



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

Perspectives on the transition to a society without animal experiments: an overview of insights from transition studies

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Table of Contents

1. Introduction	3	6. Governance in transitions	27
2. Transition studies	5	6.1 Social challenges	27
2.1 Transitions	5	6.2 Experimental approaches	29
2.2 The multi-level perspective	7	7. Synthesis	32
2.3 The variety of transition perspectives	9	7.1 Insights about the nature and dynamics of the transition to animal-free research	32
2.4 Perspectives on the transition to animal-free research	10	7.2 Insights about governance in the transition to animal-free research	33
3. Niche development and niche-regime interaction	12	Appendix 1: Methodology	35
3.1 Strategic niche management	12	Appendix 2: Review of six key articles	38
3.2 Technological innovation systems	14	Appendix 3: Analysis of the citation environment	42
3.3 Niche empowerment and niche-regime interaction	15		
3.4 Social innovations and power	16		
4. Regime change	18		
4.1 The nature of regime change	18		
4.2 The role of actors in regime change	20		
4.3 Destabilisation, phasing out and unlearning	22		
5. The influence of the landscape	24		
5.1 Society-wide value frameworks	25		
5.2 Multi-systemic changes	25		

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1.

Introduction

Transition studies is a relatively new interdisciplinary research field that focuses on the development of perspectives on social change in order to achieve long-term sustainability goals. Influenced by the major social challenges that societies worldwide are facing, this discipline has rapidly gained in importance and grown substantially over the past two decades. The principle underlying transition studies is that social changes focusing on sustainability are often not in line with the current way we organise our society, and the directions in which we are advancing through scientific and technological innovation. Instead, addressing sustainability problems requires more fundamental changes to the structure, culture and infrastructure of social systems, e.g., in the areas of energy supply, mobility, agriculture, food, health, and the chemical industry. Such changes are characterised by uncertainty about what society will look like after they ,these changes and the paths towards them. In such cases, we speak of 'transitions'.

Transition studies develops knowledge to understand these change processes and offers action perspectives for transition management. On the one hand, the science of transitions tends to be *descriptive* in that it focuses on understanding and taking a broad view of comprehensive change dynamics in social systems involving a variety of actors. On the other hand, it tends to be *prescriptive* in that it offers action perspectives that can help initiate or accelerate transitions. Knowledge of transitions is developed through constant exchange between theory and practical know-how and organising processes of social learning among stakeholders in particular social fields. This enables the more deep-rooted causes of problems to be examined and possible solutions to be identified. Thus, transition knowledge takes on a context-specific nature in each social field.

The perspectives gained from transition studies have also proved valuable in the field of animal-free research and innovation. The Netherlands National Committee for the protection of animals used for scientific purposes (NCad) issued a Policy Advice in 2016 requested by the State Secretary for Economic Affairs, titled Transition to non-animal research (Transition Policy Advice 1.0). In this report, the then prevailing insights in transition studies were used for the recommendations on ways of encouraging animal-free research and phasing out animal testing. The emphasis in the report was on using a multi-layer model or 'multi-level perspective' (MLP) focusing on the interaction between three levels of niche, regime and landscape to achieve regime change. The NCad plans to update this Transition Policy Advice in 2025 (Transition Policy Advice 2.0).

The rapid developments in transition studies and the growing demand for transition approaches among civil society organisations have meanwhile resulted in the substantial growth of the knowledge base on transitions. Thinking about transitions and transition dynamics as described in the MLP has been further refined and augmented with complementary insights from other frequently used frameworks, such as Strategic Niche Management (SNM), Technological Innovation Systems (TIS) and Transition Management (TM), including the X-curve. The diversity of subjects and scope of application in transition studies has also increased, for example in regards to its application to a variety of social fields and national contexts. As regards steering transitions, a focus has developed on new governance perspectives such as transformative governance and the Small Wins approach.

The present background document gives an overview of these frameworks and recent insights from transition studies, with particular reference to how they relate to the transition to animal-free research. Building on Transition Policy Advice 1.0, the report describes how the perspectives and insights presented further refine and deepen the MLP used there and the underlying knowledge of transition dynamics. It thus provides a basis for the preparation of Transition Policy Advice 2.0.

The insights in this background document are based on an expert review of relevant studies in transition studies, combined with a systematic literature review and citation analysis of scientific publications that have applied insights from transition studies to the transition to animal-free research. Chapter 2 gives a general introduction to transitions, and an understanding of the already published applications to the transition to animal-free research. Chapters 3–5 go on to discuss frameworks and recent insights from transition studies, organised by processes at the level of niche, regime and landscape. Chapter 6 considers approaches to the management (governance) of transitions. Chapter 7 provides a synthesis of key points and gives substance to the insights for Transition Policy Advice 2.0. Appendix 1 contains a methodological justification of the methods used for the systemic literature review.

2.

Transition studies

2.1 Transitions

The term 'transitions' literally refers to the process of change from a particular state to a different one. It is used in many scientific disciplines to describe a qualitative change in the state or configuration of a system. Transition studies specifically focuses on the study of social systems, examining how they can undergo structural, qualitative change, from a non-sustainable state to a more sustainable one. Systemic change is regarded here as the result of interplay between change processes that can operate at different levels and in different domains, and that affect and reinforce each other in particular ways.¹

The importance of transitions follows from the observation that many social sustainability problems are intractable: they have a 'wicked' character.² This means that they do not have a straightforward cause and solution. They are characterised by complexity, uncertainty and contestation between actors that have particular knowledge, values and interests. They are also difficult to define, and they display marked interdependencies with other problems.

¹ Systems theory is an important foundation of transition studies, which uses ideas from, e.g., complexity science, system dynamics and ecology to understand the structure and dynamics of systems. Generally speaking, a system is made up of multiple elements that are more or less interdependent, hence changes in an element in the system can affect other elements. Because of the interdependencies, it is difficult to determine how the system will behave if changes occur in the system elements. This is why system changes, as well as transitions, are often unpredictable. The results of the interactions between components can together produce something new and unexpected, referred to as 'emergent properties'. Feedback loops between system elements are also important to an understanding of how systems develop. In system dynamics, a distinction is made between positive feedback loops (that reinforce changes) and negative feedback loops (that resist changes and promote stability). Based on: Meadows, D.H., 2008. *Thinking in Systems: A Primer*. Chelsea Green Publishing.

² The terms 'wicked problems' and 'persistent problems' are both used in transition studies, with a similar meaning. Other related terms are 'unstructured problems', 'complex problems' and 'major social challenges'. Fundamental characteristics of these problems include: (1) **contestation**, which refers to the degree of normativity due to diverging claims, values and frameworks regarding the problem, or inherent conflicts of interest based on different social roles and ideas among stakeholders; (2) **complexity**, which refers to the multi-layered nature and multi-dimensionality of social problems. Responsibilities for action or inaction are difficult to assign, resulting in a 'problem of many hands', especially when multiple actors, areas of government and levels of government need to work together; (3) **uncertainty**, which refers to lack of knowledge, or limited availability of evidence upon which to base policy, e.g. regarding the risks of, or harm due to, action and inaction, the specific relationship between the cause and effect of a problem, or the fragmentation of knowledge between different stakeholders on the effects and side effects of tackling or failing to tackle a problem. Based on: Wanzenböck, I., Wesseling, J.H., Frenken, K., Hekkert, M.P., Weber, K.M., 2020. A framework for mission-oriented innovation policy: Alternative pathways through the problem-solution space. *Science and Public Policy* 47, 474-489. <https://doi.org/10.1093/scipol/scaa027>

Because of the nature of wicked problems, solutions focusing on one specific measure, e.g. correcting market failures or bringing together actors in a social field, often prove inadequate. Persistent problems require solutions of a more systemic nature, not only focusing on developing innovative practices but also taking account of necessary changes in the underlying social structures such as legislation or behaviour. The emphasis is on more deep-rooted changes in a multiplicity of practices and structures and the relationships between them. The solutions therefore focus on the underlying systemic configurations and are thus radical and disruptive in nature.³

The systemic configurations that are generally at the core of transition studies are socio-technical systems. They are complex systemic configurations of social and technical elements, and the interactions between them, designed to meet social needs. These systems can be found at the level of a social field within which different organisations (e.g. companies, government bodies, scientific and technological communities, and non-profit organisations) undertake activities and enter into interactions under a shared set of rules, norms and practices, to meet the particular social need. The socio-technical nature of the systems means that there is an emphasis on the role of technology in them and simultaneous interconnection between material and social elements. The functioning of the socio-technical system and the specific ways in which the social need is met are determined by the complex set of material and social elements.

At the heart of the socio-technical system is the regime: this encompasses the highly institutionalised set of rules, norms and practices in the system that are apparent in dominant ways of working, thinking and organising, and in which technology and infrastructure play a major role. The regime features substantial coordination between social and material elements, with a high degree of structuring that is

³ The term 'radical' refers to the magnitude of the change, not the speed of change. Radical change can take place very abruptly, resulting in a process of 'creative destruction', or it can take longer and occur more gradually. The related term, 'disruptive change', is also often used in transition studies. This term also refers to the magnitude of the change, specifying it as a change in multiple system components. The change therefore encompasses not only technological innovation but also other changes in systems, e.g. practices, behaviour, conceptual frameworks, infrastructure, markets, regulation and policies. Based on: Kivimaa, P., Laakso, S., Lonkila, A., Kaljonen, M., 2021. Moving beyond disruptive innovation: A review of disruption in sustainability transitions. *Environmental Innovation and Societal Transitions* 38, 110–126. <https://doi.org/10.1016/j.eist.2020.12.001>

enshrined in, for example, infrastructure and laws. This coordination creates a stable socio-technical configuration of the regime and incremental development of that configuration following on from the existing configuration. This type of incremental development is often referred to as 'path dependency'. The regime also acts as a selection environment for innovation, steering actors' activities in such a way that changes are generally only incremental in relation to that which is established. Consequently, existing components of the socio-technical system are continually reproduced.

Transitions can then be regarded as a structural reconfiguration of a socio-technical system. This requires overcoming the stability in the regime and achieving a fundamental change from one regime configuration to another. This change in the regime ('regime shift') enables a more sustainable fulfilment of the social need and it is needed to tackle wicked problems. Central to this is the development of innovative practices in close conjunction with institutional change in regime elements and the associated destabilisation and phasing out of existing regime elements.

Building on the foregoing, transitions can be described in more detail based on certain characteristics:

- Transitions are radical changes in a systemic configuration with a normative focus on sustainability.
- Transitions encompass systemic changes in material and social structures that are highly aligned with each other.
- Transitions create a dialectic between impulses for radical change in practices and forces of stability and path dependency in structures.
- Transitions are multi-actor processes, comprising interactions, coordination and alignment between various groups such as companies, policy-makers, scientific and technological communities, user groups, social movements, and groups with differing interests, perspectives, knowledge, and underlying values and perceptions.
- Transitions are processes of co-evolution. Change is achieved as a result of multiple processes and elements of a socio-technical nature affecting and reinforcing each other, e.g. technologies, markets, user practices, infrastructures, policy measures, industry structures, and supply and distribution chains.
- Transitions span a relatively long time frame of several decades. Although new innovations can break through relatively quickly, embedding those innovations in systems and changing those systems generally takes much longer.

- Transitions have an ‘open-ended’ nature, being characterised by unpredictability and uncertainty as to what society will look like after the changes and the pathways towards them.
- Transitions are characterised by resistance, contestation and disagreement. The opinions of the actors and social groups involved often differ regarding what innovations and transition pathways are most desirable. As transitions can present a threat to large, powerful organisations, those established organisations will protect their interests and contest the need for, and speed of, transitions.
- Transitions require normative steering. Individual organisations see few incentives to work on transitions, and there is often a lack of coordination between stakeholders. Policy and steering by public bodies, in the form of, for example, regulation, standardisation, taxation, subsidies, innovation policy and vision development is necessary. It should be noted, however, that because of the comprehensiveness of transition processes, they often cannot be controlled by a single organisation.

As is clear from the above, the focus of transition studies is on large-scale change processes. The comprehensive nature of the object of study contributes to the highly interdisciplinary nature of transition studies. The knowledge base is made up of insights from a variety of social science fields and disciplines. They include fields with a focus on science, technology and innovation dynamics, such as science and technology studies, history of technology, innovation studies and innovation economics, fields with an interest in policy and governance processes (e.g. public administration, policy sciences, organisation science and political sciences), and fields with a focus on social change processes (e.g. sociology, social geography and institutional theory). In the ensuing sections we discuss how the knowledge base on transitions has been developed and augmented based on these various scientific fields and disciplines, starting from the multi-level perspective.

2.2 The multi-level perspective

The multi-level perspective (MLP) provides a key framework for interpreting transitions. It describes the dynamics of transitions as an interplay of changes taking place at multiple levels in relation to a socio-technical system:⁴

⁴ The following description builds on that set out in the NCad Transition Policy Advice 1.0.

- The landscape (the macro level) comprises major social changes in the areas of politics, culture, world views and natural developments. These landscape-level changes often progress slowly or result from sudden crises (natural or human-driven). They are generally difficult to influence from the starting point of a specific socio-technical system. Examples are individualisation, globalisation or climate change or natural disasters, and health and economic crises.
- The regime (the meso level) encompasses the highly institutionalised set of rules, norms and practices at the core of a socio-technical system. The regime is characterised by a high degree of coordination between material and social elements enshrined in, for example, infrastructure, laws, routines and habits. It is because of the regime that dominant ways of working, thinking and organising are continually reproduced in the socio-technical system, and processes of – especially radical – innovation are hampered. The regime thus acts as a selection environment for innovation.
- Niches (the micro level) create new alternative ways of thinking, working and organising that deviate from the regime, such as technological and social innovations, new practices and experimental environments. In a niche, the development of innovations can be shielded from the regime, thus reaching fruition.

The starting point of the MLP is that transitions require dynamics within and between the three levels of niche, regime and landscape. These dynamics, focuses on fundamental change in the regime and enshrining more sustainable ways of meeting social needs in the socio-technical system. In the best-known transition dynamic, it is assumed that (1) niche innovations are increasingly able to create a solid institutional environment that can compete with the established regime, (2) developments in the landscape can exert pressure on the regime, and (3) as a result of these two developments, regimes can destabilise and make way for new socio-technical configurations emerging from the niches.

Niches can thus be regarded as ‘embryonic’ or ‘prototypical’ elements for future regime structures and socio-technical system elements. They are socio-technical configurations that provide a possible alternative to the regime but do not yet have a strong degree of structuring. Niches and innovations in those niches are initially often not regarded as legitimate, valuable and promising, and they cannot compete in terms of cost or quality with the dominant alternatives in the regime. Also, they are often not compatible with existing regulatory frameworks.

Niche-formation processes are needed to make innovations more viable and promising. These processes can help to link, align and stabilise the configuration, resulting in a greater structuring and internal momentum. To make this process possible, it is deemed necessary to shield niches from the selection pressure of the regime, with the aid of, for example, financial support or legislative changes (see also §3.1). This strengthens niches in their ability to influence the regime by means of ‘niche-regime interaction’ processes.

Not only are niche-regime interactions important, a transition also requires pressure to be exerted on the regime, creating temporary space for niches to break through. This is sometimes referred to as a ‘window of opportunity’. The creation of this space is attributed to exogenous landscape-level developments that are difficult to influence, i.e. slowly changing social trends or shocks such as natural or human-made crises.

At some point, landscape-level developments raise doubts as to the value of existing practices, making actors feel that it is urgent or even necessary to change current practices. Niches that are sufficiently structured and institutionalised can then take advantage of the space created and change or reconfigure the regime or parts thereof. These changes to the regime subsequently relieve the pressure that the landscape exerts on the regime.

Figure 1 provides an overview of the MLP perspective on transitions, in which the various processes at niche, regime and landscape level occur simultaneously and are linked as shown in the NCad's Transition Policy Advice 1.0 of 2016.

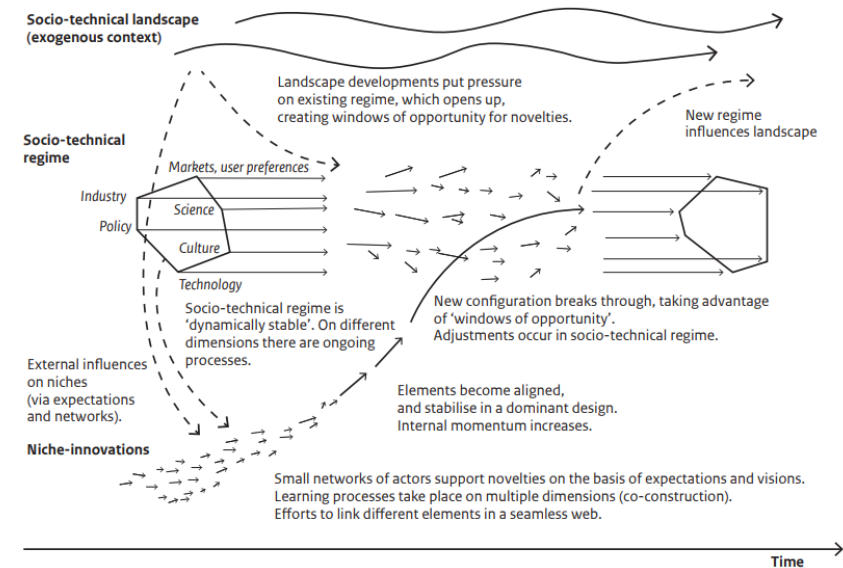


Figure 1: Multi-level perspective on transitions as illustrated in Transition Policy Advice 1.0. (According to Frank Geels. Technological transitions and system innovations: a co-evolutionary and socio-technical analysis. 2005)

Although the specific nature of transitions varies between socio-technical systems and countries, the MLP suggests that the process unfolds in four stages. These four stages are characterised by different transition dynamics. In the first stage, experimentation, radical innovation takes place in peripheral niches, where learning processes, network development and experimentation are enabled to take place in relatively small projects. In the second stage, stabilisation, the radical innovation gains a foothold in small markets and user segments. Ongoing learning processes result in the gradual stabilisation of the innovation, apparent in the articulation of technical specifications, design guidelines, best practices and user experience. The

innovation thus takes on the nature of a socio-technical configuration with a certain degree of coherence and structuring. In the third stage, acceleration, we observe the dissemination of the socio-technical configuration to larger, mainstream markets, with increasing competition developing with the existing socio-technical system (niche-regime interaction). The dissemination of the innovation is driven by internal niche developments such as the creation of economies of scale, cost reductions, the development of complementary innovations, and increasing support from powerful organisations. In this stage, dissemination is also often facilitated by landscape developments that exert pressure on the socio-technical system. In the fourth stage, reconfiguration, the existing socio-technical system and its regime elements are reconfigured. The new socio-technical configuration becomes enshrined in regulatory and professional standards, norms and values. In parallel with the third and fourth stages (acceleration and reconfiguration), destabilisation processes, including phasing out, also play an important role. These processes represent the counterpart of the third and fourth stages and should not therefore be regarded as a separate fifth stage.

2.3 The variety of transition perspectives

The multi-level perspective provides a comprehensive perspective to understand transition processes within and between the three levels of niche, regime and landscape. As a result of the rapid developments in transition studies and the demand for transition approaches among government bodies, industry and commerce, and civil society organisations, insights into transitions have continued to develop and differentiate over the years. Transition processes described in the MLP and other commonly used frameworks have been further refined and augmented with concepts from adjacent social science fields. Consideration has also been given to new topics and themes, partly as a result of the application of the transition perspective to other social systems and fields than used to be the case.⁵ Lastly, the principles of transition thinking, as set out in the previous sections, have been translated into practical approaches that provide a perspective for managing transitions (referred to as ‘governance’).

⁵ For a long time the emphasis was mainly on socio-technical systems that focus on social needs in the energy and mobility field. There has recently been more interest in systemic configurations in agriculture, food, health and the chemical industry, and transitions in specific domains such as the transition to animal-free research.

Recent overviews of the growing diversity of perspectives and insights from transition studies are available in various reports, reviews and manuals, as shown in Appendix 1. These overviews show three general trends in ‘transition thinking’ (understanding and studying transitions) and ‘transition practice’ (management and governance in transitions) over the 2000–2024 period.

- The field of transition studies has developed and grown rapidly from a basis of theoretical frameworks that provide a framework for thinking about transitions. These frameworks are abstract representations and descriptions of transition processes, in many cases derived on the basis of observations of long-term change processes in various social fields (case studies). In addition to the MLP, three other frameworks have been developed in parallel with it, starting in the early 2000s: Strategic Niche Management (SNM), the Technological Innovation System (TIS) approach, and Transition Management (TM). The dynamics described in these frameworks largely complement the MLP, describing processes within and between niches in interaction with the regime, and focusing on the construction and dismantling of socio-technical regimes and systems. SNM and TIS focus particularly on the first three stages of transitions, whereas TM is a more general practice approach that also pays particular attention to destabilisation and dismantling. In addition to increasing our understanding of transition dynamics, these frameworks provide analytical frameworks for problem structuring and/or systems analysis to examine specific transitions. They are discussed in more detail later on in this report.
- Insights on the transition dynamics within and between the three levels (niche, regime and landscape) and during the stages of transitions have been further enriched and refined, in many cases with the aid of insights from adjacent social science fields such as sociology, political science and institutional theory. The result is a more differentiated understanding of the variety of mechanisms and transition dynamics that can contribute to socio-technical change in regimes and systems, including an understanding of why changes of this kind can be difficult to realise.
- There is now greater emphasis on translating transition thinking into intervening in and managing transitions. These are perspectives that guide the direction and speed of transitions, often in light of broader social challenges and missions, such as the transformative governance approach. Transition thinking has also been translated into the development of specific governance tools that can be used as part of experimental approaches for transitions in a social field.

2.4 Perspectives on the transition to animal-free research

The various perspectives on transitions are also apparent when we examine how insights from transition studies have been used to interpret and guide the transition to animal-free research. Based on a systematic literature review, six key articles were identified that applied theoretical frameworks from transition studies to the transition to animal-free research.⁶ Based on an analysis of the citation environment of these six articles, 366 unique citing and cited articles have been analysed. Appendix 1 contains a methodological justification.

Analysis of the six key articles shows that all of them used the MLP to describe and understand the transition dynamics towards animal-free research. Five articles identified key factors that either hamper the transition to animal-free innovation (barriers) or promote/could promote it (drivers), generally based on interviews, surveys, focus groups, expert panels or a combination of these. Each article focuses on a specific context of animal/animal-free research and innovation, e.g. food safety assessment, the development of rabies vaccines, medical science, or risk assessment of chemicals and pharmaceuticals. The articles generally distinguish between key factors that are important at niche (micro), regime (meso) and landscape (macro) level. The sixth key article uses the TIS framework, focusing on processes for the regulatory acceptance of animal-free methods in drug development, and the elements and mechanisms in the regime that hamper such acceptance. All six articles also identify actions, activities and/or interventions that could promote the transition to animal-free research. An overview of the main findings of the six key articles can be found in Appendix 2.

Analysis of the content of the 366 articles in the citation environment shows a variety of transition dynamics and themes relating to the transition to animal-free research. We observe one cluster of social science articles on transitions and social dynamics that are not specific to animal-free research (n = 115), a second cluster of articles specifically about aspects of animal testing and animal-free innovation that do not

use insights from transition studies (n = 141), and a third cluster – less relevant to this background document – of articles that examine various areas of animal-free innovation (n = 110). We now briefly discuss the main themes in the 366 articles in the citation environment, based on the various levels in the MLP.

At niche level, we find that articles in the social science cluster mainly consider the nature and dynamics of technological innovation processes and the prerequisites for encouraging technological innovation in specific contexts. Consideration is also paid to the role of social innovation and movements, joint action, and organisational change processes. Many of the articles on animal-free innovation are overviews of developed methods for animal-free research that could be used in specific scientific domains, risk assessment contexts, and the development of chemicals and pharmaceuticals. In many cases they describe dynamics towards animal-free innovation in these domains and outline preconditions for, as well as barriers to, further development. Interestingly, the articles in the second cluster place a relatively large amount of emphasis on processes of validation and acceptance, including regulatory acceptance, and implementation. This cluster also contains studies on the degree of translatability of animal testing to humans, and prospective visions and expectations regarding the development of the field, such as visions on Next Generation Risk Assessment. We discuss relevant insights from transition studies that provide a better understanding of these dynamics in more detail in Chapter 3.

At regime level, we observe that a relatively large proportion of the articles in the citation environment emphasise a variety of institutional change processes, not only changes in formal institutions such as rules, legislation, standards and guidelines, but also in informal institutions such as values and cognitive frameworks. Institutional change is often explicitly linked to regime change. The emphasis on institutional change is also apparent in the cluster on animal-free innovation. For instance, the articles emphasise legal obstacles to the acceptance and implementation of animal-free innovations, and specific aspects of risk regulation and assessment of chemicals and pharmaceuticals. We discuss insights about institutional and regime change in more detail in Chapter 4.

At landscape level, we find articles that examine various society-wide trends, including shifting values regarding the human-animal relationship, and studies of risk perception and the precautionary principle. Consideration is also given to the

⁶ Transition Policy Advice 1.0 was not included in this analysis, along with the report [Samen kansrijke transitiepaden inslaan naar proefdiervrij onderzoek](#) [Taking promising transition pathways towards animal-free research together] produced by the Dutch Research Institute for Transitions (DRIFT) for the TPI network.

broader contexts within which the transition to animal-free innovation can be considered, such as sustainable development and the protection of public health and the environment in the risk society. We discuss important insights from transition studies regarding this level in Chapter 5.

Lastly, in addition to the niche, regime and landscape level, we find a number of articles devoting more general attention to the management of transitions and the underlying principles. One of the six key articles refers several times to the transformative governance perspective. References to other types of integrated management can also be found in the citation environment. We discuss recent thinking about governance in transitions in Chapter 6.

3.

Niche development and niche-regime interaction

Processes of innovation lie at the heart of transition studies. The construction of multiple small radical innovations in niches that create internal momentum, gradually gain influence and, during that process, interact with the regime (niche-regime interaction) is one of the components of the MLP framework in the experimentation, stabilisation and acceleration stages of transitions. These innovation processes also lie at the heart of related transition frameworks such as the Strategic Niche Management (SNM) approach and the Technological Innovation Systems (TIS) framework. In the early years of transition studies, the emphasis was mainly on innovation with a major technological – and often also infrastructural – component. More recently, other types of innovation, such as social and grassroots innovations, have gained more attention. We discuss the most important perspectives and recent insights in this chapter.

3.1 Strategic niche management

Much of what we know from transition studies about the development and construction of innovations in niches follows from the Strategic Niche Management (SNM) approach, a framework commonly used to understand and analyse the creation of innovation in niches. The starting point for SNM is that radical innovations come about in ‘protective spaces’ that shield those innovations from the selection pressure of the regime and regular market selection. This protection is deemed necessary, since radical innovations have the potential to provide or replace desirable functionality, that makes some actors invest time, money and resources in further development. At the same time, however, the radicalness of these innovations result in low performance standards and high costs, and they depart from the regime in one or more dimensions (e.g. being incompatible with existing regulation, cultural norms and markets). The innovations are subject to strong pressure from the regime’s mainstream selection environment and they therefore need protection in the form of, for example, subsidised demonstration projects, support from user groups, networks of laboratories, communities or activism.⁷

⁷ A good deal has been written in the innovation science literature about the nature of radical innovation. A core feature is that radical innovation is surrounded by various types of uncertainty, in the technological (e.g. performance), economic (e.g. cost), socio-cultural (e.g. social acceptance) and political areas (e.g. policy support and changes to existing frameworks). Often there are also different design variations of radical innovations, linked to different communities with diverging perspectives, visions and expectations, all of which contributes to the uncertainty.

SNM focuses on three processes that promote the creation of niches and innovations in those niches:

- Learning processes in multiple domains, such as technological learning processes to improve performance, but also social learning processes focusing on needs and demand, infrastructural requirements, business models, and appropriate regulatory and policy frameworks.
- Articulation processes focusing on the development of visions and expression of expectations. This steers the innovation and provides major pulling power for external organisations such as investors.
- Creating social networks to involve more partners, and to augment the knowledge base and increase the resources available.

SNM emphasises that these processes are promoted through series of experiments and demonstration projects that generate an innovation trajectory. It regards traditional research and development projects as important for scientific and technological innovations, but it also considers the limitations of controlled experiments in laboratories in contributing to transitions. Transition scholars emphasise the importance of pilots, demonstration projects and real-world experiments involving a variety of parties in order to learn efficiently in multiple areas. Experiments of this kind also contribute to specifying visions and expectations and making them more robust, deepening and broadening social networks, and the interlocking of learning processes in various domains, thereby increasing the momentum for development and strengthening niches.

Within SNM, there is specific consideration of how niches can be temporarily shielded from the selection pressure of the regime, especially in the early stages of transitions. Technology policy is an oft-mentioned measure to mitigate cost and performance gaps between niche innovations and dominant solutions in the regime, for example by means of subsidies, taxation and temporary exemptions from (or changes to) standards and rules. In addition, measures can be targeted at the demand side, for instance measures designed to change user preferences (e.g. through public procurement, campaigns, promoting use in particular market segments). Companies can play an important role, for example by providing opportunities for experiments in incubators or organising open innovation processes. Social groups can organise themselves into communities in order to create better conditions for the development of niches. Here, the specific need for

the different types of protection is regarded as dependent on the development trajectory of the innovations in the niche.

Besides emphasising ‘internal’ processes of niche development focused on learning, articulation and network development, SNM also considers exchanges and interactions between niches. Such exchanges take on more importance during the stabilisation and acceleration stages of a transition, taking place through processes of ‘aggregation’ and ‘generalisation’. Situated knowledge and experience gained from individual projects is translated into codified knowledge relevant to a larger community, for example through the development of guidelines, standardisation, dissemination of best practices or the establishment of rules. This translation often takes place in interaction with increasing entanglement of individual niche experiments through exchanges of personnel, experience, knowledge and resources (e.g. material and infrastructure). During this larger collaborative networks and communities of stakeholders are formed that can increasingly share common expectations, conceptual frameworks and interests. Wide-ranging learning processes in broader social networks are very important here.

Recent transition studies literature has shown that intermediary organisations such as academic or professional associations, standardisation organisations, multi-stakeholder networks and industry organisations can play an important role in exchange and interactions between niches. Intermediary actors can organise exchanges between various niches with similar innovations, and between niches with different innovations that pursue the same goal. The work of intermediary organisations is often process-oriented focused for example on bringing together particular groups of actors such as producers and users, promotional activities, representing a network, providing advice, and sharing best practices. Setting up intermediary organisations or networks can moreover contribute to a feeling of community and help to champion that communality.

Based on:

Kemp, R., Schot, J., Hoogma, R., 1998. Regime shifts to sustainability through processes of niche formation: The approach of strategic niche management. *Technology Analysis & Strategic Management* 10, 175–198.

<https://doi.org/10.1080/09537329808524310>

Kivimaa, P., Boon, W., Hyysalo, S., Klerkx, L., 2019. Towards a typology of intermediaries in sustainability transitions: A systematic review and a research agenda. *Research Policy, New Frontiers in Science, Technology and Innovation Research from SPRU's 50th Anniversary Conference* 48, 1062–1075.

<https://doi.org/10.1016/j.respol.2018.10.006>

Schot, J., Geels, F.W., 2011. Strategic niche management and sustainable innovation journeys: theory, findings, research agenda, and policy, in: *The Dynamics of Sustainable Innovation Journeys*. Routledge.

3.2 Technological innovation systems

The processes that entangle niches in the stabilisation and acceleration stages of transitions often go hand in hand with the gradual dissemination of the innovation in market and user segments. In many cases, radical innovations first gain a foothold in a small number of market segments, after which they spread to larger pre-existing ('mainstream') markets, in which niches compete with current alternatives in the regime. The initial adoption of innovations in small market segments makes innovations more visible and contributes to legitimacy, stability and certainty. This can increase interest on the part of policy-makers, companies and financial organisations in investing in human capital and financial and infrastructural resources to support the innovations, and organisations become interested in developing training courses and curricula as well. In addition, parties collectively, and government bodies in particular, can start to give more direction to innovation processes. It is generally assumed, in line with systems theory, that these processes can have positive effects on each other and can have self-reinforcing effects on the development of niches, and can influence the regime.

The role of positive and negative self-reinforcing effects in the early stages of transitions lies at the heart of the Technological Innovation Systems (TIS) framework, which focuses on describing, understanding and analysing how an alternative socio-technical configuration and system is constructed in the early stages of transitions. A key point here is that far more is needed for innovation to be successful than just processes of knowledge development and dissemination. Other processes distinguished for the creation of a system include:

- Entrepreneurship: entrepreneurs, researchers and pioneers who are willing to take risks and experiment to demonstrate the value of innovations. This includes entrepreneurs entering new markets with innovative solutions and pursuing innovation in business models in order to promote the dissemination of those innovations.
- Setting direction: formulating expectations and visions, and translating those visions into mission objectives, policy objectives and regulatory requirements. This includes actions to coordinate actors and resources to contribute to achieving the set objectives.
- Market formation: creating niche markets for the use of solutions. This involves incentivising those markets by means of, for example, subsidies, favourable legislation in the early stages, as well as the development of standards and the promotion of demand for practices and guidelines.
- Mobilising resources: mobilising financial, physical and human resources to support system processes.
- Creating legitimacy: increasing trust in, support for, and social acceptance of innovations.

The TIS framework assumes that the functioning of these seven key processes is related to the ways in which the various stakeholders enter into interactions with each other in the innovation process, in a shared framework of formal and informal rules. The framework is often used as a diagnostic tool to analyse the functioning of individual processes and understand how different processes affect each other, thus promoting or hampering innovation processes. Lack of direction-setting by policy-makers can, for instance, discourage entrepreneurs from developing knowledge. Absence of legitimacy can result in resource mobilisation stagnating.

Interpreting vicious circles of this kind can then provide leverage points for system actors such as policy-makers to develop interventions that enable the system to function better. As mentioned earlier, various processes can also have positive effects on each other and be self-reinforcing such as, for example, knowledge development and entrepreneurship, or resource mobilisation and knowledge dissemination. Analyses to identify such self-reinforcing mechanisms and vicious circles using the TIS framework have been carried out for the development and dissemination of various technologies, in particular in the domains of energy, mobility and food, but far less in health and the chemical industry.

Based on:

Bergek, A., 2019. Technological innovation systems: a review of recent findings and suggestions for future research. *Handbook of sustainable innovation 200–218*.

Hekkert, M.P., Suurs, R.A.A., Negro, S.O., Kuhlmann, S., Smits, R.E.H.M., 2007. Functions of innovation systems: A new approach for analysing technological change. *Technological Forecasting and Social Change* 74, 413–432.

<https://doi.org/10.1016/j.techfore.2006.03.002>

Hekkert, M.P., Negro, S.O., Heimeriks, G., Harmsen, R., de Jong, S. (2011). *Technological innovation system analysis: A manual for analysts*

3.3 Niche empowerment and niche-regime interaction

The insights about transitions based on the SNM and TIS frameworks provide an important basis for understanding niche development processes in the experimentation, stabilisation and acceleration stages of transitions. Both frameworks were developed in parallel with the MLP, and their relationship with the MLP is explicitly conceptualised in the literature. With the growth of the field of transition studies, however, certain criticisms of these frameworks, and of the insights about niche development in the MLP in general, have been put forward. These criticisms relate to the dominant focus on technology and infrastructure, and the lesser attention paid to social innovations and grassroots innovations. The limited attention paid to interactions between niches and regimes in the frameworks is another point of criticism that is often made.

One criticism is that studies on niche development provide only limited conceptualisation of the regime, making it appear that the dissemination and implementation of niche innovations takes place in a vacuum. This can result in a simplistic view of substitution, where an existing socio-technical system is simply replaced with a new one. There has therefore been more emphasis in the recent literature on the multi-faceted nature of interactions between niches and regimes and the influence that niches can exert on the regime. Particular attention is paid here to the role of actors in niche-regime interactions, including the role of the aforementioned intermediary organisations to bring niche actors and regime actors together,

partnerships between innovators and established organisations, and parties that can combine the roles of niche actor and regime actor and align internal developments.

Niche empowerment is a specific type of niche-regime interaction that has enjoyed a good deal of attention in transition studies. Two types can be distinguished: fit-and-conform empowerment and stretch-and-transform empowerment. In fit-and-conform empowerment, niches are regarded as protective spaces that need to become competitive, after which with the prevailing regime, following which the increasing competitiveness of the niche enables it to be disseminated. Niche innovations can then gradually conform with the prevailing rules and standards and a relatively unchanged selection environment. The aim is to promote gradual adoption by identifying similarities with dominant practices. Stretch-and-transform empowerment is the opposite of this: the emphasis here is on changing and transforming the dominant regime by supporting niche practices that can transform the regime or elements thereof. In stretch-and-transform empowerment, niche development is therefore more radical, focusing on changing the selection environment and creating a new regime.

Choices made in the balance between fit-and-conform and stretch-and-transform empowerment are politically charged: they relate to who wins and who loses, who retains or loses power, and who receives or misses out on investment when innovations emerge and are implemented. Established organisations, for instance, run the risk of losing a large proportion of their potential profit when sustainable alternatives are developed, and they will therefore try to protect their interests, often exerting considerable political influence in the process. A lesson from niche empowerment is that these politically charged choices already play an important role in the early experimentation and stabilisation stages of transitions. This is the case, for instance, with the articulation of – especially radical – visions and expectations that can steer transitions. It is also involved in choices regarding how niches are protected and supported, and the ways in which people think about how niche elements should be translated into regime elements.

Given the political nature of niche-regime interactions, transition scholars are also paying increasing attention to the role of politics in policy processes and the influence that niche actors can exert on those processes – e.g. their influence on

policy agendas and the values underlying those agendas and the broader political economy. Another factor is the capabilities and skills of niche actors to participate in political debates and policy arenas focusing on change towards sustainability.

In policy arenas, niche actors can form strategic political coalitions that share similar beliefs, values and policy objectives, enabling them to demonstrate the value of innovation with greater conviction. From the point of view of niche actors, there is also a risk of niche empowerment processes being co-opted by established organisations – e.g. if measures designed to protect niches are hijacked by organisations that benefit from the protective measures but have a limited interest in strengthening the niche and its contribution to regime change.

Based on:

Smith, A., Raven, R., 2012. What is protective space? Reconsidering niches in transitions to sustainability. *Research Policy* 41, 1025–1036.

<https://doi.org/10.1016/j.respol.2011.12.012>

Hess, D.J., 2016. The politics of niche-regime conflicts: Distributed solar energy in the United States. *Environmental Innovation and Societal Transitions* 19, 42–50.

<https://doi.org/10.1016/j.eist.2015.09.002>

3.4 Social innovations and power

In parallel with the increased interest in niche-regime interactions, more attention is being paid to processes of social innovation and power in transitions. Social innovations are broadly defined as changing social relationships, and new ways of thinking, acting and organising. These innovations are often of an explicitly transformative nature, aimed at addressing unequal power relationships, injustices, and exclusion and suppression in existing regime structures. They can therefore be regarded as a specific type of niche with the explicit aim of achieving stretch-and-transform niche empowerment, through activities manifestly designed to challenge, change or replace the dominant structures in the regime.

Grassroots initiatives are a much-studied type of social innovation in transition studies. They are social innovations of an explicitly political nature. They are developed bottom-up by citizens or civil society organisations, or come about through activism by local communities and citizens' collectives. They emerge particularly in reaction to

perceived social injustices and sustainability problems, focusing specifically on shared values, key principles and beliefs of the local communities involved in the transition. Many of these community-based solutions are designed to meet unmet local needs and emphasise the value of alternatives. They can also be organised collectively in such a way that they can pursue broader social change from the bottom up.

Social innovations in general, and grassroots initiatives in particular, play a vital role in the politics of transitions and niche-regime interactions. This is done by means of specific interactions with public and private partners, negotiations on access to resources and activism to promote such access, and through activities that influence the discourse, such as framing social problems and solutions. The power of these initiatives is thus regarded as the ability to bring about transformations in their sphere of action and achieve niche empowerment. Prerequisites for this are the alignment of internal interests, resource mobilisation, taking advantage of external opportunities, and overcoming barriers to scaling.

Insights from sociology about social movements have recently been incorporated in transition studies, in order to gain a better understanding of the development and functioning of social innovations and grassroots initiatives. These show how initiatives with different values, types of organisation and political aims stand in relation to each other; how controversies develop within different initiatives, and how shared identities, beliefs, claims and political strategies are negotiated and disseminated. Linking social and grassroots innovations can generate positive feedback loops in terms of contributing to social change (energising mechanisms, see also §6.2). Creating visions for new futures at an early stage moreover empowers these organisations more. The literature on social movements puts forward different kinds of 'collective action' to achieve new ways of decision-making and power structures, and to change imbalances of power.

The risks mentioned earlier of co-optation by established actors in socio-technical regimes have also been described for grassroots innovations. On the one hand, co-optation can undermine the degree of radicality and change of grassroots innovations; on the other, it can create an opportunity to access resources for survival and upscaling. In order to avoid the risk of co-optation and preserve their autonomy, authors of grassroots innovations often exert political power to mobilise resources and promote independence and survival in the long term.

Based on:

- Avelino, F., 2017. Power in Sustainability Transitions: Analysing power and (dis) empowerment in transformative change towards sustainability. *Environmental Policy and Governance* 27, 505–520. <https://doi.org/10.1002/eet.1777>
- Pel, B., Haxeltine, A., Avelino, F., Dumitru, A., Kemp, R., Bauler, T., Kunze, I., Dorland, J., Wittmayer, J., Jørgensen, M.S., 2020. Towards a theory of transformative social innovation: A relational framework and 12 propositions. *Research Policy* 49, 104080. <https://doi.org/10.1016/j.respol.2020.104080>
- Smith, A., Fressoli, M., Abrol, D., Arond, E., Ely, A., 2017. *Grassroots Innovation Movements*. Taylor & Francis. <https://doi.org/10.4324/9781315697888>
- Smith, A., Seyfang, G., 2013. Constructing grassroots innovations for sustainability. *Global Environmental Change-Human and Policy Dimensions* 23, 827–829. <https://doi.org/10.1016/j.gloenvcha.2013.07.003>

4.

Regime change

The increasing attention being paid to different types of niche-regime interactions, as discussed in Chapter 3, shows that regime change processes are varied and complex. In transition studies, regime change is no longer regarded as 'simple' substitution, in which a radical innovation and the associated socio-technical configuration replace the existing socio-technical regime and system. Instead, increasing consideration is being given to different ways in which a regime and system can be reconfigured, in line with the fourth stage of transitions. Particular attention has been paid to the roles and activities of different actors, including established regime actors, to successfully contribute to regime change and preservation. Reduction, destabilisation and phasing-out processes are regarded as an integral part of this reconfiguration. We now discuss the recent insights on (1) the nature of regime change, (2) the role of actors, and (3) destabilisation, phasing out and unlearning.

4.1 The nature of regime change

An important development in transition studies is the increasing understanding of the nature and dynamics of regime change. Analyses of regime change processes in transition studies have developed in two directions. First, insights from institutional sociology have been used to conceptualise the regime based on different dimensions of institutions. Secondly, a greater emphasis has developed on understanding the architecture of socio-technical systems and the ways in which it can be configured.

Taking an institutional sociological approach, the regime can be regarded as an extensive set of rules⁸ that give shape to a socio-technical system and social field. These rules, referred to as 'institutions', influence actors by facilitating certain behaviours while standing in the way of others. The regime's institutions create stability and resist change. They contribute to incremental change in the system configuration. The dialectic between institutional stability and change is thus an important aspect of socio-technical transitions.

Regime institutions have come about and evolved in accordance with the development of dominant technology and infrastructure in a social field. Institutional sociologists identify three types: regulatory, normative and cultural-cognitive institutions. Each of these types has

⁸ Institutions are defined here as the rules of the game in a social field. North, D.C., 1990. *Institutions, institutional change, and economic performance*. Cambridge University Press.

its own strong basis of legitimacy that structures the activities and practices of the various actors in a social field. In the case of regulatory institutions, that basis is enshrined in laws and formal rules that operate by means of coercion and associated legal sanctions. In the case of normative institutions, legitimacy is about what is appropriate and consistent with existing practices, and sanctioning occurs through social group formation (exclusion) and delegitimisation. Cultural cognitive institutions provide shared conceptual frameworks and common views that make sense-making possible in a social field with regard to, for example, the relationships between resources and goals.⁹

An important realisation from the institutional sociological approach is that there are various logical ways of structuring these institutional elements in a social field. They create so-called ‘institutional logics’ of underlying norms, values, beliefs and rules that guide the behaviour of actors, thus determining what is regarded as legitimate and appropriate. Social fields often consist of multiple logics that may complement each other or, conversely, conflict with each other: for example, the logic of public services (focusing on accessibility and risk avoidance), the logic of the market (focusing on efficiency and profit), and the logic of professional autonomy (focusing on expertise and self-regulation). Each of these institutional logics brings with it a characteristic ideal-typical set of beliefs, practices, goals and assumptions regarding efficiency and effectiveness, thus providing various behavioural guidelines and frameworks of legitimacy.

Transition scholars have related the existence of different institutional logics in a social field to the dynamics of change in regimes and socio-technical systems. They have observed that some regimes (and systems) consist of a single institutionalised, uncontested logic arising from a socio-technical configuration that has been dominant and relatively stable for decades, whereas other systems are characterised by less clearly developed institutional forms or a combination of partly conflicting logics. Regimes thus differ in their degree of coherence and structuring, which can be measured based on the presence of logics in the field.

⁹ A distinction can be made between epistemic and non-epistemic elements. Epistemic elements relate to knowledge, beliefs and the way in which actors understand dynamics in the social field. Non-epistemic elements relate to symbols, rituals and traditions that influence how actors understand the social field.

Transition scholars have shown that differences of this kind in logics affect the dynamics of transitions. When regimes consist of a wide variety of logics, and tensions between them, there is more scope for radical change and stretch-and-transform niche empowerment, as institutional plurality provides space for actors in the system to draw on from various logics, and to legitimise their actions and make them understandable by referring to a specific set of rules of the game. This creates freedom of action and opportunities to resolve conflicts and make compromises, which can be a valuable source for the dissemination of innovation and regime reconfiguration.

The specific conceptualisation of regimes based on institutional forms and logics provides a fresh perspective on how regime change can be brought about. Besides a perspective whereby change is made possible by stabilising and disseminating radical innovations in niches and events in the landscape, it results in more attention being paid to endogenous, gradual processes of regime change in socio-technical systems. The degree of coherence and structuring of a regime becomes a variable that can be influenced rather than a structural fait accompli. Such influence provides more scope for regime and landscape actors to actively influence aspects of the regime, as discussed in more detail in §4.2.

In addition to the institutional sociological approach, system change can be considered from a system architecture perspective. The starting point here is that socio-technical systems consist of multiple elements that cohere in a system architecture. In that architecture, elements may be linked to a greater or lesser extent, and there are specific subsystems and modules.

System change can then focus on (1) improving or replacing elements in the system, and (2) reconfiguring the links between the system elements. The most radical type of system change involves reshaping the entire system architecture by replacing both multiple elements and the links between them; while less radical types of system change focus on improving individual elements, replacing them, or adding new elements to the existing architecture.

Assessing and interpreting a socio-technical system based on its architecture makes it possible to understand and analyse, in a specific transition context, what elements are (or ought to be) subject to change in systems and subsystems at a more granular

level. It also provides possible explanations for why transition dynamics in a specific subsystem exert little influence on transition dynamics in another domain, for example because there are few linkages between the system elements.

Based on:

- Fuenfschilling, L., 2019. An institutional perspective on sustainability transitions, in *Handbook of Sustainable Innovation*. Edward Elgar Publishing, pp. 219–236.
- Fuenfschilling, L., Truffer, B., 2014. The structuration of socio-technical regimes—Conceptual foundations from institutional theory. *Research Policy* 43, 772–791. <https://doi.org/10.1016/j.respol.2013.10.010>
- Kooijman, M., Hekkert, M.P., van Meer, P.J.K., Moors, E.H.M., Schellekens, H., 2017. How institutional logics hamper innovation: The case of animal testing. *Technological Forecasting and Social Change* 118, 70–79. <https://doi.org/10.1016/j.techfore.2017.02.003>
- McMeekin, A., Geels, F.W., Hodson, M., 2019. Mapping the winds of whole system reconfiguration: Analysing low-carbon transformations across production, distribution and consumption in the UK electricity system (1990–2016). *Research Policy* 48, 1216–1231. <https://doi.org/10.1016/j.respol.2018.12.007>
- Runhaar, H., Fuenfschilling, L., van den Pol-Van Dassel, A., Moors, E.H.M., Temmink, R., Hekkert, M., 2020. Endogenous regime change: Lessons from transition pathways in Dutch dairy farming. *Environmental Innovation and Societal Transitions* 36, 137–150. <https://doi.org/10.1016/j.eist.2020.06.001>

4.2 The role of actors in regime change

The institutional sociology perspective on regime change has resulted in more attention being paid in transition studies to the roles of actors in creating, maintaining or changing socio-technical systems and the institutions in a regime. Empirical studies in institutional sociology in general, and transition studies in particular, focus on the institutional work of actors. ‘Institutional work’ is defined as the conscious, goal-oriented activities of actors targeted at the institutions that guide their behaviour in a socio-technical system. Different types of institutional work differ in terms of directionality. Much of the visible institutional work aims to create new institutions or disrupt existing ones, but it can also be mundane, focusing on minor changes and compromises between actors in order to maintain existing institutions.

The literature on institutional work in transitions has identified a broad range of strategies for creating, maintaining and disrupting institutions. Institutional work aimed at creating institutions involves, for example, representing stakeholders’ interests and advocacy, creating networks and group identity, and defining specific categories. Existing institutions are maintained through supervision and sanctioning, but also more unconsciously by mythologising existing institutions or publicly emphasising positive or negative examples of morally desirable behaviour. Institutional work designed to disrupt institutions involves, for example, consciously undermining and delegitimising rules, calling rules and underlying assumptions into question, or consciously ignoring those rules.

The types of institutional work expand our understanding of niche activities discussed in Chapter 3 and link them more explicitly to regime actors’ actions to maintain and change regime structures. Empirical studies have specifically examined which actors are most inclined to carry out institutional work and the preconditions for success. One finding is that a good deal of institutional work is unsuccessful, and success is highly dependent on actors’ social positions in a social field. On the one hand, low-status actors in peripheral positions are highly inclined to carry out institutional work and to change, as they stand to benefit less from clinging to established institutions and are likely to be sanctioned less if they depart from them. On the other hand, high-status actors in central positions have better chances of success if they carry out institutional work, as they have better access to networks and resources. These actors, however, are not so inclined to change.

The low inclination but central position of high-status actors has been specifically discussed in the literature on established organisations, referred to as ‘incumbents’. These organisations form a key part of the existing socio-technical system and regime. They have extensive vested interests due to, for example, investments in infrastructure and knowledge, skills and expertise that are vital elements in the system and required to develop, produce, distribute and sell particular products, processes and services. It is these established organisations that run the risk of losing their important position in the transition process, and they will therefore try to protect their interests, often exerting considerable political influence in the process.

Research has shown that established organisations often undertake different types of institutional work. First, established organisations often work in close collaboration with the authorities to influence institutions. They are often involved in the relevant government decision-making structures at an early stage. By presenting themselves as partners of government, established organisations are able to influence a policy in the broader sense rather than just a particular part of that policy. Secondly, established organisations often behave pro-actively, as reflected, for example, in proposals for alternative plans to the current policy reality. This pro-active approach enables them to take charge of the process of institutional change. Thirdly, established organisations are very skilful in discursive institutional work such as framing their interests.¹⁰ One strategy is to translate corporate interests into public interests, thus increasing the legitimacy of the established organisations' proposal and hence the likelihood that the plan will be implemented. Established organisations also try to draw attention to particular aspects of an institution or technology: this framing brings forward certain aspects while ensuring that no attention is paid to others. Fourthly, established organisations carry out or commission research to influence institutions. The findings of the research increase the legitimacy of the established organisations' proposal and are used in framing and addressing the general public. Lastly, established organisations influence public opinion through the media, as public opinion partly determines which political decisions will be regarded as good or bad. The more public opinion is in line with the established organisations' desired plan, the more difficult it will be for policy-makers to take a different decision. Established organisations thus carry out institutional work designed both to maintain and create institutions and to disrupt them. Their institutional work often results in incremental institutional change in line with their institutional preferences, and thus in the reproduction of the socio-technical regime configurations.

Established organisations' involvement in transition processes is far from clear-cut, however; they can also be valuable actors in transitions. As they are very effective in bringing about institutional change, they can play a major role in achieving transition goals. They are also regarded as powerful institutional entrepreneurs. Institutional activities considered important include entering into strategic alliances with niche

actors or peripheral actors in adjacent social fields; the potential to implement innovation on a large scale which can result in lower cost and broader acceptance; and the influence they can exert on policies and legislation and vision development in the field. This could provide scope for niche actors to increase their ability to achieve change and scale-up innovative solutions.

It is often assumed in transition studies that established organisations are more inclined to take on roles of this kind, once the radical new technology becomes core business within the foreseeable future, as is the case during acceleration stages. At the same time, more attention is now being paid to the observation that established organisations should be regarded not only as coherent actors but also as sometimes being highly diverse internally, with various divisions, departments and units pursuing different goals (e.g. acquisition of innovative companies, open innovation strategies, or influential sustainability departments). Research into how internal organisational dynamics of this kind can contribute to transitions is still in its infancy, although more attention is being paid to this in the areas of organisation science and corporate sustainability.

Based on:

- Berggren, C., Magnusson, T., Sushandoyo, D., 2015. Transition pathways revisited: Established firms as multi-level actors in the heavy vehicle industry. *Research Policy* 44, 1017–1028. <https://doi.org/10.1016/j.respol.2014.11.009>
- Fuenfschilling, L., Truffer, B., 2016. The interplay of institutions, actors and technologies in socio-technical systems — An analysis of transformations in the Australian urban water sector. *Technological Forecasting and Social Change* 103, 298–312. <https://doi.org/10.1016/j.techfore.2015.11.023>
- Hoogstraaten, M.J., Frenken, K., Boon, W.P.C., 2020. The study of institutional entrepreneurship and its implications for transition studies. *Environmental Innovation and Societal Transitions* 36, 114–136. <https://doi.org/10.1016/j.eist.2020.05.004>
- van Mossel, A., van Rijnsoever, F.J., Hekkert, M.P., 2018. Navigators through the storm: A review of organization theories and the behavior of incumbent firms during transitions. *Environmental Innovation and Societal Transitions* 26, 44–63. <https://doi.org/10.1016/j.eist.2017.07.001>
- Smink, M.M., Hekkert, M.P., Negro, S.O., 2015. Keeping sustainable innovation on a leash? Exploring incumbents' institutional strategies. *Business Strategy and the Environment* 24, 86–101. <https://doi.org/10.1002/bse.1808>

¹⁰ Framing is the attractive or unattractive representation of an institutional change, or an alternative technology that requires institutional change, to the widest possible audience. Based on: Hulst, M. van, Yanow, D., 2016. From Policy "Frames" to "Framing": Theorizing a More Dynamic, Political Approach. *The American Review of Public Administration* 46, 92–112. <https://doi.org/10.1177/0275074014533142>

4.3 Destabilisation, phasing out and unlearning

Examining regime change from an institutional perspective shows that it is difficult to break away from established socio-technical regime configurations, as they are institutionalised in rules, norms and cognitive frameworks in various ways. Also, established organisations often suffer from lock-in and inertia, which makes interacting with niche actors more difficult and results in clinging to existing ways of working and acting.

To overcome lock-in and inertia, it is regarded as vital to pay attention to destabilisation in transitions, especially in the acceleration and reconfiguration stages. Destabilisation in the form of reduced commitment of established organisations (incumbents) to the regime structures of the socio-technical system is required to make regime reconfiguration possible and is often seen in the acceleration stage of transitions. It becomes manifest in processes of phasing out, unlearning, break down and reduction. In this context, ‘phasing out’ refers to specific policies to outlaw certain practices or technologies. ‘Unlearning’ refers to underlying socio-cognitive processes that make destabilisation possible. In transitions, these processes ultimately become apparent in the breakdown of the regime, and in indicators of reduction such as a measurable reduction in particular outputs, usage and market shares.

Processes of destabilisation and break down have recently attracted more attention in transition research, although the literature is still thin on the ground compared with the literature on emergence and phase-in. The Transition Management (TM) framework, specifically the X-curve, was the first framework in transition studies that explicitly conceptualised processes of build-up and breakdown. The X-curve is frequently used here to help a group of people create a better understanding of transitions that are in the making and reflect on their roles and influence in build-up and breakdown processes.

There is a distinction in the X-curve between stages of destabilisation, chaos, demolition and phasing out during breakdown processes. Destabilisation is regarded as the starting point of a dynamic that can result in chaos and the demolition of the regime. Chaos is regarded as loss of certainty, institutions and established organisations becoming unstable, and drastic political interventions or sudden crises. It is a situation where a system is out of equilibrium and future directions and system

configurations still uncertain and ambiguous. Chaos can prevent the dominant regime structure from being able to perform its function, ultimately resulting in the disintegration and breakdown of all or part of the original regime elements. It thus provides a window of opportunity for change that was not possible in the existing regime configuration.

Dismantling processes have also recently been conceptualised in the context of the Technological Innovation Systems framework. The seven key processes involved in developing a new socio-technical configuration – knowledge development, knowledge dissemination, entrepreneurship, direction-setting, market formation, mobilising resources, and creating legitimacy – are mirrored in processes designed to destabilise the existing system. It concerns processes of unlearning, breaking down knowledge networks, restricting experimentation with existing technologies, market destabilisation, withdrawal of resources, and challenging the status quo.

As destabilisation and phasing out often relate to material lock-in and the discarding of technologies or products, socio-cultural facets of regime stability are often overlooked. The literature that does consider the socio-cultural facets of dismantling stages emphasises the importance of creating spaces for unlearning, such as in education and training, or through experimentation in organisations. These activities can help to deliberately step back from routine behaviour and things that are taken for granted. Unlearning focuses mainly on stepping back and abandoning skills and practices and particular ways of thinking and world views. This is a conscious process that is more likely to take place in situations of crisis and confrontation. Unlearning is thus pedagogically relevant and can be painful emotionally (also referred to as ‘transition pain’).

Based on:

- Bogner, K., Kump, B., Beekman, M., Wittmayer, J., 2024. Coping with transition pain: An emotions perspective on phase-outs in sustainability transitions. *Environmental Innovation and Societal Transitions* 50, 100806. <https://doi.org/10.1016/j.eist.2023.100806>
- Elzinga, R., Janssen, M.J., Wesseling, J., Negro, S.O., Hekkert, M.P., 2023. Assessing mission-specific innovation systems: Towards an analytical framework. *Environmental Innovation and Societal Transitions* 48, 100745. <https://doi.org/10.1016/j.eist.2023.100745>

- Hebinck, A., Diercks, G., von Wirth, T., Beers, P.J., Barsties, L., Buchel, S., Greer, R., van Steenberghe, F., Loorbach, D., 2022. An actionable understanding of societal transitions: the X-curve framework. *Sustain Sci* 17, 1009–1021. <https://doi.org/10.1007/s11625-021-01084-w>
- Kivimaa, P., Kern, F., 2016. Creative destruction or mere niche support? Innovation policy mixes for sustainability transitions. *Research Policy* 45, 205–217. <https://doi.org/10.1016/j.respol.2015.09.008>
- Turnheim, B., 2023. The historical dismantling of tramways as a case of destabilisation and phase-out of established system. *Proceedings of the National Academy of Sciences* 120, e2206227120. <https://doi.org/10.1073/pnas.2206227120>
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5.

The influence of the landscape

The landscape represents the broader, external environment that shapes the socio-technical systems and the regime, but is largely beyond the direct control of actors in those systems. It encompasses major social changes and worldwide trends in cultural values, political ideologies, or human or environmentally-caused crises. These changes can increase the pressure on the regime and provide a window of opportunity for niche innovations and actors to bring regime change. The landscape was long neglected in transition studies, and little attention was paid to the mechanisms that make interaction between the landscape and niches and regimes possible. The understanding of the landscape has changed in recent years, influenced partly by criticism of its conceptualisation. The main criticisms are as follows:

- Lack of theoretical precision: the landscape level is often criticised as being poorly defined. It can encompass a wide range of factors without clearly distinguishing how they influence transitions or interact among themselves.
- Deterministic and passive: the landscape level is regarded as being overly deterministic, as it influences the regime and niches without being influenced by them. This results in less consideration being given to how processes can be directly influenced at landscape level.
- Stability: the landscape level is often described as being very stable and only slowly changing over time. This restricts our understanding of sudden, disruptive shifts in the landscape, such as political upheavals, technological breakthroughs or crises (e.g. climate change, pandemics or financial crashes).
- The distinction between regime and landscape: it is often difficult to make a clear distinction between regime and landscape. Political and economic systems, for instance, can be regarded as part of the regime and the landscape.

As a result of these criticisms, the role of the landscape level is now interpreted differently than traditionally envisaged in the MLP. One development is that more attention is now being paid to how shifts in society-wide value frameworks, closely related to political and economic structures, can be influenced and can influence transitions. Another is that far more consideration is being given to how different transitions cohere and are interrelated. It could be said that the landscape level is thus regarded as an ecology of different socio-technical systems. Although both these developments stress the socio-technical nature of transitions, the first one particularly emphasises shifts in underlying values, norms and cultural-cognitive institutions, whereas the second one focuses more on mechanisms in the broader system dynamics. We now discuss these two developments.

5.1 Society-wide value frameworks

Slowly changing society-wide value frameworks are regarded as an important element in the landscape. These value frameworks and shifts in them can put pressure on the regime and thereby provide a window of opportunity for niche innovations to break through, or they can be a society-wide cause of a transition stagnating. Traditionally, however, they have been regarded as difficult to influence by actors directly involved in transitions. Recent thinking has criticised this somewhat passive and deterministic perspective.

This criticism is fuelled by a broader recognition that transitions are characterised by normative complexity and ambiguity. Parties involved in a transition have diverging value orientations, with concomitant interests and conflicts. This diversity can form part of different institutional logics in the regime structure, but it also often arises from more general rationalities that conceal different views of humanity and the world. These broad value frameworks affect the acceptance of new technologies, the shaping of policies, and interaction between different stakeholders. It is therefore vital to acknowledge and understand these multiple values and how they change.

Because of this, increasing attention is being paid in transition studies to continually questioning how shifts in value frameworks can be encouraged, and how that can steer transitions and changes in regime structures. A common way of doing this is to look at a specific transition dynamics in the context of broad social sustainability goals and as being fundamentally subject to basic democratic principles.¹¹ Shifts in broad social value frameworks can then be ‘projected’ directly onto the regime dynamics and result in questioning the dominant value frameworks in the regime. In the case of the transition to animal-free research, for instance, this involves considerations of the value and interests of animals, or acceptance of uncertainties in the risk society.

An additional realisation from transition studies is that dealing with contested values in transitions requires democratic legitimacy and the broad involvement of, for example, the public and consumers in transition processes. This is often described as

¹¹ A familiar compass is the United Nations’ seventeen Sustainable Development Goals (SDGs), which focus on a sustainable, just society. These provide a global compass for dealing with urgent challenges such as poverty, lack of food, education and the climate crisis. One way in which these goals are useful is that they often act as a ‘moonshot’ and a point of reference, thus providing a guiding sustainable perspective.

the ‘opening-up’ transitions and fostering reflection on the dominant institutional logics in a social field that largely structure the regime and are regarded as normal. Examples include bringing up the logic of professional autonomy or belief in the free market and innovation, or dealing with the role of science in society and the changing relationship between government and the public.

Based on:

Smith, A., Stirling, A., 2009. Moving Outside or Inside? Objectification and Reflexivity in the Governance of Socio-Technical Systems, in: *Governance for Sustainable Development*. Routledge.

Tschersich, J., Kok, K.P.W., 2022. Deepening democracy for the governance toward just transitions in agri-food systems. *Environmental Innovation and Societal Transitions* 43, 358–374. <https://doi.org/10.1016/j.eist.2022.04.012>

5.2 Multi-systemic changes

Although most of the research into transitions focuses on individual socio-technical systems, increasing attention is also being paid in transition studies to transition processes that can contribute to change in multiple systems. In the MLP framework, other socio-technical systems are generally not examined explicitly, and the shared elements in those systems are regarded as part of the landscape. The MLP perspective, however, ignores the fact that socio-technical systems do not operate in isolation; they are open systems that are to some extent linked to other systems, enabling them to engage in exchanges, in particular when they move towards shared transition goals such as sustainability.

Hence the recent increase in the attention being paid in transition studies to the relationships between socio-technical systems, i.e. the amount of interaction between them. A greater amount of interaction is associated with a greater degree of dependence between systems. The landscape, then, is not regarded merely as a set of society-wide developments that are difficult to influence; on the contrary, it reveals closer developments in adjacent systems that could possibly affect the speed of transition processes, and that could be a focus for integrative management and governance.¹²

¹² The transformative governance approach emphasises interaction between transitions, and the integrated management of those transitions in multiple systems. This is examined in Chapter 6.

The degree of linking between systems can be examined in both structural and functional terms. There are structural links between socio-technical systems when systems share the same actors, institutions and technologies. Established organisations can operate in multiple systems and even try to actively interconnect them. The same technology can be used for multiple purposes in different systems. There are functional links when systems are dependent on each other for their functioning, e.g. in the case of complex value chains or systems that are entangled through a shared infrastructure.

The literature on the relationships between systems and how they affect transition dynamics in a social field is still relatively new and constantly developing. At present, the literature focuses mainly on achieving integrational goals, such as net zero emissions in sustainability transitions that require simultaneous changes in multiple systems (e.g. energy and mobility). Achieving missions of this kind requires both examining dependencies between different 'major' systems (e.g. energy, transport and agriculture) and analysing interactions between the elements of different systems (e.g. between changes in science and regulation). We observe four areas of study in the literature:

- First, attention is being paid to how dependencies between systems affect transition processes. Dependencies can be synergetic, with transitions supporting and reinforcing each other, or they can be conflicting, with progress in one system hampering or delaying transition in another. Synergistic interactions consist, for example, of the development of technologies that can be used in multiple systems and can create positive feedback between systems (e.g. batteries in the energy transition). Conflicting interactions occur, for instance, if there is competition for resources between systems, or if a policy on a system has negative effects on the dynamics of another system (e.g. funding therapy development that leaves no resources for prevention measures in healthcare).
- Secondly, attention is being paid to how links between systems can be consciously created by actors acting as system entanglers, e.g. developing shared infrastructure such as digital platforms, but also collaborative networks and compatibility standards. Two important observations in the literature are that the development of these system linkages requires specific competences and skills, and that actors often adopt a strategic approach to creating linkages between systems because of the major interests involved.

- Thirdly, attention is being paid to managing interdependencies in order to maximise synergies and minimise conflicts. This requires integrational management between policy areas, with the main focus on coordinating different policy objectives and tools (the policy mix) rather than on individual policy tools. Goals here are often defined based on broader social challenges or missions. The transformative governance approach strongly emphasises such integrational management of transitions and the interactions between multiple systems and elements in the system. This is discussed in more detail in Chapter 6.
- Lastly, attention is being paid to how transitions become interlinked in the longer term and affect each other through the relationships between systems. The focus here is on deep transitions designed to achieve integrated sustainability goals that can only be achieved through social transformation in multiple systems and a change in the underlying value frameworks regarding sustainability in those systems. Historical research has shown that deep transitions of this kind often unfold in historical wave patterns over lengthy periods, with brief periods of radical change driven by related technological, organisational and institutional innovations, alternating with longer periods of relative stability, in which the innovations are enhanced incrementally (punctuated change).

Based on:

- Andersen, A.D., Geels, F.W., 2023. Multi-system dynamics and the speed of net-zero transitions: Identifying causal processes related to technologies, actors, and institutions. *Energy Research & Social Science* 102, 103178. <https://doi.org/10.1016/j.erss.2023.103178>
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- Löhr, M., Chlebna, C., 2023. Multi-system interactions in hydrogen-based sector coupling projects: System entanglers as key actors. *Energy Research & Social Science* 105, 103282. <https://doi.org/10.1016/j.erss.2023.103282>
- Schot, J., Kanger, L., 2018. Deep transitions: Emergence, acceleration, stabilization and directionality. *Research Policy* 47, 1045–1059. <https://doi.org/10.1016/j.respol.2018.03.009>

6.

Governance in transitions

In recent years, far more attention has been paid to the role of governance in transitions. A crucial question is whether the speed and direction of social change processes towards a more sustainable society can be influenced, and if so, to what extent. An important starting point in the literature on governance is that transitions cannot be controlled and directed by individual actors. Transitions are multi-causal, they come about through processes of co-evolution, they operate on multiple levels simultaneously (niche, regime and landscape), and they unfold over lengthy periods through the involvement of a variety of actors, as explained in Chapter 2. The phrase 'governance in transitions' is consequently often used instead of 'governance of transitions'. Governance in transitions is mainly about influencing their speed and direction.

The approaches to governance in transitions focus on both (1) developing frameworks to manage and coordinate the entirety of transition processes in the context of addressing social challenges, and on (2) developing and deploying specific tools for experimental approaches in niches and so-called 'transition arenas' in which various parties involved in transitions are brought together. In the context of social challenges, the role of policy and government have also attracted more attention in transition studies. We discuss this below.

6.1 Social challenges

Governance approaches for all-embracing transition processes are often described as a type of meta-governance, in other words, they focus on coordinating different governance processes in the complex multi-actor, multi-level environment of transitions. Examples include coordinating governance processes of a more centralised nature, such as policies and regulation on the part of national/supranational authorities, and of a more decentralised nature, such as policies of regional and local authorities. This also concerns involvement of different actors, for instance in interactive (multi-stakeholder) governance, public-private partnerships, or self-governance by, for example, private organisations. Meta-governance focuses on the overarching frameworks within which these various governance types, styles and arrangements are coordinated and integrated.

Transformative governance is a type of meta-governance focusing on the fundamental, system-wide reorganisation of technological, economic and social factors, including

paradigms, goals and values.¹³ Transformative governance focuses on the ways in which different governance processes and strategies can be coordinated to achieve profound systemic change. Governance is regarded as transformative if the types of governance focus on addressing the underlying causes of social challenges, are carried out coherently, and are implemented in the following ways:

1. Integrative, implemented in such a way that solutions also have positive effects elsewhere (e.g. at other scale levels and locations, and in other policy areas and sectors).
2. Inclusive, to empower stakeholders that represent transformative sustainability values whose interests are currently inadequately represented.
3. Adaptive, as transformative change and governance – and our understanding thereof – are developing constantly, this type of governance should enable learning, experimentation, reflection, monitoring and feedback.
4. Transdisciplinary, in such a way that different knowledge systems are respected, and the integration of sustainable and just values is brought about through a focus on currently underrepresented types of knowledge.
5. Anticipatory, applying the precautionary principle when decisions are taken that have long-term consequences, especially those relating to the development or use of new technologies.

The transformative governance approach proceeds from the assumption that direct society-wide change is possible and that it can make a major contribution to transition processes. This is in line with realisations previously presented that fundamental changes often emanate not from the regime itself but from outsiders or due to pressure from the landscape. It is also in line with realisations discussed before that innovation in social fields is often not transformative (stretch-and-transform) but incremental (fit-and-conform), and that there are relationships and links between different transitions.

In this perspective, attention therefore is shifted to society-wide change processes in the direction of sustainability, the relationship between transitions in different domains and different geographical levels of scale. Particular consideration is given

¹³ This section builds upon the description of transformative governance in the evaluation of the NCad Policy Advice, Transition to animal-free research.

to building new coalitions between actors, and to the role of democratisation processes in bringing about fundamental changes, including a larger role for the public and marginalised groups. The transformative governance approach thus goes beyond the more traditional emphasis on encouraging innovation processes in niches as an important part of transitions (see Chapter 3), as it regards transitions and the actors involved as part of a greater whole.

Specific insights from the transformative governance approach focus on, among other things, how policy processes can be organised and how policy makers can coordinate to drive transition processes effectively. The approach focuses on roles, responsibilities or principles that are important to transformative governance. These roles, responsibilities and principles can be regarded as preconditions that increase the likelihood of policies being able to respond to system change successfully.

An important realisation is that the government can contribute to governance in transition through different roles: *legitimate government* focuses on the legitimacy and legality of government action; *performing government* focuses on achieving pre-agreed results effectively and efficiently; *collaborative government* acknowledges that policy objectives are often met in collaboration with others; and *responsive government* acts on the principle that public values are achieved not only by government but also by other stakeholders. Others specify more specific roles of government, e.g. as a facilitator, mediator, lead-user, launching customer, gatekeeper, and moderator.

In the context of transitions, it is argued that a government that is transformation-focused not only operates from a collaborative governance perspective (typical of the Dutch ‘polder tradition’), but also has the courage to operate in a performing and legitimate way, and pays heed to radical construction outside existing structures and vested interests. This requires the government to chart a course with an inspirational future vision based on clear choices, to take full advantage of the innovative power in society, and to give top priority to knowledge and expertise in government and politics.

In line with the emphasis on integrated management, a good deal of attention is also paid to the policy mix in the context of policies and the role of government. The policy mix is a set of different and complementary policy tools aimed at addressing social problems in a particular jurisdiction. Policy tools are used to realize particular

policies. Various types are available, which can be classified into:

- Financial tools, e.g. subsidies, loans, guarantees and tax relief.
- Regulation and standards, e.g. laws and regulations, norms, standards.
- Information and coordination, e.g. advice desks, information campaigns, and platforms.
- Demand creation, e.g. procurement grants, investment allowances, innovation-focused procurement, and competitions.
- Infrastructures, public services such as research and testing facilities and technical infrastructure.

Transformative governance emphasises the importance of working towards a transformation-focused policy mix that not only promotes the development of new innovation pathways but also abandons entrenched pathways that are not helpful. In addition to technological innovation, a good deal of consideration is being given to new ways of thinking, working and organising, highlighted in the context of society-wide changes in value frameworks, e.g. new movements advocating a different moral attitude in the context of the transition to animal-free innovation.

Based on:

- AWTI, 2023. Transformatiegericht innovatiebeleid – Een voorstudie bij het advies in dienst van de toekomst. Report 14-12-2023
<https://www.awti.nl/documenten/adviezen/2023/12/14/advies-in-dienst-van-de-toekomst---van-optimalisatie-naar-transformatie>
- Borrás, S., Edler, J., 2020. The roles of the state in the governance of socio-technical systems transformation. *Research Policy* 49, 103971.
<https://doi.org/10.1016/j.respol.2020.103971>
- Braams, R.B., Wesseling, J.H., Meijer, A.J., Hekkert, M.P., 2021. Legitimizing transformative government: Aligning essential government tasks from transition literature with normative arguments about legitimacy from Public Administration traditions. *Environmental Innovation and Societal Transitions* 39, 191–205.
<https://doi.org/10.1016/j.eist.2021.04.004>
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Kivimaa, P., Kern, F., 2016. Creative destruction or mere niche support? Innovation policy mixes for sustainability transitions. *Research Policy* 45, 205–217.

<https://doi.org/10.1016/j.respol.2015.09.008>

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<https://doi.org/10.1016/j.cosust.2021.06.002>

6.2 Experimental approaches

Various experimental approaches have also been developed in the field of transition studies in attempts to manage the speed and direction of transitions, e.g. transition arenas, scenarios and experiments. We describe three of these approaches that provide an integrated approach to managing dynamics in transitions: Strategic Niche Management (SNM), Transition Management (TM) and the Small Wins approach.

Strategic Niche Management is both an analytical framework (discussed in Chapter 3) and a governance tool to actively influence niche development processes by initiating experiments and protecting and developing niches. The basic idea is to manage technology development and the contexts in which they develop (e.g. user preferences, networks, legislation) simultaneously. The experimental approach includes explicit attention to promoting different processes that contribute to the social embedding and acceptance of a new technology. This involves:

- Learning processes in multiple domains, e.g. technological learning to improve performance, but also social learning focusing on needs and demand, infrastructural requirements, business models, and appropriate regulatory and policy frameworks.
- Articulation processes focusing on the development of visions and expression of expectations. This steers the innovation and provides major pulling power for external organisations such as investors.

- Creating social networks to involve more partners, and to augment the knowledge base and increase the resources available.

SNM provides support to increase the impact of niches, e.g. by examining how initiatives can be linked, or how they can result in changes at regime level through legislation and other means. With regard to the latter, various proposals have been put forward in the literature for policy tools to shield niches from the selection pressure of the regime. These include:

- Subsidies: government financial support for innovation projects to make them technologically and economically feasible. Particular attention can be paid to the inclusion of various stakeholders and embedding the innovation in social structures and processes such as regulation.
- Regulatory frameworks: laws and regulations that lay down standards and requirements for technologies, thereby influencing their development and implementation.
- Public procurement: government policies that prioritise innovation and sustainable products, so as to create a market for new technologies.
- Tax incentives: tax concessions or relief designed to encourage or discourage investment in specific technologies or practices.
- Networks and partnerships: promoting the sharing of knowledge and resources among stakeholders, possibly through platforms or networks created specifically for that purpose.
- Pilot projects and demonstrations: support for initiatives to test new technologies in realistic environments, including monitoring and evaluating the demonstration process.

Transition Management (TM) provides a governance framework and a set of tools for bringing governance in transitions from a group of actors. An important tool in TM is the transition arena, a platform where various stakeholders work together on the co-creation of new visions, strategies and experiments. It provides an environment in which niche actors and regime actors can jointly search for innovations and solutions. Within these arenas, tools are used such as transition scenarios to explore various pathways for the development of a transition, transition experiments to test innovative projects and pilots (e.g. new practices or policies), and transition monitoring and evaluation to learn about the progress of transitions and how to

steer it. The X-curve, mentioned earlier, is also often used in transition arenas to improve actors' systemic understanding and promote the development of visions and interventions.¹⁴ The SNM and TM approaches are very similar, but there are some differences. While TM is strong in participatory processes, social learning and agenda development, SNM is more suitable for learning about specific innovation routes and their organisation, and for promoting technological learning in experimental contexts.

An approach developed more recently in the area of experiments is the Small Wins approach. This approach focuses on small-scale radical change initiatives with the aspiration of contributing to systemic changes. These are therefore often niche initiatives of a stretch-and-transform nature, based on radically new practices, insights and values. Small wins can also emerge within the regime, however, e.g. through new legislation, citizen initiatives, business models, enforcement initiatives or value chain partnerships.

When addressing complex social challenges, it is not easy to determine the ideal strategic direction regarding the development and desirability of these initiatives. It is seen as useful to work on small, significant steps that contribute to tangible, measurable results in relation to transitions. Some of these significant steps can then produce unexpected critical shifts in social dynamics, referred to as 'social tipping points'. These do not in themselves constitute transitions, but they can provide an important transition dynamic in a more comprehensive transition process. The emphasis on small, significant steps avoids paralysis and focus on short-term gains, and ensures progress in the transition without making major promises. Small steps can also be made more rapidly, as they give rise to less resistance.¹⁵ The Small Wins approach thus helps to avoid paralysis by avoiding the need to wait for completeness of information and focusing on generating short learning and evaluation cycles.

¹⁴ Although TM is a commonly used approach, it presents some challenges, in particular when it comes to involving marginalised groups and overcoming resistance on the part of regime actors that cling to vested interests and structures. Also, achieving large-scale system change using this approach has proved difficult. In line with the developments in transition studies as described in Chapters 3–5, partly because of the diagnosis above, more attention is now being paid to the role of power in transitions, the relationship between experiments and formal policies, and the role of politicians and institutions.

¹⁵ Small wins should not be confused with 'quick wins', where the aim is to achieve major progress quickly using familiar solutions.

The Small Wins framework is an experimental change approach par excellence, with the emphasis on managing change processes and preconditions. A prominent tool is ‘propelling mechanisms’: these enable various small steps to intertwine so as to contribute to the achievement of transition ambitions. Propelling mechanisms include creating momentum and trust by persuading and inspiring people (energising); making successes tangible and measurable so as to generate attention and attract resources (attraction); and linking initiatives that can reinforce each other through synergy or create opportunities for other small wins. Facilitating propelling mechanisms of this kind increases the likelihood that the small wins will be disseminated, internalised, and built upon in other initiatives.

The approach also includes consideration of the preconditions for energising small wins, for instance what roles and responsibilities policy-makers have or can take on in transition programmes. Other aspects include the capabilities of policy-makers and other partners to deal with uncertainties, rapidly changing circumstances, conflicting interests, political and social pressure, and stalemates in the process. The small wins framework is not suitable for determining whether the turning point towards system change is already close at hand, but it is useful in increasing the likelihood that that point will be reached, by creating the right conditions and activating energising mechanisms.

Based on:

- Kemp, R., Schot, J., Hoogma, R., 1998. Regime shifts to sustainability through processes of niche formation: The approach of strategic niche management. *Technology Analysis & Strategic Management* 10, 175–198.
<https://doi.org/10.1080/09537329808524310>
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7.

Synthesis

The developments in transition studies described (Chapters 3–6), combined with the literature review on the applications to the transition to animal-free research (Chapter 2, Appendices 2 and 3), provide an understanding of the evolution of thinking about transitions in general, and the transition to animal-free research in particular, since the publication of Transition Policy Advice 1.0. This chapter synthesises the main insights that have enriched thinking about transitions since the publication of Transition Policy Advice 1.0 and discusses how these more recent insights can contribute to the development of Transition Policy Advice 2.0. Here we distinguish between (a) insights to enable better understanding of the nature and dynamics of the transition to animal-free research and (b) specific recommendations on steering that transition.

7.1 Insights about the nature and dynamics of the transition to animal-free research

Based on the further refinement of thinking about transition processes at various levels, as discussed in Chapters 3–6, we identify three developments since the publication of Transition Policy Advice 1.0 that are relevant to the development of Transition Policy Advice 2.0.

First, the literature used for Transition Policy Advice 1.0 focused mainly on identifying barriers to, and opportunities for, the transition to animal-free research at the three levels of niche, regime and landscape. As regards the stages of transitions and the associated recommendations on governance, the emphasis was mainly on encouraging the stabilisation of new socio-technical configurations for animal-free research and innovation, and the dissemination and acceleration of this technological innovation in existing systems. Moving beyond Transition Policy Advice 1.0, and given the development of transition studies over the past eight years, there is now more emphasis on transition dynamics in the acceleration and system reconfiguration stages, and in parallel a focus on associated processes of destabilisation, phasing out and break down. The social elements and informal institutional aspects (normative and cultural-cognitive institutions) of socio-technical transitions come more into focus, as well as the importance of the broad involvement of a diverse group of actors including citizens.

Secondly, the focus in the literature has partly shifted from the dynamics at the three levels to the mechanisms that bring about interactions *between* the three levels. Ultimately it is these

mechanisms that largely determine the speed and direction of transitions. Transition Policy Advice 2.0 could devote more attention to niche-empowerment and regime-reconfiguration mechanisms, destabilisation and dismantling, especially through interaction between niche and regime actors. More consideration is now being given in transition studies to strategies designed to change institutional elements in the regime and the role of government, the public and civil society organisations in transition processes. In these developments, the political nature of transitions is made more explicit and more attention is being paid to the role of values, shifting value frameworks, and the changing conceptualisation of the landscape in transitions.

Thirdly, partly as a result of developments mentioned earlier, a variety of transition dynamics and pathways that can contribute to system change have been identified. In that sense, transitions do not always involve the simple substitution of one socio-technical system and regime configuration for another. This raises new questions regarding the multi-layered nature of transitions and entanglements between different systems and regime elements in subdomains. On the one hand, for Transition Policy Advice 2.0 this means that the transition to animal-free research can be regarded against the background of broader sustainability transitions and social challenges in agriculture, food and health systems. In these broader transitions, social challenges in areas such as pollution, safety, animal welfare and the protection of public health and the environment are being shared, but incompatible goals may also be set. On the other hand, this perspective brings to light a greater diversity of transition dynamics and pathways *within* the transition to animal-free research. These can be related to, for example, differences in the nature and speed of transitions within the defined domains (pathways) of fundamental research, translational research, regulatory risk assessment and higher education.

This latter involves recognising differences in dialectics between innovation impulses and regime elements in the various domains, and finding the right instruments and mechanisms to overcome the stability of these regime elements. In the fundamental science domain, for instance, it involves the importance of professional autonomy, the balance between epistemic (predictability) and non-epistemic values (ethics, transdisciplinarity and academic freedom), the ways in which researchers are acknowledged and valued, and the broader landscape shift that we are seeing towards open science, responsible types of research and innovation, and a changing role for universities in society. In the risk assessment domain, it is rather the

interaction between regulatory authorities and companies that comes into view, and the role of government and politicians at various levels in steering the transition to animal-free research through policies, regulatory changes and processes of regulatory acceptance of animal-free innovations.

7.2 Insights about governance in the transition to animal-free research

The insights mentioned and the more refined understanding of transition dynamics also provide starting points for governance in the transition to animal-free research. A pivotal principle is that transitions cannot be managed by an individual actor or groups of actors in terms of controlling and monitoring them. However, the direction and speed of transitions can be influenced, with, as it seems, an important role for governments to play at various levels in the case of the transition to animal-free research. Based on the insights presented, we refer to three key insights regarding governance in the transition to animal-free research.

First, the realisations from transition studies show that governance in the transition to animal-free research requires experimental approaches focusing on search, learning and innovation processes in order to influence build-up and breakdown of systems and regimes, as well as integrative governance of a transformative nature against the background of major social challenges in the areas of sustainability, safety and health. On the one hand, this means that there is an ongoing need to set short-term goals and actions in line with the approach taken in Transition Policy Advice 1.0, corresponding to the various domains of the transition to animal-free research. At the same time, it provides scope for emphasising the open-ended and multi-causal nature of transitions – as it is difficult in the long term to predict when the transition to animal-free research will be fully realised – while paying attention to both synergetic and conflicting interactions in addressing broader social challenges. This type of governance can be guided by the principles of transformative governance mentioned (integrative, inclusive, adaptive, transdisciplinary and anticipatory).

The second realisation is that an important role is set aside for government in the governance in transitions. Governance encompasses the coordination of different processes that are part of the broad policy mix that relate to the transition to

animal-free research. In addition to collaborative government which acknowledges that policy objectives are often met through collaboration and ownership by other partners, it is important to consider the role of the legitimate, responsive and performing government, e.g. in laying down frameworks and goals. Two specific challenges that make the transition to animal-free research difficult to manage are the alignment of policies at the national and European level, and the possibilities and impossibilities of influencing global dynamics. Possibilities of steering transitions by means of policies and government control would also seem to differ between domains, as in the case of transition dynamics in fundamental science, where self-regulation plays a greater role.

The third realisation is that, when setting and achieving goals in the short term, niche empowerment remains of great importance, including the associated processes of learning, vision development, and inclusive social network formation. During stages of acceleration and system reconfiguration, the main emphasis is on mainstreaming and scaling innovations, and the interactions between niche and regime actors. When it comes to encouraging technological innovation, governance from a broad socio-technical perspective is important, paying attention to various key processes to promote technological innovation. This involves not only developing and disseminating knowledge but also promoting processes of entrepreneurship, direction-setting, market formation, mobilising resources and creating legitimacy, and interaction and co-evolution between those processes. There is also an emphasis on the capabilities of innovators to exert influence on regulatory processes and in policy arenas, and on the role of actors not directly involved in the technological innovation processes, e.g. citizens, patients and consumers, and the civil society organisations representing their interests.

Involving a variety of actors, including members of the public, patients and consumers, in the transition to animal-free research could enrich the value and cognitive frameworks and institutional logics that lie at the heart of the transition to animal-free research. In parallel with the scientific and technological aspects of the transition to animal-free research, more attention is being paid to changes in social, technical and institutional aspects, including ethics and norm-setting. This could shift the balance between the emphasis on build-up and breakdown processes, and between promoting initiatives that seek solutions within existing structures and initiatives designed to transform these structures more fundamentally. Important for this is the development of a system of reflexive, learning evaluation that monitors progress in the transition based on clear targets. It is important here to direct efforts towards propelling mechanisms and to take seriously small wins in the transition to animal-free research and the roles of innovators and other highly influential parties in the transition, e.g. government, regulatory authorities, industry, and scientific organisations and associations.

Appendix 1:

Methodology

Relevant literature was identified and examined for this report with two aims in mind: (1) to create an overview of frameworks and insights from transition studies; (2) to examine how these insights provide governance perspectives for the transition to animal-free research. The various steps involved are described below.

Step 1: Developments in the transition studies literature

The first step was to create a general overview of available insights from, and developments in, transition studies that could be relevant to transitioning to animal-free innovation, based on an expert review. This involved a combination of (1) commonly used theoretical frameworks such as the multi-level perspective and the Technological Innovation Systems approach, (2) empirical studies that provide an understanding of particular transition dynamics, and (3) approaches used to manage transitions (governance perspectives). Various reports and overview studies that provide overviews of transition studies and developments in that area were used to create the overview. The overviews used were as follows:

- Elzinga, R., Janssen, M.J., Negro, S.O., n.d. Transitieperspectieven en -raamwerken: Een overzichtsstudie. Zenodo. <https://doi.org/10.5281/ZENODO.12516984>
- Geels, F.W., 2024. Advanced Introduction to Sustainability Transitions. Edward Elgar Publishing.
- Grin, J., Rotmans, J., Schot, J., 2010. Transitions to Sustainable Development: New Directions in the Study of Long Term Transformative Change. Routledge, New York. <https://doi.org/10.4324/9780203856598>
- Van der Minne, C., Hekkert M., Nijhof, A., Loorbach, D., Termeer, K., 2021. Houvast voor duurzame vernieuwers. Vier perspectieven op transitiedenken en doen. Het Groene Brein
- Köhler, J., Geels, F.W., Kern, F., Markard, J., Onsongo, E., Wieczorek, A., Alkemade, F., Avelino, F., Bergek, A., Boons, F., Fünfschilling, L., Hess, D., Holtz, G., Hyysalo, S., Jenkins, K., Kivimaa, P., Martiskainen, M., McMeekin, A., Mühlemeier, M.S., Nykvist, B., Pel, B., Raven, R., Rohrer, H., Sandén, B., Schot, J., Sovacool, B., Turnheim, B., Welch, D., Wells, P., 2019. An agenda for sustainability transitions research: State of the art and future directions. Environmental Innovation and Societal Transitions 31, 1–32. <https://doi.org/10.1016/j.eist.2019.01.004>
- Loorbach, D., Frantzeskaki, N., Avelino, F., 2017. Sustainability Transitions Research: Transforming Science and Practice for Societal Change. Annual Review of Environment and Resources 42, 599–626. <https://doi.org/10.1146/annurev-environ-102014-021340>

- Nesari, M., Naghizadeh, M., Ghazinoori, S., Manteghi, M., 2022. The evolution of socio-technical transition studies: A scientometric analysis. *Technology in Society* 68, 101834. <https://doi.org/10.1016/j.techsoc.2021.101834>
- Zolfagharian, M., Walrave, B., Raven, R., Romme, A.G.L., 2019. Studying transitions: Past, present, and future. *Research Policy* 48, 103788. <https://doi.org/10.1016/j.respol.2019.04.012>

Step 2: Systematic literature review

The second step was to carry out a systematic literature review. The aim of this was to identify how the frameworks and insights from transition studies have so far been applied to transitioning to animal-free research. A search for articles was carried out in Scopus-Elsevier¹⁶ with full coverage of PubMed/Medline. Abstracts (and if necessary the full texts of articles) were screened for the explicit use of perspectives from transition studies. The articles identified were then assessed in terms of focus, aim, use of insights from transition studies, methodology and main findings. Six key articles were identified, summarised in Appendix 2. These are as follows:

- Abarkan, F.Z., Wijen, A.M.A., van Eijden, R.M.G., Struijs, F., Dennis, P., Ritskes-Hoitinga, M., Visseren-Hamakers, I., 2022. Identifying Key Factors for Accelerating the Transition to Animal-Testing-Free Medical Science through Co-Creative, Interdisciplinary Learning between Students and Teachers. *Animals* 12, 2757. <https://doi.org/10.3390/ani12202757>
- Kooijman, M., Hekkert, M.P., van Meer, P.J.K., Moors, E.H.M., Schellekens, H., 2017. How institutional logics hamper innovation: The case of animal testing. *Technological Forecasting and Social Change* 118, 70–79. <https://doi.org/10.1016/j.techfore.2017.02.003>
- Punt, A., Bouwmeester, H., Schiffelers, M.-J.W.A., Peijnenburg, A.A.C.M., 2018. Expert opinions on the acceptance of alternative methods in food safety

evaluations: Formulating recommendations to increase acceptance of non-animal methods for kinetics. *Regulatory Toxicology and Pharmacology* 92, 145–151. <https://doi.org/10.1016/j.yrtph.2017.11.015>

- Schiffelers, M.-J.W.A., Blaauboer, B.J., Bakker, W.E., Beken, S., Hendriksen, C.F.M., Koëter, H.B.W.M., Krul, C., 2014. Regulatory acceptance and use of 3R models for pharmaceuticals and chemicals: Expert opinions on the state of affairs and the way forward. *Regulatory Toxicology and Pharmacology* 69, 41–48. <https://doi.org/10.1016/j.yrtph.2014.02.007>
- Schiffelers, M.-J., Blaauboer, B., Bakker, W., Hendriksen, C., 2014. Replacing the NIH test for rabies vaccine potency testing: A synopsis of drivers and barriers. *Biologicals* 42, 205–217. <https://doi.org/10.1016/j.biologicals.2014.04.001>
- Schiffelers, M.-J.W.A., Blaauboer, B.J., Hendriksen, C.F.M., Bakker, W.E., 2012. Regulatory acceptance and use of 3R models: a multilevel perspective. *ALTEX - Alternatives to animal experimentation* 29, 287–300. <https://doi.org/10.14573/altex.2012.3.287>

Step 3: Analysis of the citation environment

The third step was to analyse the citation environment of the six key articles identified, focusing on both cited and citing articles. The aim was to identify what theoretical frameworks and empirical findings from transition studies and related areas are referred to in the six articles that apply insights from transition studies to transitioning to animal-free research. We identified 366 unique citing and cited articles, which we divided into three clusters, with (1) insights from transition studies and bordering social sciences, (2) insights on animal testing and animal-free research, and (3) contextual insights for the transition to animal-free research. Articles were then coded thematically in each cluster. More information can be found in Appendix 3.

Step 4: Expert review

The fourth step was to bring together the main frameworks, insights and themes found in Step 1 (overview of insights from transition studies) with the results of Steps 2 and 3 (the content and themes of the articles that applied the insights to transitioning to animal-free research and its citation environment). The authors of the report selected the most prominent frameworks and recent insights from

¹⁶ The search term used in May 2024: TITLE-ABS-KEY (("NAM" AND NOT "Vietnam" AND NOT "Vietnam") OR "NAMs" OR "New Approach Method*" OR "3R" OR "Animal-free" OR "Animal Free" OR "Non-animal" OR "Non Animal" OR "Animal Testing Alternative*") AND TITLE-ABS-KEY ("Transition*" OR "transformati*" OR "innovation system*" OR "multilevel persp*" OR "multi level persp*") AND (EXCLUDE (SUBJAREA , "CHEM") OR EXCLUDE (SUBJAREA , "PHYS") OR EXCLUDE (SUBJAREA , "ENGI") OR EXCLUDE (SUBJAREA , "MATE"))

transition studies for the transition to animal-free innovation and took them as the starting point for identifying the themes discussed in Chapters 3–6. As explained in Chapter 2, it was decided, in line with the six key articles, to organise the overview based on the MLP levels, discussing the main themes for each level (Chapters 3–5). A distinction was also made between perspectives on understanding transition processes (Chapters 3–5) and perspectives on managing transition processes (Chapter 6).

Because of the narrative nature of the review, and so as to outline the major developments in the area, it was deliberately decided not to add references to individual publications in the sections. For each section, general insights were taken from the overview articles referred to in Step 1. These were then supplemented with more specific insights from individual papers, which were added to each section in a reference list or mentioned separately in footnotes.

Appendix 2:

Review of six key articles

The most important insights from the six key articles are summarised below in Table 1.

Table 1: Overview of the main insights from the six key articles in the citation environment (n = 366)

Reference	Abarkan, F.Z., Wijen, A.M.A., van Eijden, R.M.G., Struijs, F., Dennis, P., Ritskes-Hoitinga, M., Visseren-Hamakers, I., 2022. Identifying Key Factors for Accelerating the Transition to Animal-Testing-Free Medical Science through Co-Creative, Interdisciplinary Learning between Students and Teachers. <i>Animals</i> 12, 2757. https://doi.org/10.3390/ani12202757
Focus	Animal-free medical science.
Aim	<ul style="list-style-type: none"> • To identify key factors in accelerating the transition to animal-free medical science. • To reflect on the lessons learned from the interdisciplinary co-creative learning process between students and teachers.
Perspective	Application of the multi-level perspective, with an emphasis on relevant transition processes at three levels. Broader embedding in the literature on transformative governance of sustainability issues, animal welfare and ethics, and science dynamics.
Methodology	Key factors identified with the aid of documents and nine focus groups as part of an honours project involving Master's degree students. Factors identified were categorised at the levels of niche, regime and landscape, and into barriers that need to be overcome; actions taken to accelerate the transition; and opportunities that could be seized in future to accelerate the transition.
Findings	Six areas of interest that were identified as the main, most urgent factors in accelerating the transition to animal-free medical science: (1) availability of robust, translatable New Approach Methods (NAMs) for human-relevant medical research; (2) open science and data sharing; (3) targeted funding for NAMs; (4) implementing and modernising legislation for NAMs; (5) interdisciplinary teaching on animal-free medical science; and (6) facilitating dialogue on, and a shift in, views in society, as this is likely to benefit both animals and humans.
Recommendations	Emphasise the parallel implementation of the various key factors.

Reference	Kooijman, M., Hekkert, M.P., van Meer, P.J.K., Moors, E.H.M., Schellekens, H., 2017. How institutional logics hamper innovation: The case of animal testing. <i>Technological Forecasting and Social Change</i> 118, 70–79. https://doi.org/10.1016/j.techfore.2017.02.003
Focus	Animal-free development of medical drugs. Case study focusing on testing practices for assessing the potential of erythropoietin (EPO).
Aim	To increase understanding of why established practices can be so intractable when managing the innovation process.
Perspective	A combination of the Technological Innovation Systems approach and the multi-level perspective, with an emphasis on regime change and lack thereof. Broader embedding in the literature on institutional change, logics, contestation and destabilisation, and the role of actors and collective actions within this framework.
Methodology	Qualitative analysis of relevant events based on documents triangulated with the aid of nine expert interviews.
Findings	Innovation processes can be hampered by highly institutionalised practices and adherence to gold standards in regulatory regimes, especially if the innovations do not provide a direct substitute for existing practice and it is difficult to determine the commensurability between the innovation and existing practices. This is illustrated with a description of the process of codifying a mouse model for assessing the potential of EPO in a monograph in the European pharmacopeia, when animal-free methods were at an advanced stage of development. The article shows that this had a negative effect on the continued innovation of the animal-free method, as the elements in the monograph served as the frame of reference for the validation process. Validation then failed to get off the ground due to lack of resources and market formation in the area, and because the frame of reference was not regarded as entirely appropriate. This provides an understanding of mechanisms that contribute to lack of acceptance when there is a deeply entrenched practice with a gold standard.
Recommendations	Create a better understanding of the inequalities in the acceptance criteria for the use of animal-free methods versus animal testing in drug development and regulation, which can result from the way in which these criteria are entangled with, and implicitly refer to, existing drug development and regulation practices.

Reference	Punt, A., Bouwmeester, H., Schiffelers, M.-J.W.A., Peijnenburg, A.A.C.M., 2018. Expert opinions on the acceptance of alternative methods in food safety evaluations: Formulating recommendations to increase acceptance of non-animal methods for kinetics. <i>Regulatory Toxicology and Pharmacology</i> 92, 145–151. https://doi.org/10.1016/j.yrtph.2017.11.015
Focus	Toxicokinetic 3R methods for food safety
Aim	<ul style="list-style-type: none"> To provide an overview of what major stakeholders involved in food safety assessment consider to be the most relevant factors influencing the acceptance and use of 3R methods in that domain. To provide an overview of activities that stakeholders consider to be necessary to increase the acceptance and use of 3R methods, in particular for kinetics.
Perspective	Application of the multi-level perspective.
Methodology	A survey of stakeholders (11 respondents) focusing on the three main barriers and incentives (drivers), scored on a scale of 1 to 5. Barriers and drivers were categorised at the levels of niche, regime and landscape and compared with Schiffelers et al. (2014a). Specific recommendations were drawn up to promote the implementation of 3R methods.
Findings	The main barriers with the highest aggregated scores were (1) the uncertain predictability of 3R methods/lack of validation, (2) inadequate guidelines from regulators and industry, and (3) insufficient harmonisation of legislation. The main driver is the potential of 3R methods to provide more mechanistic information.
Recommendations	Place more emphasis on laying down statutory requirements for data collection using 3R methods, creating more funding opportunities for the development and validation of alternative methods for kinetics, and developing regulatory guidelines.

Reference	Schiffelers, M.-J., Blaauboer, B., Bakker, W., Hendriksen, C., 2014. Replacing the NIH test for rabies vaccine potency testing: A synopsis of drivers and barriers. <i>Biologicals</i> 42, 205–217. https://doi.org/10.1016/j.biologicals.2014.04.001
Focus	Replacing the NIH test for testing the potency of rabies vaccines.
Aim	<ul style="list-style-type: none"> To identify factors that influence the acceptance and use of 3R methods for testing vaccine potency. To identify ways of improving this process.
Perspective	Application of the multi-level perspective.
Methodology	A literature review, 15 interviews and a survey among 50 rabies experts. Factors were categorised at the levels of niche, regime and landscape.
Findings	Factors at niche, regime and landscape level and related to actors, methods, products, institutions, regulation and society were brought together in a 3R acceptance model for replacing the existing NIH potency test for rabies vaccines. Factors at niche level include limited experience of 3R models, lack of data sharing, and exacting validation processes. Factors at regime level include regarding animal testing as the 'gold standard', lack of harmonisation, and the limited motivating effect of legislation to promote 3R methods. Factors at landscape level include risk aversion in society and the increasing interest in animal welfare.
Recommendations	Regulatory acceptance and implementation of 3R models requires targeted communication, collaboration and coordination with stakeholders at all three levels (niche, regime and landscape). Make specific recommendations to promote the process of regulatory acceptance, formal adoption in guidelines and laws, and use by the industry.

Reference	Schiffelers, M.-J.W.A., Blaauboer, B.J., Hendriksen, C.F.M., Bakker, W.E., 2012. Regulatory acceptance and use of 3R models: a multilevel perspective. <i>ALTEX - Alternatives to animal experimentation</i> 29, 287–300. https://doi.org/10.14573/altex.2012.3.287
Focus	Regulatory acceptance of 3R models for chemical and pharmaceutical risk assessment.
Aim	<ul style="list-style-type: none"> To identify factors that influence the regulatory acceptance and use of 3R models. A mechanistic understanding of how these factors influence acceptance and use.
Perspective	Use of the multi-level perspective.
Methodology	Interviews (approx. 20) combined with insights from a previous project (Schiffelers 2007). Factors were categorised at the level of niche, regime and landscape, distinguishing between powerful and manipulable factors.
Findings	Factors at niche, regime and landscape level and related to actors, methods, products, institutions, regulation and society were brought together in a 3R acceptance model. Factors at niche level include the potential versus limitations of 3R models, the validation process, and limited training programmes and experience. Factors at regime level include the animal model being the gold standard, the diversity of risk assessment and regulation regimes, information asymmetry between industry and regulators, and the cost of switching to animal-free methods. Factors at landscape level include risk aversion in society, increasing interest in animal welfare, and the litigational culture.
Recommendations	Place the importance of landscape-level factors high on the political agenda. Emphasise that overcoming the inertia in the system requires thinking in small incremental steps: vitally important here are ongoing knowledge sharing, communication between stakeholders and training, paying particular attention to data sharing and communication between industry and regulators.

Reference	Schiffelers, M.-J.W.A., Blaauboer, B.J., Bakker, W.E., Beken, S., Hendriksen, C.F.M., Koëter, H.B.W.M., Krul, C., 2014. Regulatory acceptance and use of 3R models for pharmaceuticals and chemicals: Expert opinions on the state of affairs and the way forward. <i>Regulatory Toxicology and Pharmacology</i> 69, 41–48. https://doi.org/10.1016/j.yrtph.2014.02.007
Focus	Regulatory acceptance of 3R models for chemical and pharmaceutical risk assessment.
Aim	<ul style="list-style-type: none"> • To identify factors that influence the regulatory acceptance and use of 3R models. • To identify options for optimising the acceptance process.
Perspective	The multi-level perspective.
Methodology	Two expert panels were held, focusing on pharmaceutical and chemical risk assessment. Drivers and barriers at niche, regime and landscape level were identified and categorised. Factors were prioritised based on their influence on acceptance and use. Actions to influence factors were identified by the expert panel.
Findings	The most influential barriers are risk aversion, lack of harmonisation, and the uncertainty of 3R models. The most influential drivers are policy objectives and the mechanistic nature of 3R models. Most factors are similar in both domains, but differences were also observed (e.g. lower risk aversion in the case of chemicals).
Recommendations	Emphasise the importance of the four Cs (commitment, communication, cooperation and coordination) in coordinating transition processes at the various MLP levels. Take specific actions within and among the three stakeholder groups (scientists, industry and government) to facilitate acceptance and use.

Appendix 3:

Analysis of the citation environment

Analysis of the content of the 366 articles in the citation environment shows a variety of transition dynamics and themes relating to the transition to animal-free research. We observed a cluster of social science articles on transitions and social dynamics that were not specific to animal-free research (n = 115); a cluster of articles specifically about aspects of animal testing and animal-free innovation, but not embedded in transition studies (n = 141); and a less relevant cluster of articles (n = 110) that shed light on various areas of animal-free innovation, in particular the regulatory risk assessment of chemicals and pharmaceuticals.

The main themes in the three clusters are as follows:

- In the social science cluster, some of the articles focus on the development and application of theoretical frameworks for understanding and managing transition dynamics (n = 33). In addition to the MLP (n = 12), the Technological Innovation Systems framework was often used (n = 12). Four articles also discussed various governance perspectives, including the transformative governance approach (n = 4). Some other articles in the social science cluster examine more specific change dynamics, often using concepts and insights from social science areas related to transition studies. These include dynamics of institutional change such as regime change (n = 29); understanding of innovation dynamics, e.g. focusing on networking and learning processes (n = 17); policy and regulation dynamics, often focusing specifically on regulating and controlling risks and the relationships between regulatory authorities and companies (n = 18); changes in thinking about animal welfare and ethics, in some cases linked to broader sustainability transitions (n = 9); and changes in the science domain, e.g. focusing on open science or other types of recognition and valuation (n = 3).
- The articles on animal testing and animal-free research are heterogeneous. The cluster mainly comprises articles in the life sciences domain (in particular the toxicological, biomedical and biopharmaceutical sciences), and a number of advisory reports and opinion papers. It includes a large number of overviews of animal-free methods and new approach methodologies which have been developed that could possibly be used in the development and risk assessment of chemicals and pharmaceuticals (n = 87). Many of the articles include context-specific reflections on pathways towards, and barriers to, the further development and regulatory acceptance of the innovative methods. Other important themes in this cluster are studies that provide an understanding of the translatability of animal testing to humans (n = 15), and specific recommendations on animal welfare and ethics when conducting animal experiments (n = 9).

- The third cluster – less relevant to this analysis (n = 110) – comprises articles that shed light on various relevant areas of animal-free innovation. This is a very diverse cluster, including articles on basic science, e.g. descriptions of individual assays (n = 73) and documents containing guidelines, laws and standards for the conduct of animal experiments and the use of animal-free methods (n = 24).

Table 2: Overview of themes identified in the articles in the citation environment (n = 366)

1	Social science	115
1.1	Transition frameworks	33
1.1.1	<i>Multi-level perspective</i>	12*
1.1.2	<i>Technological Innovation Systems framework</i>	12*
1.1.3	<i>Governance of transitions</i>	4
1.1.4	<i>Socio-technical change</i>	4
1.1.5	<i>Transitions in general</i>	2
1.2	Transition-related concepts and processes	82
1.2.1	<i>Institutional change (often regime change)</i>	29
1.2.2	<i>Policy and regulation dynamics</i>	18
1.2.3	<i>Innovation dynamics</i>	17
1.2.4	<i>Animal welfare and ethics</i>	9
1.2.5	<i>Organisational change</i>	4
1.2.6	<i>Science dynamics</i>	3

2	Animal experiments and animal-free innovation	141
2.1	Animal experiments	34
2.1.1	<i>Human-to-animal translation</i>	15
2.1.2	<i>Animal welfare and ethics</i>	9
2.1.3	<i>Animal experiments (other)</i>	10

2	Animal experiments and animal-free innovation	141
2.2	Animal-free innovation	107
2.2.1	<i>Description of methods and frameworks in the specific area</i>	87
2.2.2	<i>Visions</i>	8
2.2.3	<i>Other (e.g. news and opinion)</i>	12

3	Other	110
3.1	Basic science (incl. individual assays)	73
3.2	Guidelines and standards (incl. pharmacopoeic)	13
3.3	Laws and regulations	11
3.4	Other (e.g. news and opinion)	13

* One article combines both of these

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