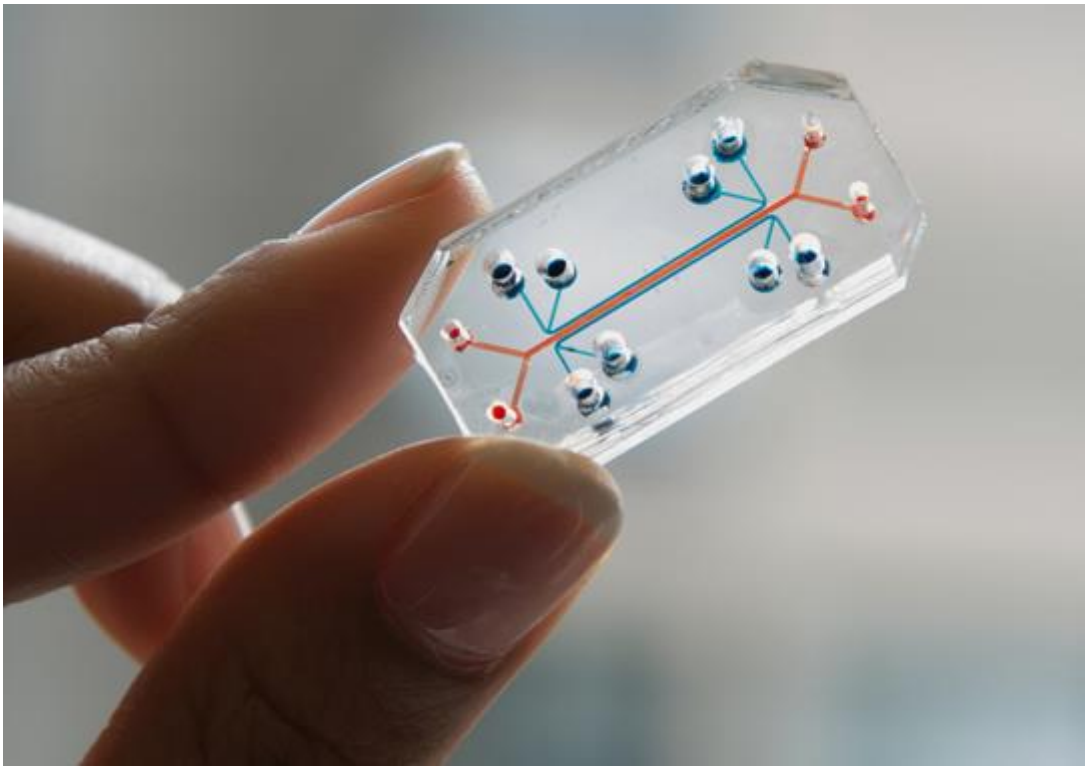
# Transitions in the risk assessment regime: prospects from the case of animal-free testing in the cosmetics industry



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| Wordcount: | 19861 |

# Abstract

**Introduction**

This thesis examines the transition from animal testing to animal-free methods in risk assessment in the cosmetics industry, specifically focusing on the ban on animal testing in the European sector. It explores how this transition affected the risk assessment regime, how actors responded and the effect on innovation in the industry.

**Theory**

This research studies transversal regimes by combining the concept of socio-technical regimes with risk regulation regimes. The study research the structural tensions that arise due to the misalignment of the regimes and how this shaped the transition towards NAMs. It uses institutional logics to characterise socio-technical regimes and identify changes in storylines over time.

**Methodology**

The study utilizes desk research to analyse regulatory changes and the context of the transition. A Socio-Technical Configuration Analysis (STCA) was performed to determine the structure of the socio-technical system and the dominant institutional logics. This was visualised with actor and concept networks, where components were identified in three time periods. Lastly, interviews with industry, scientific, and NGO representatives were conducted to validate and complement the data from STCA.

**Results**

The results show that the Cosmetics regulation forbids the use of animal tests where REACH often still requires animal tests and both regulations apply to some substances. It highlights the pivotal role that NGOs played in the development of the animal testing ban. Industry incumbents strategically delayed the transition to animal-free risk assessment methods (NAMs) until they had successfully adapted to the changes, at which point they emerged as pioneers in NAM development. Currently, a cooling phase is reached where an acceleration of the transition seems possible when looking at the industry initiative but where regulators are creating a bottleneck by ordering animal tests on chemical substances that have been used in products for years.

**Conclusion & discussion**

The structural tensions that arose due to the misalignment of REACH and the Cosmetics Regulation reduced the effectiveness of the animal testing ban and the implementation of NAMs. This research has shown the need for regulatory alignment for a successful transition and highlights how this impacts the socio-technical regime. Further research into the dynamics of safety assessment could contribute to understanding the transition towards NAMs.

# 1. Introduction

Animal tests have been a standard for the safety testing of drugs and chemical products for decades. Before this, in the 1960s, Thalidomide was commonly prescribed as a drug to combat morning sickness for pregnant women. This resulted in thousands of babies being born with deformities (Rago & Santoso, 2008). This caused a major reform in drug and chemical regulation. Governments in Europe and the US now require any new drugs and chemicals to be proven effective and safe (Rago & Santoso, 2008). Animal tests had been used in scientific research before and were therefore a logical choice for the safety testing of new drugs (Kooijman, 2013). However, in recent times the pressure for a transition towards animal-free testing has been and still is growing. This thesis aims to explore this transition and identify methods to accelerate it.

Even though animal tests became the standard for the safety testing of new drugs and chemicals, there has been resistance from the start. Three main issues with animal tests can be defined: ethical, quality, and economic considerations (Silva & Tamburic, 2022). i) Since somewhere around the beginning of the 1980s, public concerns started to grow significantly, mostly due to ethical issues (Silva & Tamburic, 2022; Taylor & Rego Alvarez, 2020). As the realities of animal testing became more public, partly due to the efforts of animal welfare NGOs, people started to rethink whether the death and suffering of millions of animal weighs up against the safety and quality of our products. This was especially the case for cosmetics as people did not want animals to suffer and die for the sake of human beauty while this issue is less common when it concerns drugs that can save lives (Kabene & Baadel, 2019). ii) The quality considerations refer to several aspects of animal tests. The main issue is that results from animal studies often cannot be extrapolated to humans. Recent study shows that out of 100 reviews of animal tests, 75 had significant limitations in predicting human outcomes (Ram, 2019). Other quality issues include inconsistent results and unsuitable methodologies for the intended goals (Silva & Tamburic, 2022; van Meer et al., 2012). Overall, the effectiveness of using animal tests to predict the response in humans has been questioned repeatedly. iii) Lastly, economic considerations arose for animal tests. Some animal tests can be extremely inefficient, using many more animals than necessary due to poorly designed methods (Silva & Tamburic, 2022). This is also the most debated issue as researchers disagree on this topic. Some argue that costs are a reason not to use alternative testing methods while others argue the exact opposite (Bones et al., 2014).

As long as animal tests have been used, efforts have been made to counteract them. As far back as 1959, *The Principles of Humane Experimental Technique* was published arguing for the three R's of animal testing: Replace, Reduce, Refine (Russel & Burch, 1959). This concept is, although adjusted over time, still used today in the context of animal testing. Since then, alternatives or New Approach Methodologies (NAMs) to animal tests have been developed. Alternatives include *In Vitro* models (cell cultures), *In Chemico* models (based on known toxicological properties of chemical structures), and *In Silico* models (Computational models based on existing data, do not require applying the substance to anything) (Silva & Tamburic, 2022). Often, these alternatives are not accepted by regulatory bodies as one-to-one replacements for animal tests (Beken et al., 2016). Proving the safety of a new drug or chemical requires a combination of several alternatives or other additional information, which are not required when using animal testing methods (Silva & Tamburic, 2022).

Due to the concerns with animal testing, actors are increasingly pushing for a transition towards NAMs. Although many alternatives exist, regulations often still require animal tests to gain market access for new drugs or chemicals. Over time, animal testing has become part of standard practice in the realm of risk assessment of products in several sectors such as cosmetics, pharmaceutics, and agriculture (Kooijman et al., 2017). It is important that we understand how such a transition can take place and learn what factors enable a smooth and fast transition and what factors inhibit the transition. The goal of this thesis is to identify these factors so that the transition towards NAMs can be accelerated.

The transition towards NAMs is a complex problem as risk assessment, and therefore animal testing, is a strong substructure at the centre of different socio-technical regimes such as cosmetics, chemicals, pharmaceuticals, and agriculture. A socio-technical regime, a core concept from the Multi-Level

Perspective (MLP), consists of the semi-coherent ruleset (codified and tacit rules) in an organisational/technological field. It represents the shared values, beliefs, routines, and taken-for-granted assumptions of actors in a system (Geels, 2011; Geels & Schot, 2007). As most actors adhere to these rules, innovation tends to become path-dependent and incremental. Regimes are generally rigid and provide pressures that make it difficult for alternative technologies to enter the regime. In conventional MLP theory, novel technologies develop in niches where they are protected from regime pressures (Geels, 2010). When the regime destabilizes, new technologies can enter the regime, which partly causes the regime to shift to a new configuration of rules. In the case of NAMs, this is different as the new technology is part of the risk assessment part of the regime and not an end-product. Therefore, the transition requires a central part of the regime to change. The risk assessment part of the socio-technical regime can be conceptualised through risk regulation regimes (RRR) (Hood et al., 2001). This is a framework for the analysis of regulations that are in place to manage certain risks. In the context of NAMs, transversal regimes exist, wherein the RRR applies the socio-technical regime of cosmetics as well as within other socio-technical regimes. As a result, both the RRR and the socio-technical regime must align internally but also align with each other to facilitate a smooth transition.

The full transition from animal testing towards NAMs based risk assessment is too large and complex for the scope of a master thesis. Therefore, a case was researched in which the core of the regime was changed and animal testing was replaced with NAMs. The European cosmetics sector was the first to ban animal testing. In 2003 the Cosmetic Directive (Directive 76/758/EEC) was agreed upon, which banned testing cosmetic products on animals from 2004 (Taylor & Rego Alvarez, 2020). In addition, it set a deadline for a ban on testing cosmetic ingredients and marketing of cosmetic products or ingredients tested on animals outside the EU in 2009. In the case of certain toxicological endpoints, which are outcomes of toxicity tests conducted for specific purposes like skin irritation, eye irritation, and acute toxicity, the deadline for compliance was extended until 2013. After that, a complete marketing ban came into effect. From that point onward, the sale of cosmetic products tested on animals or containing ingredients tested on animals was prohibited in the European market. Ultimately, this measure evolved into a formal regulation (Regulation 1223/2009) (European Commission, 2009).

The cosmetics industry in Europe is an exemplary case as they are the first industry to successfully transition towards an animal-free testing regime, therefore substituting its animal-based risk assessment approach and changing a core part of its socio-technical regime. In addition, it is already known that the transition has not been flawless as reports show that even in 2021 there were products on the market that had been tested on animals (Grover & Gilbert, 2021). The main reason for this is the REACH regulation, which requires proof from companies that produce chemicals that the chemicals they produce are safe both for consumers and workers (Knight et al., 2021). In some cases this leads to chemicals being tested on animals due to safety requirements by REACH, which are eventually used in cosmetic products. The animal testing ban has been active for over 10 years, which was another reason to study the cosmetics industry. The timeline allows for an in-depth analysis of how the incorporation of NAMs into the socio-technical regime of cosmetics, from now on referred to as the cosmetics regime, happened and also observe the effects that it has had on innovation in the cosmetics industry. The latter being of interest as research has shown that no new compounds for the exclusive use of cosmetics have been introduced since 2013 (Silva & Tamburic, 2022). Together, these arguments formulate the goals of this case study, which is to explore how the substitution of animal-based testing with animal-free risk assessment changed the socio-technical regime of the cosmetics industry and how this shaped the course of innovation. By this, I mean both the innovation activity, which refers to the rate of innovation in the cosmetics industry, and the direction of innovation, which refers to the different areas of cosmetics where innovation can take place. By doing this, I aim to identify general mechanisms that are applicable in the transition to NAMs and provide insights into similar transitions to NAMs in different industries. This leads to the following research questions:

1. *How did the animal testing ban change the risk assessment regime in the cosmetics industry?*
2. *How did different actors respond and contribute to this transition?*

3. *How did the transition influence the innovation activity and directionality of the cosmetics industry?*

The lens of socio-technical regimes was applied to formulate an answer to these problems. Specifically, I draw on the work of Fuenfschilling & Truffer (2014) in which they extend the concept of socio-technical regimes with institutional logics (Fuenfschilling & Truffer, 2014). Institutional logics represent different configurations of norms, values beliefs etc. In a regime, different actors can adhere to different institutional logics and the specific configuration of these institutional logics is what they call a 'field logic'. So if the configuration of institutional logics changes, then the field logic changes and therefore also the direction of the field. The existence of different institutional logics competing for dominance contributes to the idea of semi-coherence of regimes (Fuenfschilling & Truffer, 2014). When a specific sector is dominated by one particular institutional logic, the corresponding socio-technical regime is likely to be more resilient to external challenges such as emerging niche technologies. When there are multiple institutional logics competing for legitimacy, the regime is likely unstable and susceptible for new innovations to break in. With the substitution of animal testing, I expected different responses of actors adhering to different logics, thereby shaping the course of the transition due to how they act on problems along the way. By mapping these reactions and how they relate to one another, the aim of this thesis was to find mechanisms that support or hinder the transitions that are applicable in different sectors as well.

To analyse the regime change, a Socio-Technical Configuration Analysis (STCA) was performed. The STCA measures how different actors evaluate technologies, policies, regulations and other developments. By constructing congruence networks of statements made by actors in the public discourse, it can map the alignment of arguments and actors who support them. The statements were gathered from newspaper and magazine articles between 2000 and 2023, this allowed for an in-depth analysis of how the stances and beliefs of actors changed over time. The results of the STCA show that the dominant institutional logic in the field changes over time and that actors change their perspective on animal-free testing over the course of the past 20 years. The transition met some resistance when the ban was first talked about but the cosmetics industry adapted the risk assessment regime to NAMs. However, problems with the implementation arise due to opposing institutional logics and conflicting regulations. The results show different phases, each with its own benefits and problems.

The conceptual approach for this thesis is further elaborated upon in Chapter 2, followed by the data collection and analysis methods in chapter 3. Chapter 4 provides a broad history of animal testing is described to provide context for the SCTA. Chapter 5 explains the coding tree and shows the actor networks and concept networks of the STCA for different time periods. Lastly, the insights of the interviews are added to validate the results of the STCA. In chapter 6, I draw conclusions by using the results to answer the research questions. In Chapter 7, I discuss the theoretical and practical implications of the thesis and present the limitations of this research and possibilities for further research.

# 2. Theory

To study the problem at hand, a combination of several concepts from different literature streams is used. The main goal of this research is to explore how the substitution of animal testing with animal-free risk assessment changed the socio-technical regime of the cosmetics industry and how this shaped the course of innovation. In transition studies, radical changes in a sector have been studied using the concept of socio-technical regimes. However, this is more complex for the cosmetics case as there are transversal regimes overlapping each other, which is not addressed within transitions literature. To address this complexity, I draw on regulatory science literature and use the concept of risk regulation regimes to complement the socio-technical regimes.

## 2.1 Socio-technical regime

A socio-technical system consists of all the technologies, infrastructure, institutions, actors and interactions in a sector (Geels, 2004). The socio-technical regime is at the core of this system and guides the behaviour of the actors within the system (Fuenfschilling & Binz, 2018). It consists of the semi-coherent formal and informal rules that are deeply rooted within the practices and routines of the socio-technical system (Geels, 2002; Markard & Truffer, 2008). A popular definition is:

> *A technological regime is the rule-set or grammar embedded in a complex of engineering practices, production process technologies, product characteristics, skills and procedures, ways of handling relevant artefacts and persons, ways of defining problems; all of them embedded in institutions and infrastructures* (Rip & Kemp, 1998, P.338)

It defines what is appropriate, legitimate and feasible in a sector, it represents the dominant rationality when thinking about problems and future opportunities (Geels, 2010). Socio-technical regimes co-evolve with the technologies it surrounds and are therefore characterized by path-dependency, making it resistant to change (Fuenfschilling & Truffer, 2014; Geels, 2011).

Socio-technical regimes are at the centre of transition studies as transitions can be understood as the change from one socio-technical regime to the next (Geels & Schot, 2007). According to the Multi-level perspective (MLP), these transitions do not occur by their own but require pressure from the exogeneous *landscape*. These are macro-level developments, which happen outside the realm and influence of the regime actors (Geels & Schot, 2007). These can be things such as climate change awareness, political stances and culture (Fuenfschilling & Truffer, 2014). They destabilise the regime and provide opportunities for technological innovations to break through from the *niches* where they emerge. Technological *niches* are protected spaces where innovation can develop and grow, protected from the pressures of the regime (Geels & Schot, 2007).

Although the Multi-Level Perspective is one of the most popular transition theories, there has been serious criticism. One point of criticism being the operationalisation of regimes in MLP studies. In many studies, regimes are operationalised unsystematically and seen as rather homogenous (Berkhout et al., 2004; Markard & Truffer, 2008). This disregards the conceptual idea of a regime being a 'semi-coherent' set of rules and assuming no tensions, inconsistencies and conflict within regimes. This issue was addressed by suggesting to extend socio-technical regimes with the concept of institutional logics (Fuenfschilling & Truffer, 2014).

## 2.2 Institutional logics

By characterizing socio-technical regimes with institutional logics, I aim to make socio-technical regimes more tangible. Analysing statements made by actors in the cosmetics sector allows me to determine how these actors reacted to the change in regulation and thereby also identifying the institutional logic they adhere to. The changes in the configuration of which actors adhere to certain

institutional logics and to what degree can then be interpreted as the change of the socio-technical regime. To be able to implement this, I will first further elaborate on what institutional logics are.

Institutions are the explicit and tacit rules, norms and assumptions that guide human and organisational behaviour (DiMaggio & Powell, 1983; Scott, 1995). It explains conformity of action to these rules but also allows for agency from actors within the institutional environment to divert from the norm. An institutional environment emerges in an organisational field, which includes all actors in a certain sector ranging from consumers to suppliers and everything in between (DiMaggio & Powell, 1983).

Institutional logics are a set of certain values, norms, beliefs and rules that actors adhere to in their behaviour and decision making (P. Thornton & Ocasio, 1999). Seven basic types of institutional logics have been identified: the family, the community, the religion, the profession, the state, the corporation and the market (P. H. Thornton et al., 2012; P. H. Thornton & Ocasio, 2008; P. Thornton & Ocasio, 1999). Actors which adhere to the same institutional logic can still have different interpretations but are generally guided by the same overarching principles and beliefs. For example, actors adhering to market logic believe in free market principles and will probably speak out against new regulations but actors adhering to state logic believe that government should intervene and will support new regulations. In an organisation field, different actors can adhere to different institutional logics. Different institutional logics can co-exist and compete for legitimacy. The combination of different institutional logics and their dynamics in an organisational field are what constitutes a 'field logic' (Fuenfschilling & Truffer, 2014; Heiberg & Truffer, 2022).

Institutional logics can be used to characterize socio-technical regimes as they represent different value positions, conflicting interests and opinions on the direction of the sector. A regime where all actors adhere to the same logic is very stable (Fuenfschilling & Truffer, 2014). But alternative logics can emerge and challenge the dominant logic. A regime where conflicting logics challenge the dominant logic is more dynamic and contains friction between actors who support alternative logics. This friction comes from the different ways that the actors evaluate new developments such as new technologies or regulation. By analysing the institutional logics in the NAM transition, I aim identify how the socio-technical regime changed over time.

## 2.3 Risk Regulation Regimes

Part of the socio-technical regime of the cosmetics sector is the risk assessment. The rules of this risk assessment apply to all chemical substances, creating a transversal regime with coherent rules that apply in different sectors. To conceptualise this regime, I draw on the concept of Risk regulation regimes (RRR). RRRs are a complex set of rules and practices that are associated with regulating a particular risk (Hood et al., 2001). The boundaries of risk regimes can exist at different levels. RRRs are systems composed of many components interacting with each other. In addition, they evolve over time, for example through major incidents associated with the regulated risk.

RRRs consist of two main elements: Content & Context (Hood et al., 2001). Regime content consists of three elements of control. I) *information gathering* describes the capacity to obtain data that can be used to shape regime content. It is how risk managers obtain data on the risk. This can be done actively or passively and within or outside of the regime. ii*) Standard setting* is about setting goals or guidelines, either by the government or the industry. iii) *Behaviour modification* is about the incentive structures, preferences and beliefs that shape the RRR (Quigley & Bisset, 2014; Quigley & Mills, 2014). To analyse these elements, each one has three characteristics: *size, structure and style.* Size refers to the number and scope of regulations as well as the available resources to uphold them. Structure refers to the organisations involved and how they relate to each other, this includes the division of public and private organisations and their co-operation. Style is about the formal and informal codes that are in place to shape the RRR (Hood et al., 2001).

The second main element of RRRs is regime context (Hood et al., 2001). Again, there are three parts to regime context. i) The *technical nature of the risk* is about the positioning of the risk in regard to all the actors involved. ii) The *opinion of the public and the media* is about how the risk is perceived by society and lastly iii) the way *power and influence are concentrated in organized groups*, which describes the groups that have the most power in the regime (Hood et al., 2001). Hood et al. (2001) argue that regime context influences how the regime content is shaped. As RRRs are associated with a particular risk, the context can be very broad. For example for the risk of chemicals on human health is regulated in several sectors, but has a different context in each sector. In this thesis, I conceptualized the RRR context as the specific socio-technical regime in which the risk is being regulated.

## 2.4 Conceptual model

This research combines the concepts of Risk regulatory regimes and socio-technical regimes as these regimes transverse in the cosmetics sector. On the one hand, the RRR specifies the regulations of the socio-technical regime of the cosmetics industry, but also applies in other socio-technical regimes, for example in the pharmaceutical industry. On the other hand, the cosmetics industry's socio-technical regime contains the RRR but also extends beyond regulations into practices and routines that guide innovation. It is expected that these regime are not aligned perfectly, which causes structural tensions that have a significant influence on the evolution of the system (Wainaina et al., 2023). The overlap of both concepts is visualised in Figure 1.

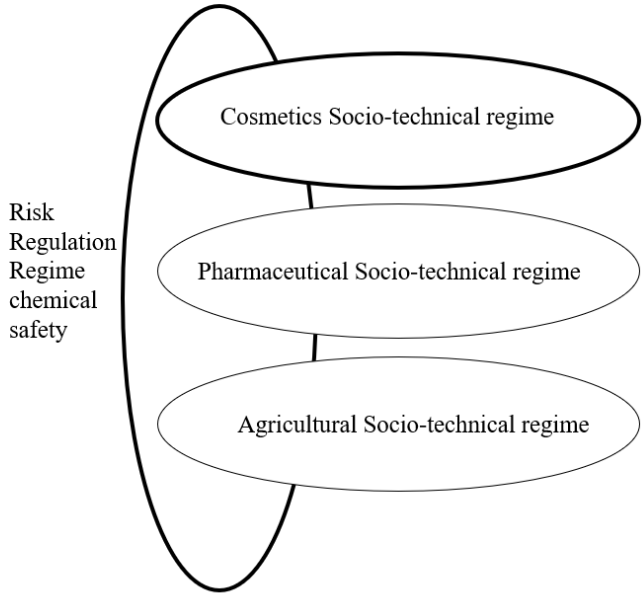


*Figure 1: The overlap of Risk Regulation Regimes and socio-technical regimes (own figure)*

From RRR, I used the regime content to analyse what has changed in the regulatory environment of the cosmetics industry. The RRR context is mostly shaped by the elements of the socio-technical system of the cosmetics industry. By identifying the structural tensions between the socio-technical regime and the new RRR of the cosmetics sector, I aim to identify how this has shaped the transition and affected innovation activity and direction of the cosmetics sector. As this is the first sector to ban animal testing, it is particularly important to investigate whether the policy actually provided directionality for the cosmetics sector and did not reduce its innovativeness.

# 3. Methodology

The goal of this thesis is to explore how the substitution of animal testing with animal-free risk assessment changed the socio-technical regime of the cosmetics industry and how this shaped the course of innovation. To achieve this, I conducted an exploratory case study of the cosmetics industry in Europe. The case study contains three parts. To answer the first research question, desk research was performed to identify the content of the RRR and how it changed due to the animal testing ban. The second research question was answered by means of a Socio-Technical Configuration Analysis (STCA), which 'captures how actors evaluate technologies, infrastructures, policies, regulations or sectoral paradigms and norms' (Heiberg et al., 2022). It consists of qualitative coding of documents followed by a quantitative network analysis of these codes. Lastly, to answer the third research question, interviews were performed to complement the data from the STCA.

## 3.1 Desk research

To answer the first research question, desk research was performed. The desk research included academic literature on the development of the regulatory framework of the cosmetics industry in Europe and the history of using animal tests for the safety assessment of new products. In addition, documents and websites of regulators, policy makers, industry and NGOs were used to determine the old and current state of regulation and regulatory bodies that impact the cosmetics industry. This part of the research was mostly descriptive and did not require any analysis methods.

## 3.2 Socio-Technical Configuration Analysis

The STCA is a method, which is based on Discourse Network Analysis (DNA). DNA is a method commonly used in political science and connects statements that indicate certain beliefs, arguments or stances to actors (Leifeld, 2017). This can then be used to create actor congruence networks, from now on referred to as actor networks, or concept congruence networks, from now on referred to as concept networks. The former can show networks of actors with similar beliefs and stances on certain topics and the latter can create 'storylines' of commonly used arguments in congruence with certain concepts (Heiberg et al., 2022).

STCA uses the basic aspects of DNA but expands the boundaries and uses discourses as a measure of socio-technical configurations (Heiberg et al., 2022). By constructing the actor networks, I aim to visualize and measure the elements of the socio-technical system. The concept networks enable us to quantify the extent to which actors adhere to specific rules and beliefs, thereby capturing the essence of the socio-technical regime. Visual representations of networks and statistics support identifying core concepts of the configurations and allow for an analysis over different time periods (Heiberg et al., 2022).

I used newspaper articles as the main data source as they represent the public discourse on a certain topic. Actors who have an interest in that topic will appear in the discourse and give their opinion, stance or belief on the topic. I operationalize institutional logics as the collection of statements being used together by actors and use the configuration of these institutional logics to measure the socio-technical regime structure.

In this study, I employed actor networks and concept networks, visualized as radar plots, to analyse the data. Actor networks offer valuable insights by depicting the frequency of actor activity in the discourse (reflected by node size) and the connections between actors who share similar arguments (illustrated by links between actor nodes). Concept networks can be interpreted to represent socio-technical configurations (Heiberg et al., 2022). In the radar plot, nodes represent arguments used by actors in the discourse where the size of the nodes correlates to the frequency that the argument was used and links represent how often two concepts were used by the same actor. Thus, a group of connected concepts represents an institutional logic or 'storyline', which in turn can be used to conceptualise the socio-technical regime. The width of the links is determined by the Jaccard similarity of concepts. Jaccard

similarity measures how often concepts appear together, in the sense that statements are made by the same actor, and is calculated with the following formula.

$$s = \frac{a}{(a+b+c)},$$

$$where\ n11 = a,\ n10 = b,\ n01 = c\ and\ n00 = d$$

In the formula, *a* represents the number of actors that have used both concepts congruently, *b* represents the number of actors which have used one concept but not the other and *c* represents the inverse of b. If s = 1, then the concepts appear only together and have perfect congruence while a low score represents low congruence between the concepts (Heiberg et al., 2022). This is represented visually as the width of the links between nodes. An example network is presented in figure 2.

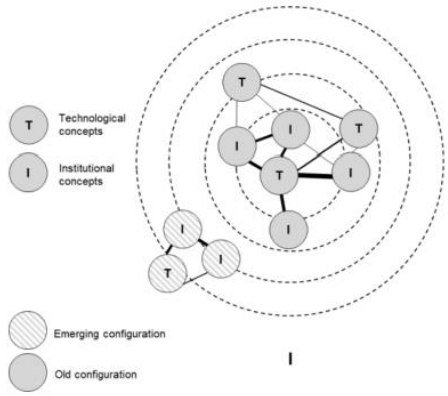


*Figure 2: Example of a radar plot of a socio-technical configuration (Heiberg et al., 2022)*

In addition to the visual representation, network indicators are used to interpret the network (Heiberg et al., 2022). *Degree centrality* represents how often concepts are used in congruence with other concepts. Concepts with a high degree centrality are central concepts that are used often with other concepts while a low degree centrality represents concepts that do not appear together with other concepts often. This correlates with the location of the nodes in the radar plot.

A group of nodes with wide links thus represents a strong storyline with arguments that are mainly used together. Such a group of nodes located at the centre of the plot indicates a coherent storyline, which is strongly embedded in the socio-technical regime. A smaller group of nodes, which has low Jaccard similarity and is located on the periphery, indicates a niche storyline that is not coherent yet. By creating these networks for different time periods, I aim at showcasing which storylines dominate the discourse, how they develop over time and which actors are using these storylines. This may provide insights into how different actors groups have influenced the transition towards NAMs.

### 3.2.1 Data collection

For the STCA to be valid, a representative data sample is required. The document stock that is used for the analysis must contain the full range of perspectives on the topic of analysis. The data was collected from NexisUni. The following search string was used: *(non-animal or animal-free) and (innovation or technology or models or method or testing) and cosmetics.* These results were then be filtered to only include documents written in English, originating from newspapers, journals or magazines and published in Europe and after 2000. By only using articles written in English, the data contains a bias of including almost exclusively UK news outlets and some international outlets. Although this reduces the

validity of the data sample, it is still representative of the discourse in Europe as the UK is home to the most important NGOs fighting against animal testing and it is therefore likely that all important events are covered in the media. Additionally, all the communication of major companies and European regulatory bodies is in English and therefore able to be covered by UK news outlets. I only used articles from Newspapers, Journals or Magazines as these are the most objective reporting sources. Articles from after 2000 are used because the cosmetics ban was introduced in 2003, therefore allowing for the analysis of all articles that could relate to the cosmetics ban. The articles were exported on February 20th 2023. In total, this resulted in 305 articles. During the coding process articles were excluded from the analysis if they were not properly filtered by NexisUni and were not related to animal testing or animal-free testing in Europe. Beforehand, it was expected about 70% of the articles would be relevant to the research but this turned out to be lower with relevant only 154 relevant articles, which is only 50%. Most of the articles were filtered out due to being duplicates or being about animal-free or vegan products but containing no information about animal testing. The final division of relevant articles per year is shown in Figure 3. The year 2023 was included as it had some articles in the initial selection but none were relevant to the topic.

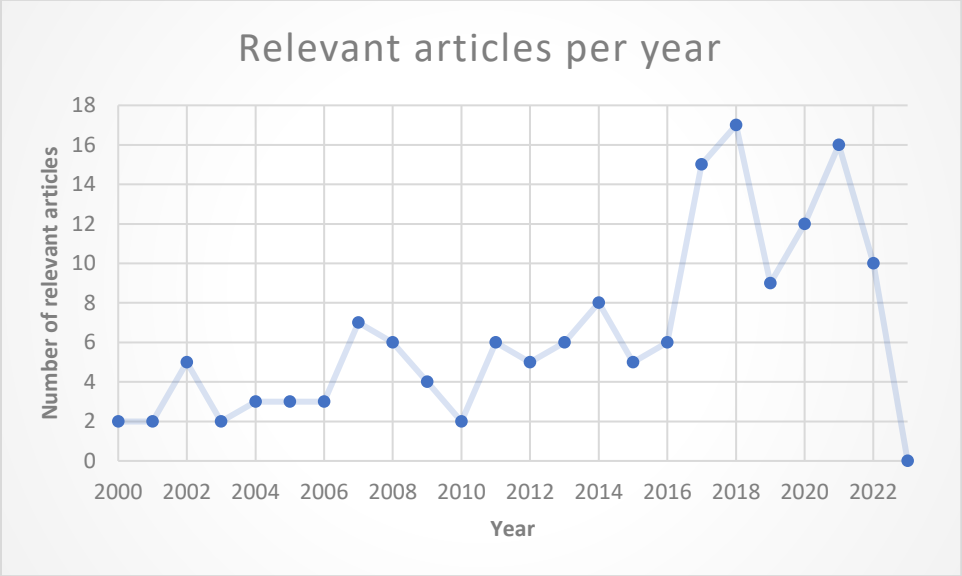


*Figure 3: Distribution of relevant articles*

The articles were divided into three time periods: 2000 – 2013, 2014 – 2019 and 2020-2023. 2000 – 2013 was chosen as a time period as it concerns the years leading up to the Cosmetics Regulation and ends in year when the full animal testing ban became active. The second time period was determined based on a controversial decision in 2020 by the ECHA board of appeal to force animal tests of some widely used chemicals. This was a pivotal moment as it was a decision which undermined many of the efforts that cosmetic companies were putting in at that time. This made 2020 a good cut-off point and therefore creating the 2014-2019 time period and the 2020-2023 time period.

### 3.2.2 Analysis

Once the data had been gathered, the next step involved its analysis. To construct the actor and concept networks, it was necessary to code the textual data. This coding process was performed using NVivo. Within the documents, specific fragments of text representing rules, beliefs, norms, and stances were assigned labels. In addition to coding the concept being referred to in the text, the actor responsible for making or supporting each statement was also coded. This coding allowed for the calculation of node size and Jaccard similarity, as outlined by (Miörner et al., 2022). The coding was done *abductively*, meaning that I iterated between the data, emerging concepts and theory, which led to the eventual coding scheme (Miörner et al., 2022). In the initial coding phase, regular meetings were held with the supervisor to discuss and refine the coding process until a reliable coding scheme was established and agreed upon.

The final coding tree and the interpretations associated with each individual code are discussed in a subsequent chapter. This process aimed to enhance the reliability and construct validity of the research through investigator triangulation.

After all the documents were coded, a co-occurrence matrix for each time period was created in Nvivo, which showed all the actors in the rows and all the concepts in the columns. For example, if Company A says animal tests are only used as a last resort and NGO B says animal tests are cruel, the resulting matrix would look like table 1.

*Table 1: Example of coding matrix*

| | As a last resort | Cruel |
|---|---|---|
| Company A | 1 | 0 |
| NGO B | 0 | 1 |

The resulting matrix was imported in R and transformed to create three new matrices. An unweighted two-mode network that simply shows which actor has used which concepts without considering the frequency, a weighted one-mode actor network that contains the Jaccard similarity of the actors and a weighted one-mode concept network that contains the Jaccard similarity of the concepts. All the transformations and analysis in R were documented in R-scripts to increase the reliability and replicability. The R scripts used originated from the STCA guidebook (Miörner et al., 2022).

### 3.2.3 Visualisation

The visualisation was done using Visone, which is software designed for visualising social networks (Miörner et al., 2022). Among other things, Visone allows the user to create the radar plots described in the STCA methodology accounting for the centrality, node sizes and link weights. Each network was created using a centrality lay-out based on node degree, which places nodes with a higher degree near the centre of the network and nodes with a lower degree at the periphery of the network. The node size correlates with the frequency and the colour of the nodes correlates with the coding category it belongs to. For actors, this means the type of organisation and for concepts it means the regime of niche it belongs to. Link width and colour is based on the Jaccard similarity between two nodes; low Jaccard index value links are thin and light yellow and high Jaccard index value links are thick and dark red. In order to enhance the interpretability of the networks, connections with a Jaccard index value of 0.15 or lower were eliminated from the graphs. The selection of the cut-off value was aimed at optimizing graph readability while ensuring that potentially significant connections were not disregarded.

## 3.3 Interviews

The STCA is used to answer the question of how the substitution of animal testing with animal-free risk assessment changed the socio-technical regime of the cosmetics industry. To complement the STCA and answer the question of how this shaped the course of innovation, interviews were conducted. The aim was to have about 6 interviews but in the end 3 interviews were conducted with different actors in the cosmetics industry. The three interviewees were respectively from the industry, the scientific community and an NGO. This includes the most important types of actors except regulators. Several interview request were sent to regulators but all of them were either declined or ignored.

The interviews were semi-structured as to ensure that certain topics are discussed but to also leave room for participants to elaborate on arguments or topics which were not predetermined (Clark et al., 2021). The interview guide contained open questions that encourage interviewees to give elaborate answers (Clark et al., 2021). The interview guide was divided into three parts; I) the period leading up to the Cosmetics Regulation, II) the implementation of the Cosmetics Regulation and the challenges that arose during this period and III) the effects of the Cosmetics Regulation on innovation in the cosmetics sector and development of NAMs. The interview transcripts were used for the analysis. interview guideline can be found in Appendix II.

## 3.4 Validity & reliability

Research quality indicators help determine the replicability and validity of the research. The replicability of this research is high. In this research, all data sources are publicly available and there is no indication that they will not be available in the future. The only data source that is less replicable is the interview data. Although interviews can be held again, it is possible that answers will differ based on different interviewees or memory if it concerns the same interviewees at a later point in time. The meetings that I had with my supervisor about the coding tree increased the inter-coder reliability of the research. It could be improved even further if more researchers would be involved in the whole coding process. The goal of this research is to explore how the substitution of animal testing with animal-free risk assessment changed the socio-technical regime of the cosmetics industry and how this shaped the course of innovation. The internal validity of the research was improved by having interviews to validate the results from the STCA. As this research is a case study, I do not expect the results to have high external validity but this is further discussed in Chapter 7.

# 4. Desk research results

The results of the desk research provided the background and context to interpret the results from the STCA. First, a general history of animal testing is presented to understand how it became the gold standard in research and what efforts have been made to initiate the transition towards animal-free science. Secondly, the content of the RRR is presented. This comprises the current regulatory framework that applies to the cosmetics industry and how the different regulations interact.

## 4.1 History of animal testing and alternative development

To understand the transition from animal testing to NAMs we must first understand how animal testing became such a prominent part of our risk regulation system. Using animals for science and research dates back several centuries with some of the earliest examples of using animals to understand human physiology dating back to ancient Greece. Later in the 16th and 17th century animals were used to understand the circulatory system of mammals, in the 20th century we even started to specifically breed animals for genetic similarity to increase the reliability of the animal model and in the early 21st century we were able to sequence and alter the genomes of rodents to further develop the animal model. (Ericsson et al., 2013)

Animal testing in the context of safety assessment is strongly connected to therapeutic disasters. In 1937 in the United States Sulphanilamide killed dozens of patients using it as medicine, which led to the introduction of the Food, Drug and Cosmetic act in 1938 (Paine, 2017). This was the first regulation that required new drugs to be tested on its toxicity before being allowed market access. The regulation was sharpened to ensure efficacy and increased safety due to the Thalidomide disaster in the 1960's, which caused hundreds of birth defects in babies worldwide. (Paine, 2017; Rago & Santoso, 2008) This was also the time when animal tests started to be used for safety testing in Europe (Stephens & Mak, 2013). Europe had several directives aimed at providing society with safe chemicals such as Directive 67/548/EEC (the Dangerous Substances Directive), Directive 1999/45/EC (Classification, packaging, and labelling of dangerous preparations), Regulation (EEC) No. 793/93 (evaluation and control of existing chemical substances), and Directive 76/769/EEC (restrictions of marketing and use of chemical substances). These were eventually all harmonized into the Registration, Evaluation, Authorization and restriction of Chemicals (REACH) in 2007 (Williams et al., 2009).

In 1959, Russel and Burch produced their seminal contribution in which they argued for more humane animal experimentation and introduced the 3Rs: Refine, Reduce and Replace (Russel & Burch, 1959). These concepts radically changed the ways animal were treated in research. Where animals previously were used for a lot of research, there were now consideration such as the justification for requiring an animal, ethical considerations, the relevance of the animal test and the possibility of alternative testing methods (Schechtman, 2002). Over time, the 3Rs were adopted in regulatory frameworks and development of NAMs was initiated. Organisations which played an important role in the development and regulatory acceptance of NAMs are the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the European Centre for the Validation of Alternative Methods (ECVAM) (Schechtman, 2002). In addition, several universities, national research centres and later also companies have contributed to the development of NAMs.

An important group of organisations in the fight against animal testing are NGOs. A wide range of NGOs have existed with the goal of stopping animal testing, all with slightly different strategies ranging from co-operative NGOs campaigning to implement incremental changes to more extremist NGOs with controversial protests calling for radical changes and abolishing animal tests (Munro, 2012). Generally, there are three main arguments used against animal testing; ethical or moral arguments, scientific validity of animal testing and economic arguments. Ethical or moral arguments consider the value of animal lives in respect to the goal of the research. The strength of this argument differs as for example people are more likely to accept animal suffering when it concerns testing life-saving drugs than beauty products (Kabene & Baadel, 2019). There are several different ways to approach the ethical argument but that is beyond the scope of this research (Munro, 2012). Secondly, animal tests are criticised for

their performance. As every animal is slightly different, animal tests are not as consistent as NAMs can be and animals are anatomically and physiologically different from humans, which reduces the predictive capabilities of animal tests (Hoefnagel et al., 2023; Ram, 2019). Lastly, raising and keeping animals for research is expensive as animal tests are required in many phases of research while NAMs are already cheaper in some cases and can lead to huge cost decreases as more accurate models will greatly reduce the number of required tests (Hutchinson et al., 2022; Meigs et al., 2018).

Animal testing on cosmetic ingredients or products became prohibited in Europe in 2013, being the first animal testing ban in the world. They were followed by many other countries and now there are 41 countries which have banned animal testing of cosmetics. There are also countries in which animal testing is not prohibited but also not required such as the US and countries where animal testing is still mandatory such as China. (Clarkson-Bennett, 2022; Humane Society International, n.d.)

## 4.2 Risk Regulation Regime content

To understand how the cosmetics industry transitioned to an animal-free regime, it is important to know what regulations apply to the cosmetics industry. There are three regulation that are important to the cosmetics industry: the Cosmetics Regulation (Regulation (EC) No. 1223/2009), the Registration, Evaluation, Authorization and restriction of Chemicals (REACH) and the Classification, Labelling and Packaging (CLP) regulation. The goal of CLP is to standardize labelling of hazardous substances and communicating the risks to everyone involved (ECHA, n.d.). The Cosmetics Regulation used to be the Cosmetics Directive (76/78/EEC), which was introduced in 1976. Directives give member states freedom in how they incorporate the directives in their own laws. As this created differences between EU countries, somewhere in 2003 it was proposed to change it to a regulation which level the rules for all EU countries (Cosmetics Europe, n.d.). The Cosmetics Regulation was adopted in 2009 with some extensions for the animal testing ban until 2013. Lastly, REACH is a regulation that applies to all chemicals produced and used in the EU. It entered into force in 2007 to create an improved database on the properties and hazards of chemicals. To give time to companies to get their dossiers in order, different deadlines were put in place based on tonnages of the chemical produced per year. (ECHA, n.d.-b) REACH concerns all chemicals, including chemicals used in cosmetic products and is therefore of importance for the cosmetics industry.

### 4.2.1 Information gathering

REACH is regulated by the European Chemicals Agency. The pre-registration phase of REACH started in 2008. Companies could pre-register substances they were producing, this allowed them to continue to produce the substances while they prepared for the Safety requirements of REACH. Based on tonnages per year, different deadlines were put in place for the complete dossiers. In 2010 was the deadline for substances in quantities of more than 1.000 tonnes/year, in 2013 substances in quantities between 100 and 1000 tonnes/year and in 2018 substances between 1 and 100 tonnes/year. For all substances that were not pre-registered, the process became pre-market registration meaning that the substance must be registered before companies can produce and use it. Every member state has appointed a competent authority, which also checks the dossiers for compliance with REACH and possibly other national laws. The final decision about the acceptance of a chemical lies with the competent authority. (Williams et al., 2009)

The Cosmetics Regulation is based on self-registration. Companies that want to introduce new cosmetic products must perform safety assessments of their product before placing them on the market. They must register their product on the Cosmetic Products Notification Portal (CPNP). Each member state has appointed an organisation in their country as a competent authority. They can ask companies for the dossiers containing the safety assessment and enact consequences in the case of non-compliance. (Cosmetics Europe, n.d.)

### 4.2.2 Standard setting

In REACH, the level of detail in safety testing varies based on the tonnage of the substance that is being produced and the type of substance (Arnesdotter et al., 2021). Figure 4 and 5 portray the different toxicological endpoints that are required for the different types of substances and different levels of production quantity. In both graphs, the Y-axis describes the required toxicological endpoints, in Figure 4, the X-axis represents the complexity of the substance and in Figure 5 the X-axis represents the tonnage bands. These are general guidelines and the European Chemical Agency (ECHA) can diverge from these guidelines and ask registrants for additional information. In general, more complex substances and substances produced in higher quantities have higher safety standards than simple substances produced in low quantities.

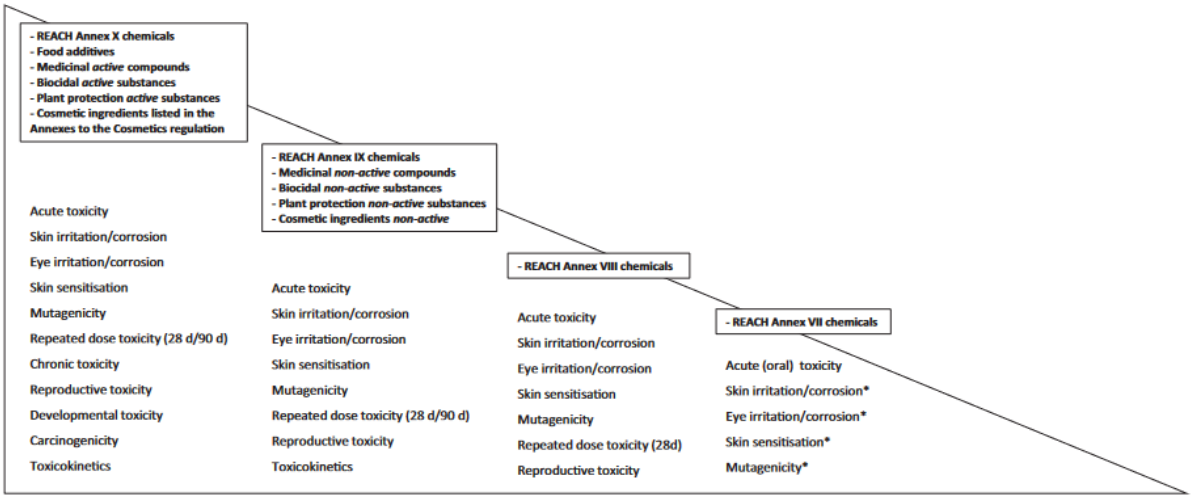


*Figure 4: Information required based on substance type* (Arnesdotter et al., 2021)

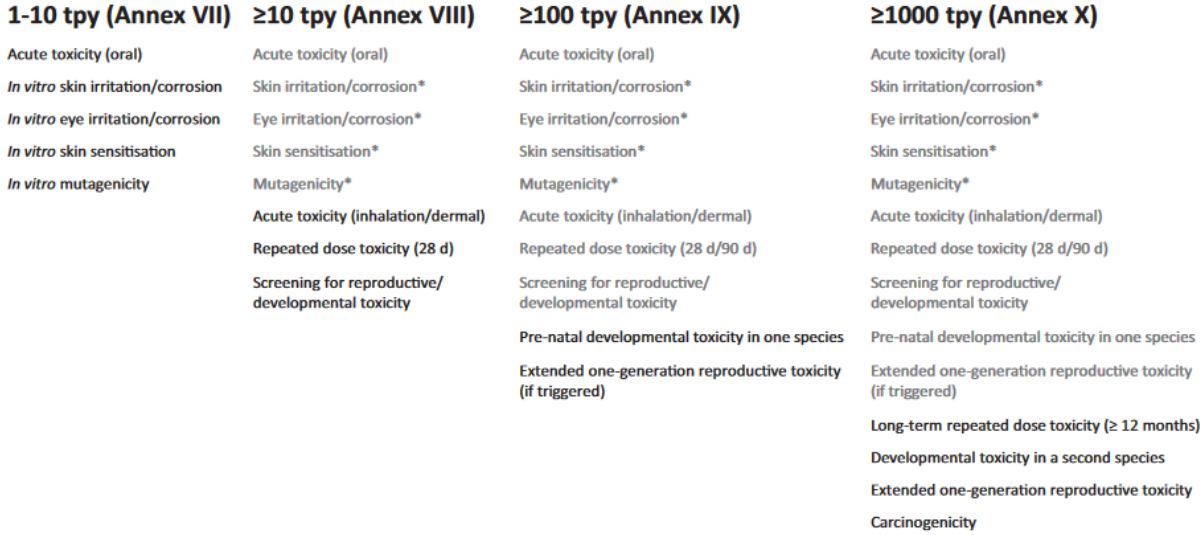


*Figure 5: Information required based on production quantity* (Arnesdotter et al., 2021)

The Scientific Committee on Consumer Safety is an organisation that supports companies by developing guidelines for safety assessments and advises the European Commission on issues regarding cosmetics (European Commission, n.d.). They have a large influence on the development of safe cosmetics but are not involved in enforcing the Cosmetics Regulation.

### 4.2.3 Behaviour modification

REACH is strictly regulated and dossiers are always reviewed before chemicals can be produced or imported in the EU. The whole process of applying for registration is a lengthy process, which incentivizes companies to have complete dossiers at registration because providing additional information can take months. REACH encourages registrants to use NAMs to provide safety

information, to share data with each other and only use animal tests when no alternatives are available. However, it does not prohibit the use of animal tests. (ECHA, n.d.-b)

Companies can self-register their products for the Cosmetics Regulation but competent authorities can check their dossiers and penalize them if they do not comply with the Cosmetics Regulation. The Cosmetics Regulation prohibits any cosmetic ingredient or product tested on animals to be produced or distributed in Europe. (Cosmetics Europe, n.d.)

## 4.3 Risk Regulation regime context

### 4.3.1 The technical nature of the risk

The risk being regulated is toxicity and is related to human health and the environment. Toxicity testing is performed to determine the negative effects that a substance can have on an organism in regard to different levels of exposure (Arnesdotter et al., 2021). The level can vary through different aspects such as the exposure route, the concentration of the substances and the duration of exposure. The wide range of toxicological endpoints indicates the complexity of managing the toxicity risk. Due to the complexity, regulation such as REACH and regulators such as ECHA are required to systematically ensure the safety of chemical substances as this would otherwise not happen so extensively.

### 4.3.2 The opinion of the public and the media

Chemical substance regulation are shaped by historical events such as the Thalidomide disaster (Paine, 2017). Generally, chemical substance risks are covered very little in the media as it is complex. This changes as a disaster happens and the media coverage is significantly increased (Quigley & Bisset, 2014). They cause the public to have less faith in the industry and to not trust them to take enough measures to ensure the safety of products. This lack of public faith leads to sharpening regulations and increasing the responsibility of regulators.

### 4.3.3 The way power is concentrated in organized groups

There are many organizations that have an interest in chemical substances and their safety. ECHA is responsible for classifying chemical substances as safe, which gives them a significant interest. Chemical producers lobby for as little testing as possible without compromising the safety as toxicity testing is expensive and time consuming. Lastly, there are several NGOs who have an interest in safety testing, where some lobby to keep animal testing as they believe it provides better results than NAMs and other lobby for more extensive use of NAMs.

## 4.4 Interaction REACH & Cosmetics Regulation

The interaction between REACH and the Cosmetics Regulation is heavily debated. The Cosmetics Regulation prohibits animal testing whereas REACH sometimes requires animal testing because NAMs are not able to provide enough reliable information on the safety of chemicals. In 2020, the ECHA board of appeal decided that the animal testing ban of the Cosmetic Regulation does not apply if workers may be exposed to a substance while producing or handling it, if the testing is required for environmental purposes or for non-cosmetic uses (ECHA, n.d.c).

# 5. Socio-technical Configuration Analysis

The results of the STCA provide insights into the structure of the actors in the socio-technical system and the arguments that they have used in the discourse. Groups of these arguments can be interpreted as the institutional logics that the actors adhere to. First, I present the emergence of the coding tree, in which the meaning of each code is explained and the choice for categories is elaborated upon. This helps to understand the interpretation of the networks. The results of the actual STCA are in three time periods. Each period is divided into four parts. First, some context of the period is provided to help understand what the main events, arguments and challenges were at that time. Second, the actor networks show which actors were active in the discourse during the time period and whether they have used similar arguments. Components are identified in each actor network to represent groups who use similar storylines. Third, the concept networks present which arguments were used in the discourse and the components in the concept networks represent the institutional logics. Lastly, the overall structure of the discourse links the previous parts together into a coherent storyline. In the interpretation a bar chart is presented for each logic, which actor group has supported that logic and how many times they have done so.

## 5.1 Coding tree

The codes are divided into high-level categories according to the subject they are about. The categories are the Animal Testing Regime, Barriers outside the EU, the Cosmetics Regulation, the Cosmetics Regime, the Medical Research Regime, the NAM niche and REACH. These categories emerged during the coding process and are based on the concepts of socio-technical regimes, niches and risk regulatory regimes. The regimes overlap to some degree as described in the conceptual model, so the codes were assigned to the regime or niche it most closely relates to but arguments can be made to have a code belong to another category. Each category contains low-level codes, which reflect the sentiment of what an actor has claimed in the data. The terms in brackets are medium-level codes, which were used to group low-level codes during the process. A full overview of the codes is also presented in Appendix I.

*Animal Testing Regime*

Codes in this category relate to arguments that are made in general about animal testing, it represents the codes regarding the old risk assessment regime. There are two subcategories; the first contains arguments about why animal tests are still being performed or should still be performed and the second contains arguments highlighting the flaws of animal testing. Apart from those two sub-categories, there are some general arguments in this category. These are a call for an European Citizens initiative to tighten the animal testing ban, a warning to include NAMs with new safety regulations as it will otherwise cause animal testing to increase again, an acknowledgement that the paradigm is shifting away from animal testing and the critical argument that technology is ready for the transition but that policy is still lacking.

*Table 2: low level codes of the Animal Testing Regime cate*

| **Low-level codes** | **Content** |
|---|---|
| (Acceptable) Already highly regulated | Animal tests is already being minimized with rules about when and how they can be used and therefore does not need to be banned |
| (Acceptable) As a last resort | We only use animal tests when there are no alternatives available |
| (Acceptable) For saving lives | Animal testing is allowed in research which may save lives of humans |
| (Acceptable)Required by law | We only use animal tests when the law requires us |
| (Flaws) AT is outdated | Animal testing is based on old principles which no longer hold true |
| (Flaws) AT's are not accurate | Animal tests are not accurate predictors for human responses |
| (Flaws) Cruel | Examples of how animals are treated in animal tests |
| (Flaws) Performed without reason | Animal tests are performed even without valid scientific reasons |

| | |
|---|---|
| Initiate ECI | A call for an EU citizens (ECI) initiative for a transition to animal-free science |
| New regulation will increase AT | Worried of newly introduced regulations which will require animal tests |
| Paradigm Shift | We see that scientists and companies no longer want to use animal tests |
| Policy behind technology | NAM technology is available but government policy hinders its implementation |

*Barriers outside EU*

This category contains all the statements made about situations occurring outside of the EU. The arguments about Brexit, Canada and the US were not specifically coded as there were very few and were mostly people calling for a ban in that country and what effect it would have. The China related codes are spread as opinions varied on the right strategy. There are defensive arguments that China tests on animals themselves so companies cannot stop that and that it is simply the law there to test on animals. Then there is the argument to not sell in China at all as a European cosmetics company so that China will change regulations to attract these companies. The other side is to operate in China (and thus do animal tests) and then try to exert influence on the government in that way. There are also actors already trying to implement NAMs in China. Lastly, there are actors calling for a global ban on animal testing for cosmetics and a supporting argument that the EU has a strong lobby with the market power they possess.

*Table 3: low level codes of the Outside EU category*

| **Low-level codes** | **Content** |
|---|---|
| Brexit | Speculating about effects of Brexit on the animal testing ban |
| Canada | Speculating about the introduction of an animal testing ban in Canada |
| (China) Change by boycott | Cosmetic companies should boycott China until they no longer request animal tests |
| (China) Change from inside | Cosmetic companies should operate in China and use influence to change the regulation |
| (China) independently tests on animals | China tests products on animals even if companies have safety assessments themselves |
| (China) Legally required | We only do animal tests because China requires it before being allowed to sell there |
| (China) Making progress | Positive statements about the progress in changing the animal testing requirements in China |
| (China) Trying to enter with alternative tests | We are trying to enter the Chinese cosmetics market with NAM data |
| Global ban | Calling for a global ban on cosmetic animal testing |
| Strong lobby | With all the European organisation, we have a strong lobby to implement animal testing ban in the world |
| US | Speculating about the introduction of an animal testing ban in the US |

*Cosmetics Ban*

This category contain arguments related specifically related to the animal testing ban of the Cosmetics regulation. We have protesting arguments that the Cosmetics regulation should not be allowed because it violates other regulations and that it will hinder innovation activities in the cosmetics sector. There are critical arguments that the industry and governments are delaying the ban, that there are too many loopholes to still do animal tests and that the surveillance needs to be improved after the ban became active. Lastly, there are some positive arguments that the animal testing ban initiated better practices in

the industry and that the Cosmetics regulation started discussions and processes in other sectors and other countries.

*Table 4: low level codes of the Cosmetics Ban category*

| **Low-level codes** | **Content** |
|---|---|
| Breaches other regulations | The animal testing ban cannot be implemented because it violates other regulations |
| Delayed by industry & gov | The industry and some governments are trying to delay the animal testing ban |
| Hinders innovation | The animal testing ban will reduce innovation in the cosmetics sector |
| Initiated industry practices | The animal testing ban has led to new practices in the industry |
| Interaction with endocrine disruptors | Expressing uncertainty about the animal testing ban and testing for endocrine disruptors |
| Need better surveillance | More surveillance on whether the animal testing ban is actually being implemented is required |
| Effect beyond cosmetics | The animal testing ban has effect in other sectors than just cosmetics |
| Effect beyond EU | The animal testing ban has effect outside of the EU |
| Too many loopholes | There are too many loopholes to get around the animal testing ban |

*Cosmetics regime*

This category contains arguments regarding the practices in the cosmetics industry. Most argument relate to the issues of the cosmetics industry. This include the fact that 'cruelty free' was a poorly defined concept, which led to some products still containing ingredients tested on animal even when it was labelled cruelty free. Additionally comments were made on the lack of transparency of industry actors. Cruelty free was promoted with the Leaping bunny trademark given out by NGOs to cruelty-free brands and the 'Save ralph' campaign, which featured celebrity voices in an animated commercial about test rabbits. There were also some defensive arguments, namely that it is easy to say that animal tests are cruel but much more difficult to explain that risk assessment is necessary to ensure consumer safety and that we simply need new cosmetic ingredients to keep innovating. The other side disagree with the latter and claim that consumer care more about the environmental impact of brands than the new products.

*Table 5: low level codes of the Cosmetics regime category*

| **Low-level codes** | **Content** |
|---|---|
| Cruelty free is not well defined | Consumers are not well informed about whether products were tested on animals |
| Difficult to defend risk assessment | It is difficult to explain why animal tests are needed and easy to claim that they are cruel |
| Industry is not transparent | Industry is not transparent about their use of animal tests |
| Innovation requires many ingredients | Cosmetic companies need new ingredients to create good new products |
| Leaping bunny trademark | A reference to how the Leaping bunny trademark contributes to promote cruelty-free products, which is given to brands which are cruelty-free |
| No cruelty for cosmetics | Animals should not suffer for beauty products of humans |
| No need for new ingredients | Cosmetic companies do not need new ingredients to create good new products |
| Safety and environment more important | It is noticed that consumers care more about a brands impact on environment and society |
| Save Ralph | A reference to the Save Ralph commercial, an animated commercial about a rabbit that lives in a testing facility which contained many celebrity voices |

*Medical research regime*

This category relates to arguments regarding the use of animal tests in medical research. There are two camps, one believing that it requires animal testing and the other believing that it is not required. The only substantial argument made was that most medical breakthroughs were made with the help of animal tests.

*Table 6: low level codes of the Medical Research regime category*

| **Low-level codes** | **Content** |
|---|---|
| Big breakthroughs happened with AT | Humanity have made very important discoveries based on animal tests and therefore we should keep using them |
| Does not require AT | We can have medical research without using animals |
| Requires AT | We need animal tests to do medical research |

*NAM niche*

This category is about argument regarding new NAM technologies. It is divided in three subcategories; better performance, development and implementation. According to proponents, NAMs are cheaper, faster, safer and can better predict human responses to substances than animal models. Regarding the development, there are a few issues namely that there is a lack of funding, that there is still much research to be done and that we need a better understanding of how to interpret the results. Positive arguments are the acceleration of development due to the animal testing ban, and the potential that NAMs have. Lastly, there is a general argument that actors support the development of NAMs. There are more difficulties with the implementation of NAMs. For example, it is difficult to get NAMs to be validated in risk assessment, there is uncertainty whether regulatory bodies will accept it in dossiers, there is a low willingness to change to NAMs, there are not enough NAMs, they cannot replace animal tests one to one and regulators are really needed to start accepting them, which is going slowly due to the bureaucratic processes. There are also some positive arguments regarding the implementation speed due to the COVID crisis and the first validated guidelines for NAMs in risk assessment. Lastly, there are actors who believe that there are many NAMs available already.

*Table 7: low level codes of the NAM niche category*

| **Low-level codes** | **Content** |
|---|---|
| (Better performance) Cheaper | NAMs are cheaper than animal tests |
| (Better performance) Faster | NAMs are faster than animal tests |
| (Better performance) More accurate | NAMs are more accurate than animal tests |
| (Better performance) Safer | NAMs are safer than animal tests |
| (Development) Ban accelerates development | The Cosmetics regulation will/has accelerated the development of NAMs |
| (Development) Lack of funding | There is not enough funding for the development of NAMs |
| (Development) More to do | There is still much research and development to do for NAMs |
| (Development) Need better understanding | We need a better understanding of how to interpret the results of NAMs |
| (Development) Potential | Acknowledgement of the potential of NAMs for risk assessment |
| (Development) Support development | A supportive statement of developing NAMs further |
| (Implementation) Difficult to validate | Complaining about the getting a NAM validated to be used in safety assessment |
| (Implementation) Faster implementation due to COVID | Implementing NAMs is speeding up due to the COVID pandemic |
| (Implementation) Increase regulatory acceptance | A call to regulators to put more effort into accepting NAM data in safety assessments |
| (Implementation) Legal uncertainty | Explaining that companies face uncertainty of their applications being rejected when using NAM data |

| | |
|---|---|
| (Implementation) Low willingness to change | Noticing that actors are not willing to change their ways |
| (Implementation) Need regulators | A call to regulators to do more with NAMs |
| (Implementation) No full replacement | NAMs cannot replace animal tests one to one, so a combination is needed |
| (Implementation) Not enough validated NAMs | There are not enough validated NAMs to do safety assessment |
| (Implementation) Slow due to bureaucracy | Complaint that the implementation of NAMs is going slowly due to the bureaucratic processes of regulators |
| (Implementation) Validated guideline | Pointing out a guideline for a validated NAM |
| Large availability NAMs | There are enough NAMs available but they are not being used |

*REACH*

This category contains arguments that relate specifically to REACH. The defensive argument state that REACH dossiers need to be extended for safety purposes, NAMs are already being implemented, that it is up to registrants to decide whether to use NAMs and that REACH safety requirements are more important than the animal testing ban of the Cosmetics regulations. The critical arguments claim that the interaction between REACH and the Cosmetics regulation is too vague, that REACH forces animal tests on substances that are already being used safely, that the 'last resort' principle is not enough incentive to actually use NAMs, that ECHA needs to be more strict in checking whether NAMs were considered in applications and that more transparency about the use of NAMs is required.

*Table 8: low level codes of the REACH category*

| **Low-level codes** | **Content** |
|---|---|
| Dossiers need improvement | REACH dossiers need to be extended to ensure safety of consumers |
| Forces unnecessary Ats | REACH forces animal tests on products that are already being safely used for a long time |
| Interaction REACH & CR too vague | Complaint that it is not clear how the Cosmetics regulation and REACH interact |
| 'Last resort' principle does not work | Complaint that the 'last resort' principle does not actually stimulate companies to use NAMs |
| NAM compliance ECHA | Belief that ECHA should check whether registrants have tried to use NAMs in the dossier |
| NAM compliance registrants | Belief that registrants are responsible for trying to use NAMs |
| NAMs extensively used | Pointing out that NAMs are being used in REACH dossiers |
| Need more transparency | A call that ECHA needs to be more transparent about how much NAMs are being used for REACH dossiers |
| REACH precedes CR | Belief that animal testing for REACH does not trigger the ban from the Cosmetics regulation |
| REACH should include as many non-animal tests as possible | A call to include NAM requirements when drafting REACH |

## 5.2 2000 – 2013: Initiation phase

The 2000-2013 period contains some important events starting with drafting the Cosmetics Regulation and ending with the final deadline of stopping animal tests. In 2003 the deadlines for the animal testing ban were agreed upon. This led to discussion in the public discourse about the Cosmetics Regulation. Several actors shared their opinion on how the regulation should be shaped and the impact it would have on the cosmetics industry in Europe and other parts of the world. In 2007, REACH was agreed upon and already had deadlines for 2010 and 2013, which started the discussion on how these regulations

should interact. It was noted early on that this regulation would require many animal tests, which caused discussion as it would directly oppose the new rules from the Cosmetics regulation. Lastly, the first part of the animal testing ban was put into force in 2009 and finally all animal testing for cosmetics was banned in 2013. From this point in time, no cosmetic products were allowed to be sold on the European market if the product or any ingredients had been tested on animals. A big challenge during this time was that some animal tests were banned while no valid NAMs existed. It remained unclear how companies should overcome this hurdle. In this period, 56 articles relevant articles were coded.

### 5.2.1 Actor networks

In the first time period, there is a wide range of actors active in the discourse. A full overview of all the actor codes can be found in Appendix I. Three different components are identified in figure 6 by looking at the links between nodes and the position in the graph. A group of closely located and well connected nodes is the starting point of identifying a component. The component is extended with other groups of nodes that are strongly linked to the component or individual nodes that are either connected by multiple links or very strong links. In this first graph, the industry component was identified as all the nodes have quite strong connections, the decision to exclude the *Seriously ill for medical Research group* was made as this node is better connected to the other component. The science component was identified in a similar fashion where nodes such as *Cosmetics Europe, Natural Resources Defence Council* and *European Parliament member* were excluded as they are further away and less connected to the rest of the component. The animal rights component has a less obvious centre and the boundaries are mainly decided by looking at the whole chain of connected nodes. Less well connected nodes such as *Cruelty Free International* and *National Anti-Vivisection society* were still included as the whole component is less well connected than the other components. *Lincolnshire Echo* was left out of both components as it seems to fulfil a bridge function and is not more strongly connected to one component or the other. Links with a Jaccard index value of 0.15 or lower were deleted from the networks to increase readability of the graphs. The links are scaled on colour and size; a thin and light yellow link has a low Jaccard index value and a thick red line has a high value.

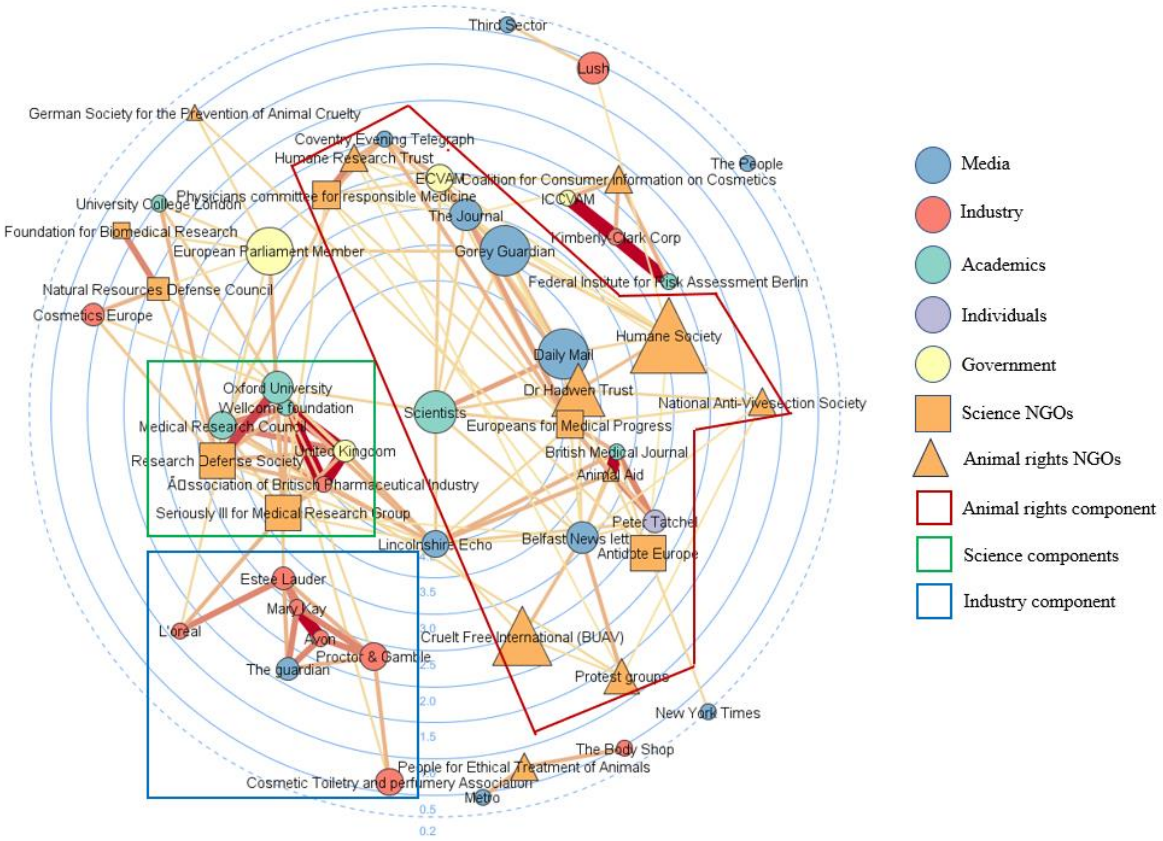

*Figure 6: Actor network 2000-2013*

*Industry component*
The industry component consists of the large cosmetic companies such as *L'oreal, Proctor & Gamble* and *Estee Lauder*. They have similar interests as the Cosmetics regulation would interfere with their daily business. The industry component is very well connected (relatively dark red and thick lines), which indicates that they used similar arguments in the discourse. *The Guardian* is also in this component as it provided a platform for the industry to present their arguments.

*Science component*
The science component comprises of actors from different groups but share the interest of protecting science. NGO's such as the *Research Defence Council* and academic actors such as *Oxford university* do not oppose banning the use of animal testing in cosmetic testing but do not want the ban to extend into scientific research as they are still dependent on animal tests.

*Animal rights component*
The biggest component in the graph is the animal rights component. In these components are the *Humane Society, Dr. Hadwen Trust* and *Cruelty Free International* (British Union for the Abolition of Vivesection at that time, which are the largest nodes in the network and therefore the most active in the discourse. They are joined by other smaller NGOs which have the goal of stopping animal testing. This component also contains most of the news outlets, which makes sense as they report on the developments regarding the Cosmetics Regulation. This includes arguments made by the NGOs lobbying for the animal testing ban and the opinion of the general public regarding animal tests for cosmetic products. *ECVAM* is making efforts to further develop and implement NAMs and therefore also belongs in this component. Lastly, unnamed scientist are at the centre of the graph but mostly connected to this component, being cited by news outlets when they wish to convey the general consensus of the scientific community.

*Other actors*
*Members of European Parliament* were also active in this time period. These were the members that proposed the animal testing ban. As can be seen from the graph, they are not very well connected indicating that they mostly have their own argumentation and do not really use the same arguments as the other groups. At the bottom of the graph is separate group consisting of *the People for the Ethical Treatment of Animals (PETA), Metro* and *the Body Shop*. This seems to fit in with the animal rights component as PETA is an animal rights NGO and the Body Shop was one of the first companies to promote cruelty free beauty but are not connected to the component with any links. In addition, the *Lincolnshire Echo* seems to be an intermediary, acting as a bridge between the animal rights component and the science component. This news outlet has tried to present different sides of the arguments in the discourse during this time. A similar argument can be made for *Seriously ill for Medical Research Group* as an intermediary between the science and industry group. This makes sense as it is an NGO pleading for medical research, including animal tests, into disabling and progressive diseases but also plead for strict requirements for reducing the number of animals used.

*General*
Overall, this time period is dominated by NGOs, which is depicted in the figure 7 below. Where academics, government and industry appear at a similar rate in the discourse, NGOs make up almost half of all the statements being made. This makes sense as we NGOs want to generate as much attention to the problem as they can. Media appearances influence the public opinion, which in turn helps strengthen the lobby position of the NGOs.
In terms of components, the science and industry component seem to be more internally coherent in their argumentation, which lead to their close proximity and darker and thicker links. The animal rights component is much more dispersed and has lighter and thinner links. It is interesting to see that some of the major NGOs in this period are not very well connected to each other, which indicates that they do share the same storyline in their lobbying activities where as the industry has a much more united front in their storyline.

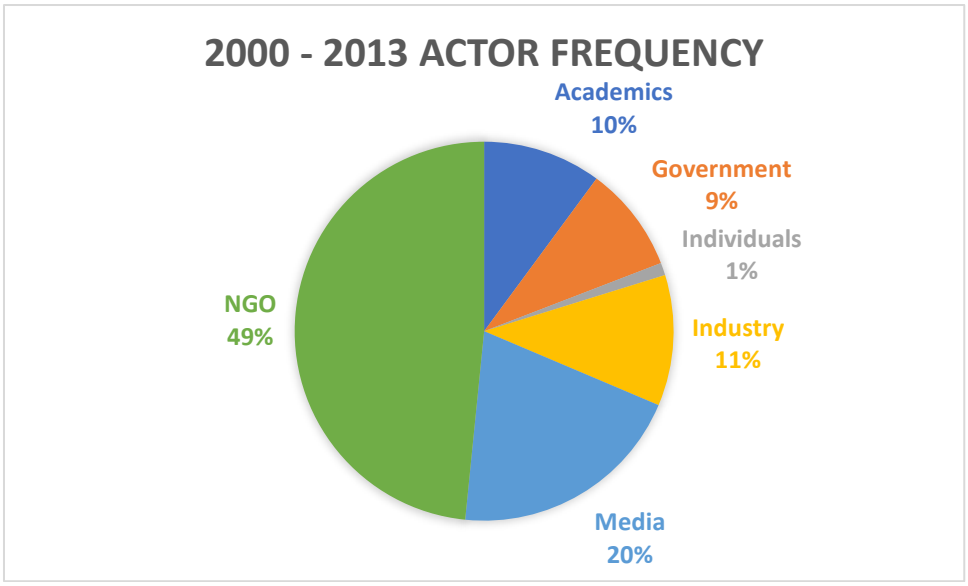


*Figure 7: Actor frequency 2000-2013*

### 5.2.2 Concept networks

The actor networks provide an overview of the core structure of the discourse but cannot show the actual arguments used in the discourse. The storylines are visualized through the concept networks, which are represented in Figure 8. Components were identified in a similar fashion as those in the actor network. In this network, links with a Jaccard index value of 0.15 or lower were removed from the graph to increase readability.

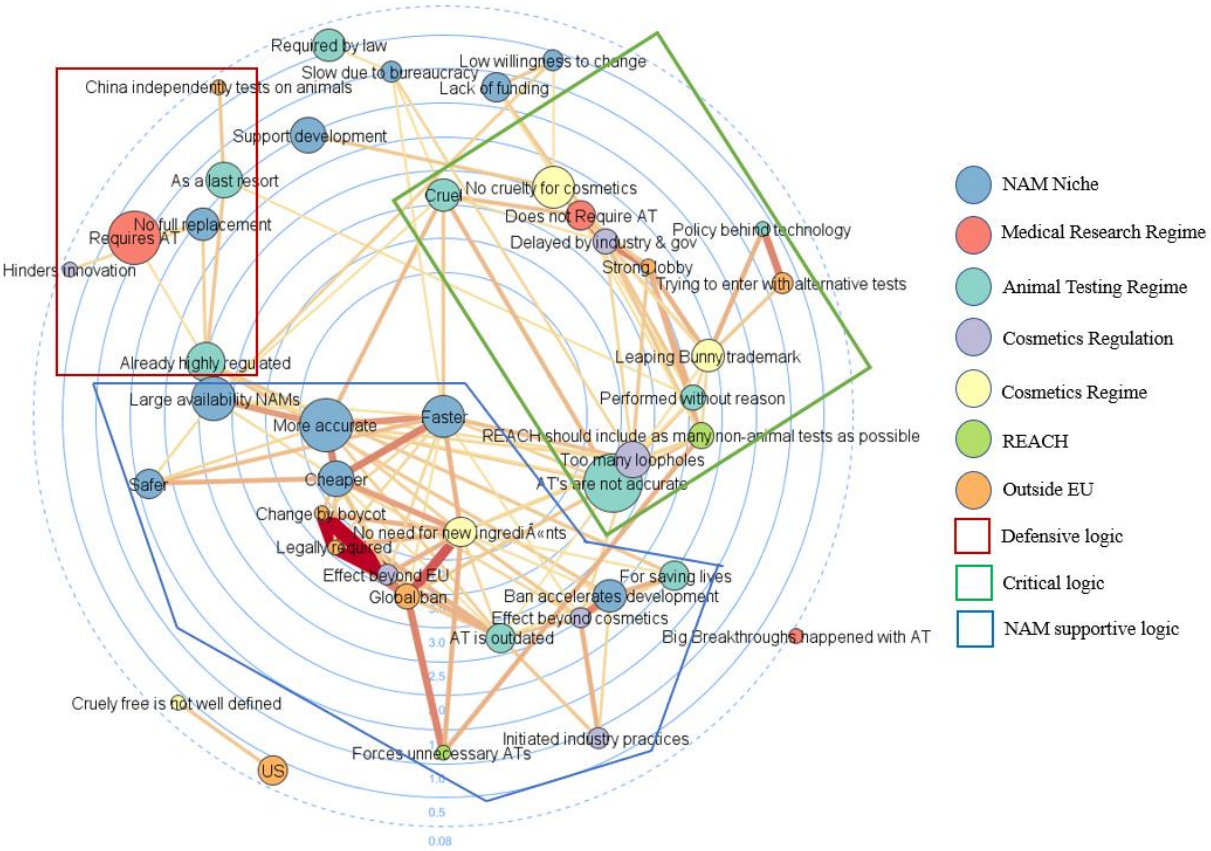


*Figure 8: Concept network 2000-2013*

*Defensive logic*
The defensive logic consists of arguments why animal tests are still being performed. Actors claim that animal testing is already highly regulated and that they only test on animals when there are no other options available. Already in this period the issue arises that China still tests cosmetic products on animals if companies want to sell their products in China. Actors adhering to this logic believe that NAMs cannot fully replace animal testing. Lastly, the largest node in this component is *Requires AT,* which represents one of the most common arguments in this time that medical research requires animal testing to make significant discoveries. This is interesting as medical research was being defended even when the proposed animal testing ban only included cosmetic products and ingredients. The graph indicates that this is a relatively weak component with few nodes, which have few and not so strong connections. This means that, at least in the public discourse, actors seemed not to see the animal testing ban as a major threat.

*Critical logic*
This critical logic is mainly about the shortcomings of animal testing and removing it from the cosmetics industry. *The AT's are not accurate* node is the largest in this component, which is the most important argument in this logic. Animal tests never had to be validated as the NAMs now have to be and according to the actors adhering to this logic, animal tests are not even good predictors for how humans will respond to certain products or ingredients. In addition, animal tests often do not have valid reasoning for the use of animals. Actors adhering to this logic are very critical of the development of both the Cosmetics regulation and REACH. The Cosmetics Regulation is being delayed by industry and government and still has too many loopholes that will allow animal testing and REACH does not include enough requirements and guidelines regarding NAMs. Actors adhering to this logic oppose arguments from the defensive logic saying that even medical research does not require animal testing. Actors of the critical logic use positive arguments by mentioning the Leaping bunny trademark, which is awarded to cosmetic brand that are cruelty free. They also argue from the other side by claiming that animals should not suffer for vain products such as cosmetics. Internationally they argue for trying to use NAMs for safety testing in China and building a strong lobby campaign. Lastly there is a small node that already identifies policy as the bottleneck in the transition and not the available technology.

*NAM supportive logic*
The NAM supportive logic focuses largely on the positive aspects of NAMs. According to the actors adhering to this logic, NAMs are widely available, more accurate, faster, cheaper and safer than animal testing. Because of this superior performance they also call for a global ban on animal testing and support this by claiming that the cosmetics industry does not need new ingredients to innovate. They point out that the Cosmetics regulation has initiated new practices in the industry, accelerated the development of NAMs and argue that the Cosmetics regulation has impact outside of the EU and outside of the cosmetics industry. Actors adhering to this want to boycott countries that require animal testing. This contrasts with the critical logic, who think it is better to co-operate and try to implement NAMs in these countries. They also have some critical notes as they think animal testing in general is outdated and that REACH will force animal tests that are unnecessary, for example on substances which have been safely used for years but will now require new safety tests. Lastly, there are some actors who adhere to this logic that also nuance the storyline and state that animal tests may be performed when it could help save human lives.

*Other arguments*
In the top of the graph are some components which were left out of the components. Most of these arguments represent explanation of why the development and implementation of NAMs is moving slowly. These arguments are closest to the critical logic but due to few links to the rest of the logic, I have decided to leave them out.

*General*
The NAM supportive logic is the most coherent and prevalent logic. The strong connection between the nodes about the superior performance of NAMs are often used together to create a strong argument of

why they should replace animal testing. Besides this, the NAM supportive logic and critical logic are quite well connected to each other. This makes sense as the arguments in both logics lead to the same goal of stopping animal testing. One group focuses on breaking down the old system whereas the other group focuses on building up the new system.

### 5.2.3 Structure of the discourse

The 2000-2013 period is a chaotic period in which many different actors are active in the public discussion. The NAM supportive logic and critical of animal tests logic are mainly supported by the NGO's, Government and news outlets as can be seen in Figure 9. The NGO's, with Cruelty Free International and Humane Society as frontrunners participated in very powerful lobby activities and really led the path towards the Cosmetics Regulation. In this period only the Body Shop and Lush actively supported the NAM transition from the side of industry.

The defensive logic is supported mostly by academics, industry and NGOs. The Cosmetics Regulation was the first regulation to completely ban animal testing and opened a broad discussion on animal test. Part of the discussion was on whether the use of animals in medical research and experiments should also be banned. This explains the involvement of many academic actors as they defend their use of animals, which was criticised by animal-welfare NGO's. It also explains the support of NGOs as these are likely the NGOs which are in the science component of the actor network. It is important to note that even though most industry actors defend animal testing, they also support NAM development, which indicates they did think a transition was imminent but were holding it off as long as possible.

In this period the discussion is very broad and arguments are often based on the fundamental idea of animal testing and NAMs. There are three basic ideas regarding animal testing: it should not be used in any circumstance, it should be used but only in very specific circumstances and it should be used whenever needed. Under which circumstances animal tests can be used seems to be the more practical side of the discussion. In this period there are very few who actively oppose the animal testing ban for cosmetics but issues are pointed out in regard to what this means for producers. They worry that they can no longer introduce new substances as NAMs have not fully replaced the animal tests. On the other side, worries about delays in the animal testing ban and the effect that REACH is going to have as its goals are not aligned with the Cosmetics Regulation.

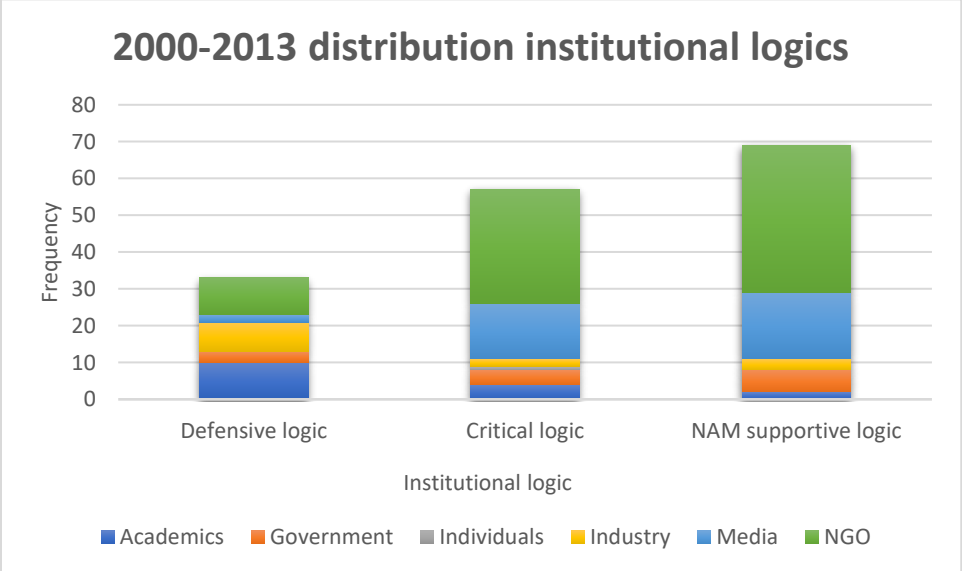


*Figure 9: Distribution institutional logics per actor group 2000-2013*

## 5.3 2014 – 2019: Implementation phase

In 2013, the Cosmetics Regulation was fully implemented, meaning that no cosmetic ingredients or products that had been tested on animals could be produced or sold in the EU. REACH also had a deadline in 2013 for the 100 – 1000 tonnes/year substances and a deadline in 2018 for the 1-100 tonnes/year substances. The main challenges in this period concerned the interaction of the Cosmetics Regulation with other regulations and requirements. For example, if a chemical substance only intended for cosmetic use is tested on animals to comply with REACH, can it be used in products sold in Europe? And does it change when the chemical substance is intended for a multitude of uses? In addition, issues regarding different countries arose as well. China demanded animal testing so if a company wanted to sell cosmetics in China, should it be prohibited to sell these products in Europe? This was the period where the actual practical issues of the animal testing became apparent and had to be dealt with. In this period, 60 relevant articles were coded.

### 5.3.1 Actor networks

Figure 10 represents the actor network for the time period 2014-2019. We can already see that there are significantly fewer actors active during this time period and that only two components can be identified in this time period. Part of decrease can be explained by the merging of organisations and another part is simply that some organisations lost interest as the ban was successfully implement. However, the number of statements increased, indicating a more active discussion between the remaining actors. To increase readability, links with a Jaccard index value of 0.15 or lower were removed from the graph.

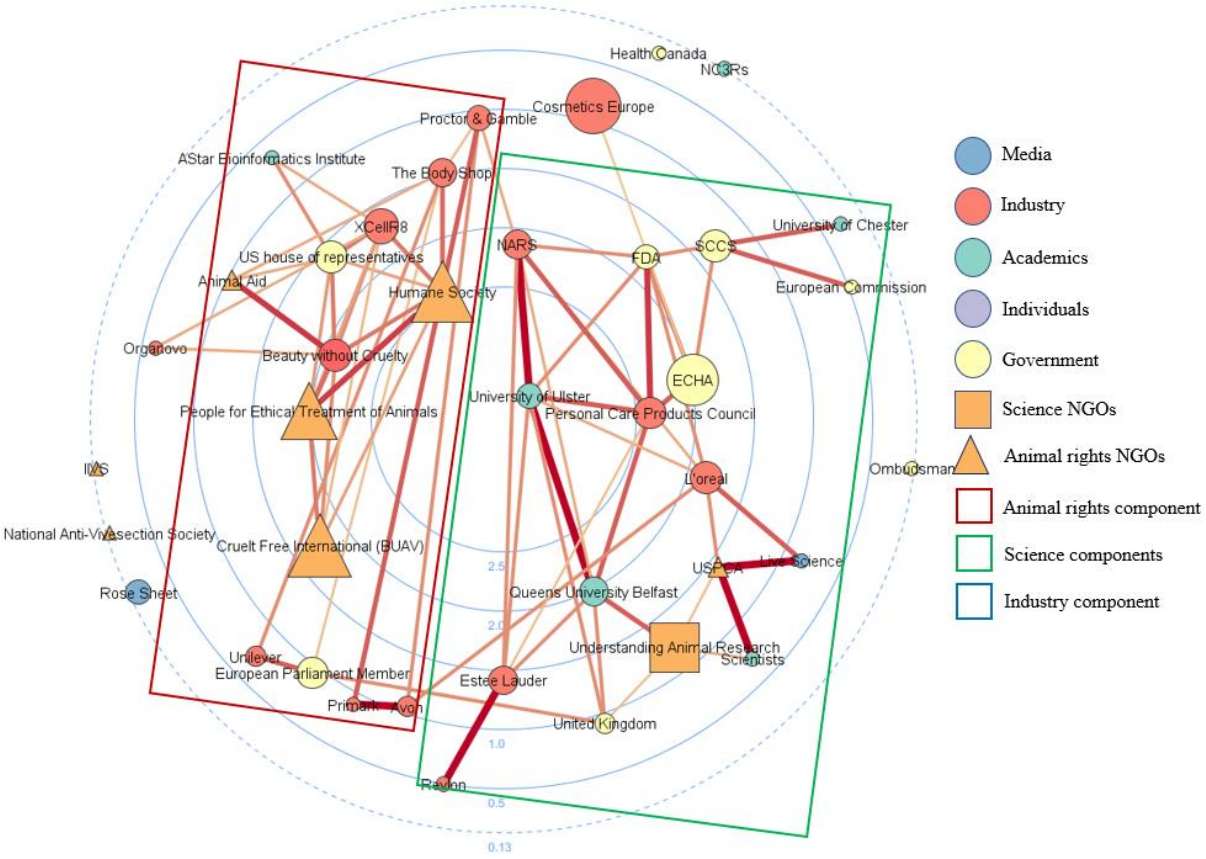


*Figure 10: Actor network 2014-2019*

*Animal rights component*

The animal rights component mainly consists of three very active animal rights NGO's. They are joined by the industry actors *Beauty without Cruelty* and *The Body Shop*, which have aligned interests as they promote cruelty free cosmetics. *XCellR8* and *Organovo* (just outside the component) are companies that develop NAMs based on human skin cells, therefore also contributing to less animal testing. More on

the outside of the network but still relatively well connected are some of the larger cosmetic companies such as *Proctor & Gamble*, *Unilever*, *Primark* and *Avon*, which seem to have also started to shift to a cruelty free perspective. The component is much more well connected than in the previous time period, indicating the alignment of strategies between these organisations. This component can be characterised as new risk assessment regime.

*Science-regulator component*
In 2014-2019, *the science component* from the previous period has adopted part of the industry component with companies such as *L'Oréal*, *Estee Lauder*, *NARS*, *Revlon* and *the Personal Care Products Council*. This component still contains all the universities which were active in the discourse. Most of these actors would benefit from being able to perform animal tests even though the industry actors no longer can while universities still can under certain conditions. In addition, the regulatory bodies such as *SCCS*, *FDA* and *ECHA* are present in this component together with NGOs who want to protect good science even if that means using animal tests, thereby transforming this component into the *science-regulator*. The regulatory bodies are responsible for the safety of products entering the markets and can be held accountable if something goes wrong with a substance or product after they have judged it as safe. Therefore these regulatory bodies are risk-averse and prioritize safety over animal welfare. This component can be characterised as actors from the old risk assessment regime.

*Other actors*
*Cosmetics Europe* is quite a large node but is not well connected to the rest of the actors. It shares thin links with *the science-regulator component* but is significantly less well connected than the rest of the component is to each other. As a trade association, *Cosmetics Europe* might have a different approach than individual companies as they represent most of the industry actors in the sector and therefore spend more time and effort into carefully formulating their stance. In the bottom left of the graph is *Rose Sheet*, this is a news outlet that came up during this period that specifically aimed at reporting on the Life Science industry.

*General*
Overall, we see a decrease in number of actors active in the discourse. A lot of the smaller NGOs have disappeared from the discourse due to merging of several NGOs or losing interest as animal cruelty was not their main goal. The links between PETA, CFI and Humane Society have become stronger, indicating that their storylines are becoming more aligned. Furthermore, the network has become less chaotic and the links have become stronger in general. The distribution of actors has also changed as can be seen in Figure 11. NGOs still make up a large part of the discourse but industry and government have an increased presence while the media is less active in the discourse. This can be explained by the method of coding where media is only coded separately if a view is presented without a direct source. In this time period, media based their stories more on specific views from other actors and are therefore less represented in the graph.

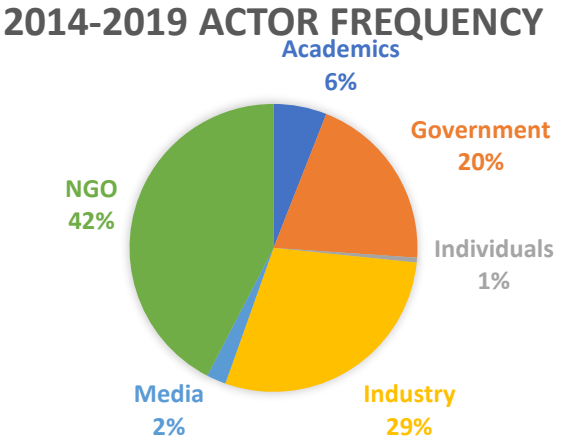

*Figure 11: Actor frequency 2014-2019*

### 5.3.2 Concept networks

We now know how the actor configuration changed but not how their arguments changed in 2014-2019. This is visualised through the concept networks in Figure 12. For readability purposes, links with a Jaccard index value of 0.15 or lower were removed from the graph.

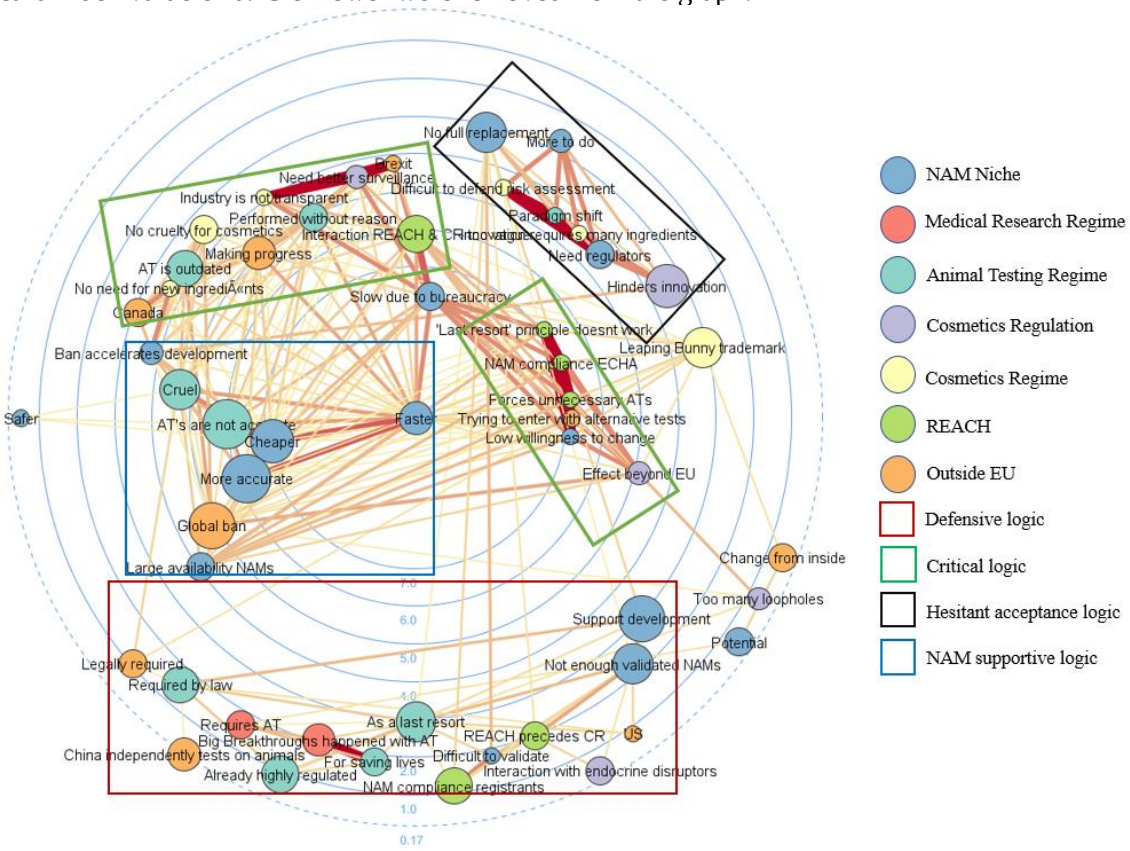


*Figure 12: Concept network 2014-2019*

*Defensive logic*

The defensive logic component has grown substantially in 2014-2019 as opposed to 2000-2013, but still also has the same core arguments. Actors who adhere to this logic still support the development of NAMs but argue that there are not enough at the time. This is caused by issues with validating new NAMs. They do not want to perform animal tests but still do so as a last resort or because it is required for REACH or for products that are sold in China. They believe REACH requirements precedes Cosmetics Regulation requirements and think that it is up to the registrants to choose whether they want to use NAMs to comply with REACH. The argument that animals tests should be allowed if it is for saving lives is new in this logic. There are still some arguments made about why animal testing is still needed in medical research, which is supported by the argument that animal testing has provided us with major breakthroughs in science but already less than in the previous time period. The defensive logic has very few and weak links between the nodes, which indicates that the storyline is not very coherent.

*NAM supportive logic*

The NAM supportive logic is almost identical to the 2000-2013 period. With regard to the performance of NAMs safety is mentioned a lot less and not together with the other performance traits. Actors adhering to this logic still call for a global ban on animal testing for cosmetics. In addition, these actors have changed their strategy slightly by focusing more on the contrast of NAMs with current practices. By combining the positive aspects of NAMs with examples of the cruelties that animals endure during

testing and the disappointing predictive capabilities of these tests, the actors aim to improve the view of the public on NAMs even more.

*Critical logic*
I have split the critical logic into two parts. The critical component in the right side of the graph is very strongly connected but has very small nodes. This means that these arguments were not used often but always together. The arguments are mostly critical of REACH and the way that it is being regulated. Actors adhering to this logic point out the 'last resort' principle, which states that REACH registrants should only use animal tests as a last resort, does not work as ECHA does not check this well enough. According to these actors this leads to unnecessary animal tests and they believe ECHA should be more active in enforcing and guiding registrants with this principle.

The component on the left side of the graph is also critical of REACH and point out that it is not clear how REACH and the Cosmetics Regulation interact and when animal testing is allowed and when it is not. Actors adhering to this logic further criticise the regulators and industry by claiming that the Cosmetics Regulation is not being monitored properly and industry is not transparent. This has led to products still being on the market even when they have been tested on animals or contain ingredients that have been tested on animals. These actors believe animal tests are outdated and being performed without proper reason. Lastly, these actors talk about progress being made with animal testing bans in Canada and China but fear the effect that Brexit will have on the regulations in the United Kingdom.

*Hesitant acceptance logic*
The hesitant acceptance logic is new in this time period but seems to be a bridging attempt between the critical logic and the defensive logic. Actors adhering to this logic are still defensive in the sense that they maintain that new ingredients are required. They also point out the problem that NAMs do not fully replace animal tests and that there is still more development required. But they also point out that the regulators are slowing down the process as they make validating NAMs difficult. This indicates that these actors are actively working on developing NAMs but are held back by the regulators. Lastly, these actors recognize that a paradigm shift has started and things are changing.

*General*
The NAM supportive logic and critical logic are centrally located in the graph and are pretty well connected to each other whereas the hesitant acceptance logic and the defensive logic are more on the outside of the graph and have very few connections to the other components. The hesitant acceptance logic seems to be a bridge between the defensive logic and the critical logic. This becomes more apparent in Figure 13 where a stress minimization layout is used, which no longer plots the nodes based on their degree. The stress minimization lay-out also shows that The critical and NAM supportive logic are even more connected than in the 2000-2013 period, indicating an integration or collaboration between these lobby groups.

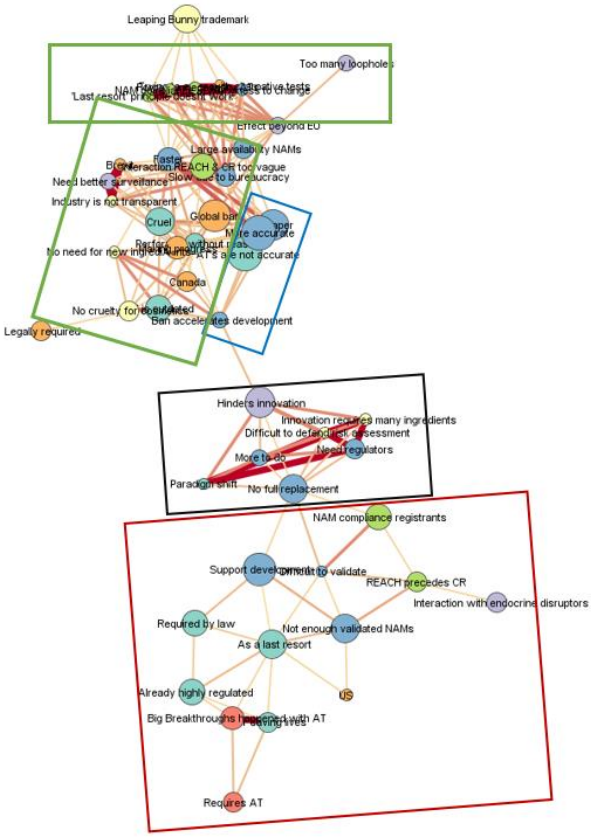


*Figure 13: Concept network 2014-2019 stress minimization lay-out*

### 5.3.3 Structure of the discourse
In 2014-2019, less actors were active but more concepts emerged, which makes sense as the previous topics remained and new topics such as the interaction between REACH and the Cosmetics regulation

emerged. The critical logic and NAM support logic are still dominated by the NGOs, as can be seen in Figure 14. Their goal is to increase animal welfare and this can be seen in how they are represented in the discourse. It is interesting to see that industry is almost evenly divided in the NAM support logic, the hesitant acceptance logic and defensive logic. Companies such as the Body Shop represent the NAM support logic as they have supported cruelty free beauty since the beginning but there are now also larger companies which start to embrace the transition. Companies such as Unilever, Proctor & Gamble and Primark have worked on developing NAMs and now encounter problem with validating the NAMs and using them to assess the safety of their products. This supports the idea that the hesitant acceptance logic is a bridging attempt from industry players to leave the old risk assessment regime.

The defensive logic is still supported by other industry players but has an increased share of actors adhering to this logic, which supports the idea that industry actors are moving away from this logic. This is explained by the regulatory bodies who became more active in the discourse and their risk-averse nature. They will only accept the use of NAMs unless it is validated that they can provide them with the same information as the current animal tests, thereby upholding the old risk assessment regime and creating barriers for the new risk assessment regime.

In this period we see the discussion shift towards more practical issues, especially regarding REACH. The question who should be responsible for using NAMs under REACH is contested as some believe it is up to the registrants while others believe that ECHA should take responsibility. In addition, the interaction between REACH and the Cosmetics Regulation divides actors in the field. For NAMs, the practical issues regarding validation and actually using them in safety assessment start to emerge. Actors call for more guidance from regulators and claim that the validation process is too difficult.

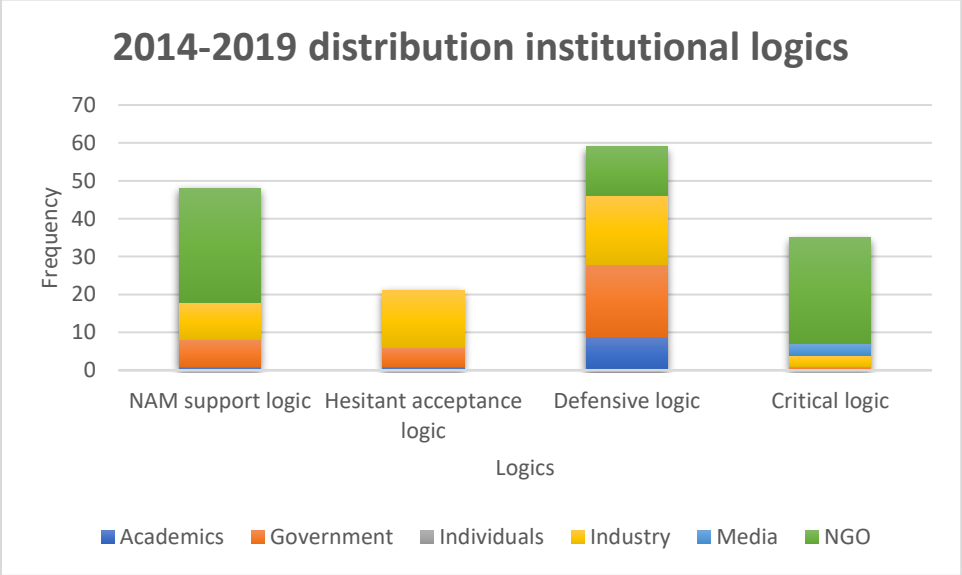


*Figure 14: Distribution institutional logics per actor group 2014-2019*

## 5.4 2020 - 2023: Cooling phase

In 2020, the ECHA board of appeal made a decision in the case of Symrise that required them to conduct additional animal tests for ingredients with only cosmetic purposes that had been used in products for years. This caused several NGOs, companies and other actors to speak out against this decision. Meanwhile, progress was being made in the US and China but these developments were much less covered than the Symrise case. In this period, 38 relevant articles were coded.

### 5.4.1 Actor networks

Figure 15 shows the actor network of the 2020-2023 network. The number of actors is similar to the 2014-2019 period and there are still two components that can be identified. For readability purposes, all links with a Jaccard index value equal or lower than 0.15 were removed from the graph.

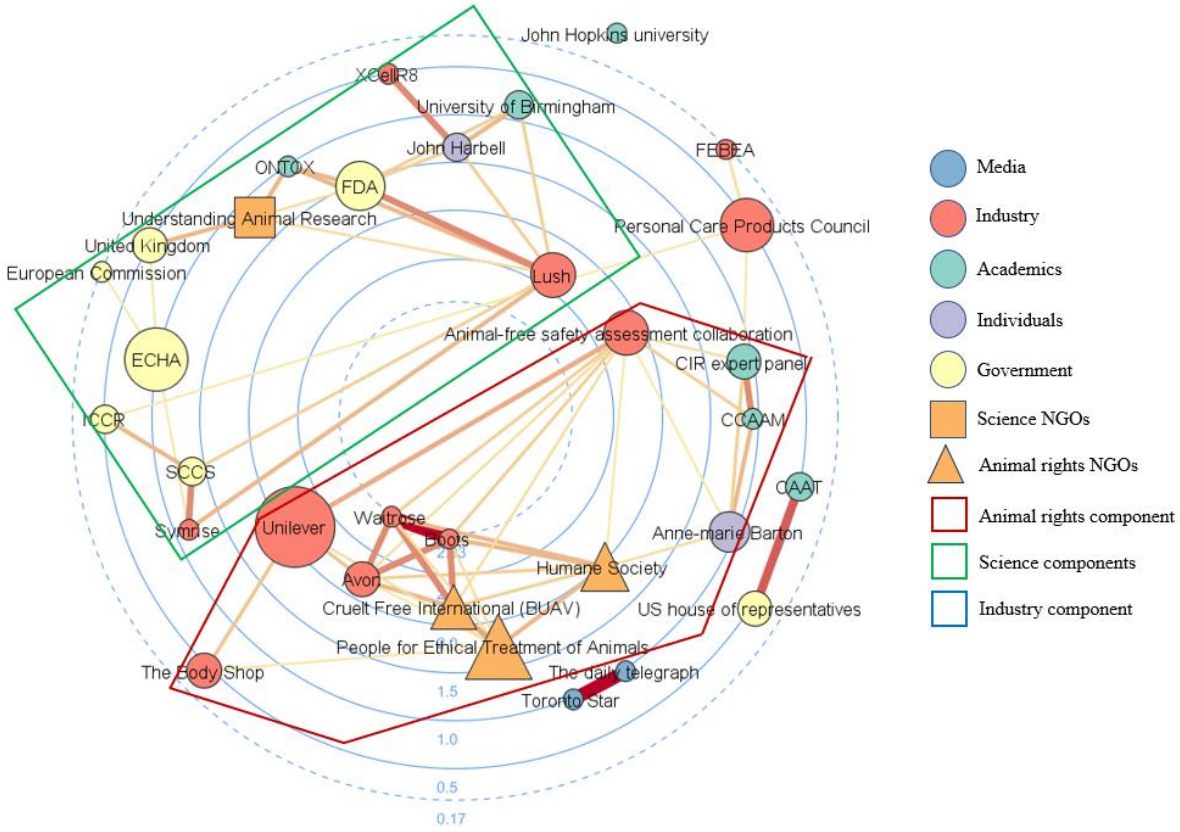


*Figure 15: Actor network 2020-2023*

*Animal rights component*

The three large NGOs that campaign for animal welfare are still at the centre of the animal rights components. For the industry, *Animal-free safety assessment collaboration* is a newcomer to the discourse. In addition, we see a large increase of the activity by *Unilever*. *Unilever* responded to the Symrise decision made by the ECHA board of appeals by calling for more explanation why these new animal tests should be conducted and by calling to uphold the animal testing ban. Other newcomers to this component are *Anne-Marie Barton* who started a personal protest campaign against animal cruelty, *the CIR expert panel*, which makes decisions for specific cosmetic ingredients and *CCAAM* who support the development and implementation of NAMs.

*Science-regulator component*

The *Science-regulator component* had no fundamental changes but it does contain some interesting connections. *ECHA* and *Symrise* are actually connected and in the same component, which is strange as they directly oppose each other in the appeal case. Additionally, *Lush* is connected to almost all nodes in this component, somehow being connected to actors whom one would not expect to be connected.

*General*
In general, we see that that industry actors have become much more active in the discourse, which is partly as a response to the Symrise appeal decision. Figure 16 shows that industry makes up 38% of the discourse, overtaking NGOs which have the same amount of activity as government actors with 23%. This is partly explained by the ECHA board of appeal decision on the Symrise case, which led to industry actors speaking out.

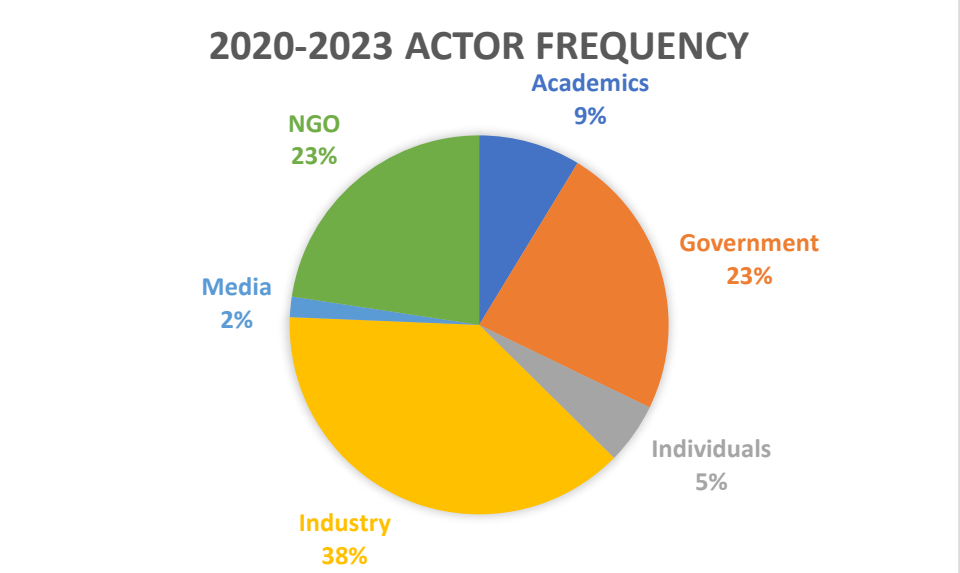

*Figure 16: Actor frequency 2020-2023*

### 5.4.2 Concept networks
The actor networks remained quite similar to the previous period, but some of the storylines have changed. This is represented in the concept network in Figure 17. For readability purposes, links with a Jaccard index value of 0.15 or lower were removed from the graph.

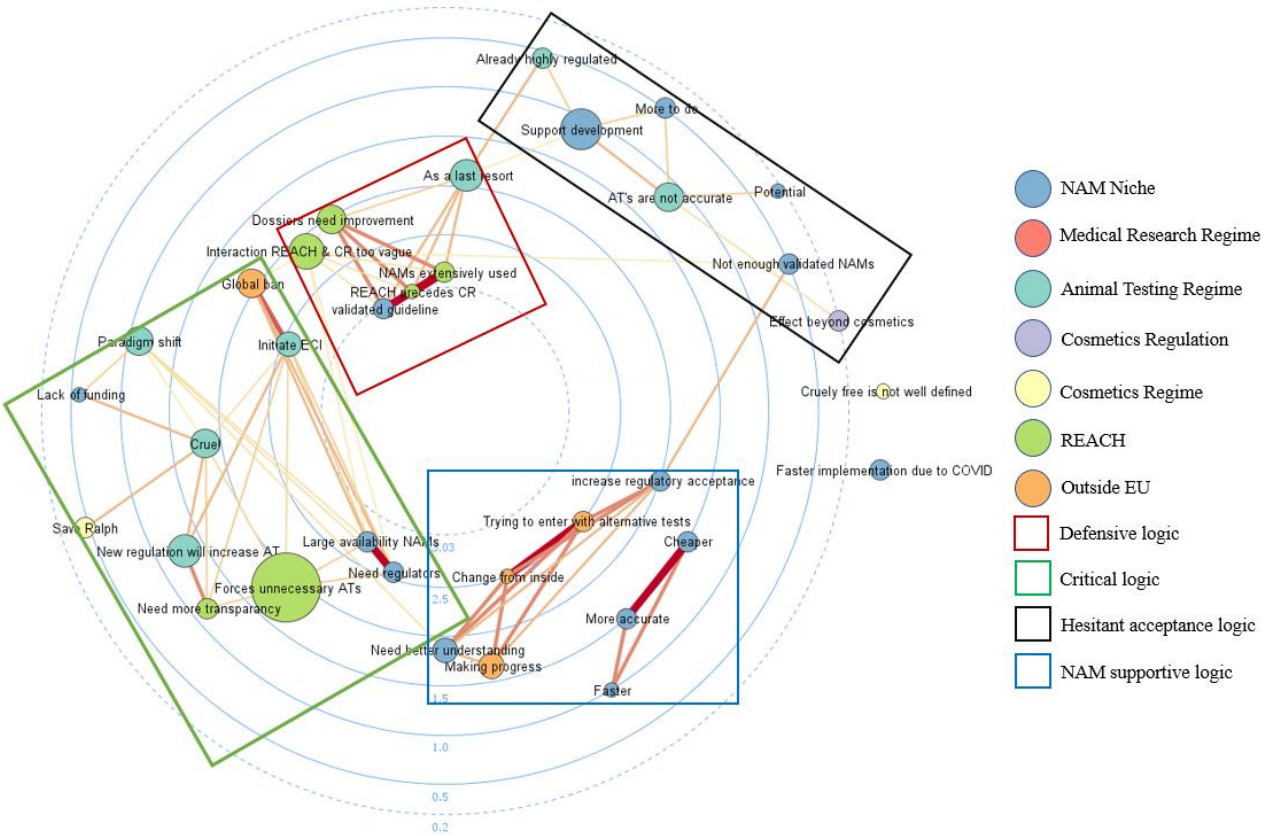


*Figure 17: Concept network 2020-2023*

*NAM supportive logic*

The NAM supportive logic has not changed much again. The arguments about superior performance are still used with the exception of safer but are no longer connected to the other arguments. Actors adhering to this logic are still positive about making progress in China and implementing NAMs there. However, they also recognize that the regulatory acceptance of NAMs is still lagging and want to stimulate the knowledge on how to interpret NAM data with regulators as they struggle to accept NAM data as a replacement for animal testing data.

*Critical logic*

The largest node in the critical logic is that REACH forces unnecessary animal tests. This is a response to decisions made by the board of appeal of ECHA deciding that animal tests in the context of worker safety do no trigger the animal testing ban and the decision in the Symrise case. Actors adhering to this logic believe a paradigm shift is in the works but that policy and regulators are falling behind. There are many NAMs available but new and old regulations force too many animal tests without proper reason. These actors refer to the "Save Ralph" commercial published in 2021 where they show the cruel reality of test rabbits in an animated video. Lastly, actors adhering to this logic call for a global ban on animal testing and want to start an European Citizens Initiative in which they call for strengthening the animal testing ban.

*Defensive logic*

The defensive logic is mostly related to REACH. Actors adhering to this logic argue that there are already validated guidelines for using NAMs under REACH, that animal tests are only used as a last resort and that NAMs are already being used in REACH applications. They claim that REACH dossiers need to be improved for the safety of humans and this overshadows the animal testing ban of the Cosmetics Regulation. Lastly, these actors argue for that the interaction between REACH and the Cosmetics Regulation is vague, which would fit better with the critical logic. However, this argument is

much less connected to the logic than the other arguments, indicating that the arguments do not occur together as much.

*Hesitant acceptance logic*
The hesitant acceptance logic is similar to the previous period but seems to be less well connected indicating an incoherent storyline. Actors adhering to this logic argue both sides, so they believe animal tests are not very good predictors for human responses and support the development of NAMs. But they also note that there is still much to be done for NAMs to fully implement them and that there are currently not enough of them available. In addition, they think animal tests are already regulated strictly and that animal tests can continue under these condition as long as the NAMs are not validated.

*General*
The logics are more separated than previous periods, only being connected with few links. This means that the storylines no longer overlap and that actor groups have dedicated to one logic more than previous periods where the logics were more connected. This could be interpreted as a hurdle in the transition as actors adhering to different logics have no shared interests or opinion. Collaboration between such actors is less likely, causing somewhat of a stalemate in the sector.

### 5.4.3 Structure of the discourse

In the 2020-2023 period, we see the discussion shift mostly to practical issues. Interestingly, we see almost no arguments related to the Cosmetics regulation anymore. Almost all issues are related to REACH. Industry has had time to develop NAMs and are ready to use them but are running into obstacles presented by ECHA. This is represented in Figure 18, which shows the NAM supportive logic and critical logic are often supported by industry actors. The NGOs are mainly critical but interestingly more than half of the actors adhering to the defensive logic are now government actors, which still represent the old risk assessment regime.

It is difficult to accurately interpret what is going on at this point in time. On the one hand, the industry seems to have fully embraced the transition, which indicates an acceleration as more actors are willing to use NAMs for their safety assessment. On the other hand, the decision in the Symrise appeal signals a reinforcement of the old risk assessment regime and a significant barrier in implementing NAMs, which means the transition is slowing down.

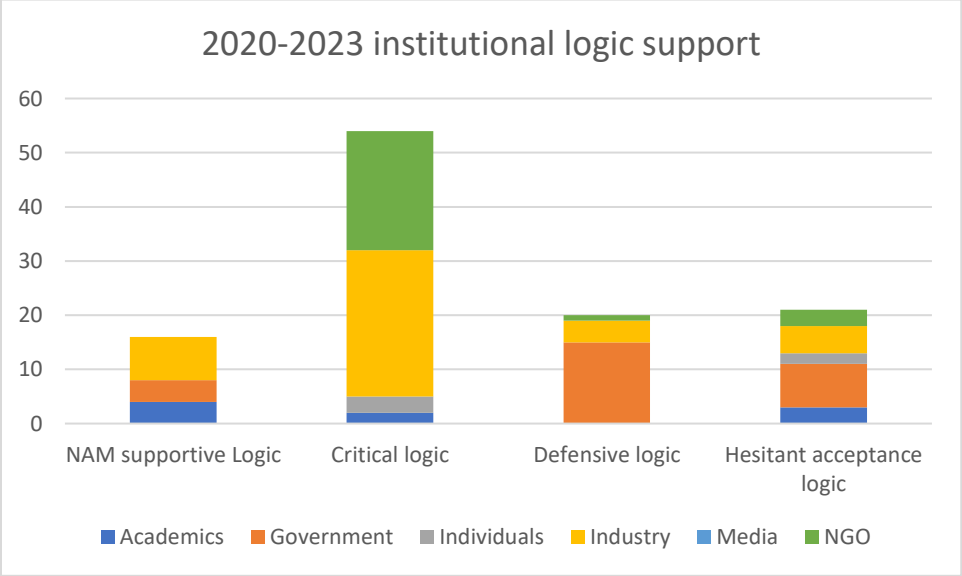

*Figure 18: Distribution institutional logics per actor group 2020-2023*

## 5.5 Interview insights

The STCA has contributed to understanding how the risk assessment regime in the cosmetics industry changed and how actors have responded to these changes over time. It provided some insights into how this affected innovation in NAMs but not on the innovativeness of the cosmetics industry. The interviews were used to validate and complement the STCA results and provide insights into the effect of the changing regime on innovation.

The interviews covered the period leading up to the animal testing ban, the implementation of the ban and the effect it had on innovation in both cosmetic products and the development of NAMs. Interviewee 1 is an industry representative, interviewee 2 is an academic representative and interviewee 3 is a NGO representative. The NGO representative was active up until 2017, the academic and industry interviewee are still active in the field.

All the interviewees agree that the introduction of the Cosmetics regulation and thus the animal testing ban is primarily due to the efforts of individuals in the European Parliament and animal welfare NGOs, which represent the opinion of the average consumer. Interviewee 2 and 3 validated the idea that the industry did not see the Cosmetics regulation as a major threat, believing that it would not be implemented or at least not in the near future, and were somewhat surprised when it was actually implemented. All interviewees agreed that there was some pushback from the cosmetics industry and some countries which host the largest companies such as France but that they also quickly started to adapt to the new rules once the ban was agreed upon. All the interviewees praised the industry for adapting to the new regime and becoming the leaders in the field of NAM development.

All interviewees acknowledged that the Cosmetics regulation was an essential event for the development of NAMs as it created incentives for industry to invest in these technologies, which would not have happened at this scale without the animal testing ban. They also emphasized the snowball effect it has had on the rest of the world as other countries followed with similar regulations. Interviewee 1 also mentioned the NAM transition in other sectors and described the issues that will arise there. He said that the cosmetic industry is suited for NAMs as most tests are based on exposure, meaning that tests will determine at what level of exposure a biochemical reaction will occur. This works well as cosmetics include small amounts of these substances, but this is different in for example the pharmaceutical industry. For drugs, it is the goal to achieve some sort of biochemical reaction for the drug to work, which makes the safety assessment more complex.

As for the final time period, the interviewees were also unsure about how the transition will further develop. Interviewee 1 stated that transition is now mostly dependent on ECHA, he mentioned that his company was working on submitting REACH dossiers containing NAM data and that he was unsure about the outcome. He confirmed the stalemate as he described the annoyance that companies feel because of the time, effort and money they have invested and lack of co-operation from regulators. Interviewee 2 agreed that a hurdle had been reached but also mentioned an event from ECHA with the topic of NAM implementation. Both interviewees agreed that the coming years will be interesting and crucial for the transition towards NAMs.

In terms of cosmetic innovation, the interviewees mentioned that the industry has been limited to some degree. Interviewee 1 and 2 described that due to the animal testing ban mostly chemical ingredients have been used that also have other purposes so that they do not fall under the animal testing ban. However, both also described that the cosmetics industry is a very innovative industry, that they have been able to bring out new products and that limitations on innovation have mostly steered it in a better direction.

# 6. Conclusion

The goal of this thesis was to explore how the substitution of animal testing with animal-free risk assessment in the RRR changed the socio-technical regime of the cosmetics industry and how this shaped the course of innovation. This was achieved by performing a Socio-Technical Configuration Analysis in which actor networks and concept networks visualize the structure of the socio-technical system and the change in socio-technical regime over time. The outcomes were validated and complemented by interviews with actors active in the sector. This chapter answers each research question, the first question was:

> *How did the animal testing ban change the risk assessment regime in the cosmetics industry?*

This research identified two major regulatory changes that impacted the cosmetics industry: the Cosmetics regulation and REACH. The Cosmetics regulation, implemented between 2009 and 2013, centralized registration of cosmetic products, harmonized the rules across the EU, improved safety assessments and introduced the animal testing ban. REACH, implemented in phases between 2008 and 2018, significantly tightened the regulation surrounding chemical substances and therefore also many cosmetic products. The main goal of REACH was to harmonize the many directives that existed before into one ruleset for the whole EU. This introduced much more elaborate safety assessment, which are evaluated before gaining market access with the exception of the pre-registered chemical substances. Together, both regulations aimed to harmonize rules across the EU but failed to harmonize the rules between these regulations. Where the Cosmetics regulation prohibit animal tests, REACH only made suggestions about using NAMs without any hard rules, which would turn into a larger issue with each deadline and amendment of REACH. So even though the Cosmetics regulation was successful in changing the risk assessment for cosmetic companies, it was not designed in alignment with other regulations, which led to workarounds and a limited impact on animal testing.

The second research question was:

> *How did different actors respond and contribute to this transition?*

In the initiation phase, NGOs were very active in their lobby activities to stop animal testing, which together with some European Parliament members led to the drafting and implementation of the Cosmetics regulation. As this would be the first animal testing ban, the discussion was broad and fundamental. The discussion was about whether animal tests were still valid and the opportunities of NAMs but also on ethical issues of balancing animal welfare and human health advances. Mostly NGO's were both criticizing the current animal tests being used and pointing out the advantages of NAMs. Both academics and the industry were on the defensive side even though academics were mostly worried about the animal testing ban extending into other parts of science and the industry was worried about their business being disrupted. Industry even seemed to ignore the threat until the law was actually passed by the European Commission.

In the implementation phase, both governmental organisations and industry become much more active in the discourse as a result of the regulations entering into force. NGOs slightly change arguments but stay consistent in their main storyline, which is to promote NAMs and discredit animal tests. The defensive arguments are now made mostly by industry and government, the latter joining this side as a response to the critique on the animal testing in REACH. Some industry players were already cruelty-free since early on but now other industry actors, which were previously using defensive argument, are starting to join the movement. They are developing NAMs and trying to validate the new ways of safety assessment but start to encounter obstacles in this process. Together with the interaction issues between REACH and the Cosmetics regulation, this shows that the discourse has become more practically oriented although discussion on the fundamental issues of animal testing also still continues.

The cooling phase sees quite a large shift in topics and stances. First of all, REACH has become the main topic of the public discussion, mostly due to the controversial decision by the ECHA board of appeal. The industry has almost completely switched sides in the discussion. Industry actors heavily criticize the ECHA decision, support NAMs and are calling for a global ban on cosmetic testing. It seems that the industry was defensive and holding off the transition until they had developed their own NAMs or otherwise prepared for the switch. Once they had developed enough, their stance switched and they are suddenly the ones leading the transition together with the NGOs. This indicates a possible acceleration of the transition if not for the regulators. At this point, the regulators have become the dominant users of defensive arguments in the discussion and are now the bottleneck in the transition. Industry claims to be more than willing to provide safety assessments based on NAM data but regulators have difficulties interpreting the new methods and often still require animal tests. At this point, the discussion has become almost solely focused on practical issues of the transition, either regarding REACH or cosmetic companies operating both in Europe and other parts of the world where animal testing is still allowed or even required.

The third research question was:

> *How did the transition influence the innovation activity and directionality of the cosmetics industry?*

During the transition, claims were made that the animal testing ban would hinder innovation and that innovation in the cosmetics industry requires new ingredients, which would become much more difficult with new REACH regulations. But even though very few new cosmetic ingredients were registered after the animal testing ban, the interview data suggested that the cosmetics industry were able to create new products. Revenue of the European cosmetics markets has remained stable since 2012, which suggests the same (Petruzzi, n.d.). In addition, the cosmetics industry has become a frontrunner in regard to NAM development as large cosmetic companies have set up NAM programmes to be able to innovate.

# 7. Discussion

## 7.1 Limitations

First of all, the number of news articles used in the STCA was relatively low. As mentioned in the Methodology chapter, the ratio of relevant articles to not relevant articles in the data sample was lower than expected, which led to only 154 articles being used in the analysis instead of around 200 articles as expected. Especially the last time period had a relatively low number of articles, which was caused by the 2020 cut-off date. In hindsight, the research could possibly be improved by including 2019 in the final time period. The appeal made by Symrise was already made in 2018, only the decision by the board of appeal was made in 2020. By including 2019 in the final time period, I might have been able to better capture the build-up to the decision. Furthermore, it is important to note that the validity of the data source is limited due to only 3 interviews being conducted. However, it is worth highlighting that all interviewees were individuals with direct experience and expertise in the field, possessing comprehensive knowledge regarding the transition. Moreover, the primary purpose of utilizing this data source was to validate the findings of the STCA, which it accomplished.

A second limitation of this research is the public discourse bias. Only newspaper, magazine or journal articles were included in the analysis, which only represents the strategy and opinions presented in the media which are often carefully thought out. Therefore no internal communication or communication between organisations was included, which may have skewed the results presented. I would argue that this is a minor issue as we see that for example the Symrise vs ECHA case is something that is covered in the media indicating that all decisions and opinions that influence the whole system are included in the analysis. As mentioned before, the analysis only included English written text, which caused a strong UK bias in the news outlets. Again, I would argue this is not a large issue as the major NGOs involved in the NAM transition of the cosmetics industry originate from the UK and topics were therefore covered in the media. Additionally, multiple topics outside of the UK were frequently discussed indicating that important developments in the industry were addressed in the data.

As expected, the external validity of the research is not very high. The results are based on beliefs and stances of actors within the European cosmetics industry, which cannot be extrapolated to other sector directly. However, there are some general dynamics that could still apply in other sectors. Especially the dynamic between industry and regulators across the different phases is something that I expect to find in other sectors where new regulations are introduced.

## 7.2 Theoretical implications

This research combined the concept of socio-technical regimes with risk regulatory regimes. It has shown that transversal regimes, in this case the socio-technical regime of the cosmetics industry and the risk regulatory regime of chemical substances, do not align, this creates structural tensions. In this case, the actors operating in the cosmetics socio-technical regime have accepted the animal testing ban and are developing in a new direction. However, they are hindered by the risk regulatory regime of chemical substances. In this friction, legal issues arise over which regulation takes priority and creates uncertainty for actors affected by both regimes.

The cosmetics socio-technical regime in Europe changed when the animal testing ban was implemented but this did not directly affect other cosmetic regimes in the world. This research showed that this also created structural tensions as these socio-technical regimes were no longer aligned in their opinions, rules and practices. This created barriers for actors operating in both regimes and for co-operation between actors in these regimes. On the other hand, it also provided opportunities for the transition to accelerate in other regions. For example, after the animal testing ban, cosmetic companies selling in Europe started to try and influence the rules in China together with the NGOs, thereby increasing lobby activity and possibly a faster transition.

This research showed that industry incumbents used strategies in which they provided argumentation against the use of NAMs while simultaneously investing in NAMs themselves. By employing this strategy, they held back the transition until they were ready and then changed their strategy to become leaders in the development of NAMs. This is a strategy incumbents more often use when new (sustainable) innovation threaten to disrupt the market they operate in (Smink et al., 2015).

This research has shown the effectiveness of the SCTA methodology as a measurement of dynamic regimes structures. The combination of the qualitative coding process and visualisation techniques was especially suited to create the storylines of different actors over time and thereby highlighting the change of the socio-technical regimes. Additionally, the interviews validated the insights gained from the STCA, thereby establishing that the public discourse is an effective indicator of the structure of the socio-technical regime.

## 7.3 Practical implications

This research has highlighted the institutional logics to which different actors in the cosmetics field adhere. This can be used to find common ground between opposing actors and help identify points of improvement. Regulators can use the insights of this research to help them understand where the bottleneck of the transition is and connect with active actors to co-operate and try to remove the bottleneck. The results can also be used by developers of NAMs to determine which actors are suitable for collaborations and coalitions to increase implement their NAMs.

An additional practical implication pertains to policymakers. This study has demonstrated that the effectiveness of regulations can be significantly constrained unless they are properly aligned with other regulations and informal rules. Therefore, policymakers must consider existing regulations and proactively assess their interactions. This can increase compliance for the various actors involved and optimize the impact of their policies.

## 7.4 Further research

This research was an exploratory case study of the transition towards NAMs. There are several options for further research into the transition towards NAMs as more countries are adapting animal testing bans in cosmetics and these developments contribute to the possibilities of animal-free science altogether. This research focused on the change in regulation, the responses of actors in the field and the effect it has had on innovation. Although the data from the STCA and interviews provided some information on the effect on innovation, a more in-depth analysis of the innovative capabilities of the cosmetics industry would be valuable research. This can include quantitative research on cosmetic patents, R&D expenditures or newly registered cosmetic ingredients and products.

For the further transition of NAMs, it would be interesting to research the interaction between regulators such as ECHA and the companies registering chemicals. Safety assessment is very complex matter in which many actors are involved. Interviewing actors from the regulatory bodies and companies can provide insights into the barriers of accepting NAMs in safety assessment for chemical substances.

# 8. Acknowledgements

First and foremost, I would like to thank Prof. Dr. Bernhard Truffer for supervising my thesis. His insights and willingness to discuss all my ideas have really shaped the thesis into what it has become. Secondly, I would like to thank Dr. Jarno Hoekman for helping me with understanding the realm of NAMs and regulatory science. Lastly, I would like to thank Timo van Arkel for sparring about the use of STCA and Brendan Oostveen & Robbert Messing for providing feedback on the final thesis.

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# Appendix I: Full coding tree

## Actors

| Name | Files | References | Modified on | Modified by | Classification |
|---|---|---|---|---|---|
| Actors | 154 | 439 | 17-4-2023 16:01 | BB | |
| Academics | 23 | 38 | 17-4-2023 16:01 | BB | |
| Councils_foundations | 11 | 16 | 17-4-2023 16:01 | BB | |
| AStar Bioinformatics | 1 | 1 | 17-4-2023 16:01 | BB | |
| British Medical Jour | 1 | 1 | 17-4-2023 16:01 | BB | |
| CAAT | 1 | 1 | 10-5-2023 10:30 | BB | |
| CCAAM | 1 | 1 | 10-5-2023 10:39 | BB | |
| CIR expert panel | 1 | 3 | 12-5-2023 12:15 | BB | |
| Federal Institute for | 1 | 1 | 17-4-2023 16:01 | BB | |
| Medical Research C | 3 | 3 | 17-4-2023 16:01 | BB | |
| NC3Rs | 2 | 2 | 17-4-2023 16:01 | BB | |
| ONTOX | 1 | 1 | 15-5-2023 14:10 | BB | |
| Wellcome foundatio | 2 | 2 | 17-4-2023 16:01 | BB | |
| Scientists | 5 | 7 | 17-4-2023 16:01 | BB | |
| Andre Menache | 1 | 3 | 17-4-2023 16:01 | BB | |
| Dr. Irwin Bross | 1 | 1 | 17-4-2023 16:01 | BB | |
| Universities | 9 | 15 | 17-4-2023 16:01 | BB | |
| Aberdeen University | 1 | 1 | 17-4-2023 16:01 | BB | |
| John Hopkins univer | 1 | 1 | 10-5-2023 15:56 | BB | |
| Leiden University | 1 | 1 | 17-4-2023 16:01 | BB | |
| Oxford University | 2 | 3 | 17-4-2023 16:01 | BB | |
| Queens University B | 1 | 3 | 17-4-2023 16:01 | BB | |
| Swansea University | 1 | 1 | 17-4-2023 16:01 | BB | |
| University College L | 1 | 1 | 17-4-2023 16:01 | BB | |
| University of Birmin | 1 | 2 | 15-5-2023 13:48 | BB | |
| University of Cheste | 1 | 1 | 17-4-2023 16:01 | BB | |
| University of Ulster | 1 | 1 | 17-4-2023 16:01 | BB | |
| Government | 55 | 86 | 17-4-2023 16:01 | BB | |
| EU wide | 32 | 58 | 17-4-2023 16:01 | BB | |
| ECHA | 14 | 26 | 12-5-2023 12:09 | BB | |
| ECVAM | 3 | 3 | 17-4-2023 16:01 | BB | |
| European Commissi | 5 | 5 | 15-5-2023 13:53 | BB | |
| European Parliamen | 9 | 15 | 17-4-2023 16:01 | BB | |
| Ombudsman | 1 | 1 | 17-4-2023 16:01 | BB | |
| SCCS | 5 | 8 | 15-5-2023 14:33 | BB | |
| FDA | 6 | 8 | 15-5-2023 15:33 | BB | |
| Health Canada | 1 | 1 | 17-4-2023 16:01 | BB | |
| ICCR | 3 | 3 | 15-5-2023 15:24 | BB | |
| ICCVAM | 1 | 1 | 17-4-2023 16:01 | BB | |
| National Governments | 9 | 10 | 17-4-2023 16:01 | BB | |
| France | 1 | 2 | 17-4-2023 16:01 | BB | |
| United Kingdom | 8 | 8 | 15-5-2023 16:12 | BB | |
| US house of representat | 4 | 4 | 15-5-2023 16:07 | BB | |
| Individuals | 6 | 8 | 17-4-2023 16:01 | BB | |
| Anne-marie Barton | 3 | 4 | 15-5-2023 12:04 | BB | |
| Consumers | 1 | 1 | 17-4-2023 16:01 | BB | |
| John Harbell | 1 | 2 | 9-5-2023 13:23 | BB | |
| Peter Tatchel | 1 | 1 | 17-4-2023 16:01 | BB | |

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|---|---|---|---|---|
| Industry | 55 | 114 | 17-4-2023 16:01 | BB |
| Firms | 41 | 73 | 17-4-2023 16:01 | BB |
| Avon | 4 | 6 | 12-5-2023 11:55 | BB |
| Beauty without Cruel | 1 | 1 | 17-4-2023 16:01 | BB |
| Boots | 1 | 1 | 12-5-2023 11:55 | BB |
| Estee Lauder | 5 | 5 | 8-5-2023 10:45 | BB |
| Kimberly-Clark Corp | 1 | 1 | 17-4-2023 16:01 | BB |
| L'occitane | 1 | 1 | 17-4-2023 16:01 | BB |
| L'oreal | 5 | 7 | 17-4-2023 16:01 | BB |
| Lush | 6 | 9 | 15-5-2023 13:46 | BB |
| Mary Kay | 1 | 1 | 17-4-2023 16:01 | BB |
| NARS | 2 | 3 | 17-4-2023 16:01 | BB |
| Organovo | 1 | 1 | 17-4-2023 16:01 | BB |
| Primark | 1 | 1 | 17-4-2023 16:01 | BB |
| Proctor & Gamble | 4 | 7 | 17-4-2023 16:01 | BB |
| Revlon | 1 | 1 | 17-4-2023 16:01 | BB |
| Symrise | 1 | 1 | 10-5-2023 14:16 | BB |
| The Body Shop | 5 | 6 | 12-5-2023 11:50 | BB |
| Unilever | 10 | 15 | 12-5-2023 11:54 | BB |
| Waitrose | 1 | 1 | 12-5-2023 11:55 | BB |
| XCellR8 | 4 | 5 | 10-5-2023 10:35 | BB |
| Groups | 20 | 41 | 17-4-2023 16:01 | BB |
| Animal-free safety a | 2 | 5 | 10-5-2023 16:02 | BB |
| Ásociation of Britis | 1 | 1 | 17-4-2023 16:01 | BB |
| Cosmetic Toiletry an | 2 | 4 | 17-4-2023 16:01 | BB |
| Cosmetics Europe | 6 | 17 | 17-4-2023 16:01 | BB |
| FEBEA | 1 | 1 | 10-5-2023 10:51 | BB |
| Personal Care Produ | 9 | 13 | 15-5-2023 15:26 | BB |
| Media | 19 | 34 | 18-4-2023 11:36 | BB |
| Belfast News letter | 1 | 4 | 18-4-2023 11:36 | BB |
| Coventry Evening Telegr | 1 | 1 | 18-4-2023 11:36 | BB |
| Daily Mail | 3 | 9 | 18-4-2023 11:36 | BB |
| Gorey Guardian | 1 | 4 | 18-4-2023 11:36 | BB |
| Lincolnshire Echo | 1 | 3 | 18-4-2023 11:36 | BB |
| Live Science | 1 | 1 | 18-4-2023 11:36 | BB |
| Metro | 1 | 1 | 18-4-2023 11:36 | BB |
| New York Times | 1 | 1 | 18-4-2023 11:36 | BB |
| Rose Sheet | 3 | 3 | 18-4-2023 11:36 | BB |
| The daily telegraph | 1 | 1 | 10-5-2023 10:43 | BB |
| The Express | 0 | 0 | 18-4-2023 11:36 | BB |
| The guardian | 1 | 1 | 18-4-2023 11:36 | BB |
| The Journal | 1 | 2 | 18-4-2023 11:36 | BB |
| The People | 1 | 1 | 18-4-2023 11:36 | BB |
| Third Sector | 1 | 1 | 18-4-2023 11:36 | BB |
| Toronto Star | 1 | 1 | 10-5-2023 10:45 | BB |

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|---|---|---|---|---|
| NGO's | 82 | 159 | 17-4-2023 16:01 | BB |
| Animal rights NGO's | 70 | 127 | 17-4-2023 16:01 | BB |
| Animal Aid | 2 | 3 | 17-4-2023 16:01 | BB |
| Coalition for Consu | 2 | 3 | 17-4-2023 16:01 | BB |
| Cruelt Free Internati | 29 | 38 | 12-5-2023 11:55 | BB |
| Doris Day Animal Le | 1 | 1 | 17-4-2023 16:01 | BB |
| Dr Hadwen Trust | 5 | 11 | 17-4-2023 16:01 | BB |
| German Society for | 1 | 1 | 17-4-2023 16:01 | BB |
| Humane Research Tr | 1 | 2 | 17-4-2023 16:01 | BB |
| Humane Society | 17 | 30 | 12-5-2023 11:49 | BB |
| IIVS | 1 | 1 | 17-4-2023 16:01 | BB |
| National Anti-Vivese | 3 | 3 | 17-4-2023 16:01 | BB |
| People for Ethical Tr | 17 | 27 | 15-5-2023 11:53 | BB |
| Protest groups | 3 | 5 | 17-4-2023 16:01 | BB |
| USPCA | 1 | 2 | 17-4-2023 16:01 | BB |
| Fund for the Replaceme | 1 | 1 | 17-4-2023 16:01 | BB |
| Science NGO's | 16 | 31 | 17-4-2023 16:01 | BB |
| Antidote Europe | 1 | 5 | 17-4-2023 16:01 | BB |
| Europeans for Medi | 2 | 2 | 17-4-2023 16:01 | BB |
| Foundation for Bio | 1 | 1 | 17-4-2023 16:01 | BB |
| Natural Resources D | 1 | 1 | 17-4-2023 16:01 | BB |
| Physicians committe | 1 | 3 | 17-4-2023 16:01 | BB |
| Research Defense S | 3 | 5 | 17-4-2023 16:01 | BB |
| Seriously Ill for Medi | 1 | 3 | 17-4-2023 16:01 | BB |
| Understanding Ani | 7 | 11 | 15-5-2023 12:07 | BB |

## Concepts

| | | | | |
|---|---|---|---|---|
| Concepts | 154 | 539 | 17-4-2023 16:01 | BB |
| Animal testing regime | 69 | 126 | 18-4-2023 11:36 | BB |
| Acceptable | 29 | 49 | 18-4-2023 11:36 | BB |
| Already highly regul | 10 | 14 | 15-5-2023 12:06 | BB |
| As a last resort | 16 | 18 | 15-5-2023 14:24 | BB |
| For saving lives | 7 | 7 | 16-5-2023 15:21 | BB |
| Required by law | 7 | 10 | 16-5-2023 15:23 | BB |
| Flaws | 38 | 62 | 18-4-2023 11:36 | BB |
| AT is outdated | 8 | 9 | 18-4-2023 11:36 | BB |
| AT's are not accurat | 23 | 29 | 15-5-2023 13:47 | BB |
| Cruel | 16 | 18 | 15-5-2023 12:04 | BB |
| Performed without r | 6 | 6 | 15-5-2023 16:24 | BB |
| Initiate ECI | 2 | 2 | 20-5-2023 15:48 | BB |
| New regulation will incr | 4 | 5 | 10-5-2023 16:01 | BB |
| Paradigm shift | 5 | 5 | 15-5-2023 11:50 | BB |
| Policy behind technolog | 3 | 3 | 10-5-2023 15:41 | BB |
| Barriers outside EU | 32 | 49 | 17-4-2023 16:01 | BB |
| Brexit | 1 | 1 | 17-4-2023 16:01 | BB |
| Canada | 2 | 3 | 17-4-2023 16:01 | BB |
| China | 19 | 26 | 17-4-2023 16:01 | BB |
| Change by boycot | 1 | 1 | 17-4-2023 16:01 | BB |
| Change from inside | 5 | 5 | 10-5-2023 10:52 | BB |
| China independentl | 4 | 4 | 17-4-2023 16:01 | BB |
| Legally required | 4 | 4 | 17-4-2023 16:01 | BB |
| Making progress | 5 | 7 | 16-5-2023 15:28 | BB |
| Trying to enter with | 5 | 5 | 10-5-2023 10:50 | BB |
| Global ban | 10 | 13 | 9-5-2023 12:26 | BB |
| Strong lobby | 1 | 1 | 17-4-2023 16:01 | BB |
| US | 3 | 5 | 17-4-2023 16:01 | BB |

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|---|---|---|---|---|
| Cosmetics Ban | 25 | 37 | 17-4-2023 16:01 | BB |
| Breaches other regulatio | 1 | 2 | 16-5-2023 15:29 | BB |
| Delayed by industry & g | 3 | 3 | 17-4-2023 16:01 | BB |
| Hinders innovation | 6 | 8 | 17-4-2023 16:01 | BB |
| Initiated industry practic | 2 | 2 | 17-4-2023 16:01 | BB |
| Interaction with endocri | 2 | 3 | 17-4-2023 16:01 | BB |
| Need better surveillance | 1 | 2 | 17-4-2023 16:01 | BB |
| Ripple effect | 9 | 9 | 17-4-2023 16:01 | BB |
| Effect beyond cosm | 4 | 4 | 10-5-2023 10:36 | BB |
| Effect beyond EU | 5 | 5 | 17-4-2023 16:01 | BB |
| Too many loopholes | 7 | 8 | 17-4-2023 16:01 | BB |
| Cosmetics regime | 29 | 35 | 17-4-2023 16:01 | BB |
| Cruely free is not well de | 2 | 2 | 16-5-2023 15:32 | BB |
| Difficult to defend risk a | 1 | 1 | 17-4-2023 16:01 | BB |
| Industry is not transpare | 1 | 1 | 17-4-2023 16:01 | BB |
| Innovation requires man | 1 | 1 | 17-4-2023 16:01 | BB |
| Leaping Bunny trademar | 10 | 11 | 17-4-2023 16:01 | BB |
| No cruelty for cosmetics | 11 | 11 | 17-4-2023 16:01 | BB |
| No need for new ingredi | 5 | 5 | 17-4-2023 16:01 | BB |
| Safety and environment | 1 | 1 | 17-4-2023 16:01 | BB |
| Save Ralph | 2 | 2 | 10-5-2023 11:21 | BB |
| Medical research regime | 17 | 25 | 17-4-2023 16:01 | BB |
| Big Breakthroughs happ | 5 | 5 | 17-4-2023 16:01 | BB |
| Does not Require AT | 3 | 4 | 17-4-2023 16:01 | BB |
| Requires AT | 12 | 16 | 17-4-2023 16:01 | BB |
| NAM niche | 84 | 159 | 17-4-2023 16:01 | BB |
| Better Performance | 28 | 58 | 17-4-2023 16:01 | BB |
| Cheaper | 15 | 15 | 10-5-2023 11:18 | BB |
| Faster | 13 | 13 | 10-5-2023 11:18 | BB |
| More accurate | 25 | 25 | 16-5-2023 15:38 | BB |
| Safer | 5 | 5 | 17-4-2023 16:01 | BB |
| Development | 35 | 45 | 17-4-2023 16:01 | BB |
| Ban accelerates deve | 7 | 7 | 17-4-2023 16:01 | BB |
| Lack of funding | 3 | 5 | 15-5-2023 11:50 | BB |
| More to do | 3 | 4 | 10-5-2023 11:26 | BB |
| Need better underst | 1 | 3 | 12-5-2023 12:16 | BB |
| Potential | 3 | 4 | 15-5-2023 13:48 | BB |
| Support developme | 22 | 22 | 15-5-2023 15:33 | BB |
| Implementation | 29 | 42 | 17-4-2023 16:01 | BB |
| Difficult to validate | 2 | 2 | 17-4-2023 16:01 | BB |
| Faster implementati | 2 | 2 | 10-5-2023 10:45 | BB |
| increase regulatory a | 1 | 2 | 15-5-2023 15:26 | BB |
| Legal uncertainty | 1 | 1 | 15-5-2023 15:21 | BB |
| Low willingness to c | 3 | 3 | 17-4-2023 16:01 | BB |
| Need regulators | 6 | 6 | 10-5-2023 16:02 | BB |
| No full replacement | 9 | 11 | 17-4-2023 16:01 | BB |
| Not enough validate | 6 | 7 | 15-5-2023 14:33 | BB |
| Slow due to bureauc | 5 | 5 | 17-4-2023 16:01 | BB |
| validated guideline | 1 | 2 | 12-5-2023 12:09 | BB |
| Large availability NAMs | 14 | 14 | 10-5-2023 16:02 | BB |

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|---|---|---|---|---|
| REACH | 25 | 51 | 17-4-2023 16:01 | BB |
| Dossiers need improve | 3 | 4 | 10-5-2023 14:31 | BB |
| Forces unnecessary ATs | 11 | 18 | 20-5-2023 11:54 | BB |
| Interaction REACH & CR | 7 | 11 | 20-5-2023 11:57 | BB |
| 'Last resort' principle do | 2 | 2 | 18-4-2023 11:41 | BB |
| NAM compliance ECHA | 1 | 1 | 20-5-2023 15:43 | BB |
| NAM compliance registr | 3 | 5 | 20-5-2023 15:43 | BB |
| NAMs extensively used | 1 | 2 | 9-5-2023 11:33 | BB |
| Need more transparanc | 2 | 2 | 10-5-2023 14:42 | BB |
| REACH precedes CR | 4 | 4 | 20-5-2023 11:54 | BB |
| REACH should include a | 2 | 2 | 17-4-2023 16:01 | BB |

# Appendix II: Interview guide

First of all, thank you for participating in this interview. My name is Ben Bresser and I am an Innovation Sciences student at Utrecht University. My master thesis is about the transition from animal testing to non-animal testing methods. In particular, I am researching how this transition occurred in the cosmetics industry as they were the first sector to prohibit the use of animals in safety testing. I contacted you because i think your perspective as someone who is active in this field would be a valuable contribution to the understanding of this transition. The interview is broken up into three parts: how the Cosmetics Regulation came to be, how the Cosmetics Regulation was implemented and lastly how the Cosmetics Regulation has impacted innovation in the cosmetics industry.
Participation in this interview is voluntary and you can quit the interview at any time without giving a reason and without penalty. Your answers to the questions will be shared with the research team. We will process your personal data confidentially and in accordance with data protection legislation (the General Data Protection Regulation and Personal Data Act). Please respond to the questions honestly and feel free to say or write anything you like.

[Read the following if the interviewee has not filled out the informed consent form yet]
I confirm that:

- I am satisfied with the received information about the research;
- I have no further questions about the research at this moment;
- I had the opportunity to think carefully about participating in the study;
- I will give an honest answer to the questions asked.

I agree that:

- the data to be collected will be obtained and stored for scientific purposes;
- the collected, completely anonymous, research data can be shared and re-used by scientists to answer other research questions;

I understand that:

- I have the right to see the research report afterwards.

Do you agree to participate? o Yes o No

Before we start I want to ask you if you consent to this interview being recorded for transcription purposes. I will delete the recordings after my master thesis is finished.
[start recording]
*Introduction question*
How do you think the field of cosmetics has evolved with the introduction of the Cosmetics regulation?

*1st block – Period that led up to the Cosmetics Regulation*
The Cosmetics Regulation was first talked about in 1997 and finally implemented in 2009 and some parts in 2013. This is the only sector where we have a full animal testing ban. To your knowledge, what have been the major factors that led to the introduction of this ban?

- What do you think the main arguments were that led to the introduction of the Cosmetics Regulation?
- What were core events that led to the introduction of the Cosmetics Regulation
- Do you think that certain groups actively delayed the Cosmetics Regulation? If so, who were they?
- What role do you think that industry/government/NGOs/Academics played in this process? (based on which groups the interviewee has not mentioned)

*2nd block – Implementation of the Cosmetics Regulation*

This part is about the first years when the Cosmetics Regulation was implemented. Animal testing was banished, even when proper alternatives were not available. To your knowledge, how did the early implementation of the Cosmetics Regulation go? Has it been a smooth process and could the original goals be reached? What goals were not reached?

- How do you think NGOs/Industry/government reacted to the implementation of the Cosmetics Regulation?
- How do you think the Cosmetics Regulation has impacted animal-free discussions in other sectors/geographical areas (US, China)?
- How has the REACH regulation influenced the effect of the Cosmetics Regulation?
- How do you see the role of ECHA (European chemical agency) in incorporating NAMs in safety testing?

*3rd block – impact of the Cosmetics Regulation on innovation*

This is the last part of the interview. Introducing new chemicals with solely cosmetic purposes became much harder due to the Cosmetics Regulation, I am interested whether this affected the innovation in the Cosmetics industry.

- Do you think the Cosmetics Regulation has impacted the innovativeness of the cosmetics industry? (both in size and direction)
- Do you think that the Cosmetics Regulation has accelerated the development of NAMs?
- In which way?

[Stop recording]

*Closing questions*

- Do you want to check the transcript?
- Do you want to see my final thesis?
- Do you know any people who could provide complementary information?