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Published in:
Regulating risks in the European Union

[Link to publication](#)

Citation for published version (APA):
de Ruijter, A. (2017). Mixing EU Security and Public Health Expertise in the Health Threats Decision. In M. Weimer, & A. de Ruijter (Eds.), *Regulating risks in the European Union: The co-production of expert and executive power* (pp. 101-120). Oxford: Hart Publishing.

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Mixing EU Security and Public Health Expertise in the Health Threats Decision

Anniek de Ruijter

It is very easy to adopt measures after Katrina for example or after the Tsunami or after something awful happens, everybody can be an expert then. But the real challenge, I think, is to look into the future and see what we think we need to do on the basis of our past experience.¹

I Introduction

This chapter analyses the relationship between the changing nature of the expertise underlying and legitimising EU response to public health emergencies, and executive power. In general, in case of the spread of a highly contagious virus on a pandemic scale or when an emergency threatens the health and life of a population, the counter measures that are approved and coordinated by the executive in charge, build on the advice of epidemiological experts, who will inform the policy makers on the speed of the spread, the likelihood that vaccines will work, or on what other public health measures may need to be taken, such as school closures or extra capacity in hospitals. Many of these experts are public health experts, epidemiologists, with a public health, or medical degree. The EU's involvement in planning for public health emergencies, such as a communicable disease outbreak has focused on the coordination and harmonisation of Member States emergency plans, ensuring the least impact on the internal market. The efforts of the EU address e.g, planning, coordination of an emergency response, assessment, prevention and communication.²

In this chapter the Health Threats Decision of 2013,³ is analysed as signifying a shift in the EU public health response model, towards a 'preparedness model' blending the underlying expertise that is used for EU health emergency response from the above-described public health experts towards security experts (economists, critical infrastructure and defence experts). The chapter also shows that this shift is the result of a transforming expert understanding of the nature of the health risks that we are facing. It describes a regulatory

¹ High level (public health) representative Commission Services, DG SANCO, interviewed in 2010 about the swine flu outbreak.

² See, chapter 5, Mark Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Bloomsbury Publishing 2015).

³ Decision No.1082/2013/EU, 'Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on Serious Cross-Border Threats to Health and Repealing Decision No 2119/98/EC (O.J. L 293/1 5-11-2013)'.

merging of the opinions and relevance of the scientific input of public health experts that believe that health risks that are manageable and perceived as statistically foreseeable, together with security experts and economists that view public health risks as unforeseeable disasters or catastrophes that should be addressed, not only in terms of health and life of humans, but also in respect to ‘security’ of the economy and preparing its ‘critical infrastructures’. The central question is whether the mixing of public health expertise at the EU level in the context of the Health Threats Decision is co-producing EU executive power in the field in ways unforeseen in the EU’s founding Treaty on the Functioning of the EU (‘TFEU’)?⁴

A The Health Threats Decision’s Legislative Context

In recent years the EU has become increasingly involved in the coordination and response to a number of major health events such as Zika, Ebola, bird flu, SARS, swine flu and the E-Coli outbreak.⁵ In 2013, the EU adopted a new legal instrument, the Decision on Serious Cross-Border Threats to Health (‘Health Threats Decision’),⁶ to regulate its involvement in the response to public health threats, chemical attacks and bioterrorism. This Decision, adopted by the Council and the European Parliament is an all-encompassing regulatory instrument, covering not only known, but also unknown health risks. It is a European effort to, in the words of the European Commission, ‘bridge the policy fields of health and security’.⁷

The main purpose for this Decision is to regulate the coordination of Member States action in responding to ‘major health threats’ by encompassing the already existing communicable disease control network and a number of health threats that before were mainly addressed, if at all, in the context of security policy.⁸ These other health threats include biochemical attacks and bio-terrorism, and hazards created as a result of climate change.⁹ Moreover, the coordinating structures created by the Health Threats Decision:

[S]hould, in exceptional circumstances, be available to the Member States and to the Commission when the threat is not covered by this Decision and where it is possible

⁴ ‘Treaty on the Functioning of the EU (O.J. 115/49)’ <13488829440080509en00470199.pdf>.

⁵ ‘European Commission, Commission Staff Working Document, Health Security in the European Union and Internationally (SEC(2009)1622 Final) Brussels, 23/11/2009’.

⁶ Decision No.1082/2013/EU (n 3).

⁷ Commission Proposal, ‘Commission Proposal for a Decision of the European Parliament and of the Council on Serious Cross-Border Threats to Health Brussels (COM(2011)866 Final)’.

⁸ Stephen J Collier and Andrew Lakoff, ‘Health Security, and New Biological Threats: Reconfigurations of Expertise’ in Chloe E Bird and others (eds), *Handbook of Medical Sociology, Sixth Edition* (Vanderbilt University Press 2010).

⁹ Decision No.1082/2013/EU (n 3). At par par 8.

that public health measures taken to counter that threat are insufficient to ensure a high level of protection of human health.¹⁰

This means that potentially the Decision casts a wide net for its possible future application. The Decision is also encompassing in that it links ‘new’ threats in with older systems for information exchange, surveillance and preparedness. For example, the Decision extends the Early Warning and Response System (EWRS),¹¹ which is operated by the European Centre for Disease Control (ECDC) that used to be available only for specific communicable diseases, to all health threats.¹² In the following section, the chapter draws out the theoretical and analytical considerations that form the perspective through which the Health Threats Decision is analysed.

II Reconfiguring Public health: Globalisation and Security

How is the changing understanding of public health risks that underlies the Health Threats Decision co-producing EU executive power? With regard to the underlying expert rationale for understanding public health risks, there are two highly interrelated frames of analysis applied at national and global levels that create a pathway for analysing the co-production of executive and expert power in the field of public health in the EU. The first frame relates to a reconfiguration of understanding public health risks. The second frame relates to globalisation and ‘securitisation’.

A Reconfiguring Public Health Risks: From Risk Management to Crisis

Preparedness

At a global level there has been an observance of a ‘reconfiguration of biomedical and security expertise’.¹³ This reconfiguration leads to new ‘forms of expertise and the practices of intervention through which disease threats are understood and managed’.¹⁴ One explanation for this reconfiguration is that the second part of the twentieth century has given rise, in the words of Sheila Jasanoff: ‘to risks that escape the framework of actuarial

¹⁰ *ibid.* At paragraph 9.

¹¹ Commission Decision (2000/57/EC), ‘Commission Decision (2000/57/EC) of 22 December 1999 on the Early Warning and Response System for the Prevention and Control of Communicable Diseases under Decision No 2119/98/EC of the European Parliament and of the Council (O.J. L 21, 26-1-2000, P. 32)’.

¹² Decision No.1082/2013/EU (n 3). At para 16.

¹³ Collier and Lakoff (n 8).

¹⁴ *ibid.* At p. 364.

prediction, in part because there is little or no historical experience to fall back on in evaluating them'.¹⁵

In the famous account of Ulrich Beck, technical innovation and modernisation processes have created risks of which we can no longer foresee the possible future harm: 'Along with the growing capacity of technical options grows the incalculability of their consequences'.¹⁶ Technological advances have produced new risks to human health, and expertise itself, is also the main source for debate on the nature of these risks and on whether the values involved are adequately addressed in its regulation.¹⁷ As a result, the authority of the expert and scientific understanding of these risks itself becomes a political question.¹⁸ This new understanding and scholarly debate on risks and their nature both by experts and policymakers has had specific implications for different types of disaster management in the recent decades.¹⁹ This is particularly true for the field of public health as a science and policy field, when it concerns the response to a major health emergency.²⁰

Public health as we now understand it in general terms, developed in the nineteenth century as a way of managing and understanding infectious diseases.²¹ Prior, communicable disease epidemics were largely seen as exogenous, unpredictable or as 'Acts of God'. However, in the nineteenth century the social conditions of populations, for instance with respect to sanitation, living conditions and circulation became predicaments that could be statistically analysed and managed through *public* policies and inoculation strategies. Within modernity's public health rationale, cost-benefit analysis could be used to legitimise an eradication campaign of polio and small-pox.²² After the Second World War, experts, particularly also biodefense experts, started recognising and hypothesising the possible

¹⁵ Sheila Jasanoff, 'Beyond Calculation: A Democratic Response to Risk' in Andrew Lakoff (ed), *Disaster and the Politics of Intervention* (Columbia University Press 2010).

¹⁶ Ulrich Beck, *Risk Society: Towards a New Modernity* (1 edition, SAGE Publications Ltd 1992). At p. 22.

¹⁷ See further on the regulation of new technologies and the 'value laden' expertise underlying EU risk regulation ie, a number of case studies M Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 *Current Legal Problems* 242. Also see M. Weimer, 'Risk Regulation, GMOs, and the Challenges to Deliberation in EU Governance: Politicisation and Scientification as Co-Producing Trends' in C. Joerges and C. Glinzki (eds), *The European Crisis and the Transformation of Transnational Governance* (Hart Publishing 2014).

¹⁸ Beck (n 16). at p. 30.

¹⁹ Sheila Jasanoff, *Learning from Disaster: Risk Management After Bhopal* (University of Pennsylvania Press 1994). Also see Andrew Lakoff, *Disaster and the Politics of Intervention* (Columbia University Press 2010).

²⁰ See chapter Scott Greer on the nature of the concept of public health in EU policy.

²¹ G Rosen, *A History of Public Health* (John Hopkins University Press 1958). At p. 168

²² F Fenner and others, *Smallpox and Its Eradication* (World Health Organisation 1988).

limitations of a public health approach to infectious diseases and to gauge the possibility of outbreaks as extraordinary events, without historical precedent.²³

In recent decades, alongside a changing understanding of public health risks as a result of technological advances as described by Beck, the rationale and understanding of the risk of pathogens – that have been around in various forms for centuries – also changed and resulted in a new public policy consensus; from public health containment strategies to a ‘preparedness approach’ to infectious disease.²⁴ The underlying idea is that increasing scientific knowledge on communicable diseases has created new threats to public health, for instance in the form of a possibly accidental or deliberate release of dangerous diseases. Prime examples here are the anthrax scare after 9/11 and the recent bird flu virus developed at the Erasmus University Rotterdam and the controversy surrounding publication on its modification in potentially human-contagious forms. This new context of ‘preparedness for the unknown and the deliberate rather than the accidental’, applied to consider disease, reconfigures experts’ understanding in the determination of public health risks.²⁵ The difference between the ‘public health frame’ and the ‘preparedness frame’ in public policy terms is that a preparedness strategy does not use statistical forecasts based on past events. Rather, it uses scenario sketches and simulation models in order to prepare for uncertain future events.²⁶

B Securitisation and Globalisation: From ‘Public Health’ to ‘Health Security’

The second, interrelated development that has led to a changed expert framing and understanding of public health risks is a move from ‘public health policy’ to ‘health security policy’. The conceptualisation of ‘health security or biosecurity’, rather than ‘public health’ refers to a layering and integration of perceived security threats to human health and general public health concerns. ‘Biosecurity’ or ‘health security’ then is used as a term to recast the

²³ Collier and Lakoff (n 8). David Fidler and Lawrence Gostin, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (First Edition edition, Stanford Law and Politics 2007).

²⁴ Wendy K Mariner, George J Annas and Wendy E Parmet, ‘Pandemic Preparedness: A Return to the Rule of Law’ (Social Science Research Network 2009).

²⁵ Fidler and Gostin (n 23). Alexander Kelle, ‘Securitisation of International Public Health: Implications for Global Health Governance and the Biological Weapons Prohibition Regime’ (2007) 13 *Global Governance* 217. Also see ‘WHO | The World Health Report 2007 - A Safer Future: Global Public Health Security in the 21st Century’ (WHO) <<http://www.who.int/whr/2007/en/>> accessed 4 May 2015.

²⁶ Collier and Lakoff (n 25). Marjolein BA van Asselt, Ellen Vos and Isabelle Wildhaber, ‘SYMPOSIUM ON CRITICAL INFRASTRUCTURES: RISK, RESPONSIBILITY AND LIABILITY · Some Reflections on EU Governance of Critical Infrastructure Risks’ (2015) 6 *European Journal of Risk Regulation* 185.

effort of public authority in relation to the protection of the health of the population. This move to security is relevant as it signifies a shift in governance discourse.²⁷

Biosecurity as Gostin and Fidler use it in the global context describes ‘society’s collective responsibility to safeguard the populations from dangers presented by pathogenic microbes’.²⁸ However, the term also refers to efforts to protect populations against harm caused by biological weapons and biological terrorism and chemical attacks. The public policy rationale behind combining the public health and security strands of policy has been argued to result from the nature of the policy and the institutional actors that (should) be involved in harnessing these types of threats:

The emergence of biosecurity reveals that the days when public health and security never intersected as governance tasks have ended. ... The policy silo’s of security and public health are not integrated as they should be in order to respond to the threats that we face today.²⁹

A crucial development in this integration has been the increased focus in the last decade on the ‘terrorist threat’ and an increased global interdependence.³⁰ In Beck’s analysis the risks as they result from modernisation may be seen as unintentional side-effects of society’s decisions. However, terrorism is an intentional ‘bad’. The management of risks has the social function of engendering trust and legitimation in the public power and authority. Terrorism however undermines trust on a global scale. In the words of Beck: ‘Since the dissolution of trust multiplies risks, the terrorist threat triggers a self-multiplication of risks by the debounding of risk perceptions and fantasies’.³¹ This means that the focus on pathogens is not just on their natural occurrence, but shifts to their intentional release.³² At the same time this shift changes the experts involved and the legitimating force of the underlying scientific basis of this policy, since according to Beck, ‘the power of definition of experts has been replaced by that of states and intelligence agencies; and the pluralisation of experts has turned into the simplification of enemy images’.³³

Globalisation, beyond terrorism, is also a factor in the recasting of public health as a security issue. The global circulation of people and goods has also increased the concern for

²⁷ Arjen Boin and others, *The Politics of Crisis Management: Public Leadership Under Pressure* (Cambridge University Press 2006).

²⁸ Fidler and Gostin (n 23). At p. 122.

²⁹ *ibid.* p. 10.

³⁰ Ulrich Beck, ‘The Terrorist Threat World Risk Society Revisited’ (2002) 19 *Theory, Culture & Society* 39.

³¹ *ibid.* at p 44.

³² *ibid.* at 45.

³³ *ibid.*

pathogens and the responsibility of governments in this regard. In 2005 the International Health Regulations (IHR) were amended, which strengthened the obligations for the World Health Organization's (WHO) members to notify public health threats.³⁴ Under the IHR a 'Public Health Emergency of International Concern' is defined in Article 1 as:

An extraordinary event, which is determined, as provided in these Regulations:

- to constitute a public health risk to other States through the international spread of disease and;
- to potentially require a coordinated international response. This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action.

Furthermore, in 2001, only a few months after the 9/11 terrorists attacks a Global Health Security Initiative (GHSI) was launched by the G7, Mexico and the WHO. The initiative particularly focuses on biological, chemical, radio-nuclear terrorism (CBRN) and influenza.³⁵ In this respect there is an international consensus,³⁶ that, in the words of the UN Secretary General:

The threats presented by biological weapons and natural disease epidemics weave together to form an independent policy challenge the likes of which we have never seen before.³⁷

Globalisation however also entails a recasting of what 'security' means. Historically security was usually used to describe 'state security', ie, the responsibility of the state to protect its citizens from harm caused by another state. However, recently there has been a move to the use of the term security in the broader sense of 'human security'.³⁸ In the words of Anne-Marie Slaughter: 'From this perspective – of human security – it really doesn't matter if you die from a bullet or you die from AIDS or you die from hunger. What matters is that you die'.³⁹ Hence, state borders become blurred and health emergencies easily become the responsibility of international efforts that focus on short-term mitigation, rather than long-

³⁴ WHO, 'World Health Organisation (2008), International Health Regulations 2005 2nd Ed.'

³⁵ 'GHSI - Global Health Security Initiative' <<http://www.ghsi.ca/english/index.asp>> accessed 3 May 2015.

³⁶ Craig Calhoun, 'A World of Emergencies: Fear, Intervention, and the Limits of Cosmopolitan Order*' (2004) 41 Canadian Review of Sociology/Revue canadienne de sociologie 373.

³⁷ 'United Nations Secretary General, United Nations Secretary High Level Panel on Threats, Challenges and Change. A More Secure World: Our Shared Responsibility (New York: United Nations)'. P. vii-x

³⁸ *ibid.*

³⁹ Anne-Marie Slaughter, 'A New UN for a New Century' (2006) 74 Fordham Law Review 2961.

term structural public health reforms, which are deemed too complex and controversial.⁴⁰ The recent Ebola crisis is a prime example of this dynamic.⁴¹ At the same time those people that are affected by a communicable disease in the ‘security frame’ become the ‘enemy’ and a threat to public health, rather than the disease itself.⁴²

C Reconfiguring Public Health, Co-producing Executive Power

Executive power at the EU level (the European Commission), ie, the legal power to control public instruments for coercion, wealth and information,⁴³ is not a clear-cut, unitary power with a single locus. Rather, it can be described as an accumulation of different layers of both internal (national constitutional law), and external executive power (diplomatic relations), with an administrative and political component.⁴⁴ It is exercised by national civil servants acting within EU institutional actors, and by EU-level civil servants. Moreover EU executive power compounds political power (leadership, ability to propose policies and legislation), and administrative power (eg, legal implementing powers and public revenue distribution).⁴⁵

Emergencies and crisis have long been recognised to ‘side-line’ representative and democratic actors within institutions and strengthen the executive.⁴⁶ Disasters and crises can trigger an informal or formal response and open a ‘window of opportunity for change’, either changing a dominant policy discourse or regulatory approach.⁴⁷ This dynamic also affects the role of experts who have a role in determining what is a disaster and the threat level. Security experts in this respect have a different frame of thinking than public health experts such as epidemiologists. Health emergencies and disasters can create ‘focusing events’ and create a change of discourse in a policy area that is dominated by scientists and technical experts, particularly also in policy areas where there is no intense public interest involvement. Birkland describes these ‘focusing events’ as an event that is ‘sudden, relatively rare, can be reasonably defines as harmful or revealing the possibility of greater potential future harms,

⁴⁰ Collier and Lakoff (n 8). At p. 369 et seq.

⁴¹ Mohini Banerjee and Chelsea Jack, ‘Responding to Ebola: Retrofitting Governance Systems’ (*The Hastings Center*) <<http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7076&blogid=140>> accessed 2 May 2015.

⁴² Mariner, Annas and Parmet (n 24).

⁴³ D.M.Curtin, *Executive Power of the European Union, Law, Practices and the Living Constitution* (Oxford University Press 2009). At p. 20

⁴⁴ *ibid.* At p. 29; also see Deirdre Curtin and Morten Egeberg, ‘Tradition and Innovation: Europe’s Accumulated Executive Order.’ (2008) 31 *West European Politics* 639.

⁴⁵ Curtin (n 43). At p. 38. Also see Simon Hix, *The Political System of the European Union* (Palgrave Macmillan 2005).

⁴⁶ Deirdre Curtin, ‘Challenging Executive Dominance in European Democracy’ (2013) 77 *Modern Law Review*.

⁴⁷ Scott Gabriel Knowles, ‘Learning from Disaster?: The History of Technology and the Future of Disaster Research’ (2014) 55 *Technology and Culture* 773.

inflict harms, or suggest harms that are or could be concentrated on a definable geographical or community of interest and that is known to policymakers and the public virtually simultaneously'.⁴⁸ Focusing events can create opportunities for the executive given that disasters may focus the attention of experts and the public, and often there will be a demand for immediate change, which puts the executive at work, given that the emergency itself will give a clear indication that the previous regulatory approach was flawed.⁴⁹

In the European Union there has been a long existing resistance against EU governance in the field of public health.⁵⁰ However emergencies – in the EU the BSE crisis is a notable example – can diminish existing policy-making constraints as they expose the weaknesses of existing policies and ‘create a sense of urgency’.⁵¹ An emergency may become viewed as proof that existing problems will become more serious if no serious steps are undertaken. Hence, during crises, existing constraints on institutional action are normally dropped or lowered to allow for swift action. The BSE-crisis for instance broke down the resistance of Member States for more EU power regarding the regulation of food.⁵² In sum, emergencies often give the executive new solutions to consider, which were not previously possible as long as existing policy was strongly entrenched. But in an emergency, existing policies will suffer from declining support and at the same time there will be more pressure to make a decision and fewer constraints to deal with, particularly when the executive is to take swift action. The next section looks at the reconfiguration of public health and security experts and expertise in the context of the legislative history and the resulting adoption of the Health Threats Decision, and a growing role for the EU executive.

⁴⁸ Thomas A Birkland, *Lessons of Disaster: Policy Change After Catastrophic Events* (Georgetown University Press 2006).

⁴⁹ *ibid.* J Birkmann and others, ‘Extreme Events and Disasters: A Window of Opportunity for Change? Analysis of Organisational, Institutional and Political Changes, Formal and Informal Responses after Mega-Disasters’ (2008) 55 *Natural Hazards* 637.

⁵⁰ TK Hervey and JV McHale, *Health Law and the European Union* (Cambridge University Press 2004).

⁵¹ John TS Keeler, ‘Opening the Window for Reform Mandates, Crises, and Extraordinary Policy-Making’ (1993) 25 *Comparative Political Studies* 433.

⁵² E Vos, ‘EU Food Safety Regulation in the Aftermath of the BSE Crisis’ (2000) 23 *Journal of Consumer Policy* 227.

III The Health Threats Decision: From ‘Public Health’ to ‘Health Security’

The Health Threats Decision defines a ‘serious cross-border threat to health’ in Article 3(g) as a:

... life threatening or otherwise serious hazard to health of biological, chemical environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.

The legal base for the Health Treats Decision is found in Article 168 (5) of the TFEU. Paragraph 5 excludes the possibility for the EU to harmonise Member States’ laws with regard to public health. However, there is a limited role for the EU envisaged in Article 168 for responding to a public health emergency:

Union action ... shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

This means that EU power for responding to a major public health threat is limited to the coordination of Member States responses.⁵³ However, although the Health Threats Decision stays within the legal parameters outlined in Article 168 of the TFEU, at the same time it allows the Commission to determine that there is a public health emergency (Article 12) and take subsequent ‘immediate implementing measures’, which allow the Commission to adopt temporary measures outside of the use of a comitology Committee.⁵⁴ Keeping in mind that the structures established by the Decision may also be used in ‘exceptional circumstance, not covered by the Decision’ these legal provisions potentially create significant executive power for public health at the EU level.⁵⁵

In order to draw an initial institutional map, the following table shows the principal institutional actors that come into play in a health emergency response at the EU level.

⁵³ Other treaty provisions that form the basis for related mechanisms on disaster prevention can be found in the context of civil protection (TFEU, art 196), the solidarity clause (TFEU, art 222), EU financial assistance to Member States (TFEU, art 122), and humanitarian aid to third countries (TFEU, art 214).

⁵⁴ Regulation (EU) No 182/2011, ‘Regulation (EU) No 182/2011, of the European Parliament and of the Council of 16 February 2011 Laying down the Rules and General Principles Concerning Mechanisms for Control by Member States of the Commission’s Exercise of Implementing Powers (O. J. L 55/13, 28-2-2011)’. art 8.

⁵⁵ See para 9 and art 2 Health Threats Decision.

EU institutional actors involved in health emergency response

Institutional Actor	Role	Legal nature
World Health Organisation	Global coordination and policy on public health (events)	International Organisation, EU has observer Status in UN
Commission General Secretariat, Crisis management unit	Coordination between and among Commission Services	EU institutional actor
European Commission, DG SANCO, Health Threats Unit -3	Surveillance, Early Warning and Response, manages information systems and exchange, including contact tracing.	EU institutional actor
European Centre for Disease Control (ECDC)	Surveillance, Early Warning and Response, scientific input/output and information on public health threats. Limited operational capabilities through public health teams. Resorts under DG SANCO	EU Agency
European Medicines Agency (EMA)	Approval vaccines and antivirals, information dissemination, resides under DG SANCO	EU Agency
Early Warning and Response Committee (EWRS)	Information exchange and dissemination and coordination of surveillance and early warning and response on Communicable diseases based on Decision 2119/1998 on early warning and response to Communicable diseases	(Examination)Committee (Health Threats Decision Art. 8)
Health Security Committee (HSC)	Member States' coordination of public health events, beyond communicable disease, including chemical, biological and radio-nuclear threats, resorts under DG SANCO	Intergovernmental cooperation (Health Threats Decision Art. 17)
Friends of the Presidency	Horizontal Council Group	Informal and ad hoc

A Public Health Expertise in the EU: From Epidemiologists to ‘Health Security Experts’

Expertise and particularly also public health experts have been part and parcel of the existence of the modern democracies.⁵⁶ Experts have a long-standing and significant role in contributing to the legitimacy and acceptability of the EU’s involvement in risk regulation.⁵⁷ With the growth of the EU’s involvement in a variety of policy matters, the need for expertise in these areas grew as well.⁵⁸ In the European Union, cooperation in the area of public health was from the very beginning a logical consequence of increased trade and integration.⁵⁹ Although with respect to veterinary disease, such as bovine tuberculosis the Community had already formulated some policy,⁶⁰ with respect to human communicable disease control the Union’s involvement started in the 1970s.

The first involvement of the Union took place in an exchange of letters on communicable disease monitoring with the WHO in 1972.⁶¹ Over the course of the 1970s European surveillance networks were set up for a number of communicable diseases, such as HIV/Aids, tuberculosis, legionella and influenza.⁶² This eventually led to a European public health research programme that was launched in 1984 on the serious spread and threat of

⁵⁶ Sheila Jasanoff, *The Fifth Branch, Science Advisors as Policymakers* (Harvard University Press 1998). A de Swaan, *In Care of the State: Health Care, Education and Welfare in Europe and the USA in the Modern Era* (Oxford University Press 1988).

⁵⁷ See Weimer & de Ruijter, and see Giandomenico Majone, ‘The Credibility Crisis of Community Regulation’ (2000) 38 *JCMS: Journal of Common Market Studies* 273. G Majone, ‘The Regulatory State and Its Legitimacy Problems’ (1999) 22 *West European Politics* 1. Ellen Vos and Michelle Everson (eds), *Uncertain Risks Regulated* (1 edition, Routledge-Cavendish 2012). E Vos, ‘EU Committees: The Evolution of Unforeseen Institutional Actors in European Product Regulation’, *EU Committees: Social Regulation, Law and Politics* (Hart Publishing 1999).

⁵⁸ Morten Egeberg, Åse Gornitzka and Jarle Trondal, ‘A Not So Technocratic Executive? Everyday Interaction between the European Parliament and the Commission’ (2014) 37 *West European Politics* 1. Åse Gornitzka and Cathrine Holst, ‘The Expert-Executive Nexus in the EU: An Introduction’ (2015) 3 *Politics and Governance* 1.

⁵⁹ M McKee, TK Hervey and A Gilmore, ‘Public Health Policies’, *Health Systems governance in Europe: The role of European Union law and policy* (Cambridge University Press 2010). P. 233. Also see SL Greer, ‘The European Centre for Disease Prevention and Control’ (2012) 37 *Journal of Health Politics, Policy and Law* 101. SL Greer, *Everything You Always Wanted to Know about European Union Health Policies but Were Afraid to Ask* (World Health Organisation on behalf of the European Observatory on Health Systems and Policies 2014).

⁶⁰ EEC Commission, ‘EEC Commission (1964), Veterinary Matters: Harmonisation of Legislation, and Other Activities, Newsletter on the Common Agricultural Policy Nr. 24’.

⁶¹ See A. de Ruijter, forthcoming 2017 Chapter 3. Exchange of letters between the European Communities and the World Health Organisation laying down the procedure for cooperation between the two organisations; Memorandum defining the arrangements for cooperation between the World Health Organisation and the European Communities (72/725/ECSC, EEC, Euratom) (OJ L 300, 28-10-1982, p. 20-22).

⁶² M Liverani and R Coker, ‘Protecting Europe from Diseases: From the International Sanitary Conferences to the ECDC’ (2012) 37 *Journal of Health Politics, Policy and Law* 913.; also L MacLehose, M McKee and J Weinberg, ‘Responding to the Challenge of Communicable Disease in Europe’ (2002) 295 *Science* 2047.; the surveillance of diseases in the EU currently is disseminated through a scientific, peer-reviewed publication, *Eurosurveillance*, available at: <www.eurosurveillance.org/>.

HIV/Aids.⁶³ In 1994 the surveillance networks became the subject of a public health network headed by the national communicable disease surveillance centres to create a unified framework for the surveillance of communicable diseases and training for epidemiological intervention (EPIET) under the auspices of the European Commission.⁶⁴ The initial Network was a bottom-up initiative on the basis of the advice of a Charter group of the heads of public health institutions with responsibility for communicable disease in the Member States.⁶⁵ However, already since the start of the 1990s epidemiologists across the EU worked together in a network to tackle particular communicable diseases together, primarily for the sake of epidemiological data sharing and exchange.⁶⁶ A Commission Decision in 1998 formalised these executive-expert networks into the Network Committee and established it as a regulatory comitology committee, composed of two representatives from each Member State, usually one epidemiologist and one representative of the Ministry of Health, chaired by DG SANCO (Directorate General for Health, European Commission).⁶⁷

Under the auspices of the Network Committee, the surveillance of single diseases was consolidated and the Early Warning and Response System (EWRS) was set up.⁶⁸ The Committee was in charge of determining the case definitions for communicable diseases, data and methods for surveillance and issue guidelines on the countermeasures to be taken in times of emergencies.⁶⁹ In the EWRS, similarly to the surveillance network, the exchange of information for the operation of this system was legally limited to information on new or unknown communicable diseases or to the list of diseases covered under the annex of Decision 2119/98/EC.⁷⁰

The Charter group as it was first conceived was a bottom-up network of experts in the field of communicable disease control as a public health matter. However, after the BSE

⁶³ Community Programme of Research into Aids (OJ C 46, 20-02-1984).

⁶⁴ J. Giesecke and J. Weinberg 'A European Centre for Infectious Disease?' (1998) *The Lancet* 352 (9136). J. Weinberg *et al* 'On behalf of the Charter Group: Establishing priorities for European collaboration in communicable disease surveillance' (1999) *European Journal of Public Health* 9 (3) 236-240

⁶⁵ J. Weinberg *et al* 'On behalf of the Charter Group: Establishing priorities for European collaboration in communicable disease surveillance' (1999) *European Journal of Public Health* 9 (3) 236-240.

⁶⁶ L. MacLehose *et al* 'Responding to the Challenge of Communicable Disease in Europe' (2002) *Science* 295 2047-2050; also see M.R. Roberts 'The European Centre for Disease Prevention and Control: Science and Political Integration in Europe' (2013) UCL STS Observatory blog at <www.blogsucl.ac.uk/sts-observatory/2013/08/02/the-european-centre-for-disease-prevention-and-control-science-and-political-integration-in-europe/> (last accessed March 2014).

⁶⁷ Decision No 2119/98/EC, '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 (O.J. L 268/1, 03-10-1998)'.

⁶⁸ See Decision No. 2119/98/EC, art 1; also see MacLehose, McKee and Weinberg (n 62).

⁶⁹ Decision No. 2119/1998/EC, art 3.

⁷⁰ *ibid* art 4.

crisis in the 1990s and with the increased perception of EU interdependence for responding to ‘health crises’, in 2004 the EU’s work on communicable diseases was further consolidated with the establishment of the ECDC.⁷¹ Important in this respect is that the locus of expertise on communicable disease control that was in the network setting a matter of national experts, was given a European counterpart. Particularly in the EU administrative space this was an important development given that the advice of the ECDC could now legitimise more far-reaching action of the executive actors involved in responding to a public health threat at the EU level, given that the input of science into the policy making at the EU level provided increased autonomy for the executive.⁷² Hence in 2003 in order to streamline the work in relation to public health threats, in DG SANCO a special administrative unit for Health Threats was established.

With the establishment of the ECDC in 2004, the coordination of the surveillance systems and related public health networks from the communicable diseases network committee was handed over to this new agency.⁷³ The ECDC ‘harmonised’ the public health expertise in issuing standard surveillance reports on the specific diseases and managing electronic systems, which allow Member States to upload health data in order for the ECDC to produce the statistics and carry out risk assessments. The EWRS has been operated by the ECDC since 2007, and although the Commission remains responsible for a user’s manager’s authorisation, i.e, who has access to the information exchange,⁷⁴ the ECDC otherwise manages the system and the information updates. The Centre has no regulatory powers,⁷⁵ but it does coordinate and is in permanent contact with Member States, the ECDC, the WHO and Public Health Departments and Centres throughout the world through the above mentioned Global Health Initiative Channel.⁷⁶

⁷¹ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control (OJ L 142/1, 30-04-2004). Liverani and Coker (n 62). See further Chapter 2 of Anniek de Ruijter, *The Expansion of EU Power in the Field of Human Health* (Oxford University Press 2016).

⁷² Gornitzka and Holst (n 58).

⁷³ See Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control (OJ L 142/1, 30-04-2004); Decision No. 2119/98/EC (1998); Commission Decision 2009/312/EC of 2 April 2009 amending Decision 2000/96/EC as regards dedicated surveillance networks for communicable diseases (OJ L91/27 03-04-2009) at Resolution 7.

⁷⁴ The national permanent representations formally assign the national contact points request the Commission and the EWR network committee for access.

⁷⁵ See Commission Decision (2009/312/EC), ‘Commission Decision (2009/312/EC) of 2 April 2009 Amending Decision 2000/96/EC as Regards Dedicated Surveillance Networks for **Communicable** Diseases (O.J. L91/27, 3-4-2009)’. Commission Decision 2009/312/EC (2009) at r. 6.

⁷⁶ The Global Health Security Initiative (GHSI) is an informal, international partnership between countries to strengthen health preparedness for pandemic influenza amongst other public health threats. This network was an initiative started in November 2001 by Canada, the European Union, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States. The World Health Organisation serves as an expert advisor to the

In terms of the reconfiguration of public health risks the 1998 Communicable Diseases Decision to ‘formalise’ the existing networks of national networks of epidemiologists and public health executives into a single European institutional actor was an important stepping stone for decoupling the different national approaches and cultures to communicable diseases and creating one European ‘best practice’. At the same time the EU involvement remained limited to communicable diseases, particularly to a predetermined list of diseases. Thus, although the reconfiguration of public health expertise in the direction of surveillance and preparedness for communicable disease outbreaks as security threats had also reached the EU level, to a large extent the focus was still on the list of known diseases that formed the backbone of these public policy efforts. This changed rather swiftly after the 9/11 terrorist attacks.

B Securitisation of EU Public Health Risks

The 9/11 attacks in 2001 and the subsequent Anthrax attack played an important role in the securitisation of EU public health. Communicable disease control generally in the EU had little political traction.⁷⁷ Scott Greer in this respect noted that:

Politically, communicable disease control policy is caught in the logic of crisis and collective action: outside of crises, it is hard to find energy for collective action, whereas in crises, countries can sometimes overcome the barriers to collective measures and take actions.⁷⁸

In response to the 9/11 attacks the Council immediately created a ‘Health Security Committee’ (HSC) which was an informal group of high level ministerial and health department representatives, principally conceived as being able to bind its Member States as a matter of intergovernmental, diplomatic executive action rather than EU action.⁷⁹ As outlined above, not long after the creation of the HSC in 2003, Unit C3, a special health threat is established in DG SANCO. This ‘Health Threats Unit’, beyond managing the EWRS

GHSI. The network is made up of the Public Health Agency of Canada, the Health and Consumer Protection Directorate-General of the Commission, Ministère de la Santé et des Solidarités of France, the Federal Ministry of Health of Germany, the Ministry of Health of Italy, the Ministry of Health, Labour and Welfare of Japan, the Ministry of Health of Mexico, the Department of Health of the UK, the Department of Health and Human Services of the USA, and the WHO.

⁷⁷ Greer, *Everything You Always Wanted to Know about European Union Health Policies but Were Afraid to Ask* (n 59). At p. 57.

⁷⁸ *ibid.*

⁷⁹ ‘European Council, Declaration by the Heads of State or Government of the European Union and the President of the Commission. Follow up to the September 11 Attacks and the Fight Against Terrorism (19 October 2001, Brussels) (SN4296/2/01 REV 2)’. European Commission, ‘European Commission, Programme of Cooperation on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security) Luxembourg, 17 December 2001 (G/FS D(2001) GG)’.

system and its management of the Network Committee and the HSC, was also made responsible for the surveillance and early warning for communicable diseases caused as a result of acts of bioterrorism and chemical threats. Furthermore, the unit was given the task to operate a Health Emergency Operations Facility in Luxembourg.⁸⁰

With the setup of the HSC, beyond the Health Threats Unit in DG SANCO, a new set of experts entered the scene. The HSC, which has been since ‘formalised’ by the Health Threats Decision, was created to provide a setting in which emergency decisions could be taken on a European level. For the large part of the last decade, the HSC has functioned as an informal, intergovernmental gathering of high level Member States’ ‘health security experts’. The intention was that the Member State representatives in the HSC are authorised by their health ministers to make coordinated decisions and commitments with respect to responding to major health threats.⁸¹ However, as practice evolved representatives of DG SANCO and other relevant Commission services and agencies, such as the ECDC and the EMA, also gave input for the HSC.⁸² The HSC invites experts and there are working groups that reside under the HSC.

An important difference between the EWRS Network Committee and the HSC is that it is not mainly public health experts and epidemiologists that form the expert-base. Rather the Committee expects its members to be able to switch between engaging with public health and security issues. Beyond the scientific aspects of the pathogen or threat to health the Committee assesses the political, social and economic implications European health emergency decisions would have.⁸³ It is meant to take decisions in an emergency, keeping in mind the interrelated systems of the economy, critical infrastructure and interlinkages of crucial sources and systems for sustaining human life.⁸⁴ In the words of a member state

⁸⁰ The Health Emergency Operations Facility is located in Luxembourg and is used for the management of alerts and emergencies notified by Member States. During an emergency situation the response of the Commission, Member States, and Agencies residing under the Commission including the liaison with international organisations such as the WHO are coordinated from this facility. European Commission, DG SANCO, The Commission Health Emergency Operations Facility: for a coordinated management of public health emergency at EU level, 2007, available at: <www.ec.europa.eu/health/archive/ph_threats/com/preparedness/docs/heof_en.pdf> (Last accessed March 2014).

⁸¹ see Communication from the Commission to the Council on transitional prolongation and extension of the mandate of the Health Security Committee in view of a future general revision of the structures dealing with health threats at the EU Level (COM (2006) 699 final); Council of the European Union, 2786th Council Meeting Employment, Social Policy, Health and Consumer Affairs, Brussels, 22 February 2007 (6226/07 Presse 23).

⁸² de Ruijter (n 71).

⁸³ ‘European Commission, Commission Staff Working Document, Health Security in the European Union and Internationally (SEC(2009)1622 Final) Brussels, 23/11/2009’ (n 5).

⁸⁴ Collier and Lakoff (n 25).

representative in the Council Working Group on Public Health, the HSC: 'is about assessing the situation and acting'.⁸⁵ In the HSC there is no divide between the 'expert' and the 'executive', or between 'risk assessment' and 'risk-management'. The guise of security and the possibility of having to take immediate action mean that these divisions could be a 'time-consuming threat' in itself. Two Member State representatives described the HSC in the following manner:

It is not a pure expert group, you also have experts group like: people meeting on cancer, ... and then you have on the other side the formalised council working groups and in between you have such things as the Health Security Committee, where it is not only experts, it is about governmental questions, what is the government doing, but not in this EU legislative sense⁸⁶

The idea is that Member States send high-level representatives. If you want the Health Security Committee to really be able to decide on something ... you put someone there that has a direct line with your minister. Since there are very important, politically sensitive issues if it is a crisis. I mean, how many ministers had to resign because of this kind of crises? It is very sensitive and once that people are dying for example, your minister, politically, is being asked questions almost daily. It's fear. The national parliament is feared. The press is alert. Citizens or civil society groups put pressure on the minister. If you want the Health Security Committee to reach something, you need a representative who has the authority and the possibility to engage his minister. Otherwise it is useless, to have an agreement in the Health Security Committee when you have representatives who are not covered politically by the minister.⁸⁷

After 9/11 a number of public health threats such as SARS, bird flu, swine flu, E-coli, and volcanic ash cloud strengthened the role of the HSC and its mandate became broader.⁸⁸ The outbreak of swine flu was a turning point with respect to the way EU response was orchestrated. In 2005 pandemic preparedness plans had been implemented in many Member

⁸⁵ Respondent 3 (MS Representative Working Party on Public Health in the Council, 2010).

⁸⁶ Respondent 2 (Deputy Permanent Representative for Health in the Council, 2010).

⁸⁷ Respondent 4 (MS Representative Working Party on Public Health in the Council, 2010) and further: 'For us this is really the forum where Member States can talk and discuss and decide. So, for us it is very clearly a forum with an intergovernmental way of working. And it should be, because we are talking about Member States competences once again'.

⁸⁸ Commission Communication, 'Communication from the Commission to the Council on Transitional Prolongation and Extension of the Mandate of the Health Security Committee in View of a Future General Revision of the Structures Dealing with Health Threats at the EU Level (COM (2006) 699 Final)'.

States on the basis of WHO guidelines and with the health of the ECDC.⁸⁹ When the first news came that there was a swine flu outbreak in Mexico, the EU immediately became highly involved in response planning, particularly also given that a ‘fast track’ procedure for the authorisation of pandemic vaccines by the European Medicines Agency had to be activated, and without the declaration of an ‘Emergency of International Concern’ by the WHO, the fast track procedure could not be activated according to the EU regulations on medicines.⁹⁰ Over the course of the unfolding of the swine flu pandemic, the HSC and the Network Committee, both acting under the auspice of the European Commission’s Health Threats Unit, were increasingly working together when decisions were made by the HSC that formally fell under the responsibility of the Network Committee, and where the HSC basically had no formal powers.⁹¹ Thus, as an institutional matter the public health experts and security experts were merged and the public health powers available at the EU level were used to formalise security measures that without the context of the Network Committee would be ‘mere’ diplomatic agreements.

The EU’s response to the swine flu outbreak represents the first time a public health emergency of pandemic scale was coordinated at the EU level. Member States were highly vulnerable due to the availability of vaccines being dependent on the EU central authorisation procedures and with respect to the information available to the public, given the plethora of open access online sources.⁹² As a result, this health emergency opened a ‘window of opportunity’ for more far-reaching legislation at the EU level. After an elaborate ‘evaluation’ and ‘learning-lessons’ period,⁹³ the Commission in 2011 proposed a new Decision on Health Threats, that would integrate the public health and security framework completely.

⁸⁹ European Commission, ‘European Commission, Interim Document, Technical Guidance on Preparedness Planning for Public Health Emergencies, April 2005’.

⁹⁰ European Commission Staff Document, ‘European Commission Staff Document, Regulatory Process for the Authorisation of Antiviral Medicines and Vaccines in the Protection against Pandemic Influenza H1N1 2009, Accompanying Document to the Communication to the Commission to the Council, the European Parliament and the European Economic and Social Committee and the Committee of Regions, Pandemic Influenza H1N1 2009 (COM(2009) 481-SEC(2009)119 Final)’.

⁹¹ See for instance HSC/EWRS Statement on priority groups for vaccination, ‘EU Health Security Committee (HSC) / Early Warning and Response System (EWRS) HSC EWRS Statement on Influenza A(H1N1) 2009: Target and Priority Groups for Vaccination. 25 August 2009, Available at: http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/hsc_ewrs_statement_en.pdf (Last Accessed March 2014)’.

⁹² EPSCO Council Conclusions, ‘Council Conclusions on Influenza A/H1N1 Infection 30 April 2009, 2965th Employment, Social Policy, Health and Consumer Affairs Council Meeting (Luxembourg, 12 October 2009)’.

⁹³ European Medicines Agency, ‘European Medicines Agency, Pandemic Report and Lessons Learned Outcome of the European Medicines Agency’s Activities during the 2009 (H1N1) Flu Pandemic (29 April 2011) Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/04/WC500105820.pdf (Last Accessed March 2014)’. European Commission Staff Working Document, ‘Commission Staff Working Document, Vaccination Strategies against Pandemic (H1N1)2009 Accompanying the Communication from the

IV Conclusion

The reconfiguration of expertise in the area of public health befitting a security framework and the co-production the EU executive changes with respect to the response to a health emergency in the Health Treats Decision have resulted in a growing role for the EU executive power in the field of human health. The lines of the executive and the expert, the ‘risk-assessor’ and the ‘risk manager’ become blurred in the Health Security Committee that is created by the Health Treats Decision. The scope of the field of public health is widened and enlarged to an ‘all hazard’ field of threats, whereby chemical attacks, bioterrorism and environmental threats are all on par with communicable diseases. The public health experts are reconfigured as ‘health security experts’ in the HSC, in which and the mode of governance is intergovernmental, rather than part of a – however imperfect – system of procedural checks of executive action as the examination procedure that the Network Committee works under the earlier Communicable Diseases Decision of 1998 prescribed.

The basic expert rationale of what major health threats require in the Health Threats Decision is that of preparedness for possible unknown risks. Given that it entails an open-ended article that allows the regulatory instruments, actors and surveillance and response mechanism to be legally used in case of emergencies unforeseen in the Decision itself, it creates a vast potential for the EU executive to engage in the response to anything that may be framed as a ‘health threat’.⁹⁴

Communicable disease control and prevention have been long-standing champions of the welfare state. The public health experts that came together in the 1990s at the EU level to exchange ideas and strategies in order to cope with these public health challenges as a network of experts, have now been overtaken by a new rationality. And this rationality of public health preparedness, threats and security put the power of expertise and knowledge about risks in the hands of ‘health security’ specialists. And this paradigm creates a new route for the EU to affect the welfare systems: vaccination schemes are no longer a way for national governments to protect its population from disease, but are reconfigured as a security

Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions (Pandemic H1N1 2009) (COM(2009)481-SEC (2009)1189 Final). Commission Communication, ‘Communication from the Commission to the Council, The European Parliament and the European Economic and Social Committee and the Committee of Regions, Pandemic (h1N1), Commission Staff Working Document on Joint Procurement of Vaccine against Influenza A H1N1 2009 (COM (2009)481 - SEC (2009)1188).’

⁹⁴ European Commission, ‘European Commission, Interim Document, Technical Guidance on Preparedness Planning for Public Health Emergencies, April 2005’.

instrument.⁹⁵ In other words, the shift from public health expertise to security expertise also shifts the attention towards critical infrastructures, which entails a much broader ‘security view’ that also keeps in mind business continuity, competitiveness and other threats to security rather than the public health view that is mainly focused on the life and health of the population.⁹⁶

Furthermore, the focus on security in the field of public health also shifts away the attention and resources from the public health problems that produce far greater morbidity and mortality, and can only be solved by socio-political interventions that focus on pervasive and on-going health problems rather than focusing on unlikely, extreme and rare events.⁹⁷ The Health Threats Decision in this regard creates a stronger base for the EU executive to coordinate and respond to public health events in comparison to previously available powers. However, beyond the growing role of the EU executive in the field of public health as co-produced by a newly-blended landscape of public health-security expertise and experts, the public health policies of the Member States are also affected by the growing role of the EU level of the expert-executive in this respect.⁹⁸ The role of the EU in this respect may affect the lives of individual Europeans significantly.⁹⁹

⁹⁵ European Commission Staff Working Document (n 93).

⁹⁶ See Flear (n 2).

⁹⁷ *ibid.*

⁹⁸ Erik Baekkeskov and PerOla Öberg, ‘Freezing Deliberation through Public Expert Advice’ (2016) 0 *Journal of European Public Policy* 1.

⁹⁹ de Ruijter (n 71).