Communicable disease control in international and European Union law: enhancing global health security through interaction and coordination between the International Health Regulations (2005) and Decision No 1082/2013/EU

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1. Introduction

Communicable diseases are infectious diseases caused by microbial agents (viruses, bacteria and parasites) which can be transmitted either directly, through human-to-human contact (contagious diseases), or indirectly, through an inanimate intermediary (airborne, foodborne and waterborne diseases) or a living intermediary (zoonoses). Their epidemic and pandemic potential makes them a major public health threat at global level.1 Suffice it to mention that the top ten causes of death reported since 2000 include communicable diseases such as lower respiratory infections, diarrhoeal diseases, tuberculosis and HIV/AIDS.2 Globalisation of travel and trade, population movements and environmental challenges have had a significant impact on the transmission of these diseases, which now cross borders at an unprecedented rate and multiply exposure and mutual vulnerability of people around the globe.3 Moreover, major health crises caused by the outbreak of emerging and newly identified communicable diseases (such as SARS, avian and swine flu and Zika) or the violent re-emergence of known ones (like poliomyelitis and Ebola), have lit the spotlight on the compelling need to guarantee a coherent global response to the most serious health threats.

Today, a paradigm shift in communicable disease control – axed on a stronger and more coordinated collective action – enables international institutions, governments and other relevant stakeholders to tackle major hazards and protect public health worldwide. A prominent role in this joint endeavour to achieve global health security is played by the World Health Organization (WHO) and the European Union (EU). These organisations are key actors in the Global Health Security Initiative, an

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2 WHO Fact sheet, The top 10 causes of death, 24 May 2018, www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death last accessed 6 February 2019. It is reported that lower respiratory infections remain the most deadly disease, causing 3.0 million deaths worldwide in 2016. The death rate from diarrhoeal diseases decreased by almost 1 million between 2000 and 2016, but still caused 1.4 million deaths in 2016. Similarly, the number of tuberculosis deaths decreased during the same period but is still among the top 10 causes with a death toll of 1.3 million. HIV/AIDS is no longer among the world’s top 10 causes of death, having killed 1.0 million people in 2016 compared with 1.5 million in 2000.

3 On the concept of mutual vulnerability, see Obijiofor Aginam, Global Health Governance. International Law and Public Health in a Divided World (University of Toronto Press 2005).
international partnership aimed at enhancing public health preparedness and response. Within this broader framework, the EU Health Security Strategy stands at the core of the EU policy to combat transboundary health threats, with the Health Security Committee serving as hub of the network and the European Commission playing the key role of a coordinating entity, also actively promoting, developing and strengthening relationships and international collaborations, including with the WHO. Against this background, this chapter offers a critical analysis of the legal framework applicable to communicable disease control at both universal and EU levels, with a focus on the WHO International Health Regulations 2005 (IHR), the only global binding instrument governing the reporting of disease outbreaks and the prevention of the international spread of public health emergencies of international concern, and Decision No 1082/2013/EU regulating the European Union’s response to communicable diseases and other serious cross-border threats to health. Both legal instruments are described in their essential features, innovative characteristics, scope of application and multi-hazard dimension. Special attention is paid to early warning and response systems and the challenges they pose in terms of coordination between Europe-wide networks and also between global and regional networks. Furthermore, the chapter explores the intersections between the IHR and Decision No 1082/2013/EU and emphasises the need to enhance cooperation between the WHO and the EU in order to maximise efficiency and minimise duplication of efforts. It concludes by advancing some proposals for possible further improvements in the coherent implementation of the IHR and the relevant EU legislation.

2. Communicable Disease Control in International Law

a. The International Health Regulations of the World Health Organization

Prevention and control of infectious diseases was the major driver for the development of international law in the field of public health. Starting from the mid-nineteenth century, the legal framework for communicable disease control has progressively evolved from bilateral and multilateral sanitary conventions, focused on the harmonisation of quarantine measures, to contemporary instruments of global health governance, first and foremost the WHO International Health Regulations. The establishment of the WHO in 1946 represented a landmark step in this evolving process. The Organization took upon itself the responsibility for the management of the international regime of

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4 The Global Health Security Initiative was launched in 2001 by the G7 countries (Canada, France, Germany, Italy, Japan, the United Kingdom and the United States) plus Mexico and the European Union. It was conceived as an informal international partnership serving as a unique forum for health ministers to meet on a regular basis and discuss health issues of global interest. As such, the Initiative’s main objective is to foster international cooperation on public health preparedness and responses to health crises and threats of biological, chemical, and radio-nuclear. In practice, it is meant to facilitate the sharing of information and the coordination of efforts, especially through joint cooperation in emergency preparedness and response plans, assessment and communication, disease outbreak containment, the procurement and development of vaccines and antibiotics, and surveillance of contamination of food and water supplies. The WHO serves as an expert advisor. See at www.ghsi.ca/english/index.asp last accessed 6 February 2019.


disease control and soon engaged in an onerous work of revision and consolidation of the existing sanitary conventions. This led to the adoption of the International Sanitary Regulations of 1951, the first universal and coherent legal regime of surveillance and control of ‘quarantinable diseases’ (plague, cholera, yellow fever, smallpox, typhus and relapsing fever) binding on all WHO Member States. In replacing all the conventions adopted between 1903 and 1944, the 1951 Regulations succeeded in remedying some of the most apparent shortcomings of the then existing conventional regime: geographical gaps, overlapping of treaties, inconsistencies due to the succession of treaties, obsolescence and inadequacy face to the developments of scientific knowledge and the increase in rate and speed of international traffic and trade. Nonetheless, they soon called for further updating and improvements, until a major revision was accomplished in 1969, when a consolidated version of the text was adopted under the name of International Health Regulations (IHR).

The IHR (1969) initially covered the six ‘quarantinable diseases’ mentioned above, but they were later amended to reduce the number of these diseases to three (yellow fever, plague and cholera) and to mark the global eradication of smallpox. The Regulations sought to guarantee maximum health security with minimum interference with world traffic. On the one hand, in order to shield States from the risk of importing infectious diseases, they established a global surveillance system based on notification duties, general and disease-specific provisions, and specific health-related capabilities at ports and airports. On the other hand, they contained provisions authorising maximum restrictive measures applicable to international movements of persons and goods, and limited government interference with regard to diseases not subject to the Regulations.

Over time, however, the IHR (1969) failed to achieve their core purposes due to a number of reasons mainly related to their narrow scope (suffice it to mention that HIV/AIDS could not be addressed by the Regulations), the dependence on official country notifications and the lack of a formal internationally coordinated mechanism to contain international disease spread. Therefore, a combination of major problematic factors determined the Regulations’ failure, prominent among them the obsolescence of the maximum restrictive measures approach, the adoption of over-restrictive public health measures contrary to the minimum interference objective, the breakdown of the surveillance system due to a regular failure to notify outbreaks, and WHO’s lack of enforcement powers. These factors, together with the growing concern about the emergence and re-emergence of diseases and the Regulations’ clear inadequacy to address them, triggered a further revision process, which was launched in May 1995. A few years later, the occurrence of the first global public health emergencies of the twenty-first century – the 2003 outbreak of SARS and the 2004 pandemic of avian influenza A/H5N1 – posed an even stronger demand for global health security and served as major catalyst for prioritising a thorough rethinking of the IHR. The revised International Health Regulations were finally adopted by the World Health Assembly in May 2005 and entered into force on 15 June 2007.

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8 Resolution WHA4.75 of 25 May 1951.
9 The Regulations are an international legal instrument binding on nearly all States of the international community. Articles 21 and 22 of the WHO Constitution confer upon the World Health Assembly the authority to adopt regulations on a broad range of topics, including ‘sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease’, which produce compulsory effects for all Member States that do not expressly ‘opt out’ or make reservations to them within a limited deadline. These provisions empower the Assembly with extraordinary and far-reaching normative powers, or quasi-legislative powers. See Gian Luca Burci and Claude-Henri Vignes, World Health Organization (Kluwer 2004) Chapter II, 124–55.
10 Ibid, 135.
11 Additional amending Regulations were adopted on 26 May 1955 and 23 May 1956.
14 Fidler, International Law (n 7) 61–68.
While the purpose and scope of the new Regulations remain substantially unaltered – ‘to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade’ – they embody a radically new strategy of global health governance. In fact, the revised Regulations devise a legal framework that engages different actors and stakeholders and places the interaction between national and international health authorities at the heart of decision-making and operational activities, with a view to sharing responsibilities and fulfilling the duty to cooperate to avoid major public health emergencies. Within this framework, the Regulations also set up a challenging interplay between public health goals and other collective interests such as human rights protection, freedom of trade, environmental safety and international security.

In essence, the IHR introduce a range of core innovations including: a much broader scope of application as compared to the past; obligations for States Parties to develop certain minimum public health capacities in terms of preparedness and response to large-scale public health emergencies; procedures for the determination of a ‘public health emergency of international concern’ and for the issuance of relevant recommendations; obligations to notify the WHO of events that may constitute a public health event of international concern; provisions authorising the WHO to rely on non-governmental sources of information and early warnings by third parties, taking into consideration unofficial reports of public health events and asking States for verification; protection and full respect for dignity, human rights and fundamental freedoms of persons and travellers; and the creation of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and the WHO.

As far as their scope is concerned, the IHR encompass a significantly broader spectrum of infectious diseases and also extend to the natural, accidental or deliberate release of biological, chemical or radionuclear materials. In practice, they confer on the WHO the jurisdiction to address any ‘public health risk’ (defined by article 1 as ‘a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger’), be it caused by ‘traditional’ communicable diseases (for example smallpox, cholera, pneumonic plague, yellow fever, meningitis), new and emerging diseases (such as SARS, human influenza caused by new virus subtypes, wild poliomyelitis, viral haemorrhagic fevers, like Ebola), or any other disease which may spread internationally and represent a serious risk to global public health. Therefore, in line with an ‘all hazards approach’, they apply to any ‘illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans’.


17 IHR, art 2.
18 See Fidler, ‘From International Sanitary Conventions’ (n 16) 326.
19 IHR, arts 5, 13 and Annex 1.
20 IHR, arts 12, 15, 49.
21 IHR, art 6.
22 IHR, arts 9-10.
23 IHR, arts 3, 23, 32.
24 IHR, arts 2-12.
25 IHR, art 1.
The concept of ‘public health emergency of international concern’ (PHEIC) is one of the core innovations introduced by the IHR. Article 1 defines a PHEIC as ‘an extraordinary event which is determined 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 the occurrence of a serious, sudden, unusual or unexpected situation, carrying implications for public health beyond the affected State’s national borders and requiring immediate international action. The responsibility of determining whether a public health event is within this category lies with the WHO’s Director-General, who may seek the views of the IHR Emergency Committee, an expert body which provides technical advice and views on whether an event constitutes a PHEIC, on the temporary recommendations that should be applied by the country experiencing such an emergency and by third countries, and on the termination of a PHEIC. Once the Director-General has declared a PHEIC, and temporary recommendations have been issued, these are communicated to the States Parties together with information on any health measure adopted by the States concerned. Such recommendations concern the appropriate health measures regarding persons, baggage, cargo, containers, conveyances, goods and postal parcels, which should be applied by States Parties in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

A similar procedure is adopted when the Director-General deems that a specific ‘public health risk’ calls for standing recommendations to be applied periodically or routinely.

b. Global Alert and Response Systems

Pursuant to article 6 of the IHR, States Parties are required to carry out an assessment of the urgent and international character of public health events occurring within their territories and detected by national surveillance systems. To this end, they are required to use the decision instrument provided in Annex 2 of the Regulations and notify the WHO of all events which may constitute a public health emergency of international concern as well as of any health measure implemented in response to those events. Annex 2 refers to: a) events concerning a restricted number of diseases (smallpox, wild poliomyelitis, human influenza due to new viral subtypes, SARS), which appear unusual and unexpected and pose a serious risk of adverse impact on public health; b) any event involving a given list of diseases (cholera, pneumonic plague, meningitis, yellow fever, viral haemorrhagic and other infectious fevers) whose dangerousness and epidemic potential are already known; c) any other unusual or unexpected event of potential international public health concern, including those of unknown causes or sources, which may have a public health impact and pose a potential risk of international spread and potential interference with international travel or trade. Any of these events has to be notified within 24 hours through the IHR portal. Notifications must be followed by ongoing communication of detailed public health information on the event, including, where possible, case definition, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed. Official event-related communications are carried out between the National IHR Focal Points and their corresponding regional WHO IHR Contact Points, both of whom are officially designated and required to be available on a 24 hours basis, 7 days a week. Furthermore, in order to provide the States Parties with the necessary technical tools to comply with the obligation of prompt notification, the Regulations also set up an integrated global alert and

26 IHR, arts 12, 49.
27 IHR, art 48.
28 IHR, arts 15, 49.
29 IHR, arts 16, 50, 53.
30 IHR, Annex 2: ‘Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern’.
response system, which relies on a number of major surveillance and emergency networks operating under the general umbrella of the IHR, including the Global Outbreak Alert and Response Network (GOARN), the International Food Safety Authorities Network (INFOSAN), the Global Early Warning System for Major Animal Diseases, including Zoonoses (GLEWS).

GOARN is a global network launched in 2000 to combat the international spread of disease, which gathers 110 technical institutions, nongovernmental organizations (NGOs) and networks, including WHO Regional Offices, Country Offices, collaborating centres and partners whose communications converge in a comprehensive ‘event management system’. The network pools human and technical resources for rapid identification, confirmation and response to outbreaks of international importance. The WHO coordinates international outbreak response using resources from GOARN.

INFOSAN is a joint WHO-Food and Agriculture Organization of the United Nations (FAO) network launched in 2004 to promote the exchange of food safety information and to improve collaboration among food safety authorities at national and international levels. Since 2012, the INFOSAN Community Website launched by the INFOSAN Secretariat is used also for disseminating food safety information to members during emergency situations. In addition to Emergency Contact Points and Focal Points from Member States, users include FAO and WHO staff, INFOSAN Advisory Group Members, regional food safety authority contact points, and WHO Collaborating Centre contact points.

GLEWS is a joint early warning system that builds on the added value of combining and coordinating alert mechanisms of WHO, FAO and the World Organisation for Animal Health (OIE). Networks from the international community and stakeholders are linked to assist in early warning, prevention and control of animal disease threats, including zoonoses. It was launched in 2006 to detect, analyse and assess each event for its potential international importance according to the risk assessment criteria set forth in the IHR. GLEWS also links with INFOSAN to ensure that food safety events are managed along the ‘farm to table’ continuum. Multidisciplinary risk assessment guaranteed by GLEWS provides added value to global early warning of zoonotic disease.

3. Communicable Disease Control in European Union Law

a. The Evolution of EU Legislation on Communicable Disease Control and Serious Cross-Border Threats to Health: from Decision No 2119/98/EC to Decision No 1082/2013/EU

Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. Following the amendments introduced by the Lisbon Treaty, article 168 TFEU has broadened the competence of the Union in the field of public health to address preparedness and response to serious cross-border threats to health. In this respect, to guarantee the highest level of health security to EU citizens, its paragraph 5 confers on the European Parliament and Council the legislative power to ‘adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health’.

So far, the most important measure adopted in this field is Decision No 1082/2013/EU on serious cross-border threats to health\(^\text{31}\), which repealed and replaced Decision No 2119/98/EC.\(^\text{32}\)

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Decision No 2119/98/EC, the core of EU legislation on communicable disease surveillance and control in the pre-Lisbon era, was adopted to set up a network to promote cooperation and coordination between Member States, with the assistance of the Commission, with a view to improving the prevention and control of given categories of communicable diseases. To this end, the Decision also established that the Commission, by way of implementing decisions, would establish an early warning and response system (EWRS) as a permanent communication network for the epidemiological surveillance and control of communicable diseases between the Commission and the competent public health authorities of the Member States.

The list of communicable diseases to be covered by the EWRS was provided in the Annex to Decision No 2119/98/EC, which was later integrated by Annex I to Commission Decision 2000/96/EC.\(^\text{33}\) The criteria for selection included consideration of the disease’s potential to cause significant morbidity and/or mortality across the Community; rarity and seriousness of the disease calling for a wider knowledge base; availability of effective preventive measures with a protective health gain. The original list of communicable diseases mentioned the following major categories: diseases preventable by vaccination, sexually transmitted diseases, viral hepatitis, food- and water-borne diseases and diseases of environmental origin, nosocomial infections and diseases transmitted by non-conventional agents. The categories added in 2000 included vector borne diseases, zoonoses, other communicable diseases of public health importance including diseases caused by deliberate release, and, most notably, communicable diseases potentially leading to emergencies of international concern identified according to Annex 2 of the IHR. The case definitions for these diseases were provided by Commission Decision 2002/253/EC.\(^\text{34}\) However, the list of diseases covered by the EWRS and the corresponding case definitions have been over time updated and integrated to include new and emerging diseases posing serious health threats of international dimensions, in parallel with the expanded scope of the IHR.\(^\text{35}\) Most remarkably, Commission Decision 2008/351/EC included any ‘[m]anifestation of a disease or an occurrence that creates a potential for a disease pursuant to Article 1 of the International Health Regulations which is a communicable disease pursuant to Annex to Decision No 2119/98/EC and related measures to be notified to the World Health Organization under Article 6 of the International Health Regulations (2005)’.\(^\text{36}\)

Despite such updates and integrations, experience gained in the implementation of Decision No 2119/98/EC showed that developments at Union and international level made a review of that legal framework necessary, especially with a view to extending its scope to cover health threats different from communicable diseases, in particular those related to other biological or chemical agents or environmental events, including hazards related to climate change. Decision No 2119/98/EC was thus replaced by Decision No 1082/2013/EU, which carried out an overall modernisation of the EU


response system laying down new rules on epidemiological surveillance, monitoring, early warning of, and response to serious cross-border threats to health. Decision No 1082/2013/EU was considered a milestone in building a stronger EU health security framework. It was intended to enable the Union and its Members to improve preparedness and strengthen capacity for a coordinated response to health emergencies, improve risk assessment and management (extending to threats different from communicable diseases and of which no EU Agency was in charge), strengthen the coordination of risk and crisis communication. In parallel, it revived the EWRS and extended the scope of the network to cover all kinds of health threats with a cross-border dimension. In fact, consistently with the concept of ‘all hazards approach’, the categories of international health emergencies to which the Decision applies, as listed in article 2, include threats of a biological origin (communicable diseases, antimicrobial resistance and health-care associated infections, biotoxins and other harmful biological agents not related to communicable diseases), threats of chemical, environmental or unknown origin, and ‘events which may constitute public health emergencies of international concern under the IHR, provided that they fall under one of the [other] categories of threats’ mentioned above.

The Decision imposed obligations on Member States and the Commission for cooperation and coordination in specific areas. First, the obligation for Member States and the Commission to consult each other within the Health Security Committee, in order to share best practices and experience in preparedness and response planning, to promote interoperability of national preparedness plans, and to address inter-sectoral dimension of preparedness and response planning, supporting implementation of core capacity requirements for surveillance and response under the IHR. Second, the obligation to communicate information for epidemiological surveillance, including events occurring in third countries, following the example of article 9 of the IHR. Third, the obligation to inform other Member States and the Commission, through the EWRS, of developments occurring at national level with regard to a cross-border health threat. Fourth, the obligation to notify an alert in the EWRS in case of an unusual and unexpected event affecting more than one Member State and requiring a coordinated response. Furthermore, it conferred on the Commission the power to adopt implementing acts in relation to a number of key aspects, and the power to adopt immediately applicable implementing acts on imperative grounds of urgency linked to the severity or novelty of a serious cross-border threat.

In essence, the major innovations introduced by the Decision consisted in the formalisation and strengthening of the role of the Health Security Committee and the rules on response coordination; extension of the EU legal framework to also cover threats other than communicable diseases (notably chemical and environmental threats and threats from unknown origin, but also antimicrobial resistance and bio-toxins); consultation on and coordination of preparedness planning; and a new legal basis for the already existing EWRS and epidemiological surveillance network. Another outstanding innovation was the mechanism for joint procurement of medical countermeasures (eg vaccinations), providing that if a Joint Procurement Agreement is signed, specific joint procurements of medical countermeasures can be organised.

b. European Rapid Alert and Response Systems

The EU response to public health emergencies relies on a number of early warning and rapid alert systems (RAS) established by the European institutions to ensure a prompt and effective reaction not only to communicable diseases (including foodborne diseases and zoonoses) but also to a wide range

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37 Decision 1082/2013/EU, art 4.
38 Decision 1082/2013/EU, art 6.
39 Decision 1082/2013/EU, art 7.
40 Decision 1082/2013/EU, art 9.
41 Decision 1082/2013/EU, art 5.
of health threats including the release of chemical, biological and radio-nuclear agents. These systems are based on a notification and information exchange network and are meant to trigger an immediate alert, in case of need, to enable EU Member States and the Commission to adopt the necessary response.

As said before, the most comprehensive RAS used in the context of communicable disease control is the EWRS, originally established by the above-mentioned Decision No 2119/98/EC. EWRS is part of the Community Network for Epidemiological Surveillance and Control of Communicable Diseases and connects the Commission, the national public health authorities responsible for communicable disease control and the European Centre for Disease Prevention and Control (ECDC). Since 2005 the EWRS is operated by the ECDC. The procedures governing the functioning of the system are currently regulated by Commission Implementing Decision (EU) 2017/253, which replaced Commission Implementing Decision 2000/57/EC in order to guarantee the uniform application of the EWRS. The system is currently used for alert notification (within 24 hours) of disease outbreaks with possible cross-border consequences, whenever the scale and severity of the threat concerned are or could become so significant as to affect more than one Member State and require a coordinated response at the Union level. It was successfully employed in a number of events such as SARS, avian influenza and other major international health emergencies. The list of communicable diseases and related special health issues to be covered by the EWRS, together with the relevant case definitions, have recently been provided by Commission Implementing Decision 2018/945, which brought both the list of diseases and the list of case definitions into line with the WHO nomenclature according to the International Statistical Classification of Diseases and Related Health Problems.

Although the EWRS is meant to be the overarching risk management IT platform, it is not the only network operating within the EU, given that other Europe-wide RAS exist in other areas of public health concern since the early 1980s. One of the earliest systems is the Rapid Alert System for Food and Feed (RASFF), which was launched in 1979 in order to share information about risks to public health detected in the food chain. While Regulation (EC) No 178/2002 provided a legal basis for this system, also specifying the criteria triggering a notification and the procedure to be managed by the Commission, Regulation (EU) No 16/2011 laid down the implementing measures, stipulating the duties of the RASFF network members and defining the different types of notifications. This Regulation provided that the system should be on duty on a 24 hours basis, 7 days a week. The Regulation entrusted the Commission with the task of verifying the RASFF notifications and informing third countries, and also introduced exact deadlines for transmitting alert notifications for Member States (48 hours) and the Commission itself (24 hours).

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47 Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions [2018] OJ L170/1.
In the field of zoonotic diseases which may have an impact on public health, the Animal Disease Notification System (ADNS), established by Directive 82/894/EEC\(^5^0\) (as amended by Commission Implementing Decision 2012/737/EU\(^5^1\)), is designed to register and document the evolution of important infectious animal diseases. This management tool ensures rapid exchange of information and immediate notification of alert messages between the competent authorities responsible for animal health in each Member States and the Commission. The system allows the coordination and monitoring of outbreaks of contagious animal diseases and enables both Member States and Commission services to take immediate measures to prevent the spread of the disease. Directive 82/894/EEC lays down the rules concerning the procedures for notification, in particular the information to be sent and time limits.\(^5^2\) It requires Member States to notify, within 24 hours of confirmation of the outbreak, primary and secondary outbreaks of listed infectious animal diseases such as bluetongue disease, foot and mouth disease, classical swine fever, African swine fever, Newcastle disease, etc.

In the field of radiological and nuclear threats, the European Community Urgent Radiological Information Exchange (ECURIE) system is the technical implementation of the Council Decision 87/600/Euratom on Community arrangements for the early notification and exchange of information in the event of a radiological or nuclear emergency.\(^5^3\) This system requires Member States to notify and provide information to the Commission and to the Member States affected, or liable to be affected, whenever a Member State decides to take measures of a widespread nature in order to protect the general public in any such event. Upon receipt of this information, Member States are required to inform the Commission of the measures taken and Recommendations issued or envisaged and, at appropriate intervals, of the levels of radioactivity measured by their monitoring facilities in foodstuffs, feedstuffs, drinking water and the environment. The Commission must then forward that information, plus information it receives from non-Community countries, to the competent authorities of all the other Member States. The point of contact and the Commission service designated to forward this information must be available on a 24 hours basis.

Concerning possible health threats due to the deliberate release of biological and chemical agents, the Rapid Alert System for Biological and Chemical Attacks and Threats (RAS-BICHAT) is the dedicated rapid alert system used for the exchange of information, notification of confirmed or suspected events, and coordination of response measures among partners. It was established under the Health Security Programme adopted by the EU Ministers of Health in December 2001. One of the priorities of this Programme is the setting up of a ‘mechanism for information exchange, consultation and coordination for the handling of health-related issues linked to attacks in which biological and chemical agents might be used or have been used.’\(^5^4\) The system links the Commission with the designated competent authority and 24 hours operational contact points of each Member States. It was established to serve in particular the Health Security Committee members to address and coordinate together with the Commission all preparedness and response issues in terms of public health threats related to attacks in which biological and chemical agents might be used.

In the specific field of incidents involving chemicals, the Rapid Alert System for CHEMical Incidents (RAS-CHEM) is a rapid alert system under development which is meant to address the existing gap in reporting mechanisms. In fact, since there is no standardised format or protocol for issuing alerts

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about chemical incidents across EU Member States or individual countries, the European Union Public Health Programme funded the Alerting System for Chemical Health Threats projects to develop an Alerting System and Health surveillance system for the deliberate release of chemicals by Terrorists. These projects established RAS-CHEM on the basis of protocols and operating procedures originally developed for EWRS. RAS-CHEM objective is to link the poison centres in the European Union, national chemical agencies and Health Ministries to facilitate the exchange of information on incidents including chemical agents relevant to terrorism and other events leading to release of chemicals, and consultation and coordination of counter-measures. It provides a mechanism to facilitate the rapid communication of information, ranging from reports on unusual cases to potential mass poisoning incidents. It also provides toxicological profiles for toxic chemicals that can be used to identify potential agents of intoxication. RAS-CHEM is meant to operate in the context of the IHR and in an international dimension using the mechanisms existing at EU level.55

c. Coordination of European Rapid Alert and Response Systems

The fragmented framework described above reveals the overall complexity of the Europe-wide network for surveillance and response and the challenges it poses. In the first place, the existence of multiple RAS, each one operating through its own portal, may create overlapping obligations and duplication of notification of events which may fall under multiple systems (as is the case with foodborne diseases and zoonoses, which are examples of cross-sectoral public health threats) and/or may cause a serious cross-border health emergency. In the second place, it has to be noted that the existing RAS operate on the basis of asymmetrical participation of European institutions and competent national authorities. In fact, while the EWRS involves all EU Member States, the Commission, ECDC, and EEA Countries (Iceland, Liechtenstein and Norway), the RASFF involves EU Member States, the Commission, the European Food Safety Agency (EFSA), EEA Countries and Switzerland; the ADNS involves EU Member States and Andorra, Faroe Islands, Norway and Switzerland; the ECURIE agreement has been signed by all EU Member States and Switzerland; RAS-BICHAT involves the Commission, the EU Member States and Norway. Such lack of coincidence between the institutional actors involved in the different systems may cause additional problems in terms of uneven circulation of notified events and communication of event-related information.

Ever since the adoption of the first measures of implementation of Decision No 2119/98/EC, the Commission has openly expressed its concern about the risk of overlapping or duplicated obligations stemming from different EU alert and response networks. In fact, in Recital 4 of Implementing Decision 2000/57/EC, the Commission stated that such decision was intended to facilitate the integration of the EWRS with other rapid alert networks set up at national or Community level for diseases and special issues to be covered by the system. According to the Commission, for the purpose of its implementation, the EWRS had to be operated by using in the first instance the Health Surveillance System for Communicable Diseases within the European Public Health Information Network (EUPHIN-HSSCD).56 The Decision also established that the EWRS should be reserved for those categories of events having the potential to become public health threats as described in its Annex I, that is, outbreaks of communicable diseases posing ‘a risk of propagation between Member States within the Community’ and ‘requiring timely, coordinated Community action’.

In line with this approach, the subsequent Commission Decision 2000/96/EC ruled on the integration of the network with other relevant surveillance mechanisms. In particular, article 4 provided that the


56 EUPHIN-HSSCD is the telematic system supporting the monitoring, surveillance of and Exchange of information on the health situation in the European Union. It offers a reliable and secure means of handling early warnings on communicable diseases. Within this framework, the EUPHIN delivers three key services: an early warning mechanism; access to and sharing of statistical and research databases; and access to textual reference data.
Community network should be put in place by modifying and integrating, as appropriate, existing Community-supported surveillance networks and by building up new networks for diseases not yet covered. Article 8 laid down the rules concerning specific networks for zoonoses for which surveillance of human cases was required under Directive 92/117/EEC (later repealed by Directive 2003/99/EC).\textsuperscript{57}

Further developments in this direction followed the establishment of the ECDC – which was specifically mandated to take action to ensure that the EWRS ‘is efficiently and effectively linked with other Community alert systems (e.g. animal health, food and feed and civil protection)’\textsuperscript{58} – and the adoption of Decision No 1082/2013/EU. In fact, Recital 8 of this decision stated that ‘to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Decision, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health’\textsuperscript{59} To meet this need for better coordination and integration it was provided that ‘the Commission […] ensure that alert notifications under the EWRS and other rapid alert systems at Union level [be] linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level’.\textsuperscript{60} Article 8 stipulated that the Commission would adopt implementing acts with a view to achieving coordination and consistency among existing structures and mechanisms.

Pursuant to this provision, the Commission adopted Implementing Decision 2017/253.\textsuperscript{61} According to Recital 7, structural duplication of alert notifications and conflicting actions should be avoided by allowing that other relevant RAS established under EU law or the Euratom Treaty use the EWRS to transmit alerts and information on events which are or may pose a serious cross-border health threat. Such interoperability is the object of a specific provision of the Decision. In fact, article 3 regulates multiple alert notifications providing that notifications have to specify whether the health threat has previously been notified through other alert or information systems at Union level or under the Euratom Treaty. It also adds that in case of multiple notification ‘the Commission shall indicate through the EWRS the lead system for the specific type of information exchange’. Pursuant to this provision, and consistently with the spirit of Decision No 1082/2013/EU, the EWRS has come to be recognised as the Europe-wide comprehensive system where notifications under RASFF, ADNS, ECURIE, RAS-BISCHAT, and RAS-CHEM converge, and where the European Commission, national public health authorities, EU agencies and international bodies are interlinked via co-notification mechanisms. In line with this approach, the EWRS also coordinates the European information exchange systems operating in other fields.\textsuperscript{62}

4. Intersections and Coordination between the IHR and Decision No 1082/2013/EU


\textsuperscript{58} Regulation 851/2004, art 8, para 2.

\textsuperscript{59} Decision 1082/2013/EU, recital 8.

\textsuperscript{60} Decision 1082/2013/EU, recital 16.

\textsuperscript{61} Decision 2017/253/EU, recital 4.

\textsuperscript{62} By way of example, the Annex to Implementing Decision 2017/253 lists the Common Emergency Communication and Information System (CECIS), the Major Accident Reporting System (EMARS), the European Notification System for Plant Health Interceptions (EUROPHYT), the Rapid Alert for Blood and Blood Components (RAB), the Rapid Alert System for Non-food Dangerous Products (RAPEX), the Rapid Alert for Tissues and Cells (RATC), the European Information Network on Drugs and Drug Addiction (Reitox).
The International Health Regulations have reinforced cooperation among the Members of the WHO, which include all Members of the European Union. This implies that for EU Member States the communicable disease control regimes established under the IHR and Decision No 1082/2013/EU inevitably overlap and need to be coordinated in order to maximise efficiency and minimise duplication of efforts.

Indeed, duplication of obligations is more than a hypothetical risk, given that Decision No 1082/2013/EU was adopted with the declared purpose of aligning EU legislation to the revised Regulations and the ‘all-hazards approach’ they embody.\(^6^3\) Suffice it to mention, by way of example, that both legal instruments impose on State Parties the duty to develop, strengthen and maintain core capacities to detect, assess, notify and report events;\(^6^4\) notification of events that may constitute a public health emergency of international concern;\(^6^5\) epidemiological surveillance and the sharing of information during unexpected or unusual public health events, including those occurring in third countries;\(^6^6\) and the duty to respond to international health emergencies with proportionate measures that do not conflict with other relevant obligations concerning restrictions on travel and trade.\(^6^7\)

Coordination between the IHR and Decision No 1082/2013/EU relies on several provisions contained in the latter, which expressly refer to the Regulations and endorse compliance with them. The most relevant ones include Recital 12, stating that the information provided by Member States to the Commission should include the elements that they are obliged to report to the WHO under the IHR; article 2, paragraph 1(e), providing that the Decision applies also to events that may constitute public health emergencies of international concern under the IHR; article 4, paragraph 1(d), imposing consultation between Member States, the Commission and the HSC aimed at supporting implementation of core capacities required by the IHR; article 9, paragraph 2, requiring simultaneous notification to the EWRS of events notified to the WHO as possible PHEIC; article 10, paragraph 2, providing that public health risk assessment by the EU shall ‘take into account’ relevant information provided by the WHO in case of a PHEIC; article 11, paragraph 1(a), requiring consultation with a view to coordinating response to health emergencies notified through the EWRS, including where a PHEIC is declared by the WHO Director-General under the IHR.

It has to be stressed, however, that Decision No 1082/2013/EU has not fully realized its objective, still allowing a few misalignments between the IHR and EU legislation. The first relevant example is offered by article 12, which enables the Commission to act independently of WHO whenever there is a specific public health danger at the Union level. In fact, this provision empowers the Commission to declare a public health emergency at Union level before the WHO Director-General has declared a situation of pandemic influenza or a PHEIC. In such cases, the risk assessment is carried out by the relevant European agencies (ECDC, EFSA or other) or by the Commission itself, taking into account any relevant information shared by other entities, especially the WHO. Once the decision to recognise a situation of public health emergency at Union level is taken, the Commission has to inform the Director-General.\(^6^8\) This is one possible situation where there might be no fully coordinated response, since the Commission’s duty to liaise with the WHO would not prevent the Union to take action before the Director-General and independently of the WHO Emergency Committee’s risk assessment.

Another major issue concerns the adoption of national public health measures. In fact, while article 43 of the IHR allows States Parties to take their own measures in response to public health emergencies of international concern, the adoption of public health measures within the EU requires coordination at Union level, as set out in article 11, paragraph 2, of Decision No 1082/2013/EU.

\(^{63}\) Decision 1082/2013/EU, recital 6.

\(^{64}\) IHR, arts 5, 13; Decision 1082/2013/EU, art 4.

\(^{65}\) IHR, art 6; Decision 1082/2013/EU, art 2.

\(^{66}\) IHR, arts 7, 9; Decision 1082/2013/EU, art 6.

\(^{67}\) IHR, arts 2.35; Decision 1082/2013/EU, recital 21.

\(^{68}\) Decision 1082/2013/EU, art 12, para 3; recital 24 states that ‘b]efore recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission’s analysis of the situation of the outbreak and to inform the WHO of its intention to issue such a decision’.
Although this Decision has 2013, the Regulations, COM (2006) 552 final.

69 members of a regional economic integration organization shall apply in their mutual relations the common rules in force with a view to achieving the optimal implementation of the IHR.

5. Concluding Remarks

Although not a party to the IHR,69 the European Union plays an important role in the implementation of the Regulations, both in consideration of the fact that they involve matters of EU exclusive competence as well as of shared competences between national governments and the Union, and also in light of the fact that the application of the IHR in the event of a PHEIC has clear EU policy implications, particularly on trade, transport and border policies.

So far, EU legislation has achieved a remarkable level of coherence between the global and the regional legal frameworks regulating communicable disease control and response to international health emergencies. As discussed before, Decision No 1082/2013/EU and the relevant implementing decisions adopted by the Commission have made a commendable effort to ensure the best possible coordination with the IHR, especially through interoperability of rapid alert and response systems, co-notification mechanisms, harmonisation of case definitions, and exchange of information relevant for risk assessment. However, although this Decision has translated into common rules and procedures most of the suggestions made by the Commission in its Communication on the implementation of the IHR,70 the legal framework set out by Decision No 1082/2013/EU is still open to further improvements.

Such improvements could be introduced by way of new Commission implementing decisions or they could otherwise be the object of an agreement between the WHO and the European Union. In this respect, it has to be noted that article 14 of the IHR envisages the possibility for the WHO to conclude agreements for the implementation of the Regulations with other competent international organisations, with whom the WHO is expected to cooperate and coordinate its activities, as appropriate. In the same wake, Recital 24 of Decision 1082/2013/EU states that it would be in the interests of the Union to conclude an international cooperation agreement with the WHO, covering the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health, involvement in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response planning, public health risk-assessment and collaboration on response coordination.

Turning to the substance of the desirable improvements to Decision No 1082/2013/EU, they should aim at strengthening cooperation and further enhancing coordination between the WHO and the EU, with a view to avoiding any residual duplication of efforts or significant misalignment, while recognising the added value that the Union brings to the implementation of the IHR. Possible interventions in this direction should include the appointment of the same national authorities as IHR National Focal Points and EWRS competent authorities for notification; the duty to simultaneously inform the EWRS and the WHO about events which are notifiable but do not represent potential PHEICs; appropriate mechanisms to liaise other global RAS (for example INFOSAN and GLEWS) with the EWRS (and the corresponding sectoral European RAS); consultation between the

69 However, the Regulations recognise the role of ‘regional economic integration organizations’ such as the EU, stating at article 57, paragraph 3, that ‘[w]ithout prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization’.

Commission and the WHO Director-General on the identification of emerging threats, the determination of the existence of an international public health emergency and the appropriate public health measures to be adopted as coordinated international response; official recognition of the role of ECDC with assignment of precise tasks linked to the implementation of the IHR (in terms of exchange of communications, information-sharing, consultation and verification of events occurring within the EU territory).

Bridging possible gaps in cooperation and coordination between the WHO and the EU, this strategy would avoid structural duplication of efforts and would improve efficiency and coherence in the implementation of the IHR in Europe.