THE INSTITUTIONALISATION OF THE PRECAUTIONARY PRINCIPLE AND AGENCIFICATION OF RISK ANALYSIS IN THE EUROPEAN UNION

INSIGHTS FROM FOOD SAFETY AND CHEMICALS REGULATION

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Abstract

Risk regulation in the fields of EU food safety and chemicals management has been characterised by two general trends of European governance over the past decade: the growing importance of the precautionary principle and agency governance. This thesis analyses the historical institutionalisation of the precautionary principle in both fields as well as the coincident establishment of the European Food Safety Authority and the European Chemicals Agency, asking for which reasons and how the respective measures have been adopted and implemented. Methodologically, a well-structured historical narrative that is informed by qualitative analysis of official Community documents will be employed in order to delineate the relevant proceedings. Since it has been argued that historical institutionalism as a theoretical approach is better suited to analyses of institutional persistence, its explanatory potential for these two cases that clearly brought forward institutional change will also be analysed. It is shown that historical institutionalism is conceptually well equipped to account for the relevant processes in both food law and chemicals regulation.

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1. Introduction

In recent scholarship on environmental and human health protection from risks, the European Union (EU) has been named "the global precautionary superpower" (Tiberghien 2009:389). After the Commission released a Communication on the precautionary principle in the year 2000, this approach to risk regulation has become the guiding principle in various policy fields of the EU. The precautionary principle in its most common interpretations entails four elements: "(1) taking preventive action in the face of uncertainty, (2) shifting the burden of proof or responsibility onto proponents of potentially harmful activities, (3) exploring a wide range of alternatives to possibly harmful actions, and (4) increasing public participation in decision-making" (Hansen et al. 2007:395). The ambitiousness with which the EU follows the precautionary principle these days raises the question as to why this approach has been adopted and how it evolved historically. Moreover, it is worth scrutinising with which instruments the EU has sought to implement the rather abstract principle into practice.

Regarding this matter, another trend of regulatory governance in the EU coincides with the amplification of precautionary risk analysis. This is the notion of 'agencification', i.e. the growing establishment of independent regulatory agencies as an adequate institutional solution for co-ordinating and carrying out regulatory duties. Indeed, since the turn of the millennium, the number of EU agencies has almost tripled. This trend also occurred in policy sectors that are highly concerned with risk analysis, where two agencies responsible for environmental and human health protection have been created both in the fields of food safety and chemicals management. In 2002, the European Food Safety Authority (EFSA) was established; whereas the European Chemicals Agency (ECHA) began its work in 2007. Interestingly, both agencies found their legal basis in regulations that also established the precautionary principle as guiding for regulation in the respective fields, namely Regulation 178/2002 laying down the general principles and requirements of food law, and the REACH Regulation 1907/2006.

The fact that the institutionalisation of the precautionary principle and the establishment of regulatory agencies went hand in hand in both cases presents an interesting departure for academic research. This thesis therefore asks which processes and motivations have led to the advancement of the precautionary principle and the coincident agency creation in food safety and chemicals regulation. In order to approach this question, historical institutionalism (HI) will be employed as the theoretical framework for analysis. Since some scholars have argued that HI is better suited to explain persistence of institutions rather than their change (Peters 1999:68), it moreover is an important intention of this thesis to examine the explanatory potential of HI in the two cases that clearly brought forward institutional change. It is argued that historical institutionalism is conceptually well equipped to account for the relevant processes and that all important features of the theory can be found along the way of the analysis. Precautionary thinking has a long tradition in Europe, although regulators ventured down the path towards supranational precautionary frameworks in a very incremental fashion until the mid 1990s. The punctuation of the BSE crisis and associated learning processes strongly accelerated this process, with decision-makers being eager to implement precautionary legislation in order to appease a rather risk-averse public. As a result, the precautionary principle has been 'locked in' to European risk analysis, which makes future departure from this principle highly unlikely.

Besides historical institutionalism, which will be located in the new institutionalist literature and characterised regarding its main features in the following chapter, this thesis will also be informed by the literature on EU 'agencification'. Such practice promises to give additional insights on the motivations behind agency establishment.

Subsequent to these theoretical parts, I will discuss the promises and pitfalls of the precautionary principle and sketch its early development in Europe. Particular attention will then be devoted to the processes that culminated in the regulations 178/2002 and 1907/2006, which will be analysed with particular attention towards the provisions on the precautionary principle as well as EFSA and ECHA respectively. Methodologically, a well-structured historical

narrative that is informed by qualitative analysis of official Community documents will be employed in order to delineate the relevant proceedings.

Eventually, both cases will be compared with regard to the implementation of the precautionary principle and its policy implications, the establishment and functionality of the respective regulatory agencies, and the explanatory potential of historical institutionalism; from which conclusions will be drawn and suggestions for further research will be made.

2. Theoretical Framework

As this thesis analyses both the institutionalisation of the precautionary principle in the EU and the role that is assigned to regulatory agencies in the context of food safety and chemicals management, two strands of theoretical literature can be put forward for the assessment. First and foremost, the respective processes shall be traced with the help of historical institutionalism as one of the 'new institutionalist' approaches. Moreover, the reasons for growing agencification of the EU shall be elucidated with the relevant literature. Both approaches shall eventually be taken together in order to operationalise criteria that help answering the research questions in the subsequent parts of the thesis.

2.1 Historical Institutionalism and its Applications in EU Integration Studies

2.1.1 New institutionalism

Since the 1980s, theoretical approaches which are subsumed under the term 'new institutionalisms' (or 'neo-institutionalism') have gained large popularity in political science. Mainly influenced by behaviouralism (Lowndes 2002:90-92), the new institutionalisms broadened the concept of institution beyond the classical understanding of formal political institutions to a more encompassing definition of formal and informal rules that affect

individuals regarding their political and social behaviour. In a widely acknowledged article, Hall and Taylor (1996) discuss the three main schools, historical institutionalism, rational choice institutionalism, and sociological institutionalism, which despite their similar academic interest have developed rather independently from one another.

Central to all variants of new institutionalism is the examination of how individual behaviour is affected by institutions. The seminal questions are "how do actors behave, what do institutions do, and why do institutions persist over time?" (Hall and Taylor 1996:939). Two wider approaches to answer these questions are provided by new institutionalists, which have been classified as the 'calculus approach' and the 'cultural approach'. According to the calculus approach, human behaviour is based on rational and strategic calculations of the individual. This is informed by institutions insofar as they provide certainty about the consequences of individual action to some extent. By altering the expectations about these consequences, institutions affect individual behaviour and strategic interactions among actors. In contrast to this 'logic of consequences' inherent to the calculus approach, it is stressed in the cultural approach that behaviour is not solely strategic but also informed by norms, beliefs, and values besides purposive or rational considerations. The choice of certain behaviour is therefore not understood as the product of instrumental calculation, but as an interpretation of the situation which is informed by a 'logic of appropriateness' (March and Olsen 1998). Institutions in this context facilitate the situational interpretation by providing cognitive or moral templates for the appropriateness of a course of action, whereby they affect the preferences and identities of actors. The persistence of many institutions is explained with their conventional character, which makes them taken-for-granted and resistant to redesign. Contrary to this cultural explanation, the calculus approach suggest the embodiment of Nash equilibria in persisting institutions, which prevents individuals from deviating from such institutionalised patterns of behaviour (Hall and Taylor 1996:939f).

With regard to the three major neo-institutionalist schools, it is quite obvious that rational choice scholars follow the calculus approach, whereas sociological institutionalists are more concerned with the cultural approach. Consequently, rational choice institutionalism sees individuals as strategic utility-maximisers with given preferences who act according to cost-benefit analyses. Formal institutions frame repetitive negotiation games to which actors correspond in accordance to the logic of consequences. Sociological or constructivist approaches on the other hand have a much stronger focus on informal institutions and how these 'constitute' actors regarding their preference construction and selection of appropriate behaviour. Finally, historical institutionalism is more eclectic, employing both logics to analyse the relationship between individual behaviour and institutions. Institutional outcomes can thus be perceived as a joint product of norm-abiding and utility-maximising behaviour (Hall and Taylor 1996:940, Pollack 2009:126).

2.1.2 Historical institutionalism

Historical institutionalist scholarship originates from the work of Kathleen Thelen and Sven Steinmo (1992) and has received large attention from further scholars over the past two decades, most notably Paul Pierson, Peter Hall and Theda Skocpol (1995). According to Pierson (1998:29, italics in original), HI is

> "*historical* because it recognises that political development must be understood as a process that unfolds over time. It is *institutionalist* because it stresses that many of the contemporary implications of these temporal processes are embedded in institutions, whether these be formal rules, policy structures, or social norms."

The most distinctive feature of historical institutionalism is the emphasis on how 'history matters'. As Steinmo (2008:164ff) points out, the historical context of political events has direct consequences for subsequent proceedings. This is especially due to learning processes of involved actors, whose behaviour, attitudes, expectations and strategic choices are moulded in experience from precedent events and thus affect future decisions. History is therefore not to be misunderstood as a disconnected sequence of events, but rather consists of strongly

interconnected occurrences that continually shape one another. Yet, historical development does not necessarily happen in a linear fashion but is a rather dynamic process that contains frictions and unintended consequences of action. The role of timing and sequencing therefore requires critical scrutiny because "*when* things happen within a sequence affects *how* they happen" (Tilly, quoted in Pierson 2004:54, italics in original).

The notion of *path dependence* and aspects of time and timing are therefore central to HI scholarship, which seeks to explain generally incremental patterns of institutional evolution as results of certain policy choices (Bulmer 2009:308). It is implied that "once actors have ventured far down a particular path, they are likely to find it very difficult to reverse course" (Pierson and Skocpol 2002:700), which is especially due to positive feedback mechanisms and increasing returns that result from continuity and entail trajectories for further policy processes, thus 'locking in' existing institutional arrangements (Pollack 1996:437f). This focus on path dependence has caused some scholars to accuse historical institutionalism of being a rather static concept which is much better suited to explain persistence of institutions than their change (Peters 1999:68). While Thelen (1999) attempts to refute such claims with the concept of '*gradual transformative change*' which is triggered endogenously by dynamic learning processes or new ideas, many other historical institutionalists have adopted the work on '*punctuated equilibrium*' (Krasner 1984) or '*critical junctures*' (Collier and Collier 1991) in order to explain the dynamics of radical change as a consequence of exogenous shocks that erode stable patterns of political behaviour and therefore allow for vivid institutional change. Historical development can then move onto a different path. A 'second-generation' literature on HI has also drawn attention on *negative feedbacks* from the social or political sphere which – in contrast to the already mentioned positive feedbacks that support path dependent institutional development – create pressures for change of existing institutions and policies (Streeck and Thelen 2005).

Besides the "twin dynamics of path dependence and radical change" (Bulmer 2009:314) and the afore-mentioned integration of the calculus and the cultural approach, the relationship between institutions and ideas as causal forces in politics is also one of the theory's core features. Historical institutionalists moreover stress power asymmetries across social groups, which are a result of the uneven distribution of power by institutions that tend to give disproportionate access to the political arena to different actors, creating winners and losers. These asymmetries often become obvious with respect to the creation of new institutions ("organisation is the mobilisation of bias", Schattschneider 1960:70), which however remains to be influenced by existing institutional templates (Hall and Taylor 1996:941f, 954).

2.1.3 Applications of HI to EU studies

Historical institutionalist scholarship has drawn from various elements incorporated in other theoretical approaches dealing with the European Union (Pollack 2009:136). The historical institutionalist notion of positive feedbacks as important for future (path-dependent) developments for instance can already be found in the 'primordial' theory of European integration, neo-functionalism (Haas 1958), which emphasises the importance of 'functional spillovers' in the integration process. Another example is Fritz Scharpf's (1988) work on the 'joint-decision-trap' in multi-layered political systems such as the EU (Scharpf uses the example of the EU's Common Agricultural Policy), which is likely to have inspired the notion of 'locked-in' policies in HI. A comprehensive application of historical institutionalism to the European integration process was published by Paul Pierson in 1996 as a critique of Liberal Intergovernmentalism (Moravcsik 1993). Despite the recognition that member state governments are important, Pierson shows how governmental powers and preferences change over time (e.g. through 'gaps' in member state control over institutional change and electoral turnover respectively) and concludes that European integration cannot be understood with the sole analysis of interstate bargaining. "Rather, integration should be viewed as a path-dependent

process producing a fragmented but discernible multi-tiered European polity" (Pierson 1996:123) that unfolds over time.

Even though historical institutionalism does not present an adequate integration theory, it can help our understanding of the EU's institutional development by specifying and testing "more precise hypotheses about types of institutions likely to generate positive or negative feedbacks, the mechanisms of path-dependence, and the impact of temporal factors on the path of European integration" (Pollack 2009:137).

2.2 Agencification in the EU

Studies of regulatory agencies in the European Union have enormously grown in popularity over the past years. Ever since Majone's (1994) initial formulation of the Europe as a 'regulatory state' in which regulation is strongly coordinated and carried out with the help of independent regulatory agencies (IRAs), the number of EU agencies has largely increased and so have scientific debates about the topic. To the date, 32 decentralised and functionally specific agencies have been established to assist the European institutions and most importantly the Commission with the exercise of their duties, a number that has almost tripled since the turn of the millennium. Accordingly, scholarly debate ascribes these agencies great importance and sees a general trend about how regulation is organised. Already in 2001, Christopher Pollitt and his associates have detected a global convergence towards 'agencification' and named 'agency fever' an international policy fashion. More recently and specifically with regard to EU agencies, Kelemen and Tarrant (2011:49) speak of an "extensive 'Eurocracy' outside of the Commission hierarchy", which on the one hand again highlights the importance scholars assign to these agencies but also challenges classical perceptions of agency governance in the sense of delegation under the principal-agent framework (Thatcher 2002 and 2005). Accordingly, scholars have devoted much attention to the formal-institutional independence of agencies over the past years (Magetti 2007, Wonka and Rittberger 2010, Hanretty and Koop 2011).

The question arises what the rationale behind this proliferation of EU agencies is. A main argument for the delegation of powers to IRAs is their capability for credible commitment. It is argued that elected politicians cannot necessarily assure coherence of policies over time, as they have a rather short time horizon and might be replaced after the next election. In order to commit themselves to more or less fixed policy outcomes and rules, they delegate regulatory powers to independent agencies that consist of experts who are not subject to public elections and therefore do not have short-term electoral incentives but a greater capacity to credibly commit to sound policy implementation (Gilardi 2002:874-876). Such practice sends "strong signals of regulatory stability to firms and consumers that a change in political majorities […] should not directly lead to an overhaul of regulatory decisions taken previously" (Wonka and Rittberger 2010:734). Owing to a certain degree of independence from political intervention, agencies can thus contribute to stable expectations for economic actors in a level playing field throughout the Union and decrease political uncertainty. A less laudable reason for delegation of powers to agencies however could also be blame-shifting for unpopular decisions (Thatcher 2002:125). Of course, such depoliticisation holds normative implications regarding accountability and legitimacy that have been discussed in the literature extensively (Curtain 2007, Busuic 2009) but shall not stand in the focus of this analysis. For the purpose of this thesis, I am content with Randall's (2006:405) notion that the "legitimacy of EU institutions, including regulatory agencies, rests on public and member state acceptance of the need for them. Such acceptance is focused on their capacity to carry out important tasks that would otherwise be left undone or would be done poorly".

This statement segues into one further explanation for the growing importance of agency governance, which is the attainment of regulatory objectives in an ever growing and more complex supranational political system. Dehousse already argued in 1997 that member state application of EU regulations needs to be much more uniform, which requires "that the actors in charge of the implementation of Community policies behave in a similar manner" (Dehousse 1997:254) for which he suggested the establishment of pan-European regulatory networks.

Indeed, the boards of EU agencies are largely constituted with experts from the member states and representatives from the EU institutions which facilitates coordination. Due to the complex technical character of many regulatory areas, decision-makers are dependent on scientific information in order to design technically efficient and effective policies. "Regulators independent from direct political intervention are commonly considered to possess the political independence and professional expertise to design regulatory rules that fulfil precisely theses functions" (Wonka and Rittberger 2010:736). Thus, there is a functional logic of delegation to agencies in the face of policy complexity.

2.3 Methodology

The vast 'mushrooming' of EU agencies in the aftermath of the Maastricht Treaty suggests the assumption that EU and member state officials highly value the contributions of IRAs towards supranational decision-making. In the lingo of historical institutionalism one would assume positive feedback mechanisms and increasing returns from past and present experiences, which have led onto a path of 'agencification' in EU regulatory regimes that is still being further developed. Such patterns shall be analysed with regard to the development of EU risk analysis in the following. Historical institutionalism as an analytical tool can certainly enlighten such analysis, as, according to Pollitt (2008:43), scholarship on EU policy dynamics lacks an exploration of issues that could be answered with the help of HI:

- What mechanisms keep policies on particular pathways?
- Under what circumstances do significant changes take place?
- Is path dependency widespread or limited to particular circumstances?
- How should 'within path' changes be distinguished from punctuations?
- And, finally, what is the velocity of policy down a pathway?

Applying these questions specifically to EU risk analysis in food safety and chemicals management, and the respective agency creation, this thesis will scrutinise the historical

processes which have given way for the advancement of the precautionary principle as well as the establishment of both EFSA and ECHA.

This shall be done with the help of a well-structured historical narrative and process tracing which is informed by an analysis of official EU documents in order to delineate all relevant processes. Such methods are commonly employed by historical institutionalists and promise to capture history in all its facets. Since HI is interested in case-specific explanation rather than prediction, it makes sense to prefer interpretive and qualitative research over a purely positivist methodology. Or, as Steinmo (2008:134) puts it in more provoking words: "Studying history with methods and models derived from physics is like studying poetry with algebra."

3. The Precautionary Principle and its Institutionalisation in EU Risk Analysis for Foodstuffs and Chemicals

3.1 Risk Analysis and the Precautionary Principle

The analysis of risk defined as "the probability that a specified harm will occur as a result of exposure to a hazard" (Rogers 2003:270) has become a major challenge for regulators over the past decades. In an ever stronger technologically advanced world, adverse effects of certain innovations and actions on human health or the environment can often not be foreseen due to uncertainty and therefore need to be subject of thorough assessment and regulation.

A common approach to regulate risk is the reactive/preventive system, which adopts preventive countermeasures for future generations after a hazard has been identified. It requires a statistically convincing standard of proof that a product or process is hazardous before interventions are being made. The burden of proof usually is on the side of the regulator. New

products are scientifically screened with regard to their potential harmfulness. The decision about whether regulation is in order and to what extent is being made on the basis of cost-benefit analyses when threats to human health or the environment are tangible (Tait 2001:176f). This preventive approach towards risk regulation is very common in the United States and most other countries around the globe.

Since the 1970s, however, many have advocated for stronger precaution with the handling of risk, acting in accordance with the principle 'better safe than sorry' before there is proof of harm. Potential hazards which might cause irreversible harm once they come into effect are to be avoided in the first place in order to forestall disasters. In the face of scientific uncertainty of a product's risks, decision-makers are supposed to take action to reduce potential hazards before full proof is obtainable. They should rather err on the side of caution and decide in favour of human health and the environment than venturing unknown risks. The burden of proof is reverse and sits with the applicants, who need to prove their product's harmlessness upon which regulators decide after consulting independent scientific experts. Moreover, the exploration of alternatives to possibly harmful products and actions is highly encouraged by this approach.

The idea of precaution is rooted in 'green thinking' and therefore holds a strong political component, embracing ethics of responsibility and environmental sustainability as well as ecological critiques (Recuerda 2008:4). Thus, the application of the precautionary principle "involves deliberation on a range of normative dimensions which need to be taken into account while making the principle operational in the public policy context" (von Schomberg 2006:33). From this normative standpoint, precautionary risk management at the interface of science, society and politics therefore requires a progressive line of deliberations "in order to eventually make the *legitimate conclusions on the acceptability of products or processes*" (von Schomberg 2006:46, italics in original).

It is also this deliberative component that has contributed to the popularity of the precautionary principle over the past decades and certainly is a major reason for NGO support of its application. Since scientists often do not speak with one voice, the public has become confused and distrusting of pure scientific evaluation, and demands the inclusion of socio-cultural criteria into risk management. The rather risk-averse European societies have become increasingly concerned about risks, especially since public trust in authorities and industry regarding effective protection has declined. The precautionary principle thus offered a welcome option for tougher environmental and human health regulation that can be employed by regulators to regain trust (Löfstedt 2003:39f).

Yet, the precautionary principle is also subject to much controversy. Critics regard it as too costly and ineffective, with especially the industry bearing too much of the burden. Moreover, the potential of arbitrary interpretation is highlighted, as understandings of when and how something is safe or uncertain and who decides on what criteria may differ (Löfstedt 2003:38). Majone (2002:106f) thus warns against the policy implications of the precautionary principle, which "may be misused for protectionist ends; it tends to undermine international regulatory co-operation; and it may have highly undesirable distributive consequences". Moreover, it "raises the possibility of a double standard for what in permissible internationally and in intra-Community relations". Various scholars therefore claim that the costs of the precautionary principle outweigh its benefits, especially as it provides incentives for EU member states to exploit it for national interests (Caduff and Bernauer 2006:153). Whether this critique finds its empirical corroborations shall be followed up later in this thesis.

3.2 The Evolution of Precautionary Thinking in the EU

The logic of precautionary measures for public health protection has a long tradition in Europe and can be traced back to the late 19th century (European Environment Agency 2001), even

though no comprehensive framework for its application had been in place for a long time. The precautionary principle as such was developed in Germany ('*Vorsorgeprinzip*') and Sweden in the 1970s as a political strategy to respond to hazards of human action and technological risks in the light of uncertainty (Recuerda 2008:15f). These countries also lifted the issue on the international stage and pressured for precautionary legislation at the European level (Löfstedt 2003:36). Although the explicit incorporation into Community law took until 1992, the precautionary logic had already been applied by the European Court of Justice in its case law without explicitly mentioning it (Recuerda 2008:32-34).

With the passage of the Maastricht Treaty in 1992, the precautionary principle found its way into primary law of the Community, as specified in Article 130r, Paragraph 2:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the definition and implementation of other Community policies.
> In this context, harmonisation measures answering these requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a Community inspection procedure.

Despite this incorporation into primary law, the definition of what exactly was understood under the precautionary principle and its implications for risk regulation remained unclear. It took the mad cow disease in the mid-1990s for the European institutions to fill this gap and react to the associated food safety crisis.

3.3 Food Law in the EU and the Establishment of EFSA

3.3.1 Traditional food safety regulation and the impact of the BSE crisis towards a new regulatory paradigm

Food law had long been dealt with at national level, and Community legislation developed from the functionalist logic of European integration in the context of the single market and common

agricultural policy. Following the principle of free movement of goods and the need of product harmonisation, the Community sought to eliminate trade barriers that resulted from different national food laws by taking over a wide range of regulatory competences. Supranational food regulation must therefore take into account issues such as fair competition, regional peculiarities, new technologies, and of course health and consumer protection (Vos 2000:228f, Randall 2006:410).

For the task of risk analysis in order to assure of food safety, the Community had established a committee structure with various committees and advisory bodies that informed the Commission and member states about potential hazards (Vos 2000:229f). These arrangements in a system of multi-level governance with a rather incoherent concept of risk regulation were however called into question with the breakout of the BSE crisis in 1996, when links between BSE and the Creutzfeld-Jakob disease were discovered. The fact that the Community had not been successful in overcoming BSE since its discovery in 1985 shattered public trust in authorities and resulted in a severe food panic. An inquiry committee of the European Parliament criticised the Commission heavily for deficiencies of its *ad hoc* approach on food safety issues and accused it of mismanagement and disinformation. Its first "Report on alleged contraventions or maladministration in the implementation of Community Law in relation to BSE" pointed out various inadequacies of the system in place and called for more transparency as well as stronger coordination of food safety concerns both within the Commission and between the committees, establishing an integrated approach with a central and powerful food authority. Shortly after publication of the report, Commission President Jacques Santer promised to radically reform food safety regulation, starting with an internal re-organisation of the Commission. All relevant scientific committees dealing with food safety were placed under the sole authority of the renamed Directorate-General (DG) on Consumer Policy and Consumer Health Protection (DG SANCO) and should be supervised by a Scientific Steering Committee (Vos 2000:231-234, Lafond 2001:4-7).

In a second step, the Commission published a "Communication on Consumer Health and Food Safety" in April 1997, which aimed at the reinforcement of consumer health protection and restoring consumer confidence in the Community's regulatory action and food production, including animal and plant health. It made clear that responsibility for legislation should be separate from that for scientific consultation and inspection and that greater transparency of decision-making processes was in need. Scientific advice, risk analysis (composed of risk assessment, risk management and risk communication), and control by national food safety authorities were named as the three complementary instruments to achieve these objectives. The approach should be guided by the main principles of scientific excellence and independence as well as full transparency of the regulatory processes towards the consumer and interested parties (Commission 1997:3, 6f, 9f). The Commission (1997:20) further notes that it "will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists". This passage was only adopted in the final version of the document, after the first draft just mentioned the less specific prevention principle (Lafond 2001:8).

Yet, a coherent framework about how to design the future regulatory space remained to be rather vague. The Treaty of Amsterdam, negotiated under the impressions of the BSE crisis, specified and tightened various provisions on environmental and health protection (Vos 2000:235f) but did not bring a breakthrough either. In April 1999, the European Council urged the Commission "to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle" (Commission 2000a:8).

In December 1999 then, a report from three members of the Scientific Steering Committee called for the creation of a European Food and Public Health Authority as an independent body responsible for questions of food safety, public health, and the environment (James et al. 1999).

This suggestion was seized by the newly elected Commission under Romano Prodi, who in his first speech mentioned food safety as one of the priorities during his tenure. Indeed, the year 2000 should become crucial for the regulatory reorganisation of food safety regulation.

3.3.2 The institutionalisation of the precautionary principle in food law and the establishment of EFSA

On 12 January 2000, the Commission published a White Paper on Food Safety which again specified the requirements for food safety and for the first time envisaged "the establishment of an independent European Food Authority, with particular responsibilities for both risk assessment and communication on food safety issues" (Commission 2000c:14), whereas competences for legislation and control as the two components of risk management should remain in the hands of the Community institutions. This agency, which was to be launched in 2002, should account for excellent, independent and transparent scientific risk assessment in order to restore and maintain consumer confidence. In the White Paper, the Commission (2000c:9) moreover stated that the precautionary principle should be applied where appropriate, announcing to present a Communication on the topic.

This Communication on the Precautionary Principle was then released on 2 February 2000, announcing that

> The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk. [...] Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty. [...] Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an 'acceptable' level of risk for society is an eminently political responsibility.
>
> (Commission 2000a:3f)

Where the application of the precautionary principle appears to be necessary, its measures should be based on the general principles of risk management which include proportionality, non-discrimination, consistency, examination of the benefits and costs of action or lack of action, and examination of scientific developments (Commission 2000a:18-21). In accordance with the precautionary principle, the Commission (2000a:21) recommends to reverse the burden of proof of a product's safety, placing it on the producer and

> "requiring that the substances be deemed hazardous until proven otherwise. Hence it is up to the business community to carry out the scientific work needed to evaluate the risk. As long as the human health risk cannot be evaluated with sufficient certainty, the legislator is not legally entitled to authorise use of the substance, unless exceptionally for test purposes."

Despite this very clear and controversial clause on the inversion of the burden of proof, the Communication in general remained to be "so vague and imprecise that it is only a good guide for arbitrariness or paralysis" (Recuerda 2008:29) but did not have clear policy implications for the application of the precautionary principle at this point.

After both the European Parliament (2000) and the European Economic and Social Committee (2000) in their reports on the Commission's White Paper devoted great attention to the division of responsibilities, budgetary issues and the general functioning of the proposed food authority, which the EP however preferred to call European Food *Safety* Authority, a 'Proposal for a regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food' was released on 9 November 2000. The proposal was very comprehensive, defining principles and requirements for food law, food safety, food trade and transparency. It moreover set out the establishment of a European Food Authority for risk assessment and communication regarding its mission and tasks, organisation, operation, financial and general provisions as well as provisions regarding independence, transparency and communication. This agency was regarded as the most effective mechanism to account for scientific and technical excellence and re-establish public confidence in the regulation of food. The precautionary principle was "recognised as an option open to risk managers when decisions have to be made to protect health or the environment but

scientific information concerning the risk is inconclusive or incomplete in some way" (Commission 2000b:10). Its implications to trade as regards restrictions on the free movement of food had also been considered, calling for proportionate measures to be adopted.

Only a good year after the proposal was published, the 'Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety' was agreed upon by Council and Parliament on 28 January 2002. It aims at the consolidation of confidence of consumers, trading partners and other stakeholders into decision-making processes that underpin food law, which is broadly defined and also includes animal feed as well as agricultural production inputs. These processes are put on the basis of objective, independent and transparent scientific evaluation, which is to be coordinated and carried out by a newly created European Food Safety Authority (EFSA). This independent agency is designed as a scientific point of reference in risk assessment and risk communication which enables the Community institutions to take informed decisions for risk management and to ensure the smooth functioning of the internal market, thus strengthening the link between risk assessors and risk managers. In order to assure the independence and scientific excellence of EFSA, its management board "should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise [… and] without any post being reserved for nationals of any specific Member State" (EC 2002:4). It therefore consists of 15 members who are appointed by the Council of the EU but come from various backgrounds such as research institutes, national ministries, consumer organisations or the food industry. This management board establishes the budget, adopts financial regulations, draws up internal rules and appoints the executive director as well as members of the scientific committee and the scientific panels which issue scientific opinions in the field of their competence. Members of the scientific committee and panels need to be independent scientists who are recruited in open application procedures. In order to ensure close cooperation with the competent bodies in the member states, an advisory forum is created as a mechanism of exchange of information.

As regards transparency and societal input, EFSA publishes all relevant documents and protocols online and is also open to contact with interest groups and consumers. It engages with civil society through a stakeholder consultative platform which meets twice a year and gives input to EFSA's Executive Director. Moreover, stakeholder meetings on technical issues regarding risk assessment can be convened on an ad-hoc basis and online consultations are being offered.

With regard to the application of the precautionary principle in risk analysis, Article 7 of Regulation 178/2002 brings forward a major advancement:

> In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

Even though the article states that measures adopted "shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community", Regulation 178/2002 (p. 2) also takes the normative dimension of the precautionary principle into account:

> It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

Despite the emphasis on scientific evaluations and trade relations that the EU has expressed throughout the process of reforming food law, it "has institutionalized the precautionary principle as a normative guide to risk regulation" (Caduff and Bernauer 2006:153). EFSA in this context plays a rather ambivalent role: it has been created as a powerful and independent authority for risk assessment (which inter alia includes the review of product applications for which according to the reversed burden of proof the food business operator has the primary legal responsibility for ensuring food safety) and risk communication that credibly commits to the highest scientific standards in order to restore consumer confidence; yet, it has very little

influence on risk management, which remains in control of the Commission and the member states.

3.3.3 Policy implications of the precautionary principle

Precaution has become the guiding principle in European food regulation, in a manner not always to the assent of the Commission. This particularly applies to the regulation of novel foods such as products containing genetically modified (GM) organisms. The previously mentioned safeguard clause, which with regard to novel foods has been reinforced in a number of legislations and allows member states to take provisional precautionary measures such as prohibition of GM crop cultivation or commercialisation of GM food, has been used by member states extensively. Under the impression of the BSE panic, ten safeguard bans on GM varieties had been invoked between 1997 and 2001, leading to an EU-wide moratorium on authorisations from 1998 until 2004. Still, after EFSA took over risk assessment, many member states would not follow favourable risk assessments on GM organisms (GMOs) and upheld their resistance, even invoking new safeguard bans on the basis of selective studies that indicated uncertainty. This restriction of GM food was generally supported by the European public and especially environmental NGOs, which attacked EFSA heavily for favourable assessments (Randall 2006:414). The Commission's efforts to make member states comply with the rules for a common food market and international trade agreements eventually failed, which eventually resulted in a recommendation to re-nationalise (or 'disintegrate') responsibility of GMO cultivation towards the member state level (Commission 2010:Art. 5).

As predicted by Majone (2002), the implications of the precautionary principle for international trade have been substantial. Safeguard bans of GM varieties in the EU following a precautionary approach have led to various accusations of protectionism in the European food market which in some cases induced retaliatory export tariffs or WTO disputes (Löfstedt 2003:39). As an example, in 2003, the USA, Canada and Argentina filed a WTO case against the moratorium

which supposedly violated rules of non-discrimination (Pollack and Shaffer 2005:341, 347f). These challenges however were rejected on the most substantive issues, even though the EU was found guilty of WTO agreement violation in a narrow and technical way, which remained without consequences though (Lieberman and Gray 2008). Quite contrariwise, the EU successfully 'exported' its precautionary approach to international regimes concerned with the regulation of GMOs such as the Cartagena Protocol on Biosafety.

3.4 Chemicals Management, REACH, and the Establishment of ECHA

3.4.1 The way towards more precaution in EU chemicals regulation

The history of European chemicals law dates back to the 1960s, when fears about the adverse effects of pesticides and their relation to cancer dominated public debate. A first European directive was passed in 1967 and more than 100 additional pieces of EU legislation followed over the years (Lenschow 2010:320). In the 1990s however, the system came under fire for lacking an adequate knowledge base, being too complex and too difficult to survey, being non-supportive for innovation, lacking coherence, consistency and transparency in a multi-level political system, and being disregardful of the precautionary principle, the polluter pays principle and the principle of sustainable development (Pesendorfer 2006:96). An important factor triggering the revision of the piecemeal system in place for a comprehensive framework was the 1995 enlargement of the European Union with Austria, Finland and Sweden. These new member states, together with Denmark and the Netherlands, issued the so-called 'five-country-paper' that suggested various measures to take in order to put EU chemicals policy to a new level. The precautionary principle was assigned an important role in this, indicating that substances could only be marketed after a risk assessment and that they should be restricted in case of doubt about their effects on the environment and human health. This initiative of 'green leader states', which aimed at uploading their ambitious domestic goals for chemicals policy to the European level (Eckley and Selin 2004:99, Lenschow 2010:320), was welcomed at an

informal meeting of the European Environment Council in April 1998, even though cost-benefit concerns between precaution and innovation were expressed (Løkke 2006:345). After the Commission published a report highlighting the main problems for chemicals regulation in November 1998 and held a first stakeholder conference on the issue in February 1999, in which further criticisms were raised, it was called on by the Environment Council in June 1999 to draft a new chemicals strategy by the end of the following year (Warhurst 2005:166).

3.4.2 The institutionalisation of the precautionary in REACH and the establishment of ECHA

Within the Commission, it was DG Environment that strongly promoted the strengthening of the precautionary principle, and its impact on the White Paper 'Strategy for a future Chemicals Policy' which the Commission published in February 2001 is clearly observable. Sustainable development is referred to as the overriding goal of the Commission's proposals and emphasis is given to a high level of protection of human health and the environment.

> Fundamental to achieving these objectives is the Precautionary Principle. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available.
>
> (Commission 2001:5)

At the core of the new strategy, the Commission proposed to "establish a single coherent system focussing public resources on those substances, where, according to experience, the involvement of authorities is indispensable and the added value in terms of the provision of safety is substantial" (Commission 2001:16). This system, called REACH, consists of the three main elements: registration, evaluation, and authorisation of chemicals. All existing and new substances of which more than a tonne per year is produced are required to be registered in a central database, providing systematic information about the properties of around 30,000

chemicals. Substances for which the production volume exceeds 100 tonnes additionally are subject to evaluation by risk assessing authorities, which also applies to chemicals of concern. For substances of special concern, which contain certain hazardous properties, an authorisation procedure requires specific permission for use.

The White Paper aroused fierce disputes among a multitude of parties. Two major advocacy coalitions (Sabatier and Jenkins-Smith 1999) evolved with a critical business coalition and a green coalition that supported the initiative. The business coalition, which feared 'overregulation' and competitive disadvantages on the global market due to high costs, was led by the chemical industry and strongly supported by DG Enterprise, business-friendly MEPs, national economic affairs ministries and member states with a strong chemical industry; whereas the Green Coalition largely consisted of environmental, animal protection and consumer NGOs, DG Environment, green MEPs, and national environment ministries, whose highest priority were health and ecological concerns. Whilst the green coalition regarded the precautionary principle as appropriate to create the right balance between economic, social, and environmental aspects, its use was rather refused by the business coalition which partially regarded it as 'junk science' and saw innovation endangered (Pesendorfer 2006:99-102).

The publication of the White Paper was followed by heavy stakeholder consultations with various interest groups and policy experts in order to raise awareness of insufficient regulation, improve the industry's acceptance, and give stakeholders the opportunity to suggest methods of constructing some aspects of REACH. An additional internet consultation on a first Commission proposal in spring 2003 resulted in 6,400 contributions regarding complex technical issues of the regulation, which largely came from the industry. Both camps also engaged in media campaigns to win over the trust of the European public and thus pressure MEPs indirectly (Pesendorfer 2006). Due to their vast financial resources, the chemical industry was capable of higher mobilisation than civil society groups and also had better access to the political arena (Persson 2007:227-230). Decision-making processes of REACH were "exemplified by a high

degree of institutional 'depillarization'" (Lenschow 2010:320) with DG Environment and DG Enterprise being jointly responsible in the Commission, and Council negotiations involving environmental and economic ministers in the horizontal Competitiveness Council. Parliament debate was highly polarised due to the effective lobbying campaigns of both environmental NGOs and industry.

After extensive debates on all relevant political levels and stakeholder consultations (Pesendorfer 2006:104-109), the Commission presented its final proposal for a REACH regulation on 29 October 2003, in which it proposed the establishment of a European Chemicals Agency for the implementation of REACH and provision of scientific and technical advice for the Community institutions. The importance of the precautionary principle was played down compared to the rather ambitious White Paper (Løkke 2006:346). The precautionary principle was not given specific interpretation any more, even though Article 3 Paragraph 1 specified in broad terms that

> This Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle as set out in the Communication from the Commission on the precautionary principle.

Yet, many of the initial 'green' parts of the White paper, especially the search for alternatives, had been blurred due to a greater emphasis on competitiveness and capital accumulation through innovation strategies. Some proposed measures were regarded as too burdensome for the European industry, for which reason the industry's direct costs for the new impact assessment were cut back by 82 percent (Pesendorfer 2006:109f). Concerns were raised that despite the incorporation of precautionary language in Community legislation, its effect on policy-making remained rather small (Eckley and Selin 2004).

After further negotiations and debates in an *ad hoc* Working Party on Chemicals, the Council reached a political agreement in December 2005. The Parliament, after demanding a number of amendments in its first reading in November 2005 and subsequently negotiating these with the

Council in July 2006, passed the REACH Regulation (1907/2006) in its second reading in December 2006. The final document contains more than 800 pages, which made it the EU's largest legislative project. REACH created a unified regulatory framework for chemicals on the European market, introducing "a mix of instruments, with obligatory procedural standards limited to hazardous substances, self-regulatory information, and risk management of industry being the core of the new system, accompanied by new rules of transparency to allow for bottom-up pressure" (Lenschow 2010:321). The centrepiece of the regulation is the new registration procedure for about 30,000 substances, with additional evaluation and authorisation requirements that allow risk management to restrict hazardous substances. These measures are underpinned by the precautionary principle, including a shift of the burden of compliance to the industry, which needs to demonstrate their products' safety through the registration processes before regulators authorise their placing on the market. Despite the strong influence of cost-benefit considerations in the legislative proceedings, the regulation has contributed to a higher level of environmental protection, consumer protection, work safety and transparency in European chemicals regulation (Lahl and Hawxwell 2006).

Another important feature of the REACH regulation is the establishment of a European Chemicals Agency (ECHA) "for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects" (Art. 75/1). The agency plays a vital role in risk assessment and risk communication, providing Community institutions and member states with independent scientific information on chemicals. Furthermore, it provides guidance to stakeholders in a transparent way, which includes the maintenance of an internet database that contains all substantial information on registered chemicals. ECHA is composed of an Executive Director who is appointed by the management board; committees for risk assessment and also for socio-economic analysis; a member state committee; a forum for exchange of information on enforcement that coordinates a network of the respective member state authorities; a secretariat and a board of appeal. The emphasis on member state coordination is also mirrored

in the composition of the management board, to which each government dispatches one representative. The Commission may appoint a maximum of six representatives including three from interested stakeholders without voting right, whereas the Parliament appoints two independent individuals. These board members are to be appointed on the basis of expertise and experience in the field of chemical safety or chemicals regulation in order to meet the agency's values of independence and trustworthiness.

3.4.3 Policy implications of the precautionary principle in the REACH regulation

The effect of precautionary language in the REACH regulation on actual policy outputs has been subject to fierce disputes. Whilst some commentators regarded especially early legislative initiatives towards a more precautionary regulatory regime as "unrealistic and even unrealizable" (Durodié 2003:389), others were concerned of an "[a]ll talk, little action" (Eckley and Selin 2004:78) result with no major improvements for public health and environmental protection. As is often the case, neither extreme turned out to be right eventually. Even though the final regulation is more industry-friendly compared to early proposals, REACH still contains numerous important elements of the precautionary principle. It allows for the restriction of substances in the face of uncertainty about their effects, reverses the burden of proof in the registration process, and creates transparency for stakeholders. Moreover, these stakeholders were involved in the making of the legislation via extensive consultations, which meets the deliberative dimension of the precautionary principle. With regard to the last important aspect of the precautionary principle, the principle of substitution, rather ambiguous findings have to be made. Although article 55 of the regulation encourages the progressive replacement of high concern chemicals by suitable alternatives, the provision is under the reserve of good functioning of the internal market as well as economic and technical viability. An amendment of this passage with a stronger focus on identification and development of alternatives proposed by the Parliament was not incorporated into the final document. Moreover, criticism has been

raised about article 60, paragraph 2 of the regulation, which allows for authorisation of substances with concern "if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies". Such exceptional practice certainly conflicts with precautionary conceptions. All in all, REACH has incorporated several elements of the precautionary principle or at least precautionary thinking, even though room for improvement persists (Hansen et al. 2007:397-401).

4. Comparative Assessment

4.1 Implementation and Application of the Precautionary Principle

EU food law has been comprehensively reformulated in a remarkably short timeframe, and competent actors in the legislative proceedings have put great emphasis on the precautionary principle from initiation up to the final passage of Regulation 178/2002. The consequent application of precautionary measures by various national risk managers who have invoked safeguard bans on GMOs has even gone beyond the recommendations of EFSA. Protection of public health and the environment has become the top priority in the field of food regulation, pushing back various economic concerns.

Even though the new chemicals legislation REACH is also underpinned by the precautionary principle, its requirements are not as far-reaching and became slightly blurred in the course of legislative proceedings. Economic concerns found a sympathetic ear with legislators and cost-benefit considerations were incorporated into the regulation. Moreover, the exploration of alternatives to potentially harmful substances could have been given more emphasis. Still, the regulation constitutes considerable advancement for environmental and health protection and allows for precautionary restriction of substances in the face of uncertainty.

Both cases entail the reversal of the burden of proof on the side of the marketer as well as provisions for great transparency of risk analysis, two important elements of the precautionary principle. With regard to the deliberative component of the precautionary principle, contrasting but interesting observations can be made. Løkke (2006:342) differentiates

> between two different approaches to precautionary practice. The first is a closed expert-orientated approach where the appropriate precautions are determined on the basis of expert assessment and integrated in appropriate regulations. The second is an open and deliberative approach where the uncertainties that require precaution are not concealed but are subject to public deliberative processes.

Risk management under the provisions of both Regulation 178/2002 as well as REACH clearly is supposed to be carried out in accordance to the first approach, with great official emphasis on scientific excellence. However, in the case of GMO restrictions it seems that public disapproval of GM food has been assigned greater importance than 'sterile' science. With regard to Council negotiations on the issue, Kurzer and Cooper (2007:1052) "suggest that the public debate on agricultural biotechnology shaped government voting decisions. [...] For once, the preferences of citizens have molded the voting behavior of national representatives. In this sense, the policy trajectory of agricultural biotechnology is relatively unique, as there are few examples of public contributions to the outcome of legislative deliberations." Interestingly, political elites refrained from such deliberations in the proceedings of Regulation 178/2002, whereas the REACH process was characterised by extensive stakeholder consultations but less deliberation after the passage of the regulation.

4.2 The explanatory potential of historical institutionalism

A major purpose of this thesis is the analysis of whether historical institutionalism can illuminate the rapid growth of precautionary risk regulation in the first decade of the new millennium. We therefore need to ask in how far general patterns of path dependence in institutional evolution can be identified in the two cases, whether critical junctures were in

place, which role dynamic learning processes played, and by what motivations actors were driven.

In the context of the Commission's Communication on the precautionary principle, the European Environment Agency issued a report entitled "Late lessons from early warnings: the precautionary principle 1896-2000" in 2001. It gave a comprehensive outline of a wide range of policies where precautionary logic had been applied in the past. This includes chemicals management, where a precautionary early-warning system had been implemented in 1973 already and first authorisation schemes were introduced in 1981 (Weill 2005:30-32). As described above, the European judiciary had also applied precautionary logic in its case law. One can therefore assume a historically evolved pathway for the precautionary principle in the EU, on which precautionary decision-making however remained to be *ad hoc* and piecemeal. The German '*Vorsorgeprinzip*' in the 1970s presented a first systematic approach towards precautionary risk management, which was promoted by 'green leaders' from the Nordic countries in the 1990s. Yet, learning processes were very slow with steps towards a European framework being rather incremental.

This drastically changed with the BSE crisis in the mid-1990s, which marks the most decisive punctuation for the institutionalisation of the precautionary principle. The resulting food crisis strongly accelerated such processes, with decision-makers being eager to implement precautionary legislation in order to appease an outraged public. In this context, a Communication on the precautionary principle was published that not only became guiding to risk management of foods, but has also been expanded to various other fields where the environment, human health, or animal welfare are affected (Recuerda 2008:31), including chemicals management. Whilst the comprehensive reformulation of food law occurred rapidly under the impression of the critical juncture food crisis, the velocity of REACH down the precautionary path was more curbed, but significant progress for precautionary risk analysis

was still made. This picture corroborates Thelen's (1999) concept of gradual transformative change which is triggered endogenously by dynamic learning processes and new ideas.

Moreover, and this is an important feature of historical institutionalism, the precautionary policy has been 'locked in' in European risk management, which is particularly obvious in the case of food safety. Whereas Caduff and Bernauer (2006:164) "assume that, when trust is established (or restored) and the costs of precautionary-type legislation are considered as outweighing its benefits, its popularity in European food safety governance will decline", the opposite has been the case. Some member states have even augmented their opposition against GM crops and foods, notwithstanding impending infringement procedures from the Commission and international trade disputes. As regards the new institutionalist camps of consequentiality versus appropriateness, the eclecticism of historical institutionalism is highly beneficial, as actors appear to have employed both logics, taken all relevant processes together.

In a nutshell, all important features of historical institutionalism can be found along the way of the institutionalisation of the precautionary principle in European risk analysis, which has unfolded over time. Starting off the path very incrementally, the punctuation of the BSE crisis and dynamic learning processes have finally locked in precautionary thinking and made it a guiding principle for risk management of foodstuffs and chemicals.

4.3 Agency Creation

'Agencification' by itself can be understood as a path dependent process in supranational regulation as well. As a result of positive experiences, numerous agencies have been established over the past two decades, especially where regulatory issues are highly complex and technical in nature. This certainly holds for food safety and chemicals management. Risk managers require sound scientific information to make informed decisions, for which reason much emphasis has been put on scientific excellence within EFSA and ECHA. The credible commitment hypothesis following the functional logic of delegation in terms of political independence and

professional expertise holds for both cases. Especially the establishment of EFSA has been an instrument to counteract public distrust in food safety regulators, shifting the responsibilities for risk assessment and risk communication to an independent expert body with high scientific reputation. It was made the agency's objective to restore consumer confidence in risk analysis, which politicians had forfeited. For this purpose, the high degree of independence given to EFSA is also mirrored in the composition of its management board, which contrary to most other EU agencies does not resemble the Council but consists of 15 experts from various backgrounds. Even though each member state sends a representative to ECHA's management board, the agency has also been equipped with a large degree of independence, for which reason both EFSA and ECHA can be found among the three highest scoring EU agencies in terms of institutional independence from their political principals (Wonka and Rittberger 2010:731f). Besides their duties in risk assessment, both agencies have also been given the responsibility to create transparency of risk analysis and communicate all relevant aspects. This includes coordination of a dense multi-level regulatory network as well as interchange with society, for which reason EFSA's stakeholder consultative platform has been brought into being. It however only debates technical issues of risk assessment and not wider socio-politic dimensions of precautionary policy-making, and therefore does not contribute to the deliberative dimension of the precautionary principle in effect.

This is also due to the fact that responsibility for risk management, i.e. the ultimate decision-making competence, remains with the member states. Ironically, despite the strong accentuation of EFSA's scientific excellence, some national governments have undermined EFSA's authority by challenging its assessments of GMOs and presenting diverging (and strongly disputed) studies in order to justify precautionary safeguard bans. Member states thus have partially shifted back from their initial proposition of competence delegation to supranational elites in the field of food safety. They re-politicised the issue of green biotechnology in order to enforce stronger precautionary measures than deemed necessary by EFSA, and thus winning support of the critical and risk-averse public.

5. Conclusion

This thesis has analysed the institutionalisation of the precautionary principle and the coincident establishment of regulatory agencies in the fields of EU food safety and chemicals governance. It has shown that in modern risk societies (Beck 1992), the management of risk is an important and challenging duty for regulators. The precautionary principle in this context presents an adequate solution to promote environmental and human health protection in the face of uncertainty. For this purpose, comprehensive legal frameworks that are underpinned by the precautionary principle have been established with Regulation 178/2002 and REACH. These include the creation of regulatory agencies for risk assessment and risk communication in order to ground regulation on an excellent scientific basis and create ample transparency of all relevant processes. With regard to food law, where precautionary protection has become the top priority of risk managers, this has even led to conflicts between supranational risk assessors and national regulators, who aim at maximal precautionary protection.

Moreover, this thesis has demonstrated that historical institutionalism is conceptually well equipped to account for institutional change in the two cases and is not limited to analyses of institutional persistence. Its main theoretical features were identified all along the way of the analysis, indicating that precautionary thinking has first unfolded incrementally over time until the BSE crisis triggered the rapid acceleration of precautionary Community legislation. Dynamic as well as gradual learning processes have contributed to the institutionalisation of the precautionary principle in EU food safety and chemicals management, even though the depth of implementation varies between the two cases. Yet, the precautionary principle has been 'locked in' to European risk analysis of foodstuffs and chemicals, which makes future departure from this principle highly unlikely.

These findings offer various starting points for further research. As this analysis has been limited to case studies in the fields of food safety and chemicals regulation, it would be important to expand the study to further matters of concern, such as water, pharmaceuticals, or

radiation, in order to draw more general conclusions about how deeply precautionary risk management is enrooted in the European Union. Moreover, with regard to the theory, historical institutionalist studies about why the precautionary principle has not been implemented in many regulatory systems outside Europe despite similar or even worse critical junctures in the experience with hazards have the potential to enrich academic debate.

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