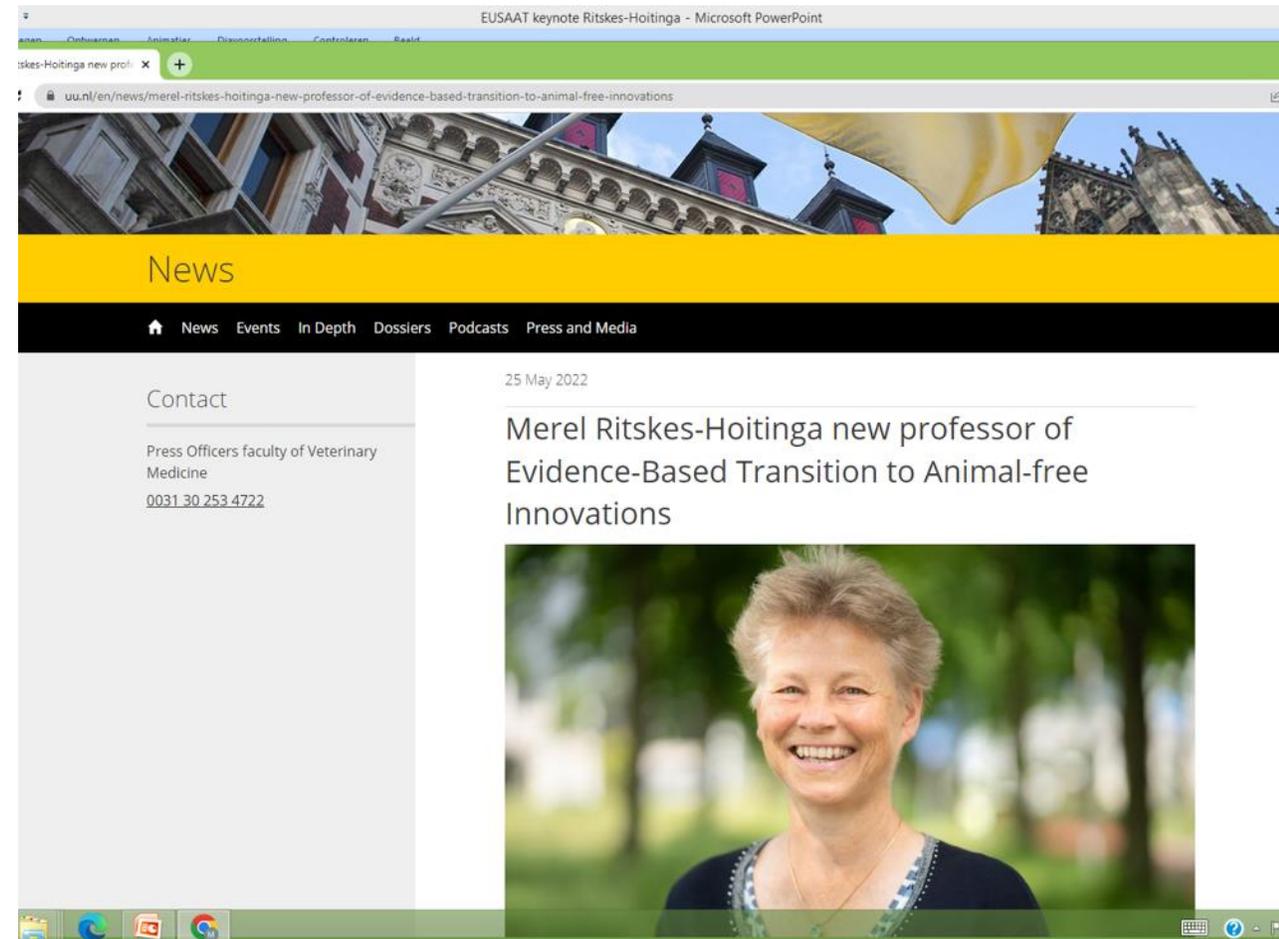
Let's make it happen together!
Phase out animal studies and embrace alternatives
asap for the benefit of animals and humans.
The science and technology *are* here!

New (academic) pathways:

More evidence-based decision making

Transdisciplinary research and
education – connecting stakeholders

Multilevel perspectives, transition
science and transformative governance



We choose to go to the moon...

..in this decade, not because it's easy, but because it's hard, it will serve to organise and measure the best of our energies and skills, a challenge we are willing to accept, unwilling to postpone and intend to win



We choose to go for New Approach Methods (NAM) only

..in this decade, not because it's easy, but because it's hard, we will only use NAMs because it will serve to organise and measure the best of our energies and skills in a challenge we are willing to accept and unwilling to postpone in the interest of all living creatures and our environment

