The Institutionalisation of Infectious Disease Control in the European Union – The Effects of the Securitisation of BSE/TSEs and SARS

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Wulf H. Reiners, M.A.

aus

Köln

Referent: Prof. Dr. Wolfgang Wessels

Korreferent: Prof. Dr. Frank Schulz-Nieswandt

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Abstract

This dissertation examines the evolution of infectious disease control in the European Union (EU). The overarching objective of the research is to analyse policy and polity developments at the EU level primarily in the fields of public health and food safety in order to identify key developments between 1993 and 2014 and to investigate the conditions under which institutionalisation took place. The study approaches the field from a security perspective which is developed as an original advancement of the 'securitisation framework for analysis' (Buzan et al., 1998). Following the hypothesis that the institutionalisation of infectious disease control in the EU can be explained as an effect of a specific construction of infectious diseases as security threats, securitisation and institutionalisation processes at the EU level are tied together in a novel analytic and explanatory framework. The framework foresees the combination of qualitative and quantitative research methods in order to allow for a specification of the form of securitisation of an infectious disease along different 'degrees' and 'kinds'. The assumed connection between securitisation and institutionalisation is subject to empirical investigation in two case studies that deal with the securitisation of BSE/TSEs and SARS on the one hand, and a set of most fundamental changes in the EU's infectious disease control structures on the other, including the revision of the public health article in the Amsterdam Treaty (1997) and the Constitutional Treaty (2004) as well as the creation of the European Food Safety Authority (2002) and the European Centre for Disease Prevention and Control (2004). In this way the dissertation offers new insights into a largely unstudied field of European integration in combination with the development and testing of a novel conceptual approach.

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[1] The specification of figures, tables and diagrams follows the system 'chapter – sequential number/chapter'.

Diagrams

List of Abbreviations

ACDP	Advisory Committee on Dangerous Pathogens
AEI	Archive of European Integration
ASEAN	Association of Southeast Asian Nations
BSE	Bovine Spongiform Encephalopathy
BTCW	The Biological and Toxin Weapons Convention
CBRN	Chemical, Biological and Radio-Nuclear
CDC	Centers for Disease Control and Prevention
CDN(C)	Communicable Diseases Network (Committee)
CECIS	Common Emergency Communication and Information System
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
Council / CO	Council of the European Union
COM	European Commission
CoR	Committee of the Regions
DG	Directorate General
DG ECHO	Directorate General for Humanitarian Aid and Civil Protection
DG DEVCO	Directorate General for International Cooperation and Development
DG SANCO	Directorate General for Health and Consumers (renamed as DG SANTE)
DSN	Dedicated Surveillance Network
EAHC	Executive Agency for Health and Consumers (renamed as CHAFEA)
EC	European Community
ECA	European Court of Auditors
ECJ	European Court of Justice
ECDC	European Centre for Disease Prevention and Control
EERC	European Emergency Response Capacity
EESC	European Economic and Social Committee
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EP	European Parliament

EPIET	European Programme for Intervention Epidemiology Training
EU	European Union
EUCO	European Council
EUDC	European Union Delegation Collection
EWRS	Early Warning and Response System for Communicable Diseases
FVO	Food and Veterinary Office
G7/8	Group of Seven/Eight
GHSI	Global Health Security Initiative
GISN	Global Influenza Surveillance Network (renamed as GISRS)
GISRS	Global Influenza Surveillance and Response System
GOARN	Global Outbreak Alert and Response Network
GPHIN	Global Public Health Intelligence Network
HEOF	Health Emergency Operating Facility
HIAP	Health in All Policies
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HSC	Health Security Committee
IGC	Intergovernmental Conference
I(G)O	International (Governmental) Organisation
IHR	International Health Regulations
(I)NGO	(International) Non-Governmental Organisation
IR	International Relations (discipline)
ISS	Internal Security Strategy
MDG	Millennium Development Goals
MEP(s)	Member(s) of the European Parliament
MNC	Multinational Company
OIE	World Organisation for Animal Health
OIHP	Office International d'Hygiène Publique
OJ	Official Journal of the European Union
PHEA	Executive Agency for the public health programme (renamed as EAHC)
PHP	Public Health Programme

RAS BICHAT	Rapid Alarm System for Biological and Chemical Attacks and Threats
RASFF	Rapid Alert System for Food and Feed
SARS (CoV)	Severe Acute Respiratory Syndrome (Coronavirus)
SSC	Scientific Steering Committee
TESSy	The European Surveillance System
TFEU	Treaty on the Functioning of the European Union
TSEs	Transmissible Spongiform Encephalopathies
UK	United Kingdom
UNDP	United Nations Development Programme
UN(O)	United Nations (Organization)
UNSC	United Nations Security Council
US / USA	United States / United States of America
(v)CJD	(variant) Creutzfeldt-Jakob Disease
WHO	World Health Organization
WMDs	Weapons of Mass Destruction

"Security / Is mortals' chiefest enemy"

William Shakespeare, The Tragedy of Macbeth
(Act 3, Scene 5, Line 31)

1. Introduction

Infectious diseases have caused more deaths than war and basically anything else in history (Price-Smith, 2002). Ebola, HIV/AIDS, influenza or SARS are recent examples for diseases that constituted severe challenges to public health systems all over the world. Facilitated by increased travel and trade pathogens nowadays "travel at the speed of globalisation" (Stephenson, 2012: 103) and are capable of quickly spreading across borders. This is even more the case in a political space like the European Union (EU)[2] which seeks to guarantee the free movements of goods and people in a Common Market. In the light of the European integration process a state-centric focus on infectious disease control has become questionable; in particular since the EU has resumed an important – but so far little-noted – role in this policy area over the last decades (Greer and Mätzke, 2012: 888).

This dissertation examines the evolution of infectious disease control in the European Union. The objective of the research is to investigate the conditions under which respective structures became institutionalised at the EU level. The study approaches the field from a security perspective which is developed as an original advancement of the 'securitisation framework for analysis' (Buzan et al., 1998). By arguing that the evolution of infectious disease control structures at the EU level can be understood as the effect of the specific constructions of infectious diseases as threats to security, securitisation and institutionalisation processes are tied together in an analytic and explanatory model. The model is subject to empirical testing in two case studies that deal with a set of most fundamental innovations in the EU's infectious disease control structures which occurred in the course of two disease outbreaks[3], the BSE/TSEs crisis on the one hand, and the SARS crisis on the other.[4]

This first chapter of the study provides an introduction into infectious diseases as a security problem and into the relevance of infectious disease control at the European Union level. On the basis of a literature review it demonstrates in how far the work can take up existing studies from three strands of research – infectious disease control, institutionalisation and securitisation in the European Union – and in which parts it approaches unexplored territory. After having introduced the main research puzzle, the chapter closes with a section on the scope and the roadmap of analysis to set out the structure of the work.

[2] The term 'European Union' refers also to the political system of the 'European Community' before the year 1993, when the European Union was established under its current name.

[3] The terms 'outbreak' and 'epidemic' refer to the occurrence of an infection that "exceeds the expected level for a given time period." It can be contrasted with 'endemic' which means a "persistent low or moderate level of disease. […] When an epidemic spreads over a wide geographical area, such as a continent or continents, it is called pandemic" (Hawker et al., 2012: 5).

[4] BSE/TSEs stands for 'Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathies', SARS means 'Severe Acute Respiratory Syndrome'.

1.1. Infectious Diseases, Infectious Disease Control and the European Union

In the middle of the twentieth century optimism was great that the problem of infectious diseases could be overcome once and for all. Prominent quotes in this respect include statements of the Nobel-prize winning biologist Sir MacFarlane Burnett who declared in 1966 that it was "time to 'close the book' on the problem of infectious diseases", and by US Surgeon General Jesse Steinfeld who claimed in 1976 that there were "no new diseases to be discovered" (quoted in Michaud, 2009: 6). In 1979, the World health Organization (WHO) optimistically launched an initiative with the aim to win humanity's war against disease by achieving 'Health for All by the Year 2000' (WHO, 1981, Hough, 2004: 156, Elbe, 2010a: 163). These examples illustrate the conviction of the post-war decades that advances in science, public health and medicine would eventually enable mankind to ultimately eliminate or at least control infectious diseases. Unfortunately, the experts were proved wrong.

For the year 2013 the WHO reported globally more than 280,000 cases of measles infections, more than 5.7 million cases of tuberculosis and more than 48 million cases of malaria (WHO, 2015b: 86f). The occurrence of chikungunya in Italy in 2007 exemplifies that diseases which were typically limited to specific geographic regions spread to previously unaffected areas (Angelini et al., 2007). The increase of antibiotic and antiviral resistant pathogens that render existing medical treatment ineffective go along with increasing number of new infections of once controlled diseases in all regions of the world (WHO, 2014). Since the mid-1980s new or previously unrecognised diseases such as HIV/AIDS, SARS or novel subtypes of the influenza virus have shown devastating effects worldwide; and are likely to do so in the future. A future influenza pandemic was estimated to affect 1.5 billion (WHO, 2007) and kill up to 150 million people (UNO, 2005) leading to US$ 3 trillion in economic damages or 4.8% of global GDP (World Bank, 2013). Against this background "it is hard to argue that infectious diseases are not a problem" (Greer and Kurzer, 2012: 904).

Infectious diseases are disturbances or anomalies in the normal functioning of the human body that are "caused by a contagious agent which may be transmitted from person to person by direct contact with an affected individual or by an indirect means such as exposure to a vector, fomite, product or environment, or exchange of fluid, contaminated with the contagious agent" (European Parliament and Council, 2013a: Art. 3).[5] Typical transmissible agents are bacteria, viruses, parasites, worms or fungi; common modes of transmission include direct transmission by touching, sneezing, biting and sexual intercourse as well as indirect transmission via vehicles and vectors such as food, surgical instruments or insects (Hawker et al., 2012: 7).

The instruments that are typically applied to control infectious diseases include (1) disease *prevention* to reduce the likelihood of its spread (for instance education and vaccination programmes), (2) *preparedness* to increase the capacities to respond to an outbreak (for instance through emergency plans and stockpiling), (3) *surveillance* activities for the purpose of directing public health action (understood as ongoing systematic collection, analysis, interpretation, and dissemination of health data, incl. risk assessment) as well as (4) *response* in order to eradicate a

[5] The notions 'infectious disease' and 'communicable disease' are used interchangeably in this study.

disease or to mitigate the effects of an outbreak (for instance through travel restrictions and medical treatment). In this sense, the notion of 'infectious disease control' encompasses, for the purpose of this study, the full spectrum of possible measures in the fields of infectious disease prevention, preparedness, surveillance and response that target diseases which are caused by a transmissible agent (CDC, 1986, European Parliament and Council, 1998, WHO, 2000, Krämer and Reintjes, 2003, ECDC, 2007: 4, Michaud, 2009: 20f, Reintjes, 2012: 956).

The classic instruments of the health systems to control infectious diseases are located in the realm of public health, a policy field that is concerned "with the state of health of the population as a whole which it aims to protect and improve" (European Commission, 2000j: 5). Accordingly, public health law can be understood as "the authority and responsibility of government to ensure the conditions for the population's health" (Gostin, 2000: 327). Reflecting the organisation of the health care systems and existing governance structures for health, public health is typically seen as a policy that belongs to the domain of the nation state or even the sub-national level. The principle of national sovereignty in public health affairs, however, is in stark contrast to the fact that germs do not respect borders. It belongs to the most obvious effects of today's historically unprecedented global travel and trade, but also uncontrolled migration, that pathogens are able to spread more easily, rapidly and globally (Cockerham and Cockerham, 2010). Moreover, the measures of an individual country to control infectious diseases as well as economic and environmental practices ultimately affect the conditions to control infectious diseases in other countries (Schreck et al., 2009: 149, Krause, 2010: 69).

It becomes clear that infectious disease control is of a genuinely cross-border nature which requires states to operate "beyond the territoriality of any individual country" (Kickbusch and de Leeuw, 1999) and opt for solutions that foresee collective actions of several (or all) governments (Karolinska Institutet and Global Health Europe Network, 2009: 9). In other words, while aiming at an effective and sovereign public health policy, nation states are facing the dilemma that they are forced to cooperate internationally and cede some of their sovereignty to international organisations (Eban, 1995). Interstate cooperation in the field of public health is not a recent development and can be traced back in Europe at least to the nineteenth century (Fidler, 2001). With the Schengen Agreement on the abolishment of internal border controls and the stepwise establishment of an Internal Market in the European Community, however, EU Member States started to face a situation of a new quality due to a "growing open sanitary space in the EU" (Steffen, 2012: 1071) and the Market's fundamental freedoms regarding the free movement of people, goods, services and capital which facilitate, as an unwanted side effect, the unhindered movement of disease agents within an increasingly borderless Europe (Martin and Conseil, 2012: 1098).

The European integration project accounts for indirect effects on health since the 1950s (Preston, 2007, Klomp and de Haan, 2009, Greer et al., 2013: 1135). An explicit public health policy and infectious disease control in particular, however, have developed since the 1990s only. Over the last two decades substantial structures were established at the EU level to contribute to the control of infectious diseases, including the establishment of specialised agencies such as the European Food

Safety Authority (EFSA) or the European Centre for Disease Prevention and Control (ECDC), various surveillance, alert and response systems as well as a public health action programme (Guglielmetti et al., 2006, Ammon and Faensen, 2009, Schreck et al., 2009, Liverani and Coker, 2012: 923).

Whereas institutionalisation processes at the EU level generally enjoy great popularity among political scientists interested in interstate cooperation and regional integration processes, infectious disease control in the European Union is largely understudied. The little attention neither matches the importance of the EU level for infectious disease control in Europe and beyond, nor does it reflect that the field comes "close to the heart of the modern state and its citizens" (Greer and Mätzke, 2012: 889). It has been argued that infectious disease control belongs to the least studied functions of the EU (Greer and Mätzke, 2012: 887). To make things worse, essential elements of the EU structures such as the ECDC can be regarded as "underresearched and underreported even by the standards of communicable disease control in the European Union. […] There has been almost no policy or political science work on it" (Greer, 2012a: 1017). The thorough literature review in preparation for the present study supports this finding. The literature that systematically deals with the EU's contribution to the control of infectious diseases is actually so scarce that it is even difficult to get hold of a study that has detected and criticised the research gap.[6]

The present study addresses this gap by mapping and analysing the evolution of infectious disease control at the EU level with a specific focus on the years from 1993 to 2014. It thus covers the time period between the introduction of the first dedicated public health article into EU primary law by the Maastricht Treaty and the most recent developments.

1.2. A Security Perspective on Infectious Diseases

Beyond the set-up of a comprehensive and so far unavailable overview of key developments of infectious disease control in the EU, the study also aims to investigate the conditions for this evolution. This investigation is carried out from a security perspective, one of the prominent research strands in the literature that deals with the governance of public health. The underlying idea is that infectious diseases do not only form public health problems but can also been seen in a wider sense as threats to security (Fidler, 2007b: 41).

The link between security and infectious diseases is both an old and a recent development at the same time. On the one hand, it would be reasonable to start a respective study with the analysis of the bubonic plague in the fourteenth century (Howard-Jones, 1950, Goodman, 1971, Howard-Jones, 1975, Hoffman, 2010). Also the use of pathogens and biological agents in warfare dates back some hundred years (Wheelis, 1999). On the other hand, it was not before the early 1990s that the recognition of trans-border health threats resulting from globalisation and emerging infections such as HIV/AIDS initiated an infectious disease-related 'security turn' (Morse, 1993, Garrett, 1996, Dodgson et al., 2002, King, 2002). In 1992, an influential report warned that "some infectious

[6] One of the few exemptions is the 2012 special issue of the 'Journal of Health Politics, Policy and Law' on the politics of communicable disease control in Europe. See Greer (2012b).

diseases that now affect people in other parts of the world represent potential threats to the United States because of global interdependence, modern transportation, trade, and changing social and cultural patterns" (Institute of Medicine, 1992: v, Elbe, 2010a: 163f). The view on infectious disease through security lenses was fuelled when bioterrorism and the proliferation of weapons of mass destruction (WMDs) by rogue states shifted the infectious diseases into the debate on national security. Finally, the terrorist attacks of September 11, 2001 and the subsequent anthrax scare fed a broadened security agenda encompassing a large set of public health components (Krause and Williams, 1996, Wright, 2006, Kelle, 2007: 225, Lee, 2009:35f).

Today, there is wide agreement in the academic literature that the notions of 'infectious diseases' and 'security' are intrinsically tied to one another (McInnes, 2004, Fidler, 2005, Enemark and Selgelid, 2012). In fact, given the high number of representatives from both the *academia* and the political world that have related infectious diseases to some form of security threat, it has been argued that "[t]he [current] prominence of security concepts in debates about public health threats and governance is historically unprecedented" (Fidler, 2007b: 42).

In this context the literature often refers to the notion of 'health security' (e.g. Feldbaum and Lee, 2004, Rodier et al., 2007, Aldis, 2008) and covers various fields ranging from a focus on biosecurity, biological weapons and bioterrorism (Collier et al., 2004, Wright, 2006, Fidler and Gostin, 2008, Stavrianakis et al., 2011) works on specific diseases as diverse as cholera (Lee and Dodgson, 2000, Enemark, 2012), tuberculosis (Koch, 2008), SARS (Hooker, 2007), influenza (Davis, 2005, van den Bulck and Custers, 2009, Abraham, 2011) or HIV/AIDS (Prins, 2004, Garrett, 2005, Selgelid and Enemark, 2008, Elbe, 2009). The connection of, for instance, HIV/AIDS to security concerns is also illustrated by the fact that the pandemic was addressed several times by the United Nations Security Council (UNSC) (UNSC, 2000, 2005, 2011).

Crucially, a large number of studies speak of a so called 'securitisation of infectious diseases', for instance in relation to war on terror, failed states, new wars, uncontrolled migrations, globalisation, the food chain, medical practices and social and behavioural change (Pereira, 2008, McCarthy, 2009, Cook, 2010, Elbe, 2012). A securitisation perspective can be found for the analysis of infectious diseases over time (Pereira, 2008, Elbe, 2012), for specific countries like China (Wishnick, 2010) and the US (Cook, 2010), specific institutions like the WHO (Davies, 2008) or for specific diseases such as influenza (Curley and Herington, 2011, Kamradt-Scott and McInnes, 2012). A prominent case is the securitisation of HIV/AIDS (O'Manique, 2006, Rushton, 2010b, McInnes and Rushton, 2013) which has been examined *inter alia* with a view to the emergence and diffusion of international norms (Vieira, 2007), the United Nations (UN) system (Kay, 2009, Rushton, 2010a) as well as for specific countries such as India and China (Lo, 2012) or the US (Sjöstedt, 2011).

In political science, the term 'securitisation' usually refers to the 'framework for analysis' as put forward in a series of publications revolving around the seminal work of Barry Buzan, Ole Waever and Jaap de Wilde in 1998 (Buzan et al., 1998). The concept offers a complex constructivist reading of security that builds on the understanding that "[an] issue becomes a security issue […] not necessarily because a real existential threat exists but because the issue is presented as a threat"

(Buzan et al., 1998: 24). The framework is a useful tool to elaborate on a set of fundamental questions, such as "what counts as a security problem? Why do certain challenges become security issues while other do not? How are threat images realised in policies? Are the realms of security and politics compatible or mutually exclusive?" (Balzacq, 2011a: xviii). In this sense the framework also suits the needs of an analysis of infectious diseases as political and security problems. Many studies on the securitisation of infectious diseases, however, mostly use securitisation in a loose sense to indicate some connection between security and diseases without referring to the original concept or without applying it with methodological rigour.

The present study is different in this respect as it explicitly builds on the core elements of the original securitisation approach that asks from a constructivist understanding "for whom security becomes a consideration in relation to whom" (Buzan et al., 1998: 18). On this basis the study advances the framework in methodological and conceptual terms by introducing a set of innovations, namely the 'degree of securitisation' and the 'kind of securitisation'. It will be explained in the chapter on the concepts and the research framework (chapter 2) why these conceptual innovations are needed and how they serve the purpose to allow for an explicit differentiation of the security dimensions of infectious diseases in a 'coordination system of securitisation'. Being able to identify the form of securitisation of a disease is of great importance not only to better understand and be able to compare infectious disease-related securitisation processes; the definition of a securitisation form in the coordination system is also crucial to be able to link securitisation to the institutionalisation of infectious disease control at the EU level.

1.3. Research Puzzle: Securitisation and Institutionalisation

The previous sections have indicated that infectious disease control in the European Union has been institutionalised in the last twenty years, albeit largely unnoticed by political science, and that infectious diseases are increasingly tied to security concepts, albeit with different ideas regarding the connection and the understanding of security. This study addresses both of these phenomena by examining the evolution and the institutionalisation of infectious disease control at the EU level from a novel security perspective that allows for the distinction between different securitisation forms of infectious diseases. Crucially, securitisation and institutionalisation are linked to each other in an explanatory model which argues that a specific form of the securitisation of infectious diseases can help explain institutionalisation processes in the field of EU infectious disease control.

The link between securitisation and institutionalisation is established by assessing securitisation as a trigger for changes that occur at the EU level. Whereas most existing studies dealing with securitisation processes examine the *causes* of securitisation and "what explains when securitisation is successful" or achieved (Buzan et al., 1998: 32), the present study is primarily interested in the *forms* and *effects* of securitisation.[7]

[7] Two of the few studies that assess impact and results of securitisation of infectious diseases are Davies (2008) and Leboeuf (2009).

In other words, in order to shed light on the dynamic development of infectious disease control at the EU level and to identify major drivers of the process, securitisation at the EU level is not treated as the *explanandum* of the research, but as the *explanans* for institutionalisation. In this context the analysis works with a definition of institutionalisation that builds on the work of Wayne Stone Sweet and Alec Sandholtz (Sandholtz and Stone Sweet, 1998, Stone Sweet et al., 2001), viewing institutionalisation – also referred to as 'structural change' – as a possible effect of securitisation in the sense of relatively persistent and systemic changes regarding rules, procedures, policy priorities, resource allocation, division of competences and organisational structures in the field of EU infectious disease control (see chapter 2.3.4.1).

The argument that securitisation can help explain the evolution of the EU's infectious disease control is derived from two observations. First, wide acceptance exists that (specific) infectious diseases were or are subject to securitisation dynamics in different contexts and countries (e.g. Davies, 2008, Cook, 2010, Herington, 2010, Curley and Herington, 2011, Jin and Karackattu, 2011, Sjöstedt, 2011, Elbe, 2012, Enemark, 2012, Lo, 2012, McInnes and Rushton, 2013). Second, security threats to health such as disease outbreaks and health crises have repeatedly been identified as catalysts for changes in the governance of infectious disease control; be it anthrax, BSE, HIV/AIDS, influenza or SARS, previous studies have suggested that infectious diseases have played a prominent role for particular steps of structural development, be it in the European (Lezaun and Groenleer, 2006, Krapohl, 2008, Groenleer, 2009, Greer, 2012b, Liverani et al., 2012) or an international context (Fidler, 2005). In fact, it has been argued that "European public health policy is […] to a large extent crisis driven" (Steffen, 2012: 1060) and that "[i]nstitutions and procedures [for communicable disease control] will tend to be strongly influenced by particular crises and particular responses" also in the future (Mätzke, 2012: 971). In this context the dictum of a 'good epidemic' (Hamlin, 2009, Greer and Mätzke, 2012: 902) essentially refers to the assumption that repeated crisis could "keep the need for robust public health constantly at the top of the political agenda nationally and internationally" and thus enable breaking the "the sustainability conundrum" of public health (Fidler, 2004b: 169f).

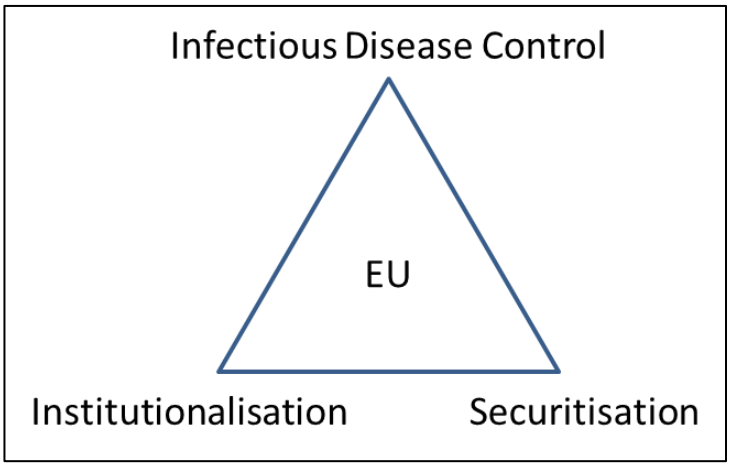
Puzzling in this context, however, is that "for every 'good epidemic' there is another one that came and went and never provoked big changes" (Greer and Mätzke, 2012: 902). Apparently, not all disease outbreaks, and most likely not those that resulted in the highest total number of deaths, were followed by institutional adaptation. Against this background it is hard to argue that the trigger for structural change can be reasonably sought only in the disease or the outbreak itself. The novel securitisation approach put forward by this dissertation is designed to deal with this peculiar situation on the basis of a constructivist reading. The key argument is that it is not the disease or the outbreak that have triggered institutionalisation in the European Union, but a specific form of securitisation of infectious diseases.

1.4. Scope and Roadmap of the Analysis

To sum up, this dissertation is interested in (1) the institutionalisation of the EU's infectious disease control, (2) the securitisation of infectious diseases at the EU level and (3) the connection of institutionalisation and securitisation. More specifically, it aims to track the key developments of EU infectious disease control, contribute to our understanding of infectious disease as security threats in the EU and explore the conditions under which the securitisation of specific diseases could explain the institutionalisation of EU infectious disease control. This research focus, however, has to be put in perspective with a view to three aspects.

First, it should be stressed that the study is carried out first and foremost from a political science perspective that aims at exploiting and combining three strands of academic research, namely infectious disease control studies, securitisation studies and regional integration (institutionalisation) studies.

Figure 1-1: Combining Three Strands of Research



Source: Own presentation.

The book is not the first that examines these strands, but it constitutes an original contribution to bring elements of all of them together in a single analysis. Scholars have started examining the institutionalisation of EU public health and infectious disease control (Guigner, 2004, Greer, 2012b), but not from a securitisation perspective. Studies have dealt with the policy tools of securitisation in the EU and securitisation in specific EU policies such as border security and migration (Huysmans, 2000, 2006, Balzacq, 2008, van Munster, 2009, Léonard, 2012), but not in the field of infectious disease control. Finally, publications dealing with the securitisation of infectious diseases have not covered the European Union; in fact, there is only a handful of studies that allude to the developments at the EU level (Fidler, 2004a, McInnes and Lee, 2006, Pereira, 2008).

The connection of these in this combination so far largely unrelated strands of research is, thus, a unique feature of the work. Despite such a comprehensive analytical approach, however, the study is a piece of political science which should not be confused with medicinal or epidemiological perspectives. To illustrate, in line with the constructivist conceptual foundations it is not the

objective to assess in how far infectious diseases constitute 'real' threats, to judge whether specific measures to combat diseases are legitimate or effective, or to generate policy advice on institutional reforms that could be deemed most functional to address public health threats.

Second, it must be noted that infectious disease control is of genuinely intersectoral nature. Intersectoral means that infectious disease control is not subject to a single policy resort on its own right or restricted to one particular policy domain. Factors that produce microbial dangers include climate and weather, changing ecosystems, human demographics, economic development, international travel and commerce, technology and industry, poverty and social inequality, war and famine and, last but not least, intent to harm (bioterrorism) (MacLehose et al., 2002, Smolinski et al., 2003: 54, Reintjes, 2008). Accordingly, a wide range of policies is of relevance, including trade (Williams, 2004, WHO, 2006, Drager and Fidler, 2007, Labonté et al., 2009, Lee et al., 2009), environment (Morse, 1993, Lee, 2000, Anderson, 2004), research (Van Aken, 2006, Rappert, 2007), global warming and migration (Khasnis and Nettleman, 2005), humanitarian aid, development and human rights (Marks, 2009, Tobin, 2012), but also foreign policy in more general terms (Garrett, 1996, Fidler, 1998, Ingram, 2004).

It is, however, beyond the scope of the study to analyse in detail the full set of infectious disease-related policies. In contrast, the primary focus is put on the major policy and polity developments in the realms of public health and food safety. The areas can be regarded as the core of infectious disease control within the European Union due to functional and, as we will see in chapters 3 and 5, also historical reasons. Whereas the typical instruments of infectious disease control belong to the realm of public health, the safety of food products and food-borne pathogens occupy a specific position within the Community following from the EU's Internal Market. The close interconnection of the two areas is today also visible in the structure of the European Commission which organises its works in these sectors in a joint Directorate General.

Third, infectious disease control efforts is a matter of all political levels, from the local sphere, where the actual treatment of an infected person takes place, to the international sphere, where WHO, the International Health Regulations[8] and initiatives such as the 'Global Fund to Fight AIDS, Tuberculosis and Malaria'[9] shape global health governance. The clear focus of this research is put on the level of the European Union, which implies that processes at neither the national (Member State) level nor the international level are systematically covered. Influences from non-EU levels feed into the study, but do not belong to the primary research interest. A detailed explanation of the levels and units of analysis is provided in chapter 2.5.3.

[8] The International Health Regulations (IHR) is an international legal regime "to prevent, protect against, control and provide a public health response to the international spread of disease" (WHO, 2005: Art. 2). It is considered a "centre piece for global health governance" (Hardiman, Fidler, 2005, Fidler and Gostin, 2006: 93, Baker and Forsyth, 2007).

[9] The 'Global Fund' is a partnership organisation of governments, civil society, the private sector and people affected by the diseases designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. See http://www.theglobalfund.org/en/about/ (accessed 22.05.2015).

Under consideration of these limitations the study proceeds as follows: The following chapter 2 reviews key concepts of security and health security from the academic disciplines incorporated into the analysis and develops an original adaptation of the securitisation framework for analysis that includes *inter alia* a 'coordination system of securitisation'. On this basis it sets out in more detail the research framework and establishes the hypothesis that a specific form of securitisation, as locatable on the coordination system, can be regarded as the cause for the adoption of institutional change at the EU level. In the following, the chapter elaborates on the operationalisation of the research focus and explains how the study complementarily combines qualitative and quantitative methods to generate and analyse the empirical data.

The following empirical part of the study is structured into three steps. Chapter 3 serves the purpose to track the evolution of the EU's infectious disease control with a particular focus on the realm of public health between 1993 and 2014. Ultimately, the analysis of relevant primary and secondary literature will yield a list of key developments in EU infectious disease control. On the basis of this overview, chapter 4 provides a reflection on the selection of two case studies and embeds them into the overall institutionalisation development. It will become clear that the case studies in chapter 5 and 6 investigate into a combination of most fundamental forms of institutionalisation, namely the combination of the revision of the EU's primary law (Treaty of Amsterdam and Constitutional Treaty) with the creation of a specialised EU agency (EFSA and ECDC). Crucially, the adoption of these structural changes can purposefully be reviewed in the framework of a securitisation analysis, as they occurred in the course of infectious disease crises, namely the outbreak of 'bovine and transmissible spongiform encephalopathies' (BSE/TSEs) on the one hand (chapter 5), and the epidemic spread of 'severe acute respiratory syndrome' (SARS) on the other (chapter 6).

The final chapter 7 synthesises the results of the case studies and provides concluding remarks on the study as a whole and possible future research.

2. Concepts and Research Framework

What is security and how is it related to public health and infectious disease control? There is neither a single nor an easy answer to this question, but responding to it and linking the key notions is a precondition for the envisaged analysis. This chapter 2 serves the purpose to do so by developing a novel analytical and explanatory framework on the basis of the 'securitisation framework for analysis' which is particularly suitable to grasp the developments related to (the control of) infectious diseases.

This novel approach is needed as it is not possible to build on research that explicitly works at the intersection of the three research strands of securitisation, infectious disease control and institutionalisation in the EU. Furthermore, related securitisation literature struggles with two major problems that are particularly obstructive for the research objectives of the present study. The first problem is that existing securitisation concepts lack the tools to adequately define the form (or status) of an infectious disease as a security issue. The second problem is that the existing approaches do not offer a model that links securitisation to institutionalisation processes at the EU level.

In order to advance the original securitisation framework in the respective ways, the development of the novel approach proceeds in five steps. First, the chapter starts with a brief introduction into the roots of Security Studies and the original securitisation approach (chapter 2.1). The overview basically serves the purpose to locate the study in the wider security discourse in political science and to familiarise the reader with the basic constituents of Security Studies.

Second, an elaboration on the elements of the original securitisation concept will make clear that securitisation builds on the idea that security issues in international affairs are first and foremost something socially constructed (chapter 2.2). This overview of the key components of securitisation also provides the starting basis for the following advancement of the concept.

Third, by drawing lessons from existing securitisation studies, two innovative elements will be introduced to be added to the original securitisation approach: the 'securitisation degree' on the one hand (chapter 2.3.1), and the 'securitisation kind' on the other (chapter 2.3.2). The former is meant to better structure the securitisation status of an issue along the spectrum between the political and the security realm, the latter serves the purpose to adequately reflect the different security understandings in the field of public health policy and infectious disease control. Ultimately, both innovations will be brought together in a 'coordination system of securitisation' (chapter 2.3.3) that eventually allows for the definition of the status of an infectious disease as a security issue. In a next step these elements are jointly integrated into the explanatory model that conceptualises institutionalisation processes at the EU level as a potential effect of securitisation (chapter 2.3.4).

Fourth, on the basis of this conceptual work, chapter 2.4 elaborates in more detail on the research question and the hypothesis. The chapter closes, fifth, with an overview of the research design and phases, the operationalisation of the research question and the research methods employed (chapter 2.5).

2.1. The Roots of Security, Security Studies and the New Security Agenda

The notion of 'security' has a rich and complex genealogy (Kaufmann, 1970, Der Derian, 1993). The word derives from Latin *securitas* (*sine cura*)[10], but its roots go back to ancient Greek philosophy (Liddell and Scott, 1843 [1961]). When the term appeared first in the work of the Roman philosopher and politician Cicero (106-43 BC) it included a positive (carelesness, heedlessness, negligence) and a negative definition (freedom from danger) (Arends, 2008: 263ff). The term also had a religious connotation which was later incorporated into *certitudo* (certitude, certainty, absolute conviction) and became in this way an integral part of Christian theology.

When Thomas Hobbes (1588-1679) took up *securitas,* particularly in his work 'Leviathan', he associated the term to the modern States' omnipotence to prevent civil war in the 'state nature's' complete absence of security (*bellum omnium contra omnes*; *nulla securitas*). For Hobbes the provision of (individual) security was the core function of the 'super state' which loses its *raison d'être* once it turned incapable of producing security (Kaufmann, 1970: 68, Rothschild, 1995).[11] Further authors such as Baron Samuel von Pufendorf (1632-1694) and his understanding of *securitas* as "interior and exterior security, peace (*pax*), protection of property [and] common prosperity (*commoditas*)", to be provided by the State, added to the roots of the contemporary concept(s) (Schrimm-Heins, 1992: 196, Arends, 2008: 274).

Departing from this heritage, *security* entered the field of modern political science in the 1940s. Within the area of International Relations (IR) the sub-field 'Security Studies' is above all interested in the interactions of international actors that bear implications for the security of these actors. In this context the meaning of security became closely associated with threats to the political and territorial integrity of states, giving rise to one of IR's key concepts 'national security' (Walt, 1991, Rosenberg, 1993). IR scholars of a realist tradition eventually located security at the heart of 'high politics' and associated it with the 'national interest' and "the integrity of the nation's territory, of its political institutions and of its culture" (Morgenthau, 1952: 973). Reflecting the tight connection between security and the integrity of the State and the State's struggle to defend its freedom, independence and values, the analysis of security was at this time primarily defined as "the study of the threat, use, and control of military force" (Walt, 1991: 212, see also Buzan et al., 1998: 3f, Hough, 2004: 3ff, Herington, 2012: 8). In other words, the traditional notion of security was primarily founded on a violence paradigm and the threat of exogenous force targeting the State, its military or people (Ikenberry and Slaughter, 2006).

Since the 1970s this traditional security definition applied by IR's Security Studies was increasingly criticised for being too narrow as regards (1) the scope of threats considered central to security, (2) the actors deemed central to the security landscape and (3) the referent objects of security, i.e. the being that faces a threat and demands protection.

[10] Latin for 'without *cura*'; *cura* meaning care, carefulness, concern.
[11] More on Hobbes as a theorist of security can be found in Waldron (2006: 456ff).

In this way a widened security understanding (1) linked a number of so called 'soft' threats to security. Reflecting the discussion on globalisation effects, scholars proposed to go beyond the military sector and to include further fields such as economic interdependence, energy security, climate change – and infectious diseases (Ullman, 1983, Mathews, 1989, Buzan, 1991, Krause and Williams, 1996). In addition, pluralist theorists argued that in the new global arena it was (2) not merely the State but a plurality of actors, including intergovernmental organisations such as the EU, international non-governmental organisations or multinational companies that were crucial players in global affairs. Here the security debate intersected with the discussions on the constituents of the global governance system (Rosenau, 1992, Weiss and Gordenker, 1996, Young, 1997, Nye and Donahue, 2000, Muldoon Jr., 2003). Finally, advocates of a widened security approach proposed to (3) replace the focus on the State as the sole referent object of security by a definition that puts human beings and communities at the heart of the concept (Booth, 1991, Wyn-Jones, 1999).[12] On a more general level the discussion about the referent object of security led to the question whether a given threat must ultimately target an actor (State, collective, human individual) or whether also the security of abstract concepts like 'identity security' (McSweeney, 1999) or 'societal security' (Waever et al., 1993, Huysmans, 2006) could fall into the realm of Security Studies.

It becomes clear that the widening of the security debate in terms of (1) threats, (2) referent objects and (3) security provider prepared the ground also for the analysis of infectious diseases and the European Union from a security perspective. At the same time, the widening of the security debate resulted in a confusingly rich offer of security understandings. Apart from the idea that security is something particularly valuable and can be found only if someone or something is secure(d) due to the absence of or the invulnerability vis-à-vis a given threat, the term can refer to fairly different things. Security sometimes refers to a state of being, sometimes to political practices and sometimes to a political ideal (Bubandt, 2005, Herington, 2012). The term is sometimes applied to human and sometimes to non-human beings, sometimes to individuals and sometimes to (social) groups. Also a great variety from local to global and from natural to manmade threats is inherent to the set of concepts, just as various needs that must be satisfied or goods that one must hold to be secure(d).

In fact, nowadays an almost endless list of conceptualisations exist and form the basis of ongoing discussions (Herington, 2012: 8), ranging from civilizational security (Bowden, 2010) through energy security (Dannreuther, 2010) and environmental security (Barnett, 2010) to emancipatory security (Booth, 1991, Wyn-Jones, 1999), financial security (de Goede, 2010), food security (Wiggins and Slater, 2010), human security (UNDP, 1994, Commission on Human Security, 2003, Centre, 2010, Owen, 2010), national security (Wolfers, 1952, Ullman, 1983, Walt, 1991) and ontological security (Giddens, 1991, Mitzen, 2006).

[12] A people-centred approach that has been widely received – although with differing conceptualisations – is the 'human security' concept which emphasises *inter alia* the protection of the individual from fear and freedom from want in various terms, also related to health (UNDP, 1994, Centre, 2010). The human security concept in relation to public health and infectious diseases is discussed in more detail in chapter 2.3.2.1. Basic information on human security can be found in, for instance, in King and Murray (2001), Paris (2001), Thomas (2001), Hay et al. (2002), Tadjbakhsh and Chenoy (2006) and (Owen 2010).

In the light of the plethora of security approaches, security has been labelled an "essentially contested concept" (Buzan, 1991: 6), a concept for which so many competing interpretations exist, each valuing different elements of the concept, that ultimately none appears to be acceptable to all (Herington, 2012: 9ff).[13] Against this background the problem arises how infectious diseases can be reasonably analysed in a security context at the EU level, if (a) security is inconsistently defined and refers to different things at the same time, and (b) if infectious diseases in the EU context are so little explored that any *ex ante* or theoretically derived definition of security bears the risk to be misguiding or too narrow? In this context it appears most promising to work with an approach that does not exclude any specific security understandings from the start but rather reflects that security is at least partly a subjective matter. The securitisation approach to be introduced in the next section has its strong point exactly in the capability to grasp all sorts of security threats and situations and to produce insights into the definition of security as it becomes manifest in a given setup.

2.2. The Securitisation Approach

The securitisation framework for analysis offers a constructivist perspective on security. Following the basic understanding that security issues in international affairs are first and foremost something socially constructed, the approach offers a flexible framework that is particularly suitable when it comes to examining which issues are actually regarded as a security problem.

The approach has its roots in the beginning of the IR security debate, when Arnold Wolfers argued that security is something that can be assessed both objectively (a threat is real) and subjectively (a threat is perceived) (Wolfers, 1952). In this sense 'objective security' is about the degree to which a referent object *is actually* secure, whereas 'subjective security' refers to the degree to which the referent object *feels* secure (Booth, 2007: 110, Herington, 2012: 20). When in the 1980s a general trend occurred to revise the conceptual basis of security analysis (Ullman, 1983, Krause and Williams, 1996) scholars took up this argument and emphasised the performative (in contrast to representational) function of language in security (Der Derian and Michael, 1989, Fierke, 1998).

Based on the theoretical groundwork of constructivist analysis of IR (Kratochwil, 1989, Onuf, 1989, Wendt, 1992)[14] and influenced by the 'linguistic turn' in philosophy and social theory they argued that security was not simply an externally given condition following the 'laws of nature' but the result of human action and the discursive reproduction of the environment – and, thus, always potentially open for restructuration. Following this interpretation nothing essentially constitutes a threat or a necessary good on its own right; an issue turns into a security issue only through discursive practice (Dillon, 1996). This implies that insecurity is not primarily constructed by policy responses to a menace but by language games (Fierke, 1998), discourses (Weldes, 1996, Campbell, 1998) and speech acts (Waever, 1995, Buzan et al., 1998). In other words "insecurity is not a fact of nature but always requires that it is written and talked into existence" (Huysmans, 2006: 7).

[13] On the concept of 'essential contestability' see Gallie (1955).
[14] For an overview of origins and evolution of constructivist thinking in IR see, for instance, Balzacq (2012).

Since the 1990s, when discursive and constructivists started to analyse the 'production of (in)security', the approaches have undergone a dynamic development and today belong to the dominant strands of IR and Security Studies (Ruggie, 1996, Wendt, 1999, Guzzini, 2000, Farrell, 2002, Zehfuss, 2002, Hansen, 2006, Balzacq, 2012: 56).[15] Within the set of constructivist approaches and the diverse range of 'wide concepts' of security the securitisation approach proved to be of particularly influence. The notion of securitisation was originally coined in the banking system and worked into IR by Ole Waever (Waever, 1989). Together with his colleagues at the Copenhagen Peace Research Institute and following Barry Buzan's *People, States and Fear* (Buzan, 1991) a particular approach to security analysis was established, today known as the 'Copenhagen School', by a series of publications with a core curriculum that essentially comprises four works (Waever et al., 1993, Waever, 1995, Buzan et al., 1998 and Buzan and Waever, 2003). Their work has been taken up in countless contributions and variations, leading to the assessment that "[e]very discussion of the topic of security since has had to deal with it, in some way or another" (Herington, 2012: 14).

In their perspective on security the Copenhagen School puts emphasis on the intersubjective elements of threat perception and construction. The framework constituted a substantial shift away from the 'narrow' conception of what is and what is not a security issue, not only beyond the military sector, but also beyond the assumption that threats are something objective. More precisely, the Copenhagen School argued that security should be understood as a political practice that can, under specific conditions, potentially take any issue into the realm of security:

> *"Threats and vulnerabilities can arise in many different areas, military and non-military, but to count as security issues they have to meet strictly defined criteria that distinguish them from the normal run of the merely political. They have to be staged as existential threats to a referent object by a securitising actor who thereby generates endorsement of emergency measures beyond rules that would otherwise bind* (Buzan et al., 1998: 5).

On a general level the securitisation approach sees security issues as something socially constructed that has been moved beyond the rules of normal politics. On a detailed level the process of securitisation proceeds in the form of „a speech act where a securiti[s]ing actor designates a threat to a specified referent object and declares an existential threat implying a right to use extraordinary means to fence it off." If and once a relevant audience consents to this move and "thus grants the actor a right to violate rules that otherwise would bind", the 'securitised' issue turns into a matter of security and "becomes […] a part of what is security" (Waever, 2000: 251).

In this understanding a securitisation process consists of three sequences:

(1) an actor's attempt to label an issue as an 'existential threat' ('securitising move'),
(2) the relevant audience's acceptance of this claimed threat,
(3) the adoption of 'emergency measures' to respond to this threat (Buzan et al., 1998: 26).

[15] A good overview of 'New Security Studies' can be found in Burgess, 2010.

(1) For the conceptualisation of the 'securitising move', the first sequence that initiates the process of securitisation, Waever and his colleagues built on the language theory put forward by Austin (see also Searle, 1969, Austin, 1975 [1962]). Austin argued that statements do not only represent reality but also realise action and that in the sense of being 'performatives' rather than 'constatives', speech acts can transform the world. Consequently, speech acts cannot be assessed as true or false. Examples referred to how utterances actually *do* things include 'betting', 'baptising', 'promising' or 'naming'. Hence, in the sense that issues 'show themselves' (from the Greek *phainesthai*) also security issues can emerge and develop through discursive practice (Dillon, 1996: 47). Rather than referring to some extra-discursive reality, the utterance of the word 'security', as Waever puts it, "is the act" (Waever, 1995: 55). The issue is thereby shifted into a security discourse which frames reality in a 'security way'. In this understanding security is regarded as an illocutionary speech act, a self-referential practice. By saying it, something is done that comprises a "'social magic' power of language, a magic in which the conditions of possibility of threats are internal to the act of saying 'security'" (Balzacq, 2011b: 1).

In practical terms the speech act is a 'securitising move' of an actor (the 'securitiser'), who employs a specific rhetorical structure to label someone or something (the referent object) as existentially threatened. This is typically done by claiming absolute priority to address a certain problem since (otherwise) the survival of the referent object is acutely endangered. In the original securitisation approach the staging of an existential issue is considered a dramatic claim to consider a certain issue more important than others and, consequently, that it needs to be moved up to the very top of the political agenda, or even above politics. In international affairs it means "to present an issue as urgent and existential, as so important that it should not be exposed to the normal haggling of politics but should be dealt with decisively by top leaders prior to other issues" (Buzan et al., 1998: 29). However, following the constructivist foundations of the approach the threats sometimes do not necessarily have to be existential (Williams, 2003). The important aspect is that the securitising actors *argues* that the "referent object's level of security (as a state of being) is what is threatened" (Herington, 2012: 13). An issue becomes a security issue not "because a real existential threat exists but because the issue is presented as such a threat" (Buzan et al., 1998: 24). Put crisply, the result of what is constructed by language is what ultimately matters; the real circumstances 'out there' are extraneous to this concept of security (Campbell, 1998, Knudsen, 2001, Balzacq, 2011b: 12).

(2) The presentation of an issue as existentially threatened, however, leads to successful securitisation only, if the securitising move is – in a second step – also accepted by the relevant audience of the securitiser, thereby generating a shared understanding of what can be collectively regarded and addressed as a threat. In other words, talking up a problem or designating it as a 'vital interest' is not enough to cause securitisation; the securitiser's securitising attempt also has to find acceptance by the relevant addressees. By acceptance, Buzan et al. mean "enough resonance for platform to be made from which it is possible to legitimise emergency measure or other steps that would not have been possible had the

discourse not taken the form of existential threats, point of no return and necessity" (Buzan et al., 1998: 25). By integrating the audience into the framework the Copenhagen School posits that securitisation can be understood as an intersubjective discursive practice which is incomplete as long as the securitising move is not followed by indication of acceptance. Hence, "security ultimately rests neither with the objects nor with the subjects but *among* the subjects" (Buzan et al., 1998: 31, emphasis in original).

(3) The third step in the securitisation process consists of the adoption of extraordinary means in response to the perceived threat. Classically, these measures refer to executive powers that fall within the juridical reserve area, immune to legal challenge (Gordon, 1991: 33) which allows governments to use all means necessary to address an emergency situation (Waever, 1995). In a wider sense these extraordinary measures refer to any means that "break the normal political rules of the game", for instance in the form of secrecy or extraordinary allocation of resources (Buzan et al., 1998: 24). Linked to the (declared) urgency of the matter the claim for the need and right to adopt these measures is usually justified in the speech act. The securitising actor thereby aims at legitimising the envisaged emergency action, including the use of force or the violation of certain rights, by presenting the measures as unavoidably required to tackle a threatening development (Buzan et al., 1998: 21).[16]

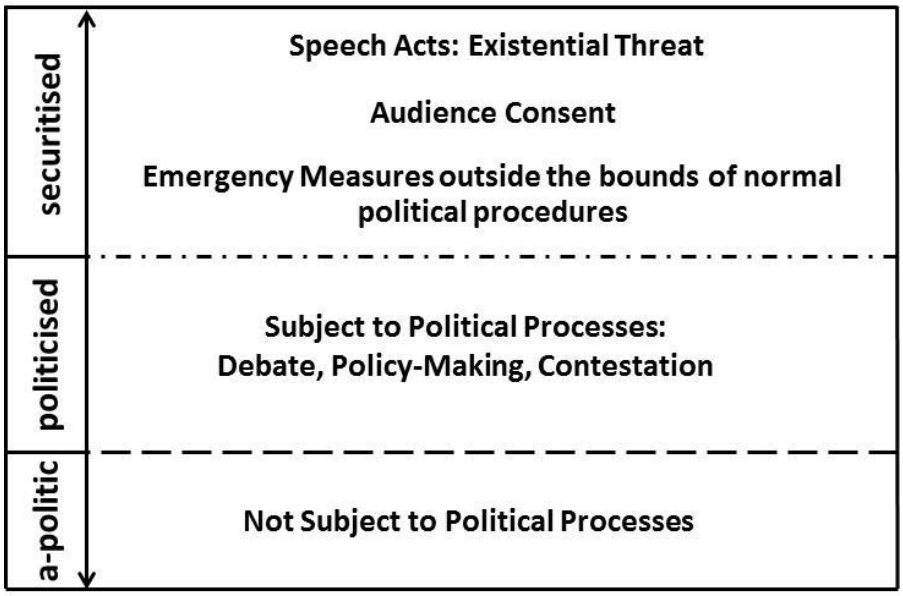
To sum up, the securitisation framework for analysis put forward by the group of scholars collectively known as the Copenhagen School sees the "intersubjective establishment of an existential threat with a salience to have substantial political effects" as the "*definition* and *criteria* of securitisation" (emphasis in original) (Buzan et al., 1998: 25). Security is understood not through its substance but through its performance, and the language of security does not primarily represent what is 'really out there' but is essentially constitutive of that very reality. In this understanding, the meaning of security is not made up *ex ante* analytically rather than on the basis of how securitiser and audience (consciously or unconsciously) frame and tackle an issue.

Successful securitisation has neither taken place if something is only seen as an existential threat without triggering subsequent measures, nor if only rules are broken on unspecific grounds. In contrast, securitisation requires the framing of "existential threats that legitimise the breaking of rules" (Buzan et al., 1998: 25). In line with this understanding the reference definition of securitisation includes a successful speech act "through which an intersubjective understanding is constructed within a political community to treat something as an existential threat to a valued referent object, and to enable a call for urgent and exceptional measures to deal with the threat" (Buzan and Waever, 2003: 491). This definition refers to securitisation as a process and provides the key elements of this process. The result of this process, in turn, is securitisation as a state of being, that is the 'successful' construction of a given issue or situation as a security problem.

[16] The idea of security as politics of prioritisation and exception can also be found in the work of other constructivists (for instance Huysmans, 2002 and McDonald, 2008; see also Herington, 2012: 12), some of them arguing that emergency measures also imply that they are beyond the public debate (Huysmans, 1998, Williams, 2003: 515).

It is important to note that the fathers of the securitisation approach considered the securitisation of an issue or of a situation as a status, which also can be de-escalated through the process of de-securitisation to the status of merely politicised matter. Similar to the securitising process that shifts an issue into the sphere of emergency politics, de-securitisation works as a reverse mechanism that returns the issue back to the realm of normal politics and its normal bargaining processes (Waever, 1995). In this sense, on a scale between issues which are not publicly debated or dealt with by the state (non-politicised), through issues which belong to the realm of public policy-making (politicised) to those which have been framed as an "existential threat, requiring emergency measures and justifying actions outside the normal bounds of political procedures", the latter, i.e. the securitised issues, constitute one extreme, but not a dead end (Buzan et al., 1998: 23f).

Figure 2-1: From A-Politic to Securitised



Source: Own presentation on the basis of Buzan et al. (1998).

Consequently, in this framework security was not meant to be seen as a conflict-free ideal in contrast to insecurity, but "as a failure to deal with issues as normal politics" (Buzan et al., 1998: 29). The designation of de-securitisation as the desired long-term status is also linked to the tactical potential of a securitisation move that could also be employed to exploit a threat in view of prioritisation and emergency measures on potentially unjustified grounds. Hence, securitisation is not "an innocent reflection of the issue being a security threat […], it is […] a political choice to securitise or to accept a securitisation (Buzan et al., 1998: 29).

2.3. A Novel Approach to Study the Securitisation of Infectious Diseases and Its Effects on the Institutionalisation in the European Union

The publication of the Copenhagen School's approach to Security Studies triggered manifold reactions in the academic world, ranging from wide recognition and numerous applications of the concept through the label 'politically irresponsible' (Eriksson, 1999) to the reactivation of the much-quoted impression that something must be 'rotten in the State of Denmark'[17] (Moravcsik, 1999, see also Williams, 2003: 512). A large number of studies also dealt with it in conceptual terms and proposed various advancement of the original approach. This discussion, however, was primarily fed by scholars who were interested in (de-)securitisation as a process which is initiated and influenced by various factors that are subject to investigation. In this sense, the debate revolved around the causes and conditions for securitisation as the *explanandum*.[18]

Given the research interest of the present study in forms of securitisation that precede institutionalisation processes (securitisation as *explanans*), the novel securitisation approach as applied in the following includes innovations that are primarily designed to systematically analyse the forms of the securitisation of infectious diseases and to integrate an explanatory framework that defines institutionalisation as a potential effect of securitisation. In order to re-conceptualise the securitisation framework in such a way, the novel approach introduces four interrelated innovations: a 'securitisation degree', a 'securitisation kind', a 'coordination system of securitisation' and the concept of institutionalisation as a potential effect of securitisation. Complemented by an analysis of the group of securitisers the former three tools serve the purpose to assess the form in which a disease has been securitised; the latter links the framework for analysis with the integration dynamics at the EU level.

What are these innovations exactly about, why are they needed and how do they fit together?

First, it has become clear that the original securitisation approach works with a binary distinction to differentiate between 'normal' political issues on the one hand and security problems on the other. This spectrum between security and normal politics, however, is somewhat simplistic and was identified to deserve further investigation in view of the state of "partial securiti[s]ation" even by one of the original securitisation authors (Waever, 2003: 26). Hence, in order to grasp more accurately the securitisation form of a disease, the next section (chapter 2.3.1) introduces a 'securitisation degree' of infectious diseases. It builds on the idea of a 'security continuum' which essentially means

[17] Satirical reference to Shakespeare's Hamlet (Act 1, Scene 4) in view of the country in which the home city of the securitisation approach, Copenhagen, is located.

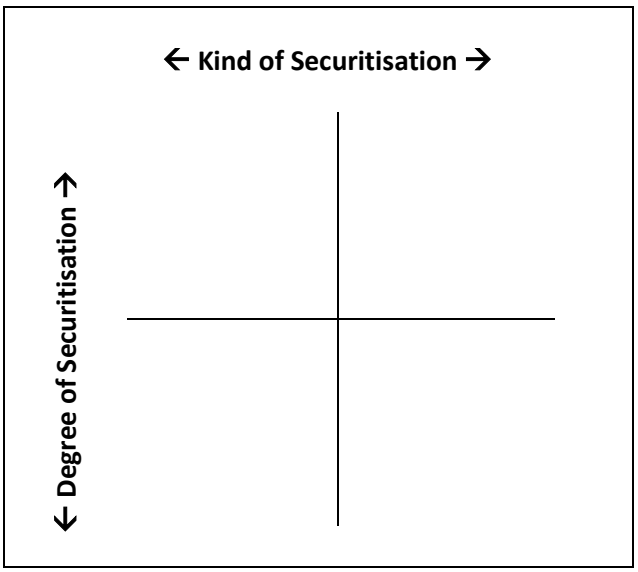
[18] In this context the debate *inter alia* addressed the securitisation approach's focus on specific 'moments' (Weldes et al., 1999: 16f, Hansen, 2000: 300f, Wilkinson, 2007, McDonald, 2008: 564, 570) and the role of the State (Wyn-Jones, 1999, McDonald, 2008, Barthwahl-Datta, 2009). A prominent advancement of the original securitisation framework got to be known as the 'sociological' school of securitisation studies which emphasises the re-definition of speech act to better integrate the 'audience' and better reflect the powers of securitisers, the kind of audience(s) that matter(s) and differences regarding the tools and mediums of securitisation, incl. other mediums and forms of communicative action such as televisual communication, images, silence etc. (Hansen, 2000, Williams, 2003: 526, Balzacq, 2005, Booth, 2007, Möller, 2007: 180, Stritzel, 2007, McDonald, 2008, Léonard and Kaunert, 2011).

that “security issues can be seen to move on a continuum from normalcy to worrisome/troublesome to risk and to existential threat” (Abrahamsen, 2005: 59). According to such an understanding, the states of ‘politicised’ and ‘securitised’ are not binary conditions “but the two end points of a spectrum” along which security issues can move “with most falling short of the existential threat required for full securiti[s]ation (McInnes and Rushton, 2013: 128).

Second, we have seen in chapter 2.1 that security is an essentially contested concept for which no generally accepted definition exists. It will become clear in chapter 2.3.2 that this ambiguity is also a dominant feature when it comes to linking security to public health and infectious diseases. Academics and practitioners regularly employ security and securitisation terminology, but they refer to different security definitions or do not make explicit the underlying security or securitisation concept. Consequently, when defining the form of securitisation of an infectious disease, we need to be capable of differentiating between different security understandings. Hence, in order to grasp what security actually refers to when an issue becomes securitised, the novel securitisation approach introduces the analytical concept of a ‘kind of securitisation’. This tool structures the spectrum of security understandings in relation to infectious diseases on the basis of a set of securitisation parameters.

In other words, whereas chapter 2.3.1 introduces a degree of securitisation in order to express, on a vertical axis, the intensity of the security dimension for a given issue, the kind of securitisation as introduced by chapter 2.3.2 shall, on a horizontal axis, allow for the qualitative differentiation between different security concepts. Together, these innovations allow for a better definition of an infectious disease as a security issue. Ultimately, degree and kind of securitisation can be combined to establish a ‘coordination system’ (see Figure 2-2 below and chapter 2.3.3) that is suitable to locate the securitisation form of an infectious disease.

Figure 2-2: The Coordination System of Securitisation (basic version)



Source: Own presentation.

Third, we have seen that the original securitisation framework lacks an elaborate explanatory model on the effects of securitisation. The question of causality has also been identified to be important for the development of a 'securitisation theory' (Guzzini, 2011). However, to the knowledge of the author the securitisation critique has not yet yielded a clear-cut model that would allow for a straightforward connection of securitisation and institutionalisation processes. Since such a link is essential for the analysis of the institutionalisation of infectious disease control in the EU from a securitisation perspective, the novel securitisation approach establishes this connection on the basis of a basic 'security logic' in chapter 2.3.4. In this context the above mentioned coordination system will be of particular value, seeing that a clearly defined form of securitisation of a disease can be employed as the independent variable in a testable hypothesis. However, before doing so it is necessary to elaborate on each of the innovations in detail. In particular, it is necessary to develop the analytic concepts of a securitisation degree and kind in a way that meets the demands of a securitisation study on infectious diseases.

2.3.1. The Degree of Securitisation

In order to establish a differentiation between different 'degrees of securitisation' the proposed framework takes up wide approaches to security which work with a continuum for the classification of securitisation and threats (Bigo, 2002, Abrahamsen, 2005, Kamradt-Scott and McInnes, 2012, Léonard, 2012, McInnes and Rushton, 2013). This continuum builds on the classification by Buzan et al. that differentiates between issues which are 'non-politicised', those which have been 'politicised' and those which have been 'securitised' (Buzan et al., 1998: 23f; see also Figure 2-1). A major concern with this classification was that the status of 'securitised' could in reality hardly be observed as a 'yes-or-no' situation but often constituted a condition that easily transcended to the state of 'politicised'. Against this background the proposed 'security continuum' provided a spectrum on which any issue could gradually move back and forth between the extremes of 'normalcy' and 'existential threat' (Abrahamsen, 2005: 59).

The novel securitisation degree follows a similar logic. It starts from the assumption that there is not only a gradual transition between the states of 'politicised' and 'securitised', but also within the status of 'securitised'. Against this background the realm of 'securitisation' can be split up into different levels or phases so that the spectrum between the end points of 'lowly securitised' and 'highly securitised' is structured into different 'securitisation degrees'. This innovation addresses one of the weaknesses of the original securitisation approach by allowing for a more adequate classification of securitisation states (Bigo, 2000). At the same time, it sets end points to the securitisation continuum, which are helpful when it comes to deriving hypotheses on the impact of the securitisation degree on the effects of securitisation, that is when a given form of securitisation serves as the independent variable.

How can we identify the securitisation degree? The novel securitisation framework takes up the key elements of the original securitisation approach that occur in the securitisation process, namely security discourse and speech acts, securitisers, audience and emergency measures.

Security discourse and speech acts in this context refer to the prevalence and intensity of security language with regard to a perceived threat, considering the number of speech acts as well as the character and dominance of security vocabulary. The group of securitisers has an impact on the securitisation degree depending on the power position of the author of the utterance. For instance, a speech act by a prime minister indicates a higher securitisation degree than a speech act by a parliamentarian. Also the consent of the audience to the speech act can move on a spectrum between moderate to strong acceptance, the former indicating a lower, the latter a higher degree of securitisation.[19] Similarly, emergency measures can range from few and soft initiatives (low securitisation degree) to the implementation of many and binding measures (high securitisation degree). This set of components is complemented by the 're-allocation of resources', which covers the commitments in response to a security situation, in particular in form of financial means and personnel.[20] In short, the underlying idea of the concept of a securitisation degree is that each of the components of the original securitisation approach essentially constitutes an indicator that can take different values representing an either lower or higher securitisation degree.

Thus, when it comes to practically defining the securitisation degree, the different components of securitisation need to be assessed and combined to make up for an overall securitisation degree. In this context two extreme types help structuring the spectrum between low and high securitisation. In the case of an ideal type 'lowly securitised issue' – at the border to a merely 'politicised' problem – we expect only occasional securitising moves from securitisers in rather weak power positions and a moderately consenting audience. The issue is only occasionally referred to as a matter of security so that the discourse in general is dominated by other narrative. Measures that are adopted in response to the security challenge are expected to be few and of a soft nature only, for instance in the form of non-binding policy instruments that go along without a substantial re-allocation of resources.

In contrast, in the case of an ideal type 'highly securitised issue' – in a most extreme variant – we expect the issue to be subject to a discourse that has reached the highest political level and is exclusively addressed as a security issue, fully dominated by security language. A high number of hard extraordinary reactions justified on the grounds of security concerns, for instance by imposing emergency rules, go along with a drastic allocation of resources and, thus, indicate a high degree of securitisation. In this context it is important to remember that the assessment of a securitisation indicator should be done under consideration of the relationship between the target and the means that are at the disposal of a securitising actor. To illustrate, earmarking a million Euros to a given protective counter measure may be a lot for an individual person, but not so much for a country.

[19] The minimum audience consent required for a lowly securitised issue is 'moderate' and not 'low', because the securitisation framework demands a predominantly consenting audience in order to regard an issue as being lifted into the realm of security in the first place. Since 'low' consent suggests that less than a majority of the audience accepts the securitising move and respective emergency measures, the lowest required consent of a securitised issue is defined to be at least 'moderate'.

[20] In the original securitisation approach the allocation of resources could be assigned to the realm of 'extraordinary measures'. With a view to the differentiation between securitisation degrees, however, it is helpful to list this particularly measurable indicator separately.

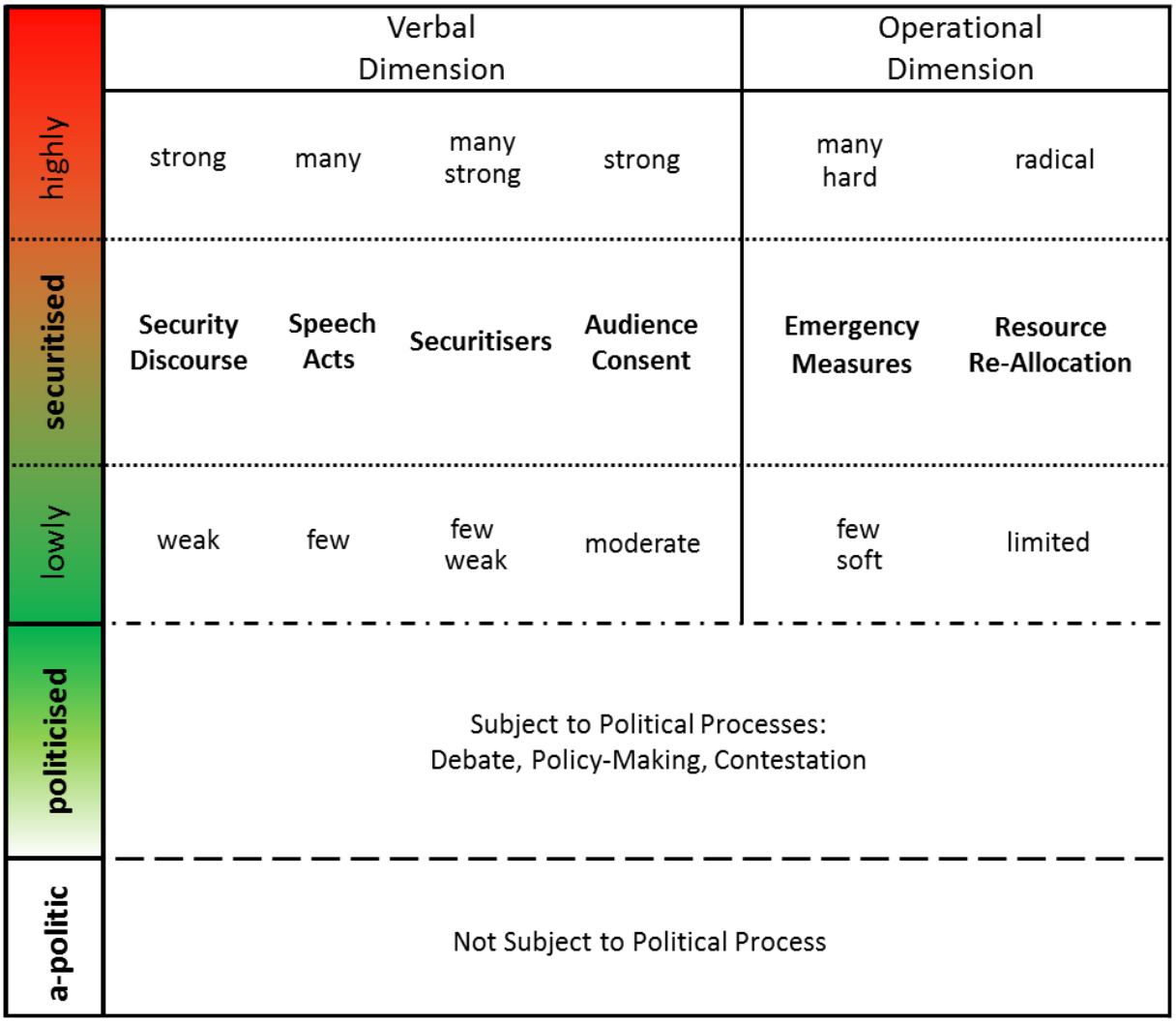
This understanding of securitisation differs from the approach of the Copenhagen School in some respects. Whereas Buzan et al. proposed that a speech act must claim that an issue represents an 'existential threat' in order to qualify as a securitising move, the criterion applied here is less demanding. A securitising speech act covers basically any threat as long as the securitiser considers it to be a security issue. In this sense, the term 'existential threat' is opened to a less demanding 'exceptional threat' (Kamradt-Scott and McInnes, 2012: S97). Adapting the notion in this way is justified for the analysis of health-related securitisation processes, because health issues seldom equal existential threats such as, for instance, exerted by a military invasion (McInnes and Lee, 2005).

A flexible gradation is also helpful for the classification of emergency measures which do not necessarily have to be extremely exceptional or be completely contrary to established good practice to qualify as a contribution to the securitisation of an issue. The novel securitisation approach considers more measures as being part of the securitisation process as long as they have never or only rarely been applied before under the impression of urgency in response to a perceived threat.

The following Figure 2-3 structures all components of the securitisation degree on the basis of the basic differentiation between a-politic, politicised and securitised issues as introduced by the Copenhagen School (see Figure 2-1). In order to help structure the various components, the indicators of the securitisation degree are grouped along a 'verbal' and an 'operational' dimension. Whereas the verbal dimension deals with the construction of (in)security by the means of language, the operational dimension refers to implemented action.

Hence, the verbal dimension includes security discourse, speech acts, securitisers and the audience. In turn, the operational dimension refers to the emergency measures and the (re-)allocation of resources. Such a basic differentiation is useful against the background that an issue can be considered to have turned into a security problem only if securitising speech acts and audience consent (verbal dimension) are accompanied by emergency measures (operational dimension). When it comes to practically assessing whether and in how far an infectious disease has been securitised, the assessment along the two dimensions thus helps verify that the disease has not only been talked up as a security threat, but also been responded to in an extraordinary way.

Figure 2-3: From A-Politic to Highly Securitised – The Indicators of the Securitisation Degree



Source: Own presentation.

By gradating the key elements of securitisation in the proposed way, a more nuanced classification is possible to express how high an issue has risen the security continuum, that is whether a disease has turned to a smaller or greater extent into a security problem. However, it should be noted that the securitisation degree it is not designed to generate statistical data or to provide an exact calculation of a mark that expresses the securitisation degree in numbers. It is also beyond the scope of this study to develop an index that could exactly express the degree of securitisation on the security continuum, even if quantitative methods will complement the qualitative content analysis employed to analyse the securitisation degree (see chapter 2.5.6).

In contrast, for the purpose of this study it is sufficient to split up the security continuum in three stages: lowly, moderately and highly securitised. Building on the distinction between verbal and operational securitisation, the highest degree of securitisation can only be achieved if we witness the combination of a high verbal degree and a high operational degree of securitisation. In turn, any combination with lower degrees of securitisation across the two securitisation dimensions ultimately leads to an overall result below the highest securitisation degree. Clearly, a more nuanced

differentiation would be possible on the basis of the securitisation degree indicators, but this basic assessment if sufficient for the purpose of the study which is, as will become clear in chapter 2.4, primarily interested in cases of high securitisation degrees. Figure 2-4 illustrates the staged classification system with basic pre-defined steps of low, medium and high securitisation in both the verbal and the operational dimensions.

Figure 2-4: Schematic Overview of Degrees of Securitisation across Verbal and Operational Securitisation Dimension

	Verbal Securitisation Degree		
Operational Securitisation Degree		Low	High
	High	**Moderate**	**High**
	Low	**Low**	**Moderate**

Source: Own presentation.

2.3.2. The Kind of Securitisation

As a second major innovation the novel securitisation approach introduces the differentiation between different 'kinds of securitisation'. Whereas the degree of securitisation was introduced to help locate the securitisation status of a given issue on a vertical spectrum between low and high securitisation, the kind of securitisation focuses on a horizontal spectrum of diverging securitisation understandings, namely between the extremes of a 'soft' and a 'hard' kind of securitisation. The logic behind this differentiation is that securitisation occurs in the context of different underlying security understandings and that the inherent security understanding has an impact on the (potential to trigger) effects of securitisation. The basic argument is that it is not sufficient to reveal that a disease has been securitised, or to what extent an issue has turned into a security issue. In contrast, for a complete picture of a security reading of diseases, it is also necessary to disclose the concept of security that is inherent to the securitisation.

The background for the idea of a 'securitisation kind' is the finding of chapter 2.1 that security is an essentially contested concept for which no generally accepted definition exists. A given matter can be regarded as a security problem by one person, but the same issue might not necessarily evoke a discomfort of insecurity for another person. We have seen that the IR security debate is characterised by competing interpretations, who or what needs to be threatened by what or whom so that one can actually talk about a security issue. It comes without surprise that also the link between security, public health and infectious disease control is characterised by diverging interpretations and competing understandings. As indicated in the introductory chapter, the field is often subsumed under the notion of 'health security' (see, for instance, Feldbaum and Lee, 2004, Rodier et al., 2007, Aldis, 2008). This term, however, can allude to basically everything pertaining to health (Elbe, 2010b).

Therefore, when it comes to the securitisation of infectious diseases, the sequences that construct health (in)security might be the same for all readings of the health security nexus (speech act, audience, emergency measure) but the construction occurs with reference to different definitions of the threat, different definition of the referent objects of security, different definitions of the security providers etc. Against this background, the kind of securitisation is designed as a tool that investigates the contestability of 'security' and its interpretative dimensions.

How can we identify the kind of securitisation of a given infectious disease? Similar to the indicators that were established in the previous chapter to determine the degree of securitisation, a set of parameters that make up for a securitisation kind will be needed. In order to generate such a list of relevant parameters, a thorough review of existing approaches at the intersection of public health, infectious disease control and security appears most promising to grasp the existing understandings. Clearly, it would be possible to work with one of the existing health security concepts that offer a specific reading of the link between (in)security and infectious diseases. However, following the idea that the kind of securitisation potentially impacts the effects of securitisation and given that the securitisation of infectious diseases at the EU level is rather unexplored territory, it is not advisable to work with a pre-defined security understanding. Also, establishing the concept of a kind of securitisation on the basis of security parameters that cover basically any security understanding contributes to a broad applicability of the concept across diseases and securitisation settings.

Hence, before developing in detail the concept of a securitisation kind, the following section will examine and structure the rich literature of the 'health security nexus' with the aim to compile a list of security parameters most relevant for the differentiation of constructions of (in)security related to infectious diseases.

2.3.2.1. Making Sense of the Health Security Nexus

We have seen in the introductory chapter that linking security to health and infectious diseases is both an old and a recent development at the same time. Against the background of the experiences of mankind with infectious diseases, for instance smallpox, which alone during the twentieth century killed three times the number of deaths caused by wars during that period (Oldstone, 1998), one might wonder how infectious diseases could be seen as something other than primarily a security concern. In this context it is important to consider a particularity of the link between health and security in general: the insight that being alive puts you at serious risk to death and that in the end we all have to die. In fact, there is nothing unnatural in dying of ill health. Otherwise, "[i]f everything that causes a decline in human well-being is labelled a 'security' threat, the term loses any analytical usefulness and becomes a loose synonym for 'bad'" (Deudney, 1990: 463f). It therefore hardly makes sense to think of death, infectious diseases and health as security concerns as such; infectious diseases can cause a 'natural' death. Consequently, linking security to health and infectious diseases only makes sense if the cause of death is considered 'unnatural' or 'premature', that is if death is considered as at least partly avoidable (Hough, 2004: 15).

Accordingly, the circumstance that infectious diseases have caused more morbidity and mortality than war and essentially anything else in human history (Price-Smith, 2002) can reasonably be contextualised from a security perspective only if a lethal infection is thought of as evitable. Since this condition could not be taken for granted for most periods of human history, only the recent advances in medicine, biotechnology and public health to respond to infectious diseases provided the stimulating background for the development and discussion of various 'health security' concepts. Among these concepts at the intersection of security, public health and infectious diseases the most prominent and influential approaches in the academic and political debate are the partly overlapping concepts of (1) biosecurity, (2) pandemic security, (3) human security and (4) global health security.

To take up the basic features of Security Studies, the biosecurity and pandemic security can be classified as the two most prominent approaches that follow the logic of a rather narrow, classic understanding of infectious diseases as a security issue. The human and the global health security approaches, in turn, represent rather wide approaches. Hence, it can be reasonably assumed these four approaches cover large parts of the wide spectrum of security approaches to infectious diseases. Their review is therefore particularly suitable to identify distinguishing features and to eventually generate a list of security parameters on the basis of which the end points of the spectrum for a kind of securitisation can be identified.

2.3.2.1.1. Biosecurity

The concept of biosecurity is usually understood as referring to the prevention of inadvertent, inappropriate, or intentional malicious or malevolent development, acquisition and use of biological agents or biotechnology (Government of Japan, 2008, cited in Kuhlau and Hart, 2010: 174, Koblentz, 2010). With the aim to ensure the "health and safety of humans, animals, and plants" (Kuhlau and Hart, 2010: 175) it includes the measures taken at the laboratory level as well as wider "preventive security measures, […] disease surveillance, preparedness, and response in the event of the use of biological weapons or biosafety and biosecurity breaches" (Kuhlau and Hart, 2010: 174). Hence, the dangers of warfare with biological weapons used as "devices for the malevolent infliction of disease" (Kellman, 2012: 232) with bacteria, viruses, rickettsiae, fungi and toxins and questions regarding the compliance with the 'Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction' (BTCW, 1972) are central components of the biosecurity concept (Kelle, 2007: 219).

In this context dual-use science research that has the potential "to be used for harmful as well as for legitimate and beneficial purposes" (Kuhlau and Hart, 2010: 181) and the advances in synthetic biology and genetic manipulation have taken the biosecurity debate into the realm of cutting-edge life science (Van Aken, 2006, Garfinkel et al., 2007). Experts fear that with the spread of expertise in molecular biology also capacities and opportunities for misuse will raise, rendering current biosafety standards and protocols on laboratory safety insufficient (Collier and Lakoff, 2008: 10).

Also the notion of 'bio-error', a composite of the terms 'bio' and 'error' (without 't'), has recently entered the debate hinting at the risks arising from the un-intentional release of dangerous materials from laboratories (National Intelligence Council, 2012: 67). Bioterrorism (with 't), in turn, refers to questions about the threat posed by a potential terrorist attack involving the deliberate release of an infectious disease (Collier et al., 2004, Wright, 2006, Fidler and Gostin, 2008, Stavrianakis et al., 2011). Triggered by reports in the 1990s on bioweapon programmes in the Soviet Union and Iraq and the menace of proliferation of WMDs by rogue states, the subway sarin terrorist attack in Tokyo and by the terrorist attacks of 9/11, 2001 and the subsequent anthrax scare in the US, infectious diseases took a central place in the lively debate about 'asymmetric threats' (Hough, 2004, Lakoff, 2010: 68f).

2.3.2.1.2. Pandemic Security

Similarly to biosecurity the concept of pandemic security – sometimes also referred to as 'pandemic preparedness' – has its roots in the 'national security' debate. However, the view is different in so far as pandemic security emphasises the direct effects of a naturally occurring disease such as AIDS, SARS or influenza on the State and its core functions and institutions. Accordingly a reading through the lenses of pandemic security includes the view on infectious diseases as security concerns in a traditional sense that can have serious effects on armed forces, combat effectiveness and military preparedness. An estimation that in the early 2000s in some African countries 40 to 60 per cent of the armed forces and, for instance, in Zambia also half of the police were HIV positive is a case in point (Price-Smith, 2001: 14, Elbe, 2010a: 165).

At the same time, pandemic security also goes beyond the military domain and acknowledges the potential impact of infectious diseases on social and political stability and economic growth (Garrett, 2005, McInnes and Lee, 2006, Maclean, 2008). In this context the exacerbating effects on social tensions, political struggle over access to medicine, reduced labour force, increased welfare costs and a "socially unstable high number of orphans" (Elbe, 2010a: 164ff, here: 166) play the most important role. Hence, following this understanding State-related insecurity can also be caused by 'medical problems' that are widely present within a given population (Elbe, 2012: 89).

In line with this concept infectious diseases have also found their way into the political sphere, for instance in the United States' or United Kingdom's national security strategies, where possible effects of pandemics on the own country, but also generally on international stability, peace and economic development were highlighted (The White House, 2006, Cabinet Office, 2008: 3, 2010: 31). The HIV/AIDS pandemic was subject of six meetings of the UNSC since the year 2000[21] which labelled the disease a threat to international peace and security. In this sense classic security issues such as peace, the functional existence of societies, internal and economic stability, and armed forces were linked to pandemics by influential political studies (National Intelligence Council, 2000, International Crisis Group, 2001), even if empirical evidence on the *de facto* influence might have been "thin and/or inconclusive" (McInnes and Lee, 2006, Selgelid and Enemark, 2008: 464).

[21] United Nations Security Council Meetings 4087, 4172, 4259, 4339, 4859, and 5228.

2.3.2.1.3. Human Security

The third concept that figures prominently in the infectious disease-related security debate is that of human security. This concept does not emphasise a particular (source of) threat but links up with the broader developmental and human rights agenda and highlights a different referent object of security by shifting the attention away from the security of the State to the security of "ordinary people […] in their daily lives" (UNDP, 1994: 22). At the same time the concept encompasses many dimensions: "not just physical security, but the security of health; not just economic security, but that of food and of the environment; not just personal security, but that of community and even politics" (Thomas, 2001, Shaw et al., 2006, Hooker et al., 2012: 162f).

The connection of infectious diseases with these elements is facilitated by the fact that health is often seen as the core of human security following the universal value of health and its ability to connect the human security approach's claims to primarily consider the needs and welfare of individuals (Chen and Narasimhan, 2003, Maclean, 2008). In this vein the human-centric approach easily translates into a view on health as a fundamental individual human right that also needs to find expression in the general rights of the citizens and the social determinants of health (O'Manique and Fourie, 2012: 246).

On a very basic level, the human security approach sees "premature and unnecessary loss of life [as] the greatest insecurity of human life" (Chen and Narasimhan, 2004: 5). Given the great number of premature deaths caused by infectious diseases, these diseases consequently constitute threats to security. Important in this context is that this understanding particularly highlights those infectious diseases that globally account for the most deaths. The concept thus implicitly shifts the geographical focus from the developed West southwards to endemic diseases in the developing world such as HIV/AIDS, malaria and tuberculosis (Elbe, 2012: 88, 92) and from the defence of borders against infectious diseases and bioweapons to relief, disease treatment and capacity building in the weak local health infrastructure. Crucially, compared to biosecurity and pandemic security, human security is grounded in a humanitarian and ethical motivation for which the self-protection of (Western) states is not the ultimate imperative.

Human security was not only subject to the academic debate but also entered the political sphere, where it found support by a range of political and civil society actors (Africa Leadership Forum, 1991, Canadian Department of Foreign Affairs and Trade, 1999, Commission on Human Security, 2003, Cottey, 2007: 46). In this vein, the United Nations Development Programme (UNDP) proposed to change the concept of security "from an exclusive stress on national security to a much greater stress on people's security, from security through armaments to security through human development, from territorial to food, employment and environmental security" (UNDP, 1993).

2.3.2.1.4. Global Health (Security)

The intertwined concepts of 'global health' and 'global health security' are perhaps the widest of the set of security related concepts that deal with infectious diseases. On a very general level, global health deals with "health problems, issues, and concerns that transcend national boundaries [and which] may be influenced by circumstances or experiences in other countries" (Institute of Medicine, 1997: 1). In other words, the concept addressed all kind of health-related phenomena that cross borders and go beyond the agency of national governments. Given their cross-border effects, these phenomena call for joint action "to influence the global forces that determine the health of all people" (Karolinska Institutet and Global Health Europe Network, 2009: 11).

Resulting *inter alia* from travel and trade between nations, infectious diseases can easily transcend national boundaries and therefore do fall under the definition of global health issues. However, the global health concept follows a wider agenda that also includes "inequities caused by patterns of international trade and investment, the effects of global climate change, the vulnerability of refugee populations [and] the marketing of harmful products by transnational corporations" (see also Lee, 2003, Smith et al., 2006: 342). The World Health Organization establishes the link between global health and security by hinting at "the collection of preventative and response activities that minimi[s]e the vulnerability of populations to communicable disease transmission across geographical, national or regional boundaries" (WHO, 2007). Here global health security is at stake primarily if a disease is involved which can be transmitted directly from human to human (Zacher and Keefe, 2008: 183, FN 1). Other scholars, however, use the notion of global health security more generally in the context of "threats […] that can spread menacingly irrespective of established natural or political borders" (Hoffman, 2010: 511).

Apparently, with a definition that generally applies to the health of people all around the world, the global health security concept shares a conceptual basis with the human security approach. A major difference, however, is that global health security does not concentrate on the health of the individual human, but on the protection of entire populations. Also global health security is not so much concerned about the security conditions for a healthy life, rather than threats of a global dimension.

Another particularity of the global health approach is its acknowledgment of the increasing importance of a wide range of non-state actors, including international non-governmental organisations, multinational companies, influential philanthropic foundations and the media and their changing position in global health governance (Brown et al., 2006, Drager and Sunderland, 2007, Fidler, 2007a, Garrett, 2007, Nichter, 2008: 156, Zacher and Keefe, 2008, Koplan et al., 2009, Aviel, 2011). Starting from the observation that an increasing number of non-state actors with significantly increased budgets has become active in the field of global health in general (Reich, 2002, Caines et al., 2004, Buse et al., 2009, Rushton and Williams, 2011), the concept highlights the involvement of these actors also in the response to the global challenge of infectious diseases.

2.3.2.2. The Parameters to Distinguish Infectious Disease-Related Security Concepts

The review of the literature of the health security nexus reveals that legal scholar David Fidler might be right in concluding that "[t]he [current] prominence of security concepts in debates about public health threats and governance is historically unprecedented" (Fidler, 2007b: 42). The link between (in)security and infectious diseases is indeed established in a rich variety that is easily capable to render health and security fundamentally ambiguous. Put crisply, there is indeed no single understanding of the link between (health) security and infectious diseases, neither among researchers nor among policy-makers (Aldis, 2008).

However, recalling the basic assumption that the way in which an issue is constructed as a security problem is fundamental to the effects it can trigger, it is necessary to structure the plethora of approaches and to establish a framework that allows for the differentiation between different kinds of securitisation. In order to do so, it helps work with a list of security parameters that distinguish the different security concepts or that the different concepts have in common. Even though additional security approaches, 'key perspectives' of global health governance (Lee, 2009: 29) and 'global health regimes' (Lakoff, 2010) could be added,[22] the list of fundamental parameters can be compiled from the four presented concepts, that is biosecurity, pandemic security, human security and global health security, complemented by a number of cross-cutting factors.

In order to ensure compatibility with the overarching framework of this study, the parameters defining the kind of securitisation are best structured along the components of the securitisation framework. In this context those components are of particular relevance, which are open to diverging interpretations depending on the underlying security understanding. Starting from the reference definition which understands securitisation as a successful speech act "through which an intersubjective understanding is constructed within a political community to treat something as an existential threat to a valued referent object, and to enable a call for urgent and exceptional measures to deal with the threat" (Buzan and Waever, 2003: 491), three elements can be singled out in that respect:

(1) The definition of the referent object (whose security is at stake?),
(2) The definition of the threat (who or what threatens security?) and
(3) The definition of the provision of security (who or what provides security?).

A detailed look at each of the components helps reveal relevant parameters as well as possible values that these parameters can take.

(1) As regards the referent object of security we see a major dividing line that separates State-centred from human-centred approaches. Linked to the ideas of 'national security'[23] the concepts of biosecurity and pandemic security put emphasis on the protection of the State and its vital constituents such as military force or a functioning economy. The concepts of human

[22] A good overview also beyond the security focus is provided by Ng and Ruger (2011).
[23] For a discussion on the historical relationships between public health and national security see, for instance, Fearnley (2005) and King (2002).

security and global health security, on the other hand, pursue a different approach by referring to the security of people. Here also the minimum number of referent objects plays a role. The human security approach with reference to the human rights discourse sees all people, that is every individual, entitled to health and security by virtue of their humanity (Donelly, 2003: 7). Global health security, in contrast, deals with the health of larger groups of referent objects and entire populations.

(2) All presented concepts relate infectious diseases to security as a menace that affects the health of a given referent object, but the understandings of infectious diseases as a threat differ. In this context six interrelated parameters can be identified that distinguish the different security concepts.

a. Source of threat: A disease qualifies as a security threat depending on its perceived source, which basically can be manmade, as it is in the case of the biosecurity approach, or natural, as in the pandemic security approach.
b. Source of pathogenicity: A disease qualifies as a security threat depending on the perceived root causes that make a disease a threat, which can range from terrorism (biosecurity) through globalisation effects (global health security) to the lack of developed public health infrastructure (human security).
c. Speed of threat: A disease qualifies as a security threat depending on the perceived speed at which the disease spreads. The speed of spread is influenced by a number of factors, primarily the infection path and the vector of the disease (food-borne, air-borne, water-borne, etc.). In this context the biosecurity concept considers fast spreading 'outbreak events' as security threats. Contagious communicable diseases which are easily transmissible from person-to-person, for instance by droplet infection, are of particular concern. In contrast, the human security approach puts more emphasis on 'attrition diseases' like HIV/AIDS or malaria which spread slower (Price-Smith, 2001: 15f, Selgelid and Enemark, 2008: 459).
d. Geography of threat: A disease qualifies as a security threat depending on the perceived geographic prevalence. Contingent upon the infection path and the vector of the disease the morbidity of a given disease varies across (world) regions. Crucially, from a biosecurity or pandemic security perspective a disease turns into a security issue only if it appears close to (and likely to affect) the own territory. The human security, in turn, emphasises the impact of a disease in developing countries, the global health approaches the (potential) worldwide dimension of an outbreak. In short, a major distinction can be made upon the criterion whether the diseases affects 'us' or not.
e. Severity of impact: A disease qualifies as a security threat depending on its perceived curability and the availability of treatment or vaccination. For most approaches it is more likely that the disease is considered a security threat, if no treatment exists and the course of disease is characterised by high mortality and quick death. By extending the view on effects of not lethal or chronic infections, global health and human security approaches apply a wider definition.

f. Predictability of threat: As a cross-cutting theme, a disease qualifies as a security threat depending on the perceived accurateness with which its speed, geographical spread and severity of impact can be foreseen. The notions of 'new' and 're-emerging' diseases are related to the insight that mutation and change of microbes that threaten human survival are natural and can occur any time anywhere in the world, just as new pathogens, unknown strains of known viruses or drug-resistant strains of known viruses can emerge in unpredictable forms (Henderson, 1993).This unpredictability renders it difficult for policy makers to adopt effective counter measures; a problem that is often addressed in relation to both counter-bioterrorism as well as pandemic security (Cooper, 2006). The human security and the global health security approaches, in contrast, consider first and foremost by now familiar diseases in the developing world as (most important) security threats (Selgelid and Enemark, 2008: 459, Liese et al., 2010).

(3) Finally, the third question to classify security concepts focuses on the provision of security. In this realm the review of existing concepts of the health security nexus suggests differentiating the views on security along four parameters, namely (a) the ethical stance that justifies the adoption of counter measures, (b) the actor that is in charge of the provision of security, (c) the primary policy engaged as well as (d) the scope and kind of measures engaged to provide security.

a. Ethical stance: This parameter reflects the fact that most security concepts work with specific underlying motivations and justifications why the challenge of an infectious disease should be addressed in the first place. The ethical stance is linked to the definition of the threat and the measures considered most appropriate to respond to the threat. The arguments range from biosecurity's dictum of self-protection, most prominently advocated by the biosecurity approach, to the human rights logic of a 'common humanity', which is fundamental to the human security approach (Lakoff, 2010: 67).

b. Security Provider: A basic distinction can be derived from IR's Security Studies, which differentiates State-centred approaches from concepts that incorporate non-state actors. This dichotomy can also be applied to the health security concepts dealing with infectious diseases. The difference is most visible in the cases of biosecurity on the one hand, where the military as well as the State's regulation and control of laboratories perform the role of security providers, and global health security on the other hand, where foundations like the Bill and Melinda Gates Foundation and humanitarian NGOs such as the Red Cross finance and carry out activities to respond to infectious diseases.

c. Naturally, the definition of the security provider is linked to the instruments and policies which are considered most appropriate to respond to the threat of infectious diseases. To illustrate, whereas the human security concept stresses development policy and humanitarian aid, the global health security approach puts emphasis on global legal initiatives and public-private partnerships. In turn, the biosecurity approach sees foreign and security policy and classic public health interventions at the heart of infectious disease control.

d. Security measures: Following the definition of infectious disease control provided in the introductory chapter, measures principally fall into the interconnected realms of prevention, preparedness, surveillance and/or response. These measures play a role in all infectious disease-related security concepts, albeit with different geographical foci. In the framework of biosecurity, for example, interventions are tied to an inside-outside dichotomy with an emphasis on internal border control and widest possible surveillance, which also extends to traditional security tools such as intelligence, espionage and international observation (Der Derian, 1992). In this context health information gathered through surveillance is seen as data which is relevant to national security (Elbe, 2008, 2010a, Salter, 2010: 192). Given its roots in the national security paradigm, biosecurity and pandemic security concepts imply "more invasive prescriptions such as shutting down airports, detaining the carriers of certain viruses and even waiving some international legislation in the name of the national interest" (O'Manique and Fourie, 2012: 243). Wide security approaches such as the human security concept also consider preparedness and surveillance important measures but stress, in view of the needs of the most affected people in developing countries, preventive and responsive measures to contain a disease or to grant humanitarian relief. The fundamental difference to narrow health security concepts is that interventions should be carried out regardless of the global location of the people, rendering any inside-outside dichotomy invalid.

The following overview provided in Table 2-1 (see below) shows how these security parameters, derived from the dominant strands of the security debate, can be brought together to constitute a framework for the analysis of the 'kind of securitisation'. A short example and a respective question help illustrate which values a parameter can take. On order to ensure compatibility with the proposed category of a 'degree of securitisation' and to be able to differentiate between securitisation kinds in language on the one hand, and action on the other, it is useful to classify the security parameters along the distinction between the verbal and the operational dimension of securitisation. This classification is straightforward for the referent object, the definition of the threat (source, speed, geography, severity and predictability) and the ethical stance as elements of the verbal dimension. In turn, parameters related to an intervention in response to the threat of an infectious disease are classified as 'operational'. Identifying a security provider is less obvious, given that deviations and tensions between utterances and actions are possible. More precisely, the verbal definition of a provider does not necessarily have to match with the actor who actually provides security. Therefore, the security provider is a parameter that deserves consideration in both the verbal as well as the operational dimension of the kind of securitisation. The same is true for the primarily concerned policy field to respond to the disease.

Table 2-1: Parameters to Distinguish Infectious Disease-Related Security Concepts

Sec[24]	Dim[25]	Parameter	Parameter Value Question	Example / Explanation
Def. of Referent Object	Verbal	*Referent Object*	Who or what is considered to be threatened / secure(d)?	Human, State, IGO, concept
		Min. No. of Referent Object	From which minimum number of referent objects upwards is a disease considered a security issue?	1, >1
Definition of Threat		*Source of Threat*	What is considered to be the source of the disease?	Natural, manmade
		Source of Pathogenicity	What is considered to be the root cause of the infectious disease to constitute a threat?	Globalisation, pharmaceutical research, lack of development, terrorism
		Speed of Threat	What is considered to be the infection path, how quick is the disease considered to spread?	Air-borne, food-borne, zoonosis, contagious human-to-human
			Of what temporal nature is the impact considered to be?	Outbreak event, attrition process
		Geography of Threat	What is considered to be the proximity of the infectious disease?	Close/internal, far/external
			At which level is the infectious disease considered to exert impact?	Individual, local, national, regional, global
		Severity of Impact	What is considered to be the prevalence of the disease?	Morbidity
			What is considered to be the number of deaths related to the infectious disease?	Mortality / death rate
			What treatment is considered to exists?	Vaccinable, (non-)curable disease, access to treatment
		Predictability of Threat	How well are the infectious disease and its characteristics considered to be known?	Emerging disease, new strands of existing disease, old or eradicated disease
Definition of the Provision of Security		*Ethical Stance*	What is the ethical position and justification for (non-)action of the security provider?	Self-protection, common humanity
	Verbal & Operational	*Security Provider*	Who or what (is considered to) provide(s) security, i.e. provide necessary goods and/or secures the referent object from the disease?	State, IO, NGO, individual, company, philanthropic foundation, public private partnership
		Primary Policy	Which policy field is (considered to be) primarily concerned?	Development, environment, public health, research, trade, veterinary policy, etc.
	Operational	*Target of Measure*	What is the major aim of the intervention?	Disease prevention, preparedness, surveillance, response
		Geography of Measure	Where does the intervention take place?	Own-territory, source of threat, inside-outside

Source: Own presentation inspired by Buzan et al. (1998), Lakoff (2010) and Balzacq (2011b).

[24] Classification along the key components of the securitisation framework which are open to interpretation due to diverging security understandings.

[25] Dimension of Securitisation, see also Figure 2-3.

2.3.2.3. Soft and Hard Kinds of Securitisation

It becomes clear that on an abstract level a high number of values and combinations of securitisation parameters exist which make it difficult to identify specific clear-cut kinds of securitisation. At the same time, an analytic framework suitable for explorative studies needs to be designed in a wide and open way to unbiasedly examine the so far unknown security understanding(s) and securitisation processes related to infectious diseases in the European Union. The strong tension between the demand for an open and at the same time manageable framework can be eased by introducing distinct kinds of securitisation prior to the analysis which define the end points of the spectrum of security kinds. These end points will be referred to as a 'soft' kind of securitisation on the one hand, and a 'hard' kind of securitisation on the other.

In other words, rather than taking up each of the dominant readings of the infectious disease-security nexus (biosecurity, pandemic security, human security and global health security) which are also neither exhaustive nor consistently defined and applied across scholars, the present study works with a set of two 'ideal types' or 'most distant cases'. Although these 'soft' and 'hard' kinds of securitisation cannot exhaust the complex security landscape of infectious disease control, their juxtaposition can still set up a field of contrasting security understandings that is valuable for the identification and specification of the securitisation of infectious diseases in the European Union.[26]

The 'soft' kind of infectious disease securitisation works with a wide concept of security derived from the human security and the global health security views. Following a comprehensive inclusive approach the referent object of security is the human being, principally also from a very small number of threatened or infected people upwards. The threat is a disease that typically stems from a natural source, spreads slowly, is known and predictable and occurs primarily in the developing world, where it exerts its impact over long periods rather than during unexpected outbreak events. On the basis of a feeling of 'common humanity' non-state actors are expected to join the forces to respond to the disease with measures that aim at the surveillance, prevention, preparedness and the response to diseases wherever they occur worldwide, employing the policy tools primarily of the fields of humanitarian aid, development and human rights policy.

The 'hard' kind of securitisation works with a traditional understanding of what is considered a security threat in the context of infectious disease control. It builds on the biosecurity and pandemic security concept which share a number of essential features. In particular, both concepts have in common the idea that infectious diseases originate primarily from the developing or non-Western world and threaten the industrialised states and societies which have to seek for self-protection. The hard kind of securitisation restricts the definition of a referent object to the State, State-related institutions and vital functions of the State, in particular to elements which are traditionally seen as security matters – such as the military, and, in a next step, core elements of the State like a functioning economy.

[26] For a similar approach to global health regimes see Lakoff (2010).

From this perspective security is at stake if the severity of a disease is great in terms of a high mortality rate and a high speed of spread, in particular from human-to-human and if the disease is man-made. At the same time the classification of a disease as a security threat is contingent upon the fact that the own territory and citizens are affected by the disease, or that the impact of the disease is at least close. In this context outbreak events and the involvement of unknown pathogens mean greater insecurity than attrition processes related to known (and more predictable) diseases. Measures and practices related to this kind of securitisation are adopted and carried out by States or intergovernmental organisations rather than non-governmental organisation in the fields of foreign and security policy, the economy and, in a wider sense also public health, following from set of invasive public health instruments. The major motivation of the interventions is self-protection; that is why preventive and responsive interventions take place in the own territory only and surveillance is done with a focus on own territory and the closer neighbourhood.

Clearly, we cannot expect to identify either of these kinds of securitisation in pure form in the speech acts and measures that contribute to the securitisation of infectious diseases. Quite the contrary, it is more reasonable to expect that the analysis of related processes for any actor reveals a mix of the hard and the soft securitisation parameter values to eventually make up a new distinct kind of securitisation. In this context it is important to bear in mind that the kind of securitisation can change over time and that the two antipodal kinds of securitisation are not mutually exclusive. In fact, it is principally possible to observe conflicting values for each parameter, even for speech acts and measures by one actor and possibly even at the same time in one speech act or securitising practice. It remains the task of the analyst to distinguish between the different views and to identify the dominant strands.

In this sense, the following Table 2-2 condenses the securitisation parameters to the two extremes of a ‘soft’ and a ‘hard’ kind. The two extremes constitute useful points of reference when it comes to analysing with which underlying security concepts a given disease has been securitised. In this context two particularities should be noted. First, as indicated in the introductory chapter, the focus of this study is put on securitisation processes at the EU level. This focus implies that the parameters that refer to ‘national’ or the ‘State’, for instance the definition of the referent object, should not be understood as limited to the national (Member State) level but as referring to the EU as a multi-level system as a whole, including the national and the European level.[27]

Second, the possible values for the security parameter ‘target of measure’ – which refers to core elements of infectious disease control: prevention, preparedness, surveillance and response – are interconnected and cannot be clearly assigned to either a ‘soft’ or a ‘hard’ kind of securitisation. Therefore, the differentiation along the soft and the hard extreme is done on the basis of the inside-outside dichotomy which relates to the interpretation with which focus these measures should be taken, either globally where the disease occurs (soft kind), or primarily nationally or regionally in the case of the EU (hard kind).

[27] More information on the conceptualisation of the EU for the purpose of this study is provided in chapter 2.3.4. Furthermore, chapter 2.5.3 explains in more details the levels and units of analysis.

Table 2-2: Soft and Hard Kinds of Securitisation

Dimension	Securitisation Parameter		Soft Kind	Hard Kind[28]
Verbal	*Referent object*		Human	State/EU / vital to State/EU
	Min. No. of Referent Object		Few	Many
	Source of Threat		Natural	Manmade
	Source of Pathogenicity		Lack of Development, Lack of Access to Health Care	Terrorism, Enemy State, Globalisation Effects
	Speed of Threat		Slow	Fast
	Geography of Threat		Far / "Not Us"	Close / "Us"
	Minimum Threat Severity		Low	High
	Predictability of Threat		High	Low
	Ethical Stance		Common Humanity	Self-Protection
Verbal & Operational	*Security Provider*		State + Non-State (INGOs, Foundations, Public Private Partnerships etc.)	States (+IGOs)
	Primary Policy		Humanitarian Aid, Development, Human Rights	Foreign & Security, Economy, Public Health
Operational	*Target and Geography of Measure*	*Surveillance*	Global	National (+Regional)
		Prevention	Global	National (+Regional)
		Preparedness	Global	National (+Regional)
		Response	Global	National (+Regional)

Source: Own presentation.

[28] When applied in the context of the EU the values referring to 'State' or 'national' can take the form of 'EU' or 'regional'. A conceptualisation of the EU in this sense is provided in chapters 2.3.4. See also chapter 2.5.3.

2.3.3. The Coordination System of Securitisation

The degree of securitisation and the kind of securitisation are tools that help locate the status of securitisation of an infectious disease. In combination, the two innovations can be seen to make up a 'coordination system of securitisation' that covers the spectrum between low and high degrees of securitisation on the vertical axis, and the spectrum between soft and hard kinds of securitisation on the horizontal axis. The coordination system covers all possible combinations of degree and kind of securitisation, but in order to work with manageable categories, it is helpful to assign labels to the system's main areas.

In the following, the distinct labels of 'weak securitisation', 'moderate securitisation' and 'strong securitisation' help differentiate between the fields in which a securitisation status can be localised. According to this differentiation a disease has achieved the status of a 'weak' securitisation once it has been securitised to a low degree in a soft kind. In turn, a disease qualifies as a 'strongly' securitised issue, if its securitisation is characterised by the combination of a high degree of securitisation of a hard kind. Any other combination – high degree of a soft kind, or low degree of a hard kind – are regarded as 'average' securitisation. A further differentiation between the latter two combinations would be possible in order to establish a fully-fledged four-field matrix. Such a matrix, however, would imply that all four fields of the matrix were comprehensively conceptualised, an endeavour which is beyond the scope of the present study. In contrast, as it will become clear in chapter 2.4, the present study is primarily interested in one specific form of securitisation as locatable on the coordination system, namely the status of 'strong' securitisation.

Figure 2-5: The Coordination System of Securitisation (structured version)

		Kind of Securitisation	
		Soft	Hard
Degree of Securitisation	High	**Average** Securitisation	**Strong** Securitisation
	Low	**Weak** Securitisation	**Average** Securitisation

Source: Own presentation.

2.3.4. Institutionalisation as an Effect of Securitisation

The necessity to be able to clearly differentiate between different forms of securitisations, understood as the degree to which and the kind in which a disease is constructed by relevant EU actors as a security threat, is grounded in the research interest of the study. Clearly, linking institutionalisation as a potential effect of securitisation is not possible without a tool that allows pinpointing a given securitisation status. After having established a coordination system that helps define the securitisation status, the question remains what the potential effects of (specific forms of) securitisation are.

The research interest in the effects of securitisation is not new and the question of the unclear explanatory status of the original approach has been subject to critical reflection (Guzzini, 2011). Certain effects of securitisation were already mentioned in the Copenhagen School's original securitisation approach, where Buzan et al. referred to the impact of securitisation on actor constellations, especially in a conflictual situation between two countries (Buzan et al., 1998: 26). The securitisation framework was also embedded in the overarching endeavour of the Copenhagen School to identify and examine the wider formation and development of a European 'security complex', understood as cross-sectoral security connections and "pattern of mutual references" among units (for instance countries), whose securitisation and/or de-securitisation processes were closely interrelated (Buzan et al., 1998, here: 169, Buzan and Waever, 2003). Also in the field of the securitisation of health and diseases some scholars have explicitly addressed the effects of securitisation when examining governance structures and the WHO's changing mandate as emergent from the securitisation of infectious diseases (Davies, 2008, Leboeuf and Broughton, 2008: 19).

However, despite the reflection on causality in securitisation studies, references to actor constellations, the EU or governance structures neither the original securitisation approach nor the following literature provided an elaborate model that fit the research focus of this study on institutionalisation processes. The Copenhagen School dealt with the European integration project but was primarily interested in exploring and understanding the combination of "concerns of major actors into a constellation, a knot of mutual security relations" (Buzan et al., 1998: 43), rather than testing specific causal effects of securitisation on the systemic evolution of the EU. In turn, the health and infectious disease-related securitisation literature did not embed their analysis into an institutionalisation or the EU context. Hence, the focus of the present study is fairly different from both the existing literature and the security complex approach; the effects of securitisation as conceptualised in this study are in fact little explored.

Against this background the following sections serve the purpose to offer a fresh conceptualisation of institutionalisation as a potential effect of securitisation in the area of infectious disease control at the EU level. It should be noted, however, that the proposed linkage is limited to the field of infectious disease control and should not be regarded as a fully-fledged theory on the dynamics of regional integration. Having said that two definitional and conceptual questions deserve clarification:

1) What is institutionalisation at the EU level?
2) Why in basic conceptual terms should securitisation affect institutionalisation at the EU level?

2.3.4.1. Institutionalisation at the European Union Level

For the purpose of this study, fundamental mid- or long-term changes regarding the EU's structural setup in the field of infectious disease control are seen as potential effects of securitisation. The research focus on systemic key developments is compatible with the definition of institutionalisation put forward by Wayne Sandholtz and Alex Stone Sweet (Sandholtz and Stone Sweet, 1998, Stone Sweet et al., 2001), which serves as a point of orientation in the following. With a particular interest in the evolution of the European political space, understood as "supranational policy arenas or sites of governance, structured by EU rules, procedures, and the activities of the EU's organi[s]ations" (Stone Sweet et al., 2001: 1, 3), they understand institutionalisation as "the further expansion of cross-border exchange, transnational policy networks, and the EC's [European Community's] authority to govern" (Sandholtz and Stone Sweet, 1998: 16-20, Stone Sweet et al., 2001: 4).

Following this understanding an institutionalisation in the field of infectious disease at the EU level goes along with changes regarding EU rules, procedures as well as policy activities of EU organisations that contribute to an overall consolidation of the EU's capacity to govern (Stone Sweet et al., 2001: 21). This process can be seen as generally characterised by an increase in formality, a shift of resources and competences to the European level, also expressed in the creation or modification of institutional actors. In fact, "[s]paces rarely emerge and institutionali[s]e without a concomitant development of organi[s]ations" (Stone Sweet et al., 2001: 19).

Viewing changes in the EU's infectious disease control setup in terms of rules, procedures, policy activities, resource allocation, distribution of competences and organisational structures as effects of securitisation deserves conceptual clarification, if these changes are to be related to the process of securitisation. In fact, securitisation and institutionalisation work with constituents that appear to overlap, making it tricky to establish clear causal connections. More precisely, if securitisation is made up by speech acts, audience consent and emergency measures by the actors involved, and if at the same time changed rules, procedures etc., which are also possibly subject to speech acts and emergency measures, can be considered an effect of the former set of actions, we run the risk of ending up in circular reasoning. Put differently, given that securitisation constantly goes along with the production of activities that could fall into the realm close to what has been defined as 'institutionalisation', how can we practically differentiate between an ongoing (de-)securitisation process and institutionalisation as the effect of securitisation?

Although both processes in fact must be seen as dynamic and interdependent processes, for analytic purposes of this study, the puzzle can be solved by demarcating the effects of securitisation (institutionalisation, rules, procedures etc.) from the constituent elements of the securitisation process (speech acts, emergency measures) on the basis of the clear-cut criterions of durability on the one hand, and scope on the other. More precisely, whereas securitisation comprises emergency measures which are per definition of temporary nature and typically adjusted or renewed on a frequent basis, a change in the European space of infectious disease control is regarded a case of institutionalisation only, if it is implemented with the intention to be not easily reversible and if it alters the existing setup in a permanent way.

Also, emergency measures typically neither address overarching questions nor are they capable of modifying deep-going institutional structures; in contrast, they are rather narrowly targeted towards a specific threat. To illustrate, whereas the *ad hoc* and temporary detachment of an expert team into a region affected by a disease outbreak can be seen as an emergency measure, the permanent setup a pool of medical or technical experts and the establishment of a fund to finance respective field trips qualify as institutionalisation.

In this understanding the research interest in institutionalisation as potential effects of securitisation refers to *relatively persistent and systemic changes regarding rules, procedures, policy priorities, resource allocation, division of competences and organisational structures in the field of EU infectious disease control*, in the following also referred to as *structural changes* or *systemic changes*.

In turn, the influence of a securitising emergency measure on the further securitisation or de-securitisation process should, for the purpose of this study, not be viewed as an *effect* of securitisation rather than as an integral part of a constant re-production process that is inherent to a (de-)securitisation 'loop'. Securitisation is not a closed process that typically comes to an abrupt halt; it progresses over time and is influenced by previous securitisation moves and emergency measures as well as new input or developments that had been previously external to the securitisation process. This is also true for periods after a systemic adaptation has taken place. Naturally, after their creation also structural changes feed into the following process. They become part of a changed game how (de-)securitisation progresses in the future and can contribute to either the perpetuation of securitisation or the de-securitisation of a disease (as probably intended when the systemic changes were adopted). Newly established institutions or new competences transferred to the EU are cases in point. However, as a major difference to emergency measures, they are not expected to dissolve or become repatriated in the course of the de-securitisation of a disease.[29]

2.3.4.2. The Logic of (In)Security in the European Union

In basic conceptual terms, why should securitisation of infectious diseases affect institutionalisation of infectious disease control in the European Union? It is beyond the scope of this study to comprehensively revisit the concept of the State and the EU as a state-like system, but two aspects deserve clarification: The logic behind politics and (in)security that drives decision-making on the one hand, and the adaptation of this basic logic to the multi-level system of the EU on the other.

As regards the former, the study builds on the security logic of the original securitisation approach that sees securitisation as a specific, if not the ultimate form of prioritisation. Securitisation "introduces a generic structure of meaning which organises dispositions, social relations, and politics according to a rationality of security" which is comparable to the logic of war by defining existential

[29] On the institutionalist argument and the stickiness of institutions in general see in particular Pierson (1996).

challenges which endanger the survival of the referent object (Huysmans, 2006: 25).[30] Due to their existential nature, threats to security are typically sought to be avoided or, if they could not be avoided, require top priority when it comes to their management; not only for the actors that seek to provide security, but also for the audience of the securitiser's speech acts. This setup implies that decision-makers perceive exceptionally high political pressure in the face of security threats so that adequately addressing them both quickly and effectively has highest priority.

In a democratic system security challenges naturally go along with consequences for policy-makers. First, actors who are considered to be responsible to provide security and who fail in doing so must expect severe political consequences. Second, actions outside the realm of normal politics, as it occurs during security crises in form of emergency measures, usually do not meet the democratic criterions in terms of representation, legitimation, standard processes etc. Hence, whereas in the light of a specific perceived security threat action on an exceptional basis is considered acceptable, such a state of emergency is democratically not accepted as a permanent condition. In this sense the necessity to deal with a security problem means a failure of politics to deal with the issue as a political problem (Buzan et al., 1998: 29). Against this background it can be assumed, although (de-)securitisation has a tactical potential that may be employed for political objectives, that in a democratic system the desired long-term status of any problem in principle is the status of an un-securitised affair. Decision-makers can be thus expected to principally seek for solutions that are within the realm of normal politics, that solve problems before they turn into security problems or that are capable of effectively de-securitising a given matter. Consequently, failing to find adequate solutions, in turn, fuels the political pressures that accompany securitisation in view of the need for more substantial reform, to ensure that similar situations do not occur in the future again.

How does this basic security logic relate to the European Union? For the purpose of this study with a focus on the developments after 1993, the EU is defined as a fused multi-level political system (Wessels, 2000) whose actors – on all political levels from the local to the European – strive for security within their realms and mandates. Due to the interconnectedness of the different political spheres, the EU system provides channels for both (de-)securitisation and problem-solving processes across all levels. Problems and security issues can occur as limited up to a given political level, for instance the national, or as a problems or security issues for the EU as a whole. Institutionalisation at the EU level, however, is not a normal element of these processes; systemic changes, be it in view of a radical re-orientation of EU policy priorities or a re-distribution of competencies from the national level, are not integral parts of the usual business. In fact, due to the involved re-allocation of power and resources as well as potentially unknown or unequal distribution of costs and benefits, institutionalisation must be seen as conflictual. Political actors therefore typically do not envisage structural change. In particular, national governments are eager to protect their sovereignty and therefore do not see new solutions at the EU level as a preferred option, even less in the realm of typical domains of the nation state such as health affairs.

[30] Since such a rationality of security is rather stable and evolves slowly "like the grammar of a language" (Huysmans, 2006: 25), it cannot be manipulated or changed easily and thus ensures that securitisation can take place under comparatively stable conditions also over longer periods.

The core argument is that a security situation, that is the perception of insecurity, can modify this situation. Under the impression that accepted speech acts and emergency measures have moved infectious diseases into the realm of security and that the problem cannot be dealt with as a matter of normal politics anymore, the calculus of Member States and other relevant EU actors changes. These actors might have detected before that cross-border nature of infectious diseases, facilitated within an increasingly borderless Europe, undermine the capacity of states to control infectious diseases at the national level (Fidler, 1998: 6, Dodgson et al., 2002: 18, Liverani and Coker, 2012: 915f). The argument, however, is that only in the course of the securitisation process do ideas that involve institutionalisation aspects eventually receive priority in political thinking. In this sense securitisation can explain the formation of coalitions of actors that seek to jointly (re-)design the setup in a way that is deemed suitable to respond to similar threats in the future (Stone Sweet et al., 2001: 18f).[31]

Securitisation is thus understood to be able to take the function of a game changer in favour of transnational problem-solving and new collective solutions, in the most extreme form even if they imply a loss of national sovereignty. Member States, when caught in the dilemma that their striving for security vis-à-vis infectious diseases appears to require problem-solving through collective action which contradicts their "inbuilt reflex to protect the national sovereignty of their home states" (Wessels, forthcoming), will eventually give priority to a revision of disease control structures in favour of an institutionalisation at the EU (or international) level due to the supremacy of the security situation. In this way securitisation can be understood as an enabler of the development of EU structures that are considered capable of responding to the threat within the realm of ordinary politics.

Institutionalisation in infectious disease control thus typically occurs with the objective to structurally de-securitise the issue or a specific aspect. Due to the typical duration of the adoption of structural changes, institutionalisation influences the (de-)securitisation processes only in the mid- and long-term. The major difference to a normal element of the securitisation process therefore is that a structural change constitutes an attempt to permanently de-securitise a problem, to shape a framework that is not an emergency measure to a given situation but that helps prevent the securitisation of the same or similar issues – or seems to facilitate the de-securitisation of respective threats – in the future.

In this context it should be recalled that the constructivist foundation of the study (see also chapter 2.5.1) implies that security situations do not have an unambiguous, self-evident meaning. It is therefore likely that different competing interpretations of the threat exist in parallel. Consequently, also the search for alternatives is usually characterised by competition. Securitisation therefore does not necessarily trigger transformations that address the perceived security-related dysfunctionality in a way that is judged by all involved actors to actually constitute an improvement (Stone Sweet et al., 2001: 10). This implies that securitisation does not necessarily trigger a functional form of

[31] This line of argumentation has been adapted from Stone Sweet and Sandholtz who make a similar point in view of institutional innovation following exogenous shocks (Stone Sweet et al., 2001: 18f).

institutionalisation; securitisation triggers first and foremost the need to do *something*. Furthermore, it should be noted that the conceptualisation of institutionalisation as an effect of securitisation in principle also implies a reduction of EU involvement or the transfer of competencies from the European to another political level. In line with the proposed security logic such a situation would turn likely should the EU itself become securitised and eventually be seen as a threat, for instance to the concept of territorial sovereignty, so that protection from the EU gains higher priority than those threats which the EU can help de-securitise.

2.4. Research Questions and Hypothesis

The previous sections have served the purpose to outline a revised model of the securitisation framework. On the basis of this detailed explanation of each of the core elements a clearer view on the research context, the exact research question and the proposed research hypothesis is possible. To recall, the objective set out for the present study is to contribute to the understanding of the EU's evolution of policy and polity of infectious disease control, primarily as a sub-field of public health and food safety, and to explain structural changes in its development. The key developments of the EU's infectious disease control and related institutionalisation processes in the sense of relatively persistent changes as regards rules, procedures, policy priorities, resource allocation, division of competences and organisational structures, thus, provides the overall research context for the study. The primary research interest is put on the developments between the introduction of public health policy to European Union law in the Treaty of Maastricht in 1993 and the year 2014.

The investigation into the causes for the evolution is carried out from a constructivist securitisation perspective. In this sense the research interest of the study goes beyond the evolution of infectious disease control and extends to the securitisation of infectious diseases at the EU level, most fundamentally with regard to the *forms* and *effects* of securitisation. As regards the former, the previous sections have developed innovative tools to determine core parameters of a disease's securitisation status as locatable on the coordination system of securitisation. More precisely, the novel securitisation approach directs the analytic interest in the *forms* of securitisation to the analysis of degree and kind of securitisation across verbal and operational dimension, to the differentiation of phases and timings of securitisation as well as to the actors of securitisation.

As regards the *effects* of securitisation, the previous sections have conceptualised institutionalisation as a potential result of securitisation. By doing so the study has established an analytical and explanatory framework to examine infectious disease-related crises, so called 'good epidemics', that have the potential to 'break' the institutional and political stability in public health (Fidler, 2004b: 169f, Greer and Mätzke, 2012: 902). Viewing EU institutionalisation and securitisation as interconnected processes, however, does not tell us in which way the two phenomena are contingent upon one another.

The fundamental research question put forward in this study therefore asks:

> *Under what conditions can the securitisation of (specific) infectious diseases explain the institutionalisation of infectious disease control[32] at the EU level?*

The research question will be approached from a basic hypothesis on the conditions in question. Seeing that institutionalisation occurs rarely, that only specific outbreak were linked to structural change, that numerous diseases have been securitised and that the richness of security understandings allows for various forms of securitisation, it seems that the securitisation of infectious diseases as such *cannot* explain institutionalisation. In contrast, the hypothesis of the study is that systemic changes can result from the securitisation of infectious diseases only, if the securitisation is characterised by a specific combination of securitisation degree and kind, namely only in the combination of a *high degree* and a *hard kind*. Put crisply, the hypothesis runs as follows:

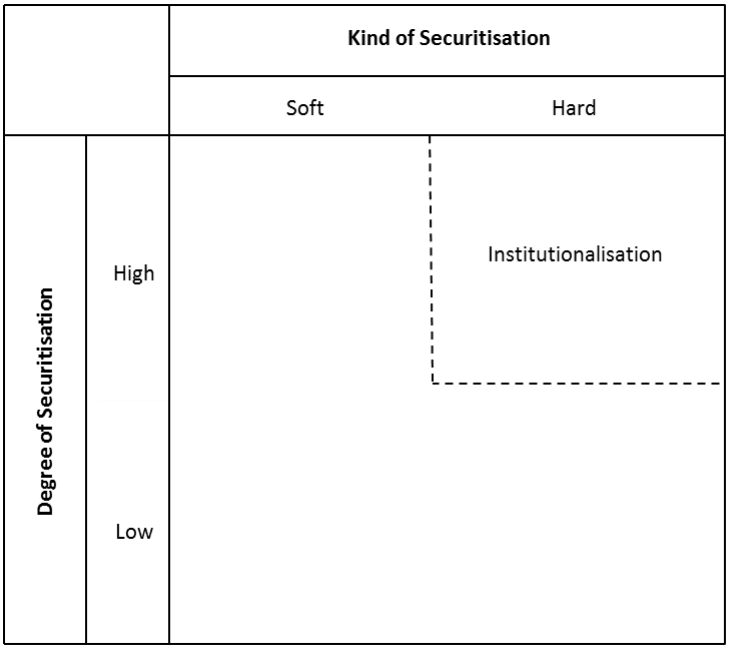
> *'Strong' securitisation[33] of infectious diseases by EU actors (independent variable) causes the institutionalisation[34] of infectious disease control at the EU level (dependent variable).*

The hypothesis builds on the basic security logic as set out in chapter 2.3.4.2, but furthermore specifies the general causal linkage between securitisation and institutionalisation in the sense that weak or average forms of securitisation do not bear the potential to trigger systemic change. The argument is that neither a high degree of securitisation nor a hard kind of securitisation alone can make up for a security situation that ultimately results in structural changes, but that political pressure and will for fundamental reform is only high enough once a combination of high degree and hard kind characterise the securitisation status of a disease. To illustrate, a given disease might be talked up as a security threat and peak the political agendas, but as long as the disease is not seen to affect the EU, its Member States and vital elements of the State, as long as it is regarded far, predictable, an attrition process etc., systemic changes are highly unlikely. The same is true for a disease that is securitised in a hard way as a contagious, fast spreading, unpredictable etc. threat, but to such a low degree that the disease is hardly recognised as a security threat at all. In such a context it does not matter for a potential institutionalisation process if a lethal disease spreads or is feared by some people within the EU territory; the disease turns into a veritable strong security problem only if at the EU level many people speak about it, embed it strongly into a security discourse (verbal dimension) and perceive the need to take many and/or hard responsive emergency measures (operational dimension) – only then the political agreement is established that similar security situations must be avoided and that structural reforms are needed to return, treat and keep infectious diseases within the realm of ordinary politics.

[32] In the sense of disease prevention, preparedness, surveillance and response as defined in chapter 1.1.
[33] In the sense of a high degree of a hard kind of securitisation as defined in chapters 2.3.1 and 2.3.2. See also chapter 2.3.3.
[34] Defined as relatively persistent and systemic changes regarding rules, procedures, policy priorities, resource allocation, division of competences and organisational structures in the field of EU infectious disease control, in the following also referred to as structural changes or systemic changes (see chapter 2.3.4.).

Taking up the coordination system of securitisation (see chapter 2.3.3 and in particular Figure 2-5), the hypothesis can be illustrated as provided in Figure 2-6 (see below). The schematic illustration locates the 'institutionalisation box' in the upper right corner of the coordination system of securitisation. The figure should, however, neither be viewed too narrowly in the sense of a binary yes-or-no distinction, nor as a comprehensive four field matrix. In contrast, the box rather indicates by approximation the location of the forms of securitisation that are hypothesised to bear the power to enable institutional change.

Figure 2-6: Hypothesising on Institutionalisation as an Effect of Securitisation (schematic)



Source: Own presentation.

Why has this combination of a hard kind and a high degree of securitisation be chosen as a point of reference for the empirical research as carried out in the next chapters? The arguments that speak in favour of a high degree might be obvious. Clearly, if a disease is only on an occasional or cursory basis subject to securitising moves, the disease is not related to the realm of security in the first place. But why is a hard securitisation required in addition to lively and predominantly security-related discourse and emergency measures? First, the literature review indicates that throughout history institution building in the field of infectious disease control occurred primarily in the context of such disease outbreaks that provided a strong fundament for high and hard securitisation. The creation of the Office International d'Hygiène Publique (OIHP) in the course of the cholera epidemic is a case in point (Lee, 1998: 1, Hough, 2004: 162).[35]

[35] This development is addressed in chapter 3.1.

Second, previous studies revealed for individual security parameters – which add up for a kind of securitisation – that 'hard' parameter values can be considered more influential than 'soft' ones when it comes to decision-making. To illustrate, it was found that the conceptualisation of a disease and its characteristics, such as transmissibility and predictability, impact how threatening a disease appears (Baldwin, 2005b: 28, 2005a: 353, Cook, 2010: 19, Fox, 2012: 1127, Mätzke, 2012: 969)[36] and that diseases, which are accompanied by a high degree of perceived unknown risks, are more likely to call for "stricter government regulation and legislative controls" than other health issues (WHO, 2002a: 32).

Third, opinion polls showed that news coverage, which can be seen as likely to fuel securitisation and thus political pressure, was particularly high for diseases that occur with 'outbreak events' (Ho et al., 2007) and thus for diseases which bear a higher potential for hard securitisation. Fourth, a hard form of securitisation implies that security is expected to be provided by the State and intergovernmental organisations rather than privately or by non-governmental organisations. Consequently, in the context of the EU multi-level system, political decision-makers on national and possibly the EU level are held responsible for situations of insecurity so that their willingness to adopt reforms can be considered to be higher.

Beyond that it should be recalled that institutionalisation belongs to the realm of political decisions which are characterised by conflict and for which the needed majority, often unanimity in the EU, is most difficult to achieve. Therefore, an actor constellation in favour of systemic change would form only as a last resort when the pressure to act reaches the highest level, that is under the impression of high and hard securitisation. Finally, due to the novel elements of the securitisation approach as applied in this study, there is also no clear pre-defined point of reference for the assumed impact of a given combination of degree and kind of securitisation. Consequently, respective predictions and attempts of generalisation need to be cautious. Given that the hypothesis reflects in part the debate between narrow and wide concepts of security, it seems appropriate to start from a conservative assumption that limits the influence on institutionalisation to a traditional security understanding.

It thus becomes clear that strong securitisation as a pre-condition for system change has been, albeit constituting a demanding criterion, established for good reasons. It should, however, be noted that the study does not consider strong securitisation as the one and only force that drives the evolution of the EU's setup in infectious disease control. Clearly, the cross-border nature of the problem and, linked to that, functional pressures exerted from both the EU common market and globalisation processes carry substantial explanatory value when it comes to identifying the sources for EU cooperation and integration moves (Greer, 2006, 2012b). The main hypothesis, however, is that a strong securitisation constitutes one of the few striking phenomena that possess an independent capacity to open 'policy windows' (Kingdon, 1983), 'windows of opportunities' in which structural change becomes possible.

[36] In this context HIV/AIDS occupies a strong position. More on HIV/AIDS as a security issue can be found in Peterson (2002), Price-Smith (2002), Singer(2002), Heymann (2003), McInnes (2006), Whiteside et al. (2006), Coupland (2007) and Ostergard (2007).

To sum up, the study combines an explorative interest in (1) the EU's infectious disease policy and polity evolution and (2) in the forms in which, and the actors by whom (specific) infectious diseases have been constructed as security issues at the EU level with (3) the application and testing of a novel analytic and explanatory adaptation of the securitisation approach. Designed in this way the research approach does not only aim at contributing to the understanding of institutionalisation processes on EU level and at advancing the original securitisation approach, it also responds to one of the major criticisms on the constructivist analysis of international affairs in general, namely that constructivism misses to make distinctive predictions about the conditions under which certain phenomena occur (Moravcsik, 2001: 227).

By focusing on the form of securitisation as a major explanatory factor the study embeds genuinely constructivist variables into a causal explanatory model. By this means it is possible to derive and test clear postulations regarding the phenomenon of structural changes on European Union level. At the same time, by tying together the many strands of security research the study's approach can also be considered as an innovative response to the claim "that the main task facing students of securitisation is not to add to the already long list of arguments and conjectures but instead to unpack and re-present these diverse approaches into a coherent set of assumptions guiding empirical research" (Balzacq, 2011a: xiv). Despite the shifted focus on securitisation effects rather than causes of securitisation the work remains still compatible with the classic securitisation literature interested in the questions when and how something is established by whom as a security threat and "who securitises, on what issues (threats), for whom (referent objects), why, with what results, and, not least, under what conditions" (Buzan et al., 1998: 32).

2.5. Research Design, Operationalisation and Methodological Considerations

The previous chapters served the purpose to clarify the exploratory and explanatory aims of the study, to outline the conceptual approach and to formulate both the main research question and the working hypothesis. It was also part of the study to carry out a thorough literature review to position the work and to show where it makes innovative contributions to the fields of EU integration research and securitisation studies.

As set out in the introduction, the empirical study follows a two-step approach which foresees the consecutive analysis of key developments of infectious disease control in the EU and the detailed analysis of selected structural changes in the framework of a securitisation study. Before turning to this empirical analysis, it is central to explicitly reveal the steps and methods envisaged to perform the research (Manheim et al., 2008: 6, 386). In order to do so the present chapter 2.5 starts with a reflection about the implications of the theoretical basis (chapter 2.5.1) and makes explicit how the study's conceptual foundation regarding the securitisation analysis can be conversed to the operational level (chapter 2.5.2). With a view to the fact that qualitative content analysis constitutes the most important research technique employed in the empirical analysis, the following part of this chapter serve the purpose to define the levels and units of analysis (chapter 2.5.3).

Chapter 2.5.4 sets out the consecutive phases of research and makes clear that the selection of case studies can be better contextualised after an initial empirical research phase has been completed. Therefore, the chapter provides only a brief introduction into the case studies.[37] In the following, the procedure to collect the data set will be discussed in chapter 2.5.5, just as the methods of qualitative content analysis and expert interviewing in view of their application in the context of institutionalisation and securitisation studies in chapters 2.5.6 and 2.5.7.

2.5.1. The Constructivist Foundation

A research design can be understood as the "logical model of proof" that "guides the process of collecting, analysing and interpreting data" and that "allows the making of valid causal inferences" (Nachmias, 1979: 21). When engaging in its development, it makes sense to reflect, in a first step, on the function and implications of the theoretical foundations of the study. The decision to analyse policy and polity developments at the EU level from a securitisation perspective implies to direct research and link research questions and findings in a basically constructivist manner. It does not belong to the objectives of the study to address the meta-theoretical debate on social constructivism as a philosophical foundation in IR, but it is important to make clear that the study blends elements of social constructivist ontology with realist epistemology to arrive at the proposed causation.

As set out before, the starting point of the securitisation approach is that language is constitutive of social reality, rather than a tool that simply describes an external reality. The rhetorical foundation of the securitisation approach reflects the general constructivist premise that "human practice makes the world intelligible and embeds this intelligibility in technological and social institutions and processes" (Berger and Luckmann, 1966/1991, Huysmans, 2006: 145). The assumption that "social relations are not laws of nature but the contingent product of human action and always potentially open for restructuration" does not prevent that a given construction – for instance an identity, the State or the language of security – is relatively stable so that it can be kept "as constant throughout one's analysis" (Buzan et al., 1998: 204f, Huysmans, 2006: 25). In a similar vein, it is assumed that the meaning of a text can be regarded as something relatively stable and independent from time, place and analyst so that it can principally be re-retrieved by other investigators (Hardy et al., 2004: 20).

Building on this social constructivist ontology, the study applies a modernist constructivist epistemology that incorporates scientific realist elements.[38] In contrast to positivist approaches this interpretation acknowledges that many relationships between social phenomena are not *directly* but only *indirectly* observable (Carlsnaes, 1992, Ruggie, 1998, Sayer, 2000: 12) and attempts to explain their "causal and constitutive effects […] in world politics" (Balzacq, 2012: 58, Wendt, 1999). The argument on the relation between constructions and the real world 'out there' is that "[t]here may be real processes at work, but the way they affect outcomes is mediated by the discursive construction(s) of these processes" (Marsh and Furlong, 2002: 35).

[37] More information on the selection, features and structure of the case studies can be found in chapter 4.
[38] More on such a combination can be found, for instance, in Wendt (1999).

For the study of infectious diseases this means that outbreak events and disease characteristics such as mortality and morbidity are not irrelevant data. In fact, according to the understanding applied in this study infectious diseases do harm health and can actually cause the death of entire populations, regardless of the way how we linguistically depict them. That is why disease outbreaks mark important points of reference for the study of securitisation. When it comes to defining security and insecurity, however, the perspective suggests that social and political processes related to the disease are decisive for the approaches to identify solutions and to govern a specific situation (Huysmans, 2006: 2).

To illustrate, viewing a disease as either a fateful, naturally given necessity or an avoidable result of ineffective disease surveillance makes a huge difference for both the perception of and the response to a given (security) situation. Death alone does not constitute a security problem in international affairs. Accordingly, it is not the 'real' spread, contagiousness, death rates, etc. of infectious diseases that are considered to affect the evolution of EU policies and polity, but the social and political construction of disease as a security issue.

Clearly, the securitisation of infectious diseases can facilitated by events such as the pandemic spread of a disease or specific characteristics of a disease. This is why securitisation typically occurs under the impression of crisis or dysfunctionality. Despite such appeals to the real world, however, for the political reaction it ultimately is the discursive construction of that world what is considered decisive (Marsh and Furlong, 2002: 35). In this sense "security issues *are* socially constructed, but the securiti[s]ation process is not divorced from empirical considerations" (McInnes and Rushton, 2013: 120, emphasis in original).

2.5.2. Operationalisation and Selection of Research Methods

The philosophical basis of the study is clearly reflected in the proposed causal relationship between securitisation of diseases and the structural evolution of EU policies and polity. The question that follows from this basis is how to get from the abstract level of the research question and the understanding of the causal relationship to concrete (direct or indirect) observations that allow to answer the question and to test the hypothesis.

In order to facilitate empirical analysis and testing, the abstract notions of securitisation and institutionalisation demand translation into statements with more precisely defined variables, understood as "as an empirically observable characteristic of some phenomenon that can take on more than one value" (Manheim et al., 2008: 27). Seeing that the adaptation of the securitisation framework included a comprehensive set of indicators for the degree and kind of securitisation, and given that the main research interest lies on structural changes in the EU's setup for infectious disease control, the operationalisation of the study's conceptual basis can be carried out straightforward along the novel securitisation approach:

Whereas the study works on the side of the independent variable with the indicators of the securitisation degree (see Figure 2-3: From A-Politic to Highly Securitised) and the parameters of the kind of securitisation (see Table 2-1: Parameters to Distinguish Infectious Disease-Related Security Concepts), it deals with the components of the definition of institutionalisation (see chapter 2.3.4) on the side of the dependent variable; together they constitute the relevant reference points when it comes to making observations and to identifying values for the properties of the phenomena of securitisation and EU structural change.

In order to examine the key developments of infectious disease control in the EU and the specific developments that meet the definition of institutionalisation, the study builds on a thorough review of secondary literature and a combination of qualitative content analysis and expert interviewing. In turn, for the analysis of the securitisation of infectious diseases the study works with a mix of qualitative and quantitative elements of content analysis, with a focus on the former. Hence, the securitisation analysis is carried out entirely on the basis of written texts, following the understanding that "if a security discourse is operative […], it should be expected to materiali[s]e in […] text" (Buzan et al., 1998: 177). Qualitative content analysis constitutes the primary research tool of the study. It is serves the needs deriving from the research interest, since it is an methodological approach "for making replicable and valid inferences from texts […] to the contexts of their use" (Krippendorff, 2013: 24). It provides a set of methods that allows to systematically count, assess, and interpret both form and substance of a text (Manheim et al., 2008: 180) in order to shed "light on the ways [agents] use or manipulate symbols and invest communication with meaning" (Moyser and Wagstaffe, 1987: 20).

In the present study, content analysis is employed to analyse a comprehensive set of primary sources from relevant EU actors. In this way it can contribute to the analysis of both securitisation processes at the EU level as well the evolution of EU infectious diseases policies and polity. The former also includes a mathematical handling of the securitisation assessment, the latter is complemented by elite and specialised interviewing; a research tool that aims at acquiring background information that is particularly valuable for an in-depth understanding of the research target from a practitioner's perspective. Before explaining in detail how the research methods are applied, it is helpful to clarify which levels and units are actually subject to analysis and on the basis of which selection criterions a relevant *text corpus* can be generated.

2.5.3. Level and Units of Analysis

Constructivist scholars have argued that "before we can be constructivist about anything we have to choose 'units' and 'levels'" (Wendt, 1999: 82). Also the preparation of content analysis starts with the definition of the set of documents envisaged to be analysed. In line with the focus of the study on the key developments at the EU level after the introduction of a genuine public health article into EU primary law in the Maastricht Treaty, the date of relevant documents on the one hand, and the author of respective documents on the other, are important selection criterions when it comes to compiling the set of documents (Manheim et al., 2008: 181).

As regards the former, the period of investigation from 1993 to 2014 sets the selection criterion for the *text corpus* as regards the date, with the exception of the first case study (chapter 5) which also includes BSE-related documents from the years from 1989 onwards.[39] The period thus principally covers the most dynamic years in the evolution of infectious disease control at the EU level from the entry into force of the Maastricht Treaty (1993) and the most recent developments for which reliable data is available.

The definition of the authors of documents to be included in the analysis is less straightforward, in particular in view of the securitisation analysis. In order to be able to generate a consistent and clearly demarcated *text corpus*, it is therefore helpful to provide a definition for each of the actors that appear in the securitisation analysis, namely (1) the group of securitisers who 'speak' security, (2) the group of security providers who 'do' security' and (3) the audience that accepts securitising moves and measures (Buzan et al., 1998: 27). The former two are jointly addressed in the following chapter 2.5.3.1, the latter in chapter 2.5.3.2.

2.5.3.1. The Definition of Securitisers and Security Providers at the EU Level

In the understanding of Buzan et al. (1998) the group of securitisers, those actors who issue speech acts, typically includes "political leaders, bureaucracies, governments, lobbyists, and pressure groups" (Buzan et al., 1998: 40). Due to the plethora of players active across all levels of the EU system and the global health governance system more generally, speech acts to securitise infectious diseases at the EU level can principally come from a wide range of actors.[40] Still, an analysis that fully covers the wide spectrum of securitising utterances is beyond the scope of the study so that a clear demarcation is needed.

Against this background the study applies a rigour focus on communications of official EU actors. In this sense, documents issued by EU institutions, in particular from the European Commission, the European Parliament, the Council of the European Union,[41] relevant committees and from the European Council, can be considered to most adequately incorporate the information needed to derive degrees and kinds of securitisation at the EU level.[42] Emphasis is, thus, put on the EU as the

[39] The extension of the time period allows better grasping the full BSE/TSEs-related securitisation chronology. See also chapter 2.5.4.

[40] As indicated before, a non-exhaustive list includes state actors such as national (health) ministries, non-state actors and non-governmental organisations such as the Red Cross, international organisations such as the World Bank or WHO, multinational companies, particularly from the pharmaceutical sector, and philanthropic foundations like the Bill and Melinda Gates Foundation. Further examples could be added (Bill and Melinda Gates Foundation, 2002, Reich, 2002, Schuppert, 2006, Graz and Nölke, 2008, Zacher and Keefe, 2008, Spero, 2011).

[41] In the following also referred to as 'Council'.

[42] Utterances by the European Court of Justice (ECJ) and of the European Court of Auditors (ECA) are occasionally taken up, but will not be systematically analysed over time. Although the ECJ can principally contribute to the production of EU law following its interpretation of existing texts and therefore play into institutionalisation processes (Stein, 1981, Weiler, 1991), court-made law in the field of infectious disease control "tends to follow a pattern of incremental change" (Hervey, 2012: 980) with less capacity to account for structural changes among the key developments. Also, due to the tediousness of ECJ proceedings and the

level of analysis, and the EU bodies most substantively dealing with infectious diseases control as the relevant units. In turn, securitising moves of individual EU Member States or involved non-state actors will not be analysed.

The same selection applies also to the definition of the group of security providers; rather than examining the activities of individual Member States or involved actors from other political levels, a clear focus is put on measures that were adopted, but not necessarily implemented, at the EU level.[43]

Limiting the analysis of utterances and measures in this way helps clearly define the *text corpus* and to draw a manageable sample from an otherwise extremely large population of communications. The approach is methodological reasonable if EU documents are understood as the outcome of a political decision-making process into which the interests of actors from different political levels and relevant stakeholders as well as pressures of functional or systemic nature have been fed. In this sense, debate and action at the EU level can be understood as an expression of an EU-wide multi-level negotiation process which concludes the input from various sources. Consequently, issues can occur as limited up to a specific political level, for instance the national, or as an issue for the EU as a whole. However, regardless of the fact whether the construction of the security situation initially started at a specific level, in parallel in different national arenas or straightforward as security problems for the EU as a whole; should the problem bear a significant cross-border dimension it can be expected, due to existing political channels across all EU levels, that the sooner or later the securitisation becomes manifest at the European level – and thus at the level where the investigation of the present study takes place.

It follows from this understanding that an issue can be regarded to constitute an EU-wide security problem once Member States opt to launch verbal and operational activity through the EU level, or if EU institutions do so on their own right. This focus is in line with the Copenhagen School's original idea that "definition and criteria for securiti[s]ation is constituted by the intersubjective establishment of an existential threat with a *saliency sufficient to have substantial political effects*" (Buzan et al., 1998: 25, emphasis added). In other words, as long as there is no effect and appearance of the issue at the EU level in form of EU speech acts and emergency measures, the securitising moves on national level or any other non-EU level are considered to not having had sufficient saliency to shift the issue to the EU arena, or the threat has been constructed without any European dimension.

typical time lag between the ECA's reports and the period under scrutiny, their utterances are not particularly suitable for the analysis of time-sensitive securitisation developments.

[43] It should be recalled in this context that the definition of the actors who are supposed to provide security can be addressed also in speech acts, for instance when a given actor stresses the need for action to be implemented by another actor. Following this understanding the *ex ante* definition of the group of security providers as official EU actors is limited to the operational dimension of the securitisation process.

2.5.3.2. The Definition of the Audience at the EU Level

Besides the group of securitisers, the securitisation approach also requires the identification of the audience, the unit that together with the securitiser intersubjectively defines the securitisation parameters. As explained in chapter 2.2, the concept foresees that an 'enabling audience' has to agree with the securitising move of the securitising actor in order to satisfy the conditions of a complete securitisation process. Hence, the audience has an important role in the process of the construction of (in)security, but it is not easy to define in the present case given the particularities of the EU's institutional setup and in the absence of a clearly defined EU public realm (Laffan 1996: 93).

In order to work with a definition that is consistent with the before mentioned conceptualisation of the EU as a multi-level negotiating and decision-making system, the audience is, for the purpose of this study, understood as an integral part of the political system. In this sense, the EU is considered as a political arena in which the full set of actors, including the major institutions like Commission, Council, European Council, Parliament, Court of Justice and Central Bank but also extending to the various committees, advisory bodies and forums, jointly make up for a political and discursive sphere that includes securitisers, security providers and audience. The argument is that due to the combination of intergovernmental and supranational elements and due to the cooperation of various political bodies with functions in the sense of 'checks and balances', the complex system inherently comprises (the) relevant 'enabling audience(s)', also across different political levels.

To illustrate, Members of the European Parliament do not only reach out in their communications and activities to their constituencies and to the national and European public spheres, but also to a substantial degree to national governments and other EU institutions. Similarly, utterances issued by the Council or the European Council are not only addressed to the rather inconsistently connected national arenas, but also to EU institutions such as the Commission and the Parliament. In other words, all EU actors simultaneously engage in political and discursive processes – which they seek to influence and to which they respond – and assume, while doing so, in rotating roles the function of both (de-)securitisers and audience(s) that together intersubjectively define (in)security. Given the representation of interests and influences from all levels, the discursive interplay of institutions can in this way be understood as a suitable framework for the intersubjective construction of EU-wide (in)security; the role of an 'enabling' audience is considered to be in-built into EU policy-making due to the contingency of EU decisions upon consent or majorities among different actors.

The duality of securitiser and audience becomes particularly apparent when it comes to exercising legislative functions, for instance in the co-decision procedure which integrates EU institutions into a framework which puts the involved institutions in positions that allow or even foresee the performance of all functions of a (de-)securitisation process: speech acts, adoption of emergency measures and consenting audience. Similar processes often precede also the publication of individual decisions or documents, for instance when action by the European Commission is contingent upon the authorisation of a regulatory committee. In this way the EU setup includes a necessary 'indication of acceptance' of a securitising move (see chapter 2.2.) as soon as relevant EU actors cooperate – relatively consistently – in a securitisation process.

In short, in absence of an EU public sphere or other clearly defined audience comparable to the national level, and following the specific composition of EU institutions as well as the genuine decision-making processes, the discursive and political arena of the EU as a whole is understood as being capable of enabling securitisation at the EU level. Treating the EU system in this way as an entity which pursues and accepts securitisation by condensing and reflecting EU-wide processes in the output of its institutions certainly does not reflect the full complexity of the discursive structures at work across the EU's multiple levels. This narrow view on the enabling audience, however, is sufficient for the purpose of this study, for which it is not decisive whether a given disease was securitised inside or outside the EU framework – important is the form of securitisation as expressed at the EU level.

Crucially, this conceptualisation of the audience meets the fundamental criterions that the audience has a "direct causal connection with the issue [and] the ability to enable the securitising actor to adopt measures in order to tackle the threat" (Balzacq, 2011c: 34). Beyond that, it helps direct the focus of the study clearly on one political level, the EU level, in the securitisation analysis for all units. Such an approach is particularly useful in the light of the findings of previous studies which suggest that securitisers and audiences change from level to level (McInnes and Rushton, 2013: 126). Hence, adding further levels or units to the analysis would imply the risk to overload the study and to prohibit an investigation in adequate detail.

2.5.4. Research Phases and Case Studies

For a period of more than twenty years, limiting the set of analysed utterances to those of the abovementioned official EU actors still leaves too many communications to reasonably analyse in depth within the scope of this study. The problem of an unfeasible high number of sources to analyse would be exacerbated if the large set of potentially relevant policy fields ranging from development and environment policy to humanitarian aid, research and trade policy would be included. As indicated in the introductory chapter, it is beyond the scope of this study to fully grasp the intersectoriality of infectious disease control and health policy as a whole. In contrast, the study concentrates on what can be regarded the core of EU infectious disease control in the realms of EU public health policy and food safety.

Still, given the long period under scrutiny and the large number of potentially securitised infectious diseases it is obvious that an in-depth analysis of the securitisation of infectious diseases cannot be carried out for all years of the period under scrutiny, for all developments and in particular not for all diseases. This is why the study works with a combination of two research phases, starting with an overview chapter on the institutionalisation of infectious disease control in the EU, followed by two case studies that focus on securitisation and specific structural changes that occurred in the course of disease crises. The overview chapter on the key developments of EU infectious disease control is not only needed to provide the research context for the study, it also serves the purpose to be able to identify relevant case studies.

The authors of the original securitisation approach suggested that "security analysis [must be] interested mainly in successful instances of securiti[s]ation" (Buzan et al., 1998: 39). The notion 'successful' refers in this context to instances where a speech act, accepted by the relevant audience, was accompanied by emergency measures to respond to a claimed existential threat to a valued referent object (Buzan and Waever, 2003: 491). This research focus seems still promising in the modified securitisation approach since studying the effects (or absence of effects) of securitisation can be performed only by looking at instances of successful securitisation. The challenge in this context is, however, that no study exists that could direct the focus straightforward to a comprehensive set of cases of successfully securitised diseases at the EU level. To make things worse, the study is not interested in any effect of securitisation, but has a particular interest in institutionalisation. Last but not least, the existing literature does not offer a comprehensive overview of the institutionalisation of EU infectious disease control.

Against this background, how is it possible to identify case studies that involve all relevant components, EU structural change and securitisation of infectious diseases, so that a basic testing of the hypothesis becomes possible? In order to respond to this methodologically challenging situation, the study will complementarily approach the field of investigation from two sides; first, from the side of the dependent variable to identify the key developments in the evolution of the EU's setup to control infectious diseases, and, second, from the side of the independent variable to analyse the securitisation of specific diseases that can be related to selected key developments.

Concentrating in the first research step on the dependent variable of the study is a strategy that is particularly suitable in an early stage of investigation (George and Bennett, 2005: 23). Since the study applies a rather new focus, it is thus reasonable to begin the empirical analysis with an investigation into the key developments of EU infectious disease control. On the basis of this analysis a list of milestone developments can be compiled which can be principally assumed to meet the criterions of institutionalisation and which thus potentially qualify to constitute an effect of securitisation. This first part of the analysis, however, does not put emphasis on securitisation; it rather prepares the following securitisation analysis. Given that a comparable overview of the evolution of the EU's infectious disease on the basis of an extensive review of relevant primary sources and secondary literature does not exist, this part of the study also has value as an independent piece of research.

Subsequently, from the generated list of milestone developments, two sets of prominent changes are chosen as case studies to be scrutinised in detail from a disease-related security perspective. These case studies deal with:

(1) The revision of the EU infrastructure for food-borne infectious diseases (1997), the legal basis in the field of public health as amended by the Amsterdam Treaty (1997), the adoption of harmonised EU law on 'transmissible spongiform encephalopathies' (TSEs) (2001) as well as the establishment of the 'European Food Safety Authority (EFSA)' (2002); and

(2) The update of the legal basis for the control of cross-border threats and communicable diseases by the Treaty Establishing a Constitution for Europe (2004) and the creation of the 'European Centre for Disease Prevention and Control (ECDC)' (2004).

These case studies will analyse the key development not only in more detail than the overview chapter could do; crucially, the adoption of these structural changes will be analysed in the sense of cases of institutionalisation that occurred in the context of the securitisation of infectious diseases. The first case study focuses on the securitisation of 'bovine and transmissible spongiform encephalopathies' (BSE/TSEs) between 1989 and 2001. Since the disease was subject to political activity at the EU level before 1993, the period of investigation was extended to 1989 in order to allow for the full coverage of the politicisation and securitisation process. The second case study deals with securitisation of the 'severe acute respiratory syndrome' (SARS) between 2003 and 2004.

The reasons for selecting these 'case groups' will be set out in chapter 4, after the milestone list of structural changes could be compiled. It will become clear that the focus is put on a set of systemic changes that belong to the most fundamental reforms in the evolution of the EU's setup to control infectious diseases. Both selected 'case groups' share a number of features such as the combination of a revision of the EU's primary law (EU Treaty) with the creation of a specialised EU agency. At the same time, the selected diseases differ in a number of positivist features such as infection path, geographical spread, speed of spread, or mortality. In chapter 4 it will be explained in more detail why these circumstances make them interesting test cases for a comparative analysis from a constructivist securitisation perspective.

Clearly, starting the analysis from the side of the securitisation of infectious diseases, the independent variable, would be desirable in the attempt to produce generalisable statements on the effects of (strong) securitisation, including cases in which institutionalisation has not taken place. Due to the research design statements of this kind will not possible on the basis of the following analysis. Starting exclusively from the securitisation end of the research object, however, would mean to begin with an analysis of the (possible) securitisation processes for all major infectious diseases at the EU level over a period of more than two decades, an endeavour which is due to the large number of potentially securitised diseases not feasible; and which could not even ensure that a testing of the hypothesis would indeed be possible, since the form of securitisation of a disease, in particular strong securitisation, can only hardly be anticipated ahead of a detailed analysis.

Against the background and in the light of the research interest in securitisation as a condition for institutionalisation it is more reasonable to pursue the envisaged two-step research approach that starts with the identification of structural changes, followed by an analysis in how far these structural changes occurred in the context of the securitisation of an infectious disease. By proceeding in the proposed way the study not only overcomes the challenge to identify a pair of cases that is actually relevant for the analysis of the assumed connection between securitisation and institutionalisation processes, it also contributes to closing a basic research gap by providing a so far missing overview of key developments in the evolution of the EU's setup for infectious disease control.

2.5.5. Collection of Documents

The sources analysed in the framework of this study are not identical in all research phases and they also required the application of different collection methods. When it comes to analysing the evolution of infectious disease control, institutionalisation processes and the course of events related to the BSE/TSEs and the SARS crises, the set of analysed sources primarily include relevant academic literature, EU Treaties, EU legislation and communications as well as expert interviews. In addition, newspaper coverage of the topic can feed into the analysis to complete the picture. In turn, for the analysis of the securitisation developments, the focus on official EU actors implies that the study exclusively deals with EU primary sources.

How have the respective data sets been compiled? For the investigation of key developments of infectious disease control at the EU level and the political processes related to the two diseases under scrutiny, academic literature was compiled on the basis of a systematic bibliographic search as well as access to EU Treaties and relevant EU legislation through internet research of the websites of the EU institutions and complementary online databases. A systematic screening of the respective webpages of the before mentioned EU institutions and media sources, however, sometimes does not provide access to documents of the early 1990s, a time when the EU did not yet pursue a fully-fledged online publication policy. For the early years under scrutiny, the set of documents was therefore complemented by the compilation of communications collected through a systematic offline search of the Archive of European Integration (AEI) and the European Union Delegation Collection (EUDC) of the University of Pittsburgh.[44] The latter is one of the most complete EU depository libraries which received a complete collection of public European Union official documents and publications from 1952 to 2007 (Wilkin, 2008). All in all, the result of this systematic online and offline search makes up, together with the information retrieved through expert interviews (see chapter 2.5.7), for a rich set of relevant sources.

In turn, the research engaging in the analysis of the securitisation of infectious diseases builds on a set of documents that was generated through a complete extraction of EU legal output dealing with the selected diseases. For the purpose of this study, the notion of legal output refers to all EU action based on EU Treaties, comprising documents in the form of various treaty-defined legal instruments (secondary law) as well as the formal rules of procedure of EU institutions and, at the most informal level, established practices of EU policy-making.

A comprehensive list of EU legal output relevant to a specific topic can be generated through 'EUR-Lex', the EU's central online database on EU law. It offers a search engine that provides direct access to and further information on all types of binding and non-binding EU legislation as well as case law, international agreements and preparatory acts. EUR-Lex is updated on a daily basis and contains a total number of more than 3 million documents, dating back to 1951.[45] The set of items related to the selected diseases can be generated by the EUR-Lex search engine in various ways, the most straightforward of which is the specification of keywords.

[44] The search of the AEI/EUDC was carried out from March to May 2013.
[45] See http://eur-lex.europa.eu/content/welcome/about.html (accessed 28.08.2014).

For the first case study (chapter 5) the EUR-Lex search covers the period from 1989 to 2001 and thus the period between the first BSE/TSEs-related output at the EU level and the creation of the European Food Safety Authority. The EUR-Lex search employed the search terms 'bovine spongiform encephalopathy', 'BSE', 'Creutzfeldt', 'mad cow' and 'spongiform'. For the second case study (chapter 6), EUR-Lex was searched for 'severe acute respiratory syndrome', 'respiratory', and 'SARS' for the years between 2002 and 2004.[46] It belongs to the advantages of an EUR-Lex extraction that the data set comprises all sorts of EU output, including legislative acts and preparatory acts such as White and Green Papers, as well as proposals, reports and further documents. That is why both speech acts and emergency measures, in the understanding of the securitisation approach, can be analysed on the basis of a data set generated by EUR-Lex. Since the database covers items by all major EU actors and across all EU policies, a respective categorisation of these items beyond the parameters of securitisation allows also for a differentiation between the author (EU institution or sub-unit) as well as the primary policy field of a securitising speech act or emergency measure. A particularity in this respect are the written questions from Members of the European Parliament (MEPs) which are part of a full EUR-Lex extraction but which are not included in the systematic analysis across both case studies due to the large number of respective documents (see also chapter 2.5.6.1). Beyond that, prior to the analysis the data set also underwent a clearing in view of items that are listed multiple times and to exclude corrigenda.

Beyond EUR-Lex, the securitisation analysis also made use of the results of an extensive search of the webpages of the European institutions, in particular of the Commission and the European Council, in order to integrate documents and conclusions that are not covered by the official EU database but which clearly relate to the diseases under scrutiny. As the Commission set up specific web sections for individual diseases, the complementary search of dedicated EU webpages could help find key documents outside the scope of EUR-Lex, for instance issued by scientific committees or expert groups. Also the Presidency Conclusions of the European Council are generally not included in the EUR-Lex database and therefore require a manual integration into the *text corpus*.

It should be noted that some of the original EU webpages of the periods in question could not be accessed anymore at the time of writing and that relevant documents were not provided on the respective updated webpages. In these cases the original documents were retrieved from the 'Internet Archive', a non-profit internet library that provides permanent access to historical digital content.[47] It offers a 'Wayback Machine' to access archived versions of websites over time.

All in all, generated in this way the *text corpus* was designed to allow for the identification of the key institutionalisation processes at the EU level and for assessing securitisation processes in both the verbal and the operational dimension at the EU level. Given that the data set was compiled in a systematic way, a comparative view across time periods and case studies is facilitated. Crucially, it covers the full spectrum of relevant actors and therefore all relevant potential (de-) securitisers and audience(s). The following Table 2-3 summarises the sources analysed for this study.

[46] Further information on the method and use of EUR-Lex extractions can be found in Klein et al. (2013).
[47] See http://archive.org/ (accessed 13.02.2015).

Table 2-3: Overview of Main Set of Analysed Sources along Research Phases

	EUR-Lex Database	Official EU Webpages[48]	AEI/EUDC Archive	Expert Interviews
Institutionalisation and Response to BSE/TSEs & SARS	**x**	**x**	**x**	**x**
Securitisation	**x**	**x**	**o**	**o**

Source: Own presentation.

2.5.6. Qualitative Content Analysis and Classification of Communications

In order to analyse the set of documents gathered, the study employs the instruments offered by qualitative content analysis. For the analysis of the EU key development in infectious disease control it is sufficient to carefully analyse and categorise the selected sources, also in view of their meaning for relatively persistent and systemic key developments regarding rules, procedures, policy priorities, resource allocation, distribution of competences and organisational structures. A combination of the analysis of primary sources, secondary literature and expert interviews (see chapter 2.5.7) is best suited to ensure that the major developments are covered indeed.

The analysis of securitisation is principally carried out in the spirit of the fathers of the original securitisation approach, who argued that the study of security does not need "any sophisticated linguistic or quantitative techniques" as long as the primary aim is to look "for arguments that take the rhetorical form defined here as security" (Buzan et al., 1998: 176f). Seeing that it is against the security argument's nature to be hidden, the major task is to read the documents in view of securitising moves and emergency measures (Buzan et al., 1998: 177).

Since the present study works with a modified securitisation approach, this starting point has to be put in perspective. Clearly, the envisaged differentiation in terms of timing, actors, dimensions, degrees and kinds of securitisation is a more complex exercise which demands substantive detail work, in particular to identify whether and in how far the content of a given communication qualifies as rather one kind and degree, or another. In this context the securitisation components that indicate the degree of securitisation, as well as the security parameters established for the kind of securitisation, will be taken up to create a tailor-made code system.

How does this work in practical terms? Coding texts means assigning values or categories to observations that can be made in the analysed communication. It can be applied to analyse both kinds and degrees of securitisation as well as to both securitising speech acts and documents that initiate emergency measures. In principle, the analysis can focus on the word, sentences, paragraphs, themes or the item, that is the communication as a whole (Neuendorf, 2002).

[48] Partly accessed through 'Web Archive', see foot note above.

Focusing on individual words is, however not advisable since "[a]ctors who securitise do not necessarily say 'security', nor does their use of the term security necessarily always constitute a security act" (Buzan et al., 1998: 33). Although notions such as 'emergency' or 'crisis' can serve as good points of orientation, securitisation often speaks through the lines. Therefore, "[w]hat is […] important is not the term itself, but the implication from the use of this term that 'business as usual' will not suffice and extraordinary measures are required" (Kamradt-Scott and McInnes, 2012: S96).

Against this background content analysis does not rely on specific key words that necessarily have to figure in the text in order to make it a securitising move. Instead, it is necessary to assess word meanings, also key notions such as "scourge, threat, collapse or cripple (in reference to impact of the disease on the economy or governments)" (Cook, 2010: 17f) in larger context, sentences and paragraphs when it comes to relating a document to the parameters of securitisation. Also the analysis of longer text segments helps identify specific themes, which often incorporate "modifiers (adverbs, adjectives) and explanatory text that both accompany usage of a particular word and [thus] help to establish its meaning" (Manheim et al., 2008: 183). In this way the general tone of the document, the presence of the security discourse and the overall nature of the file are often more important than individual words. This is particularly true for the selected *text corpus* which incorporates many documents that were written in a distinct, rather technical 'eurocratic' language and which therefore cannot be expected to feature dramatic rhetoric.

2.5.6.1. Analysing the Degree of Securitisation

For the analysis of the degree of securitisation, the study works with an analysis of the documents along the securitisation indicators developed in chapter 2.3.1., namely the (strength of the) security discourse, the (number of) speech acts, the (number and strength of) securitisers and the (number and strength of) emergency measures, incl. the re-allocation of resources.[49] The analysis and structuring of the *text corpus* is carried out in view of the identification of specific periods of times ('(de-)securitisation phases') for which the rise or fall of the securitisation degree could be detected.

In order to substantiate the differentiation of the securitisation degree of a disease along the security continuum between lowly and highly securitised, the full set of EU documents is classified in the sense of a 'scaling structuring' or 'evaluative categorisation' (Mayring, 2008: 92-99, Kuckartz, 2014: 98-114). This technique allows assigning a basic value to every speech act (verbal dimension) and emergency measure (operational dimension) that reflects the use and strength of security language as well as the 'extraordinariness' of the measure as laid down in a given communication.

In order to work with a system that both structures the communications along a manageable scale and that at the same time accurately reflects the relative securitisation degree of a given communication, the scale was designed inductively after a majority of speech acts and emergency measures could be preliminarily evaluated. It is set up as a standard 5-point interval scale which

[49] See Figure 2-3. Following the conceptualisation of the EU 'audience' in chapter 2.5.3.2, the audience consent is not subject to separate analysis.

builds on the core elements of the verbal and the operational dimension of securitisation and offers a categorisation of all communications along the range from a (highly) securitising through a neutral to a (highly) de-securitising move.

According to this system a speech act receives the attribute of a 'highly securitising' (+ +) communication on the verbal securitisation dimension if the author employs language that puts a disease directly in the context of, for instance, a 'severe' or 'acute' threat or crisis and calls for 'immediate' or 'comprehensive' responsive actions. Common elements of highly securitising speech acts are references to the disease's strong capacity to cause death or relating the disease to classic security threats, such as terrorist attacks or particular severe disease outbreaks of the past. To illustrate, members of the European Parliament stated with reference to SARS that the "virus is also spreading within Europe in a way which threatens everyone's health" (European Parliament, 2003b) and labelled it a disease which "has become the new plague of the third millennium" (European Parliament, 2003a). Such formulations, for instance, meet the criterions for a 'highly securitising' speech act.

Also in absence of explicit security language an utterance may still qualify for a securitising move, if it contains references to an existing securitising document. A call for the urgent implementation of a given emergency measure is a case in point. In turn, if the utterance is less outspoken but still deals with the disease as a security issue, for instance by pinpointing at specific risks or particularly affected referent objects, the speech act qualifies to receive the attribute of a 'securitising' (+) communication.

In the same understanding a 'de-securitising' or 'highly de-securitising' effect can be assigned to a speech act, if the text attempts to treat the disease as a non-extraordinary matter that is either harmless in principle or at least manageable by existing structures. Typically, de-securitising (-) elements describe the disease as not dangerous with overall few and negligible related risks. Also the language employed seeks to evoke the impression that 'everything is under control'. Highly de-securitising (- -) communications work in the same direction, but are more outspoken regarding the state of security. In the most extreme form, a 'highly de-securitising' utterance declares the containment or eradication of the disease.

On the operational dimension a communication qualifies for the score of a (highly) securitising effect, if the document constitutes the normative or legal basis for emergency actions that are taken in response to the disease. Whereas extraordinary measures, such as an embargo on products related to a given disease, means that the disease is highly securitised (+ +) by the document, less exceptional measures such as, for instance, the deployment of investigation groups, which still accounts clearly for an emergency measure, are classified as a merely 'securitising (+) move. Accordingly, the massive re-allocation of resources would imply a high (+ +) securitising score on the operational level, a modest investment a basic one (+). In turn, a highly de-securitising communication on the operational dimension would be, to illustrate, the lifting of a disease-related ban (- -) or the loosening of extraordinary inspections (-).

Speech acts without any direct or indirect formulations that relate the disease either to a threatening situation or the state of (in)security are labelled 'neutral' (o). These documents can be either of a rather technical nature or simply treat the disease outside the wider security context. Beyond the genuinely neutral communications the 'neutral' score is also assigned to those cases which bear both securitising and de-securitising elements in the same amount so that a distinct classification towards either of the directions is impossible. The same system is applied to classify communications regarding their impact on the securitisation degree on the operational dimension, even if it is less likely that both securitising and de-securitising actions are launched by the same document. Crucially, should a communication constitute a speech act that does not go along with the adoption of emergency measures, the attribute for the operational dimension of the respective document is 'neutral', and *vice versa* for instances that adopt an emergency measure without explanations that employ any form of security language (verbal dimension).

Since the values assigned to the EU documents will be subject to further mathematical handling (see below), the attributes ranging from + + to - - also have a numerical expression, the 'securitisation score'.

Table 2-4: The Classification of Speech Acts and Emergency Measures in View of the Securitisation Degree

Symbol	Score	Meaning
+ +	2	Securitising Content (identification of threat and/or adoption of emergency measure)
+	1	
o	0	Neutral Content (elements of securitisation and de-securitisation or no relation to security)
-	-1	De-securitising Content (re-assuring statement and/or end of emergency measure)
- -	-2	

Source: Own presentation.

The assessment and classification of the communications is a genuinely qualitative endeavour that occasionally implies difficulties to clearly differentiate between the different attributes/scores, for instance whether a given text is rather highly or a merely securitising case. This challenge and related methodological problems are alleviated by different means. First, all documents were assessed in a relatively short period of time so that a comparison among the communications could easily be done. Second, the classification was entirely undertaken by the author of this study so that the procedure could be applied consistently across all cases. Third, in order to make the evaluation and assignment of values most transparent, the documents are compiled in tables at the end of the chapters that deal with the securitisation processes of a specific period under scrutiny.

More precisely, the tables (see example below) make explicit the securitisation value assigned in addition to the date of the document as published in the EU Official Journal, the author of the document, the specific document number as assigned by the author, the reference specification as used in the list of references of the present study, as well as basic information on the content of the respective communication. Providing this comprehensive overview of reference data for each communication included in the analysis makes the list of communications not only better accessible for the reader, it also clearly relates EU activities to the respective documents as well as the impact on the overall securitisation degree of the disease.

Table 2-5: Example for List of Disease-Related Speech Acts and Emergency Measures

(OJ) Date[50]	**Author**[51]	**Reference**[52]	**Contents**	**Securitisation**[53]	
Doc. No.[54]				**Verbal**	**Oper.**
e.g. 11.11.11	e.g. CO	…as referred to in the List of References	e.g. Red alert / high risk warning: temporary (local) virus transmission (*virus carnevalis)*	e.g. **+ +**	e.g. **o**
e.g. A11. A – AF					

Source: Own presentation.

Building on the data generated, the rise and fall of the disease as a security matter can be illustrated in a timeline by setting off the scores of the securitising (2 or 1) against the de-securitising elements (-2 or -1) for a given '(de-)securitisation phase', for instance a specific year. By reflecting the total number and values of securitising speech acts and emergency measures this mathematical handling of the data helps compare the securitisation degree across different points of time. In this way it allows to reveal in how far securitisation and de-securitisation happen as "single bombshell event[s]" or take the form of longer processes (Guzzini, 2011: 335).

This simple addition, however, does not fully express the securitisation degree of a disease, as it misses to cover the overall strength of the security discourse that is linked to the disease. To recall, the concept set out in chapter 2.3.1 requires that a high number of securitising moves on both the verbal and the operational dimension is needed to shift a topic into the realm of security, it is, however, not sufficient to qualify an issue for a high securitisation degree. In addition to a substantial number of securitising documents also the overall discourse on the disease needs to be that of a security issue across the full number of communications. To exemplify, 20 securitising documents for a given disease issued over six months can be a lot in absolute terms, but the significance of this

[50] Date of publication of the document in the European Union's Official Journal (OJ).
[51] Official author of the document using the following abbreviations: Communicable Diseases Network Committee (CDNC), Commission (COM), Council (CO), Parliament (EP), European Court of Auditors (ECA), European Council (EUCO), European Economic and Social Committee (EESC), Intergovernmental Conference (IGC), Scientific Steering Committee (SSC).
[52] Document specification as used in the 'List of References' of the present study.
[53] Along the verbal and the operational (oper.) dimension.
[54] Official specification as provided in the document.

number is limited if the total number of disease-related EU documents for the same period is 200, a majority of which has a neutral or negative securitisation score.

It is for that reason that the total number of disease-related documents needs also to be assessed in view of the percentage of documents that are located in the securitisation (+ + and +), the neutral (o) and the de-securitisation (- and - -) realms in the verbal securitisation dimension. Clearly, for a highly securitised issue we expect a clear majority of the total number of documents in the first realm, the realm of securitising moves.

Finally, this assessment can be reasonably complemented by the calculation of an average score for individual securitisation phases on the basis of the scores assigned to all utterances. Building on the classification on the 5-point scale between +2 and -2, the individual scores assigned to the analysed documents can serve to calculate a mean by dividing the sum of all scores by the total number of documents. Such an average score can help substantiate the dominance of the security discourse and is a valuable point of reference when it comes to comparing the securitisation degree of two or more diseases whose securitisation occurred under different circumstances.

It should be noted at this point that it is not the purpose of this study to establish an exact expression of the securitisation degree in form of an index. The further mathematical handling of the values assigned to the set of EU documents as set out before should be rather understood as a tool kit that supports the qualitative assessment of the empirical data in view of the securitisation degree. In fact, the numbers and figures alone are not considered to cover the full picture. They need to be put in perspective by a complementary assessment of the group of securitisers and in view of their power positions. To recall, a securitising speech act of the European Council requires a different interpretation than the utterance of a scientific committee. That is why measuring the number of securitising speech acts and emergency measures is of help only in addition to the qualitative interpretation of the content of the individual communications. The final classification of the degree of securitisation of a given disease for a given time as ‘low’ or ‘high’, or any intermediary degree, can only be undertaken as a last step of analysis on the basis of the full picture.

2.5.6.2. Analysing the Kind of Securitisation

In contrast to the degree of securitisation, the analysis of the kind of securitisation is a purely qualitative exercise. In order to assess dominant security understanding of a given securitisation period, the list of securitisation parameters established in chapter 2.3.2.2 to distinguish infectious disease-related security concepts serves as a point of orientation. Given the depth of detail developed for each securitisation element, Table 2-1 can be employed similar to a questionnaire and code-book. Once individual formulations and segments of the communication could be related to these securitisation parameters, the overall categorisation of the item along the lines of a rather ‘soft’ or rather ‘hard’ kind of securitisation becomes possible. Clearly, intermediary forms that combine elements from both extreme forms are possible.

Pursuing this in-depth analysis for all selected communications shall ensure that for each document the relevant content can be identified. As it cannot be expected to find all potential parameters addressed in a single document, a definite classification table of each document along the lines of a 'soft' or 'hard' kind of securitisation is not envisaged. Instead, it belongs to the final steps of the empirical analysis to condense the values gathered from securitising speech acts and emergency measures from different actors and different moment of times to a complete picture of one dominant or several competing securitisation kind(s).

2.5.7. Expert Interviewing

Whereas content analysis is a particularly valuable tool to analyse existing documents, in particular those that can reveal information about the securitisation of a disease, the analysis to track the developments in response to BSE/TSEs and SARS as well as the investigation of the institutionalisation of infectious disease control in the EU can – beyond the analysis of secondary literature and EU documents – benefit from information acquired from elite interviews. In the present study the technique of elite interviewing refers to one-on-one or roundtable conversations with persons who possess 'elite status' due to their particular knowledge and access to information that help gain in-depth understanding of the field of infectious disease control in general and the evolution of the EU'S infectious disease policies and polity in particular.

Interviewing professionals who are or were professionally concerned with the political process under scrutiny is generally valuable for securitisation studies since they potentially belong to the group of practitioners who issue documents that qualify as securitising element and thus contribute to the definition of a security problem (Bigo, 2000, 2002). "Their discourses, routines and more generally their political role is often much less visible in the public and mediatised domain" (Huysmans, 2006: 8f) so that interviewing them can mean a valuable complement to the text analysis. Interviews could potentially also contribute to the analysis of securitisation processes, but a structured survey among practitioners is beyond the scope of the study. In contrast, the expert interviews served the primary purpose to shed light on the background against which structural changes occurred at the EU level from the view of the involved practitioner. Beyond that they were meant to gain additional insights into the background of the production of speech acts and emergency measures that were issued in response to the analysed diseases. In this sense, respondents were treated individually to reconstruct internal political processes or the background for specific legislation (Manheim et al., 2008: 372ff).

A semi-structured interview guide helped break down the research interest in sub-fields and specific questions, allowing for flexible and open ended responses by the interviewees. The flexibility provided by the interview guide was especially useful to find out what respondents considered most important in a given development and when the discovery of facts and patterns was at the heart of the conversation (Manheim et al., 2008: 373). The interview guide used for the present analysis was set up on the basis of the work of Kvale and Brinkmann (2009). In order to adjust to the specific expertise of the interviewee, the guide differed depending on research phase and respondent.

The selection of interviewees was a combination of experts approached speculatively as well as persons selected on the basis of recommendations and from the network of contacts provided by previous interviewees. Purposely the group of interview partners was not restricted to EU officials but also covered active and retired professionals from other relevant institutions in order to gain a picture of the respective policy and polity developments as comprehensive as possible.

The collection of information through interviewing proceeded in three steps. With the aim to gather background information on international efforts to control infectious disease in Europe in more general terms, a set of interviews was conducted at the WHO's Regional Office for Europe at an early stage of the research process. These interviews served basic explorative purposes and helped gain insights on joint communication and collaboration structures, including the EU facilities. These conversations also established further contacts in the European field of infectious disease control.

In a second step, halfway of the research process, research design and intermediate results were reflected with academic and professional scholars in the framework of two expert roundtable discussions. The participation of experienced practitioners such as Prof. Dr. Henderson, the head of the WHO's only successful worldwide eradication campaign (Global Smallpox Eradication Campaign) or Dr. Merkel, a Commission official who significantly shaped the design of the EU's first health programme (see chapter 3.4.1) proved to be particularly valuable for the collection of background information on the earlier phases in the evolution of global and EU-wide disease control structures.

Whereas the first interviews and the roundtable conversations applied a broader focus, a final set of interviews was conducted with a specific view on the research question of the present study. The group of interviewed EU officials of the Directorate General for Public Health and Food Safety work at the heart of the EU's public health infrastructure and are not only engaged in current disease control efforts of the EU but have also framed and participated in institutionalisation processes.

The three interview phases thus followed the idea to move from a common approach to a specific approach and to purposefully schedule the most specific interviews for a late stage in the research process. This timing was envisaged on the grounds that interviews with experts have the capability to quickly and substantially influence the researcher's view on the topic. This capability is not only an advantage but also bears the risk that research becomes excessively affected by the practitioners' views. In the light of this risk the final set of expert interviews was purposefully conducted only after the major line of argumentation as regards the EU systemic development in the field of infectious disease control had been established. In this context the interviews primarily served the purpose to complement, double check and contrast the results of the research that was done on the basis of secondary literature and EU documents (Manheim et al., 2008: 374).

The interviews carried out in the framework of the present studies were conducted between December 2011 and May 2015 as private and reflective conversations for which confidentiality was promised to the respondents prior to the interview. For this reason they are generally not cited in the text. Voice recorders were used unless the interviewee did not agree to record the conversation. All in all, the total number of 8 conversations with a total of 13 experts was conducted.

3. Key Development of Infectious Disease Control in the European Union

Joint efforts to control the spread of infectious diseases in Europe date back at least to the Middle Ages. The European Union advanced into the field from the 1980s onwards, a process which unfolded an institutionalisation dynamic particularly since the 1990s. Having laid down in detail the research purpose, research design and research methods of the study in the previous chapter, the following chapter marks the start of the empirical analysis. More precisely, it serves the purpose to provide an overview of the major developments in infectious disease control with a focus on the most recent steps since 1993, the year when the first substantial article on public health in EU primary law entered into force.

Seeing that historical events and established patterns of infectious disease control in Europe provided the background for the developments on EU level, the chapter starts with a brief examination of the history of infectious disease control in Europe. It will become visible that the EU did not enter a vacuum. Quite the contrary, particular ideas and features of infectious disease control, including the institutionalisation of international cooperation, have a long tradition in Europe.

The section on the historical background is followed by an analysis of the evolution of the EU's setup to respond to infectious diseases. Since the rapid evolution of the EU's policy field is not sufficiently reflected in the academic literature, the consolidated overview of the developments at the EU level is of particular value. In fact, to the knowledge of the author there is no work on the market that has already fully drawn together the key development of the EU's infectious disease control in the field of public health and food safety over time in a structured way. At the same time the chapter provides the background needed for the envisaged analysis of securitisation processes in the following case studies of chapters 5 and 6.

In order to structure major developments over a period of more than twenty years, the chapter sets out three consecutive periods of infectious disease control at the EU level after the Maastricht Treaty entered into force: A first phase from 1993 to 2000, the second from 2001 to 2007 and the third from 2008 until 2014. The phases are based on shifting policy priorities following the implementation of different EU health programmes as well as on specific institutionalisation processes. The overview of both historical roots and key developments after 1993 culminates in a brief analysis of overarching patterns and a summary of key developments, including a list of milestones.

3.1. Historical Roots of Infectious Disease Control in Europe

Infectious diseases have been influential factors for political order and social life throughout history. For example, when the 'Plague of Justinian' spread in the sixth century from Constantinople all over the Mediterranean, it contributed to the fall of the Byzantine Roman Empire (McNeill, 1989: 101ff, Hough, 2004: 154). Systematic political interventions in response to infectious diseases can be traced back to at least the years of the Black Death. The control measures of fourteenth-century Venice required ships and travellers from plague-infected areas to stay outside the walls of Ragusa for a period of at least a month before they were allowed to enter the city. Deriving from the Latin word for thirty, this system was known as *trentina* and later referred to as *quarantina* when the time scale was extended to forty days.[55] Over the following centuries, procedures similar to the Venetian model were adopted in other places in Europe, but it was not before the mid-nineteenth century that countries started to coordinate their efforts internationally (Conrad et al., 1995: 196, King, 2002: 764, Gensini et al., 2004, Stern and Markel, 2004, Bashford, 2006).[56]

In the nineteenth century, several pandemic waves of cholera spread from the Bengal region and the Ganges river delta throughout India and then to parts of Asia and the Western Pacific, the Russian Empire, and finally also to Prussia, France, England, and North America. The dynamics of the Industrial Revolution facilitated the risks of an epidemic due to an increased interaction of colonial powers with so far unknown diseases of other parts of the planet and rapidly growing urban populations that lived in poor sanitary conditions (Johnson, 2001: 11, O'Manique and Fourie, 2012: 245). After major European cities had been strongly affected from 1848 onwards, representatives of twelve European countries convened in Paris in 1851 for the first International Sanitary Conference to discuss harmonised rules for quarantine practices and containment of the transnational threat of cholera, but also plague and yellow fever (Hays, 2005). This meeting set the starting point for a series of gatherings, and thus a forum for regular exchange, about the control of the international spread of epidemic diseases until 1938. The conference series ultimately yielded first international public health law, first and foremost the International Sanitary Convention for cholera of 1892 and three further conventions on cholera and plague in the subsequent years, which were finally merged to a single International Sanitary Convention in 1903 (Howard-Jones, 1975, Hough, 2004: 161).

In the same year it was also agreed that a permanent institution could help better coordinate international efforts.[57] The idea finally resulted in the International Sanitary Convention of 1907 and the establishment of the Office International d'Hygiène Publique (OIHP), an international governmental institution with a permanent secretariat in Paris (Lee, 1998: 1, Hough, 2004: 162). The OIHP's major achievement was the original establishment of a standing platform to regularly discuss ideas and information on public health matters (Roemer, 1994). In the years after the first World

[55] Other scholars trace Venetian quarantine legislation even back to 1127 (Gostin, 2000: 205).
[56] A crisp chronology of major International Sanitary Conventions can be found in Fidler (1999: 22f).
[57] At that time, some regional health organisations existed already, for instance the 'Conseil Sanitaire d'Alexandrie', the 'Conseil Supérieur de Santé de Constantinople' or the 'European Commission for the Danube'. For a comprehensive overview of the cooperation in health matters in the 19th century see Howard-Jones (1950, 1975) and Weindling (1995).

War, similar tasks were also performed by the Health Organisation of the League of Nations, a body of the League of Nations that worked in parallel to the OIHP with the aim to "to take steps in matters of international concern for the prevention and control of disease" (The League of Nations, 1920). All in all, the years between 1851 and 1914 yielded eighteen international conferences on health and the creation of twelve health-related international institutions (Murphy, 1994). In this framework international collaboration on disease control was extended to further areas such as the prevention and control of malaria, smallpox and typhus or the international traffic in opium (Boudreau, 1935, Howard-Jones, 1950, Arai-Takahashi, 2001: 116f, Dodgson et al., 2002: 10, Liverani and Coker, 2012: 918f). By perpetuating their collaboration, national leaders eventuelly established the principle that joint and coordinated actions may better enable governments to protect their populations than national measures only (Dodgson et al., 2002: 9).

In addition to these international efforts of governments, also a non-governmental sector started to develop and influence the cooperation in health matters from the nineteenth century onwars; be it in the form of organisations like the International Committee of the Red Cross, established in 1863, or in the form of specific health programmes of philanthropic foundations like the Rockefeller Foundation, established in 1913. They supported the idea of a humanitarian health agenda to the benefit of all people, a mission that was taken up by humanitarian NGOs after the war period. The idea is also to some extent encompassed by the principle of 'universality of health', a key vision of international health cooperation of the post-war period (Dodgson et al., 2002: 10).

In the course of the Second World War, international cooperation in infectious disease control, and public health in general, ground to a halt. After the end of the war, when the entire League of Nations project had crumbled away, previous activities were taken up in the framework of the United Nations system and in particular its specialised agency in health matters, the World Health Organization. The WHO was established in 1948 and became the successor of not only the League of Nations Health Organisation, but also incorporated other international health institutions like the OIHP in Paris. The WHO was thus put in the centre of the new worldwide system of health collaboration.[58] Although the previous euro-centric perspective on health cooperation was resolved into a universal approach, the six decentralised offices of the WHO, one for Europe located in Copenhagen, still served a regional approach. Besides the implementation of regional programmes, the World Health Assembly, the WHO's key decision making body (WHO, 1948: Art. 21), also agreed on new international health law. In particular, in 1951 the WHO replaced the patchwork of existing sanitary conventions by a new set of rules, called 'International Sanitary Regulations', thereby *inter alia* obliging the WHO member states to report incidences of cholera, plague, smallpox and yellow fever. Over the next decades, the regulations underwent several amendments (1969, 1973, 1981 and 2004)[59] and were renamed 'International Health Regulations' (IHR).

[58] Other UN institutions such as the United Nations Relief and Rehabilitation Administration (UNRRA), the United Nations Children's Fund (UNICEF) and the Office of the United Nations High Commissioner for Refugees (UNHCR) were created in the same period to perform specific health-related tasks.

[59] On the latest revision in 2004, see also chapter 6.3.3.

3.2. The Community's Public Health and Infectious Disease Policy before 1993

The brief review of the historical roots of infectious disease control in Europe has shown that the European Community did not enter a vacuum when Member States started to include health matters in the European integration project. However, in the first decades after the Second World War, health protection and infectious disease control did not emerge as distinct fields of cooperation in the Community's Treaties. Neither the Coal and Steel Treaty (1951) nor the Treaties of Rome (1957) addressed health issues in an explicit manner or as an objective. Still, some health-related questions found a way into community law, primarily following the ruling by the European Court of Justice. In 1976, the ECJ declared in a case on the free movement of goods related to pharmaceuticals that "health and life of humans rank first among the property or interests protected by [the Treaty]" (European Court of Justice, 1976: para. 15). Hence, rather than leaving this responsibility entirely to the national level, the principle of the protection of human health became – through ECJ jurisdiction – subject to Community law (Hervey, 2012: 982).

From this period on, the interest in health matters generally rose within the Community. After a first Council meeting of the ministers of health in 1977, the further development was facilitated by the interest of a high-level politician in the beginning of the 1980s; the French President Francois Mitterand discovered, for personal reasons, an interest to launch concerted action related to cancer (Stein, 2003: 19). After a general decision of the European Council in 1985 (European Council, 1985), the first public health initiative of the Community 'Europe Against Cancer' was finally adopted in 1986 (Council, 1986a) under the impression of the disaster at reactor 4 of the Chernobyl nuclear power station (Gilmore and Kee, 2004: 219, 224). Crucially, the generally raised interest in health matters also fed into the debate that led to the conclusion of the Single European Act. Although a general provision on health was not included in the new Treaty, it addressed for the first time a number of health aspects in other policies (Coleman, 2004: 5).[60]

In the same year, a development similar to the cancer initiative can be observed for the first time with respect to an infectious disease. The Acquired Immune Deficiency Syndrome (AIDS) had received some attention since 1983, when the Commission started to provide initial funding for scientific exploration in the framework of the medical and health research programme (MH3),[61] but it was only since 1986 that the health ministers of the Member States devoted a specific series of meetings to the response to the new disease (Council, 1986b). Following the statements on AIDS during the G7 summit in Venice in 1987, the Member States of the European Community first agreed on the creation of *ad hoc* working groups and later on a joint programme to respond to the epidemic, the programme called 'Europe Against AIDS' (Council, 1991, Hervey and McHale, 2004: 337). The programme ran, after one extension, from 1991 to 1995, and focused on the collection of data and information exchange between the Member States. It was complemented by other AIDS-related programmes focusing on the reduction of intravenous drug use and migrant mobility, when open

[60] For instance, with regard to the single market (Art. 100 (a)), the protection of the health and safety of workers (Art. 118), research policy (Art. 130 (f-q)) and the environment (Art. 130 (r-t)).

[61] Since then, research into AIDS and later also other infectious diseases was part of every European research programme (Steffen, 2012: 1068).

borders to the post-communist transition countries and looming Eastern enlargement intensified the discussions about trans-border health risks. In comparison to the resources devoted to research, however, the action programmes were small (Altenstetter, 1994: 420, Steffen, 2012: 1083).[62]

Retrospectively, the political developments related to cancer and to HIV/AIDS can be seen as constitutive events for the further institutionalisation processes in health affairs at the EU level. Since then, throughout the following decades, the importance of infectious diseases as a topic on European level has increased (Schreck et al., 2009: 149). Both 'Europe Against'-programmes were established without a specific legal basis in the Treaty, they "relied on the Treaty as a whole, including its general objectives such as the constant improvement of living and working conditions mentioned in the preamble" (Coleman, 2004: 5). The Chernobyl accident and the spread of AIDS made clear that trans-border risks to health required a trans-border view, but Community-wide epidemiological data collection turned out to be incomparable and incomplete at that time (Velimirovic, 1984). In this respect the cancer programme cleared the way for all future cross-border research and data collection efforts at the European level (Trubek et al., 2008, Steffen, 2012: 1065). Beyond that the responses to HIV/AIDS set the path for the future of the EU's infectious disease control system.

In this context the establishment of a coordinated network for the surveillance of AIDS cases and later also HIV infections across Europe, EuroHIV (since 1984), set the starting point for a general and long lasting development, namely the creation of disease specific networks of national medical and research institutions with financial support from the European Commission. Besides EuroHIV, the set of pioneering networks, which were partly co-run with WHO/Europe, comprised a European working group for legionella infections (EWGLINet, since 1986) and a European network of sentinel general practices (Eurosentinel, since 1987), followed by a cooperation to establish an early warning scheme for influenza (ENS-CARE, since 1992). These early disease-specific surveillance networks before the Maastricht Treaty had in common that they were established by national research centres to study epidemiological trends and health resources in a wider geographic space with funding from the European Commission. Albeit small in size and originally funded as temporary projects, they constituted the basis for a dynamic evolution in infectious disease affairs after the founding of the European Union in 1993.

Political support for a more comprehensive European role in health matters had already crystallised before in the High Level Committee on Health, a body of senior representatives from the Member States and officials from the Commission. The committee was created in the beginning of the 1990s to facilitate reflection on Community level while at the same time safeguarding national sovereignty and responsibility for health care. The forum was active in the run-up to the intergovernmental conference in Maastricht and eventually contributed to the draft provisions for a genuine health mandate in the new EU Treaty (Coleman, 2004: 6).

[62] For an overview of HIV/AIDS-related policies of the European Communities before the Treaty of Maastricht see Altenstetter (1994).

3.3. The Years from 1993 to 2000

3.3.1. The Legal Basis Provided by the Maastricht Treaty

The Maastricht Treaty entered into force in 1993 and introduced a public health article which not only caught up with established practices and ECJ jurisprudence, but which also initiated a fundamental modification in the constitutional setup of the EU's health affairs. The protection of "human health and life was already an established principle of EU law" (Hervey, 2012: 982). The new Treaty, however, specified for the first time the general vision that „the activities of the Community shall include […] a contribution to the attainment of a high level of health protection" (Art. 3 (o)). In this sense, human health protection was, although closely linked to the other activities of the Union, "consecrated […] as a general and free-standing goal" (Coleman, 2004: 7).

The instruments to achieve this goal were laid down in Article 129, the first article at the EU-level that explicitly addressed public health as a matter of Community competence. The Treaty emphasised cooperation between the Member States, optional support of their actions to protect human health and soft measures such as research, information and education to prevent diseases (Art. 129 (1)). At the same time, Article 129 also stressed that incentive measures to achieve the objectives should be adopted "excluding any harmonisation of the laws and regulations of the Member States" (Art. 129 (4)). Furthermore, in view of substantial overlaps of EU activities with other international organisations such as the WHO, the Council of Europe and the OECD, the Treaty also provided a clause which obliged the Commission to foster "cooperation with third countries and the competent international organisations in the sphere of public health" (Art. 129 (3)).

All in all, the Treaty set out health protection requirements to "form a constituent part of the Community's other policies" (Art. 129 (1)), for instance in relation to consumer protection (Art. 129 (a)) and environment policy (Art. 130 (r)). Although the mandate for Community action was relatively weak and did not approach infectious diseases as such, it nevertheless consolidated a legal basis for existing networks and initiatives such as the 'Europe Against AIDS' programme and EuroHIV. Crucially, it provided the fundament for the establishment of a 'Framework for Action in the Field of Public Health' and, as an intertwined process, the institutional setup and the funding of further networks in the field of infectious disease control (Steffen, 2012: 1071).

3.3.2. The Framework for Action in the Field of Public Health

Taking up the new mandate of Articles 3 (o) and 129 as laid down in the Maastricht Treaty, the Commission put forward a comprehensive communication on health (European Commission, 1993), the philosophy of which remained a point of orientation for the next decade (European Commission, 1999h: 7). The document aimed at providing a framework for action by the Community in the field of public health and to develop a comprehensive Community approach. Crucially, on the basis of an analysis of the major health issues at the Community level the Commission identified a set of priority areas of activities that ranged from horizontal issues like disease surveillance to specific diseases such as AIDS and other infectious diseases.

On the basis of the approval of the priority areas by the Council in 1994 (Council, 1994), a series of in total eight multi-annual programmes was launched in the following years, beginning with programmes that addressed cancer (European Parliament and Council, 1996c) and health promotion, education, information and training (European Parliament and Council, 1996a), followed by programmes on drug dependence (European Parliament and Council, 1997b), health data and disease surveillance (European Parliament and Council, 1997a), accidents and injuries (European Parliament and Council, 1999c), pollution-related diseases (European Parliament and Council, 1999a) and rare diseases (European Parliament and Council, 1999b). A specific programme of community action was also adopted for the priority area of 'Prevention of AIDS and Certain Other Communicable Diseases' (European Parliament and Council, 1996b). The programme was designed to fund project that addressed the surveillance and monitoring of infectious diseases and their transmission or that contributed to information, education and training elements, in particular regarding AIDS (European Commission, 1994a, Hervey and McHale, 2004: 338ff, Steffen, 2012: 1069f).

The eight health action programmes shared two basic characteristics: Their budgets were tiny and they supported the establishment of networks among experts and stakeholder in order to facilitate "exchange of information and personnel, joint analysis of common problems, training, and sharing best practice" (Coleman, 2004: 7). In the case of the programme dealing with infectious diseases, the programme envisaged *inter alia* "a Community network of public health epidemiologists" (European Parliament and Council, 1996b: Annex, Art. 3). Despite the small budget of an earmarked ECU 49,6 million, the largest share of which went into disease monitoring and surveillance (European Commission, 1999g: 12), some of the activities under the action programme unfolded a remarkably durable impact.

For instance, the regular production of a peer-reviewed pan-European bulletin on disease surveillance and prevention called 'Eurosurveillance' started in 1995 in the framework of the Community action programme; today, it belongs today the basic infrastructure of the public health community in Europe (Ammon, 2005: 1041).[63] Also in 1995, the 'European Programme for Intervention Epidemiology Training' (EPIET) recruited its first cohort of trainees to form an expert cadre of public health surveillance professionals in Europe that share methods, standards and language for investigation and response. Originally built up on the basis of project funding, EPIET is nowadays an internationally recognised institution that recruited its 20th cohort in autumn 2014 (van Loock et al., 2001, Ammon, 2005: 1041, Bremer et al., 2009, Krause et al., 2009).[64]

Also facilitated by technological advances of the 1990s, when new means of electronic communication allowed for a direct connection of the participating institutions and easier exchange of data regardless of geographical distance (Liverani et al., 2012: 575), the setup of new, largely disease-specific networks accelerated rapidly in the following years (Casteren and Leurquin, 1992, Fleming et al., 2003, Ammon, 2005, Reintjes, 2008, Ammon and Faensen, 2009).

[63] See http://www.eurosurveillance.org/ (accessed 12.03.2015).

[64] See http://ecdc.europa.eu/en/epiet/Pages/HomeEpiet.aspx (accessed 12.03.2015).

3.3.3. The Communicable Diseases Network and the Early Warning and Response System

In this context the creation of a European Community Network for the Control and Surveillance of Communicable Diseases in Europe in 1998 was of particular importance. This network, also labelled Communicable Diseases Network (CDN), was funded through the framework for action in public health and comprised designated national bodies responsible for communicable diseases within the EU Member States and the Commission. The respective Decision 2119/98/EC of the European Parliament and of the Council (European Parliament and Council, 1998) established for the first time a firm legal basis for a permanent collaboration in matters of epidemiological surveillance of communicable diseases. With the aim "to promote cooperation and coordination between the Member States, with the assistance of the Commission, with a view to improving the prevention and control" (European Parliament and Council, 1998: Art. 1) it included *inter alia* the commitment for Member States to provide information regarding the appearance of infectious diseases and respective control measures, and to consult among each other in the case of an epidemiological emergency. Furthermore, the Commission was given the power to adopt binding guidelines, procedures or protective measures to be implemented by the Member States provided the approval of these measures by the Network Committee, the CDN's decision making body made up of Member State representatives (European Parliament and Council, 1998: Art. 7, Schreck et al., 2009: 151ff).

In addition to this overarching approach, the CDN was designed to operate on the basis of a 'network of networks' that comprised an (increasing) number of so called 'Dedicated Surveillance Networks' (DSNs). The underlying concept of these DSNs was that they were run by different public health institutions in one of the Member States which assumed responsibility for the surveillance of a specific disease. For instance, the 'Institut de Veille Sanitaire' in France assumed responsibility for the surveillance of AIDS ('EuroHIV') and the 'Communicable Disease Surveillance Centre' of Great Britain for food-borne pathogens ('Enter-Net'). The networks were also financed by the annual subsidies from the health programme. In this way, together with the already existing networks that were created before the CDN, new and follow-up networks for the surveillance of infectious diseases mushroomed in the following years with various foci, for instance on vaccine preventable infectious diseases ('EUVAC.NET') or invasive bacterial infections ('EU-IBIS') (Ammon, 2005, Reintjes, 2008, Ammon and Faensen, 2009, Liverani et al., 2012). In the following years, further legislation defined the scope of the activities of the networks under Decision 2119/98/EC more precisely. In particular, the Commission and the Network Committee updated definitions of key terms (European Commission, 2003e, 2007a), the lists of diseases to be progressively covered by the network (European Commission, 2003d, 2007a, 2009c, 2009b, 2012b) and agreed on (new) case definitions for individual diseases (European Commission, 2003e, 2008e, 2009f, 2009d, 2012c).

Epidemiological surveillance, however, constituted only one pillar of the Community Network which was complemented by a second pillar, the 'Early Warning and Response System' (EWRS) (European Commission, 2000k). EWRS was designed as a web-based, confidential telematics notification system with the aim to immediately circulate important information on specified events and outbreaks of Community relevance to accredited EWRS contact points (European Commission, 2000k). Its general

aim was to disseminate alerts „with a potential impact on the EU, share information, and coordinate their response" (European Commission, 2015) and allow for "immediate exchange of views on risk assessment and risk management crucial for timely public health action" (European Commission, 2003f). Member States were required to report outbreaks of defined notifiable diseases and related intervention measures, but also "any other as yet unclassified serious epidemic disease" (European Parliament and Council, 1998: Annex). Hence, the system was also meant to cover unknown pathogens, not on the list of communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC. This circumstance proved to be of particular value during the SARS crisis (see chapter 6.2). The legislation on the EWRS was also updated several times over the following years (European Commission, 2008d, 2009a).[65]

3.3.4. The Innovations of the Amsterdam Treaty and Structural Adaptations

The set-up of a framework for action in the field of public health that included a strand on communicable diseases, the establishment of the training programme EPIET and of the bulletin Eurosurveillance, the creation of numerous project-based *ad hoc* networks for the surveillance of specific diseases as well as the formalisation and integration of these networks in an overarching 'network of networks' combined with an early warning and response system belonged to the major developments in infectious disease control at the European level in the 1990s.

Beyond that, also a development in the EU's primary law influenced the Community's setup in health matters and fields related to infectious disease control when the Member States of the EU decided on a revision of the Maastricht Treaty in 1997. The Amsterdam version of the 'Treaty establishing the European Community', which entered into force in 1999, included a general extension of the Community's mandate in health affairs. The new Treaty Article on public health (re-numbered 152) foresaw that action should aim at "improving public health, preventing human illness and diseases, and obviating sources of danger to human health "by fighting" against the major health scourges, promoting research into their causes, their transmission and their prevention, as well as health information and education" (Art. 152 (1)). In contrast to the Maastricht Treaty, which only permitted Community action, the Amsterdam Treaty explicitly called for EU legislation on high standards of safety of organs and substances of human origin, blood and blood derivatives. Crucially, it shifted the veterinary and phytosanitary chapters for the protection of human health from the title on the common agricultural policy to public health. This step was of particular relevance for the control of food-borne infectious diseases at the EU level.

By doing so public health and consumer protection were no longer secondary effects of the Single Market; instead, their attainment was to be ensured in the definition and implementation of all Community policies and activities (Art. 152 (1)). The Amsterdam amendments thus established health and consumer protection as independent EU policy objectives (Vos, 2000, Coleman, 2004: 7,

[65] For further information on the EWRS, see Guglielmetti et al. (2006) and European Commission (2005f, 2007d, 2009g).

Krapohl and Zurek, 2006). The adoption of the Treaty of Nice in 2001 did not imply substantial revisions with an impact on the EU's setup for infectious disease control. Therefore, the provisions of the Amsterdam Treaty remained in force until they were replaced by the innovations of the Treaties of Lisbon in 2009 (see chapter 3.5.2). Against this background, the Treaty of Nice is not further discussed in the following.

In line with the stronger connection of public health with questions related to veterinary policy and consumer protection also the Commission underwent a re-orientation in health matters. It established a new Directorate-General XXIV for Consumer Policy and Health Protection (Vos, 1999, 2000) which was re-named DG SANCO in the course of the installation of the new Commission under Romano Prodi. Crucially, together with the foodstuff-related competencies the new DG also received the dossier for food-borne infectious diseases. Even if the portfolios for health and consumer protection did not remain under the responsibility of one Directorate General in all of the following Commission configurations, the resorts of public health and food safety remained intertwined since this reform.

3.4. The Years from 2001 to 2007

3.4.1. The First Programme of Community Action in the Field of Public Health

The transition from the first (1993-2000) into the second phase (2001 to 2007) in the evolution of the EU's infectious disease control was initiated by the Commission's attempt to update the guiding communication on public health of 1993 (European Commission, 1993, 1999h). The Commission presented a 'Health Strategy of the European Community' (European Commission, 2000j) which identified new public health priorities. The comprehensive strategy identified various activities in the public health field with infectious disease control as one of the major foci (European Commission, 2000j: 3). It described new risks to health, in particular the resurgence of major infectious diseases and the emergence of new diseases, such as new variant Creutzfeldt-Jakob Disease, as serious health problems (European Commission, 2000j: 7) and proposed to strengthen the surveillance and control of communicable diseases (European Commission, 2000j: 12). Crucially, the strategy was presented along with the proposal for a 'Programme of Community Action in the Field of Public Health'.

The new programme had been designed in 1999 and 2000, but it was not adopted before the year 2002 (European Parliament and Council, 2002c). Constituting the first overarching EU health programme it was meant to better respond to the new legal basis provided by the Amsterdam Treaty. In contrast to the Community action plans from 1996 onwards, which had been a set of eight separate programmes, the new programme was one overall public health programme, split into annual work plans covering the years between 2003 and 2008. The budget was still relatively small, even after the increase to an indicative EUR 354 million in 2004 to accommodate the ten enlargement countries. However, in general terms it meant a substantial expansion compared to the group of previous programmes (European Commission, 2005g: 2, Oortwijn et al., 2007: 3).

Against this background the Commission decided to set up an executive agency, originally named 'Executive Agency for the public health programme (PHEA), in order to run the enlarged programme in technical and financial terms. The agency gradually took over the implantation from DG SANCO after 2005 and became fully operational in 2007 (European Commission, 2004a).[66]

The Decision of Parliament and Council setting up the public health programme followed the Commission's original proposal in large parts and confirmed three general objectives, namely improving information for the development of public health (health information), reacting rapidly to health threats (health threats) and tackling health determinants through health promotion and disease prevention (health determinants) (European Parliament and Council, 2002c: Preamble (6), Art. 1, 2 (a –c)). The priority dealing with "threats to public health of a cross-border nature" explicitly included aspects related to "infectious diseases, environmental pollution or food contamination" (European Parliament and Council, 2002c: Preamble (22)). By doing so the programme also integrated priorities of the European Council which had identified the need to address threats to health, in particular related to the "safety and quality of food, use of chemicals and issues related to outbreaks of infectious diseases and resistance to antibiotics" (European Council, 2001b: 7). Also the former HIV/AIDS and communicable disease networks, activities, and projects became part of the new programme (Steffen, 2012: 1072).

At the same time, the programme also comprised new elements that had not been part of the original considerations. In particular, new elements were added in the field of rapid response to health threats, which also extended to emergency situations "relating to terrorist acts" (European Parliament and Council, 2002c: Annex 2.4). The inclusion of responses to the threat of terrorism in the EU's public health programme occurred under the impression of the terror events on September 11, 2001 and the following anthrax scare in the US (Hervey and McHale, 2004: 82). In this vein the new health programme foresaw *inter alia* activities to "react to unforeseen events" (European Parliament and Council, 2002c: Art. 3 (a)). Consequently, concerns about the use of infectious diseases in the context of terrorism also fed into the annual work plans for the implementation of the public health programme. To illustrate, the work plan for 2003 stated that "[a]ctivities regarding countering the threat of deliberate release of biological and chemical agents will be undertaken in tandem with on-going activities on communicable diseases" (European Commission, 2003i: 29).

3.4.2. The 'Health Security' Agenda

Integrating activities against bioterrorism into the public health programme was not the only change that occurred in the period after the 9/11 incidences. In a declaration following the attacks the European Council in Ghent examined the "threats of the use of biological and chemical means in terrorist operations" and called "for adapted responses on the part of each Member State and of the

[66] The agency was renamed two times in the following years, first as Executive Agency for Health and Consumers (EAHC) for the period from 2008 to 2013, and as Consumer, Health, Agriculture and Food Executive Agency (CHAFEA) since 2014.

European Union as a whole" (European Council, 2001a: 9). The Council and the Commission responded by creating a 'Health Security Committee' (HSC) as an informal cooperation and coordination forum. It was meant to serve the representatives of Member States' health ministries and the Commission as a forum to discuss common health threats from acts of terrorism, share information on preparedness and response plans and review crisis management strategies that include, for instance, different actors from the health sector and the policy, but also aspects related to public transport (European Commission, 2003l: 8f, 23, Council, 2007a: 26f, Schreck et al., 2009: 154). Its mandate was originally of temporal nature but was prolonged (European Commission, 2006b, Council, 2007a) until the body became eventually formalised in 2013 (see chapter 3.5.3.1). The informal body did not generate a lot of public output until 2009, when the full health security framework was outlined in a comprehensive way (European Commission, 2009e). In the meantime, however, the HSC's mandate was extended over the years by working on pandemic influenza and generic preparedness and response planning as well as on public health emergencies (European Commission, 2010c, Martin and Conseil, 2012: 1105).[67]

Beyond the creation of the HSC the infectious disease control at the EU level further developed in the course of the bioterrorism debate. HSC and Commission agreed on the so called 'Health Security Programme' (European Commission, 2001e) with the aim to improve cooperation between the different national authorities involved in public health preparedness for bioterrorism, partly funded from the EU's public health programme. In addition, the Commission set up an *ad hoc* task force on deliberate release of chemicals and biological agents that consisted of seconded experts from Member States under the guidance of a Health Security Committee with the major goal to implement the health security programme (European Commission, 2003b: 10, Tegnell et al., 2003). Furthermore, the Commission installed a crisis room and communication centre facility as well as the rapid alert system for biological and chemical attacks RAS-BICHAT. The latter was set up on the basis of the existing communicable diseases network to fulfil, although with a different focus and primarily targeted to inform the members of the HSC, a purpose similar to the Early Warning and Response System EWRS (Schreck et al., 2009: 154). Finally, an update of the list of diseases to be covered by the Communicable Disease Network (CDN) included *inter alia* anthrax and smallpox, two diseases that had figured prominently in the debate about potential bio-threats (European Commission, 2003d).

In the following, further re-structuration also occurred within the Commission, most notably when the 'Task Force on Bioterrorism' was linked with the former 'Unit on Communicable, Rare and Emerging Diseases' by establishing a 'Health Threats Unit' within DG SANCO in 2003 (Athanassoudis et al., 2006). The new unit took over the risk management functions of the Commission in the respective fields, in particular by coordinating the activities of the national health authorities in response to a given health threat. In 2005, the Commission furthermore installed a general rapid alert system called ARGUS as an information platform internal to the Commission with the aim to link all specialised systems for emergencies with a 'Central Crisis Centre' (CCC) in the case of an emerging

[67] On the EU's health security framework after 2008 see chapter 3.5.3.

multi-sectoral crisis (European Commission, 2005a). Finally, a further advancement of these structures was the creation of the 'Health Emergency Operations Facility' (HEOF) which was created as a part of DG SANCO's overall coordination infrastructure for emergency management and the central hub to partners, from other DGs to national health ministries and the HSC, from the EWRS and other alert systems, from the WHO to relevant EU agencies (European Commission, 2007e: 4f).

ARGUS, CCC and HEOF belong to the area of generic preparedness planning for public health emergencies in which infectious diseases can play a central role. In fact, the Commission considered public health emergencies to be "dominated primarily by events related to pathogens transmitted from person to person or through unsafe food or products" (European Commission, 2005b: 4). In the field of generic preparedness the EU developed a comprehensive framework for preparedness cooperation in the EU that focused on the review of national preparedness plans and their interoperability (European Commission, 2005b), including technical guidance files (European Commission, 2005c), and eventually led to an EU 'Strategy on Generic Preparedness' (European Commission, 2011c).

Besides generic preparedness planning in preparation for different types of health threats, special emphasis was put on pandemic influenza preparedness and response planning, for which key actions were established in the fields of "management and coordination, surveillance, prevention, mitigation and response, communication, civil protection and research", including health legislation to control influenza in animals (European Commission, 2004h: 3, revised in 2005 European Commission, 2005d). By doing so EU Member States could considerably strengthen their preparedness against pandemic influenza by developing respective plans (Mounier-Jack and Coker, 2006a, Mounier-Jack and Coker, 2006b).

3.4.3. The Creation of Specialised EU Agencies – EFSA and ECDC

It becomes clear that the health security programme and the preparedness planning were pursued with high priority since 2002 at the EU level, complemented by efforts at the international level (Coleman, 2004: 8, European Council, 2004a).[68] These infrastructural adaptations and shifts in policy priorities occurred in parallel to the build-up of new agencies in the EU's setup to control infectious diseases: the creation of a European Food Safety Authority (EFSA) on the one hand, and the creation of the European Centre for Disease Prevention and Control (ECDC) on the other.[69]

[68] At the international level the revision of the International Health Regulations (IHR) and the Global Health Security Initiative (GHSI) were of major importance. The IHR is an international treaty for the coordination of all health emergencies. It was revised in 2005 (see also foot note 8 and chapter 6.3.3). GHSI was formed in reaction to the incidences of September 11, 2001. Originally envisaged as "an informal group of like-minded countries to address health issues of the day", the GHSI Ministerial Form today comprises members from G7+ countries and the European Commission to regularly discuss concerted action to combat the threats of international biological, chemical and radio-nuclear terrorism as well as pandemic influenza (GHSI, 2015).

[69] As mentioned before, in addition an Executive Agency for the Public Health Programme (PHEA) was established to manage the programme (see chapter 3.4.1). As an executive agency, however, PHEA was rather a by-product of the establishment of the Public Health Programme and therefore did not alter the EU's infectious disease control setup on its own right.

Strictly speaking, EFSA and ECDC were not the first EU agencies to become active in the field of infectious disease control. The 'agencification' process had begun earlier with the creation of the European Environment Agency (EEA) in 1990 (Council, 1990b), the establishment of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (Council, 1993c) and the setup of the European Agency for the Evaluation of Medicinal Products (EMEA) in 1993 (Council, 1993a), later renamed European Medicines Agency (EMA). Whereas the relevance of the EEA for infectious disease control is due to its competence to deal with climate change as well as air- or water-borne pollutants, the relevance of EMCDDA is grounded in its expertise regarding drug-related infectious diseases. EMEA/EMA, in turn, has a central role in the centralised procedure for market authorisation of pharmaceuticals (Hervey, 2012: 984). Hence, all agencies were not established to specifically engage with infectious disease control, but given their overarching functions their work nevertheless contributes to the EU response to infectious disease. In this vein, the EMEA was, for instance, involved in the actions of the 2001 Health Security Programme, in particular in the evaluation of existing stocks and production capacities, as well as instruments allowing the development of medicines for the biological and chemical agents (European Commission, 2001e: 3f).

In contrast to the overarching mandates of EEA, EMCDDA and EMEA/EMA, the European Food Safety Authority (EFSA) was specifically designed to work in the realm of food safety and foodstuff regulation. The regulation of foodstuff and agriculture policy in general is an important dimension in infectious disease control since animal products can serve as a vector for food-borne pathogens that cause disease (Paarlberg, 2010: 155). The creation of the new agency in 2002 went along with new general principles and requirements of food law as well as new procedures in matters of food safety (European Parliament and Council, 2002a). As regards the latter, in particular the revision of a rapid alert system for food and feed (RASFF) belonged to the major innovations. EFSA became operative in 2003 and was dedicated to provide independent scientific advice and scientific and technical support – on request or on own initiative – that should "serve as the scientific basis for the drafting and adoption of Community measures" (European Parliament and Council, 2002a: Art. 22.6, Art. 23). Additionally, the agency communicates on risks and provides information on all matters within the fields that have a direct or indirect impact on food and feed safety (European Parliament and Council, 2002a: Art. 22.2).

The establishment of EFSA as one of the best embedded and most powerful of the EU agencies (Vos and Wendler, 2006) occurred in the context of a general revision of the foodstuff and veterinary sector in the course of a series of food scandals, in particular the 'mad cow' disease. In this context further substantial modifications occurred, such as the reinforcement of the European Commission's Food and Veterinary Office (FVO), the abolishment of a complex foodstuff committee system in favour of EFSA, as well as the adoption of harmonised rules on the prevention, control and eradication of certain transmissible spongiform encephalopathies including (variant) Creutzfeldt–Jakob Disease. As mentioned before, the above listed revisions of the food safety sector will be subject to detailed analysis in chapter 5.

The Regulation on the European Centre for Disease Prevention and Control was adopted by the European Parliament and the Council in April 2004 (European Parliament and Council, 2004a) and although it took up the work even earlier, the agency was officially established in 2005 (Wigzell, 2005, Guglielmetti et al., 2006, Ammon and Faensen, 2009: 178). The founding Regulation defined ECDC's mission to "identify, assess and communicate current and emerging threats to human health from communicable diseases" (European Parliament and Council, 2004a: 1). In particular, the Centre was commissioned to act on its own initiative in the case of "outbreaks of illness of unknown origin, which may spread within or to the Community" (European Parliament and Council, 2004a: 1). In order to perform these tasks, the ECDC gathers scientific and technical data, provide scientific opinions and assistance to EU and international institutions, coordinate the European networking of bodies and exchange information, expertise and best practices to facilitate the development and implementation of joint actions (European Parliament and Council, 2004a: Art. 3 (2a-e)).

In contrast to the previous system, in which various initiatives of national authorities or research centres had been supported by the Commission, the ECDC provided a new centralised hub for these activities. The creation of the ECDC thus meant a clear step of centralisation at the EU level (Liverani et al., 2012) due to the integration of existing network structures for the surveillance of specific diseases into the new agency and due to the perpetuation of their funding (Reintjes, 2008: 148, Ammon and Faensen, 2009: 178). The Centre, however, did neither receive a legislative nor a direct regulative mandate. It was primarily designed as a capacity of risk assessment, whose advice has no legally binding power so that the responsibility for the adoption and implementation of protective measures stayed with the Member States, coordinated by the 'Health Threats Unit' of DG SANCO (Liverani et al., 2012: 576). As explained before, as one of the most important systemic changes in the structures to control infectious disease at the EU level, creation and mission of the ECDC will be discussed in more detail in the second case study (chapter 6).

3.5. The Years from 2008 to 2014

3.5.1. The Second Programme of Community Action in the Field of Public Health

The transition from the second (2001-2007) to the third phase (2008-2013) of EU infectious disease control was initiated by the Commission's White Paper 'Together for Health' (European Commission, 2007b) which developed a new strategic approach to the EU's health policy for the EU on the basis of a consultation procedure. Together with the accompanying Staff Working Document (European Commission, 2007c) the White Paper set out three strategic fields of activity: demographic change, health threats and new technologies, of which in particular the second one was related to the field of infectious disease control. In this context "pandemics, major physical and biological incidents and bioterrorism" were identified as the major (potential) threats to health (European Commission, 2007b: 3). Furthermore, a series of principle for actions were established, including the ideas to strengthen the EU's voice in global health and to integrate 'Health in All Policies (HIAP)'. Together, these concepts reflected the interdependence of actors and the intersectoral nature of public health

policy, thereby placing communicable disease patterns in relation to external policies such as climate change, humanitarian aid and development policy.

The key instrument to finance related activities was the 'Second Programme of Community Action in the Field of Health (PHP2)', with an indicative budget of EUR 365.6 million for the years from 2008 to 2013 (European Parliament and Council, 2007: Art. 3).[70] Although the objectives remained similar to the first public health programme, the PHP2 applied a less specific focus to follow broader aims, in particular to generate and disseminate health information and knowledge (health information), to improve citizens' health security (health security) and to promote health, including the reduction of health inequalities (health promotion) (European Parliament and Council, 2007, Steffen, 2012: 1072).

The largest share of funding for infectious disease-related activities came from the 'health security' strand of the programme with activities that penetrated a wide spectrum, ranging from "strategies and mechanisms for preventing [and] responding to health threats from communicable and non-communicable diseases and health threats from physical, chemical or biological sources, including deliberate release acts [to] the development of prevention, vaccination and immunisation policies" (European Parliament and Council, 2007: Annex). The programme also served to implement a list of priorities of the Health Security Committee that had agreed to focus on preparedness and response to health threats from CBRN acts of terrorism, generic preparedness for health emergencies as well as influenza preparedness and response (European Commission, 2008b: Annex 1, 3.2.1.1, see also European Commission, 2008c). In this way, numerous projects on different aspects of infectious disease control were realised, for instance dealing with the lessons learnt from recent influenza pandemics or setting up a European Network for Highly Infectious Diseases (European Commission, 2011b, 2012a).

3.5.2. The Innovations of the Lisbon Treaty

Only one month after the second public health programme was adopted, the heads of state or government of the European Union put their signatures under a fundamental revision of the EU's primary law during their meeting in Lisbon in December 2007. The Lisbon Treaties entered into force in 2009 and implied substantial changes for the EU's setup to control infectious diseases; not only in the public health realm but also in other related fields. In particular, the 'Treaty on the Functioning of the European Union' (TFEU) comprised a number of elements that fall into the category of 'health security', including a solidarity clause and the legal basis for EU disaster management and civil protection.

[70] Article 3 specified an amount of EUR 321.5 million. The total indicative budget, however, added up to EUR 365.6 million, a part of which was dedicated to the year 2007. The programme was originally meant to cover the period between 2007 and 2013 but the starting year had to be postponed to 2008 due to delays in the legislative procedure (European Parliament and Council, 2007: Annexed Commission Declaration). For more information on the budget of the Public Health Programme see European Court of Auditors (2009).

The solidarity clause was an innovation that introduced the principle that "[t]he Union and its Member States shall act jointly in a spirit of solidarity if a Member State is the object of a terrorist attack or the victim of a natural or man-made disaster [and] mobilise all the instruments at its disposal" (Art. 222). Similarly, the Treaty article on civil protection provided that Union action shall aim to "support and complement Member States' action at national, regional and local level in risk prevention, in preparing their civil-protection personnel and in responding to natural or man- made disasters within the Union" (Art. 196). Furthermore, Member State "in difficulties or […] seriously threatened with severe difficulties caused by natural disasters or exceptional occurrences beyond its control" could also receive financial assistance (Art. 122), just as third countries could receive assistance in the form of operations "intended to provide ad hoc assistance and relief and protection for people […] who are victims of natural or man-made disasters" (Art. 214).

Whereas these provisions implicitly included the mission to respond to infectious diseases due to the overarching objective to respond to "natural or man-made disasters", the new and re-numbered public health article, Article 168 of the TFEU, comprised also direct modifications. More precisely, by introducing a paragraph on "early warning of and combating serious cross-border threats to health" the Treaty provided a new legal mandate for action in particular in infectious disease affairs; excluding any harmonisation of the laws and regulations of the Member States. Whereas in the Nice Treaty "combat[ting] the major cross-border health scourges" had not been subject to more than vague and soft 'incentive measures', the revised formulations clearly reinforced the Union's mandate for infectious disease control as one of the serious cross-border threats by defining the latter as primary subjects of Union actions in the field of public health to complement national policies.

The Intergovernmental Conference (IGC) that resulted in the adoption of the Lisbon Treaties finished its work in 2007. It is, however, important to note that the revision of the Treaty had started already in 2001 following the 'Laeken Declaration' (European Council, 2001d). The Convention on the Future of Europe concluded its work in 2003 (European Convention, 2003b), on the basis of which the 'Treaty Establishing a Constitution for Europe' was drafted and finally signed in October 2004. Although the ratification process was stopped so that the Constitutional Treaty did not enter into force, it nevertheless comprised central innovations which later became part of the Lisbon Treaties. With the entry into force of the Lisbon Treaties on December 1, 2009, the new legal basis served as the new main point of reference for the following developments in infectious disease control. A complete overview of the change of the article on public health between the Maastricht Treaty and the TFEU is provided in Annex 1; the revision of the public health article in the Constitutional Treaty also dealt with in more detail in the second case study (chapter 6).

3.5.3. The Broadened 'Health Security', 'Global Health' and 'Civil Protection' Agenda

In line with the updated public health article of the Lisbon Treaty as well as the renewed health strategy and the public health programme, 'health security' remained a central point of orientation for the EU's infectious disease policies also in the years after 2008. Member States agreed that in addition to the established structures and initiatives improved coordination was necessary to public

health alerts and cross-border threats "by taking better account of communication issues, operational aspects, interoperability and the intersectoral dimension" (Council, 2008: 2). On this basis a series of initiatives was launched which shared the importance assigned to the multi-sectoral coherence between different policies, both internally and externally. Such a broadened focus on health security and infectious disease control had already been part of the 'Together for Health' strategy, which did not only stress the general intersectoriality of health but also that "in our globalised world it is hard to separate national or EU-wide actions from global policy" (European Commission, 2007b: 6).

The new approach was further developed in the Commission's strategy paper 'Health Security in the European Union and Internationally' (European Commission, 2009e) which took up the Council's considerations on health security (Council, 2008) and influenza (Council, 2009) as well as recent developments at the international level.[71] In this way the Commission prepared a strategic framework for health security by combining (global) efforts in health-related fields ranging from bioterrorism (Council, 2007b) to disaster management (European Commission, 2008a). An important feature of the strategy was to go beyond the narrow connection between infectious diseases and classic security concerns, such as CBRN agents, by adding a stronger emphasis to related fields such as disaster management or the 'one health' approach.[72]

Increased resilience to crises and disasters was also part of the 'Internal Security Strategy' (ISS) which was adopted in 2010 (Council, 2010b, European Commission, 2010b). By identifying "hostile or accidental releases of disease agents and pathogens, sudden flu outbreaks and failures in infrastructure" as cross-sectoral threats that required long-standing crisis and disaster management, the prevention, preparedness, assessment and management of infectious diseases outbreaks became part of the EU's 'all hazard approach' which covered in principle all natural and man-made disasters (European Commission, 2010b: 13f). On this basis the EU's setup for infectious diseases control underwent fundamental changes that went along with a stronger embeddedness into new contexts such as development policy, health diplomacy or disaster management. In particular, the EU aimed to implement its new priorities

(1) by revising the legislative basis on serious cross-border threats to health, including the launch of a joint procurement procedure to procure medical countermeasures,

(2) by modifying the coordination structures for civil protection both within as well as outside the EU, as well as by

(3) by developing a distinct agenda for the EU's role in global health.

[71] Input from the international level came in form of the revision of the International Health Regulations (IHR), (see foot note 68) and the WHO's Annual Report 2007 in which the concept of global health security was advocated (WHO, 2007).

[72] 'One Health' is an interdisciplinary „collaborative and all-encompassing way to address, when relevant, animal and public health globally". World Organisation for Animal Health (OIE): http://www.oie.int/for-the-media/onehealth/. See also http://www.oneworldonehealth.org/ (accessed 17.04.2015).

3.5.3.1. The Framework for Serious Cross-Border Threats and Joint Procurement

On the basis of the reinforced legal basis of the TFEU, the White Paper on Health, the Internal Security Strategy, a consultation procedure and a set of impact assessments the Commission proposed to streamline and strengthen the EU capacities for responding to serious cross-border health threats (European Commission, 2011d, 2011a). The new framework was adopted under Decision 1082/2013/EU and repealed the long-standing legal basis of Decision 2119/98/EC for the epidemiological surveillance and control of communicable diseases, which had turned outdated in some respects, for instance with regard to the ECDC.

The new legal basis extended preparedness and response planning, risk monitoring and assessment, risk management and risk and crisis communication to basically all threats other than those associated with radio nuclear events. In fact, the new framework was extended to cover also new threats such as biological agents responsible for non-communicable diseases and threats of chemical, environmental, or unknown origin. In other words, whereas the setup of 1998 was focused on communicable diseases, the new framework included all serious cross- border threats to health regardless of their origin. In this way also the existing surveillance structures for communicable diseases, such as the ECDC operated EWRS, were expanded to cover serious cross-border threats to health on a generalised basis (European Parliament and Council, 2013a).

Beyond the general expansion of the scope of activities the revised framework on cross-border threats also included a formalisation of the Health Security Committee (HSC), a revised preparedness and response planning as well as a legal footing for the development and implementation of the joint procurement of medical countermeasures. As regards the HSC, Decision 1082/2013/EU provided the existing forum for representatives of Member States' health authorities and the Commission with a legal basis. Since its creation in 2001, the HSC had been an informal advisory and coordination group that operated under a transitionally prolonged mandate (Council, 2007a). Despite its originally limited agenda in the area of bioterrorism it had expanded the activities over the years to other fields and thus developed into one of the decisive institutions for the overall coordination of public health risk assessment and the management of serious cross-border threats to health (European Commission, 2009e). However, participation in the HSC was voluntary and the body lacked cross-sectoral interlinkage in its decision-making processes (European Commission, 2011d: 6).

The new framework placed the HSC in a central position to be able to communicate and advise quickly and coherently in a public health emergency on the coordination of national responses as well as on communication messages to the public and healthcare professionals. The task of the HSC was also defined to coordinate in liaison with the Commission the national preparedness and response planning. Despite the important and formalised role of the HSC, the new regulation did not place the HSC in the legislative centre for risk management in the EU. Instead, implementing acts in the case of an emergency situation remained the business of the Commission, whose respective decisions were made contingent upon the approval of a regulatory committee, the 'committee on serious cross-border threats'. The latter thus took over the functions which had been performed so far by the CDNC under Decision 2119/98/EC (European Parliament and Council, 2013a: Art. 18).

As for preparedness and response planning, the new framework foresaw the coordination of "national planning and between key sectors such as transport, energy and civil protection" (European Parliament and Council, 2013a: 2). Crucially, Regulation 1082/20137EU provided the legal basis for a joint procurement mechanism[73] for medical countermeasures[74], such as vaccines and antiviral medication, designed to enable Member State to jointly acquire products or develop approaches to contract negotiations with the pharmaceutical industry. An initiative of the Commission for the creation of a European stockpile of antivirals to be distributed at the regional level in the event of pandemic influenza had failed in 2006 (European Commission, 2006a). In 2010, however, the Council mandated the Commission to start the preparation of the joint procurement of vaccines as one of the lessons learned from the 2009 A/H1N1 pandemic (Council, 2010c, 2010d) which was then taken up in the new Regulation on cross-border threats. This form of harmonisation of pandemic disease policy, on a voluntary basis, has recently progressed rapidly, illustrated by the fact that by 2015 at least 20 countries had already signed the Joint Procurement Agreement (European Commission, 2014b).[75]

3.5.3.2. Health Emergencies and Disaster Management

In 2010, departing from the Internal Security Strategy's definition of "hostile or accidental releases of disease agents and pathogens, sudden flu outbreaks and failures in infrastructure" as cross-sectoral threats that required long-standing crisis and disaster management, the prevention, preparedness, assessment and management of infectious diseases outbreaks became part of the EU's 'all hazard approach' which covered in principle all natural and man-made disasters (European Commission, 2010b: 13f). In this context the ISS served also as the starting point for a general revision of the EU's emergency response system which developed in 2013 and 2014. More precisely, a new 'Union Civil Protection Mechanism' with a new 'Emergency Response Coordination Centre' (ERCC) as its operational heart was established within the Commission's Directorate General for Humanitarian Aid and Civil Protection department (ECHO).

Its aims were defined to improve the joint planning and response coordination across the EU, to circulate information and complement the response capabilities of countries affected by any disaster that "causes or is capable of causing trans-boundary effects or is capable of affecting other Member States" (European Parliament and Council, 2013b, European Commission, 2014c). The envisaged

[73] "'Joint procurement' means combined purchasing of goods by two or more contracting authorities, so that only one tender is published on behalf of them all" (European Commission, 2013).

[74] The term 'medical countermeasures' refers to "all potential medicines, medical devices, other services and goods that could be used to mitigate/treat a life threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads, or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection" (European Commission, 2014a: 4).

[75] The Joint Procurement Agreement precedes the Joint Procurement Procedure which is a still ongoing process at the time of writing. For further information see http://ec.europa.eu/health/preparedness_response/joint_procurement/index_en.htm (accessed 22.03.2015).

protection also included “acute health emergencies, occurring inside or outside the Union”, and thus, extended to infectious disease control in the EU. The creation of the new mechanism went along with the setup of a Common Emergency Communication and Information System (CECIS), a voluntary pool of pre-committed response capacities of the Member States labelled European Emergency Response Capacity (EERC) (European Parliament and Council, 2013b: Art. 11) and a financial envelope for the period 2014-2020 of EUR 370 million (European Parliament and Council, 2013b: Art. 19).

3.5.3.3. The EU’s Role in Global Health

Finally, for the years after 2010 a widening of the EU’s perspective to the control of infectious disease control can be observed, most visible in the Commission’s approach to the ‘EU’s Role in Global Health’ in 2010 (European Commission, 2010a). Community support, activities and joint programmes for and with developing countries had extended to infectious disease since many years, in particular in the framework of the WHO’s International Health Regulations and the United Nation’s Millennium Development Goals (MDG)[76] to respond to HIV/AIDS, malaria, tuberculosis and other major diseases (Council, 1997b, European Parliament and Council, 2002b, European Commission, 2005e, European Council, 2007: Annex). Still, the Commission’s communication on global health was the first overarching attempt to define the EU’s envisaged multi-sectoral contribution to the “worldwide improvement of health, reduction of disparities, and protection against global health threats” (European Commission, 2010a: 2). It included the sustained support for the MDGs, but added further elements such as “fair financing mechanisms” and the allocation to health of development countries’ national budgets (European Commission, 2010a: 7).

Despite the strengthened perspective on infectious disease control also in relation to development policy and humanitarian aid, the global health approach also put “communicable diseases such as HIV/AIDS, SARS, Avian Influenza, Influenza A (H1N1), zoonoses [and] food poisoning” in the context of peace building strategies, the growth of trade and migration and capacity building to fulfil early warning obligations (European Commission, 2010d: 17f). Crucially, as a constituent element of the external health policies the contribution to the global fight against infectious diseases was also seen of “importance for alliances, for reputation and for trade issues” (European Commission, 2010d: 24). In this understanding the EU’s infectious disease policies became part of a form of ‘health diplomacy’, a concept that refers to the cooperation in health matters as a tool for achieving foreign policy goals. In line with this understanding, the Commission declared that the EU’s global health activities could not only turn the EU into “a more trusted, more efficient and more powerful global player in the field of health”, they could also help achieve overarching goals such as “increased visibility, competence, credibility and effectiveness” (European Commission, 2010d: 28).

[76] In 2000, the Member States of the United Nations Organisation agreed on eight so called Millennium Development Goals (MDG) to foster progress in addressing poverty, hunger, disease, illiteracy, environmental degradation and discrimination against women. MDG No. 6 deals with HIV/AIDS, malaria and other diseases with the aim to have halted the spread of HIV/AIDS, malaria and other major diseases and begun to reverse it by 2015 (UNO, 2000).

3.6. Conclusions

Infectious diseases threaten human health since the beginning of mankind. Diseases have also been influential factors for the political order and the social life throughout history. Systematic measures to control diseases date back to the bubonic plague in the 14th century (Hoffman, 2010). Collaboration in the framework of the European Union was pioneered on the regional level by international conferences, treaties, and institutions such as the WHO Regional Office for Europe. For the European Community, a direct link to the idea of health protection can be traced back to the time of the European Economic Community. From the 1980s onwards the European Community progressively advanced into the field of infectious disease control. After the introduction of a clear reference to public health in the Maastricht Treaty in 1993, a complex coordination system for the surveillance of, preparedness for and response to infectious diseases developed at the EU level. As we have seen, this evolution occurred in basically three phases.

In the initial phase infectious disease control at the EU level between 1993 and the year 2000 was characterised by the transition from cooperation outside the framework of the Community Treaties into official Community activities after the entry into force of the Maastricht Treaty. The striking features of this period were the establishment of networks, primarily in the field of disease surveillance and collaboration in research and information management. In addition, the first phase provided for a strengthening of the weak public health mandate following the adoption of the Amsterdam Treaty, with effects on the joint response to infectious diseases, not least in the field of food-borne pathogens. In this way, the period meant a formalisation of mutual obligations to exchange information and to collaborate in specific aspects of infectious disease matters (Schreck et al., 2009: 149).

In the second period of infectious disease control at the EU level between 2001 and 2007 was characterised by the consolidation and institutionalisation of the early structures. The public health programme became a sustained part of the EU's infectious disease policy, supported by an executive agency to run the programme. The period after 2001 was also the phase of the appearance and growing importance of the concept of 'health security'. The notion appeared first in the context of the terror attacks of September 11, 2001, and proved to become a pivotal point of reference for the following years. The major innovations of the second period, however, were the creation of EFSA and ECDC along with the implied centralisation and structural changes at the EU level, in particular in the area of disease surveillance, risk assessment and scientific advice. Establishing these new key players in their respective fields of competence also meant a substantial step toward the permanent establishment of infectious disease policy at the EU level as a whole.

Finally, the third phase from 2008 onwards was characterised by the integration of infectious disease control into a combined 'health in all policies' and 'all-hazard' approach which aimed at including more threats and at stronger combining not only the instruments of different EU policies but also the EU with the global health level. Fuelled by the innovations of the TFEU, infectious disease control was thus further consolidated by incorporating dedicated structures into an overarching steering and coordination system, best illustrated by the Civil Protection Mechanism. Making infectious disease

control one of various natural or man-made cross-border threats to health did not mean a decrease in importance. Quite the contrary, the expansion of activities to further issues also implied that infectious disease control could build on more resources from different fields, ranging from public health programmes to disaster management. In the light of its important functions performed in the EU's response to the ebola outbreak in West Africa in 2014/2015, the EU Civil Protection Mechanism, supported by the Commission's Emergency Response and Coordination Centre (ERCC), is a case in point.

Given that surveillance, preparedness and response in the field of infectious disease control were pioneering innovations that prepared the ground for the combat of further threats at the EU level, the existing setup is comparatively advanced. 'Comparatively advanced' means that today the EU possesses a "solid architecture for disease monitoring and risk assessment, which can help national decision makers cope with the uncertainties of public health threats of international concern" (Liverani and Coker, 2012: 927). The primary responsibility for the protection against infectious diseases and health crises, however, lies with the Member States which are still in charge to individually report surveillance data and to implement the actions needed to control a given outbreak. Despite the coordination efforts at the EU level, Member States do not always work together in a coherent way. Great variation still exists among the EU Member States in national surveillance systems, the quality and comparability of data, vaccination management as well as national preparedness plans (ECDC, 2008, Reintjes, 2008: 145, Health Protection Agency and CRISMART, 2010, Liverani et al., 2012: 577, Reintjes, 2012: 958). Also the TFEU did not shift measures concerning monitoring, early warning of and combating serious cross-border threats to health to the areas of shared competences. Furthermore, the current legal basis also explicitly excludes, just as the Maastricht Treaty did since 1993, the harmonisation of the laws and regulations of the Member States in this field. Notably, the EU's role in disease control differs for specific diseases. Whereas the control of infectious diseases generally falls under the weak EU's public health mandate, exceptions exist for infectious disease control in the realms of veterinary and food safety policy, where the EU can make use of stronger financially backed regulatory measures linked to the Common Market.

It thus becomes clear that the existing structures at the EU level still have substantial room for development, best illustrated by the ongoing establishment of a Joint Procurement Procedure. With a view to the lack of a comprehensive public health infrastructure in the EU, some have even gone so far to label infectious disease control in the EU to be still in "its infancy" (Elliott et al., 2012: 936). As the third and ongoing programme in public health, which runs from 2014 to 2020, currently contributes to the further evolution of the EU's infectious disease setup (European Parliament and Council, 2014), it is far from certain that the next phase of the EU's polity and policy setup to control infectious diseases will be characterised by stability. Also the review process scheduled for 2015 to draw lessons from the handling of the ebola crisis in 2014/2015 might provide momentum for further steps. Hence, the need to add new elements to the list of key developments in the evolution of the EU's infectious disease control as provided in Table 3-1 (see next page) is almost as certain as death.

Table 3-1: List of Key Development in EU Infectious Disease Control (1993 - 2014)

Date (OJ)[77]	Author[78]	Reference[79]	Key Development
Doc. Number[80]			
12.02.1993	CO	(Council, 1993c)	Establishment of a European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
R 302/93			
24.08.1993	CO	(Council, 1993a)	Establishment of a European Agency for the Evaluation of Medicinal Products (EMEA) - renamed European Medicines Agency (EMA) by Regulation 726/2004 (European Parliament and Council, 2004b)
R 2309/93			
24.11.1993	COM	(European Commission, 1993)	Framework for Action in the Field of Public Health
COM(93) 559 final			
16.04.1996	EP+CO	(European Parliament and Council, 1996b)	Programme of Community Action on 'Prevention of AIDS and Certain Other Communicable Diseases'
D 647/96/EC			
30.04.1997	COM	(European Commission, 1997j)	Re-organisation of the Commission, foodstuff-related competencies moved to single directorate for consumer policy and health protection
COM(97) 183 final			
02.10. 1997	IGC	(Treaty of Amsterdam)	Extension of public health mandate; introduction of human health and consumer protection as an independent policy objective; competencies in the veterinary field added to public health field
Article 152			
03.10. 1998	EP+CO	(European Parliament and Council, 1998)	European Community Network for the Control and Surveillance of Communicable Diseases in Europe; incl. subsequent creation of Dedicated Surveillance Networks, list of diseases, case definitions etc.; establishment of 'Eurosurveillance' and 'EPIET'
D 2119/98/EC			
26.01.2000	COM	(European Commission, 2000k)	Early Warning and Response System (EWRS) for the Prevention and Control of Communicable Diseases Under D 2119/98/EC
D 2000/57/EC			
16.05.2000	COM	(European Commission, 2000j)	Health Strategy of the European Community
COM(2000) 285 final			
31.05.2001	EP+CO	(European Parliament and Council, 2001)	Harmonised EU Law on the Prevention, Control and Eradication of Certain Transmissible spongiform encephalopathies (TSEs)
R 999/2001			
17.12.2001	COM	(European Commission, 2001e)	Health Security Programme of Cooperation on Preparedness and Response to Biological and Chemical Agent Attacks, incl. establishment of the Health Security Committee and RAS-BICHAT
G/FS D(2001) GG			
01.02.2002	EP+CO	(European Parliament and Council, 2002a)	Establishment of European Food Safety Authority (EFSA), incl. new general principles and requirements of food law and procedures in matters of food safety, revision of Rapid alert system (RASFF) for the notification of a direct or indirect risk to human health deriving from food or feed
R 178/2002			
09.10.2002	EP+CO	(European Parliament and Council, 2002c)	First Programme of Community Action in the Field of Public Health (2003-2008)
D 1786/2002/EC			
30.04.2004	EP+CO	(European Parliament and Council, 2004a)	Establishment of European Centre for Disease Prevention and Control (ECDC) incl. the modification of the system of scientific advice and the perpetuated funding of previously *ad hoc*-financed networks
R 851/2004			
16.12.2004	IGC	(Treaty Establishing a Constitution for Europe)	Introduction of monitoring, early warning of and combating serious cross-border threats to health as field of EU action (supporting competence) // not ratified, but elements transferred to 'Lisbon Treaty' (TFEU)
Article III-278			
16.12.2004	COM	(European Commission, 2004a)	Establishment of Executive Agency for the public health programme (PHEA) – (re-named several times in the following; currently operating as Consumer, Health, Agriculture and Food Executive Agency (CHAFEA))
D 2004/858/EC			

(continued)

[77] Date of publication of the document in the European Union's Official Journal.

[78] Official author of the document using the following abbreviations: Commission (COM), Council of the European Union (CO), European Parliament (EP), European Council (EUCO), Intergovernmental Conference (IGC).

[79] Document specification as used in the 'List of References' of the present study.

[80] Official specification as provided in the document; 'D' means 'Decision', 'R' means 'Regulation'.

(continued)			
2005	COM	(European Commission, 2005a, 2005b, 2005d, 2011c)	Generic Preparedness and Influenza Pandemic Preparedness Planning, incl. Strategy for Generic Preparedness Planning, re-structuration within the Commission and establishment of health emergency capacities such as ARGUS and HEOF
COM(2005) 605 final COM(2005) 607 final COM(2005) 662 final			
20.11.2007	EP+CO	(European Parliament and Council, 2007)	Second Programme of Community Action in the Field of Public Health (2008-2013)
D 1350/2007/EC			
2007 - 2010	COM	(European Commission, 2007b, 2007c, 2009e, 2010b)	Health Strategy and Health Security Agenda in the EU and internationally, incl. elements from Internal Security Strategy (ISS)
COM(2007) 630 final SEC(2007) 1376 SEC(2009) 1622 final COM(2010) 673 final			
30.03.2010	IGC	(Treaty on the Functioning of the European Union, 2010b)	Introduction of monitoring, early warning of and combating serious cross-border threats to health as field of EU action (supporting competence)
Article 168			
2010	COM+CO	(Council, 2010a, European Commission, 2010a, 2010d)	Definition of the EU's Role in Global Health, emphasis on intersectoral linkage and external policies, elements of 'health diplomacy'
COM(2010) 128 final SEC(2010) 380 final Concl. 9505/10			
05.11.2013	EP+CO+ COM	(European Commission, 2011a, European Parliament and Council, 2013a)	Serious Cross-Border Threats to Health, incl. extension of EWRS, formalisation Health Security Committee (Repealing D No 2119/98/EC)
SEC(2011) 1519 final D 1082/2013/EU			
2013 - 2014	EP+CO+ COM	(European Parliament and Council, 2013b, European Commission, 2014c)	Development of Civil Protection Mechanism and creation of disaster management facilities covering health emergencies, e.g. Emergency Response Coordination Centre (ERCC)
D 1313/2013/EU D 2014/762/EU			
21.03.2014	EP+CO	(European Parliament and Council, 2014)	Third Programme for the Union's Action in the Field of Health (2014-2020)
R 282/2014			
2014	COM	(European Commission, 2014b, 2014a)	Joint Procurement Agreement / Procedure
in progress			

Source: Own presentation.

4. Selection, Features and Structure of the Case Studies

The previous sections have drawn a picture of the dynamic evolution of the EU's infectious disease control from the beginnings of public health policy in the EU until the most recent developments, with a focus on the last twenty years. It has not investigated into the reasons behind a given development, but could nevertheless confirm, on a general level, the relevance of the security perspective on infectious diseases and systemic change. Major outbreaks of lethal disease like cholera or influenza took the form of 'existential' security issues in Europe (Elbe, 2012: 81). Historically developed and still applied measures to control diseases, such as quarantine and ban,[81] go along with the curtailment of individual liberties and civil rights and, thus, easily meet the criteria of securitising 'extraordinary measures'. The link between security and infectious diseases is also visible in more recent developments, best illustrated by the prominent position of the notion of 'health security' in the infectious disease control infrastructure and activities at the EU level.

At the same time, the previous chapter has shown that infectious disease control developed also in economic contexts. The tension between the desire for trade and travel without barriers on the one hand, and the striving for protection from diseases on the other, is a theme that runs through all historical phases. Responses to infectious diseases, such as quarantine, can mean a severe obstacle to rapid movement of goods and people. In turn, the development of international health law and institutions also developed to prevent negative effects of disease outbreaks on international trade (Murphy, 1994). In this sense, the aim to "ensure the maximum security against the international spread of disease with the minimum interference with world traffic" (WHO, 1951: 5) is a principle that is stressed particularly in times of globalisation.

Against this background and given the EU's historically strong focus on the resolution of borders in favour of a Common Market, the EU is a particularly interesting case for the analysis of the securitisation of infectious diseases in view of related internationally concerted responses. It has, however, become clear that the development at the EU level, even with a focus on the period after 1993, is too rich and complex that it could be reasonably studied in detail in the framework of a single study, in particular not in combination with an in-depth analysis of the securitisation of infectious diseases.

The present study therefore proceeds with two case studies that deal with a set of selected key developments as identified in the previous chapter and assesses their adoption in more detail in the framework of a securitisation study of specific diseases. Following the basic understanding that securitisation often occurs in the context of a disease outbreak (Steffen, 2012: 1065f) and that institutionalisation in the EU has been crises-driven (Sauer, 2013), these case studies concentrate on:

[81] The key difference between ban and quarantine is the time period for which ill or potentially ill people were separated from the community. Whereas quarantine foresees as limited time period, ban refers to the permanent exclusion (Elbe, 2012: 83ff).

(1) The revision of the EU infrastructure for food-borne infectious diseases (1997), the legal basis in the field of public health as amended by the Amsterdam Treaty (1997), the adoption of harmonised EU law on 'transmissible spongiform encephalopathies' (TSEs) (2001) as well as the establishment of the 'European Food Safety Authority (EFSA)' (2002) in the context of the securitisation of bovine and transmissible spongiform encophalopathies (BSE/TSEs); and

(2) The update of the setup for the control of cross-border threats and communicable diseases by the Treaty Establishing a Constitution for Europe (2004)[82] and the creation of the 'European Centre for Disease Prevention and Control (ECDC)' (2004) in the context of the securitisation of the severe acute respiratory syndrome (SARS).

Since the overview of milestones in EU infectious disease control (Table 3-1) has made clear that quite a number of developments might principally meet the criterions of institutionalisation in the sense of *relatively persistent and systemic changes regarding rules, procedures, policy priorities, resource allocation, division of competences and organisational structures* (see chapter 2.3.4.1), other than the selected developments could constitute equally interesting research objects. Also, BSE/TSEs on the one hand, and SARS on the other were by far not the only diseases whose (potential) securitisation could have impacted these developments. Clearly, in the years between 1993 and 2014 a large number of infectious diseases appeared in the political agenda at the EU level with the potential to turn into securitised matters. To illustrate, alone for the year 1993, when the EU was still in an early phase of its involvement in infectious disease control, the EUR-Lex database comprises EU output that mentions diseases as diverse as anthrax, BSE, chikungunya, cholera, Creutzfeldt-Jakob, diphtheria, ebola, hepatitis, herpes, influenza, Lassa, legionella, malaria, meningitis, polio, rabies, salmonella, tuberculosis and Wesselsbron disease – to mention just a few.

Against this background, for what reasons have the two case studies with regard to both institutionalisation developments and infectious diseases been selected?

As to the first question regarding the structural changes at the EU level, the following arguments speak in favour of the proposed selection: First, both 'case groups' share the combination of a revision of the EU's primary law (Amsterdam Treaty and Constitutional Treaty feeding into the Lisbon Treaty) with the creation of a specialised EU agency (EFSA and ECDC). The resulting modifications were not only of durable nature, they are also of greatest importance both in the historical evolution and for the current functioning of the EU's setup to control infectious diseases. More precisely, after the introduction of the public health article in the Maastricht Treaty, the respective article was changed only twice, namely in 1997/1999 (Amsterdam Treaty) and in 2007/2009 (Lisbon Treaties) with the latter taking up first and foremost the innovations that had been agreed on already in the Constitutional Treaty (2004). Hence, the case studies cover the major revisions of the EU's fundamental legal basis regarding infectious disease control.

[82] As shown in the previous chapter, after being signed by the head of state or governments of all EU Member States in October 2004, the Treaty Establishing a Constitution for Europe ('Constitutional Treaty') was not ratified. Still, its content provided a strong point of reference for the Lisbon Treaties as adopted in 2007 (at that time referred to as the 'Reform Treaty'). Hence, important elements that were meant to be introduced by the Constitutional Treaty became eventually primary law following the ratification of the Lisbon Treaties.

Similarly, the Commission, EFSA and the ECDC belong to the essential infrastructural bodies on whose activities the EU's infectious disease policy is nowadays centred so that an investigation into their setup or re-organisation is particularly interesting. In terms of EU agencies, EFSA's and ECDC's importance for the EU's preparedness and response to infectious diseases is paralleled only by the European Medicines Agency (EMA).[83] In other words, investigating the revision of the EU Treaties and the setup of the EFSA and the ECDC, complemented by the examination of the re-organisation of the EU infrastructure for food-borne infectious diseases in 1997, is particular valuable in the light of their political relevance, since these developments can be regarded as belonging to the most important milestones in the entire evolution of the EU's setup for infectious disease control.

Second, we have seen that infectious disease control in the EU is heavily under-researched. The research gap is particularly huge in the case of the ECDC. Scholars working in the field have noted that "[m]ultiple literature reviews of sources […] produced almost nothing about the prehistory, origins, or current activities of this agency" and that "[t]here has been almost no policy or political science work on it" (Greer, 2012a: 1017); despite a set of contributions in the last years, the situation has not changed a lot so that the assessment is supported still today by the recent literature review undertaken for the present study. In the light of these findings, the selection of the specified institutionalisation steps for detailed analysis is also justified on the grounds of academic relevance.

When it comes to identifying the diseases for which the securitisation analysis is carried out, a selection from a wide range of potentially securitised diseases was principally possible. As argued in chapter 2.5, forms of securitisation are difficult to predict in advance; we don't know whether, by whom and in which way a given disease was securitised (or not) until we have pursued the analysis. Provided that "security issues are socially constructed, but the securiti[s]ation process is not divorced from empirical considerations" (McInnes and Rushton, 2013: 120), the social construction of a security threat *may* relate to the characteristics of a disease, for instance an outbreak event, and these characteristics *might* facilitate the securitisation of the disease; in principle, however, it is also possible that speech acts and emergency measures turn a relatively harmless disease into the subject of dynamic securitisation processes. In turn, it is also possible that a highly lethal disease is kept, intentionally or not, outside the security realm. Hence, although the fact that a disease actually appears in EU documents is a pre-condition for securitisation at the EU level, a high number of references does not necessarily imply that the disease is referred to in a security context.

Against this background, from a rich set of politically and medially visible diseases that occurred between 1993 and 2014, the selection of BSE/TSEs and SARS must be by definition to a certain extent speculative. Still, at least three reasons make BSE/TSEs and SARS particular promising cases for a comparative in-depth analysis. First, most basically, both diseases figured prominently in the political debate at the EU level during the years in which the respective decisions for the abovementioned structural changes were taken. In other words, they can not only be assumed to be sufficiently addressed at the EU level to enable securitisation in the first place, they also bear a clear temporal

[83] The European Medicines Agency is decisive in the process of marketing authorisation of medicines in general, and thus also for the treatment and vaccination against infectious diseases (see also chapter 3.4.3).

relation to the reforms at the EU level. The latter is important, as the connection of securitisation and institutionalisation implies that the prioritisation, which derives from strong securitisation, requires a rather prompt reform – within the EU's bounds of possibility.

Second, existing literature claims a connection between the course of the respective disease crisis and structural innovations at the EU level, in particular with a view to the creation of the two selected agencies and the revision of the EU's food regime (Chalmers, 2003: 532, Groenleer, 2009: 178, Greer, 2012a: 1010). These statements were also supported in the expert interviews carried out for this study. Beyond the statement on a given relation, however, existing studies have not elaborated on the proposed linkage or explained why these disease crises constituted cases of a 'good epidemic' that had the potential to break the political and institutional stability. Although both bovine spongiform encephalopathy with resultant Creutzfeldt-Jakob disease and SARS were also identified as public health threats that had an impact on European integration (Coker et al., 2004, Liverani et al., 2012: 575f), the connection was not thoroughly examined from a securitisation perspective; not to mention the novel elements of the securitisation approach put forward in this study. To make things worse, literature that deals with the EU's response to the SARS outbreak is scarce in general.

Third, in contrast to the analysed structural changes, which share a number of common features, the two selected diseases have fundamentally different characteristics. Both diseases are under surveillance in the EU (European Commission, 2000a, 2009c) but whereas BSE/TSEs belong to the group of food-borne infectious diseases, SARS is a disease that is transmissible directly from human-to-human. Another major difference is that the BSE/TSEs crisis took place primarily in Member States of the European Community, whereas SARS occurred globally but spread predominantly outside the EU, in particular in Asia. Also, whereas BSE/TSEs remained a political issue over a long period of time, at least 12 years from 1989 to 2001, SARS occurred as a short-term outbreak that was declared contained after a couple of months already. Numerous further characteristics, including the fundamentally different incubation periods[84], could be listed to distinguish the two diseases. These differences are interesting in view of the social construction of threats, and ultimately also on the linkage between securitisation and institutionalisation processes. Clearly, if the diseases are fundamentally different but are still capable of triggering similar systemic changes, the reason for this change is unlikely to be found in the disease itself. In this way the case study selection deliberately operates with the foundations of the securitisation approach.

The following Table 4-1 illustrates the combination of institutionalisation and securitisation elements in the two case studies. For illustrative purposes it is shown that besides BSE/TSEs and SARS other infectious diseases played an important role on the political agenda between 1993 and 2014 so that further case studies would be possible. On the basis of the findings of chapter 3 other promising case studies could be, for instance, an analysis of the securitisation of anthrax in view of EU's health security programme and the creation of the HSC in 2001, or a securitisation analysis of influenza in

[84] The incubation period describes "the time from infection to onset of clinical symptoms of disease" (Anderson et al., 2004: 1093).

relation to the EU's generic and influenza pandemic preparedness initiatives (2005) and the joint procurement initiative (since 2014). Further examples could be added. Still, given the specific value of the selected focus for the understanding of the institutionalisation of infectious disease control in the EU, the securitisation of infectious diseases in the EU and the possible connection of the two phenomena, the selected cases constitute a particularly promising research setting.

Table 4-1: Topical Infectious Diseases and Key Developments in EU Infectious Disease Control (1993-2014, schematic)[85]

Year	Topical Disease[86]	Reference Document(s)	Key Development
1993	HIV/AIDS <---- Influenza H5N1 ---- H7N7 ---- H5N1 ---- H3N2 ---- H1N1 ---- H7N9 ----> Anthrax BSE/TSEs → → → → ↓↓SARS	Treaty of Maastricht	Article 128: Introduction of Public Health Article
		Regulation 2309/93	European Agency for the Evaluation of Medicinal Products
		COM(93) 559 final	Framework for Action in the Field of Public Health
		Decision 647/96/EC	Programme 'Prevention of AIDS and Other Comm. Diseases'
		COM(97) 183 final	Re-Organisation of COM, Veterinary & Foodstuff, DG SANCO
		Treaty of Amsterdam	Article 152: Extension of Public Health Mandate
		Decision 2119/98/EC	Communicable Disease Network (CDN). Network of Networks
		Decision 2000/57/EC	Early Warning and Response System (EWRS) for Comm. Dis.
		COM(2000) 285 final	Health Strategy of the European Community
2001		Regulation 999/2001	Harmonised Law on Transm. Spongiform Encephalopathies
		G/FS D(2001) GG	Health Security Programme, HSC and RAS-BICHAT
		Regulation 178/2002	European Food Safety Authority (EFSA), Food Law, rev.RASFF
		Decision 1786/2002/EC	First Public Health Programme (2003-2008)
		Regulation 851/2004	European Centre for Disease Prevention and Control (ECDC)
		Constitutional Treaty	Article III-278: Serious Cross-Border Threats to Health
		Decision 2004/858/EC	Executive Agency for the public health programme (PHEA)
		COM(2005)605&07/662	Generic & Influenza Pandemic Preparedness, ARGUS & HEOF
		Decision 1350/2007/EC	Second Public Health Programme (2008-2013)
		Treaty of Lisbon	Article 168 TFEU: Serious Cross-Border Threats to Health
2008		COM(2007) 630 final SEC(2007) 1376 SEC(2009) 1622 final SEC(2010) 380 final COM(2010) 673 final COM(2010) 128 final Concl. 9505/10	Health Strategy 'Together for Health' Health Security Agenda in the EU and Internationally Internal Security Strategy (ISS) Role of the EU in Global Health
		SEC(2011) 1519 final Decision 1082/2013/EU	Serious Cross-Border Threats to Health, Formalisation of HSC
		Decision 1313/2013/EU Decision 2014/762/EU	Civil Protection Mechanism, Disaster Management, ERCC
2014		Regulation 282/2014	Third Public Health Programme (2014-2020)
		in progress	Joint Procurement Agreement / Procedure

Source: Own presentation.

[85] Blue marks structural changes that occurred in the course of the BSE/TSEs crisis (chapter 5), red marks structural changes that occurred in the course of the SARS crisis (chapter 6).

[86] The list of diseases is not exhaustive. The focus was put on diseases that figured prominently in the political and/or public debate in the EU.

5. The Adoption of Food Safety Reforms and the Creation of the European Food Safety Authority in the Course of the BSE/TSEs Crisis

We have seen in chapter 3 that major revisions of the EU structures for the prevention and control of food-borne infectious diseases and for food safety in general occurred in the years between 1997 and 2002. In 1997, a first set of changes occurred, when the EU's infrastructure in the foodstuff sector underwent a persistent re-organisation. In the same year, the Treaty of Amsterdam was concluded (entered into force in 1999) which introduced health and consumer protection as independent policy objectives and shifted food-related veterinary competences away from the agricultural sector to the realm of public health. In addition to these structural changes of the late 1990s, a second wave of innovations took place in 2001/2002, when Regulation 999/2001 provided for harmonised EU law on the prevention, control and eradication of certain transmissible spongiform encephalopathies and when Regulation 178/2002 created the European Food Safety Authority (EFSA), laid down general principles of food law and procedures in food safety and established a revised rapid alert system (RASFF) for the notification of threats from food or feed.

Chapter 4 has emphasised that these reforms occurred following a period in which the so called 'mad cow' crisis took place in Europe. Bovine spongiform encephalopathy (BSE) is a zoonotic disease[87] which appeared for the first time in 1986 in the United Kingdom (UK). It is one of a set of transmissible spongiform encephalopathies (TSEs)[88] which share the characteristic of the presence of an abnormal form of a protein, known as the *prion* – derived from *protein* and *infection*. In humans, prions are suspected to cause *inter alia* (variant) Creutzfeldt-Jakob Disease, a rare and currently incurable degenerative neurological disorder that affects the structure of the brain or other neural tissues. TSEs are not contagious, meaning that they are not transmissible by physical contact, through the air or by casual contact to contaminated objects, but they are transmissible if ingested, typically due to the entrance of the infectious agent into the food chain (Ray and Ryan, 2004: 624ff).

The aim of this case study is to assess the structural changes in the realm of food safety and food-borne infectious diseases that could be identified for the years 1997 and 2002 in the context of the developments that evolved around the BSE/TSEs crisis. More precisely, the case study takes up the fundamental research interest in the timing, context and conditions for the mentioned structural changes and the forms of securitisation of BSE/TSEs at the EU level, in particular regarding the questions when, by whom, in which dimensions, to what degree and in which kind have BSE/TSEs been securitised. On the basis of this analysis the case study aims at testing the proposed hypothesis on the connection between the specific form of 'strong' securitisation and institutionalisation processes at the EU level.

[87] The term 'zoonosis' refers to infectious diseases of animals that are transmissible to humans (Hawker et al., 2012: 6).

[88] The specification of 'BSE/TSEs' is used hereinafter to simultaneously refer to the interlinked animal and human diseases 'bovine spongiform encephalopathy' (BSE), scrapie and (variant) Creutzfeldt-Jakob Disease (vCJD), unless a specific form of TSEs, for instance BSE, is addressed individually. It will become clear in the following that the transmissibility of BSE from bovines was disputed and that political response initially addressed only BSE.

The chapter is structured as follows. The first part comprises a review of primary sources and secondary literature to re-construct the political responses to the spread of bovine and transmissible spongiform encephalopathies. This overview is provided along two phases, the first of which covers the years between 1989 when BSE showed up in EC documents for the first time and 1997 when the internal re-organisation of the foodstuff related EU bodies and the Amsterdam Treaty were adopted (chapter 5.1). The second phase deals with the years after the Amsterdam Treaty from 1998 until the beginning of 2002 when the European Food Safety Authority and the harmonised EU food-law were established (chapter 5.3). Each phase concludes with a section that analyses in detail the structural changes of the respective period (chapters 5.2 and 5.4).

This overview is followed by an analysis of the securitisation of BSE/TSEs as observable in the systematically generated set of EU documents (chapter 5.5). It ties together the investigation on the crisis years from a securitisation perspective in order to draw findings regarding the (evolving) degree (chapter 5.5.1) and kind of securitisation of BSE/TSEs (chapter 5.5.2) across both securitisation dimensions. In addition to this investigation, a separate section explores the roles of the different actors involved in the securitisation processes in order to gather information on the main EU securitisers (chapter 5.5.3).

Finally, chapter 5.6 serves to thoroughly examine the assumed linkage between securitisation and structural change, before chapter 5.7 closes with a set of conclusions on the case study as a whole.

5.1. Crisis and Response: 1989 – 1997

The regulation of foodstuff is an important dimension in infectious disease control, since animal products can serve as a vector for food-borne pathogens that cause disease (Paarlberg, 2010: 155). In the European Community the food product sector had developed since the famous 1979 *Cassis-de-Dijon* ruling (European Court of Justice, 1979) which established the principle of mutual recognition. Accordingly, in principle a product could enter the market of all Member States once it met the product standards of at least one Member State. Exceptions existed for cases in which special circumstances could be justified, for instance in relation to health and consumer protection (Dehousse, 1998: 85). In this way the Single Market for foodstuffs could be established in the 1980s, but the harmonisation of the standards of specific products was not a priority at the European level. Consequently, interventions from the European level in national food safety were limited to cases when barriers to trade where in question (Paul, 2009: 2645).

In this context European secondary veterinary legislation enabled the Commission to implement counter measures in response to the outbreak of animal diseases (Council, 1989, 1990a). With the aim to “avert any danger where it is found that there has been an outbreak of an epizootic disease, any new serious and contagious disease or other cause likely to constitute a serious hazard to animals or to human health”, Directive 89/662/EEC obliged EC countries to “notify the other Member States and the Commission of any outbreak in its territory” (Council, 1989). Furthermore, Article 9 also specified that the Member State of origin should immediately implement control measures. The

Commission's task was to review the situation and adopt "necessary measures" on the basis of the scientific advice presented by the 'Scientific Veterinary Committee'. This advisory committee was composed of national experts nominated by the Commission and served the purpose to be consulted by the Commission on all scientific and technical problems concerning animal health, veterinary public health, and animal welfare (European Commission, 1981). Following the consultation of the Scientific Veterinary Committee decisions by the Commission could be adopted only on the basis of a favourable vote of the representatives of the Member States in the 'Standing Veterinary Committee' or the Council (Council, 1968a). With other words, Community action was subject to a regulatory procedure in which Commission and Member States had to jointly agree on regulatory measures; this system implied that Member States could stop their adoption any time. In this sense, in the early 1990s the regulation of foodstuff constituted more a 'patchwork' (Héritier, 1996) with various regulatory gaps than a coherent food law (Nentwich, 1995: 200ff, Krapohl, 2008: 124f).

The existing setup was confronted with the BSE challenge at the end of the 1980s, at a time when the state of knowledge about the disease was much lower than nowadays.[89] In 1989, the Commission identified BSE "to be a new serious contagious or infectious animal disease whose presence may constitute a danger to cattle in other Member States" and in view of the "significant risk […] in respect of live animals", infected or suspected infected live cattle was not allowed to be exported from the UK (European Commission, 1989). In spring 1990, the Commission labelled BSE "a serious new disease which could threaten Community livestock" and introduced the obligation for Member States to notify the prevalence of BSE in their territories (European Commission, 1990a). Soon after, first disputes arose at the Community level, when certain Member States considered restricting British beef imports (European Parliament, 1997b: A.I.4, Vincent, 2004). Although it was discovered already at that time that BSE was transmissible from cattle to other species, the UK government insisted on the interpretation that it was not transmissible to humans. An extraordinary meeting of the Agriculture Council resolved the conflict by a compromise that dropped the envisaged import ban in favour of British export quality certificates for beef and the introduction of a system to identify cattle in the UK (Krapohl, 2008: 128). In the following, BSE was not addressed by any further Community action besides the introduction of additional requirements and export restrictions for some tissues and organs with respect to BSE (European Commission, 1990e, 1990c), a decision concerning the export of bovine embryos (European Commission, 1992c) and some non-legislative activity of the European Parliament.

In 1994, after three years in which the Council did not hold debates on BSE at all, the discussion on the transmissibility of BSE to humans was re-launched by the German and the French delegations who proposed additional regulation and stronger guarantees on British meat exports. Meanwhile, feed containing processed contaminated ruminant waste was identified as the key factor to the transmission of the disease. As a consequence, the EU adopted counter measures concerning the processing, feeding and export of live cattle and meat and bone-meal. The legislation banned

[89] Even today the before mentioned '*prion* hypothesis' is still debated. See http://www.who.int/zoonoses/diseases/bse/en/ (accessed 24.04.2015).

proteins derived from mammalian tissues for the feed of ruminants (European Commission, 1994e), set up heat treatment requirements to ensure the in-activation of BSE agents in ruminant waste (European Commission, 1994b) and further toughened the provisions regarding the dispatch of live cattle from the UK (European Commission, 1994d) and the British beef health certificates (European Commission, 1994c).

Although the counter measures of the second round (1994) of Community responses to the BSE disease included stricter measures than the first round (1990), both were directed predominantly to one Member States, the UK, and to BSE as an animal disease.

The third wave of measures in 1996 was of another quality. It was initiated by a statement of UK officials on March 20 that the non-transmissibility of BSE to humans could no longer be taken for granted and that there might be a causal link between BSE and a number of atypical cases of Creutzfeldt-Jakob Disease (Will et al., 1996, Scheu, 2003: 616). As a result, first, a number of Member States unilaterally decided to ban the entry of live bovine animals and beef and veal into their territory from the United Kingdom, and not much later also the EU level responded. Following a 14-to-1 vote in the Standing Veterinary Committee[90] – the political body of Member States representatives working in the relevant comitology procedure – the Commission Decision 96/239/EC of March 27 on "emergency measures to protect against bovine spongiform encephalopathy" imposed, as a radical extraordinary measure, an EU-wide export ban on British beef, products from bovine animals, live animals as well as meat- and bone-meal to both all EU Member States and third countries (European Commission, 1996b). By building on Article 9 of Directive 89/662/EEC, the disease was identified to constitute a "serious hazard to animals or to human health". The ban went along with monitoring obligations and followed by further measures, for instance concerning the processing of animal waste.

In a resolution on the Commission's measures with regard to BSE the European Parliament supported these steps, declared the ban "inevitable" and an "urgent measure" and claimed for "priority to safeguarding public health and protecting consumers" (European Parliament, 1996d). Beyond that it also demanded support measures to prevent the "drastic collapse" of the beef industry which faced a dramatic reduction in beef consumption. In this context the Commission could take up Regulation (EEC) No 805/68 (Council, 1968b) which provided for the payment of premiums to compensate producers for the consequences of a substantial fall in beef and veal prices. Also the Agriculture Council at its extraordinary meetings in March and April underlined the seriousness of the situation and "urged the adoption of a number of urgent measures for health protection and support of the beef market" (European Parliament, 1997b).

On this basis a series of "exceptional support measures for the beef market" was adopted, repeatedly updated in the following, starting with Regulations to support the United Kingdom (European Commission, 1996d) as well as Belgium, France and the Netherlands, where veal calves imported from the United Kingdom had to be destroyed and where owners were compensated for

[90] The EU comprised at that time 15 Member States; the single negative vote apparently came from the UK representative.

the destruction under the market regulation rules (European Commission, 1996e). The exceptional financial contribution to the purchase and slaughtering of animals was on the one hand justified on the grounds of the necessity to kill and destroy the animals "in a manner which does not pose any threat to human health or the health of other animals". On the other hand, the Commission also hinted at the "magnitude of efforts needed to support the market" in the light of "a lack of consumer confidence in beef and a disturbance of the markets" (European Commission, 1996d, 1996e).

In parallel to these supportive measures the situation escalated politically following the UK government's announcement that it did not intend to cooperate any longer in the decision-making processes of the EU in general as long as the export ban on British beef was in place (Westlake, 1997). The UK's 'empty-chair' politics was followed by a partial lifting of the ban for certain cattle products (European Commission, 1996f) and contributed to pushing the BSE/TSEs crisis to the highest political levels. The Presidency Conclusions of the European Council meeting on June 21 and 22 in Florence included a special section on BSE that comprised two key messages. First, "a step by step relaxation of the […] restrictions on the export of bovine products" could be envisaged as soon as a plan for the eradication of BSE in cattle in the United Kingdom, as put forward by the Commission, showed the desired effects. And second, support for the affected beef industry was important following the fall in beef consumption and its impact on market prices. In this context the European Council devoted ECU 850 million to support European livestock farmers in addition to the already amended budget of the Commission, which included ECU 650 million plus a reserve of ECU 200 million for beef market support (European Council, 1996). Clearly, with the focus on a framework for the removal of the UK ban, the restoration of the Single Market in beef and the agreement on further market support measures, economic questions dominated the negotiations of the Heads of States or Governments when adopting the so called *Florence Agreement*.

In the same vein, the Council Regulation to implement additional top-up payments to producers within the agricultural guideline for 1996 declared the market for beef "seriously disturbed as a result of consumer concerns in relation to bovine spongiform encephalopathy (BSE)" (Council, 1996d). In the same year, in the light of "continuing serious difficulties in the beef and veal sector resulting from consumer concerns", additional measures for the direct support of producers in all Member States (Council, 1996c) as well as further „exceptional support measures" for the beef market in Portugal and the UK were adopted (European Commission, 1996g, 1996d) soon after the eradication plans for the two countries had been set up (European Commission, 1996a, 1996j).

Concern regarding the beef consumption, aid for the beef market and financial support for affected countries also played a prominent role for many Members of the European Parliament. Amounting to the total number 79, the year 1996 yielded a large number of written questions to the Commission related to BSE/TSEs (after 1 in 1993 and 0 in 1994 and 1995), of which roughly every fifth dealt with the economic implications of the crisis and the lack of consumer confidence. Other prominent topics were connected to the uncertainty how the transmission of BSE to other animals and humans took place (milk, water, gelatine, medical or cosmetic products), the Commission's (in)activity and communication policy or the inspection and containment measures adopted in the UK. Similar

questions were also brought up by the Economic and Social Committee which expressed great worry about the harmful consequences of the economic crisis in beef-farming and related job losses throughout the meat production, processing and marketing industry, caused by the collapse of consumption and the loss of consumer confidence (EESC, 1996).

Besides the concerns regarding the consequences for industry and employment, the respective opinion of the Economic and Social Committee also illustrates the great uncertainty regarding the characteristics of BSE and vCJD in 1996, leading to a strong call for further research into the diseases. The Commission shared the view that further research was needed and launched a sizeable research initiative at the end of the year (European Commission, 1996k). Furthermore, it tried to strengthen the independent scientific advice for its decisions and set up the 'Multidisciplinary Scientific Committee on BSE' which was meant to work complementarily to the already existing bodies of the advisory system. The Council supported this institutional reform and asked the new Committee to make "recommendations […] relating to specific policies to combat TSEs […] as an essential and urgent measure" (Council, 1996b). It also demanded "the rapid establishment of epidemiological surveillance of CJD in all Member States, on the basis of comparable data" (Council, 1996b, 1996a).

Also the year 1997 witnessed further extraordinary events. Besides the continuation of emergency measures of the previous year, two conferences were held jointly by the Parliament and the Commission on animal-meal[91] and food law and food policy[92]. Additional eradication plans for France and Ireland were set up and exceptional market support measures adopted for both countries as well as Germany. Furthermore, the Commission decided on further animal waste treatment provisions and shipping restrictions (European Commission, 1997a). In addition to these steps, the Council introduced a system for the identification and registration of bovine animals and the labelling of beef and beef products from 1 January 2001 onwards (Council, 1997a). In other words, also in 1997 the BSE/TSE issue and the implications for food safety and health remained a top-priority, well-illustrated by the fact that at the end of the year, the European Council addressed the matter in a separate declaration annexed to the Presidency Conclusions of the summit in Luxembourg. The heads of state or government took up the reading of the BSE crisis and current food safety challenges as a matter of "concern for the public" and a question of "public confidence". Confirming that "the production and supply of safe food must be one of the European Union's priorities", which implied "a high level of health protection, ensured on the basis of high-quality, transparent scientific advice", the European Council made clear the support for the ongoing reform of the sector, including supplemented and simplified legislation (European Council, 1997). Furthermore, the statement "that the European Union should remain constantly alert to food safety concerns", made clear that the crisis was not considered to be overcome yet (European Council, 1997).

At that time, the functioning of the EU's institutional setup that dealt with BSE/TSEs was already subject to investigation by the European Parliament's temporary Committee of Inquiry, set up in July 1996 "to investigate alleged contraventions or maladministration in the implementation of

[91] 1-2 July 1997, Brussels.
[92] 3-4 November 1997, Brussels.

Community law in relation to BSE" (European Parliament, 1996b). The committee was the first of its kind, as the European Parliament had been granted the right to establish such a temporary body of inquiry in the Maastricht Treaty only (Westlake, 1997, Vos, 1999). Consequently, the management of the BSE crises was a test case for the application of the new competence. The committee's report gathered evidence from various sources, including national and Commission representatives, and was published in February 1997 (European Parliament, 1997b). It thoroughly analysed the developments at the EU level related to BSE with a focus on public health implications until 1997, and brought forward massive criticism concerning almost every actor involved, from the UK authorities through the Commission to the Council and the relevant comitology bodies (Chambers, 1999).

The report concluded with a comprehensive list of recommendations. The fact that the report's findings were linked to the announcement of a motion of censure against the Commission underlines the importance and urgency the Parliament attached to the issue (European Parliament, 1997b). In this context the "practical proposals for improvements to ensure that a similar situation does not occur in future" primarily addressed the need to reform the organisation, the work and the transparency of the scientific and standing committees in the veterinary field. A major reason for this claim was the Parliament's finding that scientific opinions on the transmission path were overheard during the early years of the outbreaks and that the advisory input provided to the Commission regarding BSE/TSEs was dominated by UK officials. Besides the restructuring of the committee system, the Parliament furthermore proposed a general reform of the legislative foundation of the foodstuff regulation and the idea of a European Agency for Veterinary and Phytosanitary Inspection that could improve the EU's surveillance capacity (European Parliament, 1997b).

5.2. Legal and Institutional Reform in 1997

5.2.1. The Re-Organisation of the EU's Food Safety Infrastructure

In April 1997, two months after the report of the European Parliament's Committee of Inquiry into BSE had been published (European Parliament, 1997b), the European Commission initiated a series of reforms that built basically on two publications, the Commission's Communication on "Consumer Health and Food Safety" on the one hand (European Commission, 1997j), and the "Green Paper on Food Law" on the other (European Commission, 1997h).

The documents developed the Commission's "new political departure" towards foodstuff regulation which aimed at the reinforcement of the "the protection of consumer health" (European Commission, 1997j: 7) and "the manner in which it obtains and makes use of scientific advice, and in which it operates its food, veterinary and phytosanitary control and inspection services (European Commission, 1997j: 3). Against this background it set out in detail how the processes of scientific advice, regulatory decision-making and control could be better separated from each other in the future by re-structuring both administrative organisation of food safety affairs within the Commission as well as the provision of scientific advice.

As regards the internal organisational structure, the foodstuff-related competencies, which had so far been scattered to the Commission's DGs for Agriculture, Consumer Policy, Enterprise and Internal Market, were moved to a single Directorate General (DG), DG XXIV for Consumer Policy and Health Protection (Vos, 1999, 2000). The new DG received the name DG SANCO in the following Commission under President Prodi.[93] The poor coordination and overlapping responsibilities, also among further DGs such as industry and social affairs, had been subject to massive criticism by the Parliament (European Parliament, 1997b, Grant, 2012: 1035).

In a similar step, the Office of Veterinary and Phytosanitary Inspection and Control, which was attached to the Directorate General for Agriculture, was transferred to the new and upgraded DG, strengthened in its capacity to perform food, veterinary and phytosanitary inspection and renamed the Food and Veterinary Office (FVO).[94] Finally, a new unit on the assessment of consumer health risks was established here, too (European Commission, 1997j: 4, Chambers, 1999, Krapohl, 2008:132).

In view of the advisory system, the Commission re-organised the scientific committees within the Commission in the field of consumer health and food safety by re-structuring the existing scientific committees into a set of eight reshaped committees, along with a reform of the appointment system.[95] In addition, the full set of food safety-related committees was transferred under the authority of a single Directorate General, the new DG responsible for 'Consumer Policy and Health Protection'. Finally, the Commission established a 'Scientific Steering Committee' (SSC) on the basis of the already existing Multidisciplinary Committee (European Commission, 1997k) which was mandated to be responsible only for BSE/TSEs as well as the coordination of the work of the other scientific committees (European Commission, 1997l, Krapohl, 2008: 132). By doing so the "the scientific committees were distanced from the legislative wing of the commission services, being subjected to the exclusive control of a DG totally oriented to consumers. At the same time, they were removed from direct industrial pressures" (Alemanno, 2006: 245).

5.2.2. The Revision of the Public Health Article in the Amsterdam Treaty

As a second structural innovation the adoption of the Treaty of Amsterdam in the year 1997 included a revision of the Community's public health mandate. The new Treaty re-numbered the public health Article from 129 to 152 and introduced a range of new elements, beginning with the formulation that "Community action should be directed towards improving public health, preventing human illness

[93] The DG was renamed as DG SANTE as of 2015.

[94] Already in summer 1996, the Commission had issued a proposal to convert the existing Community Office for Veterinary and Phytosanitary Inspection and Control into a European Agency for Veterinary and Phytosanitary Inspection (European Commission, 1996c). This idea was adapted by establishing a new affiliation and a strengthened role of the FVO. The FVO was later relocated to its today's location in Grange, Ireland.

[95] Scientific Committee on Food, Scientific Committee of Animal Nutrition, Scientific Committee on Animal Health and Animal Welfare, Scientific Committee on Veterinary Measures relating to Public Health, Scientific Committee on Plants, Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, Scientific Committee on Medicinal Products and Medical Devices and Scientific Committee on Toxicity, Ecotoxicity and the Environment (European Commission, 1997l: Art. 1).

and diseases, and obviating sources of danger to human health" by fighting "against the major health scourges, promoting research into their causes, their transmission and their prevention, as well as health information and education" (Art. 152 (1)).

Beyond this overall call for the improvement of public health, the Treaty also introduced and re-organised the Union's competences. Crucially, the masters of the Treaty shifted the veterinary and phytosanitary chapters for the protection of human health from the title on the common agricultural policy to the new article on public health. EU legislation in these matters, as well as in the field of standards of safety of organs and substances of human origin, blood and blood derivatives, were not only merely permitted, but explicitly called for by the new Treaty. A development that was assessed as a decisive step to establish health and consumer protection as an independent EU policy objective (Vos, 2000, Coleman, 2004: 7, Krapohl and Zurek, 2006). Following the Amsterdam amendments public health and consumer protection were no longer a secondary action of the Single Market; in contrast, their attainment was to be ensured in the definition and implementation of all Community policies and activities (Art. 152 (1)). Furthermore, the Treaty provided that the legal foundation for future veterinary proposals relating to health protection were to be based upon the co-decision procedure.

Even if the Treaty of Amsterdam defined public health – despite these innovations – still in a restrictive manner with an emphasis on the respect for the responsibilities of the Member States (Guigner, 2004: 97), in particular regarding "the organisation and delivery of health services and medical care" (Art. 152 (5)), the reformed Treaty still "established a new legal basis on which future EU measures of health and consumer protection could be based" (Krapohl, 2008: 137). In particular, by establishing a new and close connection of the fields of veterinary policy and public health protection, the Community's competence to address food-borne infectious diseases was considerably modified.

The public health article remained unchanged in the Nice Treaty (signed in 2001, entered into force in 2003), but was addressed by the 'Laeken Declaration on the Future of the European Union' (European Council, 2001d: 22) and became, as we will see in chapter 6.3.2, subject to revision in the Constitutional Treaty (not ratified) and the Lisbon Treaty. The new linkage between veterinary issues and public health objectives, however, remained unaltered after the Amsterdam amendments.[96] Also the tight connection between the formerly separated policies for food safety and public health is a key feature in the EU's internal setup still today, best illustrated by the fact that the current Commission under President Jean-Claude Juncker in 2015 includes a Commissioner and a DG for 'Health and Food Safety'.[97]

[96] A comprehensive overview of changes of the public health article is provided in Annex 1 of this study.
[97] See http://ec.europa.eu/dgs/health_food-safety/index_en.htm (accessed 23.04.2015).

5.3. Crisis and Response: 1998 – 2002

After the series of reforms of the year 1997, the BSE/TSEs crisis initially continued comparatively unspectacular in the second phase between 1998 and 2002. The year 1998 was characterised by a series of follow-up steps by the EU institutions and the Member States, including the partial lifting of the UK embargo for beef and certain beef products in respect of Northern Ireland under the new 'Export Certified Herds Scheme', combined with stricter control measures, further eased in 1999 for the entire UK under the newly established 'Date Based Export Scheme'. Furthermore, the Commission set the requirements regarding the epidemio-surveillance for all animal TSEs and commenced its series of follow-up reports on BSE (European Commission, 1998b).

At that time the impression started to prevail among most involved actors that "[s]atisfactory progress to eradicate the disease ha[d] been made" (European Commission, 1998f: 1). At the same time costs and consequences of the disease outbreak became clearer; the EU looked back at over 3 million cattle slaughtered and destroyed under the various programmes of the eradication plan (European Commission, 1998f: 1) as well as a total of ECU 2.149 million Community expenditure on BSE related measures, which equalled an increase of 32 per cent in relation to the normal premium scheme expenditure (European Court of Auditors, 1998a: 6).

Just when the European Parliament and the Commission prepared for another joint conference to draw lessons from the BSE crisis for the safety of foodstuffs,[98] it turned out that the crisis was still not overcome since in Portugal not all BSE/TSEs risk factors were adequately managed. As serious concerns existed regarding the development of the disease in the near future, a total ban on dispatch of live cattle and all cattle products from Portugal was implemented (European Commission, 1998c). If this re-emergence of the problem served to bear in remembrance the acute implications for animal and human health, the Court of Auditors in a "Special Report concerning the community financing of certain measures taken as a result of the BSE crisis" recalled the heavy economic impact of the crisis, stating that "[t]he Community beef market was pushed to the verge of collapse almost overnight as consumer confidence plummeted" (European Court of Auditors, 1998a: 27).

The following months were dominated by further follow-up reports on BSE/TSEs, further specifications of the agreed compulsory beef labelling system, further emergency measures in response to the BSE outbreak in Portugal and lively judicial activity, including a number of infringement procedures for failing to comply with BSE/TSEs legislation (European Commission, 1998b: 19ff, 1999e: 66). Beyond that, the year 1999 yielded a set of initiatives for further substantial reform steps. On the one hand, "in view of the magnitude of the risk posed to human and animal health by certain TSEs" the Commission launched a co-decision procedure by proposing a comprehensive set of general, harmonised EU rules on prevention, control and eradication these agents (European Commission, 1999f). On the other hand, members of the Scientific Steering Committee, the Committee that had been established as part of the structural reform package of 1997 to fight TSEs and to coordinate the work of the other scientific committees (see chapter 5.2.1),

[98] 30 November – 1 December 1998, Brussels.

presented an influential report to the Commission on the future of scientific advice. Under the title 'European Food and Public Health Authority' the three leading scientific advisors set out a proposal for yet a further reaching reform of the EU infrastructure for food safety by proposing the creation of an independent EU institution that could take over the tasks of risk assessment, management and communication, including the competence to take legally binding decisions (James et al., 1999, see also Buonanno, 2006, Krapohl, 2008: 138).

The Commission included the idea of an independent food agency into its draft for a 'White Paper on Food Safety", which became subject to discussions even before its final publication in January 2000 in the framework of the European Council meeting in Helsinki on December 10 and 11, 1999. In this context the European Council instructed the "Council to examine as a matter of urgency the forthcoming Commission White Paper on food safety […] as well as its communication on the precautionary principle" and agreed to keep the issue on the European Council's agenda for the next meetings (European Council, 1999).

The aim of the Commission's White Paper was to outline "[a] radical new approach" on food safety (European Commission, 2000h: 3) which consisted of essentially five components:

1. the establishment of an independent European Food Authority;
2. 80 separate actions in the field of food safety legislation;
3. the development and operation of national food safety control systems;
4. a better consumer information policy, as well as
5. the integration of the new approach into the EU's international trade system.

Justifications for reformed and strengthened capacities on EU level were located in a) the Internal Market, which required that "all aspects of food safety are addressed at EU level […] in line with the principle of subsidiarity" (European Commission, 2000h: 6), and b) the "unprecedented pressure [on Community and Member State food safety systems] during recent feed and food emergencies", which had "exposed weaknesses which call for action by the responsible authorities (Commission, Member States and the Parliament), to re-enforce, improve and further develop existing systems" (European Commission, 2000h: 7).

Almost at the same time of the publication of the White Paper, the Commission also published a Communication on the so called 'precautionary principle', a key concept in risk management decisions to which the Commission also made reference in its new food safety approach (European Commission, 2000m). Although the document did not provide an explicit definition, it entailed the core understanding that in cases of scientific disagreement as to whether a given activity is harmful to the public or not, health protection measures may be adopted, pending further scientific information. In such a case, the burden of proof that the activity was not harmful should fall on those who seek to undertake the activity. The 'precautionary approach' became an influential source and "general principle" for many following EU policies, not least in matters of product safety (Recuerda, 2006: 282f).

Although the communication only indirectly made reference to BSE/TSEs, the link to food safety is apparent throughout the document. In particular with regard to the 'burden of proof' and food substances the Commission states that "[a]s long as the human health risk cannot be evaluated with sufficient certainty, the legislator is not legally entitled to authorise use of the substance" (European Commission, 2000m: 20).

With the White Paper on Food Safety in January and the Communication on the Precautionary Principle in the beginning of February, the year 2000 had kick-offed with two documents which turned out to be influential points of reference in the future (see chapter 5.4), *inter alia* taken up by the European Council. The heads of state or government concluded their meeting in Santa Maria da Feira on June 19 and 20, 2000 with a reference to the White Paper and demanded that "[f]ood safety policy must apply to the entire animal and human food chain" and "that food legislation meeting the most stringent public health criteria is in place by 2002" (European Council, 2000a).

The preparations for these structural changes at the EU level were carried out, while the existing ban against Portugal ('Portugal embargo') was expanded (European Commission, 2000g), a compulsory Community-supported BSE tests for fallen stock and emergency-slaughtered animals were introduced (European Commission, 2000f) and the identification system and beef labelling system were amended (European Parliament and Council, 2000). Besides, following long political discussions since 1996 on specified risk materials, the Commission could finally adopt a Decision to update the list of risk materials, to prescribe slaughter techniques and introduce respective official controls (European Commission, 2000e, Krapohl, 2008: 135).

At that time, the BSE/TSEs case already headed toward another critical moment, when the Scientific Steering Committee presented a report on the geographical risk of BSE (Scientific Steering Committee, 2000) which concluded that almost all Member States were still at high risk to witness an outbreak in their territories. In the following, intensified surveillance measures were adopted at the EU level which soon yielded the unpleasant certainty that new BSE cases had occurred in Denmark, Germany and Spain and that Belgium, France, Ireland and the Netherlands were facing rising infection rates.[99]

At the end of the year 2000, "beef disappeared from Christmas menus all over Europe" (Krapohl, 2008: 134). New counter measures to prevent the spread of the disease included the prohibition to feed processed meat and bone-meal to any farm animal throughout the entire EU and the adoption of twice reinforced epidemio-surveillance programmes, backed up by the allocation of additional financial contributions for both surveillance and further exceptional support measures for the beef market (Council, 2000, European Commission, 2000d, 2000c, 2000b, 2000i). The disease once more became subject to the deliberations of the European Council which took notice of these measures to combat BSE during the meeting in Nice in December 2000 and demanded their swift and rigour implementation "in order to give consumers a lasting guarantee that beef is safe" (European Council, 2000b). The heads of state or government also demanded "[m]ore intense efforts in the field of

[99] See http://www.oie.int/animal-health-in-the-world/bse-specific-data/annual-incidence-rate/ (accessed 10.12.2014).

human medicine and veterinary research" and addressed the issue of a European Food Safety Authority which was already under preparations at that time. With regard to the latter the constitutional architects called for "the highest possible level of scientific excellence, independence and transparency, thus helping to prevent crises" and invited the Council and the Parliament "to speed up work so that the future European Food Authority may become operational as from the beginning of 2002" (European Council, 2000b).[100]

In 2001, the various measures of the year 2000 in response to BSE/TSEs were carried on, including special market support and exceptional support measures in the beef sector (European Commission, 2001j, 2001h), the large scale monitoring and testing programme (European Commission, 2001k, 2001n), and additional provisions as regards risk materials (European Commission, 2001o) and feeding stuff (European Commission, 2001a). Only when the dispatch ban against Portugal could be lifted as of 1 August 2001, the situation started to ease up to some extent. Also afterwards, bovine spongiform encephalopathy did not disappear from the political agenda, but the peak of discussions and measures related to the disease was passed. To illustrate, whereas in the year 2001 Members of the European Parliament addressed the Commission with more than 80 written questions concerning BSE/TSEs, the number decreased rapidly to 20 in 2002, 11 in 2003, 5 in 2004 and 0 in 2005.

Important legal acts of the years after 2001 were primarily concerned with amendments of the reform package of the year 2002 (see chapter 5.4) regarding ovine and caprine animals, rapid tests, breeding programmes, trade conditions and continued surveillance programmes. BSE/TSEs were still subject to numerous political decisions, but after 2002 these decisions did not take place in exceptional or urgent circumstances but were adopted and implemented principally on the legal basis as updated in 2001/2002 (see next chapter). Also judicial activity can be observed for the years after 2001, with highest numbers of case law in the years between 2001 and 2003. These cases were mainly occupied with the emergency measures of the crisis years, the special market support measures and exceptional payments. In line with a normal time lag that can be expected between policy-making and judicial review, case law related to BSE decreased considerably after 2003.

5.4. Legal and Institutional Reform in 2001/2002

5.4.1. Harmonised EU Law on TSEs

The major development in 2001 in terms of legal reform was the agreement of the European Parliament and of the Council on Regulation (EC) No 999/2001 (European Parliament and Council, 2001) which summarised into a single piece of legislation the numerous legislative steps of the years between 1990 and 2001 which had been taken in response to the BSE outbreak. The new legal basis comprised of a scheme for the classification of a country's BSE and scrapie status, both within and outside the EU, laid down the provisions for the monitoring and notifications of TSEs, prohibitions as

[100] In 2001, when the European Council meeting in Stockholm underlined once more the determination to eradicate the disease, the preferred schedule of the European Council even foresaw "the establishment of a European Food Authority […] before the end of this year [2001]" (European Council, 2001c: Art. 54).

regards the feeding of animal as well as the specified risk materials, measures to eradicate TSEs and the framework for the trading, inspections and controls of cattle, sheep and goats. Furthermore, the Regulation moved additional competencies to the European Commission, which was allowed to implement certain amendments to the Regulation.

Although the new Regulation did not significantly change the existing policies or procedures related to BSE/TSEs and food safety, in particular not in respect to the Commission's autonomy which was still tied into a committee system (Krapohl, 2008: 136), it still meant an important step for the consolidation of food safety law. Many of the measures of the previous years had been initially adopted with a temporary and exceptional nature and were now merged into one central piece of legislation. Furthermore, the new legislative basis also foresaw stronger regulation and was no longer limited to specific countries but became applicable in the entire EU. With other words, whereas most original BSE/TSEs measures of the years before were country-specific, temporary and based on the veterinary safeguard clauses, the new Regulation institutionalised preventive, responsive and monitoring measures with a new BSE/TSEs status system at its heart for all EU Member States and – in view of trade – also third countries. At the time of writing, Regulation 999/2001 is – updated and amended numerous times – still in force.

5.4.2. The European Food Safety Authority and the New EU Food Law

The official procedure leading to the establishment of the European Food Safety Authority has its origin in the Commission's proposal for a respective Regulation of March 2001 (European Commission, 2001b). The idea and plans for the creation of a central European institution in charge of food safety matters, however, had developed already in the years before. Not only had Romano Prodi as the new Commission President proposed such an institution in his first speech before the Parliament in October 1999 (Vos, 2000: 247, Groenleer, 2009: 179), the idea was also prominently enshrined in the report of three scientific advisers from the Scientific Steering Committee to the Commission in 1999 (James et al., 1999) and in the Commission's White Paper on Food Safety of January 2000 (European Commission, 2000h).

The group of experts from the Scientific Steering Committee had been commissioned to review the system of scientific advice after its revision in 1997. Along with the presentation of their findings the expert proposed the establishment of a "European Food and Public Health Authority" with an encompassing mandate far beyond food safety, meant to introduce a system for the monitoring European public health in general including the shift of competencies of risk and crisis management and decision-making to the new agency. The Commission took up the idea of an agency in its White Paper as an integral part of the EU's overall "radical new approach" on food safety (European Commission, 2000h: 3). It, however, did not include the encompassing mandate for regulatory powers, being incompatible with the EU Treaty for an independent agency, and limited the agency's objectives to risk assessment and communication in food safety matters (Buonanno, 2006: 264ff).

The Commission explained "that [these] major *structural changes* [emphasis added] [were] necessary in the way food safety issues are handled, having regard to the experience over the last few years" and that "[t]he establishment of a new Authority [would] provide the most effective instrument in achieving the changes required to protect public health and to restore consumer confidence" (European Commission, 2000h: 14). The need for reformed and strengthened capacities at the EU level was grounded in the functioning of the Internal Market and the "unprecedented pressure" of recent feed and food emergencies (European Commission, 2000h: 6f). The Annex of the White Paper comprised a timetable which lined out the envisaged reform steps of the next three years, with the most important innovations to be put forward before the end of the year 2000 "allowing for a coherent and up-to-date body of food law supported by a new European Food Authority to be in place by the end of 2002" (European Commission, 2000h: 7).

5.4.2.1. The Establishment of the European Food Safety Authority

Taking the White Paper on Food Safety as a reference point, the European Council pushed the establishment of the agency in its Presidency Conclusions of June 2000 by stating that "[f]ood safety policy must apply to the entire animal and human food chain and be supported by an independent European Food Authority to complement preventive surveillance by the national authorities". More precisely, the heads of state or government stipulated that "[t]he first of these proposals, dealing with the establishment of a European Food Authority, [was] expected by September 2000 at the latest" (European Council, 2000a).

The Commission's proposal was put into the legislative process in November 2000 as the first agency under the co-decision procedure (European Commission, 2001b). The procedure empowered the Parliament to make its opinions heard regarding the agency's scope and structures. Whereas the composition of the management board was of concern for the Council (Council, 2001), the Parliament insisted on strengthened control mechanisms and on specifying the authority's mandate to food safety (European Parliament, 2001, 2002). In turn, the European Council repeated the urgency of the issue (European Council, 2001b).

Finally, in contrast to the Commission's original design which had referred to a 'European Food Authority', the compromise agreement established a 'European Food Safety Authority' (Kelemen, 2004:139f, Buonanno, 2006: 270, Groenleer, 2009: 180f) following the adoption of Regulation (EC) No 178/2002 by the European Parliament and the Council. On a general basis the legislative actors widely agreed on the need and interest of the new agency and the respective re-organisation of the regime so that the legislative act was adopted after second reading in the Parliament without going through conciliation (Krapohl, 2008: 139). Because of an enduring disagreement between Italy and Finland over the location of the new agency, EFSA became transitionally operative during 2003 in Brussels before it was eventually moved to Parma in 2005 (European Council, 2001a, Groenleer, 2009: 107).

Table 5-1: Overview of the Documents in the Process Related to Regulation 178/2002 Establishing EFSA

Date[101] / Doc No.	Author	Reference	Contents
08.11.00	COM	(European Commission, 2001b)	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
COM(2000) 716 final			
28.03.01	EESC	(EESC, 2001)	Opinion on Proposal
2001/C 155/08			
12.06.01	EP	(European Parliament, 2001)	Legislative Resolution on Commission Proposal (1st Reading) – Approval with Amendments
A5-0198/2001			
14.06.01	CoR	(Committee of the Regions, 2001)	Report on Commission Proposal
2001/C 357/05			
28.06.01	CO	(Council, 2001)	Common Position
10235/01 (Presse 257)			
07.08.01	COM	(European Commission, 2001c)	Amended 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 safety
COM(2001) 475 final			
17.09.01	CO	(Council, 2002a)	Common Position
2002/C 4/02			
11.12.01	EP	(European Parliament, 2002)	Legislative Resolution on Amended Proposal (2nd Reading) – Approval with Amendments
A5-0416/2001			
21.01.02	CO	(Council, 2002b)	Approval by the Council of the EP Amendments at 2nd Reading
5283/02 (Presse 7)			
28.01.02	EP+CO	(European Parliament and Council, 2002a)	Adoption of Regulation 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
R 178/2002			

Source: Own presentation.

5.4.2.2. The Mission of the European Food Safety Authority

The establishment of EFSA meant an important step of re-organisation and centralisation indeed. Building on the assessment that "the present system of scientific and technical support [was] no longer able to respond to increasing demands" (European Parliament and Council, 2002a: Recital 33), the founding Regulation defined EFSA's tasks in the realm of risk assessment, scientific advice as well as scientific and technical support for the Community's legislation and policies "in all fields which have a direct or indirect impact on food or feed safety" (European Parliament and Council, 2002a: Art. 22 (2)). In particular, it belongs to the tasks of the agency to provide best possible scientific opinions, meant to "serve as the scientific basis for the drafting and adoption of Community measures" (European Parliament and Council, 2002a: Art. 22.6, Art. 23). These scientific opinions can be issued following a request from the Commission, from the Parliament or from Member States, or on EFSA's own initiative.

In addition to its primary role as the source of independent scientific "advice, information and risk communication in order to improve consumer confidence" (European Parliament and Council, 2002a: Recital 35), EFSA is also mandated to provide independent information on all matters within these fields and to communicate on risks and food safety issues to the public, together with the Commission and the national authorities. Furthermore, it was assigned a competence in the realm of

[101] Specifies the date of the document.

risk prevention, namely "the anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention" (European Parliament and Council, 2002a: Recital 50 and Art. 34).

For cases when a food crisis could not be prevented, the EU's new approach included a revision of the Rapid Alert System for Food and Feed (RASFF), a network of contact points from the Member States, the Commission and EFSA, managed by the Commission. The major task of the system is to communicate and respond to direct or indirect risks to human health deriving from food or feed and to exchange information about measures taken (European Parliament and Council, 2002a: Recital 59, Art. 35, Art. 50). In consequence, the information communicated via RASFF can lead to products being recalled from the market. The revision of the network, originally created in 1979, was needed, the Regulation set out, because "[r]ecent food crises [had] demonstrated the need to set up an improved and broadened rapid alert system" (European Parliament and Council, 2002a: Recital 59).

Complementarily to the creation of EFSA, the founding regulation also called for a comprehensive approach to emergency food safety measures in the light of "[r]ecent food safety incidents [that had] demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment (European Parliament and Council, 2002a: Recital 60). In this vein, EFSA was integrated into a crisis unit during food emergencies, providing the Commission with scientific and technical assistance "to determine the most effective measures on the basis of the best scientific information" (European Parliament and Council, 2002a: Recital 61, Groenleer, 2009: 181).

It becomes clear that Regulation 178/2002 meant a substantial revision of the EU's food safety setup, and thus for zoonoses and food-borne infectious diseases, with the creation of an authority that is one of the best embedded and most powerful of the EU agencies (Vos and Wendler, 2006). By replacing every reference in previous Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee by a reference to the European Food Safety Authority, the old committee system was abolished in favour of a centralised body that encompasses different scientific thematic panels and a Scientific Committee which took over the role of the old Scientific Steering Committee. The new body was thus detached from the Commission in order to provide more independent information.[102]

[102] For more details on the structure and internal organisation of EFSA see http://www.efsa.europa.eu/en/aboutefsa/efsawho.htm (accessed 12.12.2014) and Krapohl (2008: 140ff) and Groenleer (2009: 177-211).

Despite these innovations, however, EFSA was set up as a tool only in the field of risk assessment[103] to identify and evaluate risks in view of different policy options, but the setup for risk management[104] to actually implement responsive measures was not changed in a similar fashion. The new system foresees that the Commission builds on EFSA's advice when drafting proposals, but is still free to follow them or not. The Commission also remained in charge of risk management decisions, embedded into the comitology ('regulatory') procedure. Experts argue that "[s]uch a separation […] may prove more than a little tricky", in particular "when the Authority is expected to communicate directly with both risk managers and the general public" (Randall, 2006: 413). Also, while EFSA cannot enforce its views and assessments (Marsden and et al., 2010: 90f), the Commission's decisions in response to an emergency are still subject to a potentially blocking qualified majority of the Member States in the Council. Once adopted, it is also on the Commission and not EFSA to monitor and enforce the implementation of the measures (Krapohl, 2008: 142, Groenleer, 2009: 181).

EFSA, however, "has sought to persuade its most powerful stakeholders that it can become the vital hub of a new European institutional architecture in which risk assessors and communicators, armed with superior scientific and communications instruments, endow the Commission's actions and policy-making with greater authority" (Randall, 2006: 415, Grant, 2012: 1037). The agency can thus provide "the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food" (European Parliament and Council, 2002a: Art. 1.1), but it operates, at the same time, in the mission to ensure the effective functioning of the Internal Market. The balance between the free movement of goods and a high level of protection of human health is, thus, a tension inherent to the agency's design and constitutes also the major theme that runs through the formulations of the Regulation (Kanska, 2004: 713).

5.5. The Securitisation of BSE/TSEs

Tracking the BSE/TSEs-related developments at the EU level between 1989 and 2002 has shown that the crisis went along with lively activity in terms of political debate fed from a wide range of EU actors, a series of actions to contain the disease as well as a set of substantial changes to structurally reform the EU's setup for food safety and the control of food-borne infectious diseases. With a view to the identification of the (forms of) securitisation of BSE/TSEs at the EU level, the political response needs to be analysed from a security perspective by assessing words (verbal dimension) and actions (operational dimension) to differentiate between securitisation degrees, kinds and securitising actors.

[103] Understood as "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation" (European Parliament and Council, 2002a: Art. 3 (11)).

[104] Understood as "the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options" (European Parliament and Council, 2002a: Art. 3 (12)).

To recall, securitisation analysis is done on the basis of the full set of official EU output as generated in line with the method for the collection of documents set out in chapter 2.5.5. The degree of securitisation can be analysed by combining, counting, weighting and classifying the set of primary sources along the basic spectrum of (highly) securitising, neutral, or (highly) de-securitisation parameter values, complemented by an assessment of a possible (re-)allocation of resources, the overall strength of the security discourse and the composition of the group of securitisers (see chapters 2.3.1 and 2.5.6.1.).[105] In this way, it can be assessed whether and how the EU documents qualify as securitising speech acts and emergency measures.

In turn, the analysis of the kind of securitisation is done by scrutinising the security understanding(s) of the BSE/TSEs securitisation as comprised in the set of EU documents. In this context it will be of particular interest to investigate into the BSE/TSEs-related security construction as made up by the definition(s) of the threat, the threatened referent objects and the provision of security. In order to retrieve respective information from the EU legal output the list of security parameters as developed in chapter 2.3.2.2 serves as a basic questionnaire.[106] In order to also draw also lessons regarding the securitising actors at the EU level, the investigation into the degrees and kinds of securitisation of BSE/TSEs is complemented by a cross-cutting section that explores the role of the different EU actors in the securitisation process.

5.5.1. The Degree of Securitisation

Given the long period under scrutiny the analysis of the securitisation degree is split into four phases which reflect the overall securitisation development. The first and second section cover the years from 1989 to 1995 and from 1996 to 1997 respectively, the third and fourth section deal with the years between 1998 and 1999 and between 2000 and 2002. At the end of each phase a table provides an overview of the analysed BSE/TSEs-related documents as well as an interpretation of their meaning for the overall securitisation degree of BSE/TSEs in line with the classification system, including securitisation scores as established in chapter 2.5.6.1 (see Table 2-4).

5.5.1.1. The Years from 1989 to 1995

For the late 1980s and early 1990s, we find only few attempts to establish BSE as a security threat, although the Commission occasionally labelled BSE a “serious contagious or infectious animal disease whose presence may constitute a danger to cattle” (European Commission, 1989). By referring to the problem as a matter that bears “minimal risk for consumers” (European Commission, 1990b), however, the overall concern at that time was located outside the security realm. First weak exceptional measures in veterinary and common market policy were adopted in the early 1990s regarding the notification of detected BSE cases and the introduction of additional requirements for some tissues and organs with respect to BSE (European Commission, 1990f, 1990b), followed by

[105] See Figure 2-3: From A-Politic to Highly Securitised – The Indicators of the Securitisation Degree.
[106] See Table 2-1: Parameters to Distinguish Infectious Disease-Related Security Concepts.

stronger counter measures in 1994 which included British beef health certificates (European Commission, 1994c), provisions regarding the inactivation of BSE agents (European Commission, 1994b) as well as first limited dispatch bans of live cattle from the UK (European Commission, 1994d). Given some derogations and limitations that followed from amendments of original counter measures, also de-securitising elements occurred in the legal output.

Although some of these measures can be categorised as 'weakly securitising' extraordinary measures, in particular the restrictions on the dispatch of bovine embryos and live cattle from the UK (European Commission, 1992a, 1994d), the wordings of the respective legal output only seldom employed clear security language. Still, the exceptional meeting of the Council on BSE in June 1990 and a hand full of questions brought up by the Parliament between 1989 and 1995 document that the disease was about to be securitised temporarily also in the verbal dimension. All in all, given the limited number of speech acts and emergency measures in combination with the occasional and weak use of security language by the Commission and the Parliament as the main securitisers, both of which range not highest in the political hierarchies, the years between 1989 and 1995 can be understood as a period in which BSE/TSEs became *politicised* – rather than downright securitised.

Table 5-2: BSE/TSEs-Related Speech Acts and Emergency Measures, 1989-1995

OJ Date [107]	Author [108]	Reference [109]	Contents	Securitisation [110]	
Doc. No. [111]				Verbal	Oper.
03.08.89	COM	(European Commission, 1989)	Restrictions on the dispatch of certain live cattle from the UK	++	+
D 89/469/EEC					
15.02.90	COM	(European Commission, 1990d)	Dispatch limitation to calves under 6 months old only. Amendment of 89/469/EEC	o	-
D 90/59/EEC					
22.03.90	COM	(European Commission, 1990f)	Compulsory notification of BSE and temporarily amending the frequency of notification for BSE	++	+
D 90/134/EEC					
25.04.90	COM	(European Commission, 1990b)	Additional requirements for some tissues and organs with respect to BSE	+	+
D 90/200/EEC					
09.06.90	COM	(European Commission, 1990c)	Guarantees on identification of animals and certification for beef dispatch from the UK. Amendment of 89/469/EEC and 90/200/EEC	+	+
D 90/261/EEC					
16.07.90	EP	(European Parliament, 1990)	Resolution on Bovine Spongiform Encephalopathy (BSE)	+	o
n.a.					
22.02.91	COM	(European Commission, 1991)	Financial provision for a project relating to the inactivation of the agents of scrapie and BSE	o	o
D 91/89/EEC					
04.06.92	COM	(European Commission, 1992a)	Restrictions on the dispatch of bovine embryos from the UK	+	+
D 92/290/EEC					
28.08.92	COM	(European Commission, 1992b)	Compulsory notification of BSE (Repeals and replaces D 90/134/EEC)	o	+
D 92/450/EEC					
07.07.94	COM	(European Commission, 1994e)	Ban on the use of proteins derived from mammalian tissues for the feed of ruminants	o	+
D 94/381/EC					
07.07.94	COM	(European Commission, 1994b)	Processing of ruminant waste , inactivation of BSE agents	o	+
D 94/382/EC					
29.07.94	COM	(European Commission, 1994d)	Dispatch restrictions live cattle + ruminant products from UK; destruction of bovine offal	o	+
D 94/474/EC					
17.12.94	COM	(European Commission, 1994c)	Certification for beef dispatch from the UK. Amendment of 94/474/EC	o	+
D 94/794/EC					
18.02.95	COM	(European Commission, 1995b)	Batch rendering systems. Amendment of 94/382/EC	o	+
D 95/29/EC					
11.03.95	COM	(European Commission, 1995c)	Derogation to the feed ban. Amendment of 94/381/EC	o	-
D 95/60/EC					
01.08.95	COM	(European Commission, 1995a)	Certification for beef dispatch. Amendment of 94/474/EC	o	+
D 95/287/EC					
+ 4 written questions from MEPs on BSE/TSEs (unclassified).					

Source: Own presentation.

[107] Date of publication of the document in the European Union's Official Journal (OJ).
[108] Official author of the document using the following abbreviations: Commission (COM), Council (CO), Parliament (EP), European Council (EUCO), European Economic and Social Committee (EESC).
[109] Document specification as used in the 'List of References' of the present study.
[110] Along the verbal and the operational (oper.) dimension.
[111] Official specification as provided in the document. 'D' means 'Decision', 'R' means 'Regulation'.

5.5.1.2. The Years from 1996 to 1997

The degree of securitisation underwent a strong development in 1996 and 1997. The change commenced with the 'UK embargo' of March 1996 which imposed, as an "emergency measures to protect against bovine spongiform encephalopathy", an EU-wide export ban on British beef, products from bovine animals, live animals as well as meat- and bone-meal to both the entire EU as well as third countries (European Commission, 1996b).

This unprecedented step was followed by various financial support measures, market interventions and BSE eradication programmes in the next 1,5 years. Broadly speaking, reactions had two objectives: 1) the elimination of (suspected) infected animals and products of animal origin as well as production and transport controls, and 2) financial support aiming at the alleviation of the consequences of the slaughtering and the fall of market prices.

As regards the former, the eradication programmes in the UK, Portugal, France and Ireland (European Commission, 1996j, 1996a, 1997i, 1997g), the approval treatment systems for animal waste and shipping restrictions (European Commission, 1996l, 1997a) and the prohibition of the use of risk materials (brain, eyes, spinal cord) (European Commission, 1997f) made up for a comprehensive set of extraordinary measures explicitly targeted to combat BSE/TSEs. Due to the legal justification of these measures, partly referring to Council Directive 89/662/EEC (Council, 1989: Art. 9), the recitals and the legislation articles employed an explicit security language, referring to the disease as a "serious hazard to animals or to human health".

With a view to the economic implications of the crisis, the Council found that the market for beef was "seriously disturbed as a result of consumer concerns in relation to bovine spongiform encephalopathy (BSE)" (Council, 1996d) and facing "continuing serious difficulties" (Council, 1996c). Against this background a series of "exceptional support measures for the beef market" was adopted to support the United Kingdom as well as Belgium, France, Germany, Ireland, Portugal and the Netherlands (European Commission, 1996d, 1996e, 1996g, 1997e, 1997d, 1997c), where veal calves imported from the United Kingdom had to be destroyed and where owners were compensated for the destruction under the market regulation rules (European Commission, 1996e).

These interventions in the Internal Market, altering the rules on the free movement of goods and competition policy on the grounds of an urgent security situation, clearly meet the criterions of radical emergency measures, just as the compulsory slaughtering programmes. To illustrate, the UK's 'over 30 months slaughter scheme' and the 'calf processing premium' together have resulted in the elimination of 1.1 million cows and 522.000 calves during 1996, which represented about 2% of the EU herd at that time (European Court of Auditors, 1997: 100). All in all, these measures accounted for a strong rise of the securitisation degree during 1996 and 1997 in both the verbal and the operational dimension.

Furthermore, the labelling of these actions as "*emergency measures* [emphasis added] to protect against bovine spongiform encephalopathy" (European Commission, 1996b) and "exceptional support measures" (for instance European Commission, 1996h) speak a clear language (of

securitisation), just as statements declaring that “the British meal manufacturers caused a major threat to health” (European Parliament, 1997b). Although for the purpose of this analysis the BSE/TSEs-related written questions by Members of the European Parliament were not systematically assessed with regard to the inherent security discourse, the drastically risen number of 119 for the period from January 1996 to December 1997 in contrast to 4 for the period from January 1989 to December 1995 contributes to the picture of a risen prioritisation in the verbal dimension. Hence, in addition to an increased number and an increased strength of emergency measures, we observe an increased number of securitising speech acts with a clear prevalence of security language in the analysed key documents.

Beyond that, for the period from 1996 onwards the analysis has revealed an enlarged group of securitisers, reaching from ‘weak’ actors such as the European Economic and Social Committee through the European Parliament, the European Commission, the Council up to the highest political level, the European Council. The heads of state or government had started to become active in BSE/TSEs affairs in June 1996 following the UK’s ‘empty-chair’ politics (European Council, 1996) which resulted in two parallel effects: On the one hand it led to a partial lifting of the ban for certain cattle products (European Commission, 1996f) and thus to one of the few elements that contributed to a temporary de-securitisation. On the other, the UK’s approach ultimately accounted for the shifting of the matter to the highest political spheres which was involved in the crisis from then on, for instance addressing it in a separate declaration annexed to the Presidency Conclusions of the summit in Luxembourg (European Council, 1997).

An extraordinary strong combination of securitisation moves was put forward by the European Parliament when it set up a Committee of Inquiry on BSE whose report was then combined with the announcement of a no-confidence motion. This motion bore the potential to cause the dismissal of the entire European Commission in case that no substantial reform was envisaged by the Commission (European Parliament, 1997b).

All in all, the rising securitisation degree was thus also reflected in the change of the composition of the group of securitisers towards a higher number of securitisers, towards more influential securitisers and towards securitising moves that were linked to far-reaching consequences.

Finally, part of the set of emergency measures was a substantial allocation of resources to support the combat of the disease and to finance related market support programmes (Council, 1996e, European Commission, 1996h, 1996i). The decision of the European Council in June 1996 that “funding of ECU 850 million will be devoted to supporting European livestock farmers seriously affected by this crisis” (European Council, 1996) is a good example for this development. The figures presented by the Court of Auditors specify ECU 1.022,3 million post-BSE budgetary expenditure in 1996 (European Court of Auditors, 1997: Table 4.1., 101) and a total of ECU 2.149 million of BSE-related expenditure of the European Agricultural Guidance and Guarantee Fund in 1996 and 1997, which constituted an increase of 32 per cent in relation to the normal premium scheme expenditure (European Court of Auditors, 1998a: 6, 19).

To sum up, given the amount and the strength of emergency measures, the radical allocation of resources, a dominant security discourse and an increasing number of both speech acts as well as (politically strong) securitisers, the EU's reaction made up for a high securitisation degree in the years from 1996 to 1997, on both the verbal as well as the operational level.

Table 5-3: BSE/TSEs-Related Speech Acts and Emergency Measures, 1996-1997

OJ Date	Author	Reference	Contents	Securitisation	
Doc. No.				Verbal	Oper.
28.03.96	COM	(European Commission, 1996b)	'UK embargo'; Total dispatch ban for live cattle and all cattle products from the UK	++	++
D 96/239/EC					
20.04.96	COM	(European Commission, 1996h)	Exceptional support measures for the beef market in the United Kingdom	++	+
R 716/96					
20.04.96	COM	(European Commission, 1996i)	Exceptional support measures for the beef and veal market in Belgium, France and Netherlands	++	+
R 717/96					
22.04.96	EP	(European Parliament, 1996d)	Resolution on the Commission' s measures with regard to BSE	++	o
B4-0458/96					
12.06.96	COM	(European Commission, 1996f)	Conditional lifting of the ban for certain cattle products. Amendment of D 96/239/EC	o	-
D 96/362/EC					
21.06.96	EUCO	(European Council, 1996)	Support for producers affected by the fall in beef consumption and by the impact on market prices	+	++
SN 300/96					
22.06.96	COM	(European Commission, 1996a)	Eradication programme for BSE in Portugal	+	++
D 96/381/EC					
26.06.96	COM	(European Commission, 1996j)	Eradication programme for BSE in the UK	+	++
D 96/385/EC					
05.07.96	CO	(Council, 1996b)	Multidisciplinary scientific committee entrusted to launch activities	o	+
96/C 194/01					
08.07.96	EP	(European Parliament, 1996a)	Major crisis within EU; disastrous economic repercussions for the agricultural industry	++	o
B4-0733					
13.07.96	CO	(Council, 1996e)	Additional payments to be made in 1996 with the premiums	+	++
R 1357/96					
24.07.96	COM	(European Commission, 1996l)	Pressure cooking to inactivate TSE agents when processing mammalian waste	o	+
D 96/449/EC					
27.07.96	COM	(European Commission, 1996d)	Exceptional support measures for the beef market in the United Kingdom	+	++
R 1484/96					
30.07.96	COM	(European Commission, 1996g)	Exceptional support measures for the beef market in Portugal	+	++
R 1508/96					
17.08.96	COM	(European Commission, 1996c)	Proposal to establish a European Agency for Veterinary and Phytosanitary Inspection	+	o
COM(96) 223 final					
07.10.96	EESC	(EESC, 1996)	Opinion on BSE crisis and its wide-ranging consequences for the European Union	++	o
96/ C 295/13					
13.11.96	COM	(European Commission, 1996k)	Research initiative on BSE	+	+
COM(96) 582 final					
11.12.96	CO	(Council, 1996a)	Conclusions on cooperation in BSE matters	+	o
96/C 374/02					
21.12.96	CO	(Council, 1996c)	Additional direct support measures for producers' incomes / for the beef and veal sector	+	++
R 2443/96					
10.01.97	COM	(European Commission, 1997i)	Eradication programme for BSE in France	+	++
D 97/18/EC					
31.01.97	COM	(European Commission, 1997e)	Exceptional support measures for the beef market in France	+	++
R 164/97					

(continued)

(continued)					
20.02.97 R 299/97	COM	(European Commission, 1997d)	Exceptional support measures for the beef and veal market in Germany	+	++
07.05.97 R 820/97	CO	(Council, 1997a)	Systems for the Identification and Registration of Bovine Animals and Labelling of Beef	+	++
24.05.97 D 97/312/EC	COM	(European Commission, 1997g)	Eradication programme for BSE in Ireland	+	++
19.06.97 R 1112/97	COM	(European Commission, 1997c)	Exceptional support measures for the beef market in Ireland	+	++
08.08.97 D 97/534/EC	COM	(European Commission, 1997f)	Prohibition of the use of risk materials (brain, eyes, spinal cord)	+	+
28.10.97 D 97/735/EC	COM	(European Commission, 1997a)	Animal waste treatment and shipping; Restrictions on trade	o	+
06.12.97 D 97/65/EC	COM	(European Commission, 1997b)	Protection of workers from risks related to exposure to spong. enceph. agents at work	+	+
08.12.97 B4-0920ff	EP	(European Parliament, 1997a)	Follow-up Committee on BSE: considerable steps toward making the action to combat BSE	-	o
12.12.97 SN400/97	EUCO	(European Council, 1997)	Declaration by the European Council on food safety	++	o
+ 119 written questions from Members of the European Parliament on BSE/TSEs (unclassified).					

Source: Own presentation.

5.5.1.3. The Years from 1998 to 1999

In terms of speech acts and emergency measures the situation generally eased in 1998 and 1999. Although a series of securitising elements both on the verbal and the operational dimension occurred in the legal output, in particular related to the notification of BSE and TSEs (operational) (European Commission, 1998e, 1998h) and in the framework of the retrospective analysis of the previous years (verbal) (European Commission, 1998i, European Court of Auditors, 1998b), the general tenor of BSE-related legal output was rather unagitated. Many of the key documents of this period were follow-up measures of the dynamic years before, for instance in the form of extensions of temporary measures or minor amendments of previous legislation. The basic message, however, was that the institutions had responded to the disease and that a series of effective counter measures were put in place (European Commission, 1998b). By dealing with the disease in a tranquilised manner without the adoption of further extraordinary measures, BSE/TSEs moved back into the realm of a lowly securitised disease.

In contrast to the overall trend, one exception took place in response to the situation in Portugal, when Commission inspections led to “serious concerns with regard to the development of the disease in the near future” (European Commission, 1998a) and served as the justification for a total ban on the dispatch of live cattle and all cattle products from Portugal, the so called ‘Portugal embargo’ (European Commission, 1998c, 1999d). Naturally, respective documents shifted the topic to greater securitisation heights. However, at the same time, the partial and stepwise lifting of the ‘UK embargo’ also accounted for a number of de-securitising elements (European Commission, 1998a, 1999a).

Beyond the review of previous activities and the follow-up work resulting from the previous period, also the elaboration and implementation of additional regulation, for instance with regard to specified risk materials, the treatment of animal waste and the beef labelling system was still on the agenda (Council, 1999a, 1999b). These initiatives, however, were of a technical nature and did not entail significant elements of securitisation, neither in form of security language nor in the form of far reaching emergency measures. Although the need for further reforms "to deal, in a coordinated, effective and timely manner with this kind of crisis" in the future was voiced (European Court of Auditors, 1998b), neither substantial regulatory nor new market measures were introduced in this period (European Court of Auditors, 2001: 10).

All in all, it becomes clear that in 1998 and 1999 BSE/TSEs were no longer treated as an exceptional and prioritised issue. This interpretation is also supported by the lower number of written questions by Members of the European Parliament, which did not exceed the number of 33 in total for the entire period.

Table 5-4: BSE/TSEs-Related Speech Acts and Emergency Measures, 1998-1999

OJ Date / Author / Doc No.	Reference	Contents	Securitisation	
			Verbal	Oper.
08.01.98 COM D 98/12/EC	(European Commission, 1998h)	Further compulsory notification of BSE. Repeals and replaces D 92/450/EEC.	o	+
27.01.98 COM COM(1998) 34 final	(European Commission, 1998i)	Report on the Integration of Health Protection Requirements in Community Policies (1996)	+	o
06.04.98 EP A4-0009/98	(European Parliament, 1998)	Resolution on the Commission Green Paper on the general principles of food law in the EU	o	o
15.04.98 CO D 98/256/EC	(Council, 1998c)	Partial lifting of UK embargo (Northern Ireland), reinforcement of controls. Repeals D 96/239/EC	+	o
24.04.98 COM D 98/272/EC	(European Commission, 1998e)	Requirements for diagnostic staff &notification of TSE; Epidemio-surveillance for all animal TSEs	o	+
06.05.98 COM COM(98) 282 final	(European Commission, 1998b)	First Bi-Annual BSE Follow-Up Report	o	o
30.05.98 COM D 98/351/EC	(European Commission, 1998d)	Commence of dispatch from Northern Ireland on 01.06.1998	-	-
04.06.98 CO 98/C 169/02	(Council, 1998b)	Council Conclusions on TSEs	o	o
04.06.98 CO 98/C 169/01	(Council, 1998a)	Council Conclusions on the integration of health protection requirements in Community policies	o	o
30.07.98 COM 98/477/EC	(European Commission, 1998g)	Information necessary to support applications for the evaluation of Member States' TSE status	+	o
17.11.98 ECA 98/C 349/01	(European Court of Auditors, 1998b)	Annual Report concerning the financial year 1997. Need for crisis action plan	+	o
20.11.98 COM D 98/653/EC	(European Commission, 1998c)	'Portugal embargo'; Total dispatch ban for live cattle and all cattle products from the UK	++	++
05.12.98 COM D 98/692/EC	(European Commission, 1998a)	Principles of further lifting of the UK embargo under the Date-based Export Scheme	-	- -
09.12.98 ECA 98/C 383/01	(European Court of Auditors, 1998a)	Special Report No 19/98: Community Financing of Measures Taken as a Result of the BSE Crisis	+	o
28.07.99 COM D 1999/514/EC	(European Commission, 1999a)	Commence of dispatch of certain bovine products from the UK on 01.08.1999	-	-
				(continued)

(continued)					
29.07.99	COM	(European Commission, 1999d)	Extension of the Portugal embargo	+	++
D 99/517/EC					
18.11.98	COM	(European Commission, 1999b)	Second Bi-Annual BSE Follow-Up Report	o	o
COM(98) 598 final					
30.07.99	EP	(European Parliament, 1999)	Resolution on Second Bi-Annual BSE Follow-Up Report	++	o
A4-0083/99					
04.08.99	CO	(Council, 1999a)	Conditions for the processing of certain animal waste. Repeals D 96/449/EC	o	o
D 1999/534/EC					
04.11.99	COM	(European Commission, 1999c)	Dispatch of meat and bone meal for incineration and fighting bulls	o	o
D 1999/713/EC					
01.12.99	SSC	(James et al., 1999)	A European Food and Public Health Authority: The Future of Scientific Advice in the EU (Report Presented to the European Commission)	+	o
11.12.99	EUCO	(European Council, 1999)	Presidency Conclusions on public health and food safety	+	o
00300/1/99					
28.12.99	CO	(Council, 1999b)	Temporary application of rules for a compulsory beef labelling system	o	o
R 2772/1999					
+ 33 written questions from MEPs on BSE (unclassified).					

Source: Own presentation.

5.5.1.4. The Years from 2000 to 2001

The year 2000 started with yet another extension of the Portugal embargo (European Commission, 2000g) and continued over the summer with various securitising initiatives. In the verbal dimension, the report by the Scientific Steering Committee on the geographical risk of BSE, arguing that BSE constituted a cross-national threat with the potential to affect basically every country in Europe, set a new starting point for the re-securitisation of the disease (Scientific Steering Committee, 2000). The introduction of BSE tests (European Commission, 2000f) and reinforced surveillance measures (European Commission, 2000l) were soon followed by new emergency measures and revealed that the disease had in fact not been dealt with in a terminatory manner. Similar to the first BSE/TSEs securitisation wave in 1996/1997, counter measures had two interconnected targets: the monitoring and eradication of the disease as a threat to health in all Member States on the one hand, backed up by the allocation of additional financial contributions (Council, 2000, European Commission, 2000c, 2000f), and the financial support of the beef market on the other (European Commission, 2000i, 2000b, European Council, 2001c).

The special market support and further exceptional support measures in the beef sector (European Commission, 2001j, 2001h), the large scale monitoring and testing programme (European Commission, 2001k, 2001n), and additional provisions as regards risk materials (European Commission, 2001o) and feeding stuff (European Commission, 2001a) were also carried on in 2001, before in August the end of the 'Portugal embargo' marked the beginning of a falling securitisation degree.

A major difference between the securitisation in 1996/1997 and in 2000/2001 was the scope of the measures. In the first wave the issue was primarily a British and to some extend a Portuguese problem that was exported to a limited set of Member States and thus demanded Community action; nevertheless, BSE/TSEs remained first and foremost a national issue. In contrast, the second

wave established BSE/TSEs as a fully-fledged Community problem that demanded rapid and encompassing reactions in all Member States. Another important difference was that in the operational dimension of securitisation, measures were not primarily of responsive nature anymore. Beyond immediate protective measures, also surveillance measures significantly contributed to the securitisation of BSE/TSEs. Interestingly, these surveillance measures had been triggered as a consequence of the first securitisation wave and were finally put in place in June 2000. From then, the reinforced monitoring activities in the year 2000 constituted an important factor to move BSE/TSEs out of the area of a non- or weakly securitised matter into the realm of a highly securitised matter again.

In addition to the high securitisation of BSE/TSEs in the operational dimension, the accompanying justifications of the legal output also contributed to the securitisation of BSE/TSEs in the verbal dimension. Addressing the "instability in the market in beef and beef products caused by the bovine spongiform encephalopathy crisis" (European Parliament and Council, 2000) and the "deep crisis" in the beef sector characterised by "[c]onsumption as well as production [rates] fallen to unprecedented levels" (European Commission, 2000i), however, indicate that the lack of consumer confidence and the questions of transparency and communication in food safety affairs dominated the discourse. In this context the disease also appeared several times on the agenda of the European Council. The heads of state or government showed not only concern about the "severity of the situation in the agriculture sector" (European Council, 2001c) and welcomed the market support measures, but in this context also stressed a further revision of the structural setup (European Council, 2000a, 2000b).

All in all, between summer 2000 and spring 2001 the securitisation of BSE in the EU entered a second phase of a strongly rising degree, with a peak at the end of the year 2000. The high securitisation degree was to a large extent result of the strong statements and emergency measures related to the combat of the disease and the support of the respective market, including the comprehensive allocation of funds. After BSE-related expenditures had already added up to 2.149 million for the years 1996 and 1997 (European Court of Auditors, 1998a: 6)**,** the overall share in the EU budget to implement market support measures for the years between 1996 and 2000 added up to 4.696 million Euros (European Court of Auditors, 2001: 3). Seeing that BSE/TSE-related measures were taken beyond the field of market support and also by Member States individually, the total costs were even much higher.

Beyond that, further steps to close existing regulatory gaps supported the trend, for instance related to animal feeding or specified risk materials. The fact that utterances were issued by basically the full set of EU actors involved, ranging from the Scientific Steering Committee and the Court of Auditors through the Parliament and the Commission to the Council and the European Council, supports the classification of BSE/TSEs as highly securitised in the years between 2000 2001. Most likely, the overall assessment would be even clearer if the numerous written questions from Member of the European Parliament were systematically classified and included in the analysis; they added up to 98 for the years 2000/2001 and stand thus in stark contrast to 33 in the period from 1998 to 1999.

Table 5-5: BSE/TSEs-Related Speech Acts and Emergency Measures, 2000-2001

OJ Date / Doc No.	Autor	Reference	Contents	Securitisation	
				Verbal	Oper.
04.02.00 D 2000/104/EC	COM	(European Commission, 2000g)	Extension of the Portugal embargo	+	++
23.05.00 D 2000/345/EC	COM	(European Commission, 2000n)	Starting date for the dispatch from Portugal of meat/bone meal for the purpose of incineration	o	o
07.06.00 D 2000/371/EC D 2000/372/EC	COM	(European Commission, 2000o, 2000p)	Starting date for the dispatch from Portugal of fighting bulls to France and Spain	o	o
08.06.00 D 2000/374/EC	COM	(European Commission, 2000f)	Introduction of rapid post-mortem test in monitoring for BSE	o	+
19.06.00 SN 200/1/00 REV 1	EUCO	(European Council, 2000a)	Presidency Conclusions on public health and food safety	+	o
30.06.00 D 2000/418/EC	COM	(European Commission, 2000e)	Prohibition of the use of risk materials. Repeals D 97/534/EC	+	+
06.07.00	SSC	(Scientific Steering Committee, 2000)	Geographical Risk of Bovine Spongiform Encephalopathy	++	o
11.08.00 R 1760/2000	EP/CO	(European Parliament and Council, 2000)	Revision identification and registration system of bovine animals; Community beef labelling system. Repeals R 820/97	+	++
06.12.00 D 2000/764/EC	COM	(European Commission, 2000l)	Reinforcement of the surveillance; Amendment of D 98/272/EC	+	+
07.12.00 D 2000/766/EC	CO	(Council, 2000)	Prohibition of the feeding of processed animal proteins	+	++
08.12.00 SN 400/1/00	EUCO	(European Council, 2000b)	Pres. Conclusions on combat of BSE, market support measures and European Food Authority	+	o
08.12.00 D 2000/773/EC	COM	(European Commission, 2000c)	BSE monitoring and eradication programmes in all Member States; financial contribution	+	++
19.12.00 R 2777/2000	COM	(European Commission, 2000i)	Exceptional support measures for the beef market	++	++
19.12.00 R 2778/2000	COM	(European Commission, 2000b)	Further exceptional support measures for the beef market in Germany	+	+
04.01.01 D 2001/2/EC	COM	(European Commission, 2001o)	Extension of risk materials; Intestines of all bovines any age. Amendment of D 2000/418/EC	o	+
05.01.01 D 2001/8/EC	COM	(European Commission, 2001i)	BSE surveillance and testing. Amendment of D 2000/764/EC and update of D 98/272/EC	o	o
05.01.01 D 2001/9/EC	COM	(European Commission, 2001l)	Conditions for feeding certain animal proteins	o	o
11.01.01 D 2001/25/EC	COM	(European Commission, 2001a)	Prohibition of the use of dead animals in the production of animal feed	+	++
20.01.01 R 112/2001	COM	(European Commission, 2001j)	Further exceptional support measures for the beef market in Luxembourg	+	+
23.03.01 D 2001/233/EC	COM	(European Commission, 2001d)	Extension of the list of risk materials. Amendment of D 2000/418/EC	+	+
24.03.01 100/1/01	EUCO	(European Council, 2001c)	Presidency Conclusions on the situation in the agricultural sector	+	o
05.04.01 R 690/2001	COM	(European Commission, 2001h)	Special market support measures in the beef sector	+	++
15.05.01 D 2001/376/EC	COM	(European Commission, 2001f)	Principles for lifting the Portuguese ban; Date-based Export Scheme. Repeals D 98/653/EC	-	-
28.07.01 D 2001/5777EC	COM	(European Commission, 2001g)	Commence of dispatch of bovine products from Portugal on 01.08.2001	-	-
20.11.01 2001/C 324/01	ECA	(European Court of Auditors, 2001)	Follow-up Special Report on BSE	+	o
04.12.01 D 2001/854/EC	COM	(European Commission, 2001k)	BSE monitoring and eradication programmes in all Member States; financial contribution	+	++

Source: Own presentation.

5.5.1.5. The Rise and Fall of the Securitisation Degree

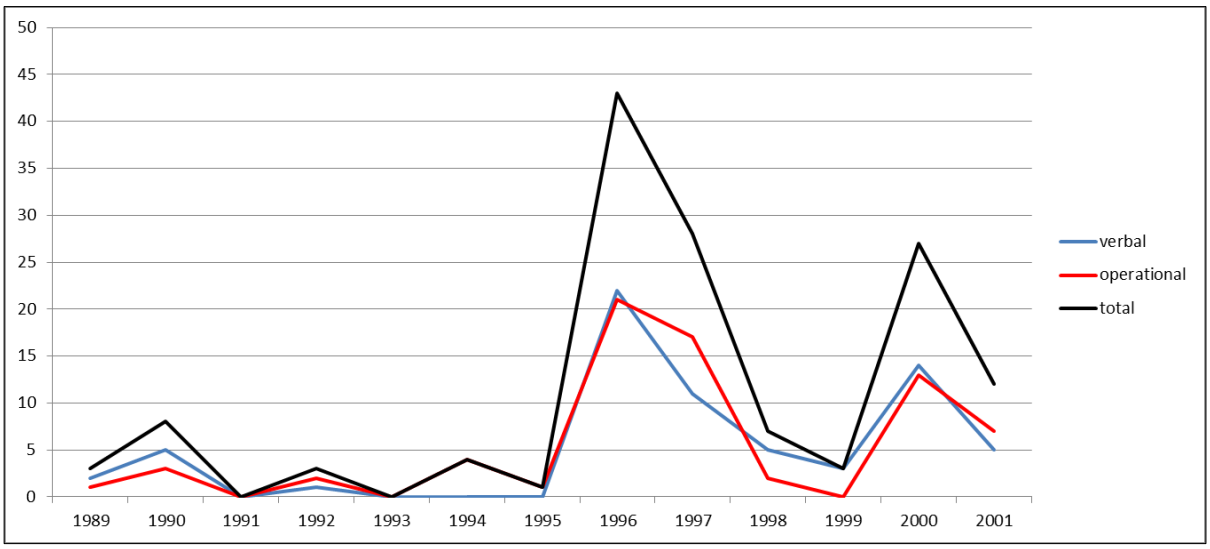
We see that bovine and transmissible spongiform encephalopathies were subject to various responses and reform processes at the EU level. The basic constituents for a securitisation of the disease (speech acts and extraordinary counter measures issued by EU securitisers) were clearly part of these political developments. Speech acts that declared BSE/TSEs a serious threat which demands top priority counter action have occurred in all phases of the process from EU actors of various kinds. First emergency measures to respond – as a matter of urgency – to a threatening situation related to BSE were adopted in 1996 and continued until the end of the period under scrutiny.

All in all, the analysis has shown that the securitisation degree underwent a series of basically four phases. Between the beginning of first securitisation moves in the late 1980s until the end of the period of analysis in 2002, the disease has reached the status of a highly securitised issue two times: first during the securitisation wave in 1996/1997 and again during the years 2000/2001. The allocation of funds, the composition of the group of securitisers and also singular events and documents such as the 'empty-chair politics' of the UK government in 1996 and the Parliament's menace to table a motion of censure against the Commission in 1997, support the overall interpretation of BSE/TSEs as an extraordinary issue beyond the realm of normal every day-to-day politics in these particular periods.

As developed in chapter 2.5.6.1, the present study does not claim to offer a precise measurement of the securitisation or the expression of the securitisation degree in form of an index. Still, a schematic representation of the securitisation degree is valuable to illustrate the phases and peaks of the (de-) securitisation process. Such an illustration to reflect the number of utterances as well as their classification along the securitisation spectrum between lowly and highly (de-)securitising is possible in a timeline, if the scores of the securitising moves as classified in Table 5-2, Table 5-3, Table 5-4 and Table 5-5 are set off against the de-securitising elements for the given period.[112] In this way, without taking into account the further indicators for the securitisation degree, the rise and fall of the overall securitisation of BSE/TSEs becomes visible.

[112] ++ accounts for 2 on the y-axis, + for 1, o for 0, - for -1 and -- for -2. See chapter 2.5.6.1.

Diagram 5-1: The Rise and Fall of the Securitisation of BSE/TSEs (1989-2001)



Source: Own presentation on the basis of securitisation degree scores assigned to the documents listed in Table 5-2, Table 5-3, Table 5-4 and Table 5-5.

Considering that a securitisation in both the verbal as well as the operational dimension is necessary to meet the criteria of a high securitisation degree, it is valuable to break the securitisation degree into the two dimensions. The distinction between speech acts and emergency measures reveals that in some years (1992, 1994 and 1997) the EU legal output securitised BSE/TSEs stronger in the operational dimension than in the verbal dimension. This circumstance can be explained to some extent by the selection of documents. Clearly, EU legal output derived from the EUR-Lex database contains a disproportionately high number of activity-related documents, the relative share of which would be much lower if parliamentary debates, press releases etc. were included in the analysis. Hence, it is not possible to put the two dimensions into absolute relation. However, it is interesting to note that the EU apparently adopted many measures in response to the diseases, dealing with it as an exceptional matter, without clearly defining a threat or providing explanations for the measures in security language in the same document. All in all, taking together the elements from the full set of analysed documents, the securitisation degree can be assessed to peak high at least temporarily in both dimensions.

Table 5-6: The Degree of Securitisation of BSE/TSEs Across Securitisation Dimensions

	Verbal Securitisation Degree		
Operational Securitisation Degree		Low	High
	High	Medium	**BSE/TSEs**
	Low	Low	Medium

Source: Own presentation.

Whereas Diagram 5-1 could illustrate that a high number of securitising moves shifted BSE/TSES (temporarily) into the security realm, it does not show the relative strength of the security discourse within the set of analysed EU documents. To substantiate the finding that security concerns were a dominant point of reference for the EU's activities, it helps classify the documents along the broad categories of either the securitisation (+ + and +), the neutral (o) or de-securitisation realm (- and - -) for the verbal securitisation dimension as provided in Table 5-7 (see below). By doing so it becomes clear that the total number of analysed BSE/TSEs-related documents was located in the former realm during the second (1996-1997) and the fourth (2000-2001) securitisation phase with shares of roughly 84 and 70 per cent respectively. In contrast, in the years from 1989 to 1995 and from 1998 to 1999 we observe a share clearly under 50 per cent of verbally securitising EU output.

A similar result can be found by calculating the average securitisation score (Ø) assigned to the complete EU disease-related output for a given period. As explained in chapter 2.5.6.1 this mean can be calculated by the division of the sum of all values of all utterances by the total number of utterances. Given the low number of de-securitising moves the average is above 0 in all phases. Assessed against a possible maximum score of +2, the scores of roughly +1 and +0,7 can be considered as high in the second (1996/1997) and still relatively high also in the fourth (2000/2001) securitisation phase.[113]

All in all, the calculations regarding the share of securitising elements as well as regarding the average securitisation score support the view that a strong security discourse on BSE/TSEs can be verified in particular for the two periods in which we also witnessed the highest number of EU output and the highest total securitisation score, namely in 1997/1997 and 2000/2001. The following table shows in detail the average for each period as well as the distribution of the analysed documents along the spectrum between highly securitising and highly de-securitising speech acts and emergency measures.

[113] In this context two particularities should be noted. First, of a total number of 96 analysed documents only 9 documents contained a de-securitising component. This circumstance feeds into the finding that the average score for all securitisation phases was above 0. Second, the figures for the first period (1989-1995) have to be put in perspective, since the period covers, in contrast to the other phases, 6 and not only 2 years. The total number of 16 documents for the entire period is very low in comparison to the other phases. Hence, despite certain strength of the security discourse on BSE/TSEs reflected in the average score, the overall presence of the issue was too low to qualify BSE/TSEs as a highly securitised matter between 1989 and 1995.

Table 5-7: The Strength of the Security Discourse on BSE/TSEs[114]

Securitisation score[115]		securitising		neutral	de-securitising			
		2	**1**	**0**	**-1**	**-2**	**total**	**ø**
1989 - 95	Nr. of Docs.	2	4	10	0	0	16	0,50
	%	12,50%	25,00%	62,50%	0,00%	0,00%	100,00%	
	% / Cat.	37,50%		62,50%	0,00%		100,00%	
1996 - 97	Nr. of Docs.	8	18	4	1	0	31	1,06
	%	25,81%	58,06%	12,90%	3,23%	0,00%	100,00%	
	% / Cat.	83,87%		12,90%	3,23%		100,00%	
1998 - 99	Nr. of Docs.	2	8	10	3	0	23	0,39
	%	8,70%	34,78%	43,48%	13,04%	0,00%	100,00%	
	% / Cat	43,48%		43,48%	13,04%		100,00%	
2000 - 01	Nr. of Docs.	2	16	6	2	0	26	0,69
	%	7,69%	61,54%	23,08%	7,69%	0,00%	100,00%	
	% / Cat.	69,23%		23,08%	7,69%		100,00%	

Source: Own calculation on the basis of the securitisation scores assigned to the documents in the verbal securitisation dimension as specified in Table 5-2, Table 5-3, Table 5-4 and Table 5-5.

5.5.2. The Kind of Securitisation

The assessment of the rise and fall of the securitisation degree in the verbal and operational dimension does not allow making statements on the underlying security understanding with which BSE/TSEs were securitised at the EU level. In order to elaborate on the kind of securitisation the following section explores the EU's key activities and documents along the list of security parameters as developed in chapter 2.3.2.2, ranging from the definition of the referent object(s), through the definition of the threat to the definition of the provision of security (see Table 2-1).

In this vein, identifying the referent object(s), the source, speed, geography, severity and predictability of the threat as well as the actors, policies and measures to provide security as specified in the EU legal output will help understand with which understanding BSE/TSEs were constructed as a security issue. The previous chapters have already indicated that several of the securitisation parameters changed their value in the course of the crisis, but we will also see in the following that different security constructions existed in parallel at the same time. However, since changes in terms of the kind of securitisation of BSE/TSEs were less dynamic than in terms of the degree of securitisation, the analysis does not have to follow the short time sections used in the previous chapter, but can be provided in a single, complete overview.

[114] 'Nr. of Docs.' specifies the number of documents with the respective score. '%' refers to the share of the respective group of documents with the same securitisation score in per cent of the total number of documents. '% Cat.' summarises the share of the two securitising (+2, +1), the neutral (0) and the two de-securitising categories (-1, -2) into three broader categories, specified in per cent of the total number of documents. 'Ø' refers to the average score as calculated by the division of the sum of all scores of all EU documents by the number of documents for the specified periods.

[115] Securitisation score in line with Table 2-4 which relates + + to 2, + to 1, o to 0, - to -1 and - - to -2.

5.5.2.1. The Securitisation Parameters

For the late 1980s and early 1990s, we find first attempts to establish BSE as a security threat by labelling it "serious contagious or infectious animal disease whose presence may constitute a danger to cattle" (European Commission, 1989) and contingently a "minimal risk for consumers" (European Commission, 1990b). Translating such references to the securitisation vocabulary means to identify the referent objects of the BSE threat at this time as animals, only a couple of which, that is a small number of referent objects, were found to be threatened by the disease. Measures took place at the national level, because BSE was regarded first and foremost a problem of animal health in or of the UK, which was also expected to be solved by the UK. Still, the disease considered to carry a potential risk also for other Member States.

Interestingly, the rise of the securitisation degree in 1996/1997 was accompanied by a fundamental change of the kind of securitisation. The BSE agent was classified by the Commission's Advisory Committee on Dangerous Pathogens (ACDP) as a human pathogen in 1997 only (European Court of Auditors, 1998a: 5), but it was with the start of the 'UK embargo' that the primary referent object threatened by BSE/TSEs was no longer the cattle population of the UK, but humans who were seen at risk to acquire a new variant of Creutzfeldt-Jakob Disease. Besides, also the number of (potential) referent objects rose dramatically as BSE/TSEs were no longer seen as a British problem only. In fact, the disease quickly became subject to interventions also in EU countries outside the UK. At the same time, the predictability of the threat was still considered problematically low; whereas some of the analysed documents explicitly speak about a high or serious risk, in particular the Commission generally seems to have had avoided formulations that declared the *de facto* transmissibility of BSE to humans. The uncertainty regarding the disease can be found interlined in formulations such as that "a definitive stance on the transmissibility of BSE to humans is not possible" (European Commission, 1996b).

In parallel to the shift of the primary referent away from animals to humans, the beef market in specific countries, producers of beef and veal and eventually the entire agriculture sector of the EU turned into equally important referent objects in the securitising measures of the EU. In this context the BSE/TSEs threat translated into BSE- and food safety-related "consumer concerns" (Council, 1996e, European Commission, 1996b) which – in turn – threatened the beef and veal market. With other words, it was not BSE and the threatened health of animals or humans that was problematic from an economic point of view, but the "lack of consumer confidence" following from the BSE crisis (European Commission, 1996i, Council, 1997a, European Council, 1997).

This interlinkage of BSE/TSEs, consumer confidence and the beef market was also coined by the Court of Auditors when summarising the developments of the year 1996/1997 as follows: "[t]he Community beef market was pushed to the verge of collapse almost overnight as consumer confidence plummeted" (European Court of Auditors, 1998a: 27). Beyond that, given the nature of the measures intervening in the free movements of goods, BSE/TSEs were ultimately constructed as a threat to the Community's Internal Market as a whole, as illustrated by the Commission's Communication on consumer health and food safety which stated that "[r]ecent experience ha[d]

clearly demonstrated that food safety is not only of concern to the consumer, but is also at the very root of a proper functioning of the market" (European Commission, 1997j: 7).

The parallel and interconnected securitisation of BSE/TSEs as a threat to the health of animals, the health of consumers, the confidence of consumers and, ultimately, the beef and veal market and the Internal Market as a whole is a phenomenon that can be observed for all years after 1996. In this context the problems related to BSE/TSEs became synonymous with problems related to food safety in general, even if the dioxin scandal in Belgian poultry in 1999, which is not covered by this analysis, fed into the development as well (Shears et al., 2001, Olsson, 2005, Lezaun and Groenleer, 2006, Groenleer, 2009: 179).

Finally, in 2000 and 2001, the kind of securitisation underwent yet another important change due to the changing geography of the threat. More precisely, the major difference to the securitisation wave in 1996/1997 was that during these years the issue was primarily seen as a British and to some extend a Portuguese problem that occasionally spread into a limited number of other countries and therefore demanded Community action and support, but nevertheless remained first and foremost a national issue. EU surveillance and support measures were limited to few countries and the risk was not regarded high anymore that the disease could spread to further countries. In contrast, in 2000 and 2001, BSE/TSEs were established as a fully-fledged threat across the entire Community that demanded rapid and encompassing reactions in all Member States.

On the basis of this chronological overview of the evolution of the securitisation kind it is possible to assess the individual securitisation parameters one by one. The changes occurred in a way that the periods before 1996 and after 1996 are most clearly distinguishable, with further adjustments in 2000.

As regards the referent object of security, we have seen that a major change occurred from the health of animals to that of humans and, in parallel, to consumer confidence, the beef and veal sector and eventually the Internal Market. In addition, the number of referent objects changed from few (animals/humans/national markets) to many, in particular after 2000 when the BSE/TSEs problem was no longer seen as a problem of individual countries but as an issue for all Member States.

Although the source of the threat was unknown until 1996 and is still disputed today, the construction of BSE/TSEs as a security threat never took place on the basis of suspicions regarding a deliberate release of a pathogen. Still, to some extent the disease was still considered 'man-made' after feeding practices and regulatory gaps in the foodstuff sector were identified as the main source of pathogenicity, that is the root causes that makes the disease a threat. In this context it is important to note that the threat for the beef market, strictly speaking, was not the disease as such but the lack of consumer confidence resulting from the BSE/TSE crisis.

At no time of the period under scrutiny was the speed of the threat considered high, in particular not after the opinion became accepted that the infectious agent in TSEs could not be transmitted through the air or casual contact but only through direct contact with infected tissues or

consumption of infected animals. With the definition of BSE/TSEs as a food-borne disease in 1996, also the perception of the predictability of the disease increased to some extent, even if comprehensive surveillance measures that allowed for an accurate stock-taking of the situation were introduced only with the second securitisation wave. Despite the rather slow infection path, the wide spread of contaminated material at the time of detection and the sudden appearance of a (suspected) high number of infections in animals, in particular in 2000, however, contributed to the construction of BSE/TSEs as an outbreak-like event. All in all, given that the view prevailed that effective treatment of the disease did not exist, neither for BSE nor vCJD, that the threat of the disease appeared to have fatal consequences and that the morbidity in the animal stock was seen as relatively high, the impact of BSE/TSEs was established as critically severe.

The geography of the threat, the securitisation parameter that covers the definition of the proximity of the threat, did not change between 1989 and 2001 when it comes to distinguishing between the EU and third countries. BSE/TSEs were, from the start, a European problem and despite some references to third countries in the framework of extra-EU trade, the disease was never explicitly constructed as a security problem for any other country or region in the world. Accordingly, the ethical stance to justify the response to the disease can be rather located in the idea of 'self-protection', be it the own animals, citizens or market(s), although a clear assessment is difficult since truly ethical justifications and positions were hardly detectable in the analysed documents.

Within the EU, however, the geography of the threat underwent a change, as we have seen, namely from the national (UK, Portugal) and limited EU level to the full regional (EU) level in 2000. Accordingly, the definition of the security provider was altered in a similar way. At the beginning of the crisis, disease surveillance and responsive measures such as slaughtering were left completely to the Member States, and EU regulation in the foodstuff sector was weak and patchy. The situation changed when EU actors started to regard the agriculture economy as being threatened, followed by substantial market support measures financed from the EU budget. And although the outbreak management to eradicate the disease was, on the operational level, principally left to the individual Member States, the Commission at least partially turned into a security provider in the (veterinary) health field, when it initiated and funded inspection trips to the Member States to monitor the disease and compliance with EU law.

The analysis has shown that the adopted counter measures primarily fell into the realms of veterinary policy, food safety at the intersection of public health and consumer protection as well as the Internal Market and competition policy. Beyond that, BSE/TSEs were also addressed by trade and research policy. As for many securitisation parameters, a major change regarding the composition of the set of active policies took place in 1996. Whereas BSE/TSEs had been first and foremost a matter of veterinary policy before 1996, it turned into a matter of economic interventions and public health affairs afterwards, the latter not least due to the fact that the Amsterdam Treaty had moved veterinary policy with the objective to protect public health to the public health mandate of the EU.

With a view to the target of the interventions along the interconnected categorisation of prevention, preparedness, surveillance and response, most initial measures were of responsive nature, best

illustrated by the various eradication and market support programmes which usually occurred as immediate emergency reaction. By closing regulatory gaps in the years after 1996, for instance regarding the specification of risk materials or provisions on the treatment of animal waste, preventive measures accompanied these immediate responses, before in 2000 also disease surveillance was expanded and strengthened. Finally, encompassing tools in the realm of disease preparedness, mostly related to the creation of EFSA, were introduced only as part of the legal and institutional reform packages rather than as part of the securitisation process. Against this background, we can retain as an overarching trend in the EU's extraordinary measures in response to BSE/TSEs a shift from initially immediate response measures towards elements of persistent surveillance and prevention. All interventions, however, were targeted primarily internally at the national and EU level, with only side effects on extra-EU trade.

5.5.2.2. Soft and/or Hard Securitisation

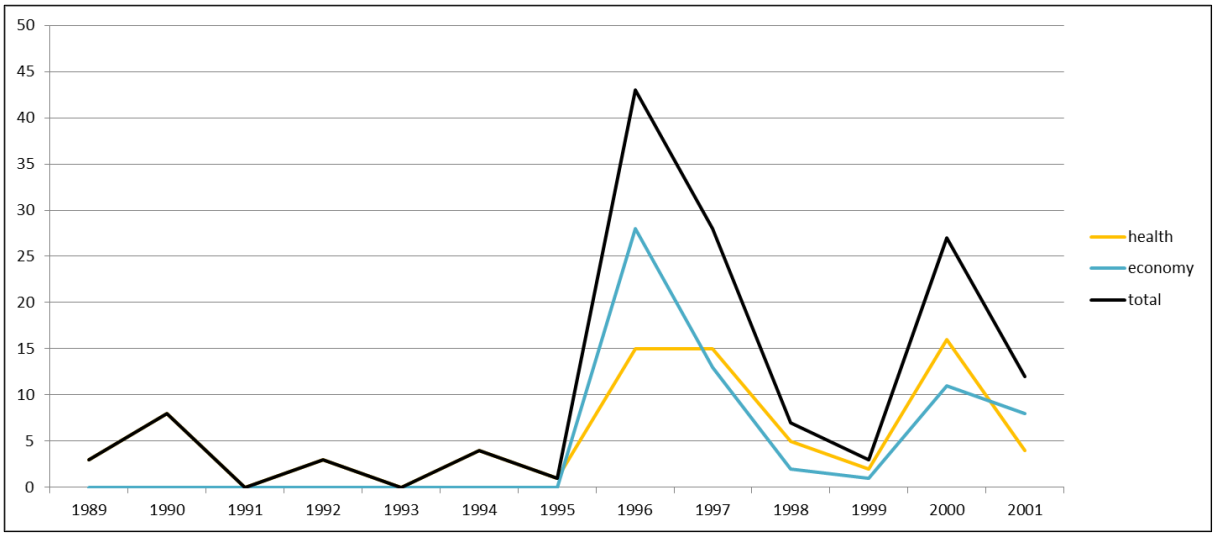
The change of several security parameters in the course of the crisis makes it difficult to identify a clear-cut kind of securitisation of BSE/TSEs. The most consistent distinction can be made along the referent object, and the closely connected parameters of the primary policy and the target of the measures. Taking these parameters together, we can identify a 'health-focused' and an 'economy-focused' securitisation of BSE/TSEs, the former employing the tools of veterinary policy and public health to protect human and animal from the disease, the latter concerned with the stabilisation of the affected industry sectors by relevant policy tools.

Interestingly, the health-centric kind of securitisation appeared already before 1996 with a focus on animal health, but in this form did not exceed the status of a merely politicised matter. Only when the referent object changed to human, the health-centred securitisation kind also moved up to a higher securitisation degree. In other words, for the year 1996 we can observe a parallelism of the rise of the overall securitisation degree and the change of the kind of securitisation (from animal to health). Additionally, the economic kind of BSE/TSEs securitisation can be found from 1996 onwards, with a high degree particularly in the beginning of the first securitisation wave.

The following Diagram 5-2 illustrates how the securitisation of BSE/TSEs was not only driven by (animal and human) health concerns, but also to a substantial, and occasionally even to a larger extent by economic concerns.[116] Crucially, it reveals that BSE/TSEs reached the highest securitisation degrees at the EU level only when both health and economy were considered severely threatened at the same time.

[116] The importance of the economy-centred securitisation kind would be even clearer, if the allocation of funds was included in the illustration.

Diagram 5-2: The Securitisation Degree of the 'Health'- and the 'Economy'-Centred Kind of Securitisation (1989-2001)



Source: Own presentation on the basis of securitisation degree scores assigned to the documents listed in Table 5-2, Table 5-3, Table 5-4 and Table 5-5 divided along the distinction of the dominant referent object.

In order to assess the overall kind of securitisation, it is helpful to structure the different elements of the securitisation process of BSE/TSEs along the extremes of the kind of securitisation of an infectious disease as developed in chapter 2.3.2.3, the soft kind of securitisation on the one hand, and the hard kind on the other.[117] With a view of these ideal types, it can be argued that despite the differences between the health- and economy-centred securitisation, both strands can be classified as oriented more towards the hard securitisation extreme, rather than to the soft securitisation extreme. After 1996 the securitisation of BSE/TSEs was dominated by a rationale of the protection of a high number of human referent objects and of vital parts of the EU system in form of the economy against a slow but extremely close and suddenly occurring, very severe threat which turned more predictable only over the years. BST/TSEs were furthermore seen to be best combatted by strong and immediate interventions from Member States and the EU inside the EU territory by public measures that covered all forms of disease control.

The following Table 5-8 provides a schematic classification of the securitisation of BSE/TSEs along the securitisation parameters. For each of the parameters a categorisation is provided on the basis of the examples developed for the soft and the hard kind, so that the securitisation of BSE/TSEs can be assorted for each parameter as leaning rather to the soft or to the strong extreme kind. Not designed to constitute an elaborate tool that expresses the securitisation kind with highest precision, the table still helps illustrate the findings that could be generated on the basis of the previous text analysis. It becomes visible in this way that the overall picture leans towards a hard security understanding across both securitisation dimensions.

[117] See chapter 2.3.2.3 and in particular Table 2-2.

Table 5-8: The Kind of Securitisation of BSE/TSEs (schematic)

Dimension	Security Parameter		Soft Kind					Hard Kind
Verbal	*Referent object*		Human[118]	x	I-----	---→ 1996	x	Vital to State / EU
	Min. Referent object		Few	x	I-----	------ 1996	---→ x	Many
	Source of Threat		Natural	x				Manmade
	Source of Pathogenicity		Development, Health Care			x[119]		Terror, Enemy Globalisation
	Speed of Threat		Slow / Attrition			x[120]		Fast / Outbreak
	Geography of Threat		Far / "Not Us"				x	Close / "Us"
	Threat Severity		Low				x	High
	Predictability of Threat		High			x	←--I 2000 x	Low
	Ethical Stance		Common Humanity				x	Self-Protection
Verbal & Operational	*Security Provider*		State (+INGO) + Non-State				x	States (+IOs)
	Primary Policy		Humanitarian Aid, Development, Human Rights				x	Foreign & Secur. Economy, Public Health
Operational	*Target and Geography of Measure*	*Surveillance*	Global				x	National / EU
		Prevention	Global				x	National / EU
		Preparedness	Global				x	National / EU
		Response	Global				x	National / EU

Source: Own presentation.

[118] Initial referent objects were animals.
[119] Feeding practices, lack of consumer confidence; not clearly attributable to either of the extremes.
[120] Slowly spreading, but with character of an outbreak event due to the sudden detection of many cases.

5.5.3. The Role of the Different EU Actors

Before it is possible to elaborate on the linkage between securitisation and institutionalisation in the case of the BSE/TSEs crisis, it belongs to the complete analysis of the form of securitisation to analyse not only when, how, in which dimensions, to what degree and in which kind BSE/TSEs were securitised at the EU level, but also by whom. Therefore, the next section offers a detailed look at the BSE/TSEs-related securitisation processes in view of the securitisers.

We have observed that speech acts were issued by members of the European Parliament, from the Commission, the Court of Auditors, EU committees and also from the European Council. Although all these (and more) EU actors have issued speech acts, they differ significantly in terms of content and timing. On the operational securitisation dimension, the division of tasks among EU institutions plays an important role. Whereas the Commission in its role as the coordination hub of crisis management naturally was the source for numerous securitising activities, the Parliament could influence EU action in the revision of legislation in the co-decision procedure, but could seldom launch a securitising activity (operational dimension) itself. The motion of censure was a clear but powerful exception in this respect. The actors can be analysed in detail as follows:

According to the data set employed for this study the European Commission was the most active securitising actor. In its role as the EU's executive, it is not surprising that the majority of speech act-like interventions and emergency measures were penned by her. The Commission was not only the most active player, it also accounted for the highest number of highly securitising moves. A high share of these securitising moves, however, occurred in the operational dimension, when the Commission performed its function to take decisions on responsive measures. In the verbal dimension the Commission played a different, rather modest role. This can be partly explained by the technical nature of many of the Commission documents, but it is also certainly linked to the fact that the Commission operated in dependence of a comitology procedure that was characterised by the tensions among Member States. Also given the strong criticism regarding the Commission's management of the crisis, in particular put forward by the European Parliament, it is also unsurprising that in its texts the Commission prevented the use of dramatic language that could have fostered further concerns.

In fact, many of the securitising moves in the operational dimension did not go along with an equivalent securitisation degree in the verbal dimension. Furthermore, in particular in the early years the Commission belonged to the group of de-securitising actors by claiming that infection rates were in decline. Also later in the process the Commission usually did not issue any highly securitising moves on the verbal dimension. It, however, took up the challenges linked to the BSE/TSEs crisis when proposing a stronger role of the supranational level (European Commission, 1998i). In this sense, following its drafting power for the harmonised EU food law and the creation of EFSA, the Commission became an influential factor for the institutional reform process once securitisation had fostered agreement among all actors that structural changes were necessary indeed.

The strongest securitiser in the verbal dimension was the European Parliament. With its resolutions and in particular the thorough investigation into the BSE affair it significantly strengthened the perspective on BSE/TSEs as a security threat to both the health of consumers as well as the beef market. Crucially, the Parliament combined the finding that "the British meal manufacturers caused a major threat to health" with a criticism to the involved actors and the announcement to table a motion of censure (European Parliament, 1997b). The decision to threaten the entire EU configuration with a no-confidence motion that would have led to the dismissal of the entire European Commission can be understood as an enormous securitisation move by the Parliament for the BSE/TSEs case, with great impact in particular on the structural changes as regards the re-organisation of the Commission. But also the revision of the committee system and the creation of EFSA were influenced by its interventions (European Parliament, 1999).

Besides its role as a securitiser in the verbal dimension, the European Parliament also turned into an important actor for the modification of the EU setup after the legal base for veterinary proposals concerning health protection had to be based upon co-decision following the entry into force of the Amsterdam Treaty.

The Council did not play an equally prominent role in the securitisation processes for two reasons. First, before the crisis, scientific advice as well as decisions on disease management belonged to the tasks of the Commission. The Commission's decisions, however, were dependent on the positive votes in the committee system, which guaranteed a strong influence of the Member States' interests and were moved up to the level of the Council only in cases when no decisions could be taken. In other words, part of the activities in the realm of the Council took place on the less transparent comitology level which EUR-Lex and the institutions' online documentations do not cover in an extensive way.

Second, the work in the Council was many years characterised by strong tensions during the BSE crisis, making it difficult to jointly issue strong securitising moves. The positions of the United Kingdom, which for a long time insisted on the non-transmissibility of BSE to humans and finally pursued a non-cooperative approach in response to the 'UK embargo', speak a clear language. The solution to the fundamental conflict was found only after a partial lifting of the ban the intervention of the European Council. Despite the occasional circumvention of the (blocked) Council in favour of either the lower or the higher political level, the Council still contributed to the securitisation of BSE/TSEs and shaped the new regulatory framework, partly in conjunction with the Parliament in the respective co-decision procedure.

The struggles within the Council show that securitisation at the EU level can be hampered or even fought by individual Member States if the system allows for respective veto options. The Scientific Veterinary Committee is a case in point. Following its function to provide scientific advice to the Commission, the BSE subgroup of the Veterinary Committee could have directed the Commission towards a stronger securitisation of BSE/TSEs before 1996. Given the facts, however, that the group was almost invariably chaired by UK nationals, that the minutes were drafted by Commission officials of British nationality and that the composition of the group was characterised by a clear

preponderance of UK scientists and officials, a strong influence of the interpretations of the British Ministry of Agriculture, Fisheries and Food Scientific on the Veterinary Committee prevailed in the committee's work (European Parliament, 1997b: A.1.2.5). In the light of the individual interests of the UK government to prevent trade bans or restrictions for its beef market, the original committee structure eventually enabled the UK to avert strong securitisation moves originating from this potential source.

Another example is the partial lifting of the UK embargo in 1996 which was enforced by political pressures linked to the UK's non-cooperation politics in the Council in the run-up to the European Council agreement in Florence. In this case an individual Member State eventually succeeded in the enforcement of a (temporary) de-securitising move.

The European Council is a special actor in the securitisation-institutionalisation nexus for several reasons. As a discussion within the European Council implies that the issue has reached the highest political level, respective discussion on BSE/TSEs also meant a massive boost for the securitisation degree. At the same time, however, a matter discussed at the level of the European Council is a security issue only if it is addressed in a security language under specification of a referent object and other securitisation parameters. For BSE/TSEs this was not always the case given the controversial views of different Member States. Consequently, BSE/TSEs were addressed in a relatively soft manner so that the European Council was not a primary driver of the securitisation process, partly due to the fact that its intervention fed the economy-centred kind of securitisation only.

An important contribution, however, was the link confirmed by the European Council between the securitisation of BSE/TSEs and the need for institutional reform, in particular with regard to the establishment of EFSA. In this way the European Council played a decisive role, the role of the institutional architect, for the overall securitisation and reform development by approving the structural changes in response to the perceived crisis under application of its political weight**.**

Finally, apart from the set of main EU institutions, also the Scientific Steering Committee was an interesting actor in terms of securitisation and structural changes. As outlined before, it was created in 1996 in the course of the first securitisation wave and from then on, following its dedicated task to deal with the disease, contributed to the further securitisation of BSE/TSEs which culminated in the second securitisation wave of 2000/2001. In this sense, and possibly deviating from the original intention of the decision-makers, the Scientific Steering Committee was an institutional reform that perpetuated the securitisation of the issue rather than contributing to its de-securitisation. In addition, it were members of the same committee who presented the idea to the Commission to establish an institution like EFSA. Hence, the influence of the actor went beyond securitisation to the realm of reform and systemic change.

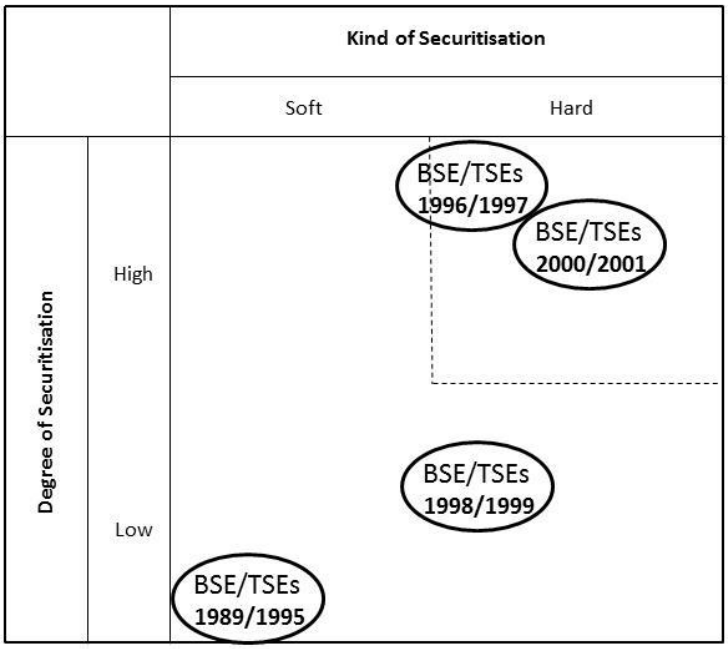
5.6. Securitisation and Structural Change

BSE/TSEs were subject to dynamic securitisation processes at the EU level in the analysed years. By constructing the diseases as a severe security threat to animal and human health as well as the economy, speech acts and counter measures jointly lifted the issue to the top of the political agendas in particular in the years between 1996 and 2001. Speech acts that declared BSE/TSEs a serious threat which demanded top priority and counter action came from the full spectrum of relevant EU actors and affiliated institutions, up to the highest political level. Measures to combat the threat comprised *inter alia* embargoes, mass slaughtering, research into the disease, strengthened epidemio-surveillance, exceptional market support measures, new standards of processing of risk materials, provisions and bans related to feeding, the introduction of an animal identification and beef labelling system, as well as the monitoring and enforcement of these measures. The measures went along with a radical allocation of resources.

In other words, the analysis has shown that in the case of BSE/TSEs all major ingredients for securitisation were part of the political developments. Crucially, the BSE-related (legal) output of EU actors comprised information on almost all relevant security parameters. By scrutinising the set of documents with regard to the securitisation degree, chapter 5.5.1 has revealed that BSE/TSEs rapidly rose on the vertical securitisation spectrum from a non-existent political phenomenon to a matter that can be regarded as highly securitised in 1996/1997 and 2000/2001. With a view to the predominant kind of securitisation for BSE/TSEs, chapter 5.5.2 has shown that the overall combination of security parameters eventually changed into the direction of a rather hard kind of securitisation.

Put crisply, we could observe that the disease was not only pushed (twice) to a *high degree* of securitisation, but that the securitisation also took place in the form of a *hard kind*. Building on the securitisation approach as developed and applied in this study, this specific combination of securitisation degree and kind qualifies BSE/TSEs as an issue that has been securitised at the EU level in the form of *strong securitisation*, at least during the years 1996/1997 and 2000/2001. Accordingly, for these phases the disease can be located in the upper right corner of the coordination system of securitisation as introduced in chapter 2.3.3. Figure 5-1 (see below) schematically locates the form of securitisation in the four phases, thereby reflecting that the highest securitisation degree in 1996/1997, and the hardest kind of securitisation in 2000/2001 after the threat was constructed as an EU-wide phenomenon.

Figure 5-1: BSE/TSEs in the Coordination System of Securitisation



Source: Own presentation.

Recalling the working hypothesis as developed in chapter 2.4, the disease was, thus, constructed as a security threat in a form which is hypothesised to have the power to trigger institutionalisation processes in the political system. Chapters 5.2 and 5.4 have shown that indeed a series of systemic modifications occurred in the course of the BSE/TSEs crisis in the EU's setup for food safety affairs, and thus also for the control of food-borne infectious diseases.

The changes occurred basically in two phases, a first in 1997 and a second in 2001/2002. The first set of structural changes in 1997 started with the Commission's Green Paper on the general principles of food law in the EU (European Commission, 1997h), and was advanced by the simultaneously launched Communication on consumer health and food safety (European Commission, 1997j). Together they established the basis of the set of fundamental changes which occurred in the following, namely the re-organisation of the advisory Committee System, the re-organisation of the Commission as well as the amendment of the legal basis for health and consumer protection in the Treaty of Amsterdam.

The second set of structural changes could be observed for the years 2001/2002. First, Regulation 999/2001 laid down a full package of harmonised EU rules on prevention, control and eradication of certain TSEs. Parts of the new regulation were not new in substance, as they basically replaced a series of individual measures as already adopted in the previous years. A major difference, however, was that the temporary and extraordinary nature of these measure was lifted in favour of a single comprehensive and permanent piece of regulative legislation. Furthermore, regulation foresaw stronger regulation and was no longer limited to specific countries but became applicable in the entire EU. Second, Regulation 178/2002 established the European Food Safety Authority and introduced revised general principles and requirements of food law.

Table 5-9: Institutionalisation that Occurred in the Course of the BSE/TSEs Crisis

Date (OJ) / Doc. Number	Author	Reference[121]	Key Development
30.04.97 COM(97) 183 final	COM	(European Commission, 1997j)	Re-organisation of the Commission , foodstuff-related competencies moved to single directorate for consumer policy and health protection; reinforcement of the Commission's Food and Veterinary Office (FVO)
27.06.97 D 97/404/EC D 97/579/EC	COM	(European Commission, 1997k, 1997l)	Re-organisation of the Committee System, moved away from industry pressures under the authority of consumer protection
02.10.97 Article 152	IGC	(Treaty of Amsterdam).	Introduction of health and consumer protection as an independent policy objective; shift of responsibilities from common agricultural policy to public health, competence to adopt measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health
31.05.01 R 999/2001	EP+CO	(European Parliament and Council, 2001)	Harmonised EU rules on prevention, control and eradication of certain TSEs
01.02.02 R 178/2002	EP+CO	(European Parliament and Council, 2002a)	Establishment of the European Food Safety Authority; General Principles and Requirements of Food Law and Procedures in Matters of Food Safety, incl. precautionary principle; Rapid alert system (RASFF) for the notification of a direct or indirect risk to human health deriving from food or feed

Source: Own presentation.

Together these measures meant a sea change for the EU's food safety regime and the setup to control food-borne infectious diseases. They also established the close connection between food safety, consumer protection and public health in general.

A series of arguments indicate a clear linkage between the securitisation of BSE/TSEs and these institutionalisation processes. First, on a general level, the systemic reforms were designed in a way that explicitly addressed the problems that were identified in the securitisation phase and which occurred as an expression of the securitisation parameters. To illustrate, after BSE/TSEs had been constructed as a key threat to consumer confidence, which in a chain reaction turned translated into a threat to the beef and veal sector, the revision of the advisory system and the creation of a specialised agency were adopted with the explicit aim to restore consumer confidence. Accordingly, Regulation 178/2002 setting up EFSA stated that "[t]he safety and confidence of consumers within the Community, and in third countries, are of paramount importance" (European Parliament and Council, 2002a: Recital 23). The formulations related to the structural change thus took up explicitly the core referent objects as identified for the securitisation of BSE/TSEs.

Except for the Amsterdam Treaty, for which no justifying texts could be analysed in the framework of this study, the reasons provided in the legislation for the comprehensive innovation package speak a clear language, even if BSE/TSEs usually do not figure by name. The absence of a direct reference to the diseases can be explained due to the fact that legislative documents dealing with structural changes are typically written in a specific technical language and are of an overarching and persistent nature beyond the scope of an individual disease. Furthermore, they are often drafted by political actors who were also responsible for the previous (mis-)management of the crisis and who try to not

[121] Document specification as used in the 'List of References' of the present study.

incriminate themselves. Against this background, the legislative texts typically referred to the 'experiences of the previous years' when it came to justifying revised control and response measures or new procedures "in order to ensure the proper functioning of the internal market and to protect human health" (European Parliament and Council, 2002a: Recital 10).

Indeed, when the rationale of a given process was grounded on 'certain recent events' (European Commission, 1997h) or 'experiences' (European Commission, 1997j), they doubtless referred to the BSE/TSEs case, in particular if the design of the reform was so closely tied to the BSE/TSEs experience. Formulations that addressed the production, manufacture, transport and distribution of feed given to food-producing animals (European Parliament and Council, 2002a: Recital 13), the use of the precautionary principle (European Parliament and Council, 2002a: Recital 20) and the traceability of food and feed to avoid "the potential for unnecessary wider disruption in the event of food safety problems" (European Parliament and Council, 2002a: Recital 28) are obvious cases in point.

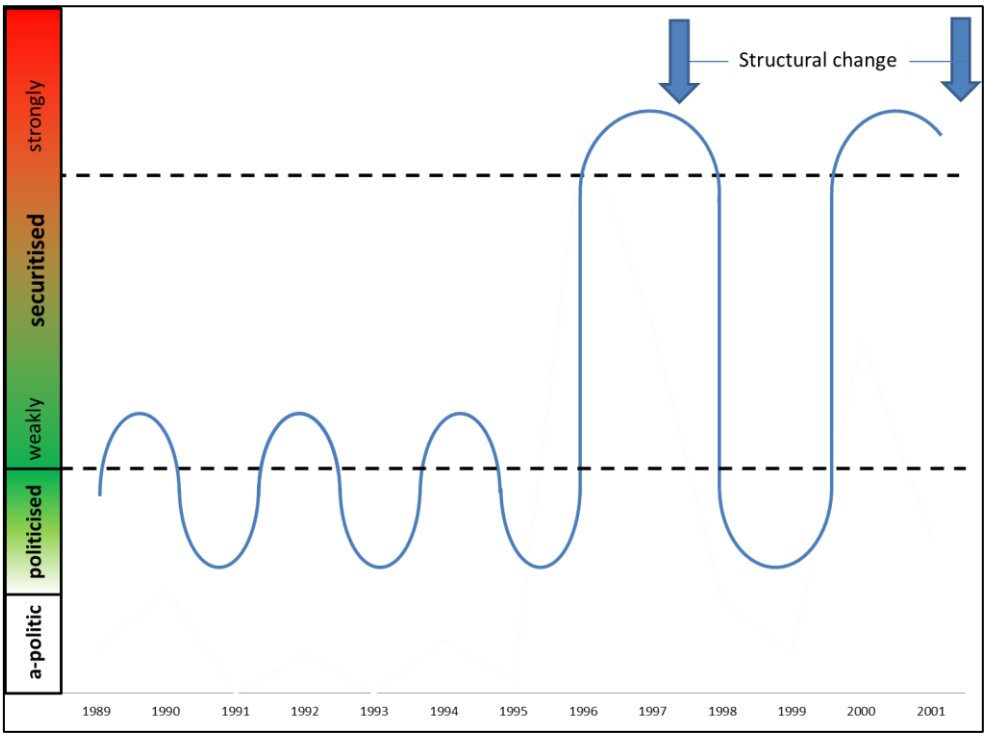
Second, beyond the linkage established by the design and the justification for the structural reforms, the process through which the institutionalisation process was initiated suggests a direct link to the securitisation processes of BSE/TSEs. To illustrate, the establishment of EFSA was first proposed in the report by three members of the Scientific Steering Committee (James et al., 1999). At that time the report constituted, technically speaking from a securitisation perspective, nothing else than a (modest) securitisation move. By taking up the priority and attention assigned to the disease in general and by including the idea of an independent agency into the White Paper on Food Safety (European Commission, 2000h), the document eventually helped the Commission establish a link between the high profile of the topic and challenges to review the general principles of food law.

In this sense, the White Paper built a sort of bridge for the transition from the securitisation phase to the phase of institutional reform. It combined a clear reference to "unprecedented pressure [on Community and Member State food safety systems] during recent feed and food emergencies" with an emphasis on the "call for action by the responsible authorities (Commission, Member States and the Parliament) to re-enforce, improve and further develop existing systems" (European Commission, 2000h: 7).

Also in the following legislative process, the direct connections between the food safety scandals and reforms were visible, for instance in the opinion of the Committee of the Regions which stated that "[a]t their worst, crises such as those over dioxins and BSE, have undermined the European Community's general credibility. The Commission's proposal [setting up EFSA] establishes an important framework for improving food safety (Committee of the Regions, 2001). A similar process could be observed for the structural changes in 1997 when the Commission's Green Paper on the general principles of food law in the EU (European Commission, 1997h) built a bridge from the phase of emergency reactions to the phase of structural change. Thus, even if BSE/TSEs as a menace to (certain sectors and Member States of) the EU were not explicitly taken up in the final legislation that made up for a structural reform, the process of the legislative production still proves the connection.

Third, the strong securitisation of BSE/TSEs clearly bears a temporal relationship to the structural innovations. Just as the degree and kind of securitisation developed in two waves, all structural changes occurred in close temporal proximity to the moment when BSE/TSEs had entered the realm of a strongly securitised issue. As explained in the previous chapters, an exact expression of the securitisation degree is not possible on the basis of the data generate in this study. However, a schematic illustration of the securitisation degree is sufficient to illustrate the development of BSE/TSEs as a politicised or weakly securitised issue in the early 1990s and the dramatic rise of securitisation in 1996/1997 and 2000/2001, moving up into the realm of 'strong securitisation'. The following Diagram 5-3 (see below) provides such a schematic illustration on the basis of the differentiation of the continuum between a-politic issues and highly securitised issues as introduced in chapter 2.3.1 and Figure 2-3 in particular.

Diagram 5-3: Securitisation of BSE/TSEs and Structural Change in the EU's Setup for Infectious Disease Control (1989-2002, schematic)



Source: Own presentation.

Put crisply, it is possible to argue that institutionalisation in response to BSE/TSEs occurred only after the kind of securitisation shifted to a hard kind and in parallel reached a sufficiently high securitisation degree. As long as the UK government succeeded in upholding the construction of BSE/TSEs as a threat which is non-transmissible to humans, securitisation stayed not only on the soft side of security understandings, but also at a low degree. However, given that the issue was still not regarded as an EU-wide problem, strong regulatory measures could not be introduced at the EU level at that time. In turn, in 2000, when BSE/TSEs were constructed as a highly securitised matter no longer limited to British and Portuguese borders, common permanent regulatory an institutional solutions were established to contain the disease. Hence, the present analysis reveals a chronology

of securitisation waves followed by systemic change which suggest – just as the rationale as laid down in the EU key documents – a clear linkage between the construction of BSE/TSEs as a security threat and the structural reforms.

Clearly, structural changes in response to securitisation developments were not immediate. We see that a certain period of time usually passes after a securitisation peak before structural changes can be observed or enter into force. The revised article for health and consumer protection in the Amsterdam Treaty is a case in point, which was negotiated and concluded in 1996/1997, but entered into force in 1999 only. Also the proposal for the creation of EFSA was discussed since 1999, but was not realised before early 2002. Whereas the first securitisation wave with its peak in 1996/1997 kicked-off a reform process in the field of foodstuff regulation, for the set of most fundamental reforms it was only after the second securitisation wave in 2000/2001 that they were actually implemented. In fact, the establishment of EFSA gained momentum primarily during the second securitisation wave, as exemplified by the statements by the European Council which asked for a speedy installation of the new authority, although the initial ideas had been brought forward in reaction to the first securitisation phase of BSE.

A similar development can be seen also for securitising elements such as the treatment of risk materials. Here the Commission's first proposal to introduce EU wide controls to remove certain specified risk material tissues was put forward in 1996 already, but the proposal was rejected, the decision postponed four times and finally repealed by a new decision in 2000 (European Commission, 2000e, 2001o), just when the securitisation of the BSE/TSEs was about to accelerate again. These examples shows how the first securitisation wave spilled into the next one and, in this sense Diagram 5-3 should not be read as a simplistic causal connection between securitisation wave and reform package. Clearly, the institutionalisation steps taken in 2001/2002 were not exclusively linked, rather than speeded up by the second securitisation wave.

A reinforcing effect of the second securitisation wave is also visible in the cases of the many innovations that were launched as emergency measures in the 1990s but perpetuated (and extended) in 2001 only. Hence, the developments showed that securitisation is partly a self-referential process and can develop its own dynamics. The creation and the role of the Scientific Steering Committee is an interesting case in this respect. Established as an integral part of the institutional reforms in 1997, the new committee soon exerted influence on the further development of the securitisation of BSE/TSEs. First, three leading members of the Committee proposed to create an independent food safety authority – an idea that was later taken up by the Commission. And second, their report on the geographical risk of BSE in the Member States (Scientific Steering Committee, 2000) meant a substantial securitisation move for the disease, which was followed by intensified controls and the detection of new cases all over Europe. In other words, being a result of the first securitisation wave, the Scientific Steering Committee contributed to the further securitisation in the following years and also influenced further structural changes. The committee exists still today, renamed Scientific Committee, as a body within EFSA to support its Scientific Panels on cross-cutting issues.

In this way the assumption is confirmed that securitisation does not (have to) stop after systemic changes have been implemented, but that they can feedback into the following securitisation process. The close feedback-connection is particularly visible if due to Treaty change a new responsibility is transferred to the EU. With the Amsterdam Treaty the protection of health and consumers became an explicit objective of the EU, thus rendering the EU a complementary provider of security in a field for which previously exclusively Member States were accountable.

Naturally, in a post-reform context also de-securitising effects can occur – and can be assumed to be generally desired by the decision-makers when agreeing on a systemic change. As the analysis was not continued for the years after the establishment of EFSA, clear statements on the effects of EFSA on the subsequent processes are beyond the scope of the present study. However, a cursory review of the developments after 2002 indicates that EFSA became at least partially a de-securitising actor as regards BSE/TSEs who contributed to a fall of the issue on the securitisation scale. Besides EFSA, de-securitising effects can also be assigned to the institutionalisation of what used to be 'emergency measures'. Clearly, if a measure, for instance disease monitoring, is carried out as a regular and constantly ongoing instrument, rather than an exceptional measure in response to a threatening situation, the measure (monitoring) becomes 'conventional' and the disease is no longer a matter subject to action in the realm of security beyond normal politics. In this context the circumstance that legislation after 2001 took place primarily in the form of technical amendments suggests that the disease eventually re-entered the realm of a merely politicised issue. Also the fact that after the establishment of EFSA and the strengthening of the Food and Veterinary Office of the Commission generally regular preventive and surveillance measures became more important than short-termed and urgent eradication programmes supports this view for the years after 2001.

5.7. Conclusions

Already in the 1980s, the Single Market for foodstuffs was established based on the mutual recognition of product standards, complemented by partial harmonisation of food safety measures. Since the detection of BSE in the UK in 1986, the existing system faced the outbreak and Europe-wide spread of the disease. Decision-making in the committee system turned out to be slow and measures adopted in the EU level incapable of stopping the further spread. These developments went along with a significant securitisation of BSE/TSEs in different ways, extending to European consumers, their confidence in the safety of food and the beef industry and ultimately to the core of the EU system, its institutions and the Internal Market (Ansell and Vogel, 2006). In the course of the crisis until the year 2002, the institutional setup and regulation related to foodstuff at the EU level underwent a fundamental change, with the BSE/TSEs crisis as "a Year Zero for the European Union food regime" (Chalmers, 2003: 532).

The evolution in the control of food-borne infectious diseases and other potential hazards to the safety of food took place in both the policy as well as the polity dimension. Starting from an unsystematic 'regulation patchwork' with low compliance rates, the reforms ultimately yielded a set

of strong EU-wide regulatory measures against BSE/TSEs based on revised primary and food law and new consumer-oriented principles for food safety, a new and powerful agency for risk assessment and risk communication (Szawlowska, 2004, Vos and Wendler, 2006) at the heart of a reformed scientific advisory system and permanently altered organisational structures in the Commission. In the light of these developments commentators have noted that the new regulatory approach to food safety occurred as "a condition for the proper functioning of the internal market", possible only after the mad cow crisis had distorted it (Kanska, 2004: 713, Alemanno, 2006: 243, Grant, 2012: 1035).

The BSE/TSEs case study has presented the main course of events in the development of the EU's infectious disease policy and polity as regards food-borne pathogens until 2002, has analysed how BSE/TSEs were subject to securitisation dynamics at the EU level of different degrees and kinds, has shown the different roles of the involved EU actors and has eventually made a point in revealing the connection between these securitisation and structural changes. By doing so it addressed the full spectrum of the basic research interest of this study.

Regarding the working hypothesis as developed in chapter 2.4, the results of the case study on BSE/TSEs, the regulation of foodstuff and the creation of EFSA strongly support the interpretation that the social construction of the disease in form of strong securitisation was decisive to trigger systemic changes and institutionalisation processes at the EU level. Admittedly, the securitisation of BSE/TSEs were supported by further crises in the fields of food safety and public health, such as a blood contamination scandal, the dioxin crisis, the outbreak of food-and-mouth disease as well as "chronic problems of health care delivery in many Member States" which were not subject to analysis in this case study (Shears et al., 2001, Coleman, 2004: 7, Olsson, 2005, Lezaun and Groenleer, 2006). Also the opening of the Schengen space in 1995 might have fed into the debate, allowing for the free movement of people without border controls (Steffen, 2012: 1071), as well as the upcoming Eastern enlargement of the Community. Still, the reading of the institutionalisation of the years 1997 and 2001/2002 from a securitisation perspective on BSE/TSEs suggest that these intervening events constituted only additional input to a development that was initiated and dominated by the BSE/TSEs case.

Under consideration of this qualification, the BSE/TSEs case confirms the view that securitisation can lead to structural changes at the EU level under the conditions of a specific form of securitisation in terms of degree and kind. Seeing that new food safety crises, if likely or not, can hardly be excluded for all times, it will be interesting to see whether the securitisation of food-borne infectious disease might trigger further structural adaptations in the future. The present study, however, at this point leaves the realm of food-borne infectious diseases and turns to the second case study which deals with two structural innovations in the EU's setup to control infectious disease that occurred in the course of the SARS crisis, namely the creation of the European Centre for Disease Prevention and Control (ECDC) and the revision of the EU's public health mandate in the Constitutional Treaty.

6. The Adoption of the Constitutional Treaty and the Creation of the European Centre for Disease Prevention and Control in the Course of the SARS Crisis

In the year 2004, as we have seen in chapter 3.4, two developments took place that were of major importance for the revision of the EU's structures for the control of infectious diseases. First, in April the European Parliament and the Council agreed on Regulation (EC) 851/2004 which established the European Centre for Disease Prevention and Control (ECDC). Second, in December the heads of state or government agreed on the 'Treaty Establishing a Constitution for Europe' which was meant to *inter alia* amend the EU's primary law in the field of public health.[122] Whereas cooperation between Member States for the surveillance of diseases was subject to networking activities before these reforms, the creation of the new Centre meant a substantial step towards the centralised identification, assessment and communication of current and emerging threats to human health from infectious diseases. Similarly, the new Treaty article III-179 established a stronger legal basis for the EU to respond to cross-border threats to health by introducing the supporting competence for their monitoring, early warning of and combating as distinctive objectives of EU action.

Both reforms fell into the year 2004 and thus not long after a period when the outbreak of the 'severe acute respiratory syndrome' (SARS) had dominated the headlines worldwide. The case study shall analyse in detail the context, characteristics and consequences of the EU response to SARS with a view to degrees, kinds and actors of securitisation as well as related institutionalisation processes. The chapter starts with a review of the international response to the SARS outbreak between the emergence of the disease in 2002 and the official announcement of its containment in July 2003. Unlike the BSE/TSEs case, where the disease was predominantly an EU-internal matter, the SARS case requires a distinction between the international and the EU response, because major SARS developments took place outside Europe but still provided a context for the EU processes. Therefore, the review looks first at the SARS outbreak in the international context (chapter 6.1). On the basis of this summary, the study investigates, second, the responses to SARS at the EU level (chapter 6.2).

The chronological review of events is followed by an examination of the establishment of the ECDC, the revision of the public health article in the Constitutional Treaty and further structural changes in the EU's setup for infectious disease control (chapter 6.3). In the following, the study analyses the securitisation of SARS (chapter 6.4) by looking into the EU documents in view of the degree (chapter 6.4.1), the rise and fall of the degree (chapter 6.4.2), the kind (chapter 6.4.3) and the EU actors of the securitisation process (chapter 6.4.4). Given that the SARS-related EU activities have not been systematically processed by existing research, the thorough examination of EU primary sources will be of particular value. The chapter closes with a section on the connection between securitisation processes and structural changes (chapter 6.5) as well as a set of conclusions on the case study as a whole (chapter 6.6).

[122] As explained in chapter 3.5.2, the ratification process for the Constitutional Treaty was stopped. Central elements, however, were incorporated in the Lisbon Treaty so that the changes as agreed on for the Constitutional Treaty exerted influence on the EU's setup. More details are provided in chapter 6.3.2.

6.1. Crisis and Response at the International Level

SARS has been described as "the first major emerging infectious disease of the twenty-first century" (Harper, 2004: 1131) and the first infectious disease epidemic since HIV/AIDS of a truly global dimension (Fidler, 2003: 486). It is a respiratory illness that is caused by the SARS coronavirus (SARS-CoV). The virus is considered to have crossed over from its original animal reservoir in bats to palm civets and from there into the human ecology in November 2002 (Peiris et al., 2003, Li et al., 2004). The first cases in humans occurred in rural farmers or food handlers in south China's Guangdong province where palm civets are farmed or caught in the wild as food animals (Heymann and Rodier, 2004, Morse, 2006: 4). After its establishment within the human population, the endogenised virus mainly spread under direct mucous membrane (eyes, nose, and mouth) contact conditions from person-to-person by infectious respiratory droplets, but the virus is also shed in faeces (WHO, 2003p: 11, Hawker et al., 2012: 211). SARS is an extremely pathogenic disease with a short incubation period and a high case fatality rate with patients becoming contagious most likely only when they have symptoms.[123] During the 2002-2003 outbreak, according to the World Health Organisation a total of 8.096 people were notified as infected with SARS, 774 of which died (WHO, 2004). After the containment of the virus outbreak in July 2003, confirmed cases of SARS-CoV infections occurred only in the context of laboratory work without secondary transmission (Hawker et al., 2012: 210).

The outbreak and the epidemic spread of SARS in 2002/2003 have been thoroughly reconstructed and documented.[124] The first infection was recorded in mid-November 2002 in Foshan, a city in Guangdong province (Huang, 2003b: 65). Respective rumours had been picked up at that time by the Global Public Health Intelligence Network (GPHIN)[125] and other partners of the World Health Organisation's Global Outbreak and Response Network (GOARN) that aim at the early detection of disease outbreaks.[126] In the course of the following months, several cases of an unknown atypical pneumonia, today associated to the SARS-CoV, began to occur in southern China, in particular among health-care professionals. In a report to WHO of February 11, 2003, the Ministry of Health of China reported an outbreak of an acute respiratory syndrome with 300 cases and five deaths since November 2002, but claimed that the outbreak was already under control (SARS Expert Committee,

[123] The incubation period is between four and five days in the case of SARS (Anderson et al., 2004: 1093). The case-fatality ratio describes "the proportion of those who acquire an infection that eventually die from the disease induced by the aetiological agent" (Anderson et al., 2004: 1094). In the case of SARS it is estimated to range from 0% to more than 50% with an overall percentage of 10 to 15% (WHO, 2003p: 10, Hawker et al., 2012: 210). See also http://www.cdc.gov/sars/about/faq.html (accessed 22.01.2015).

[124] A detailed chronology is provided by Whaley and Mansoor (2006). The most detailed report has probably been issued by The SARS Commission (2006). See also Greenfield (2006) and Kleinman and Watson (2006).

[125] GPHIN is a surveillance tool that was developed by Health Canada in collaboration with WHO in 1997 to screen media sources, government and NGO reports for "disease outbreaks, bioterrorism threats, contaminated food and water supplies, nuclear material leaks, and natural disasters" (Nichter, 2008: 129, Zacher and Keefe, 2008: 48f). About 40 per cent of the outbreaks annually analysed by WHO comes from GPHIN (WHO, 2002b, National Advisory Committee on SARS and Public Health, 2003).

[126] GOARN is a WHO-led global technical partnership which connects a set of more than 120 governmental and non-governmental partners and multi-partner initiatives worldwide to conduct epidemic intelligence, verify outbreak rumours, send out alert messages and manage global counter measures. The network was initiated in 1997 and institutionalised in 2000 (Grein et al., 2000: 97ff, Heymann and Rodier, 2001, Institute of Medicine, 2003: 154ff).

2003: 196, Zhong et al., 2003). On this basis WHO alerted its Global Influenza Surveillance Network (GISN)[127] and activated its influenza pandemic preparedness plans, fearing that a new strain of the influenza virus had occurred (WHO, 2003d). It later turned out that the situation was complicated by the fact that two respiratory disease outbreaks occurred at the same time in Guangdong province, namely influenza and the first instances of SARS (Heymann, 2004: 1128, Knobler et al., 2004: 43).

On February 21, Dr. Liu Jianlun, a 64-year-old medical professor who had treated persons suffering from this 'atypical pneumonia' and who himself showed respiratory symptoms and fever, travelled from Guangdong to attend a family wedding in Hong Kong (SARS Expert Committee, 2003: 198). Dr. Liu stayed one night in room 911 of the four star Metropole Hotel and within less than 24 hours infected at least 16 other persons who stayed on the same floor. The doctor was hospitalised but died despite treatment on March 4 (SARS Expert Committee, 2003: 18). Some of the infected persons were hospitalised in Hong Kong as well, where at least 99 health care workers contracted the disease. Other infected guests left Hong Kong and carried with them the disease to Canada, Singapore and Vietnam, thereby turning Dr. Liu into the 'international index case' for SARS (Fidler, 2004b: 76, United States General Accounting Office, 2004, Morse, 2006: 1). Thus, the global spread of SARS originated "from a single person on a single day on a single floor of a Hong Kong hotel" (Knobler et al., 2004: 43).

Soon after the 'big bang', when WHO issued an alert on the new disease occurring in Asia on March 12, 2003, and launched international surveillance measures (WHO, 2003b, 2003a), the disease had already spread to further countries. WHO's first global alert was formulated carefully, reflecting the difficult decision for the WHO staff in charge who wondered: "Are we mad? Are we going to panic the world?" (Cohen et al., 2003, Fidler, 2004b: 77). On March 15, when a medical doctor from Singapore was disembarked and hospitalised in Frankfurt during a stopover, the transmissible disease also had officially reached Europe (WHO, 2003e: 73ff). In the light of the rapid spread along international airline connections, WHO sent out a second, stronger global alert on the same day by issuing an "emergency travel advisory" to alert health authorities, physicians, and the travelling public to what was labelled to constitute "a worldwide threat to health" (WHO, 2003c, Fidler, 2004b: 136). The advisory provided not only a case definition and guidance for travellers, including airline crews, it also gave the disease a name: 'severe acute respiratory syndrome (SARS)' (WHO, 2003c, Heymann, 2004: 1128).

Given that the disease was not a novel strain of the influenza virus but a novel pathogen, health care workers and hospitals initially did not possess comprehensive knowledge neither on effective prevention measures nor symptoms nor transmission routes of SARS (Price-Smith, 2009: 142). "[S]pecific information regarding the nature of the organism causing this illness" did not exist and

[127] The WHO Network GISN, established in 1952, was one of the partners in GOARN. It today operates under the name 'Global Influenza Surveillance and Response System (GISRS)'. It connects national influenza centres, collaborating centres and WHO to give warning of a beginning pandemic and to track antigenic drift and shifts of influenza viruses with a view to the annual composition for effective vaccines (Heymann, 2004: 1127, Zacher and Keefe, 2008: 47). See also http://www.who.int/influenza/gisrs_laboratory/en/ (accessed 02.05.2015).

existing antibiotics and antivirals were not capable of effectively treating the new disease, leading Dr. Gro Harlem Brundtland, Director General of the World Health Organization, to the statement that "[t]his syndrome, SARS, is now a worldwide health threat" (WHO, 2003c). On March 16, WHO issued the first of 96 updates of its multi-country outbreak alerts on SARS. Among these updates extraordinary advisories can be found, for instance the recommendation against non-essential travel to SARS 'hot zones' such as Beijing or Toronto (WHO, 2003f) and the advice for airport authorities to screen passengers for SARS symptoms in affected areas (WHO, 2003g).

It has been estimated that after the WHO's travel advisories in April and May 2003, airline traffic went down by 40 to 50 per cent for the most affected areas. In fact, SARS meant a heavy economic damage for travel, trade and tourism. According to the World Bank, the airline industry lost an estimated 36.000 jobs alone in the Asian region (United States General Accounting Office, 2004: 35). And on a global scale, SARS accounted for an estimated loss to the economies of US$ 40 billion (Lee and McKibbin, 2004, Morse, 2006: 3).[128] The causative SARS coronavirus was eventually identified on April 16, and on July 5, 2013, the SARS epidemic was declared contained following the break of all known chains of human-to-human transmission (Whaley and Mansoor, 2006: 45).[129]

Whereas today the development of the SARS epidemic has been examined and the course of events is known, at the times of the outbreak the situation was extremely confusing. Not only was the virus unknown and initially believed to be a strain of influenza, Chinese authorities also attempted to conceal the occurrence of the disease, fearing negative consequences for the country's economy and worldwide image (Huang, 2003a, Pomfret and Goodman, 2003). In fact, in the first months after the outbreak in November 2002, information on death and panic related to a "strange contagious disease" in southern China left the country only through e-mail, Internet chat rooms and text messages (Piller, 2003, Pomfret, 2003e, Fidler, 2004b: 74). China's first official reactions were not issued before February 2003 (McNeill Jr. and Altman, 2003, WHO, 2003h, 2003i), although suspicious news had reached WHO since November 2002 already (WHO, 2003j: 4, Morse, 2006: 2). Only from mid-February onwards, China admitted that an outbreak had been taken place in Guangdong Province, but claimed that the disease was already under control (Fidler, 2004b: 75). Regardless of the request for assistance from WHO (WHO, 2003n), Chinese officials did not provide updates of their initial reports for more than a month and state-controlled media was not allowed to report on the disease (Fidler, 2003: 491, Pomfret and Goodman, 2003). Furthermore, Beijing decided to classify information on the pathogen as *top secret* so that related discussions ultimately meant a violation of 'national secrets' (Huang, 2003b: 65f, Price-Smith, 2009: 141).

In April 2003, at a time when *Time Magazine* reported that Chinese authorities were deliberately hiding infected patients from WHO professionals (Jakes, 2003) and when WHO took the unprecedented step to publicly accuse China for disguising the situation (Pomfret, 2003a), the Chinese government eventually changed its approach. It announced a 'nationwide war' on SARS,

[128] Other sources speak of US$30 billion to US$100 billion, but these figures may be too high (Keogh-Brown and Smith, 2008, Michaud, 2009: 28).

[129] A comprehensive summary with further details on the outbreak development and WHO's activities after March 16, *inter alia* in order to identify the virus and to trace the outbreak, can be found in (Fidler, 2004b).

publicly apologised for not having properly informed the public, instructed officials to stop hiding the severity of the situation and recalled the mayor of Beijing and the Minister of Health from their Party posts (Fidler, 2003: 491, Pomfret, 2003d, 2003c, 2003b, 2003f, Fidler, 2004b: 98, Price-Smith, 2009: 141f). These measures, however, could not prevent the situation that by the end of April 2003 about a million people, afraid of the disease, had left Beijing for the country side and their hometowns, where in some parts riots occurred and roadblocks were set up by the villagers to stop the entry of the potentially infected refugees (Huang, 2003b, Pomfret, 2003g, Price-Smith, 2009: 143).

China was the country of origin of the SARS outbreak and also the country with the highest number of infected persons (WHO, 2004). However, the disease, as we have seen, turned into a global epidemic to which politics also responded in a global manner. In this context WHO adopted a central role to coordinate international efforts. It provided communication structures and set up virtual networks of scientists to bring together expertise and resources from all over the world. Under the coordination of WHO, scientists, epidemiologists, public health experts, laboratories and clinicians collaborated in order to analyse the cause and characteristics of the pathogen, to monitor the disease and to second specialists to the regions affected by the disease. On the basis of information shared globally by scientists and governments, WHO also issued guidelines and advice for responding to SARS, including travel information and recommendations on how to detect and report cases and how to perform diagnostic tests. In this context the worldwide network of WHO Country and Regional Offices were the primary hubs to organise the support to affected regions (Knobler et al., 2004: 44, Doberstyn, 2006, Heymann et al., 2006: 54, Morse, 2006: 2).

A legal obligation to report SARS cases or to collaborate in SARS matters did not exist for WHO members at that time since the International Health Regulations had been formally revised in 1969 and required governments to report the incidence of four diseases only: smallpox, cholera, plague, and yellow fever (WHO, 1983). However, in the wake of the global SARS challenge, virtually all countries afflicted by SARS were willing to share information and forewent their exclusive sovereign rights to address the problem unilaterally. And although WHO made use of previously uncommon measures, such as the issuance of travel advisories without explicit authorisation by WHO Member States or the public criticism of individual countries, its engagement was generally supported by its Member States (WHO, 2003j, 2003e, Heymann, 2006, Reintjes, 2008: 150). The support found expression not only in the daily collaboration, but also in joint statements by the World Health Assembly (WHA), in which Member States showed deep concern “that SARS, as the first severe infectious disease to emerge in the twenty-first century, poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies” (WHO, 2003o). In addition to the resolution on SARS, the WHA also expressed – in the light of the experiences with SARS – its dissatisfaction with the existing International Health Regulations and called the WHO Member States to back a substantial IHR revision process (WHO, 2003m, Fidler, 2004b: 103f, see also chapter 6.3.3).

Without a detailed analysis it becomes clear the WHO-led responses to SARS at the international level included elements that hint at a securitisation of the disease at the international level in both

the verbal as well as the operational dimension. Speech acts can be found in the context of WHO's public accusations of the Chinese government, global network alerts, and statements by the Director General or the World Health Assembly. Emergency measures included *inter alia* unprecedented travel advisories, the work of international expert teams in affected areas and extraordinary global conferences on SARS.[130] The Member States of the European Union and their relevant national bodies were part of these international efforts, but additional SARS-related activities also took place at the European Union level. The next section explores these responses, tracks the EU activities and reviews the primary documents in order to prepare the ground for an analysis of the securitisation of the new disease at the EU level in the years from 2003 to 2004.

6.2. Crisis and Response at the EU Level

As outlined in chapter 3, essential EU structures to control infectious diseases were already in place at the time of the SARS outbreak. Most important, Decision 2119/98 /EC of the European Parliament and of the Council had established a 'Network for the Epidemiological Surveillance and Control of Communicable Diseases in the Community', also called the 'Communicable Disease Network' (CDN), "to promote cooperation and coordination between the Member States, with the assistance of the Commission, with a view to improving the prevention and control, in the Community" (European Parliament and Council, 1998: Art. 1). At the time of creation, the Network was coordinated by the Commission, supported by the Network Committee of Member States representatives (CDNC), and comprised two pillars: epidemiological surveillance on the one hand and early warning on the other.

The first pillar set up permanent communication structures that linked the Commission with the competent national public health authorities and surveillance institutes on specific diseases of the Member States to exchange information and to track these diseases. The second pillar constituted the 'Early Warning and Response System' EWRS, a web-based, confidential telematics notification system designed to immediately circulate important information on specified 'events' and outbreaks to accredited EWRS contact points (European Commission, 2000k, see also chapter 3.3.3). SARS was at the time of appearance, as a so far unknown pathogen, not on the list of communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC (European Commission, 2000a), but EWRS could still serve as the key instrument for the rapid exchange of information and crisis communication on the highest level of public health authorities (European Parliament and Council, 1998: Annex, Ammon, 2005: 1039, Guglielmetti et al., 2006, Reintjes, 2008: 147, Schreck et al., 2009: 150ff).

Similar to the developments at the international level, the SARS crisis covered also in the EU a relatively short period of time. The developments can be structured into basically three phases, starting with a phase from the first official EU statement on SARS in March 2003 to April 2003 (chapter 6.2.1), a second period over the early summer 2003 in May and June (chapter 6.2.2), and a post-outbreak phase from July 2003 onwards (chapter 6.2.3).

[130] The first global conference on SARS took place on June 17, 2003 in Kuala Lumpur, Malaysia.

6.2.1. The Months from March to April

At the time of the crisis, the CDN could look back at some years of cooperation, but SARS turned out to be the first practical test case for the warning system. The Commission had been in contact with WHO and monitored the SARS situation through the EWRS, but did not issue any official statement before March 19, 2003, when it informed the public that the first two cases of SARS in the EU were confirmed by German health authorities and that suspected cases had been reported by several Member States. It furthermore stated that the CDNC had already held an extraordinary meeting in Luxembourg in order to coordinate the responses of the Member States at the national level. The Commission's task in this context was to encourage common approaches and criteria and to integrate the national responses with global measures "through regular meetings, audio-conferences and consultations with the Member States, Candidate Countries and WHO" (European Commission, 2003g). The participants of the extraordinary network meeting concluded that an efficient surveillance system was put in place to pick up suspected and probable SARS cases, that special guidance for airlines and medical personnel was essential and that the EWRS would continue to provide the main hub for regular updates (European Commission, 2003f).

Although the Commission declared in an initial press statement that SARS had reached the EU territory already and was known to spread from person-to-person, the Commission's message was also formulated in a way that reassured the reader: only specific groups of persons were at particular risk and a functioning surveillance system was in place. At the same time, the Commission took the opportunity to underline that SARS demonstrated too clearly "the danger of communicable diseases" and that "contagious diseases require[d] a high level of preparedness across borders". Against this background the Commission set up and started regularly updating a specific SARS section on the European Commission's website on public health.[131] It furthermore identified the need to strengthen existing coordination and surveillance structures on Community level. The document quoted David Byrne, Commissioner for Health and Consumer Protection, that the EU needed "to establish a structure at European level that has the scope, the stability and the capacity to respond to the threat from diseases in the longer term." In order to do so, Commissioner Byrne outright announced his plan to prepare a proposal for the establishment of a 'European Centre for Disease Control' "responsible for carrying out tasks on the control of diseases relevant to public health" (European Commission, 2003f).

Whereas in March 2003 SARS did not figure prominently in official documents at the EU level, the situation changed from April onwards. On April 7, Commissioner Byrne turned to the European Parliament to address the fundamental questions on SARS: "What is it? Where does it come from? How does it spread? And how can we stop it?" (European Commission, 2003g). In his speech before the plenary he highlighted the great uncertainty linked to the disease, the "unknown factors" and the spread in a truly global environment that had triggered wide media attention and the labelling of

[131] The original URL was http://europa.eu.int/comm/health/ph_threats/com/sars/sars_en.htm. The link does not work anymore, but snapshots of the website are accessible via the Internet Archive. On the Internet Archive as a source for documents see also chapter 2.5.5.

SARS as “killer pneumonia”. His report on the successful work of the EU’s surveillance system in full connection to the global surveillance by WHO was accompanied by the warning that there were no “grounds for complacency“ and that the EU had to “be cautious, and err on the side of safety”, even if most of the suspected SARS cases were outside its territory (European Commission, 2003g). He furthermore recommended complying with the extraordinary WHO travel advisories, continuing strict control procedures, carrying out health screenings on departure from affected regions and generally reducing exposure to the disease by discouraging unnecessary travel to affected regions (European Commission, 2003g). Beyond the risks for public health, the Commissioner also hinted at the implications of the SARS outbreak in political and economic terms. In particular, travel and tourism in Asia were affected by the travel advisories, but also business meetings and industry exhibitions had to be cancelled with effects on Asia’s economy (European Commission, 2003g).

Interestingly, just as in the first official reaction to SARS in mid-March, the Commissioner stressed that in his opinion the EU’s capacity to deal with infectious diseases and surveillance and coordination at Community level needed to be strengthened “to address the threat to public health” (European Commission, 2003g). By declaring that the Commission’s capacity “to extend its coordinating and facilitating role any further” was “at its very limit” so that new arrangements would be inevitable, the Commissioner straightforward established a link between the outbreak situation and fundamental steps of reforms – not as an emergency reaction to SARS but in view of additional services in the mid- and long-term (European Commission, 2003g). In this context he reminded the Parliament of the plans to put forward enabling legislation for the establishment of a ‘European Centre for Disease Prevention and Control’.

On April 9 and 10, two days after the Commissioner’s speech at the European Parliament, the Communicable Disease Network Committee met again to agree on actions by Member States and Commission beyond EWRS surveillance to monitor and control SARS in Europe. The meeting resulted in two key documents to combat SARS and comparable diseases at the EU level, one on immediate activities (CDNC, 2003b) as well one on future actions for the longer-term (CDNC, 2003c).

Immediate actions agreed on by the Network Committee included four areas of actions as well as a recommended check list for national authorities. The objectives of the agreed actions were the reduction of infection in travellers in affected areas, the limitation of the importation of infections, the early detection of imported cases and extensive public information to prevent the further spread of SARS. Individual measures ranged from recommendation to postpone “all but essential travel to areas where transmission of SARS is ongoing outside the hospital setting, from which a significant number of cases have been exported, or where there is concern about the completeness of reporting and contact tracing and strong suspicion of ongoing community transmission” to essential information for both passengers as well as air crews. In this respect the document also included clear instructions how to react in the event that a passenger or crew member was suspected to be infected. The Committee furthermore agreed to promote departure screenings of passengers leaving affected regions, but not to support general registration or health screening at ports of arrival as they were considered of little value and could “give the public a false sense of security” (CDNC, 2003b: 2).

Many of the recommendations, such as the activation of a surveillance system with specific case definitions and reporting procedures, were comparable to what WHO had issued a few weeks before. Also various explicit references to WHO lists or guidance documents can be found in the Committee's conclusions.[132] Obviously, a major difference to the WHO recommendations was that Member States were instructed to report not only to WHO, but also the Commission, be it on a daily basis in the case of probable detections, or "immediately" [emphasis in original] should a country experience the first suspected case or local transmission (CDNC, 2003b: 3). Consequently, the check list for national authorities, ranging from information for travellers, airport staff, political delegations abroad and the public, to guidance for the health services and hospitals, surveillance, alerting and laboratory capacities, included various points similar to the WHO's recommendations. But also additional elements, such as considerations regarding the arrangements for potential restriction of SARS infected persons and their contacts, such as quarantine, were included. Finally, Member States decided to set up an 'EU Expert Group on SARS' to advise the Commission and Member States and to rapidly react to new issues, and expressed support for the global efforts to combat the disease, in particular by identifying experts "willing to go abroad to join EC/WHO field teams" (CDNC, 2003b: 5f).

With a view to future actions in the mid- and long term, the Network Committee took a number of decisions to provide the Network with tools to better prepare for and address SARS in Europe, but also with the aim to respond to similar public health threats beyond SARS. As the document was meant to complement the agreement on instant actions, activities partly overlapped with the immediate measures, but none of the actions had been addressed or put in place before at the EU level (CDNC, 2003c: 1). Activities included further details on the SARS Expert Group and the assistance to WHO's field trips, which were agreed to take place on behalf of the EU under the GOARN framework with EU resources to cover the missions. Furthermore, participants mandated the Commission and the Network Committee to standardise guidance and advice across Europe, also for the work of laboratories, to work on a common procedure "to minimise the risk of transmission […] by restricting movement (quarantine)" as well as a mechanism to "provide immediate practical support to EU countries […] that suspect they are experiencing an outbreak" (CDNC, 2003c: 1f).

Other areas identified for future action at the EU level were the fields of vaccination and research. In this context the Commission was asked to set the development of new antiviral drugs as a priority of research and to explore possibilities for the coordination of the production, stockpiling and distribution of antivirals, antibiotics and protective equipment at the Community level (CDNC, 2003c: 2f). In addition, it was proposed to take the SARS outbreak as an occasion to test preparedness plans for other diseases and also to consider a Community approach in this area (CDNC, 2003c: 3).

Besides the central documents issued by the Network Committee, further key documents on SARS were issued by the Commission in April. On the one hand, the Commission put forward a proposal for extraordinary procedures regarding the allocation of slots in the air transport sector. The Regulation in place at that time (Council, 1993b) foresaw a "use-it-or-lose-it" rule which implied that "air carriers were not entitled to the same series of slots in the next equivalent scheduling season, unless they

[132] For instance to WHO 2003l and WHO 2003k.

can prove […] that they have operated them […] for at least 80%" (European Commission, 2003m). In the light of the severe decline of air travel in the beginning of 2003 resulting in part from the SARS outbreak, in part from the war in Iraq that had started in the same period, the Commission proposed a change of the rule in these exceptional circumstances (European Commission, 2003m).The European Economic and Social Committee supported the Commission's proposal as it took into account the "exceptional circumstances" for the carriers (EESC, 2003b).

On the other hand, SARS also played into the Commissions foreign policy activities, when President Romano Prodi voiced condolence about SARS cases in China in his letter to the Chinese President Hu Jintao. In this context Prodi labelled SARS "the first global threat toward human's health in the new century" and a deadly disease "that the whole world [was] endeavouring to control and fight" (also referred to in Council, 2003d: 6, Ministry of Foreign Affairs of the People's Republic of China, 2003).

6.2.2. The Months from May to June

Although the EU level was strongly involved in the international and the Member States' national responses to SARS in March and April already, discussions and activities reached yet another peak in May and June. In the beginning of May, Member States convened for an extraordinary meeting of the 'Employment, Social Policy, Health and Consumer Affairs' configuration of the Council, in which also Gro Harlem Brundtland, Director General of the WHO, as well as the accession countries participated. A Member of the European Parliament had claimed already on April 4 that such as meeting was necessary, when he found that "[t]he only certainty is that we do not know enough about [SARS]" (European Parliament, 2003f); the meeting, however, did not take place before May 6 (Council, 2003c).

In their conclusions the health ministers showed concern about the "rapid global spread of SARS and the significant increase of reported cases" and expressed "determination to contribute effectively to the containment and, hopefully, to the eventual elimination of this threat to human health" (Council, 2003c: 5f). Although the Council underlined that the implementation of health protection measures was the responsibility of the national authorities, it also welcomed and expressed support for the work of the CDN and the Network Committee. The Council Conclusions recalled the detailed list of measures to combat the transmission of the disease and urged Member States as well as accession countries to implement both immediate and future actions. In addition to the ongoing activities, the Member States' representatives also expressed the will to further strengthen both European as well as international capacities. In this context they encouraged the Commission to prepare a report by June and "consider developing a general preparedness plan on communicable diseases and health threats". With a view to the international arena, the Council expressed support for WHO's efforts to accelerate the revision of the International Health Regulations (Council, 2003c: 7f). The document closed with the acknowledgment of the "Commission's intention to submit a proposal to create a European Centre for disease prevention and control" and agreed to review the situation again in June (Council, 2003c: 5).

After the extraordinary meeting of the Council, SARS also became a prominent topic for the European Parliament, best illustrated by the rapidly increasing number of related written questions to the Commission and to the Council. With reference to the rising number of suspected cases and deaths as well as the absence of effective antibiotics or antiviral drugs, the interventions dealt with the disease in the context of specific issues such as illegal migration (European Parliament, 2003g), the Schengen system (European Parliament, 2004k), airline air recycling (European Parliament, 2004j), (additional) travel and airport checks (European Parliament, 2003d, 2004b), the import of textiles (European Parliament, 2004a) or in connection to the influenza virus (European Parliament, 2004d, 2004l). Beyond that, more general questions regarding EU-wide measures and the EU's prevention and control system as a whole were raised (European Parliament, 2003d, 2003b, 2003e, 2004m). In many of the written questions considerable concern about the spread of the disease became visible, leading Members of the European Parliament to call for "urgent action by the Union authorities […] to devise common protection measures and strengthen cooperation between Member States" (European Parliament, 2003c, 2004k). When answering the questions in June and July 2003, the Commission applied a rather technical approach by referring to the actions already in place, the relevant Council conclusions (Council, 2003c) as well as the preparations regarding the envisaged Centre for Disease Prevention and Control.

In June 2003, the Commission also presented its report on the measures undertaken by Member States and accession countries to control the outbreak of SARS. The report had been drafted following the request from the extraordinary meeting of the Health Council on May 6 and was discussed in the Council meeting on June 2/3 (Council, 2003b, European Commission, 2003a). It included information gathered through a questionnaire which had been prepared by the EU Expert Group on SARS and was sent out to the national authorities in order to compile an overview of adopted emergency and protection measures across all countries. The report consisted of basically two chapters, one on the implementation of measures and one on recommendations for future actions. Additionally, annexed to the report the document comprised a 'Road Map of EU Action' and summary tables.

In general, the Commission showed satisfaction with the implementation of measures reaching from detection of cases and isolation measures through measures for protection of health care workers and infection control to guidance and information to the public, travel advice and laboratory organisation. In the light of the short period of time passed after the official WHO alert on the SARS outbreak, measures were generally considered as rapid, consistent, largely effective and in line with both the advice of the Network Committee and WHO's recommendations, even if variations existed among Member States. Besides, the report also stressed the contribution of European laboratories to the global work to identify the SARS coronavirus as well as the efforts in the field of humanitarian assistance. Regarding the latter, in addition to the expertise provided by several countries, partly through EU funded programmes such as the European Programme for Intervention Epidemiology Training (EPIET; see also chapter 3.3.2), the European Commission's humanitarian aid office (ECHO) had set up a coordinated plan with recipient countries and implementing organisations (European Commission, 2003a: 13f).

Despite the fact that "speed and efficiency at which public health measures were implemented throughout the European Union [was] reassuring", the Commission also voiced severe concerns, in particular in the case that a localised outbreak should happen in one of the Member States (European Commission, 2003a: 5). It labelled SARS still "a serious threat" because of an "unprecedented combination of features", including the circumstances that "no vaccine and no treatment" existed and the incubation period allowed "rapid spread via air travel between any two cities in the world" (European Commission, 2003a: 14). In general, all health systems were put under considerable stress, not least due to the fact that the "disease continue[d] to hit front-line human resources – health care staff – essential to combat the threat" (European Commission, 2003a: 14). Crucially, the Commission found that SARS had "incited widespread public anxiety, spreading faster than the virus, and causing social discomfort, economic losses and political stress". Further consequences of the public's fear such as the emergence of discrimination towards vulnerable communities were identified, too (European Commission, 2003a: 15). This kind of fear also repeatedly spoke through written questions from Members of the European Parliament to the Commission, for instance when labelling "SARS […] a disease whose origins have not yet been established and for which there is so far no cure", which had "become the new plague of the third millennium, thanks to the ease with which it spreads", and which was "affecting dozens of new victims every day" (European Parliament, 2003a).

In the light of this ongoing threat scenario as drawn in the report, the Commission did not miss to identify further fields of activity beyond the immediate actions implemented already. In this context it occasionally proposed a stronger role for the Commission itself. To illustrate, proposals included the ideas to develop "[a]n EU consistent approach to the contents of the information communicated to the public, coordinated by the Commission" (European Commission, 2003a: 8), to strengthen SARS expertise on Community level by attaching Member States experts to DG SANCO (European Commission, 2003a: 15), and to apply "a common approach […] at EU level on traceability for passengers arriving or in-transit from affected areas, and their follow up, as well as control actions on the effective screening for SARS at exit sites (European Commission, 2003a: 11). Furthermore, the Commission envisaged to "identify best practices and sustainable actions for the development of an EU preparedness plan on communicable diseases with epidemic potential" (European Commission, 2003a: 7). In the framework of such a general preparedness plan on communicable diseases, the Commission had already extraordinarily committed EUR 9 million to support research, in particular related to diagnosis, medication and vaccination before the end of 2003 (Council, 2003b: 9, European Commission, 2003a: 17).

Just as in its previous interventions, the Commission took the opportunity to conclude the proposal for following activities with the idea of a structural reform, the establishment of a European Centre for Disease Prevention and Control. In this vein, the comprehensive set of future actions were explicitly declared to pave the way for the establishment of such a centre by 2005 (European Commission, 2003a: 17), also clearly set out in the annexed 'EU Action Road Map' (European Commission, 2003a: Annex).

In the course of the month, the Commission's report was followed by a series of EU guidance documents, which were prepared with the assistance of the EU Expert Group on SARS under the Network Committee. A 'Registration Card' was designed to inform travellers to countries of the European Union that they were leaving an area affected by SARS and that it was possible that during the flight they could have been exposed to an infected person. For this reason the EU requested these travellers to provide contact information for the next 14 days (CDNC, 2003d). 'Important Health Information' notified travellers of their risk to have caught an infection, for which the incubation period could be up to 10 days so that symptoms could develop accordingly (CDNC, 2003e). Passengers who had possible contact with SARS during a flight were informed by a technical guidance document that there was a risk that they had become infected as well. The document advised the passenger to consult a doctor, to "have contact with as few persons as possible before your physician sees you and gives further instructions" and not [to] go to the hospital or sit in the waiting room with other patients" (CDNC, 2003a).

6.2.3. The Post-Outbreak Phase

After the disease was declared contained by WHO in July 2003, also EU efforts entered a post-outbreak phase. The period was characterised by the combination of views that the immediate threat of SARS had disappeared, but that activities to prepare for the re-emergence of SARS or similar threats were needed. The update of advice for airline personnel, where the "current risk of SARS in Europe" was assessed to be "very low" (CDNC, 2003f, version of September 25, 2003) or in relation to influenza vaccination (European Commission, 2003c) are two cases in point.

In this context the Network Committee issued an updated guidance document on the risk of escape of the SARS coronavirus from laboratories (CDNC, 2004) after instances of this kind in Singapore and Taiwan had become public. Against the background that SARS was now seen as a "dangerous infection" that could re-emerge from laboratories, including those in Europe, the Committee recalled the WHO guidelines for handling of SARS-CoV specimens and cultures (CDNC, 2004). Parliamentarians remembered the Commission "that the SARS virus can strike at lightning speed" (European Parliament, 2004i), feared that also "[b]iological terrorism [could] never be ruled out" (European Parliament, 2004h) and raised the question of crisis management plans again. The Commission routine responses, however, showed that on their end the disease was not defined as an imminent threat anymore, rather than a lesson from the past from which "a great deal was learnt" (European Parliament, 2004i). As long as SARS was not declared contained, the assessment had been different, illustrated by the fact that the Commission had decided – in the light of "the significant threat of SARS" – not to send Commission officials to conduct anti-dumping verification visits under Regulation (EC) No 384/96 (Council, 1996f: Art. 16 (1)) to SARS affected areas as long as these regions appeared on the respective WHO list (European Commission, 2003n).

Beyond that, issues that had been launched during the SARS crisis were finalised in the months after July 2003. Taking up the request from the Council to foster research in the relevant areas, the Commission published a special call "with the aim of developing an EU capability for strategic use of

R&D resources against SARS and in the event of similar outbreaks" and funded seven projects from this *ad hoc* EU research budget of about EUR 13.6 million (European Commission, 2005f: 8). Besides research, the initiative to find a flexible solution for air carriers regarding the allocation of slots could be finalised too. Seeing that "[t]he war launched in March 2003 against Iraq and the political developments that followed, as well as the outbreak of the Severe Acute Respiratory Syndrome (SARS) [had] seriously affected the air transport operations of air carriers and have triggered a significant reduction in demand", Parliament and Council agreed still in 2003 on an amendment on the common rules for the allocation of slots at Community airports (European Parliament and Council, 2003), before they approached a more substantial revision in 2004 (European Commission, 2004b, European Parliament and Council, 2004c).

6.3. Legal and Institutional Reform

Coming to terms with the SARS experience did not end with the declaration that the disease was controlled. In fact, the crisis year 2003 was followed by a reform package in 2004 which *inter alia* comprised the two milestone innovations under scrutiny in this case study: the creation of the European Centre for Disease Prevention and Control and the revision of the public health article in the EU's primary law in the Constitutional Treaty. The following section will investigate these innovations in detail, embed them into the process of the SARS crisis and will also address further legal and institutional reforms that occurred in the wake of SARS.

6.3.1. The European Centre for Disease Prevention and Control (ECDC)

We have seen that right after the SARS outbreak had reached EU territory in March 2003, the European Commission started to announce and advertise a proposal for the establishment of a new European institution, first under the title of an 'EU Centre for Disease Control' (European Commission, 2003f), later as the 'European Centre for Disease Prevention and Control' (European Commission, 2003g). Thus, SARS and the idea of an EU centre were tied together from the start, but the establishment of the centre was not meant to constitute an emergency measure to immediately address the disease. Instead the Commission proposed the creation as a reform step in view of enhanced surveillance and better coordination in the future.

The idea for such an EU centre, however, had been born already before the SARS outbreak occurred. In fact, in April 2003, when Health Commissioner David Byrne spoke about SARS before the European Parliament and when the Network Committee prepared the document on future actions for the longer-term, the Commission was already "well advanced in the preparation of the enabling legislation […] to establish such a Centre by 2005" (CDNC, 2003c: 3, European Commission, 2003g).

The original idea to establish such a European dates back to the 1990s (MacLehose et al., 2002). In the years before 1998, when the CDN was set up, a basic discussion took place between advocates and opponents of a more centralised approach to infectious disease control at the European level.

For instance, during the negotiations to establish the Community Network, the Parliament had proposed, in a request for amendment of the respective Regulation, that information was collected at the level of each Member State "in order then to forward them to a central body: the European Centre for the Surveillance of Communicable Diseases" (European Parliament, 1996c: Amendment 8, Art. 1 (2)).

The debate intensified in 1997 and 1998 with publications by experts partly arguing in favour of a central EU structure (Tibayrenc, 1997a, 1997b) and partly in favour of a network of national surveillance authorities (Giesecke and Weinberg, 1998, The Lancet (Editorial), 1998). Critics argued that informal meetings of the heads of the national centres surveillance centres, the so called 'Charter Group', had produced good results in the past, *inter alia* by assisting the Commission in the prioritisation of infectious disease surveillance and structures (Giesecke and Weinberg, 1998, Weinberg et al., 1999). As we have seen in chapter 3.3.3, the decision was finally taken against the creation of a centre and in favour of legislation that supported the operation of an intergovernmental set of disease networks (European Parliament and Council, 1998).

It was widely agreed that the network approach would be preferable, given the already available structures in Europe and the existing networks (European Commission, 2000a, Reintjes, 2008: 147). But while some contributions claimed that "[t]he idea of a central edifice seems to be politically dead" (Giesecke and Weinberg, 1998: 1308), other experts continued discussing the aims and implementation of a 'European Centre for Infectious Diseases' (Dove, 1998). One approach was to copy the structures of the US 'Centers for Disease Control and Prevention' (CDC) which act as a "higher coordinator, adviser, and data collector" whereas the US states retain responsibility for surveillance and prevention (Bradbury, 1998: 969). The ECID project, however, was not necessarily seen as an institution embedded in the EU framework but tried to build on official support from further countries such as Switzerland or Turkey (Tibayrenc, 1998).

In the following years, when the CDN had been established already, the Commission fuelled the debate on an EU centre by contracting a set of scientists with the aim to evaluate the performance and improvements to be introduced in the operation of the Community network for communicable diseases (Brand et al., 2000, MacLehose et al., 2001). At the same time, health cooperation in health matters and infectious disease control became subject to high level discussion, for instance during the G8 meeting in Évian-les-Bains and the European Council meeting in Gothenburg, both of which took place in June 2001. Crucially, the Presidency Conclusions noted "that the possibility of the creation of a European surveillance and early warning network on health issues [should] be examined" (European Council, 2001b). Furthermore, a public seminar took place in November 2002 under the auspices of the Parliament. The consultations generated fresh input and included recommendation to support "EU level preparedness, EU coordination of outbreak investigations, and provision of assistance by experts on behalf of the European Union" (European Commission, 2003b: 5f).

Although national state epidemiologists, the Network Committee and further experts adopted conclusions favouring the creation of an EU coordinating centre (Petersen and Catchpole, 2001, European Commission, 2003b: 2), a main finding of the revitalised discussion was that not necessarily the creation of an EU institution, but that also the strengthening of the existing networks could be the basis for the future development (European Commission, 2003b: 6, Greer, 2012a: 1009). As Scott Greer puts it in one of the few academic publications dealing with the origins of the ECDC, despite positive voices "many of the key advocates made it clear in publications up to 2003 that they preferred networks to a centre" (Greer, 2012a: 1009).

6.3.1.1. The Establishment of the European Centre for Disease Prevention and Control

On July 23, 2003, two and a half week after the SARS outbreak was declared contained by WHO, the Commission put forward its official proposal to establish a 'European Centre for Disease Prevention and Control' (European Commission, 2003b). The first eleven pages of the document were dedicated to an explanatory memorandum that drew a general assessment of the infectious disease challenge both internationally and in the EU, explaining the limitations of the EU's current network activities and why the Union needed the proposed institution.

The document brimmed over with references to SARS, starting with the very first sentence of the memorandum that named SARS as a recent example for the "significant threat to the health and wellbeing of the European Union's citizens", which communicable disease outbreaks could pose (European Commission, 2003b: 2). The Commission declared that SARS had demonstrated "the shortcomings of present model of disease control" (European Commission, 2003b: 4) and the "lack of capacity to deal with serious health threats at the Community level" (European Commission, 2003b: 36). It stressed that the virus was able "through migration or tourism […] to spread in just in a few weeks from China to Europe, the Americas, and Asia" (European Commission, 2003b: 4) and warned that "[t]he next time could well be a pandemic" (European Commission, 2003b: 36f). Beyond SARS, the proposal also included references to the possibility of deliberately start of an outbreak (bioterrorism) and further diseases or pathogens such as anthrax, HIV/AIDS or tuberculosis (European Commission, 2003b: 3, 10).

The Commission described the centre as a significant step to mobilise synergies between the national disease centres, to better manage the existing operational instruments related to the existing Community Network and to provide EU policy makers and citizens with „authoritative and independent scientific advice on serious health threats" necessary for effective EU-wide response (European Commission, 2003b: 3). The plans of the Commission, however, did not foresee the transfer of legislative powers to the independent EU agency or the abolishment of the existing Communicable Disease Network (CDN). Instead, the Commission proposed to maintain the existing division of labour with risk management being the competence of national authorities, supported by the coordination and legislative provisions of the Commission in conjunction with the Network Committee. The ECDC's task was meant to constitute a "centre of excellence to which the Commission and the Member States can go for authoritative advice and opinions" (European

Commission, 2003b: 7) and which ensures "efficient networking and pooling of Member States' scientific expertise" with the overarching aim to facilitate more effective preparedness planning (European Commission, 2003b: 10f). In line with the limited field of activity, the initial budget was proposed to be comparatively tiny, just as the number of staff.[133]

Despite the various references to SARS, the Commission's proposal for a centre was not intended to constitute an extraordinary measure particularly designed to address the threat of SARS. In fact, what the Commission aimed at was structural change of the EU's infectious disease setup towards a centralisation of the existing elements and a general strengthening of capacities at the EU level in the future. In this vein, the Commission proposal stated that "[t]aking rapid and effective action against a disease outbreak, and thus being able to reassure citizens that the outbreak has been contained, will protect Member States' economies, as well as their public health" (European Commission, 2003b: 4). The Commission proposal was forwarded to the Council, the Parliament and the European Economic and Social Committee in August. In its opinion of October 2003, the EESC agreed "wholeheartedly with the Commission's analysis" (EESC, 2004: 59). It considered the creation "a boost to the EU's public health policy as defined in Treaty Article 152" (EESC, 2004: 60) and documented that – after years of discussions – "since June 2003, following the outbreak of the SARS epidemic, support from the Member States for the proposed centre has grown considerably" (EESC, 2004: 57).

Following an extensive policy debate on the Commission's proposal which dealt with questions such as to whether the European centre should also cover non-communicable diseases, the Council reached a general agreement during its meeting on December 1 and 2, 2003 (Council, 2003a: 23). Only ten days later, on December 12, the European Council declared that the establishment of the centre was envisaged on the basis of the Commission's proposal and that the seat of the centre should be in a town in Sweden (European Council, 2004b). On January 27, the European Parliament's Committee on the Environment, Public Health and Consumer Policy adopted the report on the proposed ECDC Regulation (European Parliament, 2004f) which was eventually endorsed by the Parliament in first reading on February 10 (European Commission, 2004f). The proposed amendments included conceptual clarifications and editorial changes with regard to the mission of the ECDC, the Centre's management and advisory bodies as well as the financing arrangements and the provisions for the review in the third year.

Besides the amendments, the report acknowledged the value of the old system as "so far so (fairly) good" and stressed once more various limitations, from coordination problems to the small number of specialists available to advise the Commission. Also the fact that the financing of the old system was dependent on the public health programme – a circumstance that was to change with the creation of the new centre – was seen as counterproductive (European Parliament, 2004f: 22).

[133] The proposal foresaw a budget increasing from roughly EUR 5 million in 2005 (European Commission, 2003b: 39) to EUR 30 million annual operational costs in 2007 (European Commission, 2003b: 41). The number of staff during the start-up phase was set to 35, progressively rising to estimated ultimate staffing level of 98 persons (European Commission, 2003b: 41). The numbers were subject to later change. For instance, in July 2005 the Commission mentioned in its hand-over file to transfer the responsibilities from the Commission to ECDC the number of an estimated staffing of 300 in the year 2013 (European Commission, 2005h).

Following the green light from the Council during the meeting on March 30, 2004 (Council, 2004), the proposal was adopted by Parliament and Council and entered into force on April 21, 2004 (European Parliament and Council, 2004a). As a Regulation passed on the first reading, it didn't take more than nine months between July 2003 and April 2004 to complete the co-decision procedure; record time for the establishment of a new EU agency. Despite the intense discussions prior to the adoption, in particular between Commission and Member States (Ammon, 2005: 1042), the quick finalisation of the procedure proved all actors were willing to quickly solve the existing conflicts. According to Greer, "[a]lmost no interest group politics were opposed" (Greer, 2012a:1012). Although activities started earlier, the European Centre for Disease Prevention and Control was officially established on May 20, 2005 with its head office in Stockholm (Wigzell, 2005, Guglielmetti et al., 2006, Ammon and Faensen, 2009: 178).

Table 6-1: Overview of the Documents in the Process Related to Regulation 851/2004 Establishing the ECDC

(OJ) Date	Author	Reference	Contents
Doc No.			
16.09.03	COM	(European Commission, 2003b)	Proposal for a Regulation establishing the ECDC
COM(2003) 441 final/2[134]			
02.12.03	CO	(Council, 2003a)	General agreement on COM(2003) 441 final/2
15443/03 (Presse 354)			
29.01.04	EP	(European Parliament, 2004f)	Report on the Proposal for a Regulation establishing the ECDC
A5-0038/2004			
05.02.04	EUCO	(European Council, 2004b)	Determining that ECDC should have its seat in Sweden to be determined by Swedish Government
5381/04			
05.02.04	EESC	(EESC, 2004)	Opinion on Regulation establishing the ECDC
2004/C 32/11			
30.04.04	EP+CO	(European Parliament and Council, 2004a)	Regulation establishing the ECDC
R 851/2004			

Source: Own presentation.

6.3.1.2. The Mission of the European Centre for Disease Prevention and Control

The creation of the ECDC meant a clear step towards centralisation at the EU level in various aspects (Liverani et al., 2012). In contrast to the previous system in which the Commission played a supportive role for the coordination of various initiatives of national authorities or research centres, the ECDC provided a central hub for these activities. The legislative basis defined the agency's official mandate to "identify, assess and communicate current and emerging threats to human health from communicable diseases" (European Parliament and Council, 2004a: 1). In particular, the Centre is mandated to act on its own initiative in the case of "outbreaks of illness of unknown origin, which may spread within or to the Community" (European Parliament and Council, 2004a: 1).

[134] The first draft was published on July 23, 2003 (European Commission, 2003h).

In order to perform these tasks the ECDC shall:

1) search for, collect, collate, evaluate and disseminate relevant scientific and technical data,
2) provide scientific opinions and scientific and technical assistance including training,
3) provide timely information to EU and international institutions,
4) coordinate the European networking of bodies and
5) exchange information, expertise and best practices to facilitate the development and implementation of joint actions (European Parliament and Council, 2004a: Art. 3 (2, a-e)).

Taking over these tasks implied the gradual transfer of various responsibilities to ECDC, such as the editorial office of Eurosurveillance and the coordination of the training network EPIET, both of which became part of the ECDC in 2007, as well as the incorporation of nearly all European surveillance networks, previously run by national health authorities or laboratories on a project basis (Greer, 2012a: 1016, Liverani and Coker, 2012: 922, Liverani et al., 2012: 576). Also the ability to set up EU teams for the technical assistance to Member States or third countries in the case of an epidemiological crisis were incorporated. Crucially, the ECDC was integrated into all activities related to the operation and further development of the Early Warning and Response System (EWRS), which had played a vital role during the SARS outbreak (Ammon, 2005: 1042).

The centre did not receive legislative or direct regulative powers. In particular, the agency is not allowed to harmonise national law or prescribe specific measures to be implemented across the EU. The agency can provide risk assessment, but the management of a public health threat stayed with the 'Health Threats Unit' of Commission's DG SANCO which coordinates the activities of the national institutions in line with the principle of subsidiarity (Liverani et al., 2012: 576). Member States are not obliged to follow ECDC's arguments and a Decision by the Commission on the change or setup of new measures requires authorisation by the regulatory committee[135] (Schreck et al., 2009: 150ff).

This setup makes the ECDC a comparatively weak agency from a legal point of view. The competencies conferred to ECDC reflect the idea of a coordinator who facilitates the collaboration between national agencies and other organisations, who informs EU and Member State decision-makers and who supports and standardises infectious disease surveillance at the EU level. In this way existing network structures for the surveillance of specific diseases, which had worked largely independently from one another, were incorporated into the new agency in view of a future harmonisation of their methodologies. By doing so the establishment of the ECDC did not only mean new support and a standardisation of infectious disease surveillance at the EU level, for instance in the form of a new interface for the reporting and pooling of surveillance data, the European Surveillance System 'TESSy' (since April 2008) (Ammon and Faensen, 2009: 179).[136] It also perpetuated the funding for the surveillance networks, which had previously relied on a project-based arrangement (Reintjes, 2008: 148, Ammon and Faensen, 2009: 178).

[135] Originally the Communicable Diseases Network Committee (CDNC); since the entry into force of Decision 1082/2013/EU (see chapter 3.5.3.1), the respective committee is the 'committee on serious cross-border threats to health' (European Parliament and Council, 2013a: Art. 18).
[136] For more information on TESSy, see Ammon and Faensen (2009) as well as http://ecdc.europa.eu/en/activities/surveillance/TESSy/Pages/TESSy.aspx (accessed 18.03.2015).

However, the Regulation establishing the ECDC did not set a finite list of projects. Quite the contrary, the agency is allowed to start discussion on new issues on its own initiative. Furthermore, provided an approval of the budget and a green light from the ECDC management board,[137] the agency can "add projects on new diseases and problems at will" and, thus, "grow without new legislation" (Greer, 2012a: 1013). However, since viable infrastructures exist in many Member States, the expansion of the ECDC's tasks is expected to occur primarily in a form of consolidation (Mätzke, 2012: 972).

6.3.2. The Revision of the Public Health Article in the Constitutional Treaty

In addition to the creation of the ECDC, SARS also played into the reform process for fundamental EU law, given that the disease also appeared in the discussions of the 'European Convention on the Future of Europe' which completed its work on July 10, 2003, with the 'Draft Treaty Establishing a Constitution for Europe' (European Convention, 2003b). Several members of the Convention identified common security problems in the realm of public health as an area in which strengthened Union powers would be desirable. To illustrate, Andrew Duff, a UK member of the Convention and Member of the European Parliament, explained in the justification for a proposed amendment to the article on public health that "[t]he objectives of this article badly needs to be modernised to provide the necessary instruments to effectively respond to the real and new threats that exist from cross-border communicable disease, such as SARS" (European Convention, 2003c).

In this context partly far reaching formulations were put forward, for instance the right for European Parliament and Council to adopt "measures to combat threats to health, including communicable diseases and the deliberate release of biological or chemical agent" (European Convention, 2003c). Joschka Fischer, German Foreign Minister and member of the European Convention, proposed that the formulations laid down in the Constitutional Treaty should extend to "epidemiological surveillance of communicable diseases" and include "the establishment of an early warning and response system to prevent and control these diseases" (European Convention, 2003a). Support for a stronger EU role and easier decision-making procedures also came from the Commission during the Conventions proceedings. Commissioner Byrne argued in favour of Treaty references to a central EU power that "coordinates vaccinations, travel advice and other measures to prevent the spread of diseases such as Severe Acute Respiratory Syndrome" (Parker, 2003).

In contrast to these suggestions, the Convention's *Praesidium* under President Giscard d'Estaing eventually decided that the legal basis for the coordination of action in the field of public health should not be changed in a fundamental way; the 'Draft Treaty' left major parts of the Treaty article on public health unchanged, despite the discussions in the Convention (Parker, 2003). Thus, the changes proposed in the Draft Treaty were limited to the further specification of possible

[137] The management board is the strategic and administrative body that comprises one member from each Member State, two from the Parliament and three from the Commission. Its work is supported by an advisory board that is in charge of the evaluation of the scientific quality and independency of the agency (Schreck et al., 2009: 154).

coordination measures such as the "establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation" (European Convention, 2003b: Art. III-179 (2)). One innovation in the realm of infectious disease control, however, was the extension of the scope of "incentive measures" which, unlike in the past, were also meant "to combat the major cross-border health scourges" in the future (European Convention, 2003b: Art. III-179 (5)).

However, after Giscard d'Estaing's Convention had rejected a stronger constitutional basis for infectious disease control at the EU level, the article on public health underwent a substantial revision before the heads of state or government finally signed the Constitutional Treaty at the Intergovernmental Conference in Rome on October 29, 2004. In fact, in contrast to the *Praesidium*'s decision many of the far reaching ideas originally discussed in the Convention found their way into the final text.

More precisely, the final formulations of the Constitutional Treaty foresaw that "monitoring, early warning of and combating serious cross-border threats to health" was no longer subject to soft "incentive measure" but belonged to the primary Union actions in the field of public health, designed to complement national policies (Art. III-278 (1)). In line with this rise in the degree of priorities, the final Treaty article also added an explicit paragraph stating that "European laws or framework laws shall [address] measures concerning monitoring, early warning of and combating serious cross-border threats to health (Art. III-278 (4d)). Crucially, this formulation meant that cross-border threats to health were shifted to the realm of shared competences by the new Treaty, in contrast to protection and improvement of human health in general which remained in the area of supporting, coordinating and complementary action.

Tracking the developments between the adoption of the Convention's Draft Treaty and the signed Constitutional Treaty is beyond the scope of the study, just as the revision of the Constitutional Treaty that ultimately led to the 'Lisbon Treaties'. Future studies might reveal the reasons for the significant differences between the documents and assess the role of the actors involved.[138] Important in the present context is that major innovations of the new legal basis included references to 'serious-cross border threats to health' as well as surveillance and response measures. Apparently, SARS as an individual disease did not make it into the new constitutional basis of the EU. Still, the new formulations were clearly designed in a way to include and address SARS and similar threats.

The ratification process for the Constitutional Treaty was stopped after the negative referendums in France and the Netherlands. The new provisions concerning infectious disease control nevertheless partly turned into EU primary law as the reference of cross-border threat to health as a field of EU activity was included in the Lisbon Treaties, namely in the form of Article 168 (1) of the Treaty on the Functioning of the European Union (TFEU) which entered into force on December 1, 2009. In this way, the change of the EU Treaty article on public health following the SARS outbreak determines infectious disease action at the EU level down to the present date. As a major adulteration in

[138] For instance, Commissioner Byrne announced after the final adoption of the 'Draft Constitutional Treaty' by the Convention that he would "continue his fight in the intergovernmental conference" (Parker, 2003).

comparison to the Constitutional Treaty, however, Article 168 of the TFEU did not locate measures concerning monitoring, early warning of and combating serious cross-border threats to health in the area of shared competences. A complete overview of the changes of the public health article across the different EU Treaties can be found in Annex 1.

6.3.3. Further Reforms

Structural changes outside the EU are not subject to the present analysis. It should be noted, however, that beyond the EU level also crucial developments at the international level fell into the post-SARS period. In particular, the Group of Eight adopted the G8-Action plan on health in June 2003 (G8, 2003). SARS was also subject to discussions in the Global Health Security Initiative (GHSI)[139] during the meeting in Berlin in November 2003 (GHSI, 2003). Furthermore, following the intensified cooperation of the ten ASEAN[140] countries with China, Japan and South Korea during the SARS epidemic (Price-Smith, 2009: 150f), several Asian countries developed the idea to establish a central Asian Centre for Disease Control (Tibayrenc, 2005).

Crucially, experiences from the SARS outbreak also fed into the revision process for the International Health Regulations (IHR), the "only set of international legal rules binding WHO member states" concerning the prevention and control of infectious diseases with a potential to spread across borders (Heymann, 2004: 1127). According to the IHR's last revision of 1969, the Regulations required the reporting of only three communicable diseases: cholera, plague and yellow fever (WHO, 1983). In contrast, the new regulations (WHO, 2005) included broadened disease coverage, but also further reforms such as the use of non-governmental information on the disease outbreaks as well as the work with up-to-date means of communication.[141] According to public health experts and legal scholars, the SARS case thus constituted a "historic moment in public health governance which induced the successful revision of the IHR in 2005" (Fidler, 2004b: 186, Price-Smith, 2009: 154).

Also at the EU level further reforms and initiatives beyond the creation of the ECDC and the revision of the public health article in the Constitutional Treaty, could be observed for the field of infectious disease control the context of the SARS outbreak. Some of these changes were quite immediate, such as the "complete technological overhaul" of the Early Warning and Response System (Guglielmetti et al., 2006). Other reforms, such as the development of preparedness planning at the EU level, did not take place as promptly.

[139] On the Global Health Security Initiative (GHSI) see also foot note 68.

[140] ASEAN stands for 'Association of Southeast Asian Nations'. It is a regional economic and political integration organisation with the participation of Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam.

[141] Due to its importance for global and thus also European infectious disease control, the International Health Regulations (IHR) was, although adopted outside the EU context and without the EU being a contractual partner, identified as a milestone of infectious disease control for the EU by one interview respondent. For more information on the IHR new see, for instance, Fidler (2003), Tucker (2005), Baker and Fidler (2006), Baker and Forsyth (2007) and Michaud (2009).

As regards the first, the Commission found that the SARS outbreak had ”caused a huge and rapid flow of messages” through ERWS, which from the second week of the outbreak was characterised by ”an overload of the EWRS mailbox [which] had a negative impact on processing and interpreting data and on control activities” (European Commission, 2005f: 9). Against this background the EWRS was technically modified, the new version of which was launched in May 2004. Besides, also the permanent entry of SARS to the list of communicable diseases covered by the Community Network (European Commission, 2007a) and the respective case definition of SARS (European Commission, 2008e) are direct long-term updates.

With a view to preparedness planning, the revitalisation of the idea of a strengthened supranational framework on pandemic planning, including measures to coordinate surveillance, public health interventions, vaccines, and antivirals can also be seen in the context of the SARS crisis. The Commission had proposed the development of a pandemic influenza preparedness plan at the EU level already in 2001 (European Commission, 2001m), but only with the SARS outbreak cross-country coordination mechanisms in this area gained sufficient momentum to kick-off a proper reform process (European Commission, 2005d). Seeing that a ‘Community preparedness plan’ was part of the list of ‘Future Actions’ as agreed on in response to SARS in April 2003 (CDNC, 2003c), the following influenza and generic preparedness planning at the EU level, initiated in 2004 (European Commission, 2004h) and 2005 respectively (European Commission, 2005b)[142] can also be linked to the SARS outbreak. Setting the direction for several developments, the list of future measures in response to SARS unfolded indeed a structural impact in the further development of the further EU integration process.

Finally, it is noteworthy that we can find references to infectious diseases in the EU’s security strategy ‘A secure Europe in a better world’ which was adopted in December 2003 (European Council, 2003: 2). The document was presented by the High Representative for the CFSP, Javier Solana, to the European Council in Thessaloniki in 2003 and formed an important reference point for EU external action. The document addressed especially AIDS as a global challenge, but also stated that “[n]ew diseases can spread rapidly and become global threats” (European Council, 2003: 2).

6.4. The Securitisation of SARS

The analysis of the response to SARS at the EU level has shown that soon after the first official statement by the WHO on the disease also EU institutions became active to respond to the outbreak. The topic triggered manifold responses by the EU and its Member States between March 2003 and the end of 2004, during which SARS, as a political and security issue, underwent a short and rapid development. On the basis of the official documents, the period under scrutiny can be best classified along the three phases of EU activities:

[142] On the development of preparedness plans at the EU level see also chapter 3.4.2.

During the initial phase in March and April 2003, SARS appeared for the first time in public documentation and underwent a rapid rise in terms of EU output and attention. During the second phase between May and June 2003, the disease reached the highest spheres in terms of both political agenda and SARS-related output. In July 2003, the post-outbreak phase began, during which the urgency of the issue faded out significantly, coming to almost an end of directly SARS-related activities by the end of 2004.

The following section explores these developments from a securitisation point of view to reveal whether and in how far the EU utterances and reactions related to SARS fulfilled the criterions of securitising speech acts and extraordinary measures. In this context the first section on the degree of securitisation looks into the responses to SARS in terms of speech acts, security language and emergency measures, whereas the following section explores the rise and fall of SARS as a security issue. The section dealing with the kind of securitisation, in turn, investigates into the understanding(s) of security along the list of security parameters which were inherent to the construction of the disease as a matter of security concern. A final section of securitisation analysis deals with the roles of the involved EU actors. As set out in chapter 2.5.5, the list of documents was compiled on the basis of EUR-Lex extractions on the one hand and the official documentations made available in the internet on the other.[143]

6.4.1. The Degree of Securitisation

EU activities related to SARS began with the monitoring of the new disease through the Early Warning and Response System. Since the system was in place and working at that time already, this activity, however, could still be considered a standard procedure that did not necessarily mean a securitising activity. The begin of the securitisation process, in turn, was marked by the extraordinary meeting of the Network Committee and the Commission's public statement on the outbreak in March, which both shifted SARS out of the realm of ordinary politics. In the following four months, SARS yielded numerous securitising elements.

The speech of Commissioner Byrne before the European Parliament on the "killer pneumonia" (European Commission, 2003g) accelerated the development of securitisation in April and culminated in two key documents prepared by the Network Committee on immediate and future actions to combat SARS (CDNC, 2003b, 2003c). Comprising a comprehensive set of emergency measures, in particular the agreement on immediate actions constituted a significant boost for the securitisation of SARS in the operational dimension. From the outset, EU institutions repeated and called for strong support of the WHO recommendations and travel advisories which meant a substantial intervention into travel habits and economic prospects indeed. Whereas this reference to

[143] For explorative purposes, SARS-related written questions from the European Parliament as provided by EUR-Lex were analysed and classified in addition to the *text corpus* as defined in chapter 2.5.5. In order to ensure the operation with a consistently generated and analysed set of documents and to produce comparable results across both case studies, however, the classification of written questions and responses did not feed into the mathematical handling of the securitisation degree. An overview of the written questions and their classification is provided in Annex 2.

WHO already carried extraordinary measures from the international to the EU arena and can therefore be considered as elements of an *indirect* securitisation, the documents on immediate and future actions by the Network Committee constituted original contributions by EU Member States and Commission. As shown in detail in chapter 6.2, these documents encompassed numerous individual emergency measures ranging from recommendations to postpone "all but essential travel" to affected regions to the activation of a particular surveillance system and the creation of an EU Expert Group on SARS. In this way SARS approached the status of a highly securitised issue.

The fact that Commission President Prodi addressed SARS in his correspondence with the Chinese President meant also a rise of SARS in the political hierarchies. For the European level this was even more the case in the beginning of May, when the EU's Health Ministers met in an extraordinary meeting to discuss the situation, joined by the Director General of the WHO. The fact that the meeting was convened except the terms and that the Commission was assigned to compile a comprehensive report with information on the implementation of SARS prevention and management across Europe illustrate that the disease had reached a high sphere of the political agenda. The high number of written questions from Parliamentarians in May, many of which identified SARS as an extraordinary threat to public health in clear security language,[144] underlines the urgency of the matter also from the perspective of the European Parliament.

In June 2003, the last month before the declared containment of SARS, the Commission report (European Commission, 2003a) proved that Member States in the EU had indeed implemented a long list of emergency measures addressing specifically the spread of SARS. Although not all countries implemented the previously agreed recommendations in the same scope, the overall compliance rate was very high, in particular regarding the provision of guidance and information to the general public. In support of national crisis management, the Network Committee and the EU Expert Group on SARS also issued a set of technical guidance documents for all EU countries which revealed the EU level engagement beyond the constantly ongoing coordination and surveillance efforts by the Commission and the ERWS. The documents were designed for different target groups but did all employ a language that clearly pronounced the threat of SARS to the health of individuals, travellers, medical personnel and their relatives in general. The fact that specific documents – in contrast to other health risks – were set up for SARS as an individual disease to be distributed in dedicated environments such as airports, aircrafts or hospitals illustrates how the acute severe respiratory syndrome was dealt with as an exceptional issue beyond the realm of an ordinary health event.

For the post-outbreak period after July 2003 until December 2004 less sources document a substantial securitisation status of SARS. In this phase, the disease was still subject to legal output, for instance in the context of left-overs from the outbreak period such as the slot allocation and flight schedule or annual reports on the affected regions. In comparison to the months before July, however, EU documents did not deal with SARS as a severe security threat anymore on a regular basis. Exceptions were mainly linked to a possible re-emergence, first as a general matter and more specifically after the escapes of the virus from laboratories in Asia, which occasionally fuelled the

[144] See Annex 2.

debate and lead the Network Committee to update the technical guidance documents. After the reports on the laboratories events in January 2004, the disease was subject to few securitising utterances only and almost disappeared from the political agenda by the end of 2004.[145]

The following table provides an overview on the classification of security language and action for the selected EU key documents. To recall, labelling SARS "the new plague of the third millennium" (European Parliament, 2003a) or "a serious threat […] hits front-line human resources" (European Commission, 2003a: 14) was interpreted as a strong securitising move. Also permanent references to the rapidly rising number of reported infections and deaths contributed to the framing of SARS as an imminent threat. In turn, the comprehensive set of emergency measures outlined before (common rules for outbreak management incl. airport departure screenings, guidance documents etc.), complemented by the allocation of extraordinary resources to finance EU/WHO missions to affected countries and research on SARS, can be considered extraordinary actions which added to the securitisation of SARS on the operational level in response to the perceived threat. And although measures of a non-binding nature did not constitute highly securitising elements from the start, the extraordinary high compliance rate of the Member States with these requirements turned the measures *de facto* into hard emergency responses.

Table 6-2: SARS-Related Speech Acts and Emergency Measures, 2003-2004

(OJ) Date	Author	Reference	Contents	Securitisation	
Doc No.				Verbal	Oper.
19.03.03	COM	(European Commission, 2003f)	Pneumonia/SARS: risks, measures and plans for reform	+	+
IP/03/409					
07.04.03	COM	(European Commission, 2003g)	Commission statement before the European Parliament: risks, measures + reform	+	+
Speech 163					
10.04.03	CDNC	(CDNC, 2003b)	Immediate Actions for Member States and the Commission for the surveillance and control of SARS in Europe	+ +	+
n.a.					
10.04.03	CDNC	(CDNC, 2003c)	Future Actions for the longer term to address SARS and similar health threats in Europe	+	+
n.a.					
24.04.03	COM	(European Commission, 2003m)	Air transport services: Common rules for the allocation of slots at Community airports	+	o
COM(2003) 207 final					
14.05.03	CO	(Council, 2003c)	Extraordinary Council Meeting on SARS: Council Conclusions on immediate and future measures	+ +	+ +
9328/03[146]					
05.06.03	COM	(European Commission, 2003a)	Measures undertaken by Member States and Accession Countries[147]	+ +	+ +
280503V3					
(continued)					

[145] The fact that also the number of articles on SARS in the EU's weekly online journal Eurosurveillance (see chapter 3.3.2) went down from 32 in 2003 to 6 in 2004 supports the overall trend. The content of the articles, however, were not subject to analysis from a securitisation perspective.

[146] Document is identical in content with Council Document 8954/03 (Presse 122) (Council, 2003d) which, in turn, does not appear in the list.

[147] Annex B containing an overview table on the SARS-related measures on national level in each Member State and accession country, was updated in September 2003 to complete data missing in the original document of June 2003 (European Commission, 2003j).

(continued)					
03.06.03	CO	(Council, 2003b)	EPSCO Council meeting, takes note of report 280503V3 from the Commission	o	o
9688/1/03 REV 1					
14.06.03	CDNC	(CDNC, 2003d)	Technical Guidance Document: Registration card for travellers to the EU	+	+ +
WD 116/V3					
14.06.03	CDNC	(CDNC, 2003e)	Technical Guidance Document: Health information for international passengers from affected areas	+	+ +
WD 117/V3					
14.06.03	CDNC	(CDNC, 2003a)	Technical Guidance Document: Important health information for passengers	+	+ +
WD 118/V3					
14.06.03	CDNC	(CDNC, 2003f)	Technical Guidance Document: Recommendations for Airlines and personnel	+ (-)[148]	+ +
WD 119/V3					
13.08.03	COM	(European Commission, 2003n)	Consequences of SARS on Anti-Dumping and Anti-Subsidy Investigations	+	o
2003/C 191/02					
04.09.03	EP+CO	(European Parliament and Council, 2003)	Exceptional circumstances for air carriers and allocation of slots due to SARS	+	+
R 1554/2003					
10.09.03	COM	(European Commission, 2003k)	SARS in EU-China Relations	+	o
COM(2003) 533 final					
16.09.03	EESC	(EESC, 2003b)	Exceptional circumstances for air carriers and allocation of slots. Comparison to “9/11”	+	o
2003/C 220/14					
25.09.03	CDNC	(CDNC, 2003h)	Technical Guidance Document: SARS Reporting Form and Reporting Form Explanation	o	+ +
n.a.					
25.09.03	COM	(European Commission, 2003c)	Technical Guidance Document: Important Health information on influenza vaccination and SARS	+	o
Doc 250903-9.1					
30.09.03	EESC	(EESC, 2003a)	Dramatic mishandling of the SARS epidemic in China; lack of change in political culture	o	o
2003/C 234/17					
20.01.04	COM	(CDNC, 2004)	Technical Guidance Document: Risk of escape of SARS CoV from laboratories	+ +	+
n.a.					
20.01.04	COM	(European Commission, 2004c)	Technical Guidance Document: Procedure for communication to Member States and the Commission about SARS events	o	+
n.a.					
24.02.04	COM	(European Commission, 2004b)	Proposal for substantial revision of Regulation 95/93 on common rules for the allocation of slots at Community airports	o	o
COM(2004) 136 final					
12.03.04	EP	(European Parliament, 2004n)	Resolution (April 8, 2003) on Hong Kong SAR: public health & disease cooperation, establishment of alert system	+	o
P5_TA(2003)0142					
17.03.04	EP	(European Parliament, 2004c)	Taiwan's observer status at the 56th World Health Assembly	+	o
P5_TA(2003)0224					
17.04.04	EP	(European Parliament, 2004e)	EP Minutes: Statement of May 13, 2003, on SARS, followed by debate	n.a.	n.a.[149]
2004/C 67 E/002					
28.06.04	COM	(European Commission, 2004d)	Annual Report 2003 Hong Kong SAR: effects of SARS on economy, health systems, politics	+	o
COM(2004) 414 final					
16.07.04	COM	(European Commission, 2004e)	Annual Report 2003 Macao SAR: SARS prevention and effects on economy	+	o
COM(2004) 506 final					
27.12.04	COM	(European Commission, 2004g)	Annual Report on Anti-Dumping, Anti-Subsidy and Safeguard Activities, Reference to 2003/C 191/02 (European Commission, 2003n)	o	o
COM(2004) 828 final					
+ 17 written questions from Members of the European Parliament on SARS (see Annex 2)					

Source: Own presentation.

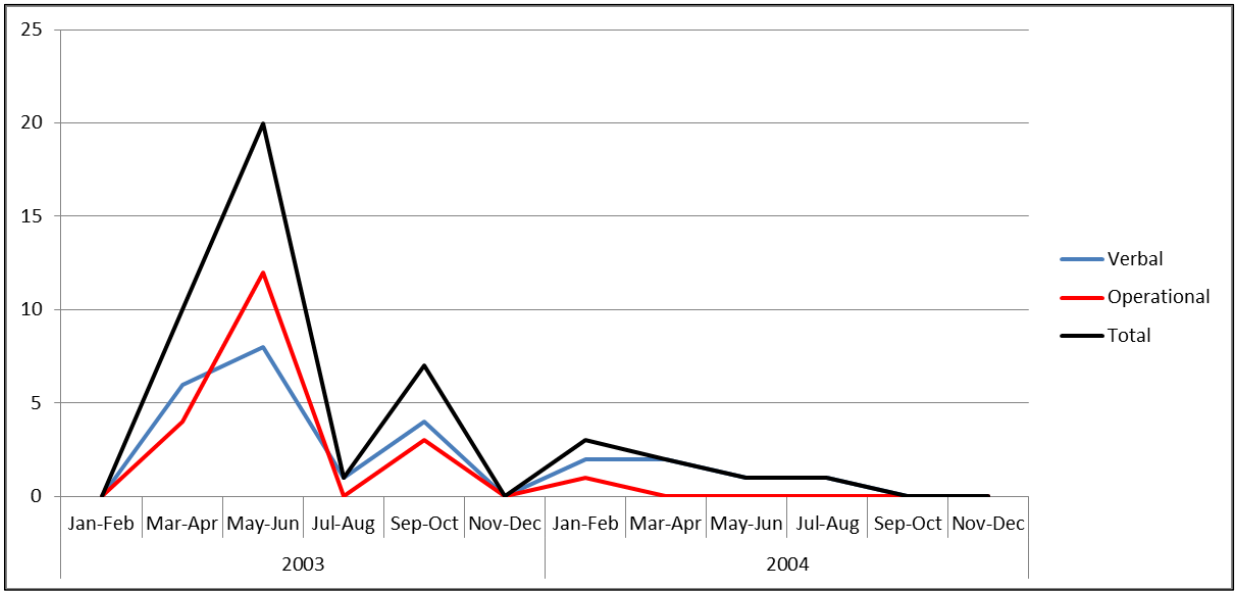
[148] The original document of June 2003 was updated in September 2003. The update adapted the guidance sheet to the post-SARS phase and a particular re-emergence of the disease. Whereas in the original version SARS was still considered a topical threat, in the updated version the document specifies that SARS was declared contained and that “the current risk of SARS in Europe is estimated to be very low” (CDNC, 2003f: 1, version of September 25, 2003).

[149] The document was not accessible at the time of writing.

6.4.2. The Rise and Fall of the Securitisation Degree

We see that the disease which became to be known as 'Severe Respiratory Syndrome' was followed by various responses at the EU level that meet the criterions of securitising speech acts and emergency measures. The basic constituents for a securitisation of the disease were thus part of the political developments linked to the SARS outbreak. As developed in chapter 2.5.6.1, the present study does not claim to offer a precise measurement of the securitisation or the expression of the securitisation degree in form of an index, but it employs three tools to substantiate the analysis of the securitisation degree. First, a representation of the number of SARS-related documents and their assigned values is valuable to illustrate phases and peaks of the (de-)securitisation process. Second, for the assessment of the strength of the security discourse in the analysed set of documents it is helpful put the securitising elements in relation to the total number of SARS-related communications and to, third, calculate the average securitisation score. As regards the former, building on the classification of (de-) securitising elements as provided in Table 6-2 the following timeline illustrates the number of SARS-related documents and their assigned values by setting off securitisation moves against the de-securitising elements.[150]

Diagram 6-1: The Rise and Fall of the Securitisation of SARS (2003-2004)



Source: Own presentation on the basis of securitisation degree scores assigned to the documents listed in Table 6-2.

Over a period of approximately four months between March and June 2003, SARS was a highly securitised disease, followed by a longer phase until December 2004 in which the main EU actors progressively returned to a less active security-oriented *modus operandi* and *modus loquendi,* no longer beyond the realm of ordinary politics. More precisely, the timeline illustrates three securitisation phases, 1) acceleration from March to April, 2) peak from May to June, and 3) post-outbreak phase after July 2003. Within the third phase two further securitisation waves can be detected. The first temporal rise in autumn 2003 occurred after a neutral phase during the summer,

[150] ++ accounts for 2 on the y-axis, + for 1, o for 0, - for -1 and -- for -2. See chapter 2.5.6.1.

which can be explained by the political summer break, which typically shifts EU output to September. The short rise in January 2004 was linked to the escape of the SARS CoV from laboratories and the respective fear of a re-emergence of the virus.

The graph also demonstrates that the securitisation of SARS took place on both the verbal as well as the operational level throughout the period under scrutiny. This finding is important as the securitisation approach requires the securitisation of an issue to occur in both dimensions in order to qualify the problem or situation for the status of an overall highly securitised matter. The securitisation degree of SARS was particularly high in the operational dimension during the second outbreak phase between May and June, when numerous measures were implemented. However, since emergency measures were adopted in groups rather than individually, the graph presented in Diagram 6-1 offers an approximation for illustrative purposes only.

All in all, despite the possible identification of securitisation phases for SARS at the EU level, the exact timing of securitising moves is not of greatest relevance in the case of SARS, seeing that the core of the securitisation process took place in less than a year. In a short period like this it is decisive that the disease was indeed addressed and treated as a security issue in both securitisation dimensions, but it's not particularly important to differentiate between individual months as it is valuable for the analysis of securitisation processes over a longer period of time.

Table 6-3: The Degree of Securitisation of SARS Across Securitisation Dimensions

	Verbal Securitisation Degree		
Operational Securitisation Degree		Low	High
	High	Medium	**SARS**
	Low	Low	Medium

Source: Own presentation.

To confirm that the overall securitisation degree can in fact be considered high, it is essential to verify that not only the substantial absolute number of 28 communications between March 2003 and December 2004 shifted SARS into the realm of a highly securitised disease, but that also the discourse on the disease was dominated by a security perspective. In order to do so it is helpful to calculate the share of securitising communications in relation to the total number of SARS-related documents. The following Table 6-4 reveals that the discourse was indeed dominated by security language and concerns, proven by the result that roughly 78 per cent of the complete EU output was at least of a weakly securitising nature. In fact, the table makes visible that not a single document treated SARS without a securitising impact on either of the securitisation dimensions. Accordingly, the average score (Ø) for the EU output of +0,93 (see chapter 2.5.6.1) on the scale between the securitisation degree value maximums of -2 and +2 is relatively high.

Table 6-4: The Strength of the Security Discourse on SARS[151]

Securitisation score[152]		securitising		neutral	de-securitising			
		2	**1**	**0**	**-1**	**-2**	**total**	**ø**
2003 - 04	Nr. of Docs	4	17	6	0	0	27	0,93
	%	14,81%	62,96%	22,22%	0,00%	0,00%	100,00%	
	% / Cat.	77,78%		22,22%	0,00%		100,00%	

Source: Own calculation on the basis of the securitisation scores assigned to the documents in the verbal securitisation dimension as specified in Table 6-2.

6.4.3. The Kind of Securitisation

In order to make statements on the kind of securitisation the following section explores the EU's key activities and documents along the list of security parameters as developed in chapter 2.3.2.2, ranging from the definition of the referent object(s), through the definition of the threat to the definition of the provision of security (see in particular Table 2-1). To recall, in this context, the referent object(s), the source, speed, geography, severity and predictability of the threat as well as the actors, policies and measures to provide security as specified in the EU legal output are analysed in order to reveal the security understanding(s) with which SARS was constructed as a security issue.

A clear change in the security parameters did not occur in the short period in which the SARS crisis developed so that a differentiation across different phases is not necessary.

6.4.3.1. The Securitisation Parameters

At the European Union level SARS was primarily constructed as a threat for two referent objects, to public health and the health of specific groups of persons on the one hand, and to specific sectors of the economy on the other. Regarding the latter, damaging effects on business travel, trade and tourism sector played a noticeable role in the analysed securitising moves. Thus, we can observe a certain economy-centred securitisation of SARS, which was stronger linked to the economies of the Asian countries most affected by the disease. To illustrate, a drop by 37 % in tourist arrivals in May 2003 to China's Special Administrative Region (and former Portuguese colony) Macao was reported by the Commission to Council and Parliament (European Commission, 2004e).

In view of the impact on the EU's economy, the difficult situation for the air transport sector was part of the debate. SARS was declared to have had "seriously affected the air transport operations of air carriers [followed by] a significant reduction in demand" (EESC, 2003b) that triggered "an unprecedented crisis" (European Parliament, 2004g). The identification of air carriers as referent

[151] 'Nr. of Docs' specifies the number of documents with the respective score. '%' refers to the share of the respective group of documents with the same securitisation score in per cent of the total number of documents. '% Cat.' summarises the share of the two securitising (+2, +1), the neutral (0) and the two de-securitising categories (-1, -2) into three broader categories, specified in per cent of the total number of documents. 'Ø' refers to the average score as calculated by the division of the sum of all scores of all EU documents by the number of documents for the specified periods.

[152] Securitisation score in line with Table 2-4 which relates + + to 2, + to 1, o to 0, - to -1 and - - to -2.

objects of an economic securitisation, however, was not linked exclusively to the SARS threat. In parallel to SARS, the war in Iraq and fear of terrorist attacks were also claimed to show effects on the European flight economy, so that SARS was identified as only one of a series of threats in that respect.

As a menace to public health SARS appeared to be an extremely dangerous threat also for the countries inside the EU. Although the populations of the Asian countries, and in particular China, were identified as the main referent object of the threat, depending on the author of a securitising utterance also travellers, Commission officials, medical and air carrier personnel, their relatives and eventually the wider public in the EU were seen to be at risk. In this context it might be instructive that SARS entered public EU documents only after the first case had been reported for an EU Member State. However, throughout all outbreak phases, a high number of referent objects directly affected by SARS were identified only for countries outside the EU. A high number of referent objects inside the EU appeared only in the framework of the *risk* of a further transmission or potential infections, but not in terms of a *de facto* prevalence.

As regards the securitisation parameter 'source of threat', the origin of SARS could not be specified in the first months of the outbreak. Still, suspicions that SARS could be something other than a naturally occurring, albeit new disease, were not raised. Only in the post-outbreak phase, when the re-emergence of SARS was a topical question, the disease was discussed in view of an accidental or deliberate release, but not as its original source. All in all, the lack of knowledge on the disease and its characteristics played a crucial role for the securitisation of SARS, because it also affected the parameters 'speed', 'geography', 'severity' and 'predictability'. Being a completely new phenomenon, great uncertainty spoke through numerous EU documents of securitising but also neutral actors. In particular the quick spread of the disease, combined with doubts on the reliability of data, was a reason for major concern, even if in some documents the risk was put into relation by mentioning that for a transmission from person to person very close contact was needed. Whereas securitising actors, in particular Members of the European Parliament, stressed the rapid increase in infections, neutral interventions, in particular from the Commission, underlined that only a few cases had been detected on the European continent so far.

Also after the coronavirus had been identified, SARS continued to be labelled an exceptionally harmful menace, capable of rapid spread and with a high mortality rate in the countries of origin. However, effects of a SARS outbreak inside the EU were discussed mostly on a hypothetical basis. A main concern voiced in this context was the lack of treatment; repeatedly, we find concern expressed in the EU's key documents that no effective antiviral existed. However, content related to the source of pathogenicity, that is the root cause of SARS to constitute a threat, was not only the non-availability of effective drugs, but also insufficient communication politics by the Chinese government whose information were considered not always reliable and distributed lately. Beyond that, in the post-outbreak securitisation phase, SARS was repeatedly associated with the possibility of the deliberate release of the virus as one form of bioterrorism.

With a view to the provision of security, the authors of the EU key documents identified the EU's Member States as primarily responsible to implement adequate measures to protect the public from the threat of SARS. Clearly, it was principally up to the national authorities to inform the public and specific target groups, to report cases to the Commission and WHO, to setup isolation measures, etc. In this sense, the Member States can be seen as the primary security providers during the SARS crisis. The Council also repeatedly stressed the national competence in terms of outbreak management.

WHO and EU institutions, first and foremost the European Commission (DG SANCO, partly also DG ECHO and DG DEVCO) as well as the Network Committee, were assigned important roles in the fields of disease surveillance and coordination of the nationally implemented efforts, but generally not for the implementation itself. In this sense, at the EU level tasks in terms of security provision were limited to monitoring, coordinative and advisory functions, the latter closely interconnected with national authorities, be it in the framework of the Network Committee, be it in the form of the EU Expert Group on SARS. However, due to the EU's financial engagement related to EU/WHO assistance to affected countries and following the Commission's investments into SARS research, EU institutions also contributed directly to the outbreak response.

The ethical position and justification for action voiced in the EU key documents on SARS comprised two complementary aspects. On the one hand, the protection of referent objects on the European continent was a primary declared objective. Clearly, in both speech acts and emergency measures Member States and EU institutions aimed at the prevention of the spread of the disease into EU countries. At the same time, several of the EU-internal or nationally implemented measures, such as the information campaign or the isolation of a passenger on a stop-over flight, also meant a contribution to the fight against the global spread. Arguably, the containment of the disease in one part of the world is a pre-condition for – and a contribution to its control worldwide. Reasoning on this basis, however, was not explicit in the analysed documents. Still, the support of most affected countries in Asia also went beyond a purely self-protective stance at the EU's borders, for instance due to the seconded expert teams. In other words, the basic ethical stance as part of the securitisation process is difficult to be determined unambiguously in the case of SARS, seeing that we can observe elements of self-protection focusing on the own territory as well as elements of a global approach of collaboration and assistance.

It becomes clear that the EU actors dealt with SARS also in the foreign policy realm when supporting global efforts to fight the disease, but also beyond, as a matter in EU-China relations (European Commission, 2003k) or in the context of Taiwan's status at the WHO (European Parliament, 2004c). However, the major policy concerned with the disease was the field of public health and only few activities fell into other realms such as the economy or the field of research. Interventions in the public health sphere also most fundamentally contributed to a rising securitisation degree. Place of the interventions were within the EU territory as well as in third countries, but clearly with a focus on the former. Despite the support for field trips to Asia and the international collaboration with WHO, the largest share of coordinative activities concentrated on EU borders and the immediate response and preparedness inside the Member States.

6.4.3.2. Soft and/or Hard Securitisation

In order to sum up the different elements of the securitisation process of SARS it is helpful to return to the ideal types of the kind of securitisation of an infectious disease as developed in chapter 2.3.2.3. In view of the two extremes, the soft kind of securitisation on the one hand and the hard kind on the other (see Table 2-2), the SARS case seems to feature at first sight many elements of the former form. Throughout the different outbreak phases, we find security parameters values that specify mainly the health of people living outside the EU as being directly threatened and only particular groups of persons inside the EU. These referent objects are threatened by a naturally occurring disease that appears somehow manageable in the EU. In other words, the impact of the disease was considered to be strong only far away. Despite these securitisation parameters that tend to the soft extreme, the overall assessment of the securitisation of SARS is different. In fact, it can be argued that also SARS was securitised in a way close to the hard kind, for mainly four reasons.

First, the EU actors identified as security referent objects did not only belong to the group of travellers and businesspeople, which is potentially a very large group, but also the group of health care professionals. The latter is essential for the functioning of the basic health system which in turn belongs to the vital functions expected to be provided by the State. In other words, the particularly threatened groups comprised both many EU referent objects as well as referent objects vital to the functioning of the health systems in Europe as a whole. Beyond that, also the securitisation of SARS with a view to specific sectors of the economy supports the view of a securitisation in the sense of a hard kind.

Second, the EU actors' view on SARS was dominated by uncertainty. A great number of unknown but important factors such as the identification of the pathogen or the exact route of its transmission went along with a securitisation of SARS as an unpredictable and extremely severe threat, in particular during the early outbreak period. The unpredictability and severity seem to have superimposed arguments like the far distance of the outbreak or the low morbidity in the EU by increasing the assumed *potential* of SARS to mean a substantial threat also inside the EU.

Third, the values for the security parameters 'security provider' (states and IOs rather than (I)NGOs) and the primary policies concerned (public health, economy) in both the verbal and the operational dimensions also shift the securitisation of SARS rather to the hard extreme. Fourth and finally, in line with the expected values for the hard kind, surveillance was carried out at the regional level through the EWRS (although reported globally in parallel), prevention and preparedness were limited to the own territory and also the immediate response concentrated on the European continent, although assistance to affected countries was provided too.

The following Table 6-5 provides a schematic classification of the securitisation of SARS along the full set of securitisation parameters, identifying for each a tendency rather towards the soft (left side) or the hard kind (right side) on the horizontally illustrated spectrum of security understandings. On the basis of the full breakdown of all parameter the table makes visible what the text analysis has found, namely that in the period between 2003 and 2004 SARS was securitised at the EU level in a way closer to a hard kind of securitisation.

Table 6-5: The Kind of Securitisation of SARS (schematic)

Dimension	Security Parameter		Soft Kind				Hard Kind		
Verbal	*Referent object*		Human				x		Vital to State / EU
	Min. Referent object		Few					x	Many
	Source of Threat		Natural	x					Manmade
	Source of Pathogenicity		Development, Health Care			x	---→	x[153]	Terror, Enemy Globalisation
	Speed of Threat		Slow / Attrition					x	Fast / Outbreak
	Geography of Threat		Far / "Not Us"				x		Close / "Us"
	Threat Severity		Low					x	High
	Predictability of Threat		High					x	Low
	Ethical Stance		Common Humanity				x		Self-Protection
Verbal & Operational	*Security Provider*		State (+INGO) + Non-State					x	States (+IOs)
	Primary Policy		Humanitarian Aid, Development, Human Rights				x		Foreign & Secur. Economy, Public Health
Operational	*Target and Geography of Measure*	*Surveillance*	Global			x			National / EU
		Prevention	Global			x			National / EU
		Preparedness	Global					x	National / EU
		Response	Global				x		National / EU

Source: Own presentation.

[153] Initially Chinese reporting practice, later globalisation effects and bioterrorism.

6.4.4. The Role of the Different EU Actors

Studying the forms of securitisation is not limited to the timing, the dimensions, the degrees and kinds of securitisation, but also includes an analysis of the set of securitisers that contributed to the processes at the EU level. We have seen that the securitisation of SARS cannot be understood as a homogenous process in which all EU actors were involved in the same manner. Quite the contrary, some potentially influential actors such as the European Council did not contribute to the (de-)securitisation of SARS at all. And also among the active institutions, ranging from the Parliament and the Council to the Network Committee and the Commission, we could observe quite different approaches to the (de-)securitisation of the disease.

Building on the EU documents without considering the Parliaments written questions and respective answers from Commission or Council, the European Commission and the Communicable Disease Network Committee were the most important actors for the securitisation of SARS. In line with the tasks and competences assigned to these institutions, the Network Committee was a stronger securitiser in the operational dimension, whereas the Commission contributed to securitisation more in the verbal dimension. However, a clear-cut differentiation between Commission, the EU Expert Group and the Network Committee is difficult in some cases, given that these documents were issued jointly and published without further details on the main or responsible author.

With the Network Committee as a specialised tool for Member States to coordinate their efforts with the support of the Commission, and after its establishment also with the support of the EU Expert Group on SARS, the Council was comparably passive as regards SARS-related output. By convening extraordinarily and by deciding on the immediate and future measures to combat SARS in the European Union, the Council, however, was despite its limited output one of the most influential actors for the EU's SARS response, in particular for the mid-term development of EU-wide measures. In this context it is noteworthy that the European Council did not address SARS in any of its Presidency Conclusions of the period in question, not even when the creation of the European Centre of Disease Prevention and Control was discussed and finally decided. For this reason the Council on the side of the intergovernmental institutions of the EU, and the President of the European Commission on the side of the supranational institutions were the highest political levels that dealt with SARS in the European arena.[154]

For the European Parliament it can be noted, on the basis of the official statements, that the institution as a whole was not a particularly strong securitiser. In fact, besides its contribution to Regulation 1554/2003 (European Parliament and Council, 2003) regarding the exceptional circumstances for air carriers, the Parliament did not produce any output. Naturally, the picture would change, if the Parliament's debates and written questions were taken into account as well. However, as outlined in chapter 2.5.5, written questions are not part of the *text corpus* as generated and analysed consistently across the case studies of this work. A look into the written questions for

[154] In the international arena SARS was also addressed in June 2003 by the Group of Eight (G8), a forum in which not only four EU Member States (France, Germany, Italy and the UK) but also the European Commission participates. SARS was in particular addressed by the 'G8 Action Plan on Health' (Group of Eight (G8), 2003).

explorative purposes, however, shows that in particular during the peak securitisation phase in May 2003, the members of the European Parliament were extraordinarily active and substantially contributed to the securitisation of SARS on the verbal dimension.[155]

For the European Commission we could observe an overall ambiguous picture regarding its role as a securitiser. On the one hand, DG SANCO and Commissioner Byrne constantly underlined the threat exerted by SARS, in particular with reference to the upcoming proposal for the establishment of the ECDC. On the other hand, the Commission balanced strong securitisation moves with reference to the future tasks of ECDC or by emphasising that surveillance measures were in place and well-functioning. In this sense, the report on the measures undertaken by Member States is instructive, in which the Commission summarised:

> *"The first lesson learnt is that EU was able to contain the outbreak and to deal with a low number of SARS cases. This reflects the general success of the public health measures put in place. The question remains if the EU could respond with the same efficacy to a larger SARS epidemic or to outbreaks of different communicable diseases. A comprehensive and intersectoral preparedness plan is needed to strengthen the health services at local as well as at central level"* (European Commission, 2003a: 14).

Apart from Parliament, Commission, Network Committee and Council, few other further actors contributed to the securitisation of SARS at the EU level, namely the European Economic and Social Committee (EESC) as well as the WHO. The EESC's influence was limited to an intervention related to the air transport crisis. In line with the institution's general mandate, it emphasised the threat of SARS to the air carrier economy rather than securitising SARS as a threat to public health. In contrast, WHO emphasised SARS' danger for public health. The WHO, in turn, does not belong to the actors under scrutiny for the securitisation procedures in the present study. However, given the numerous references in the EU documents, it can nevertheless be regarded as an influential *indirectly* securitising actor also at the EU level.

Similar to this indirect securitisation further securitising elements from non-EU actors appear in the EU documents. In particular the public fear of the disease became part of the equation, when the Commission found that SARS had "incited widespread public anxiety, spreading faster than the virus" (European Commission, 2003a: 15). Crucially, according to the Commission these concerns of the public also caused "social discomfort, economic losses and political stress" as well as the emergence of discrimination towards vulnerable communities (European Commission, 2003a: 15). In other words, it was, strictly speaking, not only SARS that was securitised as a threat; additionally it was also the *public fear of SARS* that was securitised at the EU level with own or reinforcing effects for not only the economy, but also more generally for social life. Clearly, the present analysis of the securitisation of SARS is limited to utterances and counter measures of EU actors, but this example shows how pressure from the public or "extensive media attention" (European Commission, 2003g) can become manifest or at least shine through in EU documents.

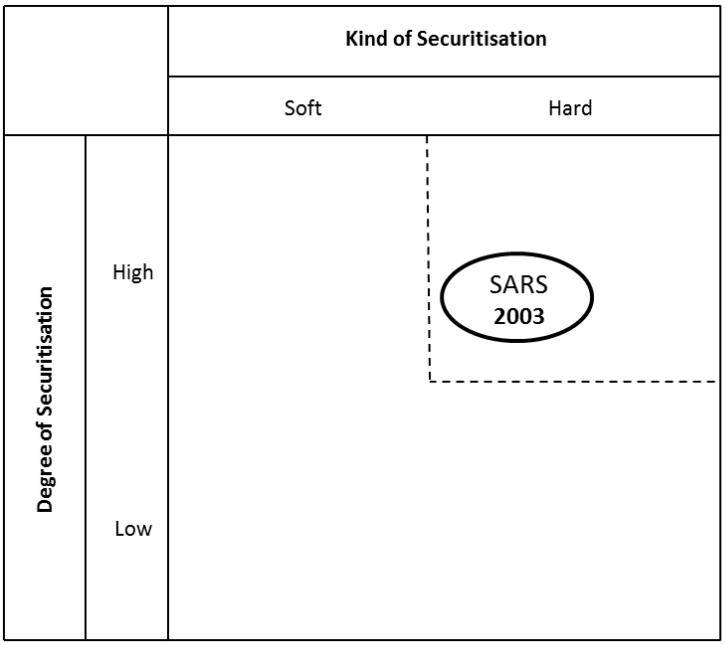
[155] A full classification of the SARS-related written questions and responses was carried out for explorative purposes and can be found in Annex 2.

6.5. Securitisation and Structural Change

Chapter 6.4.2 has shown that SARS underwent a rapid rise on the vertical securitisation spectrum from a non-existent political phenomenon to a matter that can be regarded as highly securitised at least during the first half of the year 2003. With a view to the predominant kind of securitisation for SARS, chapter 6.4.3 has shown the overall combination of security parameters predominantly leaned to the extreme that made up for a rather hard kind of securitisation. Probably linked to the overall short securitisation phase, a substantial shift from one kind to another could not be observed.

Taking these findings together it becomes clear that the disease was not only pushed to a *high degree* of securitisation, but that the securitisation also took place in the form of a *hard kind*. Taking up the securitisation approach as developed and applied in this study, this specific combination of degree and kind makes up for SARS as an issue that was *strongly securitised* at the EU level – even if the securitisation was limited to a relatively short period of time. Accordingly, the disease can be located in the upper right corner of the coordination system of securitisation as introduced in chapter 2.3.3.

Figure 6-1: SARS in the Coordination System of Securitisation



Source: Own presentation.

The securitisation of the disease thus assumed a form which was hypothesised to bear the potential to cause institutionalisation in the political system of the EU. Recalling the definition as developed in chapter 2.3.4.1, a systemic change is understood as relatively persistent and systemic modification of rules, procedures, policy priorities, resource allocation, distribution of competences and organisational structures in the field of EU infectious disease control. With a view to these criterions not all of the legal and institutional reforms revealed in chapter 6.3 do qualify as a structural change.

However, the two innovations that were selected for an in-depth case study from the list of key developments in the EU's evolution of infectious disease control (chapter 4), namely the establishment of the European Centre for Disease Prevention and Control and the revision of the public health article in the Constitutional Treaty, certainly meet the definition of institutionalisation.

The establishment of the ECDC was a particularly visible reform that became even physically manifest in Swedish bricks and stones, but beyond that the decision also implied further systemic changes. First, the allocation of an annual (albeit comparatively small) budget to run the new institution also meant a structural re-allocation of resources. In addition, also the agency's responsibility for the coordination of the already existing disease networks came along with financial implications. While those networks relied to a large extent on *ad hoc* financing by the EU's public health programme before the transfer to ECDC, the new institutional embeddedness implied a perpetuation of the funding.

Second, the creation of the ECDC also changed procedures and collaboration patterns, given that the system for scientific advice was modified due to the outsourcing of risk assessment to the ECDC, a body with strongly increased scientific capacity. At the same time, however, it should be noted that despite the setup of ECDC, the collaboration in infectious disease matters at the EU level also showed strong aspects of continuity. More precisely, basic forms of cooperation remained the same, given that Member States remained the responsible actors in terms of outbreak management and the provision of health care, disease treatment etc. Beyond that also the network approach to cooperation remained principally the same, even if the ECDC took over the coordinator function from the Commission.

As analysed in chapter 6.3, the revision of the EU's primary law occurred somewhat circuitous and delayed. Whereas the Convention's Draft Treaty Establishing a Constitution for Europe (2003) had not foreseen a major revision, the finally signed Treaty Establishing a Constitution for Europe (2004) did include major innovations in the field of infectious disease control. Finally, following the stop of the ratification process of the Constitutional Treaty, some of these changes were nonetheless taken over in the Lisbon Treaty with the amendment that measures concerning monitoring, early warning of and combating serious cross-border threats to health were not assigned to the realm of shared competences. Expert interviews could not help reveal how these changes occurred, an explanation for which is beyond the scope of the study. For future research, however, translating the working hypothesis of the present study to this situation it could be argued that cross-border threats to health were no longer sufficiently securitised at the time when the Lisbon Treaty was concluded in 2007 (at that time called 'Reform Treaty').

However, since the Lisbon Treaty did not enter into force before 2009, the substantial revision of the public health article turned into EU law only more than six years after the securitisation of SARS. The introduction of the monitoring, early warning of and combating serious cross-border threats to health as a distinctive field of EU activity eventually resulted in one of the cornerstones of the EU's infectious disease control today, namely Decision 1082/2013/EU on serious cross-border threats to health (European Parliament and Council, 2013a). Hence, these developments originally date back to

the period of the SARS crisis. Although the TFEU located the revised article on public health and its infectious disease-related innovations in the field of supporting competences, the new formulation still meant a clear and far-reaching revision of the EU's competencies as laid down in primary law.

Against this background it is possible to summarise that an alteration of the previous EU setup took place in all four aspects of institutional change, namely regarding the forms of collaboration and procedures (e.g. system of scientific advice), the allocation of resources (ECDC and perpetuation of network funding), the (limited) transfer of competencies (Constitutional Treaty / Treaty of Lisbon) and the establishment and organisation of institutions (ECDC).

Table 6-6: Institutionalisation that Occurred in the Course of the SARS Crisis

<table>
<tr><td>30.04.04</td><td>EP+CO</td><td rowspan="2">(European Parliament and Council, 2004a)</td><td rowspan="2">Establishment of a European Centre for Disease Prevention and Control, incl. the modification of the system of scientific advice and the perpetuated funding of previously ad hoc-financed networks</td></tr>
<tr><td colspan="2">R 851/2004</td></tr>
<tr><td>16.12.04</td><td>IGC</td><td rowspan="2">(Treaty Establishing a Constitution for Europe)</td><td rowspan="4">Introduction of monitoring, early warning of and combating serious cross-border threats to health as field of EU action (supporting competence)</td></tr>
<tr><td colspan="2">Article III-278</td></tr>
<tr><td>30.03.10</td><td>IGC</td><td rowspan="2">(Treaty on the Functioning of the European Union)</td></tr>
<tr><td colspan="2">Article 168 TFEU</td></tr>
</table>

Source: Own presentation.

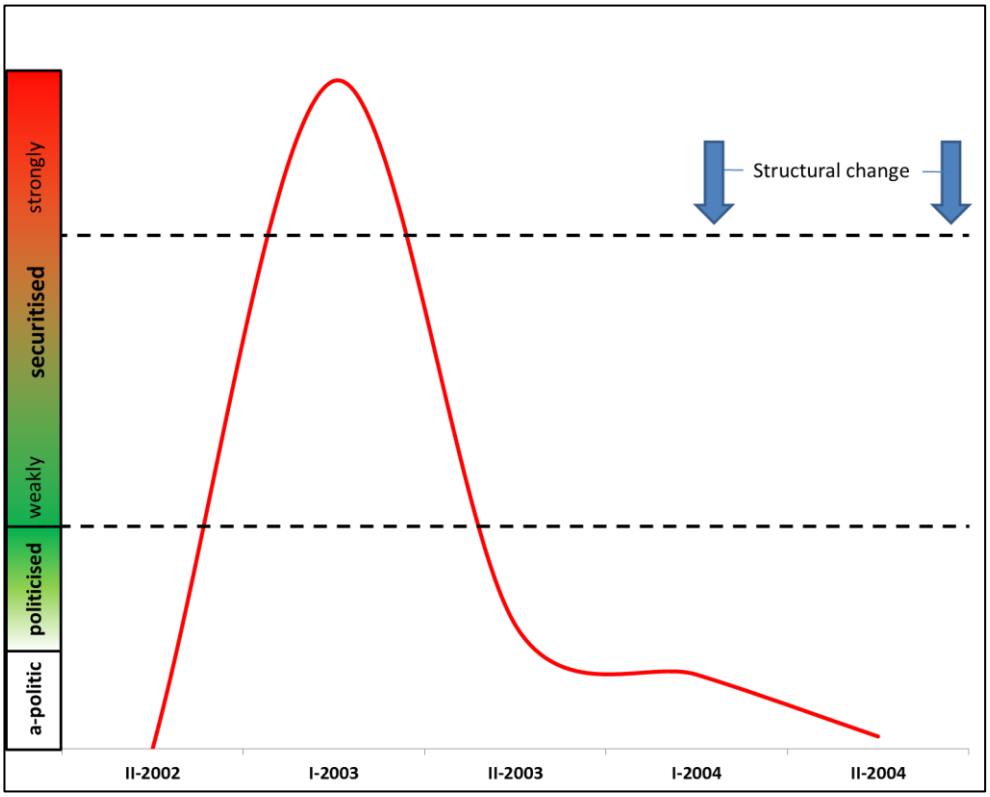
A series of arguments indicate a clear connection between the securitisation of SARS and the identified institutionalisation processes. The reforms fell not only into the realm of EU cooperation in infectious disease matters and made reference to security language, they were also designed in a way that exactly addressed the central components used during the SARS outbreak. To illustrate, the ECDC was mandated to "identify, assess and communicate current and emerging threats to human health from communicable diseases" and to act, also on own initiative, to "outbreaks of illness of unknown origin, which may spread within or to the Community" (European Parliament and Council, 2004a: 1). SARS falls, more than any other disease of the years under scrutiny, in this category. Also the ECDC's ability to set up EU teams for the technical assistance to Member States or third countries in the case of an epidemiological crisis, as it had just taken place in the case of SARS, and the incorporation of the revised Early Warning and Response System (EWRS), which was one of the central communication instruments during the SARS crisis, exemplify the close connection. This interpretation is also supported by the information retrieved from elite interviews.

Crucially, rather than addressing infectious diseases as one of a set of health challenges, both ECDC's founding regulation and the Constitutional Treaty address infectious diseases as 'threats' or 'cross-border threats' and, thus, with the vocabulary of security language – despite the technical nature of the documents. An interesting side not is that in the 480 pages of the Constitutional Treaty the word 'threat' occurs only seven times in total. Most references are linked to war or terrorism, but two of them occur in relation to (potential) cross-border health problems.

The close connection between the use of security language and reform is also visible in the context of the production: Not only was the creation of ECDC repeatedly proposed by Commissioner Byrne in the same breath that constructed SARS as a security issue (European Commission, 2003f). Also the proposal made explicit reference to a set of threatened referent objects, when stating that "[m]ajor communicable disease outbreaks impact the whole of a society, not just its health sector. For instance, the SARS outbreak had an immediate, negative impact on economic growth in the Asian countries it affected. SARS may also, more indirectly, have had a negative impact on the EU economy" (European Commission, 2003b: 4). In this context the Commission's proposal salvaged the idea of agency creation from the securitisation phase by combining the language of securitisation with a legislative proposal for a substantial reform. In a similar fashion also the proposed modifications of the public health article of the Constitutional Treaty in the discussions of the Convention were backed by references to the threat of SARS.

On a most fundamental level, the temporal relation between securitisation and structural change is another strong argument in favour of the assumed linkage between the two processes. As explained before, the precise timing in terms of weeks or months of securitising moves is not particularly relevant in the SARS case since the main process developed over a phase of less than a year. It is rather important that the period of rapidly increasing and ultimately strong securitisation of an infectious disease was indeed followed by fundamental modifications in the EU's setup to respond to infectious diseases – as schematically illustrated by Diagram 6-2 (see below).

Diagram 6-2: Securitisation of SARS and Structural Changes in the EU's Setup for Infectious Disease Control (schematic, 2003-2004)



Source: Own presentation.

Given the scope of the modifications, agency setup and Treaty change, the time span between the strong and hard securitisation of SARS on the one hand and systemic change on the other is actually very short.[156] This circumstance can be explained for both structural changes by the fact that the SARS threat hit the EU authorities at a time when revision processes were already in progress anyway. In the case of the amendment of the public health article, the Convention on the Future of Europe constituted a forum that had been particularly designed to discuss a fundamental change of the Treaty. Naturally, when SARS appeared as an issue at the EU level it was not a far-fetched idea to take up the then-ongoing outbreak and feed respective reform ideas into the ongoing revision process. In other words one could say that the securitisation of SARS occurred at the right time to provide an obvious justification for strengthened EU competencies to combat infectious diseases.

Also the creation of the ECDC was about timing, but in a different way. We have seen that the original idea for a central European disease control institution dated back to the 1990s and that since then discussions went on, even after the – for the time being – final decision in 1998 to opt for a network-approach at the EU level. In particular the Commission pursued the idea of an EU centre in detail already before the SARS crisis. The visit of Commissioner Byrne in October 2001 to the US Centers for Disease Control (CDC), the world leading institution of its kind and desired role model for an EU equivalent in the eyes of for many advocates, and his experience with the creation of the European Food Safety Authority in 2002 might have contributed to the conviction within the Commission that the creation of an ECDC was a desirable innovation, already before 2003.

When in 2003 the debates on the risk of SARS in particular and infectious diseases in general intensified, it seems that from the Commission's perspective the right time had come to launch a campaign in favour of the establishment of the agency. As shown in chapter 6.2.1, the plan for the creation of the ECDC and references to an advanced state of affairs regarding the respective legislative proposal could be found already in the very first interventions in response to the outbreak.

Hence, whereas the securitisation of SARS was capable of intensifying the already ongoing revision process of the EU's primary law during the Convention's discussions, it served a different function in the context of the ECDC creation. Here, the strong securitisation opened a window of opportunity for the establishment of the agency which proponents had advocated already for many years.

[156] In this context 'treaty change' refers to the signing of the Constitutional Treaty.

6.6. Conclusions

In its resolution on the Severe Acute Respiratory Syndrome the World Health Assembly labelled SARS "the first severe infectious disease to emerge in the twenty-first century" (WHO, 2003o). When the virus appeared, it had never been detected in humans before. It turned out to be transmissible from human-to-human and was characterised by a worrying case fatality ratio. Neither adequate diagnosis nor treatment existed, let alone vaccination. The last time the world had seen a pathogen emerge with comparable characteristics was in the 1980s, when the human immunodeficiency virus (HIV) started unfolding its devastating effects worldwide (Fidler, 2003: 490).

In June 2003, a month before the disease was declared contained, the European Commission concluded "that EU was able to contain the outbreak and to deal with a low number of SARS cases" (European Commission, 2003a: 14). At that time, in line with the division of competences leaving disease management to the national level, Member States had – with the support and coordination from both the EU and international level – undertaken a comprehensive set of measures to control the outbreak of SARS; however, concerns persisted, also in view of similar situation in the future. In this situation advocates of a stronger EU role, many of which had strong ties to the European Training Programme EPIET (Greer, 2012a: 1008), stressed the value of the joint efforts to successfully combat the disease. At the same time, concerns were further fuelled by interpreting SARS a 'warning shot' for something worse to come.

In this atmosphere the experts from the Commission and Member States agreed on a series of ideas what could be done at the EU level in the future. As explained in the previous section, the facts that a Convention on the future of Europe was convening at the same time and that plans for an agency for infectious disease matters had already been drawn up, facilitated a rapid and fundamental reform. In the end, the EU's structural setup was substantially reformed, although SARS cases occurred in eight Member States only, with a total number of 32 infected persons, all of which but one recovered from the disease (CDNC, 2003g).

Reviewing these developments makes clear that in the EU SARS was primarily about the perception and construction of a potential threat to human health and not about *de facto* infections, illness and death. It does not belong to the objectives of the present study to evaluate the adequacy of activities or effects. The fact, however, that SARS was described as an "epidemic of fear" (Price-Smith, 2009) with an enormous impact on the political and social level, the media and specific industry sectors disproportionate to the direct human health impact (Knobler et al., 2004: 1, Michaud, 2009: 29) supports the constructivist core argument of the securitisation approach: (in)security is essentially subjective.

Consequently, once security concerns start influencing or even become the main driver of the political processes, immediate actions and structural changes do not necessarily respond to the threat, but to the subjective perception of the threat. In this context it is not decisive whether alternatives existed, for instance to the creation of an agency in form of "the pre[-]existing division of labo[u]r among the [M]ember [S]tates, WHO, the Council of Europe, existing EU networks, and to a

lesser degree the European Commission" (Guigner, 2006, Greer, 2012a: 1008). It also does not matter whether the ECDC is a weak agency a "hub or hollow core". By contrast, the deciding factor was the "political imperative to 'do something'" after the SARS experience (Greer, 2012a: 1010).

The results of the case study on SARS strongly support the interpretation that the social construction of the disease in form of strong securitisation was pivotal for this political imperative and thus the trigger for institutionalisation processes in the EU. This finding does not exclude that parallel developments and other factors fed into the process. To illustrate, further potentially influential factors were the generally changed view on infectious diseases after the spread of HIV/AIDS and the link to bioterrorism after the 2001 anthrax scare, the perceived threat of an influenza pandemic, the war in Iraq, the upcoming 'big bang' enlargement of the European Union, the establishment of EFSA and EMA and the experience of pro-integrationist policy advocates such as Commissioner Byrne with the creation of these agencies. Still, the investigation into the SARS case on the basis of the selected key documents first and foremost suggests a confirmation of the hypothesis set out in chapter 2.4 on the linkage between a specific combination of degree and kind of securitisation on the one hand, and structural change on the other.

In order to address the fundamental research question as put forward in the introduction and in more detail in chapter 2.4 of this study, this case study has analysed how the EU responded to SARS and how the disease was subject to securitisation dynamics at the EU level. In this context the chapter has also examined the different roles of the involved EU actors. It has furthermore gathered information on the development of the EU's infectious disease policy and polity between 2003 and 2004, in particular the creation of the ECDC and the change of the EU's legal basis for action in the field of infectious diseases in the Constitutional Treaty, and has connected them to the securitisation processes. In the following concluding chapter, the results will be related to the findings of the case study that focused on the revision of the EU's legal basis for food safety in the Amsterdam Treaty and the creation of EFSA following the BSE/TSEs crisis.

7. Conclusions

Infectious diseases affect millions of people worldwide every year and are one of the main causes of death (WHO, 2015a). In the last years there was hardly any time when specific disease outbreaks did not appear somehow prominently in the media and on the political agendas, be it the novel avian influenza subtype H7N9 that occurred in China in 2013, be it the epidemic spread of ebola in West Africa in 2014/2015.

The variety of diseases that are labelled infectious is rich, and so is the variety of ways how the threat exerted from infectious diseases is perceived and politically responded to. Not every disease is regarded as an acute threat to security or even health. While in some regions vaccination rates for measles decrease, suggesting that it has lost the image of a terrifying disease, public outcry is typically intense as soon as reports occur about a new or re-emerging 'killer virus'. Also political and public health interventions differ significantly from disease to disease, ranging from the massive stockpiling of antiviral medication, as occurred in the course of the H1N1 'swine flu' outbreak in 2009, to largely inactivity and neglect, for instance with regard to leishmaniasis or dengue fever.

At the European Union level a dynamic development took place in the realm of infectious disease control in the last decades. In the year 1990, EU primary law did not even enshrine the protection of public health as an independent policy objective; in 2015, the EU's mandate and setup to control infectious diseases *inter alia* comprises a clear legal basis in the Lisbon Treaties to combat cross-border health threats, a complex system of facilities to surveil and respond to a large number of diseases, including unknown pathogens, a set of specialised agencies that communicate about health risks and that advice decision-making in the EU, as well as an encompassing public health programme which is run by a dedicated executive agency.

Astonishingly, this vibrant evolution in the EU's setup to control infectious diseases took place largely unobserved by academic scholars. It was therefore the purpose of the present study to shed light on these institutionalisation processes and to investigate into the reasons for the development. Against the background that health in general and infectious diseases in particular are nowadays tied to security by both the political realm as well as academia in an unprecedented way, the investigation into the reasons for the EU's infectious disease infrastructure was undertaken from a securitisation perspective. Seeing that the existing literature on the subject is, however, inconclusive, in particular regarding the European Union, the study aimed at responding to the striking political and academic relevance of the topic at the intersection of three – in this combination so far unrelated strands – of research, namely European integration, infectious disease control and securitisation.

The following concluding chapter of the study will bring together the core elements of the study in five steps. The first sections serves the purpose to provide a synthesis of the empirical findings regarding the institutionalisation of infectious disease control in the European Union (chapter 7.1) and the securitisation of infectious diseases at the EU level (chapter 7.2). The aim is to derive overarching conclusions across the case studies before returning in chapter 7.3 to the research question and the hypothesis on the potential effects of securitisation on institutionalisation

processes in the EU. Chapter 7.4 is dedicated to assessing the limitations of the study that result from the conceptual and the methodological approach. Seeing that the novel securitisation framework as developed and applied by the present study contains a set of innovations, a thorough reflection on concept and methods can also contribute to direct future research. Therefore, the chapter continues with an agenda for future analyses that could complement the findings and advance the approach, before some final thoughts on the topic close the study as a whole (chapter 7.5).

7.1. The Institutionalisation of Infectious Disease Control at the EU Level

With a basic research interest in the evolution of the *EU's infectious disease policy and polity between 1993 and 2014,* the study put a focus on key developments and institutionalisation processes at the EU level, the latter understood as *relatively persistent and systemic changes regarding rules, procedures, policy priorities, resource allocation, division of competences and organisational structures in the field of EU infectious disease control*, also referred to as structural or systemic changes. Before turning to the conditions under which this evolution took place, it is valuable to recall what exactly has been or is being institutionalised (Stone Sweet et al., 2001: 22).

On the basis of the empirical analysis we can conclude that the institutionalisation of EU infectious disease policy occurred basically in four interconnected areas.

First, we could observe a stepwise increase of EU competences to combat infectious diseases. The widening and deepening of the EU's public health portfolio has been fed in two ways: in a horizontal way following the shifting of responsibilities from other EU policies to the realm of public health, particularly regarding veterinary and food safety affairs, and in a vertical way, for instance due to the introduction of additional policy objectives at the EU level and the compulsory adjustment of existing national surveillance and disease reporting structures to the administration at the EU level. This development found expression in the change of the EU's legal fundament, the EU Treaties, and in the form of extensive regulatory legislation whose implementation is monitored and enforced by EU actors, for instance by the inspections of the Commission's Food and Veterinary Office (FVO).

Second, the EU's setup to control infectious diseases was subject to persistent changes regarding its institutional and organisational structures. For the period between 1993 and 2014, we could observe the establishment of not less than four specialised agencies (EMA, EMCDDA, EFSA, ECDC) as well as one executive agency (PHEA/EAHC/CHAFEA) all of which decisively contribute, albeit working under broader mandates, to the control of infectious diseases at the EU level. With the Health Security Committee (HSC) another key forum has transformed from a temporary informal institutions into a key consulting and advisory institutions for the overall coordination of public health risk assessment regarding cross-border threats to health. Beyond the creation of these new institutions also permanent re-organisations of existing structures took place, best illustrated by the fusion of the public health and the food safety portfolio within the European Commission or the combination of the grown set of surveillance, warning and outbreak response facilities into a clustered management structure for acute health emergency crises (HEOF).

Third, changes related to EU competences and infrastructure implied far-reaching consequences for infectious disease control-related rules and procedures. At the most fundamental level we have seen modifications in the relevant legislative procedures, for instance by the introduction of the co-decision (ordinary legislative) procedure for the adoption of measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

At the applied level the (re-)focusing of the disease reporting and alert infrastructure to the European level is a pattern that occurred for infectious disease threats (EWRS), but also for food and feed (RASFF) and health threats due to deliberate release of chemical, biological and radio-nuclear agents (RAS BICHAT). In particular regarding the EWRS the creation of the ECDC was a pivotal step as it meant a clear centralising transformation of an existing network of disease surveillance networks to a single host. A fresh example for a change of procedures that bears the potential to constitute a systemic transformation is the recently established framework regarding the joint procurement of pandemic vaccines and medications.

Fourth, the empirical analysis has shown that the evolution of EU infectious disease control also included the development and a shift of policy priorities. Infectious diseases were and are subject to a wide range of EU policies, including research, humanitarian aid, development policy and veterinary policy, which could not be investigated in detail in the framework of the present study. In the confined field of public health and food safety, however, we could observe how the expansion of infectious disease control activities went along with a shifting focus from disease-specific research networks to regulation in consumer protection and veterinary issues to the development of preparedness and response facilities for cross-border health threats.

The latter progressed primarily under the label of 'health security', illustrated by initiatives from the Health Security Committee, the 'health security' strand in the EU's 'Programme of Community Action in the Field of Public Health' and the development of a 'Health Security Agenda in the EU and Internationally'. As one of the most recent developments, we could observe a certain form of *externalisation* of the previously only EU-internal role for public health to the global arena. This step includes the definition of the EU's role in global health and the use of external policies for health objectives in the sense of health diplomacy, aiming at the strengthening of the voice and credibility of the EU as an external actor.

The study has not examined in detail the budgetary implications of this evolution but it goes without saying that these developments included a substantial and permanent allocation of resources, for instance to run the infectious disease-related tasks of the agencies or to implement the infectious disease-related activities of the public health programme. It thus becomes clear that institutionalisation does not refer to a single phenomenon or a distinct field of EU activity. Instead, institutionalisation in the context of EU infectious disease control refers to multifaceted formalisation, perpetuation and extension processes in an intersectoral arena of governance (Stone Sweet et al., 2001: 22).

Today, the still evolving system at the EU level can be characterised as a setup of a first and foremost territorial and self-protective nature that focuses on infectious disease threats to EU citizens, in particular in their roles as consumers, travellers or workers. At the same time, infectious disease policy is also related to the support of affected economic sectors from the impact of health crises. Given the fundamental roots of the EU in a Common Market, the system therefore features a triangle of partly conflicting priorities which can be found in similar forms for most phases in the history of infectious disease control, namely the simultaneous desire (1) to protect public health, (2) to protect the economy from consequences of disease and (3) to protect the free movement of goods and people. In the last years, also rising awareness of EU-external aspects of disease control and the objective to combine internal and external policy tools have contributed to this setup, which becomes more complex the more relevant policy fields are considered.

Public health ranks low in terms of EU competences so that infectious disease control in this realm generally needs to build on the political will of Member States to follow the advisory and coordinative engagement of relevant EU institutions. EU infectious disease control, however, also takes place when EU-wide inspections are carried out to audit and enforce the compliance of Member States with EU food safety regulation. In this realm, infectious disease control is better integrated into the dynamics of the Internal Market. It follows from this connection that the gradual harmonisation and centralisation process in infectious disease control towards the EU regional level is farther advanced in the field of human diseases that are linked to animals or products than in the field of, for instance, contagious or air-borne diseases.

Both of the two interlinked areas under scrutiny, public health and food safety, however, have developed in connection to some form of security reference and under the guiding principle of a clear distinction between centralised risk assessment on the one hand, and a management system to coordinate national responses on the other. The development of the last decades took place under the general dictum of the Member States to defend health management affairs as a national domain. Still, over the last decades, occasionally the system transformed in a way that established or strengthened EU-wide structures to support this ‘national task’.

7.2. The Securitisation of Infectious Diseases at the EU Level

Beyond the research interest in the institutionalisation of infectious disease control, it belonged to the objectives to investigate the conditions for the systemic development at the EU level. More precisely, the study worked under the basic assumption that the institutionalisation of EU infectious disease control was linked to specific forms of securitisation of (specific) infectious diseases. This assumption was reasonable in the light of the general trend to relate infectious diseases to the term ‘securitisation’ and given the claim of previous research that institutionalisation and regionalisation of disease prevention and control in Europe had been impacted by public health threats in the sense of a ‘good epidemic’. Crucially, the general linkage was also confirmed by practitioners who were involved in the institutionalisation processes.

Against this background the study approached a set of most relevant systemic changes – food safety reforms, the revision of the public health article in the Amsterdam and in the Constitutional Treaty as well as the creation of EFSA and the ECDC – from the perspective of a modified securitisation approach which was designed to accurately grasp and differentiate between the various forms securitisation can take.

With the overarching aim to explore the conditions of the linkage between institutionalisation and securitisation, and by reflecting the components of the novel securitisation framework, the study engaged in two case studies that followed the question when, by whom, in which dimensions, to what degree and in which kind the securitisation of two selected infectious diseases took place at the EU level. BSE/TSEs on the one hand and SARS on the other were selected for a detailed analysis on the basis of a review of the (little) available literature dealing with (some of) the selected structural changes. The selection seemed reasonable due to the temporal relation of the occurrence of the diseases and the adoption of the reforms and was later also strongly supported by interview respondents. At the same time, given some fundamental differences between the diseases, such as incidence rates, infection paths or outbreak period, the two diseases promised to constitute a particularly interesting choice for the analysis from a constructivist angle.

Building on the findings of the case studies it is possible to draw lessons regarding the forms of securitisation of infectious diseases in the EU by examining and comparing (1) the timing of securitisation, (2) the actors of securitisation, (3) the dimensions of securitisation, (4) the degrees of securitisation as well as (5) the kinds of securitisation.

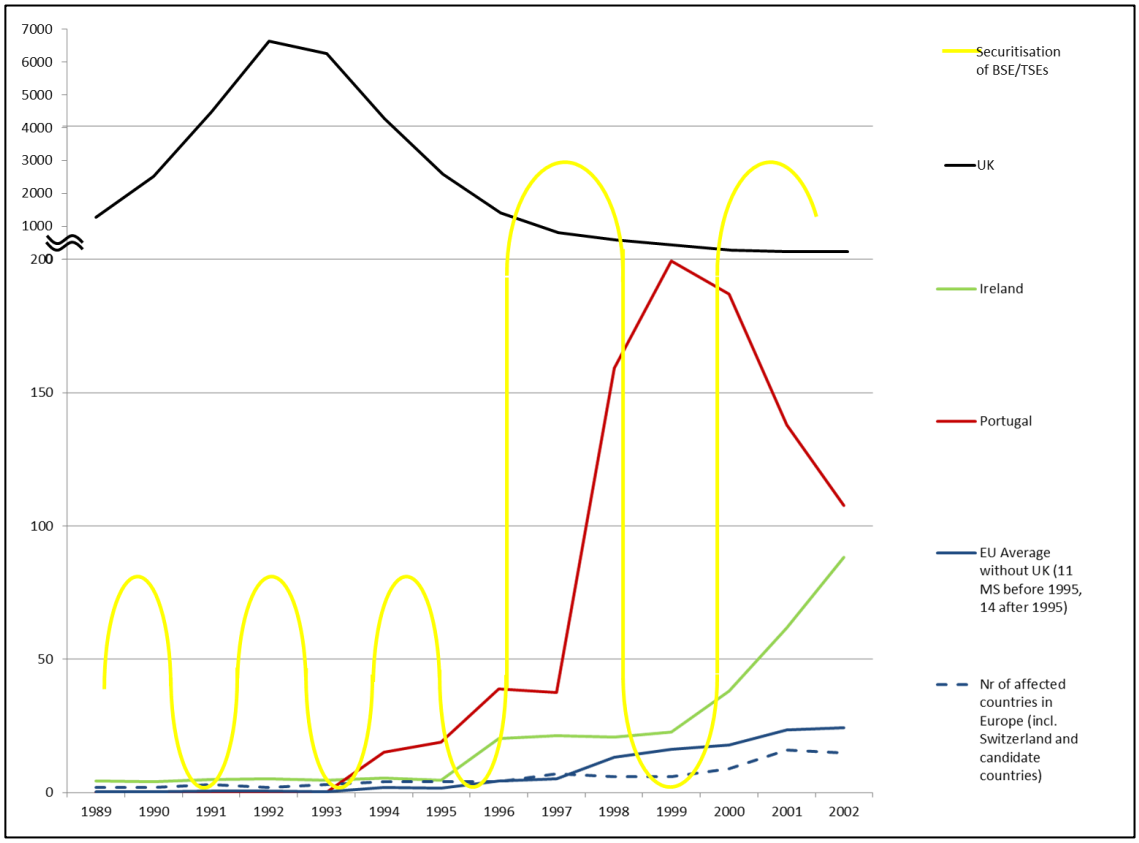
7.2.1. The Timing of Securitisation

The securitisation of BSE/TSEs and SARS occurred at times when outbreaks of the respective diseases were already ongoing. In the case of BSE/TSEs, the overall development referred to a long process over a period of more than 12 years in total in which the disease underwent different, self-reinforcing securitisation phases and two securitisation peaks; in case of SARS case the period of less than 12 months was rather short. Hence, it follows that securitisation in the EU as such is not bound or limited to specific time frames. At first glance, the securitisation of SARS and BSE/TSEs seemed to have occurred quite differently, namely very quickly after the detection of SARS, whereas BSE was observed for a couple of years without a substantial shift regarding its securitisation.

This observation is, however, not the full story, because in both cases the securitisation occurred rapidly after a critical key development had taken place: the confession that BSE was transmissible to humans on the one hand, and the news that first cases of SARS had been confirmed in the EU on the other. This finding suggests not only that the detection of a new disease alone does not make up for a security problem, it also allows for the statement that also ongoing disease outbreaks can become subject to rapidly altered securitisation dynamics.

Given the focus of the study on securitisation as an *explans* rather than an *explanandum*, the question as to *when* securitisation occurs does not extend to the conditions for successful securitisation. However, it should be noted that despite the clear indication that securitisation was triggered by 'real world' events in the course of a *de facto* disease outbreak, securitisation should not be regarded as an expression of diseases incidence rates or be confused with the sheer detection of the disease. Diagram 7-1 (see below) contrasts the annual incidence rates[157] for BSE for the countries with the highest incidence rates (UK, Ireland, Portugal) with the schematic illustration of the securitisation degree for BSE as presented in chapter 5.6. The diagram makes clear that incidence rates and securitisation were largely decoupled from one another. During the peak of the BSE epidemic in the UK, that is the time when most animals were infected in the entire Community, the disease was basically un-securitised; BSE/TSEs turned into a highly securitised matter for the first time when the number of BSE cases was already in decline. Hence, the morbidity rate of the disease does not allow drawing conclusions on the understanding of the disease as a security threat.

Diagram 7-1: Annual BSE Incidence Rates and the Rise and Fall of the Securitisation of BSE/TSEs (schematic)



Source: Own presentation on the basis of Diagram 5-3 and annual incidence rates for BSE as provided by the World Organisation for Animal Health (number of indigenous cases per million bovines aged over 24 months) at http://www.oie.int/animal-health-in-the-world/bse-specific-data/annual-incidence-rate-in-the-united-kingdom/ and http://www.oie.int/animal-health-in-the-world/bse-specific-data/annual-incidence-rate/ (accessed 09.01.2015).[158]

[157] Since the incubation period is unknown for man who has consumed BSE contaminated beef products, but can be up to 30 years in the case of other human TSEs, the incidence rates refers to BSE.

[158] Due to the high incidence rates for the UK in comparison to other countries, the diagram features a broken y-axis. The illustration of the securitisation of BSE/TSEs (yellow line) should not be read as an expression of the values as specified on the y-axis; it is a schematic illustration on the basis of Diagram 5-3, the overlay of which serves only the purpose to reveal possible dependencies between the overall securitisation development and the *de facto* prevalence of confirmed BSE cases.

If an influence of the incidence rate on securitisation can be deducted from Diagram 7-1, it is not the total number of infected animals, but the number of countries with infected animals. In the case of BSE/TSEs the number of countries with confirmed BSE cases increased throughout Europe from 6 in 1999 to 16 in 2001 (both incl. Switzerland). As this development went along with a (second) securitisation wave, it can be argued that the number of countries in which infections could be found played into the securitisation at the EU level. It thus feeds into the analysis of the securitisation kind that disease outbreaks in individual Member States are less likely to translate into securitisation processes at the EU level than EU-wide developments.

7.2.2. The Actors of and in the Securitisation Process

At the EU level securitisation of infectious diseases cannot occur on the basis of the activities of a single actor; it requires the collaboration of different actors and majorities within institutions to lift a disease out of the realm of ordinary politics. To illustrate, due to its role in the coordination of disease management the Commission had a pivotal role in the securitisation processes related to BSE/TSEs and SARS, in particular on the operational dimension. However, decisions by the Commission could be adopted only following the approval of Member States' representatives, typically established in the respective committee. Such a system of checks and balances leads to the circumstance that securitisation can be hampered or even prevented, if the stance toward a given diseases is disputed either among or within involved institutions. In the case of BSE/TSEs the 'BSE Subgroup of the Veterinary Committee', the Council and the European Council were cases in point. In this sense, if securitisers typically adhere to the means and functions foreseen by the political system, be it the executive function of the Commission or the control function of the Parliament, securitisation is contingent upon the same structures as ordinary policy-making.

This finding supports the conceptualisation of the 'audience' of securitisation as developed for the purpose of this study. To recall, according to the securitisation framework the process of securitisation can be understood as an intersubjective discursive practice which is incomplete as long as the securitising move is not followed by indication of acceptance by a relevant audience (see chapter 2.2). As explained in chapter 2.5.3 the audience acceptance was not subject to distinct analysis in the present study following the assumption that the political system of the EU requires acceptance among various actors to produce (potentially) securitising documents in the first place. Following the empirical analysis dealing with the disease-related political interactions it can be concluded that the conceptualisation of the enabling audience as inherently in-built into the configuration of EU actors was well justified.

Beyond that, the fact that securitisation can follow the decision-making patterns as laid down in the political system also implies that securitisation potentially bears, just as any political process, a tactical component. In the cases of BSE/TSEs and SARS this tactical aspect of securitisation found expression in emphasising, downplaying or omitting the security dimension of a disease, depending on the actor in question. To illustrate, during the BSE/TSEs crisis crucial actors like the Commission or the UK government (within the Council and committee system) took a neutral stance or trivialised

the problem and thus contributed to de-securitisation or at least did not fuel further securitisation. The former actor was possibly considering economic export interests, the latter faced severe criticism for the administration of the crisis. Furthermore, calmative efforts are an integral part of any crisis management process. Consequently, none of the respective actors had an interest in a prioritisation of the issue. In turn, if a higher securitisation might promise or facilitate desired effects, actors can also deliberately fuel the securitisation process. The Commission's position in the SARS crisis is an interesting point in that respect. On the one hand it tried to convey the impression that, with input from the Commission, efficient crisis management was pursued; on the other hand it fed the securitisation of infectious diseases beyond SARS when it argued in favour of the creation of the ECDC.

Examining the exact actor constellation that finally enabled the securitisation of the diseases was beyond the scope of the present study. It is however important to conclude that actors at the EU level can make use of existing structures when it comes to influencing the securitisation process. The political system provides in-built capacities for (de-)securitisation on both the verbal and the operational dimension so that rules do not necessarily have to be broken in order to account for a securitising move. The capacity is most clearly illustrated by the Parliament's right to table a motion of censure against the Commission, but also less exceptional emergency measures which are jointly adopted by Commission and Member States or at the level of the European Council serve the same function. Actors might still leave the realm of ordinary rules in specific instances, but this is also true for attempts to achieve the de-securitisation of a threatening disease. The UK's empty chair politics during the BSE/TSEs crisis that eventually resulted in a partial lifting of the UK embargo is a case in point.

Finally, with a view to the group of securitisers it is noteworthy that the typical set of potentially securitising EU actors (Parliament, Commission, Council, European Council etc.) was not the only source for securitising elements and documents that influenced the analysed securitisation processes. In the case of SARS we could observe how the WHO as a non-EU actor could 'speak through' the legal output of the EU and accounted for a securitising point of reference. In other words, although being located outside the group of EU securitisers, the influence of WHO as an external securitiser became manifest and fuelled the securitisation processes at the EU level. Additional sources for securitising moves were also *established* during the securitisation of the diseases. The Scientific Steering Committee, a body that had been created in the course of the securitisation of BSE/TSEs, contributed to the further securitisation of BSE/TSEs following its dedicated task to deal with the disease. A similar example in the SARS case was the EU Expert Group on SARS. These examples make clear that the *ad hoc* creation of institutions which are typically sought to ease the situation and thus to contribute to de-securitisation, can at least temporarily perpetuate or even increase the securitisation of an issue.

7.2.3. The Dimensions of Securitisation

The study has shown that the picture of verbal and operational securitisation was almost identical for both securitisation processes. Both BSE/TSEs and SARS were securitised in a balanced way in both the verbal as well as the operational dimension. Clearly, different results in favour of the predominance of the securitisation on the verbal dimension would be possible if the data set was compiled in a different way, for instance by including parliamentary debates or press releases. However, a higher number of speech acts or a different relation between verbal and operational securitisation would not have changed the basic – and decisive – finding that a substantial number of both emergency measures and speech acts together met the basic criterions for an overall high securitisation of the diseases.

Having said this, two points are particularly notable with regard to the securitisation across dimensions: First, it seems that at the EU level securitisation can be driven substantially by action (in the operational dimension). An example is the legal output during the BSE/TSEs crisis, when the European Commission issued a series of securitising moves in the operational dimension without reaching an equivalent securitisation degree in the verbal dimension.[159] Second, actors were capable of an operational securitisation not only in the case of BSE/TSEs, where the Community could build on stronger legal competences in the EU Treaties and established case law; also SARS was highly securitised on the operational level, although the responsive measures to be adopted in the EU were agreed on in the Network Committee without a specific point of reference in the Treaty and in the form of non-binding recommendations. The measures still accounted for operational securitisation since Member States responded with a high compliance rate.

These finding illustrate that the adoption of joint extraordinary responses does not require an explicit mandate at the EU level; quite the contrary, operational securitisation can also be initiated at the EU level on the grounds of weak (and principally also without) legal competence and still turn into veritable operational securitisation following the *de facto* implementation of the Member States. In this sense, through encouragement, providing information, establishing legislative frameworks and the transfer of best practice the EU is capable to securitise at the operational level by 'nudging' Member States in particular directions (Grant, 2012: 1032f).

7.2.4. The Degree of Securitisation

The securitisation degree was introduced in the present study as an innovative instrument to locate – at least schematically – an issue on the security continuum between a lowly and a highly securitised matter. Following the analysis along a set of securitisation degree indicators it has become clear that due to the strength of the security discourse, the number of speech acts, the position of the securitisers and the number and strength of emergency measures, including the allocation of resources, both BSE/TSEs and SARS entered the realm of a highly securitised issue – with BSE/TSEs having reached an overall higher securitisation degree. The finding could be derived from thorough

[159] Due to the activities of other actors, however, the overall distribution remained balanced.

text analysis which revealed that both diseases were (temporarily) subject to intensive debate in security language up to the highest levels of the EU's political spectrum. A full wide-ranging set of extraordinary measures was adopted and went along with massive budgetary implications, particularly in the case of BSE/TSEs, that resulted from the emergency responses.

The qualitative content analysis of the EU legal output in view of the securitisation degree indicators was substantiated by the application of a set of measuring instruments. More precisely, we have seen a rapidly rising number of documents dealing with BSE/TSEs in its securitisation peaks, adding up to more than 31 for the years 1996/1997 and 26 in 2000/2001, as well as 27 documents for SARS in 2003/2004. This rise in the sheer number of disease-related documents was accompanied by the rise of the total securitisation score, which is the sum of the scores assigned to the EU documents on the scale between +2 and -2 for each dimension (verbal and operational). The respective calculation yielded the result that BSE/TSEs achieved the highest peak in 1996 with an overall score of 43. SARS, in turn, reached a total score of 38 in 2003.

A similar picture could be drawn regarding the strength of the security discourse. Calculating the share of the set of securitising document in relation to the total number of disease-related documents illustrated for both diseases that security language clearly dominated in the phases when the securitisation degree peaked. In the case of BSE/TSEs the share was exceptionally high in 1996/1997 when roughly 84 per cent of all utterances were of a securitising nature in the verbal dimension, and still dominant in 2000/2001 with a share of roughly 70 per cent. SARS, in turn, reached a share of approximately 78 per cent of securitising utterances in 2003/2004. Finally, also the average securitisation scores, that is the mean score between +2 and -2 calculated by the division of the sum of all values of all utterances by the total number of utterances, speaks a similar language. BSE/TSEs reached a high average of +1,06 in 1996/1997 and still a substantial mean of roughly +0,7 in 2001/2002. The average score of SARS was +0,96.

Comparing these figures does not only help verify the analysis and interpretation of the *text corpus* regarding the rise and fall of the securitisation degree. From a methodological point of view it is also interesting to note that calculated figures for both case studies – produced under identical systematic conditions regarding the compilation and analysis of the data set – are clearly located in the same ranges for (1) the total number of documents, (2) the total securitisation score, (3) the share of securitising documents as well as (4) the average securitisation score. As emphasised from the start, the tool kit to examine the securitisation degree was not designed as direct mathematical expressions or as a sort of index. Nevertheless, it is noteworthy that the measuring instruments to assess the securitisation indicators from a quantitative side, with which so far no experience existed, yielded results across case studies that can be reasonably put in relation.

Hence, the results that could be generated by the introduction of the securitisation degree did not only allow for a novel comparative assessment of the strength and the rise and fall of diseases as security threats, and thus for a clearer assessment of securitisation as such; beyond that, the results also militate in favour of the combination and application of methods.

7.2.5. The Kind of Securitisation

The kind of securitisation was developed in the present study as an innovative tool to reveal the underlying understanding(s) of security as inherent to the securitisation process. Building on a comprehensive set of securitisation parameters to distinguish between different disease-related security concepts depending on (1) the definition of the referent object, (2) the definition of the threat and (3) the definition of the security provision, the instrument was designed to reflect *academia*'s consent that security is an essentially contested term. In the light of a high number of possible combinations of the securitisation parameters the study worked with a spectrum of security understandings that ranged from the soft to the hard extreme.

The analysis of the diseases-related documents in view of the securitisation parameters has produced the result that EU actors have securitised both BSE/TSEs and SARS in a rather hard kind. After the securitisation of BSE/TSEs had undergone changes, particularly following the change of the referent object from animals to humans and the beef and veal sector and following the expansion of the problem from a few Member States to the entire EU, both diseases were similarly seen as close and severe security problems for which no cure existed, which were hard to predict and which threatened not only the health of many people but also specific sectors of the European economy. Accordingly, in both cases the adopted measures, partly extremely invasive, were located in the realm of the Common Market and public health, the latter primarily via veterinary measures with the direct objective to protect public health in the case of BSE/TSEs. All major fields of disease control, ranging from surveillance to prevention, preparedness and response, were predominantly targeted towards the EU territory and the close neighbourhood, except for a number of international support and surveillance measures by the EU in the case of SARS and extra-EU trade affairs in the case of BSE/TSEs.

Given the great differences between BSE/TSEs and SARS, be it with regard to the infection path, the incubation period or the time span of the outbreak, this general finding supports the constructivist approach to the study of security. It belongs to the insights of this research that the securitisation of both diseases occurred, on an abstract level, in a comparable fashion regarding the underlying security understanding, regardless of the characteristics of the diseases and the features of the outbreaks.

Still, despite the overall dominance of hard securitisation parameters, the kind of securitisation was more complex it both cases than it could be expressed in detail by the placement of the disease-related security construction on the simplified axis between soft and hard. This is not only due to the schematic classification of a comprehensive set of parameters, each of which can take multiple values; it is also because of the fact that not all of the parameters that could be derived as relevant elements from the existing research, were similarly applicable in the case studies. To illustrate, for a case like the BSE/TSEs crisis, which constituted a problem that originated inside the EU, it is not reasonable to expect that EU activities primarily target referent objects outside the EU.

At the same time, a clear differentiation was not always possible as specific parameters did not figure prominently in the analysed *text corpus.* More precisely, the ethical stance, the source of the threat or the source of pathogenicity could not always be unambiguously derived so that a clear definition or differentiation along the pre-defined extremes was difficult. Also, although the list of security parameters that make up for a securitisation kind was compiled in a comprehensive fashion (chapter 2.3.2), the empirical analysis has brought up new elements which did not appear in the existing literature and were therefore difficult to fit into the existing concept. To illustrate, China's (dis)information policy during the SARS crisis turned out to be an important source for the perceived pathogenicity of the disease; a value that is hardly classifiable along simplified security spectrum between soft and hard. Still, these challenges were limited to exceptional cases and the fact that some parameters did not occupy a prominent position in the cases of BSE/TSEs and SARS does not mean that they are irrelevant for the construction of other diseases as security threats in general.

All in all, on the basis of the experiences from the two case studies it seems that the definition of the referent object and the number of referent objects, the geography of the threat, its severity and predictability belong to those parameters that were addressed most clearly and that were of greatest relevance for the overall securitisation kind. The analysis thus suggests that probably not all elements on the predefined list of security parameters are of the same importance in securitisation processes. In the case of the SARS crisis we have seen that in particular the parameter regarding the predictability of the threat can superimpose other factors. At the same time, a striking feature of both case studies was that parallel constructions of the disease as a threat to different referent objects took place. To recall, for BSE/TSEs we observed a construction of insecurity regarding the health of animals, the health of consumers, the beef and veal market, and the Internal Market (all inside the EU); for SARS, in turn, a definition of the disease as a threat to the health of persons and the economies in Asia and the EU, within the latter most notably related to travellers and aircrews, medical personnel and the (air) transport sector – with a high perceived risk of a further spread.

What lessons can we draw from these observations? First, public health and economic questions played the most important roles for the construction of the diseases as security threats. The share of speech acts and extraordinary measures that aimed at safeguarding the health of important industry sectors and more generally the functioning of the Internal Market, in particular during the BSE/TSEs crisis, might appear high at first glance. In this context, however, it is important to remember that the Community is bound to the legal mandate enshrined in EU law when it comes to implementing action. Public health was and is located among the EU policy fields that complement national policies and which foresees that the individual Member States are responsible for the implementation of protective or responsive measures. In contrast, agriculture policy, on which basis the exceptional market support measures during the BSE/TSEs crisis were adopted, is an integral component of the Community's Common Market.

Against this background the high number of files that dealt with the economic implications of the disease can be put in perspective. The division of competences in the multi-level system simply provides more opportunities for securitisation at the EU level in the economic realm. Since the

economy is not only one of the 'core businesses' of the Union but also belongs to the elements that are vital to both the State and the EU, a hard securitisation of infectious diseases was eventually facilitated by the EU's Common Market competences in both cases. However, the case of SARS has shown that also a weaker public health legal mandate can yield hard securitisation.

Second, in the course of the securitisation process the original threat exerted by a disease can translate into the securitisation of related aspects. We have seen that in the case of BSE/TSEs it was not directly the disease that was considered to threaten the beef market, but the lack of consumer confidence in food safety that became manifest in the course of the crisis. It was not directly BSE/TSEs that threatened the political regularity at the EU level, but the no confidence motion of the European Parliament that followed from the credibility which the Commission had lost during BSE/TSEs crisis. In a similar fashion, in addition to the threat that SARS meant to human health, the widespread public anxiety of SARS was seen to threaten social and political life. Hence, it appears that the securitisation of infectious diseases sometimes shows itself indirectly through other 'vectors of danger' which construct further threats to further referent objects of security, thereby initiating a chain reaction of self-reinforcing securitisation processes.

On the whole, the manifold valuable results that could be generated under consideration of the securitisation parameters established in this study confirm the usefulness and relevance of the kind of securitisation as a novel tool to better capture and analyse the securitisation of diseases. The fact that it was purposefully designed as an open instruments that is capable to grasp basically any security understanding of any actor implies that it demands accurate and careful handling; it is, however, not only the first tool that offers an explicit structure for the systematic comparison of disease-related constructions of (in)security, but also one of the few attempts to adequately reflect the constructivist nature of securitisation.

7.3. Securitisation and Institutionalisation

The examination of the research question on the conditions under which the securitisation of (specific) infectious diseases could explain institutionalisation was carried out in consideration of a hypothesis on the assumed linkage. It was argued that it was the specific combination of a high degree and a hard kind of securitisation of infectious diseases by EU actors (independent variable) that constitute the critical conditions and ultimately the *cause* of institutionalisation of infectious disease control at the EU level (dependent variable). Research question and hypothesis aimed at shedding light on one of the main puzzles that the academic literature on infectious disease control currently faces, namely that in the past some epidemics or disease-related crisis provoked big changes, whereas others came and went without (Greer and Mätzke, 2012: 902). The argument was that in order to break the stability of public health policy and polity and to enable major modification of the infectious diseases control setup the condition of a specific construction of 'strong' insecurity was decisive; and not just any form of "repeated crises that keep the need for robust public health constantly at the top of the political agenda nationally and internationally" (Fidler, 2004b: 169f).

When it comes to examining the link between securitisation and institutionalisation it is helpful to recall four conditions that are essential for the test of causation. In order to verify that securitisation (the cause) has indeed triggered institutionalisation (the effect) at the EU level it is required a) that cause and effect change together or co-vary, b) that the effect occurs after the cause, c) that the process by which effects are caused can be identified and d) that cause and effect do not change due to some third factor (Manheim et al., 2008: 23f).

The case studies have shown, illustrated by Diagram 5-3 and Diagram 6-2, that the first two conditions were met in both cases. Strong securitisation and institutionalisation clearly followed in a reasonable temporal relation in which the former preceded the latter. In view of the causal linkage in terms of the process by which changes regarding securitisation caused changes in institutionalisation, both case studies revealed that the reforms did not only exactly address contentwise what had been subject to the securitisation process, but that the reform processes referred to previously securitising initiatives and built on the security reasoning of the securitisation phase.

The scenarios in which securitisation and institutionalisation occurred in this connection, however, were not all of the same form. To recall, the extension of the public health article in the Constitutional Treaty in favour of the inclusion of a mandate to "combat cross-border threats to health" took place in the context of an overall fundamental revision of the EU's primary law which was ongoing anyway. In contrast, the re-organisation of the food safety infrastructure in the 1990s occurred after the European Parliament had set up a temporary committee of inquiry that reported on "alleged contraventions or maladministration in the implementation of Community law" (European Parliament, 1997b). Hence, the securitisation of infectious diseases seems to affect structural changes in different ways and on the basis of different settings. Based on the investigation of the two case studies we can identify basically five scenarios.

1) Strong securitisation can be followed by institutionalisation in the form of the formalisation, perpetuation and centralisation of structures that already existed in an informal, temporal or de-centralised form (exemplified by the communicable diseases networks).
2) Strong securitisation can be followed by institutionalisation in the form of a consolidation, formalisation and perpetuation of emergency measures that were originally adopted separately as informal or temporary arrangements (exemplified by the measures regarding the feeding of ruminants).
3) Strong securitisation can be followed by institutionalisation in the form of a deepening and/or widening of an ongoing reform process (exemplified by the Constitutional Treaty).
4) Strong securitisation can be followed by institutionalisation in the form of new, original reform processes that address the problem in view of an improved setup for similar situations in the future (exemplified by the re-organisation of the system for scientific advice).
5) Strong securitisation can be followed by institutionalisation in the form of an acceleration of a reform process to adopt structural changes that had been envisaged by advocates before (exemplified by the creation of the ECDC).

The scenarios differ in terms of the course of action and the exact institutionalisation content, but they share the characteristics that during the reform process the proposals for systemic change were connected to the securitised diseases, be it in form of an accompanying explanation, such as the Commission's communication on the re-organisations in the area of consumer health and food safety in 1997, be it in the form of contributions to a larger revisions process such as the European Convention in 2003. And although there is, naturally, no evidence that the other institutionalisation steps in the evolution of EU infectious disease control as provided in chapter 3.6 also fall under one of the scenarios, at least for the two case studies of this study it seems indeed that three of the four conditions to test causation (joint change, temporal relation, identified process) are clearly met.

The fourth condition demands that cause and effect should not change due to some third factor (Manheim et al., 2008: 23f), a criterion which is more challenging to meet for two reasons. First, the number of two case studies, even if one of them covers a long period over two securitisation phases as in the case of BSE/TSEs, is not high enough to rule out that developments other than securitisation constituted the cause for institutionalisation. Clearly, more analyses with results that are consistent with the proposed relation could provide overall stronger evidence and allow for better generalisability. Second, the investigation has shown that other factors cannot be ruled out to have affected the analysed processes. In the case of the BSE/TSEs-related institutionalisation also the dioxin scandal and the foot and mouth disease have fed into an overall risen securitisation status for infectious diseases, just as the anthrax incidences following 9/11 in the US and the experiences with HIV/AIDS and influenza pandemics in the case of SARS-related institutionalisation. These incidences can not only be considered to have provided a breeding ground for the securitisation of BSE/TSEs and SARS, most likely they were also subject to securitisation dynamics themselves. In other words, claiming exclusive explanatory power for the securitisation of the analysed diseases could go too far.

Beyond that, it should be noted that approaches that are not directly related to the construction of (in)security also offer convincing explanations for the observed phenomena. For instance, we have seen that scientific experts played a prominent roles in both infectious disease-related securitisation and institutionalisation processes. Consequently, an investigation of the influence of epistemic communities (Haas, 1992) can produce valuable insights (Mätzke, 2012: 970, Steffen, 2012: 1085). Similarly, the analysis of the evolution of infectious disease control has indicated that both functional pressures (Haas, 1964) as well as path-dependencies (Pierson, 1996) were important features of the development (Krapohl, 2008: 13).

It follows from parallel developments and the value of additional explanation models that we must be cautious when it comes to claiming exclusive explanatory power for securitisation as the *cause* for institutionalisation. Still, on the basis of the case studies we can principally answer the basic research question of this study that securitisation can explain institutionalisation *under the condition* that securitisation occurs at least temporarily to a high degree in a predominantly hard kind. Beyond this specific form of strong securitisation, securitisation and institutionalisation need to be tied together as regards content as well as in a procedural and temporal way. More precisely, institutionalisation can be explained by securitisation under the condition that the institutionalisation step addresses

(aspects of) the securitised situation, that the negotiation on the institutionalisation step is related to the security discourse and that the institutionalisation process is initiated, not necessarily concluded, in a timely manner. Furthermore, the set of scenarios compiled on the basis of the case studies suggest that ongoing reform processes, policy advocates and the existence of institutionalisation plans that had already been drawn up may mean important facilitating conditions.

Under these conditions strong securitisation indeed seems to constitute a convincing explanation for the analysed changes in the EU's infectious disease control setup, if it is understood as the decisive factor to change the calculus of the relevant EU actors so that a re-evaluation of the existing setup became possible, and thus as the ultimate driver of the institutionalisation process.

This assessment should be seen against the background that the hypothesised linkage was not proposed as an explanation that precludes the influence of intervening factors. In contrast, parallel developments might not only have fuelled the securitisation of BSE/TSEs and SARS, they might also have directly influenced the institutionalisation process in other ways. It therefore appears appropriate to assume that institutionalisation occurred under the influence of a convergence of different factors, among which, however, securitisation occupies the dominant position. With a view to the working hypothesis this qualification suggests that the overall picture should be viewed in the sense that securitisation served the function of a potent facilitator of change, a dynamic process that unfolded the power to open windows of opportunities for institutionalisation, but not as the single cause.

7.4. Limitations of the Study and a Future Research Agenda

The reflection on a chosen (or developed) approach should not be restricted to a true-or-false assessment in an absolute sense but extend to an evaluation in terms of greater or rather limited usefulness (Manheim et al., 2008: 17). Given the detailed insights which we could gain from the analysis into an observed phenomenon which so far had been neither systematically conceptualised nor assessed with analytic rigour, the approach of the present study can be viewed as useful indeed.

Still, despite the advancements of the framework also the present study faced conceptual and methodological challenges. One of the difficulties is familiar to every scholar engaged in the study of infectious disease control, namely the fact that the intersectoral and multi-level nature of infectious disease control makes it difficult to separate the different relevant policies and political levels. Dealing primarily with infectious disease control in the realms of EU public health policy and food safety as two most relevant fields thus means that the focus can neither adequately cover relevant developments in other related fields, nor factors that derive from other political levels, be it the local, national or international level. In addition, the investigation with a strong focus on the unidirectional connection between securitisation and institutionalisation for selected diseases and examples of institutionalisation does not fully reflect the dynamic feedback influences that operate between the processes.

Naturally, (de-)securitisation does not stop after the adoption of structural changes but continues under changed circumstances - an aspect that could in part be covered by the case study dealing with the food safety reforms but which deserves further clarification in the future.

The dynamic of securitisation could also not fully be covered due to the composition of the data set. In absence of a clearly defined European public sphere and with a view to the primary research interests the *text corpus* was systematically generated as a set of documents that was limited to official EU utterances. It thus allowed for a good comparability across case studies. The clear focus on EU output from EUR-Lex and official disease-specific websites, however, came with the disadvantage that the analysis did not include media sources and parliamentary debates, which implied that the presumably strongest securitisation moves were not included in the analysis. In fact, securitisation is usually much clearer visible in oral and media contributions than in official output which often is cautiously formulated due to the reassuring function of official statements in the process of risk and outbreak management.[160]

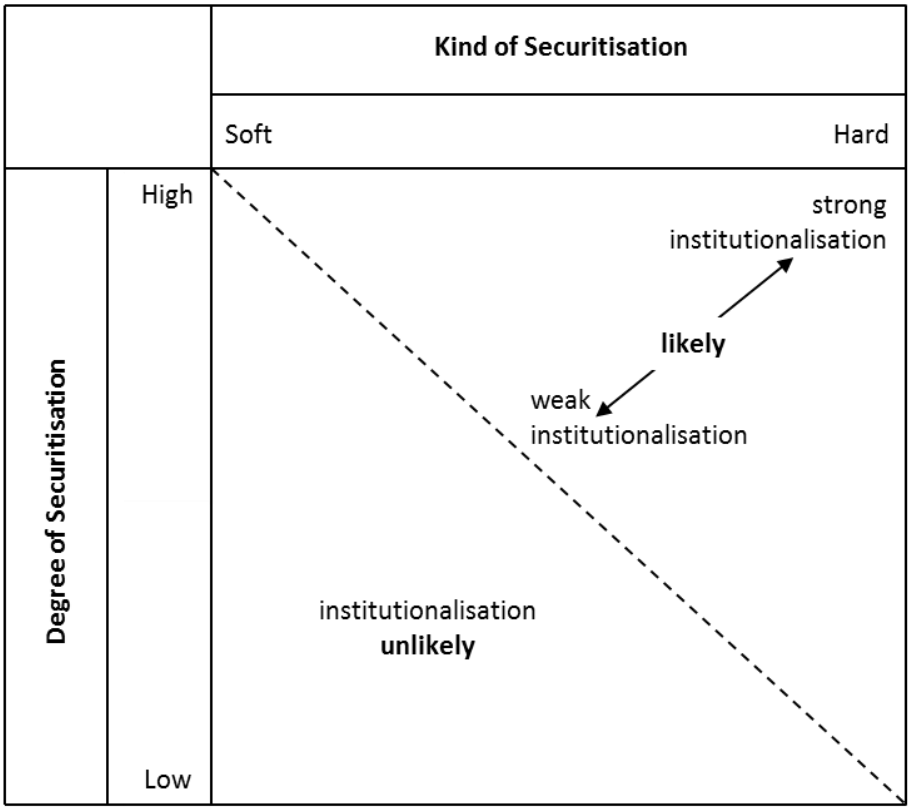
The clearest limitation of the study follows from the exclusive research focus on successful examples of institutionalisation as an effect of securitisation. The case studies were selected explicitly with the aim to examine examples of institutionalisation which were preceded by disease outbreaks whose securitisation characteristics were not known but could be expected to be of a rather strong form. Hence, empirical testing with this focus constitutes only a first step for the verification of the hypothesis. In order to waterproof the proposed connection, the analysis should be followed by a series of attempts of falsification, in particular by analysing further diseases that assumed the status of a weakly or averagely securitised issue only and that most comprehensively address the spectrum of securitisation parameters. For the purpose of this study, however, limiting the evidence in this respect can be deemed appropriate in the light of the novelty of the concept, the limited existing research in the field and in particular the primary research interest of the study in the reasons for change in the EU's infectious disease control structures, rather than in the (absence of) effects of weak or average securitisation or the unclear causes of systemic stability.

However, the study could show that the securitisation approach as developed for this analysis is characterised by good applicability, that it allows for the generation of valuable results also in unexplored territory and that the basic hypothesis could be positively approved in two cases. It is up to future research to refine our understanding of the linkage of securitisation and institutionalisation by analysing more cases and examine in detail whether actually only strong securitisation facilitates structural change, whereas other forms do not. In this context the further development of the hypothesis towards a dynamic model appears a particularly promising step. More precisely, future studies could continue to engage with the same research question on the conditions under which securitisation explains institutionalisation, but should approach the question from the hypothesis that the form of securitisation determines the probability and eventually also the form of

[160] A test on the impact of parliamentary interventions on the securitisation process in the case of SARS as provided in Annex 2, however, has shown that despite an overall increased height of the verbal securitisation degree the results did not differ significantly from the results generated by the ordinary assessment method.

institutionalisation. In this sense, case studies could deal with the securitisation of diseases that are less likely to be subject to strong securitisation than it was the case for BSE/TSEs and SARS and also focus on forms of institutionalisation that are weaker than the creation of an agency or the revision of primary law. By doing so future research could differentiate between combinations of softer kinds or lower degrees of securitisation and examine them in view of the potential to trigger (what form of) structural change. Based on the experiences and results gained from the present study, the following sophisticated model in Figure 7-1 could serve as a point of reference to be debugged by future studies.

Figure 7-1: Hypothesising on Institutionalisation as an Effect of Securitisation (dynamic)



Source: Own presentation

Beyond the testing of a further developed hypothesis, future research could particularly add value to the findings of the present study in four ways:

First, additional case studies could help identify overarching pattern which are not visible at the moment but for which first indication could be detected. An assessment of the potential interdependence between the change of degree and kind of securitisation would be interesting just as an examination of cases of asymmetric securitisation across verbal and operational securitisation dimension.

Second, additional case studies could work on determining the importance of certain securitisation indicators and parameters which did not occupy a prominent position in the securitisation of BSE/TSEs and SARS. In this context the thorough analysis of the securitisation of a set of diseases that is typically assorted to the developing world appears fundamental. Future studies would thus allow for the refinement of the methods employed, in particular related to the study of the securitisation parameters.

Third, further case studies on the securitisation of different diseases in the same period would mean that the effects of parallel securitisation processes could be better understood. In principle it seems that infectious diseases are not securitised as *one* threat, but that securitisation occurs for specific diseases (Reiners, 2013). However, the SARS case has shown that the disease was frequently put in relation to the anthrax scare of 2001 so that the securitisation of anthrax was eventually re-activated and fuelled the securitisation of SARS. In the same way did also the impact of the securitisation of SARS did not come to an end in 2004. Similarly, the parallel occurrence of diseases on the political agendas might add up to a general securitisation of infectious diseases. Hence, it seems valuable not only to examine in more detail the mutually reinforcing influences of consecutive or parallel securitisation processes, but also to establish instruments that express the overarching predominant securitisation degree and kind which accumulate the securitisation processes related to individual diseases.

Finally, case studies that cover more infectious disease-related policies, such as development and humanitarian aid, could add to the validity of the core arguments beyond the realms of public health and food safety. In particular the external dimension of the EU's infectious disease control structures and the link to the global governance structures deserve detailed analyses from a securitisation perspective. Also the review of the infectious disease-related efforts in the field of research policy could address existing gaps in the complex picture; even if tracing such elements might be a challenging endeavour (Ernst et al., 2010). Last but not least, it seems promising to test the applicability of the novel elements of the securitisation approach in other policies outside the realm of infectious disease control, for instance in the field of energy policy. Clearly, such an adaptation would require the abstraction of the existing and possibly the development of additional securitisation parameters.

Many further important questions and aspects could be added to the research agenda of the future, not least due to the fact that the EU's infectious disease control policies and polity are still subject to ongoing development. The joint procurement initiative is expected to yield first concrete results soon and the Commission's review process in autumn 2015 to draw lessons from the ebola crisis of 2014/2015 will provide an opportunity to envisage future structural adaptations.

7.5. Security Advice

The link between infectious diseases and (in)security is as old as the link to travel and trade (McNeill, 1989). Also in the evolution of infectious disease control in the European Union these notions were intrinsically tied together, illustrating how the field is characterised by tensions that arise from contradictory demands related to health, security and the economy. Common institutions, rules, procedures and programmes have functional advantages in times of globalisation and even more within a Single Market when it comes to efficiently managing cross-border threats to health. The establishment and extension of these cooperative structures, however, is a political question that involves the struggle for power, competences and resources, just as most other political affairs.

Observers of these processes have noted that disease outbreaks and crises could facilitate the evolution of such structures throughout history; be it the creation of the Office International d'Hygiène Publique in 1907 following a cholera epidemic, be it the European Centre for Disease Prevention and Control in 2004 after the spread of SARS. The present study has put this observation into perspective by arguing that the construction of diseases as specific threats to security open windows of opportunities that enable fundamental policy and polity change in the European Union. Given the large potential for the securitisation of infectious diseases in the future, analysts and stakeholders are advised not to leave the institutionalisation of EU infectious disease control unattended.

The perceived need that follows from securitisation to structurally change *something*, however, does not necessarily imply that the adopted reform actually improves the situation substantially for the future. For instance, the creation of EFSA was generally welcomed by analysts for the increased transparency (Kreher, 1997: 242, Groenleer, 2009: 101), but some stakeholders did not consider the reform a great difference in practical terms and more of symbolic nature (Krapohl, 2008: 164). This fact reminds us that at the end of the day, from a securitisation point of view it neither matters whether a disease or situation is ‘really’ dangerous, nor whether any systemic reform constitutes a ‘real’ improvement for the security situation. Decisive are the reform’s implications for the perception of the threat, in particular the reform’s power to structurally de-securitise the issue and treat the previously securitised matter as a matter of normal politics in the future.

It has not been the purpose of the study to assess the usefulness of institutionalisation of infectious disease control in the European Union. However, given that structural change in response to securitisation can be as rational or irrational as the securitisation of the issue itself, it should not be forgotten that both the securitisation of diseases as well as institutional change are subject to highly tactical considerations. Consequently, advocates of reform who feel tempted to understand this study as a guidebook on how to securitise a disease in which form must bear in mind that securitisation is not necessarily in the interest of the ‘best’ or most functional reform. Accordingly, advocates of systemic stability who understand the absence of securitisation as a suitable indicator for a state of ‘real’ security are advised to remember that “security / Is mortals' chiefest enemy" (Shakespeare, 1988: Act 3, Scene 5, Line 31).

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Annex 1: The Evolution of the Public Health Article in the EU Treaties

Table A-1-1: The Amendment of the Public Health Article in the Course of the BSE/TSEs Crisis[161]

Treaty of Maastricht	**Treaty of Amsterdam**	**Treaty of Nice**
1992 / 1993[162]	**1997 / 1999**	**2001 / 2003**
Art. 129	**Art. 152**	**Art. 152**
1. The Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lending support to their action.	1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.	1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.
Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education.	Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges by promoting research into their causes, their transmission and their prevention, as well as health information and education.	Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.
Health protection requirements shall form a constituent part of the Community's other policies.	[moved to 1.]	
	The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention. [taken from 1.]	The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.
	2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.	2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.
2. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.	Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.	Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.
3. The Community and the Member States shall foster cooperation with third countries and the competent international organizations in the sphere of public health.	3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.	3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.
4. In order to contribute to the achievement of the objectives referred to in this Article, the Council: - acting in accordance with the procedure referred to in Article 189b, after consulting the Economic and Social Committee and the Committee of the Regions, shall adopt	4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:	4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:
	(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;	(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(continued)

[161] Changes to the previous Treaty are tagged yellow.

[162] First year refers to the year when the Treaty was concluded, the second to the year when the Treaty entered into force.

(continued)		
	(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;	(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
incentive measures, excluding any harmonization of the laws and regulations of the Member States;	(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.	(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.
- acting by a qualified majority on a proposal from the Commission, shall adopt recommendations.	The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.	The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.
	5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.	5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood

Source: Own presentation.

Table A-1-2: The Amendment of the Public Health Article in the Course of the SARS Crisis[163]

Treaty of Nice	**Draft Treaty Establishing a Constitution for Europe**	**Treaty Establishing a Constitution for Europe**	**Treaty of Lisbon**
2001 / 2003	**2003**	**2004**	**2007 / 2009**
Art. 152	**Art. III-179**	**Art. III-278**	**Art. 168**
[…]	[…]	[…]	[…]
Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.	Action by the Union, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.	Action by the Union, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover: (a) the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education; (b) monitoring, early warning of and combating serious cross-border threats to health.	Union action, which shall complement national policies, shall be directed towards improving public health, preventing ~~human~~ physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.
[…]	[…]	[…]	[…]
2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.	2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.	2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.	2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.
			(continued)

[163] Changes to the previous Treaty are tagged yellow.

(continued)			
Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.	Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.	Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.	Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.
…	…	…	…
4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:	4. European laws or framework laws shall contribute to the achievement of the objectives referred to in this Article by establishing the following measures in order to meet common safety concerns:	4. By way of derogation from Article I-12(5) and Article I-17(a) and in accordance with Article I-14 (2)(k), European laws or framework laws shall contribute to the achievement of the objectives referred to in this Article by establishing the following measures in order to meet common safety concerns:	4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:
[…]	[…]	[…]	[…]
		(c) measures setting high standards of quality and safety for medicinal products and devices for medical use;	(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.
		(d) measures concerning monitoring, early warning of and combating serious cross-border threats to health.	*[deleted, extenuated in 5.]*
	European laws or framework laws shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.	Such European laws or framework laws shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.	*[moved to 4.]*
			(continued)

(continued)			
(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.	5. European laws or framework laws may also establish incentive measures designed to protect and improve human health and to combat the major cross-border health scourges, excluding any harmonisation of the laws and regulations of the Member States. It shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.	5. European laws or framework laws may also establish incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, as well as measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States. They shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.	5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.
[…]	[…]	[…]	[…]
5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood	7. Union action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.	7. Union action shall ~~fully~~ respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.	7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Source: Own presentation.

Annex 2: The Securitisation Degree of SARS Including the SARS-Related Written Questions from the European Parliament and Respective Answers

Table A-2-1: SARS-Related Written Questions and Respective Answers

07.11.03 EP+COM 2003/C 268 E/212	(European Parliament, 2003f)	EP Written Question of April 4, 2003: Preventive measures to combat SARS	+ +	o
		COM Answer of May 12, 2003: risks and measures	o	o
21.11.03 EP+COM 2003/C 280 E/174	(European Parliament, 2003g)	EP Written Question of May 6, 2003: Illegal immigration and the spread of the SARS virus	+	o
		COM Answer of June 10, 2003:[164] Reference to Council Conclusion 9328/03 (Council, 2003c), reference to ECDC preparations	o	o
21.11.03 EP+COM 2003/C 280 E/176	(European Parliament, 2003d)	EP Written Question of May 6, 2003: European-wide measures, creation of ECDC, airport checks	+ +	o
		COM Answer of June 10, 2003:[165] Reference to Council Conclusion 9328/03 (Council, 2003c), reference to ECDC preparations	o	o
21.11.03 EP+COM 2003/C 280 E/174	(European Parliament, 2003b)	EP Written Question of May 7, 2003: SARS prevention and control plan for the continent as a whole	+ +	o
		COM Answer of June 10, 2003:[166] Reference to Council Conclusion 9328/03 (Council, 2003c), reference to ECDC preparations	o	o
21.11.03 EP+COM 2003/C 280 E/176	(European Parliament, 2003e)	EP Written Question of May 13, 2003: coordinated EU response to SARS	o	o
		COM Answer of June 10, 2003:[167] Reference to Council Conclusion 9328/03 (Council, 2003c), reference to ECDC preparations	o	o
26.02.04 EP+CO 2004/C 51 E/131	(European Parliament, 2004k)	EP Written Question of May 13, 2003: urgent action to stop SARS, improve Schengen	+ +	o
		Council Answer of October 7, 2003: Reference to Council Conclusion 9328/03 (Council, 2003c)	o	o
26.02.04 EP+COM 2003/C 280 E/178	(European Parliament, 2003c)	EP Written Question of May 13, 2003: urgent action to stop SARS, improve Schengen	+ +	o
		COM Answer of June 10, 2003: Reference to Council Conclusion 9328/03 (Council, 2003c), reference to ECDC preparations	o	o
15.01.04 EP+COM 2004/C 11 E/233	(European Parliament, 2004l)	EP Written Question of May 16, 2003: WHO warning about H7N7 A virus	o [168]	o
		COM Answer of July 18, 2003:[169] risks and measures, reference to ECDC preparations	+	o

(continued)

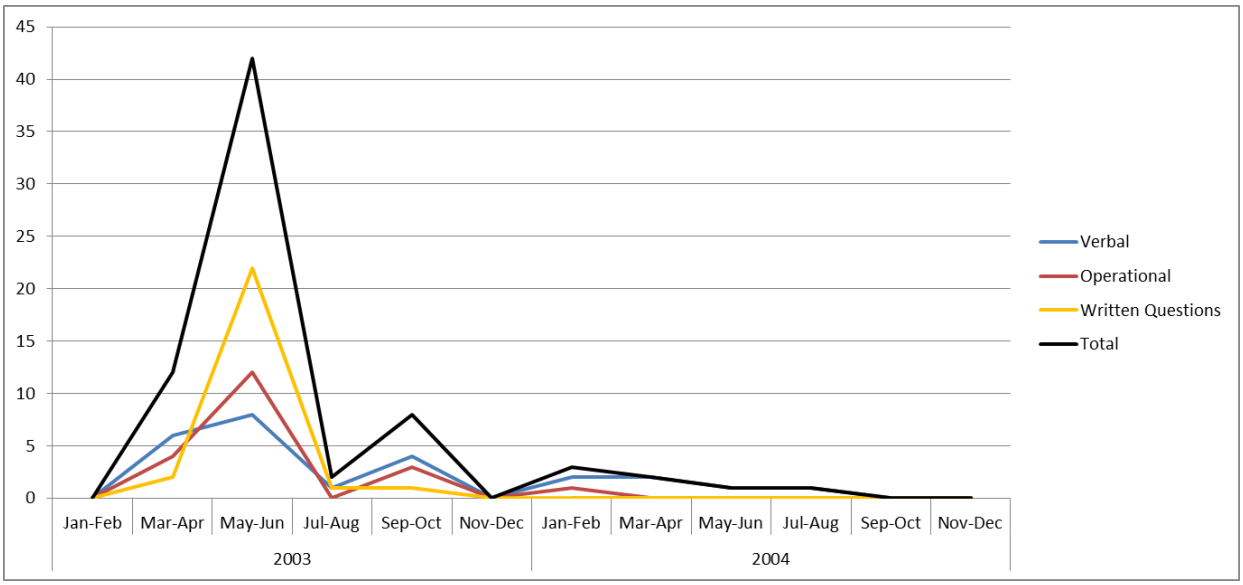
[164] Joint answer to written questions E-1521/03, E-1547/03, P-1604/03, E-1613/03 and E-1617/03.
[165] Joint answer to written questions E-1521/03, E-1547/03, P-1604/03, E-1613/03 and E-1617/03.
[166] Joint answer to written questions E-1521/03, E-1547/03, P-1604/03, E-1613/03 and E-1617/03.
[167] Joint answer to written questions E-1521/03, E-1547/03, P-1604/03, E-1613/03 and E-1617/03.
[168] The MEP question securitises infectious diseases in general and influenza in particular, but does not make reference to SARS. The answer by the Commission, however, also refers to SARS.
[169] Joint answer to written questions E-1651/03 and E-1657/03.

(continued)					
15.01.04	EP+COM	(European Parliament, 2004b)	EP Written Question of May 19, 2003: danger of imported SARS by air travel; lack of checks upon arrival in EU	+ +	o
2004/C 11 E/236			COM Answer of June 24, 2003:[170] risks and measures	+	o
15.01.04	EP+COM	(European Parliament, 2004m)	EP Written Question of May 19, 2003: Genesis of new diseases, preparations for a SARS epidemic	+ +	o
2004/C 11 E/235			COM Answer of June 24, 2003:[171] risks and measures	+	o
15.01.04	EP+COM	(European Parliament, 2004d)	EP Written Question of May 19, 2003: link between avian influenza and SARS	+	o
2004/C 11 E/234			COM Answer of July 18, 2003[172]: risks and measures, reference to ECDC preparations	+	o
15.01.04	EP+COM	(European Parliament, 2004a)	EP Written Question of May 26, 2003: Measures to prevent SARS in textiles	+	o
2004/C 11 E/262			COM Answer of June 27, 2003: goods from affected countries do not pose risk	o	o
08.04.04	EP+COM	(European Parliament, 2004j)	EP Written Question of May 28, 2003: SARS and airline air recycling	+	o
2004/C 88 E/379			COM Answer of 15 July, 2003: Reference to (CDNC, 2003f)	+	o
06.02.04	EP+COM	(European Parliament, 2004g)	EP Written Question of June 6, 2003: Air carriers and unemployment	o	o
2004/C 33 E/186			COM Answer of 14 July, 2003: Unprecedented crisis of air transport sector	+	o
06.02.04	EP+COM	(European Parliament, 2003a)	Written Question of June 25, 2003: SARS emergency: preventive measures needed?	++	o
2004/C 33 E/217			Commission Answer of July 15, 2003: disease contained, no additional measures needed	- -	o
27.03.04	EP+COM	(European Parliament, 2004h)	EP Written Question of September 23, 2003: Isolation units in hospitals	+	o
2004/C 78 E/0457			COM Answer of October 16, 2003: Competences and measures	o	o
27.03.04	EP+COM	(European Parliament, 2004i)	EP Written Question of January 20, 2004: EU prevention and response, changes since 2003	+ +	o
2004/C 78 E/0971			COM Answer of February 19, 2004: better preparedness, reference to ECDC preparations	- -	o

Source: Own presentation.

[170] Joint answer to written questions E-1658/03 and E-16589/03.
[171] Joint answer to written questions E-1658/03 and E-1659/03.
[172] Joint answer to written questions E-1651/03 and E-1657/03.

Diagram A-2-1: The Rise and Fall of the Securitisation Degree of SARS (2003-2004) including SARS-Related Written Questions from MEPs and Respective Answers



Source: Own presentation on the basis of the securitisation degree value assigned to the key documents listed in Table 6-2. and Table A-2-1.