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# EU external health security policy and law

Anniek de Ruijter

*In an interdependent society, health risks may come from anywhere: health crises may start with industrial pollution, a veterinary epidemic or a natural disaster. It is therefore not only geographical boundaries that need to be removed, but also sectoral ones.*<sup>1</sup>

## 1. INTRODUCTION

The link between public health and security is not new. As early as 600 BC, infectious disease was recognized for its possible use in warfare.<sup>2</sup> Polluting the water or infecting the enemy's livestock was a common strategy of war.<sup>3</sup> The use of smallpox in the Americas is another example of the use of infectious disease as a biological weapon in history.<sup>4</sup> In 1975 the United Nations (UN) Biological Weapons Convention (BWC) entered into force, banning the development, production and stockpiling of biological weapons.<sup>5</sup> More recently, the term 'health security' or 'biosecurity' has been used to identify the integrated approach to 'society's collective responsibility to safeguard the population from dangers presented by pathogenic microbes – whether naturally occurring or intentionally released'.<sup>6</sup> What is new in this approach is that where the terms 'biosecurity' or 'health security' would once generally refer to the use of pathogens in bio-warfare, 'health security' now also refers more broadly to the dangers of *naturally* occurring infectious disease and other traditionally singular public health issues.<sup>7</sup> One of the underlying reasons for the new approach is the potential scale and threat posed by these events to the changed global trade and travel environment in which public health emergencies occur.<sup>8</sup>

Similarly, in the EU the term 'health security' generally refers to policy that aims to address the security aspects of public health emergencies that can be the result of

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<sup>1</sup> See para 2.7 of the Opinion of the European Economic and Social Committee, 'Proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health' COM (2011) 866 final.

<sup>2</sup> Stefan Riedel, 'Biological Warfare and Bioterrorism: A Historical Review' (2004) 17 *Proceedings* 400.

<sup>3</sup> M Wheelis, 'Biological Warfare at the 1346 Siege of Caffa' (2002) 8(9) *Emerging Infectious Disease Journal*.

<sup>4</sup> In South America Pizarro wilfully gave the natives variola-infected clothes: Riedel (n 2).

<sup>5</sup> Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, entry into Force 26 March 1975.

<sup>6</sup> David Fidler and Lawrence Gostin, 'Biosecurity Under the Rule of Law' (2007) 38 *Case Western Reserve Journal of International Law* 437, 438.

<sup>7</sup> David Fidler and Lawrence Gostin, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (Stanford University Press 2007).

<sup>8</sup> *ibid.*

communicable disease outbreaks, pandemics, emerging or re-emerging diseases, antimicrobial resistance, natural or man-made disasters, and humanitarian emergencies with health consequences. This includes threats from chemical, biological, radiological and nuclear accidents or attacks (CBRN).<sup>9</sup> Internally, this policy is created on the basis of Article 168 TFEU and the 2013 ‘Health Threats Decision’.<sup>10</sup> Externally, the EU coordinates its actions with the World Health Organization (WHO) Regional office, which has 53 member states. In this context, the EU and the WHO work together within the framework of the International Health Regulations (IHR).<sup>11</sup> Furthermore, the EU recently launched a European Medical Corps to contribute to a Global Health Emergency Workforce.<sup>12</sup>

In this chapter the external outlines of the EU’s health security law and policy are traced as a newly emerging aspect of EU external relations law and policy.<sup>13</sup> To what extent is EU health security policy emerging and what questions does this development raise with respect to EU law and policy? The protection of human health is particularly salient at the heart of the EU’s external relations law in its Common Commercial Policy and as part of its development policy.<sup>14</sup> In the Area of Freedom Security and Justice and the EU’s Common Foreign and Security Policy, the links are less obvious but, as this chapter will outline, do exist in their early stages.<sup>15</sup> Hence, the EU Global Strategy in the area of Security and Defence does touch on a number of specific aspects of health security. Furthermore, EU health security as a new type of policy showcases a specific example of the broadening of the EU’s CFSP/CSDP to bring the internal–external nexus of EU security closer together.<sup>16</sup>

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<sup>9</sup> Hylke Dijkstra and Anniek de Ruijter, ‘The Health-Security Nexus and the European Union: Toward a Research Agenda’ (2017) *European Journal of Risk Regulation* 1.

<sup>10</sup> 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 OJ 2013 L 293/1.

<sup>11</sup> WHO, ‘International Health Regulations 2005 (2nd edn, 2008).

<sup>12</sup> ‘The Objectives, Principles and Modalities for Continued Cooperation between the European Commission and the WHO Regional Office for Europe (September 2015). Available at: <[http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0009/287829/65id07e\\_Cooperation\\_EC\\_\\_150761.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0009/287829/65id07e_Cooperation_EC__150761.pdf?ua=1)>.

<sup>13</sup> TK Hervey and JV McHale, *European Union Health Law* (CUP 2015); see Tamara K Hervey, ‘The EU’s (Emergent) Global Health Law and Policy’ in Tamara K Hervey, Calum Alasdair Young and Louise E Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017).

<sup>14</sup> Hervey and McHale (n 13) 457; Panos Koutrakos, *The EU Common Security and Defence Policy* (OUP 2013), where he outlines the central place of EU commercial policy as being at the heart of its external relations law. Also see references by Bart Van Vooren and Ramses A Wessel, *EU External Relations Law: Text, Cases and Materials* (CUP 2014); Hervey and McHale (n 13) 515.

<sup>15</sup> See Hervey (n 13).

<sup>16</sup> Johan Eriksson and Mark Rhinard, ‘The Internal–External Security Nexus: Notes on an Emerging Research Agenda’ (2009) 44 *Cooperation and Conflict* 243.

The chapter first maps the relationship between public health and security and conceptualizes health as a possible transboundary security issue. The second step is to trace health policy more generally in EU external relations law in the context of the TFEU. Third, the chapter moves to a more specific exploration of EU health as a security issue, particularly, but not solely, in the context of the CFSP. In a last step the chapter delves into the internal–external nexus, where generally it is concluded that EU health security policy largely takes place under the TFEU heading rather than under the heading of the CFSP. The chapter builds in part on the first exploration of a research agenda on the public health–security nexus in various policy domains.<sup>17</sup>

## 2. HEALTH AS A TRANSBOUNDARY SECURITY ISSUE

Health security can be understood as a policy that is developing in a context of broadening security policy – beyond the realm of foreign security and defence (national security). The 1994 United Nations Development Programme report for the first time introduced the concept of ‘health security’ to refer to an important aspect of a broader idea of ‘human security’. Human security was meant to differ from the concept of (state) security, which relates to conflicts between nation states.<sup>18</sup> This blurring of the definition of security policy has also crept into the EU’s use of the concept of security, the latter being understood to also include the environment, cyber security, energy security and health.<sup>19</sup> Indeed, the broadening of what security policy entails has been put forward as a ‘paradigm shift’ in which the post-Cold War assumptions about the security threats facing nation states came with relatively clear understandings, entrenched and institutionalized practices, rules and organizations.<sup>20</sup>

Hence, health security is a relatively recent policy issue that challenges the internal–external security nexus. One of the theoretical frameworks used in the literature to explain its occurrence is ‘securitization’.<sup>21</sup> In this view, ‘normal’ public health issues such as infectious

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<sup>17</sup> Dijkstra and de Ruijter (n 9).

<sup>18</sup> United Nations, *Human Development Report* (OUP 1994) chapter 2.

<sup>19</sup> Panos Koutrakos, *The EU Common Security and Defence Policy* (OUP 2013) 82.

<sup>20</sup> Arjen Boin, Magnus Ekengren and Mark Rhinard (eds), *Security in Transition, Towards a New Paradigm for the European Union* (National Defence College 2008).

<sup>21</sup> Barry Buzan, Ole Wæver and Jaap de Wilde, *Security: A New Framework for Analysis* (Lynne Rienner Publishers 1998). Colin McInnes and Kelley Lee, ‘Health, Security and Foreign Policy’ (2006) 32 *Review of International Studies* 5. Stefan Elbe, ‘Pandemics on the Radar Screen: Health Security, Infectious Disease and the Medicalisation of Insecurity’ (2011) 59 *Political Studies* 848. See further discussion of securitization and health security policy in Dijkstra and de Ruijter (n 9).

disease can become securitized by political actors and reframed as security threats.<sup>22</sup>

Furthermore, as Elbe outlines, health security policy may also have the effect of ‘medicalizing’ security issues.<sup>23</sup> At the same time, besides their framing,<sup>24</sup> health problems, in a quickly globalizing and more interdependent world, can become ‘systemic risks’ and actual transboundary security issues.<sup>25</sup>

In this perspective security issues are now more difficult to predict.<sup>26</sup> An unknown pathogen may become a threat to security, given that we do not know how fast it will spread, what infrastructures may be affected and to what extent. But responses to CBRN threats may also intertwine with public health alert and response systems.<sup>27</sup> This means that we have moved from a world of calculable predictable epidemiological risks to a world in which we need ‘preparedness’ for unknown and incalculable security threats.<sup>28</sup>

On the whole, security is currently considered to be more than the absence of a military threat between nation states. Internationally, health security can be positioned within the internationalization of civil protection and security policy and has both a societal and individual connotation.<sup>29</sup> Health security focuses on preparing for and reducing the possibilities of a major threat to public health. The scale, size and impact matter for its designation as a health security issue. A local or seasonal flu outbreak will remain squarely within the policy realm of public health, but if that flu virus mutates from birds to humans (H5N1) or from pigs to humans (H1N1) it is likely to be considered as a threat to health

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<sup>22</sup> Anniek de Ruijter, ‘Mixing EU Security and Public Health in the Health Threats Decision’ in Anniek de Ruijter and Maria Weimer (eds), *EU Risk Regulation, Expert and Executive Power* (Hart Publishing 2017).

<sup>23</sup> Elbe (n 21).

<sup>24</sup> Stephen J Collier and Andrew Lakoff, ‘Health Security, and New Biological Threats: Reconfigurations of Expertise’ in Chloe E Bird, Peter Conrad, Allen M. Fremont and Stefan Timmermans (eds), *Handbook of Medical Sociology, Sixth Edition* (Vanderbilt University Press 2010). Stefan Elbe, ‘Haggling over Viruses: The Downside Risks of Securitizing Infectious Disease’ (2010) 25 *Health Policy and Planning* 476. Stephen J Collier and Andrew Lakoff, ‘The Vulnerability of Vital Systems: How “Critical Infrastructure” Became a Security Problem’ in Myriam Dunn Cavelty and Kristian Soby Kristensen (eds), *The Politics of Securing the Homeland: Critical Infrastructure, Risk and Securitisation* (Routledge 2008).

<sup>25</sup> Eriksson and Rhinard (n 15). 247.

<sup>26</sup> Marlies Glasius and Mary Kaldor, *A Human Security Doctrine for Europe: Project, Principles, Practicalities* (Routledge 2006). Commission on Human Security, ‘Human Security Now’ (United Nations 2003).

<sup>27</sup> Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (OUP 2018).

<sup>28</sup> Eriksson and Rhinard (n 15). Also see David Fidler and Lawrence Gostin, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (Stanford University Press 2007). And see David Fidler, ‘A Pathology of Public Health Securitism: Approaching Pandemics as Security Threats’ in Andrew Cooper (ed.), *Governing Global Health: Challenge, Response, Innovation* (Routledge 2016).

<sup>29</sup> David L Heymann and Sudeep Chand, ‘Diplomacy and Global Health Security’ in Ilona Kickbusch and others (eds), *Global Health Diplomacy: Concepts, Issues, Actors, Instruments, Fora and Cases* (Springer 2013).

security. The speed at which humans travel and the increased globalization of trade in food and animal products changes the context as well.<sup>30</sup>

Furthermore, to speak of ‘naturally occurring’ does not mean that human activity has no role to play in the emergence and rapid spread of disease. Contemporary medical and veterinary practice with its (over)use of antibiotics, leads to the emergence of incredibly strong drug-resistant strains of e.g. streptococcus and staphylococcus infections, tuberculosis, malaria, cholera and influenza.<sup>31</sup> Another factor that contributes to the current threats of natural causes is overpopulation, particularly in large cities, where in the closely populated areas the lack of access to clean water and sanitation in developing countries can increase the risk of a large-scale outbreak of infectious disease.<sup>32</sup>

Health security, however, refers to more than a policy relating to large-scale and severe public health events. Health security in terms of its techniques and approach is closely linked to existing security issues, such as that of the use of biological weapons. Internationally, the Geneva Protocol of 1925 banned the use of bacteriological agents in warfare (international cooperation on public health and infectious diseases dates back to the 19th century).<sup>33</sup> The current approach, however, both internationally and in the EU, is that in health security (or ‘biosecurity’) the policy effort addresses the use of biological and chemical weapons and the threat from naturally occurring infections *together*.<sup>34</sup> The underlying idea is that the current rate at which pathogens can originate in unknown locations and cross boundaries, such that societies, critical infrastructures and human lives disintegrate, demands similar policy and response mechanisms to those required by any other security issue.

‘Health security’ also differs from ‘public health’: the latter is seen as a field of policy, law or science that refers to the responsibility of public authorities to protect the population as a whole (vertical legal relations) as opposed to health care, or medical care, which addresses access to individual health care (horizontal legal relations – depending on the public/private

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<sup>30</sup> Thea Emmerling and Julia Heydemann, ‘The EU as an Actor in Global Health Diplomacy’ in I Kickbusch, G Lister, M Told and N Drager (eds), *Global Health Diplomacy: Concepts, Issues, Actors, Instruments, Fora and Cases* (Springer 2013) <[https://doi.org/10.1007/978-1-4614-5401-4\\_16](https://doi.org/10.1007/978-1-4614-5401-4_16)>.

<sup>31</sup> Catherine Lo Yuk-ping and Nicholas Thomas, ‘How Is Health a Security Issue? Politics, Responses and Issues’ (2010) 25 *Health Policy and Planning* 447.

<sup>32</sup> *ibid.*

<sup>33</sup> Fidler and Gostin (n 28) 2.

<sup>34</sup> Fidler and Gostin (n 28); David Fidler, ‘A Pathology of Public Health Securitism: Approaching Pandemics as Security Threats’ in Andrew Cooper (ed.), *Governing Global Health: Challenge, Response, Innovation* (Routledge 2016). Christian Enemark, ‘The Role of the Biological Weapons Convention in Disease Surveillance and Response’ (2010) 25 *Health Policy and Planning* 486.

nature and organization of the health care system).<sup>35</sup> Public health has been part of human life for centuries, particularly with respect to combating infectious disease. There are old religious texts that refer to isolation and quarantine strategies – detaining sailors on boats and in ports.<sup>36</sup> Public health as a science and a policy, as we now know it, developed in the 19th century and initially focused on the understanding and combating of infectious disease through public inoculation strategies.<sup>37</sup> However, also the conditions of populations, including the occurrence of disease more generally, has increasingly become the subject of exhaustive statistical analysis.

The development of public health over time has contributed to intensive eradication campaigns for a number of diseases, particularly polio and smallpox.<sup>38</sup> The general focus of public health policy is to curb the naturally occurring spread of infectious disease and to promote the overall health of the population, also with regard to non-communicable disease. Health security policy can hence be seen as being beyond public health, or somewhere between public health and security policy, where public health problems (man-made, or naturally occurring) can create sudden disruptions to the normal functioning of society, and the manner in which these problems are addressed is through a mix of public health and security expertise, law and policy.<sup>39</sup> In the following section the outlines of EU external, or global health law are considered, before zooming in on EU external health security policy and law in health security.

### 3. EU EXTERNAL HEALTH LAW

The EU's internal public health policy and law find their origins in the programmes to address 'black lung disease' in coalmines and in the development of health and safety standards for the steel industry.<sup>40</sup> Externally, however, the EU has developed its cooperation with the WHO on infectious diseases from the 1970s onwards.<sup>41</sup> The WHO is one of the most important

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<sup>35</sup> Lawrence O Gostin, Lindsay F Wiley and Thomas R Frieden, *Public Health Law: Power, Duty, Restraint* (3rd edn, University of California Press 2016).

<sup>36</sup> Philip A Mackowiak and Paul S Sehdev, 'The Origin of Quarantine' (2002) 35 *Clinical Infectious Diseases* 1071.

<sup>37</sup> G Rosen, *A History of Public Health* (Johns Hopkins University Press 1958) 168.

<sup>38</sup> F Fenner and others, *Smallpox and Its Eradication* (World Health Organization 1988).

<sup>39</sup> de Ruijter (n 22); Mark Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Bloomsbury Publishing 2015); Dijkstra and de Ruijter (n 9).

<sup>40</sup> Mackowiak and Sehdev (n 36) 1071. Also see, Commission de la Sécurité, de Hygiène Du Travail et de La Protection Sanitaire (Commission Permanente) Resolution OJ 1058 L 1.

<sup>41</sup> Exchange of Letters between the European Communities and the World Health Organization Laying down the Procedure for Cooperation between the Two Organizations – Memorandum Defining the Arrangements for

international actors for the EU's external relations in the field of public health; the Union has created a powerful role for itself in WHO policy and law<sup>42</sup> and is seen as a 'Global Health Actor' in this regard.<sup>43</sup> The main aim of the WHO as a specialized agency of the UN is to promote the principles of happiness, harmonious relations and the security of all peoples.<sup>44</sup> The WHO's International Health Regulations are binding on its member states. The IHR regulate the response and international coordination of public health emergencies. Both EU trade law and the work of the European Centre for Disease Control (ECDC) are linked to the IHR system.<sup>45</sup> Furthermore, the EU, although not a member of the WHO, is signatory to a number of conventions of the WHO.<sup>46</sup>

The EU's role in global health law is a relatively underdeveloped and under-researched one.<sup>47</sup> The research and development of the understanding of a 'global health law' itself is disputed and is largely seen in the compound of norms and processes of international law and fundamental rights that intersect with health.<sup>48</sup> Global health law as outlined by Gostin and others has a specific 'public health' dimension, which refers to the law as it aims to protect and promote the health of populations rather than as enabling individual access to health care ('health care law/medical law').<sup>49</sup> However, access to medical care and health care services, once seen as the last 'secret garden' of national welfare states,<sup>50</sup> has also become part of a

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Cooperation between the World Health Organization and the European Communities (72/725/ECSC, EEC, Euratom) OJ 1982 L 300/20; Exchange of Letters between the World Health Organization and the Commission of the European Communities Concerning the Consolidation and Intensification of Cooperation (2001/C1/04) OJ 2001 C 1/7; J Giesecke and J Weinberg, 'A European Centre for Infectious Disease?' (1998) 352 *The Lancet*.

<sup>42</sup> Samantha Battams, Louise van Schaik and Remco van de Pas, 'The EU as a Global Health Actor: Policy Coherence, Health Diplomacy and WHO Reform' (2014) 19 *European Foreign Affairs Review* 539.

<sup>43</sup> Vincent Rollet and Peter Chang, 'Is the European Union a Global Health Actor? An Analysis of Its Capacities, Involvement and Challenges' (2013) 18 *European Foreign Affairs Review* 309. Also see, on EU-ASEAN relations, Marie Lamy and Kai Phua, 'Southeast Asian Cooperation in Health: A Comparative Perspective on Regional Health Governance in ASEAN and the EU' (2012) 10 *Asia Europe Journal* 233.

<sup>44</sup> Preamble WHO Constitution, 'Constitution of the World Health Organization' (World Health Organization 1948).

<sup>45</sup> Hervey and McHale (n 13) 448.

<sup>46</sup> Hervey (n 13).

<sup>47</sup> Hervey and McHale (n 13) 432.

<sup>48</sup> *ibid* 435. LO Gostin, 'Public Health, Ethics, and Human Rights: A Tribute to the Late Jonathan Mann' (2007) 29 *The Journal of Law, Medicine and Ethics* 121; B Toebes, *The Right to Health as a Human Right in International Law* (Hart/Intersentia 1999); J Rothmar Herrmann and B Toebes, 'The European Union and Health and Human Rights' (2011) 4 *European Human Rights Law Review* 419.

<sup>49</sup> LO Gostin, 'A Theory and Definition of Public Health Law' (2007) 10 *Journal of Health Care Law and Policy* 1.

<sup>50</sup> S Greer, *The Politics of European Union Health Policies* (Open University Press 2009).

globalized market place, where medical tourism is revolutionizing and globalizing the health services industry.<sup>51</sup>

As Gostin outlines:

‘Global health law is the system and practice of international law – both hard law (e.g. treaties that bind states) and soft instruments (e.g. codes of practice negotiated by states) and soft instruments (e.g. codes of practice negotiated by states) – that shapes norms, processes and institutions to attain the highest possible standards of physical and mental health for the world’s populations.’<sup>52</sup>

The emerging external health law of the EU encompasses a wide range of policy topics in the field of human health such as: medical tourism; communicable disease; the health and safety of globally traded products; the regulation of pharmaceuticals and medical devices; international clinical trials regulation; trade (and foreign direct investment) in health services; the migration of health professionals; access to medicines; and the ‘right to health’.<sup>53</sup> As Hervey and McHale outline in their seminal textbook on EU health law, the field lacks the conceptual unity of EU health, law which has become increasingly prevalent in internal EU health law,<sup>54</sup> but the EU’s role in global health law is increasingly recognized.<sup>55</sup>

Legally, the Treaty seems to leave little space for developing a far-reaching EU external health law: Article 207(4)(b) TFEU outlines that with respect to actions in the field of trade, health services (but not public health) are subject to unanimous voting in the Council, and where the Treaties exclude harmonization, Article 207(6) TFEU applies. Article 207(6) TFEU iterates the limits of the use of EU powers to adopt regulations that reflect trade agreements, to the extent that the Treaty excludes harmonization. Article 168(7) TFEU retains competences in the field of health for the definition of their health policies and the organization and delivery of health services and medical care. This paragraph is particularly aimed at limiting EU powers in the highly redistributive area of Member States’ *health care* policy – although internally a number of important health care ‘markets’ are regulated by

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<sup>51</sup> I Glenn Cohen, *Patients with Passports: Medical Tourism, Law, and Ethics* (1st edn, OUP 2014); IG Cohen, *The Globalization of Health Care: Legal and Ethical Issues* (OUP 2013); Nathan Cortez, ‘Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care’ (2008) 83 *Indiana Law Journal* 71.

<sup>52</sup> Lawrence O Gostin, *Global Health Law* (1st edn, Harvard University Press 2014).

<sup>53</sup> Hervey (n 13).

<sup>54</sup> Dorte Sindbjerg Martinsen and Hans Vollaard, ‘The Rise of a European Healthcare Union’ (2015) *Special Issue Comparative European Politics*. Hervey, Young and Bishop (n 13).

<sup>55</sup> Tamara K Hervey and Jean V McHale, *European Union Health Law: Themes and Implications* (CUP 2015).

internal market law.<sup>56</sup> Furthermore, Article 6 TFEU also limits legislation and regulatory harmonization, and merely outlines a complementary and coordination role for the EU in *public health*. The external and internal connection for making EU action in the field of health possible due to Article 207(6) might imply that for most EU external health law, mixed agreements would be the only way the EU could create EU external health law.

Article 168(1) TFEU is a ‘mainstreaming provision’, echoed in the general provision of Article 9 TFEU. Both articles are aimed at the protection of a high level of (public) health in all EU policies and regulation. This means that in the formulation of its trade agreements and regulations, the EU would have the obligation to protect public health. Generally then, the possibility for EU external health law is limited, depending on how narrowly EU competence in the field is construed.<sup>57</sup> Nonetheless, the EU plays an important role in norm-setting with regard to public health in a number of more or less formal ways, particularly in the area of trade,<sup>58</sup> where the EU’s role has been important in carving out health protections.<sup>59</sup> Many of the international agreements between the EU and other countries address goods and services. And since most of these can have an impact on public health, such as food, tobacco or alcohol, pharmaceuticals or medical devices, the public health aspects are built into the very fibre of international relations law.

A case in point is the EU’s role in the United Nations Food and Agriculture Office (FAO), including its membership in the Codex Alimentarius Commission (CAC).<sup>60</sup> The CAC creates harmonized standards for the health and safety of food. Another site of EU impact in this regard is the GATT of the World Trade Organization (WTO). Some of the GATT (Article XX(b) GATT) exceptions are created for the protection of public health.<sup>61</sup> Also in Article 2.2

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<sup>56</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients’ Rights in Cross-Border Healthcare OJ 2011 L 88/45. Commission Regulation (EC) No 507/2006 of 29 March 2006 on the Conditional Marketing Authorization for Medicinal Products for Human Use Falling within the Scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council OJ 2006 L 92/6.

<sup>57</sup> Hervey, Young and Bishop (n 13) 449 et seq.

<sup>58</sup> Mark Flear, ‘Ensuring Post-Brexit UK Is a “Maker” Rather than a “Taker” of Global Norms and Standards: The Case of the International Council on Harmonisation’ (Social Science Research Network 2017) SSRN Scholarly Paper ID 2992551 <<https://papers.ssrn.com/abstract=2992551>>. Mark L Flear, “Technologies of Reflexivity”: Generating Biopolitics and Institutional Risk to Supplement Global Public Health Security’ (2017) 8 *European Journal of Risk Regulation* 658.

<sup>59</sup> Holly Jarman and M Koivusalo, ‘Trade and Health in the European Union’ in Hervey, Young and Bishop (n 13).

<sup>60</sup> The EU is highly active in the trade of food and feed. Public health protection mechanisms are a central concern in this regard. See for a number of examples of the roles and memberships of the EU in this regard (also in bilateral relations and neighbourhood policy): <[https://ec.europa.eu/food/safety/international\\_affairs\\_en](https://ec.europa.eu/food/safety/international_affairs_en)>.

<sup>61</sup> WTO, the General Agreement on Tariffs and Trade 1994 (GATT 1994).

of the Agreement of Technical Barriers to Trade, mandatory requirements are carved out for food and its characteristics that must not go beyond what is needed to meet legitimate objectives, which include the protection of public health. Pharmaceuticals, medical devices, blood and blood tissue and even the provision of health services are also affected by EU trade policies.<sup>62</sup> In a recent publication Jarman and Koivusalo trace the nature of these external EU health policies in detail and sound a note of caution about the lack of an actual health perspective and expertise at the EU negotiating table on these matters.<sup>63</sup>

Health also features prominently in EU development law, the latter is based on Article 208 TFEU, which for the EU creates a complementary competence to the development programmes of its Member States. Article 208 TFEU outlines the objective of reducing and eradicating poverty. With the ‘Millennium Development Goals’ there were a number of programmes supported by the EU that were related to poverty as a cause for ill-health and poverty as it relates to building infrastructure and capacity.<sup>64</sup> Furthermore, Article 208 TFEU underpins a number of international agreements between the EU and third states on supporting projects in the field of public health, which also focus on primary care and communicable disease control.<sup>65</sup> Other important policies for international agreements have been the illegal trade of narcotics and access to essential medicines, and the application of TRIPS health. The Millennium Development Goals have now been replaced by the Sustainable Development Goals, which have a wider connotation and create certain difficulties in reaching their global health objective.<sup>66</sup> Importantly, development goals are increasingly interwoven with trade policies. In this respect the EU is becoming more focused on the creation of ‘fourth wave’ trade agreements, which have a wide scope and include the fields of external EU health policies, which have been considered to be part of EU development law. In this regard, health is increasingly seen as a growth and competitiveness factor in external relations, rather than as a development matter.<sup>67</sup>

In sum, the EU is increasingly developing an ‘external health law’, which became more pronounced in 2010 when there were a number of EU initiatives to jump-start an explicit EU external health policy. This was related to the Lisbon amendments in 2008, when the EU was

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<sup>62</sup> Hervey (n 13).

<sup>63</sup> Jarman and M Koivusalo (n 59).

<sup>64</sup> Hervey and McHale (n 55) 463.

<sup>65</sup> Hervey (n 13).

<sup>66</sup> Meri Koivusalo, ‘Global Health Policy in Sustainable Development Goals’ (2017) 17 *Global Social Policy* 224.

<sup>67</sup> *ibid.*

given greater competences to act in the field of public health. The Commission outlined the EU's ambition to take on a leading role in global health in the Communication 'The EU in Global Health'.<sup>68</sup> In its subsequent Conclusions, the Council draws a clear link to the Millennium Development Goals (MDG) in the field of health and calls for focus on five priority areas: trade and financing, migration, security, food security and climate change.<sup>69</sup> Later that year, the WHO and the European Commission reviewed and gave fresh impetus to the existing EU-WHO partnership.<sup>70</sup> The important focus area here is health security, particularly the development of a uniform and efficient surveillance and alert system where the case definitions and methods for data collection, platforms on epidemic intelligence and response are harmonized.<sup>71</sup> The following section looks more closely at the role the EU is able to play in its external health law policy with respect to health security, whereby the concept of health security as transboundary security determines the scope of the exploration, rather than the exact boundaries between the CFSP and the TFEU.

#### 4. EU (EXTERNAL) HEALTH SECURITY POLICY

Alongside trade and development, EU external action in the area of health security became more focused after the 9/11 attacks, and particularly in the aftermath of the 2001 anthrax attacks.<sup>72</sup> In 2001 the threat of bioterrorism was specifically addressed by the G7 Global Health Security Initiative (GHSI), in which the EU is a partner, as is the WHO.<sup>73</sup> Legally, in 2005 the IHR strengthened the obligations for WHO members to notify public health threats,<sup>74</sup> which includes the deliberate release of a deadly pathogen. Under the IHR a 'Public Health Emergency of International Concern (PHEIC)' 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;

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<sup>68</sup> Global Health Comm. 445.

<sup>69</sup> Council Conclusions on the EU Role in Global Health (Brussels, 10 May 2010, 9644/10).

<sup>70</sup> Exchange of Letters between the World Health Organization and the Commission of the European Communities Concerning the Consolidation and Intensification of Cooperation (2001/C1/04) OJ 2001 C 1/7. European Commission and WHO Regional Office for Europe: A Shared Vision for Joined Action – Annex 2 Joint Declaration (EUR/RC60/12) (+EUR/RC60 Conf.Doc./6, 9 September 2010, 102442).

<sup>71</sup> *ibid*, 3.

<sup>72</sup> Dijkstra and de Ruijter (n 9).

<sup>73</sup> GHSI – Global Health Security Initiative <<http://www.ghsi.ca/english/index.asp>>.

<sup>74</sup> WHO (n 11).

- 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.

The 2005 strengthening of the IHR and the G7 GHSI may be seen in the light of some of the shortcomings of the WHO system: the notification and warning obligations that follow from the IHR are often not in the affected states' interest. Reporting a disease may harm trade interests. An example is the SARS epidemic, where China did not immediately notify the WHO, and where Canada did not comply with WHO travel advice, which could have warranted notification under Annex 2 of the IHR, or the Ebola crisis, which claimed over 10,000 lives before a PHEIC was declared.<sup>75</sup> Furthermore, the WHO only has limited powers to implement sanctions for non-compliance. At the same time, some Member States do not have the capacity to respond to the public health emergencies covered by the IHR. In the WHO context the EU itself is not a state party, but does have a seat at the table and coordinates Member States' contributions to the WHO, in order to speak as one bloc. The GHSI focuses on biological, chemical, radio-nuclear terrorism (CBRN) and influenza.<sup>76</sup> In this respect there is an international consensus<sup>77</sup> that, in the words of the UN Secretary General, '[t]he 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'.<sup>78</sup>

In the GHSI the G7 countries work together on the joint procurement of vaccines and antibiotics, the regulation of research into the creation of a smallpox vaccine, to improve, share and coordinate emergency plans and surveillance and create improved linkages on laboratories and preparedness for radio-nuclear and chemical events. The initiative facilitates a number of working groups and networks.<sup>79</sup> The Global Health Security Action Group (GHSAG) was established by the ministers of the G7 and is made up of senior officials that have to implement concrete actions and create a network of rapid communication in the event

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<sup>75</sup> Lawrence O Gostin and Rebecca Katz, 'The International Health Regulations: The Governing Framework for Global Health Security' (2016) 94 *The Milbank Quarterly* 264.

<sup>76</sup> *ibid.*

<sup>77</sup> 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.

<sup>78</sup> 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) vii–x.

<sup>79</sup> See <[https://ec.europa.eu/health/preparedness\\_response/cbrn\\_threats/ghsi\\_en](https://ec.europa.eu/health/preparedness_response/cbrn_threats/ghsi_en)>. Also see <<http://eu-un.europa.eu/questions-and-answers-on-the-global-health-security-initiative-ghsi/>>.

of a crisis.<sup>80</sup> The current networks and groups that operate under the GHSI are a Risk Management and Communications Working Group; Global Laboratory Network Working Group; Pandemic Influenza Working Group; Chemical Events Working Group; Radio-Nuclear Threats Working Group; Early Alerting and Reporting; Research Collaboration Support to the WHO in the implementation of the IHR.<sup>81</sup>

The GHSI has a Ministerial Forum, which is formed by the EU Commissioner for Health and ministers from the G7 countries. The WHO has a seat at the table as a technical advisor.<sup>82</sup> The EU's membership in the GHSI is taken into the EU Health Security Committee (HSC) where at EU level all Member States have high-level ministerial representation in the field of health security, which is designed to be able to take direct action if there is a health security threat to the EU.<sup>83</sup> The EU also hosts an international information platform for sharing information and data on CBRN threats, particularly when these relate to terrorist threats.<sup>84</sup>

The 2009 swine flu and Ebola outbreaks have spurred on further development in this area of EU external health security policy, where it is the United States that takes the lead, rather than the EU.<sup>85</sup> After the Ebola crisis in 2014, the US, with the support of the GHSI, launched a Global Health Security Agenda (GHSAG). At this point about 50 member states joined this initiative, which assesses countries' response capacities and action packages to improve preparedness. The implementation and effectuation of the IHR is also reiterated in this context.<sup>86</sup> It is difficult in these initiatives to draw the line between development, security and public health policy.

One possible interpretation of both the GHSI and the GHSAG is the creation of a 'coalition of the willing' in the reporting of public health events – with possibly disastrous effects. For instance, in the aftermath of the Ebola outbreak, the special representative of the DG for Ebola Response indicated that the IHR failed because countries reported to the WHO that

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<sup>80</sup> European Commission, 'Commission Staff Working Document, Health Security in the European Union and Internationally' (SEC(2009)1622 Final) Brussels, 23/11/2009.

<sup>81</sup> See the GHSI website and <<http://www.ghsi.ca/english/members.asp>>.

<sup>82</sup> See *ibid* and see further European Commission, DG Health (Public Health, Country Knowledge, Crisis Management Crisis Management and Preparedness in Health), High-Level Conference on Global Health Security 22–23 March 2016, Lyon, France – 'Flash Report'.

<sup>83</sup> Decision No. 1082/2013/EU (n 10). de Ruijter (n 22).

<sup>84</sup> European Commission Unit C3 (Health Treats) GHSAG on Risk Management and Communication – Meeting on Early Warning for CBRN Threats Luxembourg – 26 to 28 February 2008. Available at: <[http://www.episouth.org/doc/r\\_documents/GHSAG\\_short\\_report\\_for\\_PHEA\\_web.pdf](http://www.episouth.org/doc/r_documents/GHSAG_short_report_for_PHEA_web.pdf)>.

<sup>85</sup> Elizabeth M Speakman, Martin McKee and Richard Coker, 'If Not Now, When? Time for the European Union to Define a Global Health Strategy' (2017) 5 *The Lancet Global Health* 392.

<sup>86</sup> See <<https://www.ghsagenda.org/>>.

their health care was reaching 85 per cent of its capacity, while in his estimation 15 per cent was closer to the reality. These gaps in preparedness can make a considerable difference in the global spread and impact of a disease.<sup>87</sup> This is a major problem for the effectiveness of the work of the WHO.

At the same time, these health security initiatives may be a means of strengthening the capabilities of certain IHR members that do not have the necessary response capabilities to prevent a global outbreak. Another instrument that these multilateral networks may provide is a bigger platform for expert, multidisciplinary collaboration between agencies, such as the European Centre for Disease Control and the US Centres for Disease Control. At the last GHSI meeting in 2017, hosted by the EU, Europol requested more international collaboration in the area of terrorist attacks, particularly in the technical collaboration that is needed between the security sector and the health sectors' response measures. The EU further hosted a platform to advance this interface with experts from the GHSI and the security sector.<sup>88</sup>

The GHSI, the Joint Research Centre of the European Commission (JRC) and the WHO have also created an Epidemic Intelligence of Open Source platform to enhance the capacity to assess the threat of pandemics to global health security. A further operationalization of global EU involvement in health security is the sharing of viruses through the Pandemic Influenza Preparedness (PIP) Framework. In 2016, the GHSI were able to share Zika virus and serum samples for the purposes of risk assessment, as well as developing and expanding diagnostic capacity<sup>89</sup> outside of the PIP but through a more general agreement on the rapid sharing of emerging pathogens.

With respect to CBRN, although these are also part of the GHSI efforts and are integrated with the alert and response mechanisms for public health<sup>90</sup> within the EU, externally the EU is still involved in a rather fragmented manner. In the area of CBRN, the EU has adopted UN

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<sup>87</sup> European Commission, DG Health (n 80). Heinz Ellerbrok and others, 'External Quality Assessment Study for Ebolavirus PCR-Diagnostic Promotes International Preparedness during the 2014–2016 Ebola Outbreak in West Africa' (2017) 11 *PLoS Neglected Tropical Diseases*; GianLuca Quaglio and others, 'Ebola: Lessons Learned and Future Challenges for Europe' (2016) 16 *The Lancet Infectious Diseases* 259; Sarathi Kalra and others, 'The Emergence of Ebola as a Global Health Security Threat: From "Lessons Learned" to Coordinated Multilateral Containment Efforts' (2014) 6 *Journal of Global Infectious Diseases* 164.

<sup>88</sup> European Commission, DG Health (n 80). European Commission, DG Health, (Public Health, Country Knowledge, Crisis Management. Crisis Management and Preparedness in Health), Flash Report from the Plenary Meeting of the Health Security Committee 9 November 2017, Senningen/Luxembourg.

<sup>89</sup> European Commission, DG Health (n 82).

<sup>90</sup> European Commission, 'Health Security in the European Union and Internationally', SEC(2009) 1622 final. European Commission, 'Bridging Security and Health: Towards the Identification of Good Practices in the Response to CBRN Incidents and the Security of CBR Substances' COM(2009) 273.

Security Council Resolution 1540. This resolution creates obligations for all Member States to enforce measures against the proliferation of CBRN weapons and sets up a Global Initiative to Combat Nuclear Terrorism (GICNT), the G7 Non-Proliferation Directors' Group and Global Partnership, and the Nuclear Security Summit.<sup>91</sup> In the EU, over the last two decades particular attention paid has been paid to the threat of non-state actors' access to CBRN materials.<sup>92</sup> These concerns led to the adoption of a number of legal instruments at EU level. The European Security Strategy of 2003, adopted by the European Council after the 9/11 attacks, places special emphasis on the possibility of non-state actors gaining access to Weapon of Mass Destruction (WMD).<sup>93</sup> In 2003 the EU also formulated the EU Strategy against the proliferation of WMD, and a European Counter Terrorism Strategy.<sup>94</sup>

In the EU, in 2010 a CBRN Action Plan was adopted alongside a Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence Initiative, which aims to limit unauthorized access to CBRN materials, and improve Member States' capacity to prevent and detect CBRN incidents.<sup>95</sup> With regard to health issues that have a more direct link to the realm of security, action on CBRN threats became more pronounced in 2009 when the Commission adopted a Communication on CBRN security in the EU, with an 'Action Plan' annex that presented a number of national and EU measures to tackle these threats.<sup>96</sup> CBRN have also made their way into the new Counter Terrorism Directive, which was finally adopted in January 2017.<sup>97</sup> As will be outlined, the interfaces between CBRN and naturally occurring deadly pathogens are increasingly blurred in what concerns the internal or external nature of their policy implications.

The EU's neighbourhood policy is also an important site for external EU health security efforts, where the EU works with partner countries to strengthen the implementation of the IHR. This entails investment in capacity-building for prevention, early detection and response

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<sup>91</sup> See Chapter 9 in this volume.

<sup>92</sup> Caitríona Mcleish, 'Recasting the Threat of Chemical Terrorism in the EU: The Issue of Returnees from the Syrian Conflict' (2017) 8 *European Journal of Risk Regulation* 643.

<sup>93</sup> European Council, 'European Security Strategy: A Secure Europe in a Better World' (Brussels, 12 December 2003).

<sup>94</sup> Where biological and chemical attacks are found to pose a special threat: Council of the European Union, 'EU Strategy Against the Proliferation of Weapons of Mass Destruction' (Brussels, 10 December 2003 – 15708/03).

<sup>95</sup> See Action plan, Regulation (EU) No 98/2013 on the marketing and use of explosives precursors.

<sup>96</sup> Riedel (n 2); Christopher Baker-Beall, *The European Union's Fight against Terrorism: Discourse, Policies, Identity* (OUP 2016) 90, arguing that the manner in which the threat of CBRN was presented in these documents as a 'new threat'.

<sup>97</sup> Directive (EU) 2017/541 of the European Parliament and of the Council of 15 March 2017 on Combating Terrorism and Replacing Council Framework Decision 2002/475/JHA and Amending Council Decision 2005/671/JHA OJ 2017 L 88/6.

through training programmes in field epidemiology such as the MediPIET project.<sup>98</sup> This programme creates a network of competent public health professionals in 18 countries that would be available in the event of cross-border health threats.<sup>99</sup> The last section looks at the internal–external nexus in EU health security law and policy.

## 5. EU HEALTH SECURITY: BLURRING THE CFSP AND TFEU LINES

Health is a transboundary security issue that creates a nexus between internal and external and CFSP-TFEU security policy. In EU health security, however, this nexus is not neatly defined, but rather one of blurred lines. The current role of the EU in the field of health security presents itself as patchwork of policy areas, institutional actors, mechanisms and surveillance and response systems. Many consider that the EU Global Health Agenda as it was launched in 2010 has not delivered on its promises,<sup>100</sup> while at the same time, beyond the strictly public health agenda, the ‘security’ angle seems to have allowed more activity and more prominence for the EU<sup>101</sup> in a political landscape otherwise dominated by the US and the UN.<sup>102</sup>

Security as a frame for policy can easily encompass threats to human health. The widening of EU (external) security to encapsulate certain public health-related issues is taking place in a number of sites: globally, in the context of the WHO and the GHSI-GHSA and CBRN frameworks, and in the EU in the role of the HSC, which was intended only to involve internal health security issues but has increasingly also been the go-to forum for external EU health security coordination and policy.<sup>103</sup> Furthermore, the ‘mixity’ of threats to security, including the blurring of internal–external lines, is increasingly addressed within security policy. In a recent joint Communication of the High Representative of the Union for Foreign Affairs and Security Policy and European Commission, it is proposed to ‘adapt and increase’ the ‘EU capacity as a security provider’.<sup>104</sup> Further to the European Council Conclusions of

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<sup>98</sup> <[www.medipiet.eu](http://www.medipiet.eu)>, but see Speakman, McKee and Coker (n 85).

<sup>99</sup> With involvement of ECDC.

<sup>100</sup> Hervey and McHale (n 55) 446. Speakman, McKee and Coker (n 85). And see the response by Lies Steurs and others, ‘Role of the European Union in Global Health’ (2017) 5 *The Lancet Global Health* 756.

<sup>101</sup> Not without criticism: Steurs and others (n 100).

<sup>102</sup> Colin McInnes and Kelley Lee, ‘Health, Security and Foreign Policy’ (2006) 32 *Review of International Studies* 5. ‘Oslo Ministerial Declaration–Global Health: A Pressing Foreign Policy Issue of Our Time’ (2007) 369 *The Lancet* 1373.

<sup>103</sup> European Commission, ‘Flash Report from the Plenary Meeting of the Health Security Committee’ (n 88).

<sup>104</sup> High Representative of the Union for Foreign Affairs and Security Policy and the European Commission, Joint Communication to the European Parliament and the Council, ‘Joint Framework on Countering Hybrid Threats a European Union Response’ JOIN(2016) 18 Final.

June 2016,<sup>105</sup> the Communication calls for the creation of an ‘actionable’ framework to address ‘hybrid threats’. The concept of hybrid threats, according to the High Representative, aims to

‘capture the mixture of coercive and subversive activity, conventional and unconventional methods (i.e. diplomatic, military, economic, technological), which can be used in a coordinated manner by state or non-state actors to achieve specific objectives while remaining below the threshold of formally declared warfare. There is usually an emphasis on exploiting the vulnerabilities of the target and on generating ambiguity to hinder decision-making processes. Massive disinformation campaigns, using social media to control the political narrative or to radicalise, recruit and direct proxy actors can be vehicles for hybrid threats.’<sup>106</sup>

In the context of addressing these hybrid threats, the High Representative proposes to utilize the EU internal framework of the HSC, whenever there are health aspects involved in these threats.<sup>107</sup> This Committee is based on the 2013 ‘Health Threats Decision’ based on Article 168 TFEU, which was adopted after the 2009 swine flu outbreak to regulate EU involvement in the response to public health threats, chemical attacks and bioterrorism.<sup>108</sup> This Decision, adopted by the Council and the European Parliament, is an all-encompassing regulatory instrument and covers both known and unknown health risks. It is a European effort to, in the words of the European Commission, ‘bridge the policy fields of health and security’.<sup>109</sup> This ‘bridging’ also blurs the line between CFSP and TFEU policy fields and legal instruments, and the internal and external security nexus.

The Lisbon amendments to the Treaty under Article 168 TFEU created the possibility for the EU to coordinate cross-border threats. The Health Threats Decision regulates the coordination of Member States’ response to ‘major health threats’ by encompassing the already existing communicable disease control network and a number of health threats that were previously mainly addressed, if at all, in the context of security policy.<sup>110</sup> These other health threats include biochemical attacks and bioterrorism, and hazards caused by climate change.<sup>111</sup> Moreover, the coordinating structures created by the Health Threats Decision

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<sup>105</sup> European Council Conclusions, June 2015 (EUCO 22/15).

<sup>106</sup> ‘Joint Framework on Countering Hybrid Threats’ (n 104).

<sup>107</sup> *ibid*, para 4.

<sup>108</sup> See Decision No. 1082/2013/EU (n 11); de Ruijter (n 22).

<sup>109</sup> Commission, ‘Commission Proposal for a Decision of the European Parliament and of the Council on Serious Cross-Border Threats to Health’ COM(2011) 866 Final.

<sup>110</sup> Collier and Lakoff (n 24).

<sup>111</sup> Decision No. 1082/2013/EU (n 10).

‘should, 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 that public health measures taken to counter that threat are insufficient to ensure a high level of protection of human health’.<sup>112</sup>

The Decision thus casts a relatively wide institutional net as it brings a number of new security-related (CBRN threats) aspects into the fold of older systems for information exchange, surveillance and preparedness. For example, the Decision extends the Early Warning and Response System (EWRS),<sup>113</sup> which is operated by the ECDC and used to be available only for specific communicable diseases, to all health threats.<sup>114</sup> For coordination between Member States the Decision also links in with the Civil Protection Mechanism (Article 11(4) Decision). However, importantly, it also gives the HSC a legal basis, although the nature of the Committee is different from a more classical EU committee for EU regulation or implementing law.<sup>115</sup>

The HSC was initially installed after the 9/11 attacks and operated in a more or less intergovernmental manner.<sup>116</sup> In the Health Threats Decision the HSC:

‘In exceptional emergency situations, a Member State or the Commission may request response coordination within the HSC, as referred to in Article 11, for serious cross-border threats to health other than those covered in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.’

Its members are senior officials of the Member States’ health departments that have the ability to reach ad hoc decisions in an emergency, depending on the particular setting in which the HSC is convened. When in 2010 the EU’s Internal Security Strategy established a four-year strategy to help increase Europe’s resilience to crises and disasters, including hostile or accidental releases of disease agents and pathogens, the Commission at the same time asserted

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<sup>112</sup> *ibid*, recital 9.

<sup>113</sup> 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, OJ 1999 L 21/32.

<sup>114</sup> Decision No. 1082/2013/EU (n 10), para 16.

<sup>115</sup> 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, OJ 2011 L 55/13.

<sup>116</sup> See for a more elaborate history de Ruijter (n 22).

that the global nature of communicable disease ‘makes it futile to separate national/EU policy from global policy’ particularly in health security.<sup>117</sup>

The European Medical Corps, set up in 2016, is also in place to help medical and public health teams and equipment within and outside the EU and can make medical teams, public health coordination teams, mobile biosafety laboratories, medical evacuation planes and other assets available before a health security threat evolves. The recent Ebola outbreak prompted the setting up of this ‘white helmets’ initiative.<sup>118</sup> The Commission manages the initiative through the Emergency Response Capacity. The Medical Corps also works together with the WHO Global Health Emergency Workforce and is part of the European Civil Protection Mechanism.<sup>119</sup>

## 6. CONCLUSION: QUESTIONS FOR RESEARCH, POLICY AND LAW

The nature and existence of an internal EU health law is a matter of debate – one that is seen as problematic by some because of the EU’s limited powers in this field, the highly redistributive nature and the ethical and culturally loaded aspect of health care policy and law generally, and the fact that, in terms of underlying shared values, the Member States’ approaches are still largely asymmetrical. Yet it is also widely acknowledged that health may be affected locally, nationally, regionally and globally. Given the EU’s limited possibilities for harmonizing Member States’ laws on the basis of Article 168 TFEU, the EU’s global role is and has also remained limited. This overview of the EU’s external health security law has identified certain areas of increased policy efforts, as well as some of its failures.

The areas where the EU can have an international role to play in health are mostly within the context of trade, development and, to a lesser extent, security. The EU may impact health through these domains, but is not necessarily implementing a health policy for its own sake. In the field of development, health seems to be an obvious parameter for promotion, but in trade, health is an add-on factor to growth or competitiveness.

With respect to health security, a real blurring of internal and external and CFSP and TFEU policy lines occurs, which is mostly related to the manner in which health security threats present themselves. Where they are man made (biochemical threats), their origin can be non-

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<sup>117</sup> Hervey and McHale (n 55) 517. See further Commission, ‘The EU Role in Global Health’, COM (2010) 128 final.

<sup>118</sup> Joana M Haussig and others, ‘The European Medical Corps: First Public Health Team Mission and Future Perspectives’ (2017) 22 *Eurosurveillance* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5607656/>>.

<sup>119</sup> European Commission Press Release, ‘EU Launches New European Medical Corps to Respond Faster to Emergencies’ (MEMO/16/276).

government actors. Where the threat level of deadly pathogens rises to the level of a security problem in the EU, the institutional and legal actor that has a role in both internal and external matters is the HSC, which has a predominantly coordinating role. In this regard the EU has been increasingly present in responding to major outbreaks, such as in the highly pathogenic avian influenza (HPAI) crisis and the recent Ebola outbreak, where the EU requested longer-term efforts.

EU external health security law and policy raises a number of questions for research and policy. In terms of policy the question is to what extent the ‘security frame’ is helping in external relations. Does it make a difference to the problems of lack of compliance with and effectiveness of the WHO IHR model when addressing major public health threats? Or does it have the opposite effect? Does the security frame help the internal EU commitment to a health policy for major disease outbreaks? The question is also to what extent there really is an integration or nexus. In a recent meeting, GHSI defence and security experts were asked to help train some of the public health experts, but the precise impact on response and mitigation efforts has not been recorded in detail.<sup>120</sup>

There are also obvious downsides to the shift in entrenched perspectives on public health and security towards separate fields of policy. One important consequence this may have is for the international exchange of knowledge, for instance, and the supervision of biological science as part of the integration of public health and security. In the context of public health, science is ideally freely accessible because research is conducted under the protections of academic freedom and exchange of knowledge. However, in the context of security, science may pose a threat if it allows access to knowledge that could be used to create bioweapons.<sup>121</sup>

As public health and security intertwine, state borders may become more blurred, which is controversial with regard to public health in the EU, where competences are limited. Furthermore, health emergencies can easily become the focus of international efforts to mitigate the crisis in the short term, rather than bring about long-term structural public health reforms, which are deemed too complex and controversial.<sup>122</sup> The recent Ebola crisis is a prime example of this dynamic.<sup>123</sup> Furthermore, there are possible implications from an individual rights perspective: the people affected by a communicable disease in the ‘security

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<sup>120</sup> European Commission, DG Health (n 82).

<sup>121</sup> Ron AM Fouchier and others, ‘Transmission Studies Resume for Avian Flu’ (2013) 339 *Science* 520.

<sup>122</sup> Collier and Lakoff (n 24).

<sup>123</sup> Mohini Banerjee and Chelsea Jack, ‘Responding to Ebola: Retrofitting Governance Systems’ (The Hastings Center 2014).

frame' become an 'enemy' rather than a 'patient' and can become framed as a threat to public health, rather than the disease itself being seen as the threat.<sup>124</sup>

In view of these developments, a recent research agenda has been proposed that looks at the nexus between EU public health and security policy.<sup>125</sup> In light of this research agenda legal questions can be asked. The protection of individual fundamental rights and the interlinking of public health and security policies is also highly relevant in this regard.<sup>126</sup> Following the 9/11 attacks and their aftermath, there were calls to reassess and rebalance fundamental rights and security.<sup>127</sup> In the field of public health, there is a long-standing discussion about balancing public health and individual rights.<sup>128</sup> Public health in this respect has a long policy tradition of trading off public goods and private interests, keeping in mind the justice perspectives in this regard. This balance in most EU Member States has resulted in a finely tuned set of rules and public health practices. Changing the public health perspective into a security perspective may change this balance. This is important, because curtailing individual rights to protect the population at large has the potential to affect a particular group or part of the population more severely. Such was the case during the HIV/Aids outbreak in the 1980s, where containment strategies had an enduring impact on the individual rights of patients and groups suspected of carrying the HIV virus.<sup>129</sup> Hence, in exploring the emergence of EU external health security law and policy, important issues for law and policy can be identified that lead to a number of new questions for future research.

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<sup>124</sup> Wendy K Mariner, George J Annas and Wendy E Parmet, 'Pandemic Preparedness: A Return to the Rule of Law' (Social Science Research Network 2009).

<sup>125</sup> Dijkstra and de Ruijter (n 9).

<sup>126</sup> Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (OUP 2018).

<sup>127</sup> Jeremy Waldron, 'Security and Liberty: The Image of Balance' (2003) 11 *Journal of Political Philosophy* 191.

<sup>128</sup> David Fidler and Lawrence Gostin, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (Stanford University Press 2007). Gostin, Wiley and Frieden (n 35).

<sup>129</sup> Stefan Elbe, 'Should HIV/AIDS Be Securitized? The Ethical Dilemmas of Linking HIV/AIDS and Security' (2006) 50 *International Studies Quarterly* 119; JM Mann and D Tarantola, 'Responding to HIV/AIDS: A Historical Perspective' (1998) 2 *Health and Human Rights: an International Quarterly Journal* 5; Simon Rushton, 'AIDS and International Security in the United Nations System' (2010) 25 *Health Policy and Planning* 495.