

# Cultures and Strategies in the Regulation of Nanotechnology in Germany, Austria, Switzerland and the European Union

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This interdisciplinary, social scientific analysis of the regulatory discourse on nanotechnology in the three German-speaking countries of Germany, Austria and Switzerland and in the EU between 2000 and 2013 has shown three distinct phases, characterised by shifts in the configuration of actors and in the thematic scope from nanotechnology to nano-materials. Compared to modes of governance based on traditional statutory law, modes of governance based on less binding forms of soft law and self-regulation (like codes of conduct, guidelines and certification systems) and new modes of governance (like assessment studies, risk management frameworks as well as participatory and cooperative forms of communication and negotiation) have gained importance. Despite some similarities, two different cultures in governing nanotechnology can be distinguished: a product-oriented culture in statutory regulations (when speaking about products, the article is also referring to substances) and a risk-based

culture in applying soft law based on new modes of governance. In addition, the different regulatory cultures have led to four strategic approaches: modes of governance mainly based on hard law and soft law at the EU level, modes of governance mainly based on cooperative and self-regulatory approaches in Germany, cooperative governance approaches in Austria and modes of governance mainly based on self-regulatory and soft law approaches in Switzerland.

**Keywords** Nanotechnology · Regulatory culture · Governance · Austria · Germany · Switzerland · EU

## Introduction

Discourses on regulatory implications of nanotechnology emerged in direct response to the launch of new

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research and development support programmes and initiatives in almost every Western industrialised nation in the early 2000s. This early start of regulatory discourses, compared to previous technological developments, was associated with intensive efforts of assessment activities. These started almost concurrently with the establishment of national research initiatives [87], which mainly consisted of traditional technology assessment (e.g. [115, 124]), toxicological studies (e.g. [20, 42, 92, 112]) and analyses in ethical, legal and social implication (ELSI) and cultural studies.<sup>1</sup> Regulatory discourses, however, developed not only in almost every country involved in research and development of nanotechnologies but also on the supranational level of the European Union (EU) and in international organisations, like the OECD.

Besides modes of governance based on *statutory law* – referred to as ‘*hard law*’ and as such based on less binding and more voluntary measures, referred to as ‘*soft law*’<sup>2</sup> – lying in the jurisdiction of parliaments, governments and administrations, various actors in the field of nanotechnology have developed modes of governance based on self-regulation and informal, distributed and participative approaches – referred to as ‘*new governance*’ [116, 117]. As for example the current trend in the EU shows, these two modes can coexist (e.g. [55, 132]). In political discourses and in decision-making related to science policy, a shift from “governmental forms of regulation” to “governance” was described [121]. Depending on the analytical perspective, literature refers to a “governance turn” [21, 122], a “deliberative turn” [72], a “qualitative turn” [88] or a “turn from modernist to post-modernist forms of statecraft” [68]; with regard to science and technology policy reference is made to a “new governance of science” [67, 79, 86, 140]. Furthermore, the rise of a ‘new governance turn’ has been described (e.g. [41, 102]). ‘New governance’ stands for informal regulatory approaches, like technology and risk assessment, risk management frameworks as well as participatory and cooperative forms of communication and negotiation, combined with forms of self-regulation (e.g. [55, 132]).

Against this background, this interdisciplinary, social-scientific study, which is neither a legal nor a

sociological analysis, has evaluated regulatory discourses on nanotechnology in the three European countries of Germany, Austria (both EU members) and Switzerland (non-EU member), as well as at the EU level, since 2000. This comparative study, has followed a discourse analysis approach and has used methods from both fields, like legal and document analysis, interviews and participant observation of the authors in events and panels of the regulatory discourse. The analysis has focused on discourses carried out within governmental institutions, like the parliament and administration, and on discourses pursued outside government. It further studied the related modes of governance based on hard and soft law, as well as new modes of governance, including self-regulatory approaches of non-governmental organisations and the private sector, like risk management frameworks, various codes of conduct, certification systems, safety guidelines and manuals of manufacturers and industry associations. Moreover, in the context of new governance, participatory approaches like stakeholder dialogues and citizen conferences have also been analysed, as have private regulatory assessment reports and reports initiated by government on the impact of technology, opportunities, risks and innovation. Documents analysed consisted of legislative texts, regulations, council minutes, printed materials, legal opinions, documentations of informal approaches, reports made by officials and other governmental organisations and commissions as well as reports from external actors, like documentations of self-regulatory approaches, dialogue protocols etc.

The comparison is based on research approach driven by qualitative science and technology studies (STS), using the concept of *regulatory culture* [22 p. 73–76, 86 p. 21 seq.] The categories of *representation*, *participation* and *negotiation*, developed by Jasanoff [86] for a comparison of political cultures, have been further specified and adapted for the needs of this study. It has become clear that an analysis of a regulatory discourse that aims to compare regulatory cultures requires *discursive* elements as well as *practices* of regulation to be analysed. This has led to three analytical categories: *issues*, *actors* and *practices*, and the following analytical framework for the comparison:

- *Issues*: Which subjects, topics, contents and themes are discussed in the regulatory discourse on nanotechnology?

<sup>1</sup> On ELSI and cultural studies analyses (see e.g. [3, 10, 30, 31, 65, 69, 70, 74, 75, 90, 93, 95, 96, 97, 103, 104, 111, 131]).

<sup>2</sup> Such voluntary approaches consist of aspects like risk assessment schemes, various codes of conduct and the establishment of advisory boards and committees for dialogue (see e.g. [76, 89, 100]) for specific measures.

- *Actors*: Who participates in regulatory discourses; who is involved in governing nanotechnology and who is not?
- *Practices*: What modes of governance and what kind of policy tools are used in governing nanotechnology, how are they implemented, where are they included, and how are they further developed?

However, regulatory cultures are not taken for granted, nor are issues, actors and practices considered to be stable and separate entities. Rather, regulatory discourses and the social order are framed as being coproduced, as issues and practices emerge in relation to actors and vice versa [85]. In this notion, the analysis of regulatory cultures looks at specific discourses, measures or modes of governance that shape the interaction between actors, issues and practices in specific ways.

Section 2 provides a chronological overview of three phases of the regulatory discourse of nanotechnology between 2000 and 2013. Here, specific measures and modes of governance are discussed that have shaped the regulatory cultures of nanotechnology in the three countries and the European Union.<sup>3</sup> Based on this overview, section 3 discusses those specific measures and modes of governance according to the three categories: issues, actors and practices. Section 4 focuses on the temporal dimension of the regulatory discourse based on the three categories in three phases. Here, the shift of the topics and the configuration of actors within the three phases is outlined, as is the way that legislation, self-regulatory and informal approaches have been established. The final section 5 presents the categorisation of the observed issues, actors and practices into two regulatory cultures with different culture-specific strategies.

<sup>3</sup> This analysis focuses on selected initiatives and measures with regard to the governance of nanotechnology. They were selected in an exemplary way according to their documentation in related literature, and according to whether they were observed and mentioned in interviews and participant observation conducted by the authors in the three countries. Therefore, the discussed measures have served as examples or cases upon which to build the argument rather than providing a comprehensive list of all relevant governance measures. This has never been the aim of the authors. Therefore, the qualitative approach selected for this study leads to the consequence that some measures are analysed while others are missing.

### Three Phases in the Regulatory Discourse from 2000–2013

This section gives a chronological overview of the regulatory discourse on nanotechnology in Germany, Austria and Switzerland as well as in the EU between 2000 and 2013. This discourse can be seen as having three phases that may overlap at times but are largely distinct: an early phase of a broad thematic discussion of nanotechnology by a relatively small range of participants, a middle phase of intensive and broad thematic discourse with a wide range of actors and a late phase with a specific thematic emphasis on nano-materials and a simultaneously extended range of participants.

The study has further showed that technology assessment in all analysed countries played an important role at the beginning of the discourse and thus chances, risks and the need for research were centrally negotiated. The discourse became more intensive in a phase of broadened participatory occasions, which included stakeholders as well as civil society. At the end of our analysis, the regulatory discourse decreased and narrowed its thematic scope to the environment, health and safety issues (EHS) of nano-materials and was mainly conducted by the relevant social and political actors.

#### The Early Phase: Research, Innovation and Assessment

In Germany and Switzerland, the regulatory discourse on nanotechnology emerged in the years 2000 and 2001 and intensified in 2005–2007. Both countries saw parliamentary interventions and debates. The first issues within the German Bundestag focused on the state and development of nanotechnology, its opportunities, risks and specific scientific guidelines. Further issues discussed in the Bundestag covered nanotechnology research and development and nano-specific regulation relating to the protection of consumers, health, data and the environment.<sup>4</sup> Furthermore, the research policy administrations faced a phase of orientation in which the definition of the research area as well as the precise formulation and financial funding of support programmes were still fairly open.<sup>5</sup> The Swiss Parliament's National Council discussed and rejected the set-

<sup>4</sup> See also printed matter [43–46] and plenary protocol [119] of the German Parliament.

<sup>5</sup> On that, see e.g. [12–14].

up of an advisory board on new technologies with the aim of covering political and ethical questions, chances, risks, social implications, national and international co-operation as well as military applications.<sup>6</sup>

In 2002 the German Federal Ministry of Education and Research (BMBF) published a position paper, showing the status of an early “action plan” without explicitly using this term [12]. In 2004 the BMBF published another position paper, which was—although the title once again failed to indicate this—considered as the first nanotechnology action plan of Germany [13].<sup>7</sup> Herein, the BMBF stated that there was no need for a separate regulation of nanotechnology [14].

From 2003 onwards, the first publicly funded research policy analyses and technology assessment (TA) studies (e.g. [9, 115])<sup>8</sup> were released in Germany and Switzerland. Furthermore, private actors began to publish assessment studies (e.g. [105, 134]). The publicly-commissioned studies in Germany focused on TA [115], financed by the Parliament, and on innovation and technology analyses with a focus on economic potential [101]. Further studies covering sustainability effects and health were both supported by the BMBF [1, 73]. In addition, a research policy position paper on nanotechnology analysed its market potential and stressed the strategic need to exploit it for the German economy [13].

Another study, funded from public resources, focused on nano-materials, their definitions and scientific development and was conducted by the TA institution *European Academy for Research and Assessment of Consequences of Scientific and Technical Developments* [129].

In Switzerland, the national Centre for Technology Assessment (TA Swiss) issued a report on

nanotechnology in medicine [9]. Private studies like those conducted by the Swiss reinsurance company Swiss Re and the think tank International Risk Governance Council (IRGC) analysed nanoscience and nanotechnology from a wide thematic range as well as nano-materials and their potential toxicity (e.g. [78, 134]).

In Germany, the Chemical Industry Association (VCI) and the multinational chemical company BASF developed a code of conduct for the safe handling of nano-materials at the workplace [4]. While many of these early studies showed a wide range of visions, applications, implications, hazards and risks, particular attention was paid to the potential adverse effects of nano-materials on health and environment.

At the EU level, the regulatory discourse started when the EU Commission published a nanotechnology strategy in 2004 [37] and released an action plan in 2005 [38]. In these communications, the EU Commission assessed nanotechnology as a core research and development field and put emphasis on the technology’s potential for international competition and economic leadership. The EU Commission further argued that the existing regulatory framework was sufficient to cover the hazards and risks and that any regulation must be embedded into the existing legal framework. Furthermore, the Commission advertised for a comprehensive review to be carried out of the adequacy of the existing law to cover nanotechnology [32, 33].<sup>9</sup>

Discourses in this phase were mainly conducted in promise- and expectation-oriented innovation rhetoric. They mainly focused on nano-materials and nano-phenomena and already covered a wide range of issues. This phase was also framed by futuristic discourses and ‘speculative’—as the scientific community sometimes called them—future scenarios of nanotechnology (cf. e.g. also [71, 98, 110]). Particularly in the U.S., such visions played an important role in attracting the initial focus of the science policy discourse to nanotechnology and in allocating public funding to the field of nanotechnology in around the early 2000s (e.g. [131, 133]). They were initially taken up in other countries, like in the parliamentary discourses in Germany and Switzerland (see above), and particularly influenced the first German nanotechnology strategy [12]. Moreover, it is difficult to make statements about the role that the early, visionary debates about nanotechnologies played as

<sup>6</sup> See Swiss National Council postulate submitted by National Councillor Hans Widmer (SP) of 14.12.2000, in which he requests the Swiss Federal Council to establish a council for new technologies and Swiss National Council request by National Councillor Barbara Haering (SP) from 01.12.2004 to the Swiss Federal Council regarding potential environmental and health risks from military uses of nanotechnology ([http://www.parlament.ch/d/suche/seiten/geschaefte.aspx?ge-sch\\_id=20003686](http://www.parlament.ch/d/suche/seiten/geschaefte.aspx?ge-sch_id=20003686)/visited 04.06.2014).

<sup>7</sup> In Germany the term “action plan” was first explicitly used in the BMBF [15] publication.

<sup>8</sup> The studies were financed by the Federal Ministry of the Environment (BMU) and by the Swiss organisation for technology assessment TA Swiss, respectively.

<sup>9</sup> For this and further analysis see [62].

regards future regulatory strategies. We can only speculate on the role of visions or ‘speculative ethics’ in the nanotechnology discourse. Nanotechnology might have been put on the political agenda because the visions about molecular nanotechnologies and its potential impacts created substantial media awareness, not least in quality newspapers.<sup>10</sup> The visionary discourse might also have prompted groups that were more interested in allocating funding to ‘conventional nanotechnologies’ to develop counter-narratives, highlighting the everyday use and more current opportunities of nanotechnologies.<sup>11</sup> The early nanotechnology debates addressed more prominently ethical issues like distributional justice or the role of science in economic policy, topics that almost entirely disappeared from later nanotechnology discourses (see e.g. [99]). Furthermore, the visionary discourse attracted the interest of German environmental organisations. In discussing the importance of nanotechnologies as a future topic for their work, they considered several visions to be overly speculative. At the same time, they discovered the potential of other visions and found parallels and differences between nanomaterials and chemicals policy problems. Chemicals policy, in turn, is a core area of activity (and expertise) for civil society organisations, above all in Germany. The reframing of nanotechnology as nanomaterials resulted in benefiting both the influential proponents of nanotechnology research funding, who were mainly based in academia and industry, and its critics, who came mostly from environmental organisations. In this notion, nanotechnology became a development that was related to the broader political agenda of dissident organisations.

As the next section shows, visions lost their importance in the middle phase of the regulatory discourse. For example, they no longer played any significant role in the nanotechnology action plans or implementation reports of the EU, Switzerland, Germany and Austria that emerged in 2004 and later (e.g. [15, 29, 34]).

<sup>10</sup> E.g. the *Frankfurter Allgemeine Zeitung*, one of the most influential daily newspapers in Germany, published a series of articles by futurists, scientists and engineers about nanofutures, which was widely discussed in political circles.

<sup>11</sup> For example, this later led to the ‘nano for ...’ strategies of the German Federal Ministry of Education and Research (BMBF).

### The Middle Phase: Intensifying Discourses in the Context of Participation

For a relatively short phase between 2005 and 2007, the regulatory discourses in Germany and Switzerland became fairly intensive. This was also the time when the discourses started in Austria. In this phase, besides the ongoing research policy issues, the regulatory discourses in all the analysed countries started to focus on favourable applications of nanotechnology for human health and the environment. Particularly in Germany, the research policy discourses were associated with a focus on nanotechnology research and development in applications considered to be particularly relevant to the economy and society, like nano-electronics, automotive manufacturing, optical technologies and life sciences.

Like in the early phase in Germany and Switzerland, the regulatory discourses in Austria began with a technology assessment study. While nanotechnology implications were discussed in a wide thematic range in Austria, the discourses in the two other countries started to focus more on concrete applications and implications such as the environmental, health and safety (EHS) implications of nano-materials. In this phase, the visions almost entirely disappeared from the regulatory discourse, something Lösch [99] describes as ‘defuturization’.

In Germany, the involved actors particularly consisted of the federal institutions in charge of economic and innovation policies. Since 2006, institutions with protective functions (environment, health, employment and consumer protection) have increasingly entered public and regulatory discourses. Thus all parliamentary groups in the Bundestag, the federal government as a whole, several federal ministries (in particular the Federal Ministry of Education and Research BMBF and the Federal Environment Ministry BMU), as well as higher federal authorities and departmental research institutes like the Federal Environment Agency (UBA), the Federal Institute for Occupational Safety and Health (BAuA) and the Federal Institute for Risk Assessment (BfR), became involved in the discourses. Further actors consisted of environment and consumer protection agencies like the environmental association BUND and the Federation of German Consumer Organisations (vzbv), as well as industry associations like the Association of the Chemical Industry (VCI) and the German Federation of Food Law and Food Science (BLL). In this phase, the German government funded governance-

oriented, EHS-related research studies. In this context, the Society for Institutional Analysis (sofia) Darmstadt and the Ökoinstitut Freiburg published for example a legal opinion [66] and the Karlsruhe Institute for Technology Assessment and Systems Analysis (ITAS) issued several studies (e.g. [63, 70, 71]). In addition, a number of research programmes in the fields of nanotoxicology, standardisation and instrumentation with public and private participation were initiated and leading scientists regularly took part in the evolving risk discourses. In parallel, the multinational corporation BASF launched a dialogue forum on EHS issues of nano-materials in Germany. The two sessions organised so far aimed to share nanotechnology issues with trade unions, civil society organisations, scientists and representatives of other companies (suppliers and customers) and resulted in the formulation of two individual position papers [5, 6]. In addition, BASF developed a workplace safety guideline for nano-materials in 2006 [4]. Besides manufacturers, the German Association of Chemical Industries (VCI) also published positions and recommendations for the handling of nano-materials [137] and developed a guideline for workplace safety together with the Federal Institute for Occupational Safety and Health [7]. They updated their guidelines in 2012 [8]. The German manufacturing industry is particularly active as compared with the other analysed countries and has influenced both the development of regulatory discourse and some governance choices of the German government, for example that the Ministry of the Environment did not develop a voluntary reporting scheme as has been the case in the U.S. and the UK.

In Germany and Switzerland, first participatory processes were carried out. While the German Federal Ministry for the Environment (BMU) initiated a stakeholder dialogue on environmental protection and occupational health and safety, TA Swiss carried out three focus group hearings with the public and one involving stakeholder groups on nanotechnology in a broad thematic scope [25, 120]. The German BMU stakeholder dialogue, initiated by an initiative of the former Federal Minister of the Environment, was turned into the *NanoKommission* in 2006.

Then, the German NanoKommission was introduced by the Federal Government as the national dialogue forum. Its administration was assigned to the Environment Ministry (BMU). Although perceived as a single entity, the “NanoKommission” actually consisted of two

consecutive commissions with partly different memberships and different key areas of activity [94]. The first NanoKommission (2006–2008) comprised 15 people representing science, economy, politics and NGOs and was supported by three working groups (each comprising approximately 20 members from all active stakeholder groups) focusing on issues such as “chances for environment and health”, “risks and safety research” as well as “guidelines for responsible handling of nano-materials”. This phase was followed almost seamlessly by the second working period from 2009–2011, described either as the “second phase of NanoKommission” or as “the second NanoKommission” [94].

In 2006, the German Bundestag particularly discussed issues such as benefits and risks, environment and health protection, research policy, and food.<sup>12</sup> In August 2006, three higher federal authorities, the Environment Agency (UBA), the Institute for Occupational Safety and Health (BAuA) and the Institute for Risk Assessment (BfR), published a joint research strategy [18]. In the same year, the UBA published a background paper on opportunities and risks of nanotechnology for human health and the environment [135] and the Federal Ministry of Education and Research (BMBF) developed the NanoCare information platform on synthetic nano-particles.<sup>13</sup> Environmental organisations also published reports on issues such as environmental and health protection (e.g. [23, 24]). Furthermore, in November 2006, the BMBF as lead ministry presented the “Nano-Initiative – Action Plan 2010” within the framework of the HighTech Strategy of the German Federal Government [15]. In this initiative, the BMBF described the requirements of the market success of a German “knowledge lead” in various areas of nanotechnology and presented an expanded and cross-departmental action frame. It further specified the aim of the German government to establish a national dialogue board: the NanoKommission (see above).

In Switzerland, the regulatory discourses were characterised by several discussions in the Parliament, covering issues like public health and the environment, the need for a regulatory framework, the support of innovation as well as the call for a national research funding programme for an in-depth analysis of potential

<sup>12</sup> Cf. printed matter [47, 48] of the German Parliament.

<sup>13</sup> Meanwhile transferred into the follow-up project DaNA [www.nanopartikel.info/cms/Projekte/NanoCare](http://www.nanopartikel.info/cms/Projekte/NanoCare) (viewed, 4.6.2013).

risks and benefits of synthetic nano-materials and nano-technological applications (reference to own research).

In Austria, the regulatory discourses started in 2006 with the publication of a TA report on accompanying measures in nanotechnology commissioned by the Federal Ministry for Transport, Innovation and Technology (BMVIT) and conducted by the Institute for Technology Assessment (ITA) of the Austrian Academy of Sciences [80]. The report dealt with issues relating to the state of knowledge, regulation, self-regulatory approaches, voluntary agreements and best-practice initiatives particularly recommended for the field of chemicals. In parallel, the study “NanoHealth – health risks of nanotechnology” funded by the Federal Ministry of Economy (BWA) and the Zukunftsfonds Steiermark was published by BioNanoNet Styria [109]. Both projects developed joint recommendations urging the government to adapt existing regulations, in particular those in the fields of chemicals legislation, product liability, insurance and consumer protection, and if necessary to develop a new regulatory framework. Furthermore, the authors of these studies suggested that—comparable to other countries—EHS and ELSI research activities on nanotechnology be initiated (cf. [80]).

#### The Late Phase: Flattening of Discourses and Focusing on Materials, Environmental, Health and Safety Issues

Subsequently, the regulatory discourses in Germany and Switzerland decreased, though they remained on a significantly higher level than before 2006 and expanded in Austria. In all the analysed countries, and in the EU, this phase once again entailed an expansion of the range of actors with a simultaneously comprehensive thematic focus on *nano-materials*. The discourses focused on issues such as the application of nano-materials in consumer products, environmental, health and safety (EHS) and related regulatory issues. The range of issues narrowed from thematically extensive negotiations on nano-sciences and nanotechnologies as a whole to a rather restricted and almost exclusive concentration on nano-materials.

In Germany, parliamentary interventions and debates still played a major role. Thus the German Bundestag discussed issues like regulation, the precautionary principle, risks, occupational health and safety, consumer protection, responsible approach, the promotion of research, development and innovation, environment and health protection, nano-silver, reporting obligations,

product register, labelling requirements, chemical regulation, hazardous substances, action plan as well as research policy and accompanying research.<sup>14</sup> The (first) NanoKommission of the Federal Government published its final report in 2008 [106]. The report developed a ‘Declaration of Principles for Responsible Use of Nano-materials’, with the intention that the participating stakeholders should consider it as a code of conduct for the stakeholders participating in the nano-dialogue. The subsequently initiated second NanoKommission was expanded to 16 people and slightly modified: instead of the BDI (the umbrella Association of German Industry) and representatives of the hard sciences, members from churches, the Ministry of Consumer Protection as well as lawyers were included. The working structure remained similar and the work of the commission was supported by four thematic groups (“Monitoring the implementation of the principle”, “Development of a technical guidance for a survey and comparison of benefit and risk aspects of nano-products”, “Examination of regulations of nano-materials and nano-products” and “Criteria for a preliminary assessment of nano-materials with regard to their effects on human health and the environment” as well as an additional working group “Sustainable nanotechnologies – Green Nano”). The working groups consisted of 20 to 25 members each. The second NanoKommission placed a stronger thematic focus on regulatory issues, which reduced the chances of reaching a consensus, particularly in the thematic groups 1 and 3. In 2011, the second NanoKommission published its final report, which mainly focuses on the better implementation of the five principles for responsible handling of nano-materials [16]. Furthermore, the report provides the basis for a guideline to oppose the benefits and risks of nano-products and criteria to assess nano-materials with regard to their environmental, health and safety implications. It further consists of an opinion on the need for regulation and recommends developing a guideline on green nanotechnologies ‘Green Nano’ [17]. Both reports showed that governance strategies issued by the NanoKommission focused on risk management approaches rather than on soft or hard law.

The Federal Environmental Agency published an updated edition of the background paper of 2006 [135]. Further governmental and non-governmental

<sup>14</sup> On these issues see e.g. printed matter [49, 51, 53, 54] of the German Parliament.

organisations such as the Federation for Food Law and Food Science and the Federation of German Consumer Organisations as well as the Federal Government discussed issues like food and consumer protection.<sup>15</sup>

Regulatory issues were discussed in a legal opinion commissioned by the Federal Ministry of Environment (BMU) and composed by the Ökoinstitut Freiburg and the Society for Institutional Analysis Darmstadt, published in December 2006 [108]. This report focused on potential adaptations of the existing legal framework to the needs of nanotechnology. In particular, this report suggested adapting the European chemical regulation REACH to nano-materials and explicitly mentioning them, reducing the product volume from one ton per year for the registration of nano-materials and developing specific test and monitoring approaches. Furthermore, the report also suggested more voluntary governance forms such as encouraging self-regulation and work on standardisation (ibid.). The suggestion to adapt the chemical regulation was also picked up on in reports by the Federal Government and by consumer groups, in the latter case particularly with regard to consumer protection.<sup>16</sup> The Association of the Chemical Industry (VCI) – in cooperation with the trade unions and occupational safety organisations – further advanced the issue of occupational safety and health. In this context, the VCI and companies and authorities like the BAuA developed another code of conduct for the chemical industry with respect to the handling of nano-materials in the workplace and guidelines for workplace safety involving nano-materials [7, 137].

In 2011, the second NanoKommission of the Federal Government published and presented its final report and the working group reports in a public discussion [107]. Furthermore, the State Committee of Experts on the Environment analysed the environmental implications of nanotechnology in a special report [52].

Further topics of the German regulatory discourses after 2010 included questions like environmental and health protection and a nano-product register, whose feasibility was analysed by the Ökoinstitut Freiburg in a study published in 2010 [113]. At the beginning of 2013, the Federal Departmental Research Establishments presented the initial review of their joint research strategy on health and environmental risks of nano-

materials, which simultaneously provided an outlook regarding the further strategic alignment of nano-EHS research [136].

In Switzerland, the regulatory discourses after 2006 focused almost exclusively on synthetic nano-materials. Thus the Federal Office for Environment (BAFU) and the Federal Office of Public Health (BAG), together with invited authors and coordinated by the Innovationsgesellschaft, composed a basic report. This report covered issues like innovation potential, chances, environmental and health risks and the need for accompanying research and dialogue [26]. On the basis of this report, the Swiss government (the Federal Council) adopted the action plan “*Synthetic Nano-Materials*” in 2008.

This action plan outlined the Swiss government’s assessment that no additional regulation on the legislative level was needed. However, the government announced that it would be making adjustments at the ordinance level. The report concluded with four recommendations: 1. communicating and promoting the public dialogue on benefits and risks of nanotechnology, 2. supporting scientific and methodological conditions for identifying and avoiding potential harmful effects on human health and the environment, 3. establishing regulatory conditions for the responsible development of nanotechnology, 4. better use of existing funding instruments [29].

In 2008, the Swiss National Science Foundation (SNF) launched a national research programme, ‘Opportunities and Risks of Nano-materials’, with a strong focus on hard science and toxicological research.<sup>17</sup> In 2008, the Swiss Academies of Arts and Sciences published a policy document on nanotechnology [118]. This paper presented an inventory of ethical, legal and social implications (ELSI) related to nano-science and nanotechnology as well as risk, social science and cultural studies research in Switzerland [123]. Furthermore, this policy document recommended the promotion of research, risk and ELSI research, independently of the private sector, as well as proactive exchange between science and society.

Issues discussed in the Swiss parliament covered the question of a need for statutory regulations, risk and accompanying research as well as the application of

<sup>15</sup> See the following policy documents and printed matter of the German Parliament [11, 50, 139].

<sup>16</sup> See also printed matter [49] of the German Parliament.

<sup>17</sup> See: 22.10.2008: tender of the national research programme NFP 64 by the Swiss National Science Foundation (SNF) ([www.nfp64.ch](http://www.nfp64.ch), viewed 17.7.2012).



the precautionary principle, governmental activities to identify risks, occupational and product safety, disposal and consumer information.<sup>18</sup>

Moreover, in the years 2011–2013, the responsible authorities in Switzerland developed a number of informal (soft law) measures such as the creation of a precautionary matrix, voluntary guidelines for the industrial identification of nanotechnology-specific risks, and a voluntary code of conduct for workplace safety, safety data sheets, guidelines for disposal, recycling and labelling, and a dialogue platform on consumer information on synthetic nano-materials in products and the infonano website.<sup>19</sup> In particular, Switzerland introduced a ‘registration and product register for chemicals and nano-materials’ in 2012 [2]. Since then, the registration and notification of nano-materials requires additional information with regard to their identity, particle size, shape and composition. Regarding cosmetics, Switzerland plans to harmonise its cosmetic law with that of the EU in 2015. Meanwhile, nano-materials in cosmetics can be declared on a voluntary basis.<sup>20</sup>

Self-regulatory initiatives were also developed in Switzerland in the years 2005–2008. The Innovationsgesellschaft, a private consulting company with a focus on risk management and safety issues of nano-materials, together with additional partners such as TÜV Süd and Interessengemeinschaft Detailhandel Schweiz, thus established the platform “Nano-Regulation” in 2005, the certifiable risk management and monitoring system CENARIOS and a principles-based code of conduct in 2007, all with a focus on nano-materials.<sup>21</sup> In the 2007 code of conduct, the Swiss retail trade interest association declared that the signing members would take responsibility for their own actions, ask for nano-material-related information within the supply chain and provide transparent information to consumers [77]. In the same year, the International Risk

Governance Council IRGC, located in Geneva, developed a *Risk Governance Framework* for nanotechnology [78]. This framework consisted of a conceptual scheme to analyse nanotechnology regarding international regulatory and science policy aspects with the aim of supporting risk management for decision makers. This scheme particularly covered general aspects and visions of future generation nano-materials that lead to a rather broad and vague governance approach (ibid.).

In Austria, the BMVIT engaged the ITA with the project NanoTrust in 2007, with the aim of identifying knowledge gaps and potential regulatory deficits and offering a discussion platform.<sup>22</sup> At the same time, parliamentary initiatives and debates emerged. They covered issues such as regulation, occupational safety and health, health and the environment, food, cosmetics, labelling, precaution and cosmetics.<sup>23</sup> In 2009, the Federal Ministry of the Environment (BMLFUW) established a platform on which stakeholders and representatives from the administration, NGOs and science met on a regular basis. In 2010, the Austrian government adopted the Austrian Nanotechnology Action Plan (ÖNAP), prepared by working groups from the BMLFUW nanotechnology platform. The ÖNAP identified three strategic fields for governmental activity: the environment, health and occupational safety. The ÖNAP further provided recommendations for the review and securing of the legal framework and worked out the legal situation in Austria and the EU. This particularly concerned the field of occupational safety and consumer protection. Furthermore, the ÖNAP recommended examining whether nano-labelling or a nano-register would be needed and, if necessary, launching a corresponding initiative on the EU level. Other recommendations consisted of coordinating with international legal developments (REACH, definition, standardisation) and promoting voluntary measures to strengthen the precautionary and polluter-pays principles. Furthermore, the establishment of a NanoInformationsPlatform (NIP) was scheduled to enable the exchange of information on nano-governance and regulation within the administration and with the public (NIP went online in late 2012).<sup>24</sup>

<sup>18</sup> See e.g. Swiss National Council motion by National Counsellor Maya Graf (gps) on the statutory regulation of nanotechnology and the launch of a national risk research programme 11.05.2006 and postulate from then National Counsellor Didier Burkhalter 13.06.2006, regarding the promotion of innovation (see [http://www.parlament.ch/D/Suche/Seiten/geschaefte.aspx?gesch\\_id=20114201/visited](http://www.parlament.ch/D/Suche/Seiten/geschaefte.aspx?gesch_id=20114201/visited) 04.06.2014).

<sup>19</sup> See <http://www.bag.admin.ch/nanotechnologie/12167/12168/index.html?lang=de> and <http://www.bag.admin.ch/nanotechnologie/12171/index.html?lang=de> (visited 04.06.2014).

<sup>20</sup> See also [27, 28] and <http://www.bag.admin.ch/nanotechnologie/index.html?lang=de>, viewed 21.11.2013).

<sup>21</sup> See <http://innovationsgesellschaft.ch/> (visited 28.11.13).

<sup>22</sup> <http://nanotrust.ac.at>.

<sup>23</sup> For this and further references see [61].

<sup>24</sup> <http://nanoinformation.at>.

In Austria in 2010, the issues of the environment, research, economy and health thus dominated the regulatory discourses. Further governmental activities were mainly concerned with participation in the regulatory processes at the EU level and with monitoring of the Austrian market, in particular of consumer products, but not with any concrete regulatory action [94]. After the implementation of the ÖNAP, EHS research was promoted to some extent.<sup>25</sup> The TA project NanoTrust has constantly been active in feeding the ongoing debates and was prolonged twice (in 2010 and 2013). It is now a project funded not only by BMVIT, but also by three other federal ministries<sup>26</sup>. In 2013, the informal working party coordinating the NIP became institutionalised as the Austrian “Nano-Information-Kommission”, managed by the Federal Ministry of Health, and chaired by an ITA researcher.

Furthermore, the authorities of German-speaking countries responsible for labour protection, environment protection, health protection, consumer protection etc. formed networks in a more formalised structure. Thus the annual International Nano Authorities Dialogue (Nano-Behördenialog) was established, where representatives of the protective authorities of Austria, Switzerland, Germany and Liechtenstein – as a rule in the presence of guests from science, economy, and NGOs – exchange views on current developments and regulatory perspectives in nanotechnology.

At the EU level,<sup>27</sup> discourse intensified after the Commission issued the First Implementation Report 2005–2007 on the action plan [34]. In the report, public health, safety, environmental and consumer protection issues were the main regulatory targets. Nevertheless, the Commission maintained that the existing legislative framework, in principle, was suitable and adequate. One year later, in 2008, the Commission published a communication on regulatory aspects of nano-materials [36]. This communication still argued that, in general, the existing legal framework covers hazardous implications and risks

emerging from the use of nano-materials. Parallel to these activities however, the Commission adopted the first nano-specific legal act, a non-binding recommendation on a code of conduct for responsible nanosciences and nanotechnologies research, consisting of principles and guidelines for member states, public and private actors involved and interested in nanotechnology research [35].<sup>28</sup> Furthermore, the Commission also established a stakeholder dialogue (“Safety for Success”).<sup>29</sup>

Until 2009, the discourse was as good as monopolised by the European Commission and the prevailing argument was that the legislative framework was adequate for governing nanotechnologies. A turning point, however, came in the form of the Resolution of the European Parliament on regulatory aspects of nanomaterials [114] in answer to the Commission’s communication on regulatory aspects of nanomaterials [35]. With the resolution the Parliament partly took over thematic leadership from the Commission. In its resolution, the Parliament challenged the assessment of the EU Commission concerning the adequacy of the existing legal framework and demanded comprehensive legal steps to adapt the existing regulation to new nano-materials. The Parliament particularly confirmed the “no data, no market” principle developed within the context of the European chemicals regulation REACH,<sup>30</sup> and insisted on its enforcement also in the field of nano-materials. The Parliament also requested political and institutional reactions such as the establishment of a “nanotechnology coordinator” to link the policies of the various Directorates General.<sup>31</sup>

In 2009, the Commission issued the Second Implementation Report [39]. At this point the Commission acknowledged that some areas of legislation would need adaptation. The Commission referred to chemicals, novel food, food additives and cosmetics as being the main areas of regulatory interest. Important advisory

<sup>28</sup> For a further analysis of the code of conduct see [19, 60, 138]

<sup>29</sup> For the first of four organised dialogues between 2007 and 2011, see [http://ec.europa.eu/health/nanotechnology/events/ev\\_20071025\\_en.htm](http://ec.europa.eu/health/nanotechnology/events/ev_20071025_en.htm)

<sup>30</sup> Regulation EC 1907/2006.

<sup>31</sup> For further analysis of the European Parliament Resolution see [61].

<sup>25</sup> [www.ffg.at/nano-environment-health-and-safety](http://www.ffg.at/nano-environment-health-and-safety).

<sup>26</sup> Namely the federal ministries for the environment, for health and for consumer protection.

<sup>27</sup> For the developments up to 2010, further analysis and references see [61].

functions were taken over by the European Group on Ethics in Science and New Technologies (EGE)<sup>32</sup> and by Scientific Committees (see in particular the Scientific Committee on Emerging and Newly Identified Health Risks – SCENHIR and the Scientific Committee on Consumer Products – SCCP)<sup>33</sup> as well as by European agencies (such as the European Chemicals Agency – ECHA or the European Food Safety Authority – EFSA) which composed various reports on nanomaterials (e.g. [56, 57]). In 2010, the STOA panel of the European Parliament launched a separate TA study on NanoSafety.<sup>34</sup> In addition, various research groups funded by the EU started analysing nanotechnology regulation (e.g. NanoCode)<sup>35</sup>.

From 2009 onwards, the regulatory discourse in the EU was mainly dominated by the Commission and the Parliament and focused on regulatory issues of nano-materials. The discourses involved further EU institutions, like the EU Council and the European Economic and Social Committee,<sup>36</sup> although their role was minor.

Partly in response to the European Parliament Resolution [114], the European Union basically started to develop nano-specific provisions from 2009 onwards.<sup>37</sup> These regulatory efforts so far concerned primarily food,<sup>38</sup> cosmetics<sup>39</sup> and chemicals<sup>40,41</sup>. The nano-specific provisions within these regulations follow a similar model: the regulations regularly define nano-materials and contain notification and labelling require-

ments.<sup>42</sup> In the area of chemicals regulation, nano-specific adjustments (REACH regulation and CLP regulation) have been discussed in detail and negotiated, though so far only implementations at the application level have been conducted.<sup>43</sup>

In addition to these hard law efforts, the European Commission adopted a further non-binding recommendation on the definition of nano-materials.<sup>44</sup>

The following section discusses how the constellations of the most prominent actors, issues and practices in the discourses of the three analysed countries and the EU have shifted over the three phases.

### Issues, Actors and Practices in the Three Phases

Issues: From Nanotechnology to Nano-Material and from ESLI to EHS

The *early phase* (2000–2005) was characterised by a broad thematic scope in the negotiations of nanosciences and nanotechnologies in Germany and Switzerland and at the EU level. Those discourses comprised issues such as economic potential, promotion of innovation, research policy, sustainability, nano-materials, nano-phenomena and visions, as well as potential implications. The discourse on implications initially covered more general and higher-level areas such as ethical, legal and social implications (ELSI). During the *middle phase*, the issues discussed shifted in all the analysed areas in two respects; first, there was a shift from nanotechnology to nano-materials and, second, a shift in accompanying research from ethical, legal and social implications (ELSI) to environmental health and safety issues (EHS). The *late phase* was characterised by a comprehensive and stabilised thematic focus on nano-materials used in consumer products and specific related (EHS) regulatory issues such as precaution as well as on questions of definition and nomenclature. More broadly scoped and visionary issues discussed in early TA stud-

<sup>32</sup> See in particular [58]

<sup>33</sup> See e.g. [125–128]

<sup>34</sup> [www.europarl.europa.eu/stoa/cms/studies](http://www.europarl.europa.eu/stoa/cms/studies) (visited 13.08.2013).

<sup>35</sup> <http://www.nanocode.eu>.

<sup>36</sup> For further references see [61].

<sup>37</sup> Nano-specific provision can already be found in EC 1333/2008 (food additives). Art 12 states the following: “When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.”

<sup>38</sup> Regulation EU 1169/2011 (food information).

<sup>39</sup> Regulation EC 1223/2009 (chemicals).

<sup>40</sup> Regulation EU 528/2012 (biocidal products).

<sup>41</sup> For the early developments up to 2010 with further references see e.g. [61]. For labelling requirements see e.g. [59]. See also the directives on electrical and electronic equipment (Directive EU 2011/65) and on waste electrical and electronic equipment (Directive EU 2012/19).

<sup>42</sup> For further analysis and references see [59] and the proposal for a Regulation on medical devices COM [34] 542.

<sup>43</sup> For further references, see e.g. [61] and [http://echa.europa.eu/view-article/-/journal\\_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated](http://echa.europa.eu/view-article/-/journal_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated) (visited 14.06.2014).

<sup>44</sup> 2011/696/EU.

ies and public debates, such as human enhancement and nano-medicine, became less important in the late phase.

Actors: Expanding the Range from Political Institutions to non-Governmental and Commercial Organisations

The spectrum of actors involved in the discourses expanded throughout the three phases and shifted from political institutions traditionally involved in regulatory issues to various societal and non-governmental actors. The regulatory discourses in the *early phase* was particularly characterised by activities of the related authorities, members of parliament, TA organisations and actors of the private sector such as chemical companies and their industry association in Germany; and of re-insurance companies, advisors and think tanks in Switzerland. In the *middle phase*, the spectrum of involved authorities, parliamentary groups and organisations of the private sector widened. New actors such as NGOs and, in Germany, a national advisory board composed of the most important stakeholders, stepped onto the stage. This led to a shift from actors who first and foremost framed innovation and technology issues to actors who focused more on environment, health and safety related issues, such as members of the related authorities and civil society organisations. This shift was further accentuated in the *late phase*, in which additional actors specialised in issues such as nano-materials, environment, health and safety issues, such as consumer organizations, entered the discourse.

The analysis of the actors involved throughout the three phases showed that it was in particular actors representing non-governmental and commercial organisations that gained in importance. Due to their openness to soft law and discursive regulatory approaches, they obtained increased influence in nano-related regulatory issues. In Germany, for example, the association VCI, the chemicals company BASF and the environmental association BUND actively participated in the early phase of the discourse and became members of the NanoKommission—the national dialogue committee that considerably influenced German nanotechnology policies. This enabled such actors to integrate their objectives, interests and intentions at the core of political decision-making.

Discourses on legally binding and hard law measures, like the proposed amendments to the EU chemicals legislation REACH and the idea of implementing reporting and communication tools on a

mandatory level, showed a profound gap between the interests and positions of the various stakeholder groups. It has not been possible to obtain political consensus so far, neither *within* nation-states with distinct stakeholder differences as regards national regulation nor *between* nation-states with different economic and political preference structures for European regulation.

Practices: ‘Governance turn’ or ‘Hard law shift’?

Our analysis of the regulatory discourse on nanotechnology showed that self-regulatory and soft law practices in particular played an important role, such as assessment studies, action plans, safety recommendations, guidelines, precautionary matrix and research-policy papers, cooperative forms of communication and negotiation such as stakeholder dialogues and dialogue platforms, as well as codes of conduct, product guidelines and certification systems. In contrast to modes of governance based on traditional statutory regulations, these new governance forms dominated the discourse throughout all phases and gained in importance over time in all the analysed countries.<sup>45</sup> The EU, however, followed an approach between 2004 and 2009 which tried to foster the adoption of soft law measures (such as the EC CoC). Due to some pressing initiatives of the European Parliament, the EU started to implement nano-specific provisions (e.g. cosmetics, food labelling, biocidal products). In this regard, there is a coexistence at the EU level of two different approaches (a mix of soft and hard law), though EU law in this field seems to be moving (slowly) towards more detailed regulation in several domains and sectors.

However, with regard to more formalised steering approaches and schemes, such as codes of conduct, guidelines and monitoring instruments, the countries showed some differences. While such forms have not as yet been developed in Austria, their individual shapes and the actors involved differed considerably in Germany and Switzerland. In Germany, mainly manufacturers in cooperation with associations and authorities developed such schemes (BASF, VCI, BAuA), while in Switzerland this was mainly done by think tanks and tertiary sector firms, like re-insurance and consulting firms, the latter also and in cooperation with authorities (IG-DHS, Innovationsgesellschaft, IRGC and SwissRe).

<sup>45</sup> This is particularly applicable at state level (cf. [62]).

## Two Regulatory Cultures in Governing Nanotechnology

The analysis of the regulatory discourse on nanotechnology in Germany, Austria, Switzerland and the EU showed that the discussed issues, the involved actors and the observed practices corresponded in many respects. This might be due to the strong link between the three countries and the EU in various regulatory fields related to nanotechnology. However, the comparison of the thematic focus in the analysed cases showed two different governance approaches: on the national level, besides the conventional, visionary and innovation-driven discourses, technology assessment was an early issue in all the three analysed countries. TA issues were followed by a general and overall focus on substance *risks* and on potentially adverse implications of nano-materials, mainly in consumer products. Furthermore, all three countries showed governance approaches based on soft law, self-regulation and forms of new governance. None of the analysed countries used such approaches based on hard law, however.

At the EU level, on the other hand, statutory regulation was also used and the regulatory discourse focused on both products and risks. Until 2009, the EU governance approach was based on using and adapting the existing regulation and used soft law to foster the self-regulatory capacities of mainly private actors (like e.g. [35]). After 2009, selected laws were adapted to nano-materials (e.g. cosmetics, biocidal products, food), which is thus indicative of a product-oriented approach. In this sense, the EU Commission prioritises the general regulatory framework or the *incremental approach*, which provides for an ongoing and case-specific introduction and implementation of nanotechnology-related issues in the existing legal framework as opposed to the idea of establishing an entirely new regulatory framework for nano-materials [64].

In addition to adapting the existing legal framework, the European Commission also introduced modes of governance based on more informal instruments of a soft law nature. While the modes of governance based on statutory law (or the hard law measures) focused on nanotechnology *products* and developments, such as cosmetics, food and biocides, the soft law measures and the new modes of governance mainly concentrated on *risks*. This was the case with the EU CoC as well as with the recommendation for a definition of nano-materials.

In addition to the *risk-based* orientation within the nation states, the regulatory culture of the EU is characterised here as *risk-based and product-oriented*. Therefore, while governance measures in the individual countries primarily focused on potentially hazardous implications and *risks*, those on the EU level also focused on *products*. These two approaches cannot be clearly distinguished from each other, rather they are intertwined and aspects of both can be found in all the analysed countries. In this notion, ‘regulatory cultures’ are not stable entities, as the boundaries between the various political spaces are vague and overlapping. This is particularly true of Germany and Austria as EU members, but also of the non-member Switzerland. In conclusion, this study argues that risk-based regulatory culture approaches could have been observed in all the analysed countries (Germany, Austria and Switzerland) as well as on the EU level. A product-oriented regulatory culture approach was only observed on the EU level, however.

Besides these more general, issue-focused cultural characteristics of the regulatory discourse in the analysed countries and at the EU level, this study highlights different *strategic approaches* regarding the actors involved and the regulatory practices. The risk orientation implies a focus not only on predictable and scientifically measurable implications but also on hypothetical, unclear, uncertain and imprecise aspects, which on the country level opened up a wide range of soft law and self-regulatory approaches. Thus the analysed countries showed different nation-specific approaches and strategies in the thematic and formal treatment of nanotechnology, each linked to local political cultures:

In *Germany*, among the various involved actors, it was particularly manufacturers, federal authorities and the national dialogue committee NanoKommission which played prominent roles. Manufacturing companies and associations developed self-regulatory instruments at a relatively early stage, also in cooperation with authorities. These activities might have an important impact on the consensual and cooperatively oriented German culture in governing nanotechnology. Federal authorities were involved in such activities as well as in assessment studies and national and international collaborations. The NanoKommission was particularly important in framing the overall consensus-based atmosphere in the German nanotechnology discourse, despite observable differences between the innovation-oriented

actor groups and those primarily representing protective aims. Thus in Germany the involvement of various stakeholder groups constituted an important emphasis and was institutionalised at the highest political level.

The guiding strategy in the German nanotechnology discourse can therefore be characterised as *cooperative and self-regulatory*. This approach might have its roots in a strong tradition of a neo-corporatist culture in the governance of science and technology and substance-related risks (e.g. [40, 86, 130]). However, this culture might be constantly challenged by the divergent claims and expectations of stakeholders regarding the formal legislation of nano-materials and nano-products.

In *Austria*, the regulatory discourse began later than in the other observed places and mainly reacted to international activities. Here, particularly TA played an important role within the regulatory discourse. In the context of the national action plan almost all interested actors were incorporated, which could also be explained by the neo-corporatist regulatory culture that is also observable in the Austrian context. In particular the implementation of the Nano-Informationen-Plattform constituted a cooperative procedure in which not only authorities and agencies but also industry, social partners and NGOs were included. However, the discourse was particularly dominated by authorities with support from TA and other interested actors. Self-regulatory and cooperative governance approaches by non-governmental actors, such as manufacturers, have not been observed in Austria. The Austrian strategic orientation can thus also be classified as *cooperative*, though not as self-regulatory as is the case in Germany.

In *Switzerland*, in contrast to the other analysed places, the regulatory discourse, particularly in the early and middle phases, was characterised by the absence of authorities and manufacturing companies. Instead, mainly, tertiary sector companies composed assessment reports and established self-regulatory approaches, such as monitoring systems and risk management schemes for the manufacturers. Only the last phase was characterised by an assumption of thematic leadership by the authorities. The relevant authorities issued an

action plan, primarily focusing on opportunities and risks and the need for research and dialogue, contributed to initiating a national research programme funding EHS research and issued a precautionary matrix and recommendations for workplace safety. This might have been a reaction to international and supranational activities, parliamentary inquiries and activities of non-governmental actors. Thus the Swiss regulatory discourses also showed a *self-regulatory* orientation.

Compared to the other two countries, however, the regulatory discourse in Switzerland, despite its regulatory culture oriented towards grassroots democracy, did not show any distinct focus on participation, consensus and cooperation. Instead, a wait-and-see strategy could be observed on the part of governmental actors, which initially, with the exception of the national TA organisation, left nanotechnology governance basically to non-governmental actors. They, similar to those in Germany but with different actor constellations, established self-regulatory approaches. In the late phase, these were adopted by the authorities, which developed soft law approaches. Therefore the strategic orientation of the risk-based regulatory culture in Switzerland can be described as *self-regulatory* and *soft law-oriented*.

*European Union* Until the EU Parliament issued its resolution on regulatory aspects, the EU mainly followed a risk-based culture in governing nanotechnology by focusing on non-binding, informal governance approaches (a strategy, an action plan, a recommendation for a code of conduct, a recommendation on definitions and a TA report). After 2009, the EU also used hard law governance and applied a product-oriented culture, focusing on some selective sectorial fields (like food, chemicals and cosmetics). In general, the regulatory discourse took place within the institutional framework laid down in the EU treaties (Table 1).

Hence these two regulatory cultures led to different regulatory outcomes: at the level of the nation-states, informal strategic orientations such as cooperative and participative approaches, including stakeholder groups

**Table 1** Two regulatory cultures and their strategic characteristics on supranational and national level

	EU	Germany	Austria	Switzerland
regulatory culture	product based/risk based	risk based	risk based	risk based
strategic characteristics	hard law/informal	cooperative/self-regulatory	cooperative	self-regulatory/informal

in the regulatory discourse, were important in Germany and Austria. Furthermore, self-regulatory approaches were developed by authorities; in Germany often in cooperation with manufacturers and in Switzerland mainly after such approaches were developed by tertiary sector companies. That is not to say that hard law will be replaced by these soft law measures and new governance in the future; however, governance modes based on soft law, self-regulation and new governance framed the regulatory discourse in the analysed countries to a considerable extent.

Modes of governance based on hard law have only been used at the EU level. In this context, the hard law discourse in the two member countries Germany and Austria was delegated to a great extent to the supranational level.

The high degree of convergence in the regulatory cultures of Germany and Austria is surprising as the constitutional framework would suggest wider difference. Oriented to fundamental rights, the rights-based Austrian constitution basically permits research as long as it is not forbidden.<sup>46</sup> By contrast, the value-based German constitution requires governmental authorisation for hazardous technologies<sup>47</sup>.

Why this genuine regulatory difference has not manifested itself more profoundly in the analysed discourses might be due to the various elements shaping the regulatory discourse in the analysed countries. In this context, the influence of the constitution on subjacent regulatory levels proved to be more limited than intuitively presumed. Furthermore, EU law might have gained in importance as compared to national constitutions. In addition, the individual actors involved in regulatory discourses on emerging technologies might have acquired an increasingly dominant role in framing the used modes of governance.

The important role played at the national level by governance based on soft law and self-regulation might have contributed to strengthening the influence of non-governmental actors in the regulatory discourse on emerging science and technology fields. However, as the genuine logics of external stakeholder groups differ significantly from those of institutions traditionally involved in the regulatory process, side aspects have

gained importance within the regulatory discourse. These concern issues such as contributing their own agenda, securing their own market, posing questions of power and increasing influence in science policy and regulatory issues, such as avoiding statutory regulation. Not only do these aspects distract from the genuine aim of environmental regulation, namely protecting public health and the environment, they might also contribute to regulatory uncertainty. Not least, this uncertainty conflicts with another aim of science policy, namely the promotion of innovation.

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<sup>46</sup> In this context see e.g. [91].

<sup>47</sup> In this context see the Constitutional Court's decision in the Kalkar case (BVerfG, decision 8. 8. 1978–2 BvL 8/77; OVG NRW (lexetius.com/1978,2)).

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