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All Quiet on the Health Front?

A Historical Analysis of 55 Years of Public Health Policy Integration in the European Union

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Ever since the establishment of the European Coal and Steel Community with the Paris Treaty in 1952, the European Union and its predecessors have been involved in public health policy. This study investigates the mechanisms driving public health policy integration within the European Union by posing the research question '***Why does integration in the policy area of public health occur?***'. Aligned with this research question, the study pursues two primary objectives: first, to chronicle key occurrences of public health policy integration from 1952 to 2007, and second, to evaluate whether the concept of functional spillover and a crisis-driven approach can account for these integrative occurrences. In this time frame, 14 key integrative public health policy occurrences are identified. In line with the comparative-historical analysis research tradition, and through a qualitative, small-N comparative research design employing historical narratives and pattern matching as research methods, this study finds that functional spillover and exogenous shocks can effectively explain ten of these instances. Functional spillover is particularly effective in accounting for broader integrative occurrences, such as treaty changes. A crisis-driven approach, on the other hand, is better suited for issue-specific occurrences. Four occurrences, categorised as soft law and policy initiatives, could not be fully explained by these frameworks, highlighting the complexity of public health integration and suggesting that, while functional spillover and crisis-driven explanations provide valuable insights into EU public health integration, they are not exhaustive. By providing a comprehensive historical account of EU health policy integration and testing alternative explanations, this study contributes to a deeper understanding of the dynamics of European integration in the area of public health. The implications of this research are particularly relevant in the current political context, as the EU contemplates its future role in public health policy and with a possible European Health Union on the horizon.

Keywords: European Union, public health, integration, comparative-historical analysis, public health policy, neofunctionalism, Historical Institutionalism, historical analysis

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List of Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
BSE	Bovine Spongiform Encephalopathy
CHA	Comparative-Historical Analysis
CJEU	Court of Justice of the European Union
DG	Directorate-General
DG SANTE	Directorate-General for Health and Food Safety
DG SANCO	Directorate-General for Health and Consumers (*)
EC	European Communities
ECDC	European Centre for Disease Prevention and Control
ECJ	European Court of Justice (*)
ECSC	European Coal and Steel Community
EEA	European Economic Area
EEC	European Economic Community
EHU	European Health Union
EMA	European Medicines Agency
EP	European Parliament
EU	European Union
HI	Historical Institutionalism
HIA	Health Impact Assessment
HiAP	Health in All Policies
HIV	Human Immunodeficiency Virus

MS	Member State
NGO	Non-governmental Organisation
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2
SEA	Single European Act
TEC	Treaty on European Community
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
vCJD	Variant Creutzfeldt–Jakob disease
WHO	World Health Organization

S'il est une richesse de leur patrimoine national sur laquelle les peuples d'Europe ont veillé tout au long des âges, s'il est un bien précieux entre tous que chacun de nous s'efforce de sauvegarder et d'accroître sans cesse, pour lui et les siens, c'est bien la « santé ».

– Paul Ribeyre, 24th September 1952, proposing the establishment of a European Health Community

1.Introduction

The initial European Union ('EU') responses to the outbreak of SARS-CoV-2 in 2020 faced widespread criticism for being inefficient, slow, and generally hampered by bureaucratic obstacles (Brooks & Geyer, 2020:1058-1060, Gontariuk *et al.*, 2021 5-7). Much of the criticism of the EU's response arose from misconceptions about the EU's public health competences and the perception that the EU had failed to adequately support its Member States ('MS') in the face of existential threat (Nabbe & Brand, 2021:6). The pandemic, thus, revealed the weakness and fragmentation of EU powers in health, showcasing the Union's apparent unpreparedness to handle public health emergencies swiftly and effectively (ibid., Alemanno, 2020:721).

In the wake of these shortcomings, there have been increasing calls from citizens, the European Parliament, and NGOs for greater health powers at the EU-level (Guy, 2020:757-758, Guy, 2023:247). Supported by an initial request by the European Parliament's S&D party group and by heads of states and governments, a persistent proposal has been the establishment of a '*European Health Union*' ('EHU') (Guy, 2023:247). Despite the broad support from various stakeholders and despite the crisis context, the formation of such a union has not yet materialised. This has been commonly associated with MS reluctance to delegate health competences to the EU (Nabbe & Brand, 2021:6, Guy, 2023:257). This averseness of MS to relinquish further powers to the EU in the policy area of health has been a lasting trend, with unsuccessful calls for increased cooperation in health policy matters dating back to the 1950s (Nabbe & Brand, 2021:1).

The safeguarding of nation-state competences in the domain of health policy is often attributed to the political significance of social and welfare policies (de Ruijter, 2019:5-6). Public health and healthcare also possess "state building" capacities: the collectivisation of instruments to address health-related challenges is closely linked to a "civilizing process" wherein citizens of a nation-state come to regard healthcare as an expression of solidarity, typically delivered by the nation-state (ibid., 5-6). Concurrently, public health policy has a strong legitimising potential, corresponding to public and social imperatives that justify state control. Health policy, therefore, forms part of the material and symbolic resources of any government, which further explains the imperatives of MS to preserve health competences nationally (Guigner, 2004:96-97). Accordingly, public health policy has been referred to as the "least likely candidate" (Sindbjerg Martinsen, 2012 *in* Guy, 2023:250) for integration, with

some even calling into question whether a European health policy actually exists (Greer & Rauscher, 2009:53-54).

Considering the strong reluctance of Member States to cede powers in public health to the European Union, one might assume that EU health policy is either non-existent, or at most minimal. However, since the establishment of the European Coal and Steel Community, public health policy – ranging from occupational health to the mutual recognition of medical degrees – has steadily evolved and continuous to do so (de Ruijter, 2019:63). This raises the obvious question: *why does integration in health policy occur*?

1.1. Research Question, Objectives, and Relevance

Health policy of the European Union and its predecessors is a well-researched field. Over time, scholars have studied this policy area from various perspectives, including legal analyses (*see*, i.a., Hervey, Young & Bishop, 2017, de Ruijter, 2019), actor-centric explanations (*see*, i.a., Guigner, 2004, Brooks, 2012, Coggi & Hackbart, 2013, Brooks & Bürgin, 2021), case studies of specific pieces of health legislation (*see*, i.a., Krapohl, 2007, Greer, 2008, Geyer, 2011) or through integration theories (*see*, i.a., Lamping, 2005, Greer, 2006, Lamping & Steffen, 2009, Greer & Löblová, 2017). While some studies have provided descriptive historical accounts of EU health policy or have included chronologies as part of their research (*see*, i.a., Guy & Sauter, 2017, Palm & Wismar, 2018, Greer *et al.*, 2022), none have done so in a comprehensive and comparative manner, testing alternative explanations as to why health policy integration occurs.[1]

To address this gap in research and by assuming a historical perspective, the thesis aims to investigate health policy integration at the European Union-level, posing the research question ('RQ') ***'Why does integration in the policy area of public health occur?'***. Accordingly, the objectives of this study are to first compile a list of comprehensive accounts of key integrative occurrences in public health and then, to assess the causes of integration in health policy historically by testing alternative hypotheses. As such, the thesis has both ideographic and nomothetic aims – the comprehensive description of public health policy integration occurrences in the timeframe of **1952** to **2007** and the testing of alternative theoretical explanations of the causes of health policy integration. In the 55-year time span, the paper identifies 14 key integrative public health policy occurrences, i.e., happenings through which aspects of public health policy became at least partially regulated at the European-level when they before were within the competences of the nation-states.

To answer the research question, the paper employs a qualitative, small-N comparative research design, based on the comparative-historical analysis ('CHA') research tradition. This entails historical narratives as a primary research method, and pattern matching as a secondary method. The historical narratives-method organises primary and secondary data into objective accounts of historical occurrences – here, of the 14 key integrative public health policy occurrences. In a second step, theoretical concepts of two predominant theories –

[1] Brooks and Geyer (2020) compare EU health policy action post-COVID-19 with historical EU health action. The timeframe, however, is limited to 2000-2020 and the research focusses on a complexity perspective, not on integration.

neofunctionalism and functional spillover, and Historical Institutionalism and crisis-driven integration – are tested by means of pattern matching to assess whether they can explain why public health policy integration occurred in each of the integrative occurrences. In response to the research question, the thesis finds that in a majority of the 14 key occurrences, public health integration could be explained as an outcome of either functional spillover or exogenous shocks.

In the aftermath of the SARS-CoV-2 pandemic, health policy can be considered as having emerged as an increasingly politicised policy area (Guy, 2023:246-247). The COVID-19 crisis has also revealed significant gaps in the understanding of the involvement of the European Union in matters concerning health (Nabbe & Brand, 2021:6). In the context of a possible European Health Union on the horizon, this thesis seeks to provide a comprehensive historical account of EU health policy, an area that until recently has oftentimes been overlooked. By testing hypothesised explanations of integrative actions, particularly pertaining to health integration, this research further aims to contribute to the broader body of literature on European integration. As such, the findings of this paper do not only impact the understanding of health policy, and specifically, public health policy at the European-level, but also add to the general insight regarding the effects of integration and authority migration.

1.2. Structure of the Thesis

To systematically address the research question and to follow the research objectives, the thesis is organised into five chapters, including the introduction. The second chapter *'Health Policy, Integration, and the European Union'* outlines health policy in the EU, explores two possible explanations – neofunctionalism and Historical Institutionalism – as to why integration in health policy occurs, and identifies how key occurrences in public health policy integration can be determined. In the third chapter, the methodological framework of the thesis is introduced. The paper adopts a qualitative, small-N comparative research design adapted from the CHA research tradition, choosing historical narratives and pattern matching as its methods The following chapter – *'55 Years of Public Health Policy Integration'* – comprises two critical subsections. The first subsection provides a comprehensive, ideographic description of the 14 identified key occurrences. In a second step, the previously outlined explanations as to why health policy integration occurs are tested through pattern matching. The second subsection discusses, compares, and contrasts the results of the prior subsection. Finally, the fifth chapter, *'Not so Quiet Afterall.'*, summarises the findings of the thesis and identifies future research avenues. In

response to the research question as to why health policy integration occurs, the thesis finds that in a majority of the 14 key occurrences, public health integration can be understood as an outcome of spillover or exogenous shocks, including crises. Seeing, however, that four cases could not or only partially explained by the concepts, it is integral to recognise that there is no single overarching explanation for health integration.

1.3. ECSC, EC, or EU?

Given the historical focus of this thesis, it is essential to use historically appropriate and correct terminology for the European Union and its predecessors. Since its establishment in the 1950s as the ECSC, the European Union, as it is known in the present, has undergone significant changes in terms of membership, institutional structure, and the extents of its competences. To reflect these developments accurately and to ensure conceptual clarity, the terms used throughout the paper correspond to the historical periods discussed, specifically in the analysis chapter. This approach does not only ensure historical accuracy, but also aids in understanding the development of health policy within the broader trajectories of European integration and institutional development. Similar applies to institutional entities (e.g., European Court of Justice → Court of Justice of the European Union), specific pieces of legislation (e.g., Treaty Establishing the European Economic Community → Treaty Establishing the European Community), and articles of the Treaties (e.g., Article 129 EEC Treaty → Article 152 EC Treaty). When discussing secondary sources, the research adopts the terminology used in the literature, unless inappropriate to the context.

2. Health Policy, Integration, and the European Union

What is the definition of public health policy integration? And what types of explanations for integration in public health exist? This chapter addresses these questions. Accordingly, the chapter is divided into three sections. The first section outlines the present scholarly debates and issues of EU health policy, defining central concepts to the paper. In the second section, the concept of integration is defined, leading to a discussion of hypotheses explaining why integration in the policy area of health occurs. The section thereafter discusses how key occurrences in EU health policy integration can be determined and how these occurrences can be categorised.

2.1. Too Wide a Field?

Despite the obligations of the EU to ensure "high levels of human health protection" (Art. 168 TFEU) as outlined in the Treaties, there is no single, authoritative *European* definition of *public health*, *human health*, or *health* itself (de Ruijter, 2019:57; Heard-Lauréote, 2013:124). This absence of a conceptual definition reflects the general difficulties associated with establishing an all-encompassing and widely accepted conceptualisation of 'health' (de Ruijter, 2019:53). Emphasising the potentially varied political, normative, or social implications of adopting *one* definition of 'health', a selection of differing definitions of the term have been implemented.

In the context of the EU, the lack of an authoritative legal text defining the term 'health' has further been exacerbated by the concurrent use of 'human health' and 'public health' in Treaties and Directives (de Ruijter, 2019:55). Vos (1999) interprets this as referring to different aspects: while 'human health' should be understood as relating to the life and health of humans, 'public health' has as its objective the prevention of disease and ill-health (*in* de Ruijter, 2019:55-56). De Ruijter (2019) disagrees, stating that such a differentiation is not supported by the Treaties and by highlighting the interchangeable use of public and human health by the CJEU. Guy and Sauter (2017) identify another issue arising from the lack of a conceptual definition. Distinguishing 'public health' from 'healthcare', they discuss the combination and overlap of both concepts in the broader EU understanding of 'health'. Concurrently Guy and Sauter emphasise the importance of the context in which the term 'health' in EU documents is being

used to determine whether 'public health' or 'individual health' is meant. The interchangeable use of various health-related terms extends to academic research, in which seldomly the same terms are used.

The aforementioned ambiguity of health extends further to EU health *policy*. There is an ongoing scholarly debate regarding *whether a distinctive and cohesive EU health policy actually exists*. McKee *et al*. (2010) contend that while there is EU health policy, it is not possible to discern *one*, all-encompassing, and distinctively supranational EU health policy. Instead, what exists is more so a patchwork of disjointed, partially connected laws and policies that impact health to varying extents. Greer and Rauscher (2009) uphold a related argument, highlighting, however, that *no* EU health policy *in itself* exists as of yet, as EU health policy should be more so considered a byproduct of EU activities in other policy areas that may have an impact on health. Similarly, Guigner (2004) characterises EC health policy as a cross-cutting policy area, defined primarily by its intersectoriality. The intersectoriality of EU health policy is also identified by de Ruijter (2019), who further emphasises the ambiguity of current Art.168 of the Treaty on the Functioning of the European Union ('TFEU') and questions the effects of the policy mainstreaming provision embedded within it. According to de Ruijter the mainstreaming provision of Art.168 permits two possible interpretations: either EU health policy does not exist as an autonomous policy area, or *all* EU public policy should also be considered health policy.

As has been addressed previously, EU health policy is commonly divided into 'public health' and 'healthcare' policy (*see*, i.a., McKee *et al.*, 2010, Guy & Sauter, 2017, de Ruijter, 2019). This separation into two sub-policy areas is generally motivated by the differences in objectives, addressees, and legal bases. De Ruijter (2019) defines EU public health policy as policies that have as their objectives the management of collective health risks as well as the prevention of disease outbreaks (62-63). EU healthcare policy, on the other hand, relates to policies that govern the provision of medical care and individual health, and are generally justified by imperatives of the internal market (ibid., Greer, 2014:13-14). The differences between public health and healthcare policy become especially evident when considering treaty bases. An explicit treaty basis for public health policy was first introduced in Article 129 of the Maastricht Treaty. Currently, Article 168 TFEU functions as the central legal basis for actions in public health. Unlike public health policy, healthcare policy does not have a treaty basis (de Ruijter, 2019:78-79). Instead, the delivery of healthcare and healthcare systems are explicitly excluded from the competences of the EU (Art. 168(7) TFEU). As such, healthcare policy has

developed mainly through judgements of the CJEU – primarily in the Kohll and Decker cases, which clarified the applicability of internal market logics to healthcare (Greer & Rauscher, 2009:36-37, Greer *et al.*, 2013:1136-1138). Greer (2014) introduces a third sub-area – which he refers to as "faces of health policy" – of EU health policy. By reference to the introduction of the strengthened fiscal governance mechanisms and, particularly, the European Semester in the 2010s, Greer argues that the EU does not only shape health policy through public health and healthcare policy, but also through fiscal governance (2014:17).

Having presented the current and past academic debates surrounding EU health policy and having showcased the ambiguity and interchangeable use of different health concepts, it is integral to clarify the terms and concepts used in this paper. Reflected in the research question, the paper examines only integration in *public* health policy. This choice can be justified on two counts. First, the paper explores a time frame from 1952 – 2007. This time frame inherently excludes Greer's (2014) third sub-area of fiscal governance, which only emerged in the 2010s. A second reason relates to the different treaty bases, objectives, and modes of public health policy and healthcare policy. As has been mentioned, healthcare policy does not have an explicit treaty basis and has generally developed through private litigation, and CJEU judgements (de Ruijter, 2019:78-79). Given these differences, explaining why integration has occurred in the two sub-areas would require the usage of different hypotheses as well as key occurrences. As such, the thesis focuses on *public* health policy integration, defining public health policy, following de Ruijter's (2019) definition, as "[policy that] has the objective of managing collective health risks and preventing major disease scourges" (90). For future research inquiries it might be interesting to comparatively explore the similarities and differences between the reasons why public health and healthcare policy integration occur.

2.2. The A, B, C of Integration

Integration can take various forms and may be defined differently depending on the theoretical lens used. Schimmelfennig and Rittberger distinguish between three types of integration, two of which are relevant to the thesis. Here, *sectoral* integration is described as a process whereby policy areas become regulated, either partially or exclusively at the European level. A second type, *vertical* integration is defined as competences becoming shared across MS or delegated to supranational institutions (Schimmelfennig & Rittberger, 2006:74).

Taking Schimmelfennig and Rittberger's definitions of *sectoral* and *vertical* integration and in accordance with the objectives and research question of this paper, *public health policy integration* should therefore be understood as a process through which an aspect of health policy becomes regulated at the European level, or whereby the competences concerning said aspect become shared or delegated to European level institutions.

2.2.1. Neofunctionalism: Functional Spillover

As a theory of regional integration, neofunctionalism seeks to explore processes of political integration. Emerging in the mid-20th century, neofunctionalism focuses on explaining increasing levels of integration as well as the impact of supranational entities on these integration processes (Greer, 2006:135-137, Niemann & Schmitter, 2009:45-46). Neofunctionalism is often considered the predominant theory for explaining the phenomenon of health policy integration in the EU and has been widely applied in numerous studies (*see*, i.a., Greer, 2006, Geyer, 2011, Greer & Löblová, 2017, Brooks *et al*., 2023). One key theoretical component of neofunctionalism used to explain public health policy integration is the concept of *spillover*. Greer asserts that spillover should be considered the fundamental driver of EU health policy (*in* Geyer, 2011:588).

As an effect, spillover can be applied to explain why integration in one policy area might *spill over* to an adjacent policy area. Thus, spillover describes the mechanism through which integration in one policy area might generate functional pressures for integration in a different area (Niemann & Schmitter, 2009:49). Greer and Löblová (2017) outline two analytically separate types of spillover applicable to health policy integration, the relevant one to the thesis being *social spillover* (396-398). In the case of social spillover, integrative activities in one policy area might create unintended consequences, or issues, in society, which, in turn, increase pressures for European solutions to the problem (ibid., 396). To explain the effects of social spillover on public health policy integration, Greer and Löblová name the spread of Bovine Spongiform Encephalopathy ('BSE') through the development of a pan-European trade in livestock. To curb the outbreaks, pressures increased to introduce tighter regulations for farm animals (ibid.). The example of the spread of BSE and the introduction of new regulations, thus, showcases the effects of social spillover: an increase in trade in farm animals and less stringent regulations regarding animal farming led to an unintended consequence – the spread of a disease – which, in turn, increased pressures to solve and avoid similar problems in the future. As such,

a problem unintentionally caused by integrative activities is addressed through more integration. Despite using the term *social* spillover, the described concept resembles more so the more commonly used *functional spillover* (*see*, i.a., Guigner, 2004, Niemann & Schmitter, 2009, de Ruijter, 2019). Accordingly, in this research the term *functional* spillover is used.

Building on the established prevalence of functional spillover in explaining integration in EU health policy, this research adopts the effects of the concept as a potential explanation as to why integration in EU public health policy occurs. By adapting and combining the understandings of spillover from Greer and Löblová's (2017) and Niemann and Schmitter's (2009), functional spillover in this paper is defined as the mechanism through which integration in one policy area (X) might generate functional pressures for integration in a different area (Y). The operationalisation of functional spillover and how to test and identify whether spillover has occurred is further detailed in chapter ***3.2.1. Functional Spillover***. The following section introduces Historical Institutionalism, and the *crisis-driven approach* based on critical junctures as a rivalling explanation for health policy integration.

2.2.2. Historical Institutionalism: Crisis-driven Integration

A second theory for explaining EU public health policy integration is Historical Institutionalism ('HI'), which emphasises how past decisions shape present policy choices (Pollack, 2009:127-129). HI explores both continuity and change in institutional development, challenging the functionalist assumption that political institutions are deliberately designed (ibid., 127). To address questions of continuity and change, HI presents two central concepts, (i) *path dependency*, and (ii) *critical junctures* (Minogiannis, 2003:8-10). This paper focuses on the *crisis-driven approach*, rooted in the concept of critical junctures, which suggests that exogenous shocks or crises create opportunities for substantial institutional change.

Unlike neofunctionalism, HI has been less frequently applied to explain EU health policy (*see*, i.a., Minogiannis, 2003, Krapohl, 2007, Greer, 2008).

To explain the differences in the development of regulatory regimes for pharmaceuticals and foodstuffs in the EU, Krapohl (2007) makes use of the central HI concept of *critical junctures*. A critical juncture is defined as a period during which an exogenous shock creates opportunities for significant institutional change. Such a crisis can reveal the inadequacies of inefficiencies of existing institutions in fulfilling specific, functional tasks, hence opening a policy window

for substantial institutional reform (28). It is, however, important to emphasise that not every critical juncture necessarily leads to institutional change. Krapohl identifies the 1960s Thalidomide scandal as a crisis that prompted the harmonisation of pharmaceutical regulations in the EU (ibid., 36). As such, Krapohl showcases how exogenous shocks can serve as pivotal moments that shape the development and possibly the direction of health policy. Geyer (2011) further explores the impacts of crisis events, a crisis-driven approach, on health policy (590).

A crisis-driven approach, as outlined by Krapohl (2007) and Geyer (2011) provides a nuanced perspective on how public health policy develops in response to past crises. On this basis, a *crisis-driven approach*, adopted from the concept of critical junctures, is chosen in this study as a possible explanation as to why public health policy integration occurs. The broader concept of critical junctures was not adopted because it focuses on opportunities rather than the actual triggers for change. Similarly, as the research inquiry investigates integration, that is, a change in competences, using path dependency does not appear suitable.

Following Capoccia's (2016) understanding, an exogenous shock is defined as an external event, for example a major outbreak of a disease, affecting the EU. The contextualisation and operationalisation of exogenous shocks and of the crises-driven approach is outlined in chapter ***3.2.2. Crisis-driven Integration***.

2.2.3. Alternative Explanations

The prevalence of neofunctionalist and HI explanations in understanding the integration of health policy does not preclude the existence of alternative, less commonly employed perspectives. The following section provides a brief introduction and overview of two alternative explanations – (i) *networks and epistemic communities*, and (ii) *DG impact* – and clarifies the reasons for why they were not adopted as explanations.

Exploring the role of EU institutions in the Europeanisation of health policy, Heard-Lauréote (2013) discusses European Commission-funded networks and epistemic communities as the most influential drivers of Europeanisation and integration in health policy (123). Networks and epistemic communities are defined as national and European-level interest groups that promote and diffuse EU policy ideas, fostering policy discourse (ibid., 132). Through support from EU institutions, including the Commission and the European Parliament, health-related organisations are brought together in health communities, for instance the EU Health Forum,

to participate, advice, and actively shape EU health policy (ibid.). The importance of networks and epistemic communities in health policy integration is shared by Greer (2009), who highlights the consultative work networks and lobbying entities conduct, specifically influencing the Commission (24-25). As such, networks and epistemic communities impact health policy and integration actively through lobbying, policy diffusion, informal interaction with EU institutions, and through advisory activities.

Another alternative explanation of health policy integration focuses on the role and interactions of the Directorate-General concerned with health policy matters. While the Directorate-General for Health and Food Safety ('DG SANTE' formerly DG SANCO) is generally considered to be a "weak" DG, it has played integral roles in health policy integration, for example through the *Patient Mobility Directive* (COM(2008)414) (Greer, 2009:26-27, Greer & Rauscher, 2009:41-43). By building supra- and transnational coalitions with other DG and stakeholder networks, Lamping and Steffen (2009) contend DG SANTE to be a "policy entrepreneur" and "purposeful opportunist" in EU health policy, actively impacting health policy integration (1372-1374). Consequently, the proactivity of DG SANTE can be considered as a driver of EU health integration, specifically in healthcare policy.

Having showcased two alternative explanations for the continuous integration in EU public health policy, it is important to address why these perspectives were not adopted as general explanations in this study. This decision is based on two central reasons.

First, alternative explanations tend to be fairly issue-specific. For instance, the DG impact-approach, used in previous studies like Greer & Rauscher (2009) to explain the Patient Mobility Directive, focuses on the role and influence of DG SANTE, established only in 1999. This makes the approach unsuitable for analysing integrative occurrences prior to 1999. To ensure a systematic analysis of all occurrences in this study, broader theoretical explanations that *can* apply to all cases are necessary. A second reason concerns feasibility and theory-method synthesis. Some explanations, like the networks and epistemic communities-approach, require specific data sets, such as interviews with EU institution staff and stakeholders. Acquiring the necessary data is unfeasible, especially for occurrences that took place over 70 years ago. The research design of this study relies on historical narratives as its method, making certain alternative explanations impossible to test.

Considering the reasons why alternative explanations were excluded also motivates why the functional spillover-concept and the crisis-driven approach were selected for testing. Both are

broad explanatory constructs that, while possibly not suitable for every key occurrence, can be tested, nonetheless. Additionally, testing functional spillover and a crisis-driven explanation require similar data sets, for which comprehensive historical accounts appear suitable.

2.3. Integrative Public Health Policy Occurrences

The thesis has as its objectives to provide a comprehensive list of key integrative public health policy occurrences at the European-level and to test whether these occurrences can be explained through functional spillover or crisis-driven integration. *But what exactly is meant by integrative public health policy occurrences?*

Following Griffin's (1993) definition, an *occurrence* can be understood as "a distinguishable happening, one with some pattern or theme that sets it off from others, and one that involves changes taking place within a delimitated amount of time" (1096, *in* Lange, 2013: 44). Combining Griffin's definition of an occurrence with Schimmelfennig and Rittberger's (2006) concepts of *sectoral* and *vertical integration*, in this paper, an *integrative public health policy occurrence* can be conceptualised as "a distinguishable happening within a delimited time frame in which aspects of public health policy become regulated at the European institutional level or in which public health competences become shared or delegated to supranational institutions".

2.3.1. Looking Back: Determining Key Occurrences

Understanding the historical development of European Union health policy is integral for comprehending the mechanisms behind its integration process. Despite that importance, only few studies (*see*, i.a., Rosenkötter *et al.*, 2013, Guy & Sauter, 2017, Palm & Wismar, 2018) provide exhaustive timelines of EU and predecessor activities in health policy. Generally, the focus tends to lay more so on specific pieces of legislation, actor involvement, or present developments in health policy – even if chronological overviews of health policy developments are provided. Due to the limited number of publications outlining specific chronologies of important health-related developments, combining the findings of these publications appears viable.

In the light of Brexit, Palm and Wismar (2018) discuss the role of the EU in health policy, exploring how involvement in this policy area has changed throughout history. Listing 22 key occurrences in the timeframe of 1965 to 2017, Palm and Wismar provide a non-exhaustive overview of "milestones in the development of EU health policy" (2017:21). Using Palm and Wismar's list of developments in EU health policy as a basis, this paper adapted their chronology by contrasting the mentioned occurrences with other chronological overviews. One such timeline is provided by Rosenkötter *et al*. (2013). Rosenkötter *et al.* (2013), exploring which EU health policies have improved public health the most, present a comprehensive list of approximately 60 key EU activities organised into five groups dependent on the type of activity. Based on interviews and surveys Rosenkötter *et al*. rank EU health activities according to reported influence and importance.

While these publications provide lists of EU public health activities, the criteria leading to the selection of said activities are not specified. To avoid risks of selection bias and to ensure transparency and reproducibility of this study, outlining how cases were selected is crucial. This case selection-process was divided into three parts. First, an initial list of health policy occurrences from 1952 to 2007 was compiled, based on Palm and Wismar's (2018) and Rosenkötter *et al*.'s (2013) overviews. Through a thorough review of literature published on EU health policy, the list was extended to events not initially included by Rosenkötter *et al.* and Palm and Wismar. In a second step, any occurrences that did not explicitly relate to *public* health policy were removed. Third, occurrences were eliminated if they were not *integrative*. For an occurrence to fulfill this condition, it had to be possible to identify an integrative nature, i.e., a change in competences or level of regulation to the European institutional-level. This process reduced selection bias and ensured that chosen occurrences were relevant to the focus of the study.

Consequently, through a review of studies published on EU public health policy and by combining the key integrative public health policy occurrences discussed in these, this research identified 14 key occurrences in public health policy integration from 1952 to 2007. It is necessary to discuss why a time frame of 1952 to 2007 was chosen. Certain publications (*see*, i.a., Palm & Wismar, 2018) present later dates as the starting points of EU activity in public health policy. However, other scholars (*see,* i.a., de Ruijter, 2019) highlight that the 1952 Treaty of Paris, which established the ECSC, already referenced public health, for instance in Article 69(1). Hence, the 1952 Treaty of Paris is considered the baseline for integrative action in public health in this paper. Selecting 2007 as the end date of the investigated time frame can be justified

on two main grounds. First, 2007 marks the beginning of the Lisbon era of the EU, owing to the signing of the Lisbon Treaty. While the Treaty would only enter into force in 2009 it introduced significant changes to the institutional structure of the EU, which extended to public health policy. Second, there is an extensive body of research focussing on public health initiatives post-Lisbon Treaty. As to avoid redundancy, 2007 was chosen as the end year of this study.

Adopted from Brooks and Geyer's (2020:1063) and Rosenkötter *et al.*'s (2013) typologies, each of the 14 key occurrences can be classified as either (i) treaty changes, (ii) secondary EU law, (iii) soft law and policy initiatives, or (iv) changes in institutional structure. This classification helps in systematically analysing public health policy integration by introducing another avenue for comparison. Categorising key occurrences into different classes allows the identification of possible patterns, i.e., whether one explanation is better suited for a specific type of integrative occurrences than another. Applying the typology, four key occurrences were identified as treaty changes, two as secondary EU law, six as soft law and policy initiatives, and two as changes in institutional structure. A table of the key occurrences and their classifications can be consulted in the appendix.

3.Methodology

To investigate the research question of ***why integration in the policy area of public health occurs*** a qualitative small-N comparative research design – adapted from comparative-historical analysis ('CHA') – examining key integrative public health policy occurrences, is chosen. The chapter motivates this choice, outlines the research methods, *historical narratives*, and *pattern matching*, operationalises the theoretical concepts of *functional spillover* and *crisis-driven integration*, and discusses data collection as well as the associated methodological advantages and disadvantages.

Pertaining to theory, the research assesses the applicability of the concept of functional spillover and crisis-driven integration to explain why integration in public health policy occurred in 14 instances. The choice to test concepts from neofunctionalism and Historical Institutionalism is motivated by their prevalence in previous research examining health policy integration. Nonetheless, while both theoretical frameworks have been used to explore specific pieces of current legislation or policy developments (*see*, i.a., Greer, 2008), a comprehensive application to historical instances has not been tested.

The study is broadly based in its approach and research methods on the CHA tradition. Consequently, it shares certain key assumptions and concerns of CHA, including the importance of temporality and history, even to understand present developments, and the focus on systematic and contextualised comparison to explain outcomes (Mahoney & Rueschemeyer, 2003:10-12). CHA, while a research tradition and not a set of unified theories or methods, has also partially informed the choice in methods. Following the broader tenets of the CHA research tradition, this paper can be situated in a largely interpretivist framework. Interpretivism acknowledges that the natural and the social world are fundamentally different and emphasises that reality is inherently subjectively constructed (Halperin & Heath, 2017:40, 49-50).

3.1. Research Design

To investigate why public health policy integration occurs in the EU and its predecessors, the paper adopts a qualitative, small-N comparative research design based on the research tradition of comparative-historical analysis.

Small-N comparisons combine the possibility for detailed, in-depth analyses commonly associated with case studies with the advantage of a greater scope for contextualisation (Halperin & Heath, 2017:217-218). Unlike large-N comparisons, however, small-N comparisons offer less certainty in respect to the generalisability of the findings (ibid., 231). Similarly, given the fewer number of cases, careless case selection might introduce risks of selection biases. To avoid biases or cherry-picking, soundly justifying and motivating the choice of cases becomes integral (ibid., 218). Addressing the associated disadvantages, it is important to emphasise that a high internal validity is more so significant for the objectives of this paper than generalisability. The research question addresses a specific policy area, further narrowed down, and delimitated by an established time frame. As such, it is not the aim of this thesis to determine the general reasons as to why integration in the EU happens. Instead, the objectives are to ideographically present integrative public health policy occurrences and to test whether public health policy integration can be explained by functional spillover or a crisis-driven approach. To counter the risk of a selection bias, the paper addresses cases in a lengthy time frame, further motivated by the process and criteria for case selection outlined in chapter ***2.3.1. Looking Back: Determining Key Occurrences***. While these measures do not entirely remove the risk of an unintentional selection bias, the approaches greatly reduce the risk.

The choice to select a small-N comparative research design can be justified on two counts. First, and as has been established, the research inquiry follows the broader tenets and assumptions of the CHA research tradition. In comparative-historical analysis, comparative designs have a high prevalence. Similar applies to previous studies concerning public health policy in the EU (*see*, i.a., Greer & Löblová, 2017, Brooks & Geyer, 2020). Consequently, using comparative research designs is not only common in the research tradition, but also in the field of public health. A second motivation relates to the case selection. Using 14 cases, the number of selected cases is not extensive enough for an adequate large-N study. While this could be changed by increasing the number of cases, or the time frame under investigation, this would entail substantial changes in respect to the research methods. Seeing, however, that the research methods were chosen to align with the objectives of this paper, this does not appear viable. A similar reasoning explains why a case study-design was not considered.

3.2. Operationalisation

3.2.1. Functional Spillover

A key analytical concept of neofunctionalism, *functional spillover*, in this research is defined as the mechanism through which integration in one policy area (X) might generate functional pressures – incentives and conditions – for integration in a different area (Y). Adopting this definition is generally motivated by its analytical clarity and previous use in related literature (*see*, i.a., Greer & Löblová, 2017). Following the definition presented, the mechanism of functional spillover comprises three main components (i) *integration in policy area (X)*, (ii) *functional pressures*, and (iii) *subsequent integration in policy area (Y)*. Each component is defined and conceptualised below, followed by the operationalisation of the conditions necessary to identify functional spillover.

'Integration in policy area (X)' is understood as an activity through which aspects of a policy area become regulated at the European institutional level or through which competences become shared or delegated to supranational institutions. This integration must occur prior or concurrent to subsequent integration in policy area (Y). 'Functional pressures' are conceptualised as any type of reason, incentives, conditions, or pressure that might encourage an actor to perceive further integration as a necessity. This can for instance occur when integration in policy area (X) leads to issues or dysfunctionalities that are assumed to be resolvable only through subsequent integration (Bergmann, 2019:1256-1257). 'Subsequent integration in policy area (Y)' can be equated to any integrative public health policy occurrence Y_1.

Accordingly, for the thesis to successfully identify that public health policy integration (*subsequent integration in policy area Y*) has possibly occurred due to the effects of functional spillover, three conditions need to be met. First, it must be possible to identify a public health integration occurrence Y_1. As has been established, such an occurrence should be understood as a distinguishable happening within a delimited time frame in which aspects of public health policy become regulated at the European institutional level or in which public health competences become shared or delegated to supranational institutions. If this condition is not met, assessing the subsequent conditions becomes obsolete. As for the second condition, it must be possible to identify a second integration occurrence X_1 in a policy area X. Occurrence X_1 must have occurred *before* or *concurrent* to the public health integration occurrence Y_1. The

third condition pertains to whether integration occurrence X_1 has generated any functional pressures – incentives, conditions, issues, or dysfunctionalities – that can be identified as having led to occurrence Y_1. If all three conditions are fulfilled, it is possible to argue that public health policy integration might be a result of functional spillover.

3.2.2. Crisis-driven Integration

In accordance with Geyer's (2011) outlining of the approach, unpredictable crises – exogenous shocks – can play a central role in the development of public health policy in the EU (590). Krapohl (2007) similarly links exogenous shocks to opportunities for significant institutional change. In this context, a crisis-driven approach can be operationalised with two key concepts: (i) *exogenous shock*, and (ii) *resulting institutional change*.

An exogenous shock refers to a largely unpredictable external event that impacts an entity without being explicitly generated by the affected entity itself. In HI, exogenous shocks are typically understood as crises of some form (Capoccia, 2016:6-7). As such, for the purpose of this paper, an exogenous shock is defined as an external event, for example a major outbreak of a disease, affecting the EU or one of its predecessors. To ensure conceptual clarity, it is crucial to emphasise the *exogenous* nature of the shock. Unlike the functional pressures discussed in the context of functional spillover, the shock must be external to the entity and cannot be explicitly caused by it, distinguishing it from internal functional pressures. Institutional change, in this context, is understood as integrative public health activities at the European level.

Consequently, for a crisis-driven approach to explain an integrative public health occurrence, two conditions must be met. First, it must be possible to identify some form of institutional change. As per the conceptualisation of institutional change in this context, institutional change is equated to an integrative public health occurrence. Second, there must be an identifiable exogenous shock preceding or concurrent to the integrative occurrence. This shock should be external to the Union and work as a catalyst for the observed integrative occurrence. By systematically examining each case for these conditions, this approach might offer a clearer understanding of how crises can drive integration in public health policy.

3.3. Primary Method: Historical Narratives

In CHA, primary within-case methods are considered data producing methods, as they generate insight into the respective cases or phenomena that secondary methods rely on. Following the CHA tradition, any method that offers reliable evidence and data about the phenomenon under analysis can be used as a primary within-case method (Lange, 2013:55-56, Mahoney, 2003:337). A prominent primary within-case method is *historical narratives*.

In the CHA tradition, a narrative can be understood as "a sequential account […] of an [occurrence] or series of [occurrences] which organizes material chronologically to provide an overview of either what happened or the characteristics of some […] phenomenon"[2] (Lange, 2013:44). Following this definition, a narrative necessarily comprises two components, one or several *occurrences*, and *temporality*. An *occurrence* can be defined as "a noncomparable happening, that is, by definition distinctive to a single case" (Falleti & Mahoney, 2015:233). The second component of a narrative is *temporality*. Narratives present occurrences in a particular order by presenting how they unfold over time, additionally offering temporal orderings of sequences pre- and post-occurrence (Lange, 2013:44). Hence, in practice, the historical narratives-method entails constructing objective accounts of historical occurrences.

In this research, historical narratives is combined with evidence gathered from secondary sources. This choice can be justified on three counts. First, while it is common in CHA research to solely depend on historical data presented in secondary sources, there are only few historical accounts recounting the history of EU public health policy (Lange, 2013:55-56). Even less so for the early years of public health policy in EU predecessors. As such, it is not possible to only rely on previously published historical accounts. Second, and as to counter a commonplace criticism of comparative-historical research (*see* Goldthorpe, 1997 *in* Lange, 2013), depending overly on secondary evidence creates concerns in respect to potential biases, possibly leading to erroneous findings (Lange, 2013:144). Thus, establishing historical narratives by combining primary sources with evidence gathered from secondary sources appears as a solution to avoid reproducing possible biases of secondary sources. Thirdly, and evidently, however, the usage of primary data is strictly limited by the extent to which sources – specifically early EU predecessor sources – have been archived and made available (Kreuger & Neuman, 2006:435-

[2] In the original quotation, Griffin uses the term 'event' instead of 'occurrence'. For the sake of conceptual clarity, the term 'event' has been replaced with 'occurrence' by the author.

436). Primary source scarcity, hence, highlights the necessity to use a combination of secondary and primary sources (Møller, 2017:2340).

Consequently, for this paper the central objective of the historical narratives method is to organise information gathered about the 14 key integrative public health policy occurrences into objective accounts of each case. These narratives, then, build the basis for the application of the secondary method, *pattern matching*. As such, the historical narratives-method makes use of primary sources, for instance policy documents, white papers, or newspaper articles, in combination with secondary sources to provide an objective description of the occurrences and their circumstances.

3.4. Secondary Method: Pattern Matching

As has been outlined above, within-case analyses are necessarily multi-method affairs, combining one or several *primary* within-case methods with a *secondary* within-case method (Lange, 2013:43-43). Secondary within-case methods combine and synthesise evidence to arrive at a conclusion (ibid.). The most common secondary within-case methods used in the CHA research tradition include (i) *process tracing*, (ii) *causal narrative*, and (iii) *pattern matching* (Mahoney, 2003:360-361).

In this research paper, *pattern matching* is chosen as the secondary within-case method. This choice can be justified on three grounds when contrasted with the other methods. First, and in respect to the research question, this research has the aim of assessing why integration in health policy occurs in specific cases. As such, it is in the scope of the research to assess the applicability and viability of pre-existent theories and concepts to explain the phenomenon – that is, integration in the policy area of public health. Choosing *process tracing*, a technique that aims to uncover and explore potential causal mechanisms linking two related factors would not generate the type of evidence necessary to adequately answer the research question (Lange, 2013:48-49). Second, *causal narratives* is a method used to analyse complex processes, allowing for detailed and holistic analyses considering the impact of various factors as well as their sequencing and interactions (ibid., 45-46). While causal narratives appear suitable for the objectives of this paper due to its holistic approach, this research is more so focused on testing theories and less so on developing new hypotheses. *Pattern matching*, on the other hand, is a method mainly used to test whether patterns predicted by pre-existing theory match a set of cases (ibid., 53-54). Unlike process tracing or causal narratives, pattern matching is advantaged

at testing hypotheses. Two key disadvantage of pattern matching are that theories and concepts explaining the phenomenon under investigation need to exist, and that it offers limited insight into causal processes (ibid.). Given, however, that the objective of this paper is not to develop new causal processes but to evaluate the applicability of functional spillover and crisis-driven integration, these disadvantages can be largely disregarded.

Emphasising the overlap in aims of pattern matching and the research endeavour and the mismatch between the other two secondary methods, employing pattern matching as a secondary method appears as an appropriate choice.

3.4.1. Data Selection and Collection

The research employs a combination of primary and secondary sources. Beginning with primary sources, their main purpose is as evidence to establish the historical narratives for each of the key integrative occurrences. Primary sources collected include (i) *policy documents*, (ii) *statements and recollections of key figures*, and (iii) *news articles and press releases*. The primary within-case method, *historical narratives*, is used as a technique to establish objective narratives of historical events. As such, primary data is necessary to identify sequences of occurrences, and to ideographically describe these occurrences in-depth. Due to the scarcity of primary sources, the established historical narratives are supplemented by relevant secondary data when necessary.

The main disadvantage associated with primary sources is *data scarcity*. Addressing (historical) *data scarcity*, it appears evident that only a small fraction of data from the past survives to the present day (Møller, 2017:2338; Kreuger & Neuman, 2006:435-436). While issues of availability of reliable historical data are exacerbated the further in the past a historical event occurred, data scarcity already affects certain – if not most – time periods under analysis in this paper. This holds particularly true for primary source documents of early EU predecessors, namely the ECSC. To address data scarcity, this research makes use of secondary data when primary data is insufficient. It is also important to highlight that it is generally impossible as well as unfeasible to present a "full" picture of a past event. As such, having perfect information should be treated solely as an ideal type, which one, nevertheless, should attempt to approximate.

Due to the scarcity of primary sources, the thesis additionally uses secondary data. The function of secondary sources is twofold. First, secondary sources are used to complement primary sources in cases in which the amount of primary data is deemed inadequate. The second purpose is to inform the theoretical framework and to provide further insights for the analysis. As such, the main types of secondary sources used are (i) *research articles*, and (ii) *(edited) literature*. A common disadvantage of secondary data usage concerns the potential of the promotion and reproduction of researcher bias (Lange, 2013:144). To minimise the risk of reproducing such biases, a variety of secondary sources are used to ascertain that accounts of historical occurrences are as objective as possible.

4. 55 Years of Public Health Policy Integration

In line with the research question of this paper – ***Why does integration in the policy area of public health occur?*** **–** the analysis is set out to present ideographic historical narratives of key integrative public health policy occurrences and to examine these cases through the lens of functional spillover and a crisis-driven explanation. Hence, the analysis aligns with the two central objectives of the thesis, that is (i) to generate a comprehensive chronology of key integrative public health policy occurrences of the EU and its predecessors between 1952 – 2007, and (ii) to test whether these occurrences can be explained by theoretical concepts of functional spillover and crisis-driven integration. Accordingly, the analysis is organised into two sections.

The first section presents the ideographic accounts of the 14 key integrative public health policy occurrences, including a description of the baseline – i.e., 1952. The historical narratives are followed by a discussion examining why the chosen occurrences should count as key occurrences. These discussions form the basis for the application of functional spillover and the crisis-driven approach, as both require as their primary condition that the occurrence can be identified as integrative, as outlined in chapter ***3.2. Operationalisation***.

In the second section the findings of the analysis are briefly discussed. Special attention is given to certain key occurrences, such as *'Europe Against Cancer'* or *"Together for Health"*, that could *not* be explained through spillover or exogenous shocks. This is followed by a critical examination of the analysis.

A table summarising the results of the analysis can be found below.

Key Occurrence	Date	Functional Spillover?	Crisis-driven?	Alternative?
Treaty of Rome	1958	Yes		
Directive 65/65/EEC	1965		Yes	
Community Programmes of Research on Medicine and Health	1978	Yes		
Single European Act	1987	Yes		
'Europe Against Cancer' Programme	1987		Partial	Yes
Directive 89/381/EEC	1989		Yes	
Maastricht Treaty	1993	Yes	Yes	
Communication on the Framework for Action in the Field of Public Health	1993	Partial		
Amsterdam Treaty	1999		Yes	
DG SANCO	1999	Yes	Yes	
EU Public Health Framework Programme	2003		Partial	
European Centre for Disease Control and Prevention	2004	Yes, combined with crisis-driven	Yes, combined with functional spillover	
'Health in All Policies'	2006	Yes		
White Paper "Together for Health"	2007			Yes

Table 1. *Overview of the findings, assessing the applicability of the theoretical explanations.*

4.1. 1952: Setting the Scene

The foundation of EU action in the field of public health policy can be traced back to 1952. The earliest involvements of the European Coal and Steel Community in health policy occurs with the coming into force of the Treaty of Paris, which introduces provisions for the health and safety of steel workers (de Ruijter, 2019:63). Coming into force in 1952, Article 69 of the Treaty establishing the ECSC addresses concerns of social security and non-discrimination (Art. 69(4)) and establishes the first public health provision, restricting the freedom of movement of workers on the basis of general public health concerns (Art. 69(1)). These provisions in Article 69 highlight the dual importance of maintaining high public health standards and protecting

workers' rights and demonstrate health and safety as being primary objectives (COM(93)559, 1993:5).

Apart from the introduction of the first public health provision in the Paris Treaty, 1952 also marks the inception of the idea of a "European Health Community". In September 1952, French Minister of Public Health and Population Paul Ribeyre proposes the establishment of a European Health Community in the Council of Ministers (Ribeyre, 1952). To match the objectives of the European Coal and Steel Community, Ribeyre suggests common products and medicines standards, shared research and resources, and integrated training. The proposal is declined by the ministers (Greer, 2009:13).

Consequently, 1952 presents the baseline for any later integrative public health activities.

4.2. 1958: The Treaty of Rome

The 1957 Rome Treaty, which came into force in 1958, establishes the European Economic Community and introduces several provisions relating to public health (Heard-Lauréote, 2013:124). Notably, Articles 36, 48(3), and 56(1) of the Treaty establishing the European Economic Community ('EEC Treaty') are of special interest, as they set out further restrictions to the free movement of goods and workers on accounts of public health (de Ruijter, 2019:64). Article 118 encourages, furthermore, the cooperation of Member States in social questions, with a particular emphasis on occupational health and safety (EEC Treaty).

Explaining the Treaty of Rome

As a Treaty, the Rome Treaty counts, following the established typology, as *treaty changes*. Before testing whether functional spillover or a crisis-driven explanation can explain the inclusion of public health references in the Treaty, it is necessary to assess why the Treaty should be considered as a key integrative public health policy occurrence. This is motivated by two reasons. First, and while the Treaty did not introduce a formal public health competence, it extended Community action, nonetheless. The expansion can be exemplified by the introduction of Article 118, which encourages the Commission to facilitate MS cooperation in the social field. Second, the Treaty included indirect references to public health objectives, namely the "accelerated raising of the standard of living" (*see*, i.a., Art. 2 EEC Treaty) (COM(93)559, 1993:43). This had not been done to a similar extent in the Treaty of Paris. Having identified the Treaty of Rome, and in particular the introduction of certain Articles (i.a.,

Art. 36, 48(3), 118) as an integrative public health policy occurrence, condition one of the neofunctionalism and HI-test is fulfilled.

The Treaty of Rome serves as a classical example of functional spillover. This can be exemplified on the inclusion of Article 36 EEC Treaty. Article 36 specifies Article 30 and 34, which prohibit quantitative restrictions on imports between MS. A total prohibition of such measures will evidently lead to problems, for example on grounds of public security concerns. As such, Article 36 allows for certain exceptions to Article 30 and 34, including, specifically protection of human health as one such reason. An example of this is the, albeit rejected by the ECJ, British ban on poultry imports in 1981, which was linked to concerns of importing Newcastle disease (McKee *et al*., 2010:250). Consequently, the inclusion of Article 36 follows the traditional logic of functional spillover: integration (Article 30) leads to potential problems, which creates pressures for further integration (introduction of Article 36).

4.3. 1965: Directive 65/65/EEC

The first Directive addressing matters of public health is the Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products ('Pharmaceuticals Directive') (COM(93)559, 1993:44). Using Article 100 of the EEC Treaty as its legal base, the Directive outlines comprehensive rules regulating the production and distribution of medicinal products. The preamble emphasises that the primary objective of the Directive is to safeguard public health by ensuring that medicinal products are safe and effective for consumers. The Directive establishes clear guidelines for the authorisation of medicinal products, namely through competent authorities in the MS. Articles 5 and 11 specify that authorisation might be refused, suspended, or revoked if medicinal products are harmful under normal conditions of use or lack therapeutic efficacy. Additionally, the Directive standardises the labelling and packaging of such products, as outlined in Article 13 (Art. 13 ff.). Standardisation aims to provide consistent information to consumers and providers, facilitating identification and verification of products. In 1989, its scope was extended by Directive 89/381/EEC, which is discussed below.

Explaining Directive 65/65/EEC

Following the adopted typology, Directive 65/65/EEC can be categorised as *secondary EU law*. In the preamble of the Directive, it is stated that the protection of public health is central

objective of Directive 65/65/EEC. At this point, there is no formal public health competence or legal basis however, which is why Article 100 of the EEC Treaty is used instead. This implies a clear extension of activities in the field of health, despite the absence of a formal competence. It is also the first Directive that directly addresses health objectives. Consequently, Directive 65/65/EEC should be considered as a key integrative public health policy occurrence.

A crisis-driven explanation is suitable to explain the enactment of Directive 65/65/EEC due to the proximity to the 1961 Thalidomide scandal (Hervey & McHale, 2004:285). Thalidomide, a medication, was used in the late 1950s and early 1960s as a treatment for morning sickness in pregnant individuals. Thalidomide's harmful effects on unborn children led to stillbirths and thousands of children suffering from life-threatening deformities (EMEA/543524/2007, 2008:1). This scandal was caused by inadequate safety testing, particularly in pregnant individuals, and lacking regulations regulating how drugs should be tested (de Ruijter, 2019:65-66). As such, the rules concerning production and distribution outlined in Directive 65/65/EEC can be understood as an explicit response to the Thalidomide scandal as well as the absence of prior legislation regulating the pharmaceutical market. Consequently, the introduction of the Pharmaceuticals Directive matches the predictions of a crisis-driven explanations, as an exogenous shock – the Thalidomide scandal – led directly to policy changes.

4.4. 1978: First Community Programmes of Research on Medicine and Health

Beginning in 1974, MS of the EEC commit themselves to extending joint research endeavours, aiming to introduce joint public health and medical research (Backer, 1986:241, COM(86)549, 1986:3). On the basis of Commission proposals for a Council Decision, in 1978, the Council of Ministers adopts its first two Community programmes for research on medicine and health (OJ No. C 208, 31.8.1977). The first programme is adopted in February, and the second in July of 1978 (P-16-78, 1978:1, P-84-78, 1978:1). Given that at this point the Treaties have not conferred any specific powers to the EEC to address health and health research, the research programmes are based on Article 235 TEC, which allows the adoption of appropriate measures when considered necessary for the operation of the common market (78/167/EEC, 1978:1). By establishing the Community research programmes, the Commission aims to coordinate research in MS between 1978/79 and 1980/81 in seven distinctive research areas. These areas include,

i.a., "attempted suicide as a public health problem" or "registration of congenital abnormalities" (ibid.). Both research programmes are based on initiatives and proposals made by a Commission member, supported by the Committee on Medical Research and Public Health. The programmes include participation by all MS and invite non-member countries. Financing is split between participating states and the Community budget, in which the Community finances coordination costs (ibid.).

Taking 'registration of congenital abnormalities' as an example, the research is to be conducted within three years, from 1978 to 1980. Here, Community action is justified by highlighting that the number of cases of congenital abnormalities is not high enough in any participating nation-state alone to produce satisfactory research at the national level. This motivates Community-scale efforts as to generate statistically valid data and requires standardisation procedures for the registration of medical data between participating states (P-16-78, 1978:3). The first research programmes adopted in 1978 would prove successful in creating closer European collaboration in health research and in improving the efficiency of national research, paving the way for further research programmes beginning in 1982 (Backer, 1986:241).

Explaining the 1978 Community Research Programmes

Following the typology, the first 1978 Community research programmes are classified as *soft law and policy initiatives*. As a first step in testing whether functional spillover or a crisis-driven explanation can be applied to the case, assessing why the occurrence should count as a key integrative occurrence is necessary. The 1978 Community research programmes can be understood as integrative occurrences on three counts. First, they present the first instance of coordinating health and medical research at the Community-level (COM(86)549, 1986: 5). While joint Community research programmes had already been established in other research areas, for instance in agricultural research, the 1978 programmes were the first to extend Community activities to public health research. Prior to these programmes, medical and health research consisted of national research programmes comprised of a large number of small research projects lacking cooperation. Second, through coordinating research efforts between MS and between MS and third countries, the programmes also encouraged harmonisation and standardisation of research practices. Before the Community research programmes, existing national research methods differed widely between MS, reducing the usability of collected data and findings (ibid.). A third reason relates to the Community-added value of the 1978 programmes. The programmes responded to collective health needs, that is, researching public

health-related matters that affected most MS. The programmes contributed also to the strengthening of the Community's social and economic cohesions (ibid., 9, COM(93)559, 1993:41). Consequently, the 1978 research programmes indicated a shift in regulatory activities to the Community-level.

Functional spillover can provide an explanation as to why the 1978 research programmes were adopted. This is generally substantiated by the explanations offered in the Commission proposal. Apart from the Community-added value outlined above, the preamble of the proposal specifies that the Council has conferred the task to the Community institutions to ensure the gradual coordination of national policies in science and technology (OJ No. C 208, 1977:2). This is further confirmed by a report by the European Parliament, which highlights that "[t]hese actions were elaborated on the basis of criteria and considerations involved in the implementation of gradual coordination between the research organizations of the Member States […]" (PE 50.488, 1977:9) and by the Bulletin of the EC, stating the programmes to have the objective of "gradually [coordinating] national research activities in this sector at Community level […]" (Bull. EC 6-1977:20). As such, the 1978 programmes can be considered the direct results of earlier integrative occurrences, in particular deepened integration in research activities between MS, to further the coordination of national research at the Community-level.

4.5. 1987: Single European Act

The Single European Act ('SEA'), signed in 1986 and coming into force in July 1987, presents the first major revision of the founding treaties of the European Communities and expands the Community's competences in new areas, including social and health policy (Ludlow, 2014:227-229). For health policy, SEA establishes the competence to legislate on health policy-related matters connected to the internal market (Greer, 2006:138). Central in this context is the introduction of Article 100a EEC Treaty[3]. Subject to qualified majority voting in the Council, Article 100a allows the adoption of public health protection measures when addressing the functioning and the establishment of the internal market (de Ruijter, 2019:69). This is further specified by Article 100a(3), which commits the Commission to take a high level of protection as a base when proposing single market legislation that might have an impact on matters

[3] Now Article 114(3) TFEU.

relating, among others, to health and safety (Geyer, 2011:592-593, Art.18 SEA). The Single European Act also supplemented the EEC Treaty by introducing Article 118a[4], which states that MS are to foster improvements in working conditions, specifically addressing health and safety of workers (Guy & Sauter, 2017:23, Art.21 SEA). Further impacting public health policy is Article 130r EEC Treaty. Article 130r introduces public health protection as an objective of environmental policy, stressing that Community action relating to the environment should also contribute to protecting human health (Art.25 SEA, COM(93)559, 1993:10, Van der Mai & Waddington, 1998:132-133).

Explaining the Single European Act

The Single European Act can be categorised as *treaty changes*, following the typology. Identifying the SEA as a key integrative occurrence in public health policy appears evident. Through the introduction of Article 100a EEC Treaty, the Community was granted the competence to adopt public health protection matters if connected to the functioning of the internal market. Article 130r formalised public health protection as an objective of Community activities in environmental policy. Consequently, the SEA promoted the indirect extension of competences in health policy as well as the formalisation of public health protection as an objective of Community action, albeit only in environmental policy.

Similar to the Rome Treaty, the inclusion of health-related articles in the SEA can be explained through functional spillover. The SEA had as one of its expressed objectives the establishing of the internal market, as stated in Article 13 SEA. Deepened economic integration, as through the internal market, might, however, lead to potential unintended consequences, for instance for public health. As such, the inclusion of Article 100a through Article 18 SEA allows for the handling of such matters. The importance of including articles that allow to react to unintended consequences of deepened economic integration can be exemplified by Directive 89/381/EEC, regulating medicinal products of human origin, and based on Article 100a EEC Treaty. The Directive is discussed below. Consequently, functional spillover applies to the extent that increased economic integration (as set out in Art.13 SEA) can lead to unintended consequences. To address these consequences, even in a preventative manner, further integration is needed. This is exemplified, here, by the introduction of Article 100a, through Article 18 SEA.

[4] Now Article 153 TFEU.

4.6. 1987: 'Europe Against Cancer'

In the same year as the coming into force of the Single European Act, the first European public health programme was introduced: '*Europe Against Cancer'*. The programme is initiated in 1985 by the European Council of Heads of States and Governments, which adopts an opinion outlining the main objectives of a comprehensive programme in 1986. On the basis of this opinion, the European Commission develops the 1987 – 1989 action plan 'Europe Against Cancer'[5] (COM(95)356, 1995:1). The programme plays a significant role in European legislation against smoking, leading to several proposals for Directives in the field of smoking prevention in 1987 to 1989 (ibid., 25). 'Europe Against Cancer' is also one of the first health-related cooperations of the EC with the World Health Organization (ibid., 33, COM(93)559, 1993:31). The action plan contains 75 actions in the areas of prevention, information, health education, training, and research and has as its objective to reduce the cancer mortality by 15% between 1987 and 2000 (COM(86)717, 1986:8). Owing to the fact that there is no legislative public health basis at that point, the programme is generally based on the Treaty establishing the EC (de Ruijter, 2019:73-73).

Explaining 'Europe Against Cancer'

The 1987 'Europe Against Cancer' programme – categorised as *soft law and policy initiatives* – should be considered as an integrative key occurrence in public health policy for several reasons. First, 'Europe Against Cancer' is the *first* public health programme instigated by the European Communities. Its success set a precedent for subsequent public health initiatives, including the 1991 'Europe Against AIDS' programme as well as a follow-up cancer programme, thereby establishing a framework for Community-level interventions in public health issues (COM(93)559, 1993:10). Second, the 75 actions proposed in the programme contained a wide range of public health activities, ranging from information campaigns to training for healthcare professionals. The programme also included legislative proposals specifically targeting tobacco advertising and consumption, illustrating the proactivity of the European institutions even in the absence of a formal public health competence. As such, most of the activities proposed by the programme had never been proposed by Communities in public

[5] COM(86)717 'EUROPE AGAINST CANCER' PROGRAMME – Proposal for a plan of action, 1987 to 1989 including a proposal for a Council Decision on informing the general public and the training of members of the health professions.

health to this extent. Finally, the programme marked a fundamental moment in the Communities' approach to public health, showcasing a shift towards integrated efforts among its MS. Consequently, the success of the initiative demonstrated the potential for collective action to address significant public health concerns shared by all MS (COM(93)559, 1993:10-11).

Neither functional spillover nor a crisis-driven explanation provides a convincing rationale for why public health integration occurred in the case of 'Europe Against Cancer'. Through the lens of functional spillover, there is no clear prior integrative event that would have created functional pressures for the initiation of the programme. There is a truly weak case to be made for a crisis-driven explanation. In 1986 the Chernobyl nuclear accident occurred, which led to a major release of radioactive material into the atmosphere (PE 581.972, 2016:1). COM(86)717 takes note of this accident when addressing protection against carcinogenic agents, particularly radioactivity and ultraviolet radiations (1986:20). Actions for the protection against ionising radiations, related to Chernobyl, are also outlined (ibid., 22). Despite this connection and the fact that the Chernobyl accident did increase public awareness of cancer, it appears far-fetched to argue that the initiation of the entire programme can be linked to the incident (de Ruijter, 2019:72). Therefore, while a crisis-driven approach might account for specific aspects of the program, it cannot fully explain the initiation of the programme *per se*.

A possible alternative explanation of the creation of the programme is offered in literature (*see* Guigner, 2004, Greer, 2009, McKee *et al*., 2010). Guigner contends that 'Europe Against Cancer' was set up primarily due to the personal commitment of the French President Mitterrand, possibly driven by his own cancer diagnosis (2004:110, McKee *et al*., 2010:240).

4.7. 1989: Directive 89/381/EEC

In 1989, Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma is enacted. Extending the scope of the aforementioned Directive 65/65/EEC, the Directive is a significant piece of legislation for Community action in public health (de Ruijter, 2019:71-72). In absence of a public health legal basis, the Directive is based on Article 100a of the EEC Treaty, which, introduced by the SEA, allows for the adoption of measures, including in public health, when

addressing the functioning of the internal market. As such, the Directive is motivated both by the special nature of medicinal products derived from blood, specifically its potential to spread infectious diseases (Art. 3(1)) as well as by the risks that disparities in laws and regulations between MS may cause for the trade in medicinal products (DIR 89/381/EEC). Directive 89/381/EEC addresses two key areas: (i) *authorisation procedures* (i.a., Art. 4(1)), and (ii) *safety* (i.a., Art. 3(1)).

Interestingly, the Directive only applies to *medicinal products* derived from blood and human plasma. This explicitly excludes whole blood, blood plasma, or blood cells from the measures outlined in the Directive (Art. 1(2)). This exclusion can be explained as being due to the absence of a public health legal basis. If *whole blood* had been included in the Directive, this would have entailed the commoditisation of blood and parts of the human body, which was ethically difficult to justify (de Ruijter, 2019:71-72, Hervey & McHale, 2004:345). The commoditisation of blood is further countered by the inclusion of Article 3(4) which states that blood and plasma for the production of medicinal products should originate from voluntary and unpaid donations.

Explaining Directive 89/381/EEC

Directive 89/381/EEC, categorised as *secondary EU law*, should be considered a key integrative public health policy occurrence on two counts. First, the Directive is an early example of using Article 100a EEC Treaty to pursue public health-related policy objectives through internal market legislation. This is further underlined by the exclusion of whole blood as to not categorise blood as a commodity. Second, as an extension of Directive 65/65/EEC, the Directive exemplifies the extension of Community competences in public health to a new area. Prior, blood products had been solely regulated at the national level. Later Directives, including Directive 2002/98/EC would be based on the extensions created by Directive 89/831/EEC.

A crisis-driven explanation of Directive 89/381/EEC appears compelling. In the 1980s, the first AIDS-cases were reported in MS, leading to the adoption of the 'Europe Against AIDS' programme in 1984. With increasing numbers of AIDS-cases in the Community, public concern rose. Concurrently, several contamination scandals occurred in which transfusions containing HIV- or hepatitis C-contaminated blood were administered, infecting thousands (de Ruijter, 2019:71, Hervey & McHale, 2004:345). The introduction of Directive 89/381/EEC and the involvement of the Community appears as a direct response to these scandals. This can be further substantiated when considering Article 3(1) of the Directive, which emphasises the prevention of the transmission of infectious diseases as an objective.

4.8. 1993: The Treaty of Maastricht

A cornerstone of Community activities in public health are the treaty changes brought by the Treaty of Maastricht. Coming into force in 1993, the Treaty of Maastricht (the Treaty on European Union, 'TEU') amends, among other Treaties, the Treaty Establishing the European Economic Community and introduces the first proper public health competence through the inclusion of Article 129. In Title II of the Maastricht Treaty, 'Provisions amending the Treaty Establishing the European Economic Community with a View to Establishing the European Community', Article G 38) presents how Article 129 should be included. Article 129(1) introduces that the Community should contribute to ensuring high levels of human health protection by encouraging cooperation between MS. It further specifies that Community action should be particularly directed towards the prevention of diseases by promoting research as well as information and health education. Article 129(1) also forms the basis for public health mainstreaming, emphasising that health protection should be considered in all other Community policies. Paragraph (2) outlines the role of the MS and the Commission, stating that MS ought to coordinate among themselves, allowing the Commission to promote initiatives. Article 129(3) extends this cooperation between MS and the Community to third countries, including competent international organisations. In paragraph (4), the Council's role is described, allowing the Council to adopt measures facilitating the achievements of the objectives outlined in the Article (TEU, Art. G 38)). Public health is also addressed in the amended Article 3(o), which emphasises that activities of the Community shall include contributions to the attainment of high levels of health protection (TEU, Art. G 3)).

Explaining the Maastricht Treaty

Using the established typology, the Maastricht Treaty can be categorised as *treaty changes*. This Treaty, and more so, the introduction of Article 3(o) and 129, represents a significant integrative public health occurrence, as the Treaty did not only introduce the first public health competence, but also established a clear legal foundation for Community actions in this area. While public health activities at the Community level had previously occurred, partially without a legal basis or based on objectives pursuant to the functioning of the internal market, Article 129 provided the Community with a proper public health competence on which future actions could build on. Examples of later actions using Article 129 as their basis include the 1993 Framework for Action in the Field of Public Health ('COM(93)559'), which is discussed below. Similarly,

Article 3(o) formally recognised the attainment of a high level of health protection as a Community activity, solidifying public health as an established competence.

The inclusion of public health articles in the Maastricht Treaty can be explained by both functional spillover (*see*, i.a., Pritchard, 1994, de Ruijter, 2019) and a crisis-driven approach (*see*, i.a., Hervey & McHale, 2004, Stein, 2014, Fischhut & Greer, 2017). From a crisis-driven perspective, the emergence of infectious diseases in the period before the development of the Maastricht Treaty, in particular HIV/AIDS, can be seen as an exogenous shock leading to the introduction of public health provisions. This is substantiated by the view of MS that certain health issues could no longer be addressed solely within national borders, particularly with the rise of new communicable diseases (Hervey & McHale, 2004:73-74). Likewise, Fischhut and Greer (2017) contend that MS willingness to transfer competences in health to the Community was a direct result of infectious disease outbreaks (321). Stein, an official of the German Health Ministry and Head of the EU Health Policy Unit, corroborates this, noting that the introduction of public health articles was in response to the Community's inability to effectively react to emerging health challenges (2014:9). The mention of "prevention of disease, in particular major health scourges" in Article 129(1) further reinforces this interpretation.

On the other hand, a functional spillover explanation highlights how the introduction and completing of the Single Market through the SEA created unintended consequences for public health (de Ruijter, 2019:74, Pritchard, 1994:10). The Single Market increased mobility, which exposed disparities in health care and heightened demand for convergence in health and social policies as a consequence. The created functional pressures could not be addressed without a proper legal basis (Pritchard, 1994: 10). Pressures, particularly for public health, were also created due to the political changes in Central and Eastern Europe, predominantly in the context of a widening Community with the ambitions of establishing the European Economic Area ('EEA') (ibid.). Such a widening would necessitate stricter legislation for disease prevention, as increased trade and mobility would also facilitate the spread of infectious diseases (de Ruijter, 2019:74).

Consequently, the introduction of public health articles in the Maastricht Treaty can be explained by functional spillover as well as a crisis-driven explanation. For functional spillover, the completion of the Single Market and the ambitions of extending the Community through the establishment of the EEA created pressures for a public health article. According to a crisis-driven explanation, the emergence of new communicable diseases, in particular HIV/AIDS, might have functioned as an exogenous shock necessitating an explicit public health legal basis.

4.9. 1993: Framework for Action in the Field of Public Health

In November 1993, the first Commission Communication on the Framework for Action in the Field of Public Health ('COM(93)559') is published. It presents the Commission's proposal for advancing the Community's work in the policy area of public health to meet the objectives outlined in the TEU, particularly in Article 129. Consequently, the Communication is based on the newly introduced Article 129 and Article 3(o). The Communication consists of two parts: (i) *Background to Public Health Policy*, and (ii) *European Community Approach* (COM(93)559, 1993:1c-1d). The first section outlines the main health-related problems in MS as well as expected trends in public health (ibid.). The second chapter sets out the scope for Community action. It specifically addresses critical public health concerns such as AIDS and cancer, recognising these areas as priority areas for Community action. COM(93)559 proposes a range of Community activities to target these issue areas, including the enhancement of research and surveillance systems, the provision of financial assistance, the creation of information networks or the adoption of action programmes (ibid., 16-17, Guy & Sauter, 2017:29). By setting out priority areas and proposed actions, COM(93)559 has the objective of formalising and establishing a coherent and comprehensive framework for Community activities in public health, aligned with the requirements of Article 129.

Explaining the Framework for Action in the Field of Public Health

Following the typology, the Framework for Action in the Field of Public Health can be categorised as *soft law and policy initiatives*. COM(93)559 should be considered as a key integrative public health policy occurrence for two main reasons. First, it serves as the first comprehensive framework for public health action. Building on Article 129, it further formalises the role of the Community by outlining potential activities in public health. Second, the progress achieved through this framework set a precedent for subsequent Community health initiatives, including the 2003 – 2007 EU Health Programme, which is discussed later.

COM(93)559 clearly articulates the reasons behind the framework's implementation, citing concerns such as an aging population, the emergence of new diseases due to environmental changes, and increasing population mobility (COM(93)559, 1993:3). Notably, the framework emphasises the implications of increased mobility, as the intermingling of populations also heightens the risk of communicable diseases and the potential for illicit drug use. The

Communication explicitly links increased mobility to the "coming into effect of the single market,", underscoring the Single Market as a variable impacting population mobility (ibid.).

Consequently, the introduction of the framework can be partially explained as an outcome of functional spillover. The establishment of the Single Market, particularly through the SEA, led to an increase in population mobility, which, in turn, increased the potential for the spread of communicable diseases and drug abuse. Hence, the framework's proposed actions to mitigate these risks can be seen as a response to the unintended public health consequences of the Single Market. Although functional spillover may not fully account for other aspects of the framework, such as measures addressing the trend of an aging population, it does provide a plausible explanation for the inclusion of actions aimed at controlling infectious diseases and reducing drug abuse.

4.10. 1999: The Amsterdam Treaty

Signed in 1997, the Amsterdam Treaty amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts comes into force 1999. Central to public health policy in particular is the extension of Article 152 (renumbered, ex. Article 129). There are three significant differences between Article 152 and Article 129. First, Article 152(1) strengthens the public health mainstreaming-clause by emphasising that public health protection shall be ensured in the definition and implementation of all Community policies and activities. In contrast, the Maastricht Treaty only stated that health protection requirements should form a constituent part of other Community policies. Similarly, paragraph (1) of Article 152 introduces that Community action shall complement national policies, while in Article 129 it solely emphasised the encouragement of cooperation between MS. Another change concerns Article 152(4), which outlines the role of the Council in public health policy. According to Article 152(4)(a) and (b) the Council may adopt measures to set high standards for the quality and safety of substances of human origin, including blood and blood derivatives and its powers are also extended to veterinary and phytosanitary fields. These specifications are absent in Article 129. Article 152 also introduces a new paragraph (5). Paragraph (5) explicitly excludes the organisation and delivery of healthcare and medical services from Community competences by stressing that Community action shall respect MS responsibilities.

Changes affecting public health are also made to Article 95 (renumbered, ex Article 100a). Paragraph (8) is introduced, which states that when a MS raises specific problems concerning

public health in a field that has been subject to harmonisation measures, the MS must bring this to the attention of the Commission. The Commission shall immediately examine whether it is necessary to propose appropriate measures.

Explaining the Amsterdam Treaty

In accordance with the typology, the Amsterdam Treaty can be categorised as *treaty changes*. The Amsterdam Treaty and in particular the changes to Article 152 and Article 95, stand out as pivotal integrative public health occurrences for two main reasons. First, the extensions of Article 152 to include, for instance, matters of safety of substances of human origin (Art. 152(4)(a)) represents a significant extension of Community competences. This is especially notable given that previous Directives (*see* DIR 89/381/EEC) were unable to regulate blood and human organs due to the absence of a legislative basis. A second reasons concerns the strengthening of the public health mainstreaming-clause (Art. 152(1)), which mandates the cross-sectoral integration of public health concerns into other Community policies. Consequently, this clause ensures that potential health implications are considered even in policies not directly addressing public health.

There is broad consensus in literature (*see*, i.a., Van der Mai & Waddington, 1998, Guigner, 2004, Hervey & McHale, 2004, Greer, 2006, Geyer, 2011) that the changes introduced in the Amsterdam Treaty are best understood through a crisis-driven lens. Two exogenous shocks appear as particularly relevant: (i) the blood contamination scandals of the 1980s, and (ii) the BSE crisis. These crises played a significant role in public health becoming a major issue in the run-up to the Amsterdam Treaty (Heard-Lauréote, 2013:125).

During the 1980s, several high-profile scandals emerged involving blood transfusions contaminated with HIV and hepatitis C (Van der Mei & Waddington, 1998:137). These incidents led to increased public demand for stricter regulation of blood and blood products. However, at that time, the Community lacked specific public health competence concerning blood and could only legislate health matters through Single Market legislation established by the SEA. Regulating blood under this framework would have entailed the commoditisation of blood and human body parts, raising significant ethical concerns (de Ruijter, 2019:71-72, Hervey & McHale, 2004:345). Consequently, the Community was unable to enact comprehensive regulation of blood, choosing instead to legislate only medicinal products derived from blood, as seen in Directive 89/381/EEC. The inclusion of Article 152(4)(a), which would allow the regulation of whole blood, is, thus, widely considered as a response to these

incidents and the shortcomings of the Community to legislatively address them (Van der Mei & Waddington, 1998:129-130, 137, Hervey & McHale, 2004:79).

The BSE crisis represents another significant exogenous shock influencing the amendments to the public health article (Guigner, 2004:109). Discovered first in British cattle in 1986, the consumption of BSE-infected meats was linked in 1996 to Variant Creutzfeldt–Jakob Disease ('vCJD') in humans (Fodor, 1998:250, Hervey & McHale, 2004:354). The Community's failure to effectively manage the BSE crisis, particularly after the link between vCJD and BSE-contaminated beef became apparent, severely undermined confidence in the Community's health protection systems. This also led to the European Parliament launching an inquiry into the failure of the Community to protect its citizens (Hervey & McHale, 2004:348, Heard-Lauréote, 2013:125). The EP's active role during and after the BSE crisis is also believed to have attributed to the strengthening of Article 152 in the Amsterdam Treaty (Merkel, 2015:4-5). Consequently, the modifications to the public health article in the Amsterdam Treaty, particularly the inclusion of veterinary concerns in Article 152(4)(b), can be considered to be a direct result and response to the BSE scandals (Van der Mei & Waddington, 1998:137). This perspective is further substantiated by Article 95(8), which now requires MS to inform the Commission when identifying health issues within previously harmonised policy areas – as for example in agriculture.

4.11. 1999: DG SANCO

In 1999, the Directorate-General for Health and Consumers ('DG SANCO', since 2014 known as 'DG SANTE') is established (Clemens *et al*. 2017:597). Prior to the creation of DG SANCO, the European Commission did not have a dedicated Directorate-General specifically designed to address public health matters. Instead, health issues were the competence of the Directorate for Health and Safety at Work, based in the former DG V (Guigner, 2004:110). This Directorate primarily focussed on developing occupational safety standards rather than addressing broader public health concerns (ibid., 111). The Maastricht Treaty, which introduced an explicit public health competence for the Community, led to a change in titles of the Directorate to *Public* Health and Safety at Work. However, this did not yet entail a substantial shift in focus towards public health issues. During the restructuring of the units of the Commission, the responsibility for public health matters was transferred to the former DG XXIV, dealing with consumer affairs. In 1997, DG XXIV was renamed to DG Consumer Policy and Consumer Health Protection,

reflecting a gradual shift in focus (ibid.). The most significant transformation occurred under the Prodi Commission in 1999, when DG Consumer Policy and Consumer Health Protection was restructured and became the Directorate-General for Health and Consumer Protection, DG SANCO. The creation of DG SANCO implies the merging of responsibilities from several existing DGs, including DG XXIV on consumer protection, feed and animal policies from DG Agriculture, food policies from DG Enterprise, and public health policies from DG Employment (Clemens *et al*., 2017:596).

Explaining DG SANCO

The establishment of DG SANCO, categorised as *changes in institutional structure*, should be considered a key integrative public health policy occurrence on two grounds. First, by creating a separate Directorate-General for health matters, scattered competences for differing aspects of public health were moved from several non-health related DGs into one central DG. This integration ensured that public health policies were more coherent, efficient, and effective, exemplified by the Patient Mobility Directive (COM(2008)414) or the EU Health Programme proposed by DG SANCO (Rosenkötter *et al*., 2013:7). Second, the historical circulation of authority of public health between different DGs leading to the creation of DG SANCO mirrors the development of the policy area of public health at the Community level. With the introduction of the public health competence in the Maastricht Treaty, and the subsequent strengthening in Amsterdam, public health became a policy area deserving of its own Directorate-General.

On that basis, the restructuring of health competences leading to the establishment of DG SANCO can be explained as a case of functional spillover. When a public health competence was established in the Maastricht Treaty, and reaffirmed by the Treaty of Amsterdam, this also entailed the conferring of specific obligations to the Community. To adequately manage these responsibilities, a proper Directorate-General, designed to address health concerns, became necessary. This is substantiated primarily by the tasks conferred to DG SANCO. Article 152(1) of the Amsterdam Treaty, through the reinforcement of the public health mainstreaming-clause, restated the Community obligation of health impact assessments ('HIA') for all Community policies. Accordingly, HIA became a central task of the DG (Greer, 2006:146-147, McKee *et al*., 2010:235-236). As such, functional spillover appears suitable to explain the creation of DG SANCO: treaty changes, including the Maastricht and specifically the Amsterdam Treaty, established new obligations – pressures – for the Community in public health. To handle these responsibilities, in particular the assessment of the impact of other Community policies on

public health, further integration, the establishing of a DG centred around health, was chosen as a solution.

It should be noted that certain scholars (*see* Guigner, 2004, Ryś & Ptak-Bufkens, 2024) attribute the creation of DG SANCO to the mismanagement during the BSE-crisis. Following a crisis-driven explanation, the BSE crisis created pressures to separate public health matters from economic and commercial issues, encouraging the creation of a designated health DG (Ryś & Ptak-Bufkens, 2024:132). As such, Guigner (2004) contends that the BSE crisis and the politicisation of public health as a result of the crisis led to the reorganisation of the DGs, including the creation of DG SANCO (111).

4.12. 2003: Public Health Framework Programme

Based on Decision No 1786/2002/EC[6], the first Public Health Framework Programme (2003 – 8) is introduced in 2003. As its enabling instrument, the Decision structures the Framework Programme according to general and horizontal strands, breaking with the vertical and disease-based approach of prior health programmes (Guigner, 2004:113). The Framework Programme uses Article 152 of the Treaty establishing the European Community as its legal basis, stating that the Community has to play an active role in public health by taking actions that cannot be taken by individual MS, in accordance with the principle of subsidiarity (Decision 1786/2002/EC, 2002). Clause (5) of the preamble of the Decision emphasises the need for a new health strategy, citing new Treaty provisions and the advent of new health challenges as justifications (ibid.). To address these challenges, Article 2(2) outlines the general objectives of the Framework Programme (ibid.). These are improving information for the development of public health, enhancing capabilities to react rapidly to threats to health, and tackling health determinants through health promotion and disease prevention. In order to pursue the outlined objectives, Article 3(2) sets out Community actions and activities, including activities related to monitoring and rapid action systems, related to legislation, on health determinants, on consultation, knowledge, and information, and on the promotion of coordination of NGOs at the European level (ibid.). The outlined actions are to be implemented through Community-level support for activities in cooperation with the MS (McKee *et al*., 2010:241).

[6] Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008).

Explaining the Public Health Framework Programme

Categorised as *soft law and policy initiatives*, the Public Health Framework Programme represents a key integrative public health policy occurrence for two primary reasons. First, while the Framework Programme was not the Community's first public health programme, it marked a significant shift in approach. Earlier programmes (*see*, i.a., 'Europe Against Cancer') were focussed on specific health determinants or diseases. In contrast, the Framework Programme adopts a horizontal approach, emphasising broad public health objectives instead of particular diseases. This shift underscores a more comprehensive strategy at Community-level. The second reason relates to the Treaty revisions. As discussed in the preamble of Decision 1786/2002/EC, the Framework Programme is, i.a., adopted in view of the new Treaty provisions introduced by the Amsterdam Treaty. This incorporation of new competences into the Framework Programme signifies the practical implementation of the extended competences of public health at the Community-level.

The necessity for a new health strategy is clearly specified in the preamble of its enabling instrument, Decision 1786/2002/EC, similar to the 1993 Framework for Action in the Field of Public Health (COM(93)559). Clause (5) of the Decision emphasises recent treaty revisions and emerging health challenges as the underlying reasons for the strategy. A crisis-driven explanation can account for the inclusion of certain actions, in particular rapid reaction systems as outlined in Article 3(2)(a) (Hervey & McHale, 2004:82). According to Hervey and McHale the introduction of such rapid reaction system was a direct reaction to 9/11 and the subsequent anthrax incidents (ibid.). The crisis-driven approach is further supported by the Annex to Decision 1786/2002/EC, which explicitly mentions measures to "counter health threats from […] sources in emergency situations, including those relating to terrorist acts," (Decision 1786/2002/EC, 2002:2.4). Similarly, during the second reading of the Decision by the European Parliament, amendments to Article 3(1) were justified on the grounds that "[t]he Council's reference […] is vaguely worded, particularly given the obvious threats to health from *terrorist acts*" (Report - A5-0420/2001, emphasis added). Commissioner for Health and Consumer Protection, David Byrne, also confirms this perspective, stating that "[a]s recent events have shown, mechanisms need to be in place to ensure that the EU is able to respond effectively and in a coordinated way to potentially serious threats to public health" (Byrne, 2001:3). Consequently, a crisis-driven explanation can be used to partially explain the Framework Programme, particularly the inclusion of rapid reaction systems: the exogenous shocks of 9/11

and the anthrax attacks functioned as a catalyst, prompting the introduction of specific measures set out to address such threats.

4.13. 2004: European Centre for Disease Control and Prevention

In 2004, the European Centre for Disease Control and Prevention ('ECDC') is established. The ECDC is an independent agency for risk assessment, preparedness, and capacity-building (Greer & Löblová, 2017:400, Regulation 851/2004/EC, 2004). The agency is established through Regulation No 851/2004/EC. Article 3(2) outlines the missions and tasks of the agency, which generally revolve around the collection and evaluation of scientific data, the provision of scientific opinions and assistance, the communication of current and emerging threats from communicable diseases, the exchange of expertise and best practices, and the coordination of relevant bodies.

Community action in communicable disease control predates the creation of the ECDC. First references to disease control are already made in the 1952 Treaty of Paris, in which Article 69(1) limits the freedom of movement on grounds of public health concerns. With the Maastricht Treaty, communicable disease control and prevention become explicitly named as Community objectives through Article 129(1), emphasising that Community action shall be taken to prevent "major health scourges". In the 1990s, some MS consider creating a specific agency set out to combat communicable diseases, particularly due to their prior experiences with AIDS (Greer & Löblová, 2017:401). Instead of an agency however, Decision 2119/98/EC[7] formalises the creation of a network for epidemiological surveillance and control of communicable diseases in Europe. This intergovernmental body consists of competent MS bodies with the objectives of ensuring epidemiological surveillance and functioning as an early warning and response system for the control and prevention of communicable diseases (Decision 2119/98/EC, 1998:(1)). In 1999, a Commission-financed reports assessing the quality of communicable disease control coordination finds numerous weaknesses in the Community's ability to respond to communicable disease threats, particularly emphasising gaps and stark divergences between MS (Greer & Löblová, 2017:401, McKee *et al.*, 2010:251-252). The

[7] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.

report gives new impetus for the debate of how to increase Community communicable disease control – whether through strengthening existing networks or by creating an independent agency (McKee *et al*., 2010:252).

Explaining the ECDC

Categorised according to the typology as *changes in institutional structure*, the creation of the ECDC in 2004 can be considered as a key integrative public health policy occurrence on two counts. While the Community had been active in communicable disease control prior to the establishment of the ECDC, the creation of an independent and specialised agency formalised and centralised Community competences in public health. Second, creating the ECDC also signified an expansion of Community competences by shifting regulatory tasks revolving around communicable diseases to the Community-level. This becomes particularly visible when considering the prior decision to create an intergovernmental body – the network for epidemiological surveillance – in the same public health policy area.

The establishment of the ECDC can be best explained when combining both functional spillover and crisis-driven explanations. Functional spillover can be used to explain the context leading to the creation of the ECDC. Since the 1990s, some MS were interested in establishing closer cooperation in communicable disease surveillance, possibly through the creation of a designated agency. The political climate, at that time, however, was unfavourable for the creation of another institution and, instead of an agency, networks for epidemiological surveillance and control of communicable diseases were established through Decision 2119/98/EC (Greer & Löblová, 2017:404-401). Following the creation of such networks, the Commission financed research to evaluate the Community's ability to respond to communicable diseases in 1999. The report found substantial gaps and divergences between MS. One critical finding addressed disease surveillance, which is dependent on national systems. The report made note of outbreaks, which, even if detected, were not notified to neighbouring MS (McKee *et al*., 2010:252). While the Commission evaluation gave impetus to a debate as to best respond to the weaknesses in disease surveillance, a consensus existed that the existing networks were to be strengthened in response to the report (ibid., Greer & Löblová, 2017:401). The developments up to this point can be explained by functional spillover: integration in disease surveillance occurred through the setting-up of surveillance networks. These networks, and the national bodies they relied on, were deemed inadequate, creating pressures for further integration. A crisis-driven explanation can explain the subsequent developments, finally leading to the creation of the ECDC. The anthrax attacks in 2001, and the

emergence of the severe acute respiratory syndrome ('SARS') in 2003 led to a drastic change (McKee *et al.*, 2010:252-253, Fischhut & Greer, 2017:322). As a response, particularly to the rapid global spread of SARS, the Commission presented a proposal for a Community agency focused on infectious disease control in 2003. Understood as a sign of urgency, the proposal was passed in the first reading of the EP and the Council, creating the ECDC in 2004 (Fischhut & Greer, 2017:322). The importance of the SARS outbreak for the creation of the ECDC is further substantiated in a speech given by Commissioner David Byrne, who stated that "Sars was a 'wake-up call' for Europe to get better prepared and to substantially enforce cooperation at an EU-level" (EU news, 2003:37).

Consequently, functional spillover can explain the developments up to the Commission report, while a crisis-driven explanation can account for the drastic changes, leading to the creation of the ECDC.

4.14. 2006: 'Health in All Policies'

Under the Finnish Council Presidency in 2006, the 'Health in All Policies'-approach ('HiAP') is introduced. The approach is outlined and formally legitimated as part of European policy in Council Conclusion 16167/06. HiAP is a policy-related strategy, aiming to complement disease prevention and health promotion activities by addressing health determinants that are controlled in policy areas other than health (Puska & Ståhl, 2010:320). As such, it addresses the intersectoral nature of public health by encouraging other sectors to consider potential impacts on health and to implement health-related policies (ibid.).

Prior to the formal adoption of the HiAP-approach in 2006, the commitment of considering the impact of non-health policies on public health had been introduced with the public health mainstreaming-clause in Article 129 of the Maastricht Treaty, later affirmed by Article 152 of the Amsterdam Treaty (de Ruijter, 2019:74-75). The first inclusion of the idea of protection of human health as a cross-sectoral issue occurred, however, already in the SEA, in which Article 100r set out that Community action addressing the environment should also contribute to the protection of human health. In response to the obligations in public health conferred to the Community through the Maastricht and subsequent Amsterdam Treaty the Directorate overseeing health policy prepared annual reports between 1995 and 1999 assessing the effects of other Community policies on public health. In 1999, the Directorate shifted its focus from health impact assessments to also proposing concrete actions for mainstreaming health matters

in key Community policies (Puska & Ståhl, 2010:322). In the second half of 2006, the Finnish Council Presidency chose HiAP as the main public health theme of its presidency, justified by three concerns. These reasons included the contention that Community policies were not considering health properly, that the Community policy-making system was not using available structures efficiently, and that implementation shortcomings had occurred in how health was integrated in other Community policies (ibid.).

In preparation for the introduction of the HiAP-approach, a conference on HiAP was held in Finland in September 2006. Council Conclusion 16167/06 adopts some of the objectives and findings of the conference. Conclusion 16167/06 addresses, with reference to the conference, i.a., that central health determinants influenced by Community policies should be identified and monitored, including the evaluation of the health impacts of the most significant policies. Policies with overlapping health objectives could benefit from intersectoral cooperation and collaboration. This is also emphasised in the request that health determinants-related objectives ought to be included in all Community policies. Lastly, an improved population health status would have positive impacts both for the economy as well as for general social development (Council Conclusion 16167/06, 2006:4-5). Apart from endorsing the findings of the conference, the Conclusion also emphasises the obligation of ensuring a high level of health protection in all Community activities, as determined by Article 152 of the Amsterdam Treaty, including that health and wellbeing of Community citizens should be considered important values per se (ibid., 2-3). The Conclusion further incentivises MS, the European Parliament, and the Commission to take actions that facilitate the inclusion of the HiAP-approach. Addressing the Commission, the Council requests, i.a., the Commission to consider the inclusion of HiAP in its new Health Strategy and to ensure the continuing reporting of current Commission practices in health impact assessments (ibid., 6-7).

Explaining 'Health in All Policies'

The introduction of the 2006 'Health in All Policies'-approach can be categorised as *soft law and policy initiatives* and should be assessed as a key integrative public health policy occurrence on two counts. First, the adoption of the approach renewed focus on the public health mainstreaming-clause established by Article 152 of the Amsterdam Treaty. The objectives set out in the Council Conclusion furthermore formalised, affirmed, and institutionalised the methods by which public health mainstreaming was to be implemented by the Community institutions. As a result, HiAP would be included as a guiding principle of the first European Community health strategy – "Together for Health" – discussed below. Second, the recognition

of public health promotion and protection not merely as objectives of specific public health policies but as a concern of non-health policy areas signals an increasing level of integration, as public health began to be recognised as a cross-sectoral matter.

HiAP can be understood as an outcome of functional spillover. The approach reinforced the public health mainstreaming-clause initially introduced in Article 129(1) of the Maastricht Treaty and subsequently reinforced in Article 152(1) of the Amsterdam Treaty. As such, Article 129(1) and Article 152(1) obligated the Community to consider and assess the health implications of other Community policies. The Finnish Presidency, which introduced HiAP, justified this initiative by pointing to prior shortcomings in the integration of health considerations into non-health Community policies (Puska & Ståhl, 2010:320). This is further substantiated by the accompanying Council Conclusion 16167/06, which outlines how MS and Community institutions are to actively incorporate HiAP (2006:6-7). Consequently, HiAP can be explained through the lens of functional spillover: integration in public health through the inclusion of the mainstreaming-clause in the Treaties led to implementation shortcomings (functional pressures). In response to these pressures, further integration – the introduction of the 'HiAP'-approach – was proposed as a solution.

4.15. 2007: "Together for Health"

In 2007 the European Commission publishes a White Paper "Together for Health: A Strategic Approach for the EU 2008 – 2013" ('COM(2007)630'), introducing a cross-policy framework, and outlining shared health values, challenges, and potential solutions. The White Paper is complemented by a Commission Staff Working Document ('SEC(2007)1376').

The White Paper sets out a coherent framework for Community activities in the field of public health. As such, it is the first comprehensive Community health strategy and is valid until 2013, after which a review will take place (COM(2007)630, 2007:3). The health strategy is structured according to four principles and three strategic objectives. Furthermore, implementing mechanisms for cooperation, and measures to reinforce the 'Health in All Policies'-approach and to increase the visibility of public health at the Community-level are outlined (ibid.). The four principles include (i) *shared health values*, (ii) *"Health is the Greatest Wealth"*, (iii) *Health in All Policies*, and (iv) *strengthening the EU's voice in global health* (ibid., 3-7). Each principle also presents actions to be pursued. The three strategic objectives included in the health strategy concern fostering good health in an aging Europe, the protection

of citizens from health threats, and supporting dynamic health systems and new health technologies (ibid., 7-9). To implement the principles, action, and objectives outlined within the White Paper, the strategy presents two implementation dimensions. The first dimension addresses structured cooperation between MS, while the second dimension concerns financing of activities (McCarthy, 2008:554). Based on the public health competences set out in Article 152 of the Amsterdam Treaty, the strategy includes a range of instruments, such as Directives and soft law-measures consisting of recommendations and guidelines (ibid., SEC(2007)1376, 2007). While emphasising the importance of MS proactivity and cooperation, the strategy also recognises national and local organisations as integral contributors (McCarthy, 2008:554). This is further underpinned by the variety of stakeholders that were involved and consulted in the development of the White Paper (COM(2007)630, 2007:3).

Explaining "Together for Health"

The White Paper "Together for Health", categorised as *soft law and policy initiatives*, stands out as a significant integrative public health policy occurrence for two key reasons. First, it represents the first comprehensive Community health strategy, consequently signalling a shift in regulatory authority towards the Community. While the strategy largely formalises existing public health policies, it notably introduces global health as a new principle of Community action, reflecting the Community's aspirations for global leadership in health (COM(2007)630, 2007:6-7). The introduction of global health into public health policy, thus, indicates an evident extension of health competences.

However, neither functional spillover nor a crisis-driven explanation sufficiently accounts for the adoption of this new health strategy. There does not appear to be a clear exogenous shock that precipitated the strategy's adoption, nor does any specific legislation or integrative event appear to have created functional pressures necessitating its implementation. Clemens *et al*. (2017) offer a possible alternative explanation. Outlining the process that led to the publication of the White Paper, Clemens *et al*. highlight the pivotal role of DG SANCO in the development of the strategy (2017:599). The strategy is widely regarded as the key document demonstrating DG SANCO's capacity to develop both general and sectoral policies (ibid.). Clemens *et al*. further emphasise the extensive preparatory process of the strategy, including numerous stakeholder consultations, beginning in 2000 (ibid.). Therefore, the White Paper, and the subsequent public health integration, might be better explained by the policy entrepreneurialism of DG SANCO, as outlined as in the DG impact-approach discussed in chapter ***2.2.3. Alternative Explanations***.

4.16. Applicable, but under Certain Conditions?

The analysis had the purpose of establishing a list of ideographic accounts of 14 key integrative public health policy occurrences in the time frame of 1952 – 2007. On the basis of these accounts two theoretical concepts, functional spillover, and a crisis-driven explanation, were applied as to test whether they could explain why public health policy integration occurred in these cases. For analytical purposes and to ensure a variety of integrational activities, each key occurrence was categorised as either (i) *treaty changes* (n=4), (ii) *secondary EU law* (n=2), (iii) *soft law and policy initiatives* (n=6), or (iv) *changes in institutional structure* (n=2).

Accordingly, the analysis showcased that – excluding *'Europe Against Cancer'* and the *White Paper "Together for Health"* in which alternative explanations were necessary, as well as the *Communication on the Framework for Action in the Field of Public Health* and the *EU Public Health Framework Programme*, which the concepts could only partially explain – functional spillover and a crisis-driven approach applied to all remaining ten key integrative occurrences. Functional spillover could fully be applied to four key occurrences and partially to one occurrence. For two occurrences, both functional spillover and a crisis-driven explanation could be used. In one case, a combined approach of functional spillover and crisis-driven integration appeared suitable. A crisis-driven explanation applied fully to three cases, and partially to two cases. A summary of the findings can be found in the beginning of chapter ***4. 55 Years of Public Health Policy Integration***.

Functional spillover worked best to explain more general key integrative occurrences, for example treaty changes. This tendency can possibly be explained when considering how the functional spillover approach works. Functional spillover can be caused by functional pressures from integrative actions in *all* policy fields. As such, a functional spillover-approach is less dependent on functional pressures from actions in a particular field, in stark contrast to crisis-driven approaches. Consequently, there is a broader range of functional pressures to consider as triggers for public health integration. The broader applicability, however, also increases the risk of misidentifying functional pressures that do *not* directly or explicitly incentivise health integration as pressures eventually leading to public health integration.

Crisis-driven integration explanations, on the other hand, tended to generally apply more to issue-specific occurrences, specifically Directives, as for example *Directive 65/65/EEC*. This can be partially explained when considering the essence of the crisis-driven approach. In itself, the approach focuses on an exogenous shock, a crisis event, that generally pertains to a specific

issue area – for instance the outbreak of HIV/AIDS. Consequently, a reaction to a certain crisis tends, too, to be issue-specific – so for example the introduction of a Directive addressing medicinal products as a reaction to a scandal centred around drug testing. This issue-specificity might explain why crisis-driven explanations were applicable to the sole two cases of secondary EU law and could be partially used to explain the inclusion of specific policy aspects in, e.g. *'Europe Against Cancer*'.

For occurrences which could be partially explained by functional spillover or a crisis-driven explanation, the partial applicability tended to be the result of the inclusion of specific aspects, which either functional spillover or a crisis-driven approach could explain. This is, for example, the case for the 2003 *Public Health Framework Programme*. In this instance, a crisis-driven approach could explain the inclusion of a rapid reaction system as a response to the 2001 anthrax attacks. A crisis-driven approach could, however, not explain the Public Health Framework Programme in itself.

Two cases, *'Europe Against Cancer'*, and the 2007 *White Paper "Together for Health"* could not, or only partially be explained by the chosen concepts. In both cases, alternative explanations for the occurrences not explicitly considered in this paper were offered in literature. The 2007 White Paper is particularly interesting to briefly re-examine. While neither functional spillover nor a crisis-driven approach could satisfactorily explain public health integration in this occurrence, a previously addressed and discarded explanation – the DG impact-approach – could make sense of it. On the basis of Clemens *et al.*'s (2017) exploration of the process leading to the White Paper, DG SANCO's impact, proactivity and policy entrepreneurialism might explain the adoption of the strategy. As such the *"Together for Health"* occurrence re-emphasises that not every theoretical perspective is able to explain every phenomenon and that sometimes, even initially discarded explanations can prove useful.

Interestingly, *all* occurrences which could not or only partially be explained by functional spillover or crisis-driven explanations belonged to the category *soft law and policy initiatives*. While correlation evidently does not imply causation, there some possible explanations for this trend. First, all four key occurrences were programmes, strategies, or frameworks. These generally included a broad approach to a variety of public health- and especially medicine-related matters, sometimes ranging from eHealth to measures reducing the number of cases of coronary artery diseases. Specifically due to the technical and medicinal nature of certain outlined measures, it is difficult to use approaches such as functional spillover to make sense of their inclusion. Unsurprisingly, functional spillover does not have much to say about artery

clogging. As such, the highly technical focus of some of these documents was evidently not a good match. For future research, it might be advisable to consider the nature of specific documents more extensively. Approaching these key occurrences from a less specific perspective tended to be also difficult. In most cases, the reasons as to why a new programme was initiated included treaty changes or the expiration of a previous programme. While there surely could have been a case to make to connect functional spillover to treaty changes leading to the initiation of a new strategy, this did appear rather far-fetched in most cases. Nevertheless, the inclusion of these four key occurrences is important, as pursuant to the first objective of this paper – the creation of a comprehensive list of key integrative public health policy occurrences. After all, showcasing that a theoretical approach cannot or can only partially explain a case is still a finding.

Another deviant case worth further consideration is the 2004 introduction of the *European Centre for Disease Control and Prevention*. For this occurrence, the analysis established that the creation of the ECDC could be best explained by applying a combination of functional spillover and a crisis-driven explanation. While functional spillover could explain how cooperation in disease surveillance came to be, a crisis-driven approach could shed light on how an exogenous shock, particularly the spread of SARS, finally led to a rethinking and the eventual establishment of the ECDC. Only by combining the two approaches a fuller explanation of the occurrence could be provided. In a sense, the ECDC occurrence and the two occurrences in which both functional spillover and a crisis-driven approach could be applied also strengthen the understanding that functional spillover and crisis-driven explanations should not be considered as opposing or contrary. Instead, specifically in the case of the ECDC, it becomes apparent that both approaches can be used in combination to create even more in-depth explanations of cases under investigation. Comparing the two occurrences in which both could be applied further emphasises the strengths of each approach and also how different theoretical perspectives can lead to different explanations, even for the same phenomenon. As such, these three occurrences highlight the importance of minding the effects of different theoretical frameworks in explaining research findings and make a case for combining different theoretical approaches when appropriate.

Consequently, the analysis reached the objectives set out for this research inquiry. For the first objective, the analysis presented a list of comprehensive accounts of key integrative public health policy occurrences in the time frame of 1952 – 2007. In terms of the second objective, the analysis showed that both functional spillover and a crisis-driven explanation can account

for ten of the 14 key occurrences, and thus, that both approaches can be used to explain public health integration to similar extents. Due to the nature of the functional spillover concept, functional spillover was advantaged at explaining more general integrative occurrences, while a crisis-driven explanation could be best applied to more issue-specific occurrences. Accordingly, the research question can be answered: in a majority of the 14 cases of public health policy integration, public health integration can be explained as an outcome of functional spillover or as a reaction to exogenous shocks or crises.

5. *Not* so Quiet Afterall.

This thesis sought to investigate public health policy integration at the level of the EU, posing the research question ***'Why does integration in the policy area of public health occur?'***. Aligned with the research question, the paper had two central objectives. The first objective was to present a chronology of accounts of key integrative occurrences in the policy area of public health between 1952 and 2007. To explore why integration occurred in these key occurrences, the second objective was set out to test whether two theoretical frameworks – functional spillover from the neofunctionalist tradition and a crisis-driven approach adopted from Historical Institutionalism – could explain health integration in these cases.

In the analysis, the historical accounts of the 14 key integrative public health policy occurrences were presented and, for each occurrence, it was explained why these should count as integrative happenings. On that basis, functional spillover and a crisis-driven approach were applied to test whether these theoretical concepts could explain the occurrences of health integration. The analysis found that functional spillover and crisis-driven explanations could account for ten of the 14 key occurrences, concluding that both approaches are able to explain public health integration to a similar extent. While functional spillover was advantaged at explaining more general health integration occurrences, namely treaty changes, crisis-driven explanations were best applied to issue-specific integration occurrences, including secondary EU law. As such, this demonstrated the different explanatory advantages and disadvantages of these explanations. Four occurrences, all categorised as soft law and policy initiatives, could not or could only in part be explained by the two concepts. This was reasoned to be partially connected to the essence of the occurrences, which were generally programmes and strategies. As such, these cases consisted of broad approaches to varied public health matters and were much more technical in nature than other key occurrences. Three cases could be explained by both theoretical concepts, and these emphasised how different theoretical perspectives can highlight different aspects, even when examining the same phenomenon. Among these occurrences was one case which could be best explained by combining functional spillover and a crisis-driven explanation. This occurrence in particular reaffirms the importance of considering how combining concepts might lead to more detailed examinations of phenomena.

On the basis of the analysis and after achieving the objectives of the paper, it becomes possible to answer the central research question. The findings reveal that, in a majority of the 14 key integrative occurrences examined, public health policy integration can be primarily

understood as outcomes of either functional spillover or exogenous shocks, including crises. Over 55 years, these mechanisms have repeatedly demonstrated their ability to drive EU public health integration, particularly in response to crises or systemic inefficiencies.

However, it is important to recognise that not all instances of public health integration fit within these explanatory frameworks. The four occurrences that could not or could only partially, be explained by functional spillover or a crisis-driven approach serve as important reminders of the complexities of integration, particular in the "least likely candidate" public health. These exceptions emphasise that there is no *single* overarching explanation as to why public health policy integration occurs. Instead, public health integration is a multifaced progress, influenced by varied factors, including political will by single politicians or the political entrepreneurialism of a Directorate-General. As such, while functional spillover and crisis-driven approaches offer valuable insight into why public health integration occurs, they are by no means exclusive. Future research should evaluate alternative explanations for public health integration, specifically also addressing *healthcare* policy integration. This could also be expanded to include the years *after* 2007, and in particular public health policy integration during and after the SARS-CoV-2 pandemic.

The implications of these findings are especially significant in the current political context. As the European Union reconsiders its role in public health after the SARS-CoV-2 pandemic, and with a possible European Health Union on the horizon, lessons from historical public health policy integration are more relevant than ever before. Understanding "lessons learned" from past integrative health activities can inform future public health policy decisions, ensuring that the EU is better equipped to address ever emerging public health challenges.

Reflecting on the historical journey of public health policy integration in the European Union, it is evident that the health front has been anything but quiet. And with new health challenges continuously emerging, it should be clear that it will not stay quiet either.

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Appendix

Table 1.

Overview of Key Integrative Public Health Policy Occurrences 1952 – 2007

Key Occurrence	Type	Date	Description	CF.
Treaty of Rome	(i)	1958 (1957)	Introduction of i.a., Article 34, 48, and 56.	de Ruijter, 2019: 64, Heard-Lauréote, 2013: 125
Directive 65/65/EEC	(ii)	1965	First Directive regulating pharmaceutical products.	de Ruijter, 2019: 65, Palm & Wismar, 2018: 21
Community Programmes of Research on Medicine and Health	(iii)	1978	Two consecutive programmes. Extending joint Community research for the first time to the field of medicine and health.	de Ruijter, 2019: 70, Backer, 1986: 241
Single European Act	(i)	1987 (1986)	Introduction of i.a., Article 100a.	de Ruijter, 2019: 69, Greer, 2006: 138
'Europe Against Cancer' Programme	(iii)	1987	First Community public health programme.	Palm & Wismar, 2018: 21, Greer, 2009: 29, de Ruijter, 2019: 72, Guigner, 2004: 96, Hervey & Gilmore, 2010: 240, Greer, 2006: 138
Directive 89/381/EEC	(ii)	1989	Directive regulating medicinal products of human origin.	de Ruijter, 2019: 71
Maastricht Treaty	(i)	1993 (1992)	Inclusion of the first public health competence with Article 129. Introduction of Article 3(o).	de Ruijter, 2019: 69, 74, Palm & Wismar, 2018: 21, Brooks & Geyer, 2020: 1065, Rosenkötter *et al*., 2013: 2
Communication on the Framework for Action in the Field of Public Health	(iii)	1993	Introduces the first public health framework programme.	Palm & Wismar, 2018: 21, Guy & Sauter, 2017: 29, Heard-Lauréote, 2013: 125, Rosenkötter *et al*., 2013: 6
Amsterdam Treaty	(i)	1999 (1997)	Inclusion of Article 152 reaffirming the public health competence of the Community.	Brooks & Geyer, 1965, de Ruijter, 2019: 77, Heard-Lauréote, 2013: 125, Greer, 2006: 139, Lamping & Steffen, 2009: 1364

DG SANCO	(iv)	1999	Reorganisation of the DGs leading to the creation of a separate DG for health and consumer protection.	Clemens *et al*. 2017: 597, Palm & Wismar, 2018: 21, Greer, 2009: 27, Greer, 2008: 224, Brooks & Geyer, 2020: 1066, Guigner, 2004: 111, McKee *et al.*, 2010: 233
EU Public Health Framework Programme	(iii)	2003	First health framework programme based on Article 152 introduced by the Amsterdam Treaty. Shift from health determinant-specific to a horizontal approach.	Palm & Wismar, 2018: 21, Greer, 2009: 44, Brooks & Geyer, 2020: 1067, Rosenkötter *et al*., 2013: 2
European Centre for Disease Control and Prevention	(iv)	2004	Creation of an agency promoting public health through the monitoring of health threats.	Palm & Wismar, 2018: 21, Lamping & Steffen, 2009: 1366, Guy & Sauter, 2017: 31, McKee *et al*., 2010: 253, Rosenkötter *et al*., 2013: 6
'Health in All Policies'	(iii)	2006	Introduction of the 'Health in All Policies'-approach under the Finnish Council Presidency.	de Ruijter, 2019: 75, Puska & Ståhl, 2010: 316, Rosenkötter *et al*., 2013: 6
White Paper "Together for Health"	(iii)	2007	Introduction of a health strategy establishing shared health values and outlining emerging health challenges and potential solutions.	Palm & Wismar, 2018: 21, Rosenkötter *et al*., 2013: 2, Clemens *et al*., 2017: 599

Table 2.

Application of the Typology to the Key Integrative Public Health Policy Occurrences

ID	Category	Date	Item
(i)	Treaty Changes (n=4)		
		1958	Rome Treaty
		1987	Single European Act
		1993	Maastricht Treaty
		1999	Amsterdam Treaty
(ii)	Secondary EU Law (n=2)		
		1965	Directive 65/65/EEC
		1989	Directive 89/381/EEC
(iii)	Soft Law and Policy Initiatives (n=6)		
		1978	Community Programmes on Research on Medicine and Health
		1987	'Europe Against Cancer' Programme
		1993	Communication on the Framework for Action in the Field of Public Health
		2003	EU Public Health Framework Programme
		2006	'Health in All Policies'
		2007	White Paper "Together for Health"
(iv)	Changes in Institutional Structure (n=2)		
		1999	DG SANCO
		2004	European Centre for Disease Control and Prevention