

# **Waterborne Disease Surveillance: The Case for a Closer Interaction between the UNECE Protocol on Water and Health and the International Health Regulations (2005)**

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## **Abstract**

The UNECE Protocol on Water and Health prioritises prevention and control of waterborne diseases in the European Region. In order to protect public health from water-related outbreaks, the Protocol mandates the Parties to establish, improve and maintain comprehensive national and local surveillance as well as early warning systems. It also promotes international cooperation among Member States and fosters the development of joint and coordinated action aimed to complement or strengthen national capacities of response. Coordination and liaison with competent international agencies and organisations acting in the field of public health and disease surveillance is instead almost completely neglected. Despite the gap in the agreement, the relevance to the Protocol of existing surveillance networks has increasingly been acknowledged. Following this trend, the Protocol Bodies are exploring the opportunities for a closer interaction with regional and global alert and response systems. This effort is commendable, but much more can be done to reach a more intense cooperation and achieve a globally integrated system of disease surveillance. Harmonisation of legal frameworks (in this case, the UNECE Protocol, the EU legislation and the IHR 2005) and a better synergy among relevant networks will enhance protection of global health security, avoid useless duplications of efforts, and ensure coherence of the whole body of international law on public health.

## **Keywords**

waterborne diseases; public health; disease surveillance; UNECE Protocol; IHR 2005

## **1. Waterborne Diseases and Global Public Health Security**

Safe water is a vital determinant of global health. Waterborne diseases (WBDs) show a spectrum of possible health outcomes with different levels of severity ranging from asymptomatic infection to death. They are a cause for major concern worldwide, since many of the pathogens responsible for water-related infections can lead to extensive outbreaks affecting large sections of the global population. According to the World Health Organization, unsafe water and sanitation is one of the five leading risk factors. It is in fact estimated that the global burden risk of pathologies due to contaminated drinking, ambient and recreational waters, as well as poor sanitation and hygiene, corresponds to 4% of

global DALYs.<sup>1</sup> Although the WHO reports that these risks particularly affect populations in low-income countries, especially in the Regions of South-East Asia and sub-Saharan Africa, European countries are not exempt from waterborne outbreaks. The health burden of WBDs in all countries of the European Region is still considered “significant” and emergent diseases have been reported in areas of the Region where they had been previously undetected.<sup>2</sup>

The focus rests on water-related communicable diseases. Both their potential to spread and the phenomena of emergence and re-emergence of waterborne pathogens make reducing the burden of WBDs a priority public health goal. Successful prevention and control of these diseases demand effective large-scale surveillance<sup>3</sup> and epidemiologic intelligence is at the heart of preparedness and response. As a consequence, identification and prompt reporting of waterborne outbreaks to health authorities at all levels of intervention is essential, while the rapid sharing of information and data becomes crucial for public health action to be timely and effective.

Early warning and response systems are thus fundamental for national, regional and global health security and the need to strengthen surveillance key functions is recognised globally.

The major challenge in this respect is to succeed in standardising and harmonising existing systems. National surveillance rules, methods and procedures are quite different even in the same Region, like in Europe, and there is a general demand for improving outbreak investigation capacities, sensitivity and comparability of data. The same applies at both the regional<sup>4</sup> and the international level. A more coordinated approach and a better interface among surveillance networks can in fact lead to an integrated and cooperative system that may guarantee global public health security while ensuring complementarity of mechanisms and minimum duplication of efforts.

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<sup>1</sup> WHO, *Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks* (2009), pp. v, 9–10; DALY is the acronym for “disability-adjusted life years”, a time-based measure used for assessing the overall burden of a disease, that combines years of life lost due to premature mortality and years of life lost due to time lived in states of less than full health.

<sup>2</sup> See the most recent report on food- and waterborne outbreaks jointly published on 28 January 2010 by EFSA and ECDC: “The Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in the European Union in 2008”, 8 *The EFSA Journal* (2010) 274; see also WHO Europe, *Consultation on Waterborne Disease Surveillance*, Budapest, 9–10 May 2006, Final report by Hiroko Takasawa, p. 3.

<sup>3</sup> Surveillance is by general consensus defined as the ongoing systematic collection, analysis, interpretation and dissemination of data concerning health-related events that enable public health authorities to plan, shape and implement policies and practices aimed at reducing morbidity and mortality.

<sup>4</sup> ECDC, *Surveillance of Communicable Diseases in the European Union. A Long-term Strategy 2008–2013* (available at [http://www.ecdc.europa.eu/en/activities/surveillance/Pages/StrategiesPrinciples\\_Long-term-Strategy.aspx](http://www.ecdc.europa.eu/en/activities/surveillance/Pages/StrategiesPrinciples_Long-term-Strategy.aspx)); see also Andrew Amato-Gauci, Andrea Ammon, “The Surveillance of Communicable Diseases in the European Union – A Long-Term Strategy (2008–2013)”, 13 *Eurosurveillance* (2008) 290–292.

## 2. Regional and Global Surveillance Networks: Complementarity of Mechanisms or Duplication of Efforts?

### 2.1. *WBD Surveillance in the European Region: Moving Towards a Pan-European Integrated Network*

WBD surveillance in the European Region relies on two major legal frameworks provided by the United Nations Economic Commission for Europe and the European Union. Since the Nineties both institutions have approached the problem of reducing the burden of WBDs as a public health concern to be addressed in the context of pan-European integration.

The Protocol on Water and Health<sup>5</sup> and EU legislation on water quality and health protection<sup>6</sup> constitute the regulatory frameworks devised at UNECE and UE level to develop a common European architecture for surveillance and control of water-related diseases.

The UNECE Protocol is the very first international agreement specifically dedicated to the management of waterborne hazards. Its primary objective is “the protection of human health” at both national and international level “through preventing, controlling and reducing water-related disease”.<sup>7</sup> To this end, Article 4 imposes on Member States the obligations to “take all appropriate measures to prevent, control and reduce water-related disease within a framework of integrated water-management systems”, and to ensure both “sufficient safeguards for human health against water-related disease” and “effective systems for monitoring situations likely to result in outbreaks or incidents of water-related diseases and for responding to... them”.<sup>8</sup> These obligations must be fulfilled in consideration of, and consistently with, the relevant targets and target dates set by each State Party under Article 6 for the standards and levels of performance that need to be achieved or maintained, especially those concerning “the reduction of the scale of outbreaks and incidents of water-related diseases”.<sup>9</sup>

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<sup>5</sup> Protocol on Water and Health to the 1992 Convention on the Protection and Use of Transboundary Watercourses and International Lakes, done in London, on 17 June 1999, in force since 4 August 2005.

<sup>6</sup> See especially the Drinking Water Directive (Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, *OJ L* 330, 5 December 1998, p. 32), the Water Framework Directive (Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, *OJ L* 327, 22 December 2000, p. 1), the new Groundwater Directive (Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, *OJ L* 372, 27 December 2006, p. 19), the new Bathing Water Directive (Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC, *OJ L* 64, 4 March 2006, p. 37).

<sup>7</sup> Article 1.

<sup>8</sup> Article 4, paras. 1 and 2 (d, e), respectively.

<sup>9</sup> Article 6, para. 2(b).

In order to attain the goals set by the Protocol, Article 8 specifically mandates the Parties to ensure the establishment – within the maximum time span of three years from ratification – of comprehensive national and/or local surveillance and early warning systems. These are aimed at identifying outbreaks of WBDs or significant and imminent threats to public health and at giving prompt notification to the relevant public authorities. Moreover, as far as effective and timely response to waterborne outbreaks, incidents or risks is concerned, the Parties are requested to ensure that national and local contingency plans are prepared in due time and that public authorities have adequate capacities of reaction. For implementation of these primary obligations of target setting, monitoring and reporting, WBDs are divided into the following categories: priority diseases, defined as “dangerous diseases with severe health consequences and with high tendency for secondary spreading” (cholera, shigellosis, enterohemorrhagic *Escherichia coli*, typhoid fever and viral hepatitis A); diseases of secondary importance caused by sporadic outbreaks of pathogens (*Campylobacter*, *Cryptosporidium*, *Giardia intestinalis*, *Calicivirus*); and infrequent acute gastro-intestinal syndromes of undetermined aetiology.<sup>10</sup> The Parties to the Protocol are supposed to progressively make primary and secondary diseases mandatorily notifiable to public health authorities; national reporting capacities are to be strengthened accordingly.<sup>11</sup>

Along with the duties above, the States Parties are requested to promote international cooperation in support of the objectives of the Protocol. In this respect, Articles 11 to 14 play a pivotal role in fostering the management of waterborne risks through enhanced cooperation and mutual assistance among the Parties to the Protocol. Article 12, in particular, places emphasis on joint and coordinated international action as part of, or as a complement to, national surveillance and

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<sup>10</sup> Primary and secondary diseases can be transmitted directly through consumption of drinking water, but also in an indirect way through the consumption of contaminated fish, shellfish, vegetables and fruits, or as a consequence of the exposure to contaminated recreational waters. Although the focus is on communicable diseases, it is important to take into due consideration also WBDs caused by contamination with chemicals (nitrate, iron, arsenic, manganese, fluoride, iodine, strontium and pesticides), whose burden is normally under-reported. See *Waterborne Disease Surveillance: Goals and Strategies*, Report on a meeting of a working group, Budapest, 29–30 November 2001, p. 4; Second Meeting of the Signatories to the Protocol on Water and Health, Geneva, 2–4 July 2003.

<sup>11</sup> Not all Parties to the Protocol have mandatory dedicated WBD surveillance and notification systems; most of them survey priority diseases, but some neglect *E. coli*; secondary importance or emerging diseases are only partially if not at all monitored in several States. A survey on the status of surveillance systems on communicable diseases in the UNECE/WHO Euro Region was carried out by the Task Force on Water-related Disease Surveillance (see *infra* note 52) and its findings reported in detail in “Surveillance and Early-warning Systems, Contingency Plans and Response Capacities, Status of Water-related Diseases Surveillance Systems in the UNECE/WHO European Region: Results of a Dedicated Questionnaire” (Working Group on Water and Health, Second meeting, Geneva, 2–3 July 2009, Agenda item 4, Information paper 4). An assessment of the shortcomings detected in national surveillance systems are summarised by Enzo Funari, Chair of the Task Force, and Monica Blasi in their presentation on “Surveillance Systems of WRD in the UNECE /WHO European region”, available at [http://www.unece.org/env/water/meetings/documents\\_WGWH.htm#Presentations2](http://www.unece.org/env/water/meetings/documents_WGWH.htm#Presentations2).

early-response systems established and maintained under Article 8. It also encourages communication among competent national authorities for the development of integrated information systems and databases, as well as for the prompt reciprocal notification of waterborne outbreaks and significant threats to public health. Further, special attention is paid by Article 13 to cooperation in preventing, controlling and reducing transboundary effects of WBDs. By the combination of these provisions, the Protocol urges its Parties to achieve successful surveillance and containment of WBDs at the regional level through close interaction among national early-warning and response systems, with a view to their further developing into a joint and cooperative international network.<sup>12</sup>

In the context of international cooperation, however, the Protocol does not address an aspect which is relevant to the achievement of its purposes, and which probably deserved more consideration in the agreement: the importance of developing liaisons with other existing regional systems of alert and response.<sup>13</sup>

This is indeed not a minor element, since most of the Protocol's Parties are Member States of the European Union and, as such, they are bound by the obligations stemming from the EU *acquis*. Therefore, while the Protocol may complement the objectives of Article 168 of the Treaty on the functioning of the European Union – concerning EU policies and action in the field of “monitoring, early warning of and combating serious cross-border threats to health”<sup>14</sup> – the two legal frameworks overlap to the extent that the obligations set out in the Protocol find their counterpart in EU legislation.

In fact, as far as monitoring and control of water-related communicable diseases are concerned, both surveillance functions and reporting of notifiable

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<sup>12</sup> Actually, the need for an integrated action through improved international cooperation both in data collection and reporting, as well as in notification and response, has progressively gained importance in the meetings and reports of the Protocol Bodies. For example, on the occasion of their very first meeting, the Signatories to the Protocol, drawing from the replies of countries to a questionnaire concerning the implementation of the agreement, came to the conclusion that no common systems of monitoring, data analysis and data reporting of WBDs existed on a pan-European basis and that many countries had no legal obligation to report specifically on WBDs but covered this subject as part of other reporting programs (for example reporting on infectious diseases). The Signatories thus called for harmonisation and standardisation of existing mechanisms as a fundamental prerequisite for implementation of the Protocol (see Report of the First Meeting of the Signatories to the Protocol on Water and Health, Budapest, 2–3 November 2000, MP/WAT/AC.2/2000/2 – EUP/ICP/5021651/2, p. 5, para. 17). For further insights, see Ros Stanwell-Smith, “Water Related Surveillance in Europe”, 3 *Eurosurveillance* (1999) 1445; D.A. Poullis, R.W. Attwell and S.C. Powell, “An Evaluation of Waterborne Disease Surveillance in the European Union”, 17 *Reviews on Environmental Health* (2002) 149–161 (the authors denounced lack of a EU-wide uniform scheme based on common criteria, reporting that surveillance systems in the EU show inconsistencies in notifiable diseases, legal requirements for notification, national schemes for surveillance and reporting mechanisms).

<sup>13</sup> The only generic mention of the possible participation of other competent international organisations or non-governmental bodies to the activities pertinent to the scope of the Protocol is to be found in Article 16 (f).

<sup>14</sup> See Consolidated version of the Treaty on the Functioning of the European Union, *OJ* C 115, 9 May 2008, p. 47.

diseases under the Protocol are absolutely in line with EU directives<sup>15</sup> and with the EU's epidemiological network instituted by the relevant decisions adopted since 1998 and amended over time,<sup>16</sup> namely Decision 2119/98/EC,<sup>17</sup> Decision 2000/57/EC,<sup>18</sup> Decision 2000/96/EC,<sup>19</sup> and Decision 2002/253/EC.<sup>20</sup>

Suffice it to remind that Decision 2119/98/EC provides the basic legal framework for the adoption of a coordinated approach to the prevention of major health threats caused by communicable diseases. The decision sets up a network for the epidemiological surveillance, early warning and response system of a list of communicable diseases (including waterborne diseases), which is based on a permanent flow of information between the Commission and national public health authorities. Decision 2000/96/EC defines criteria for the selection of communicable diseases of special areas to be covered by epidemiological surveillance within the network set up under Decision 2119/98/EC. Decision 2000/57/EC defines events related to communicable diseases to be communicated by competent public health authorities of Member States to the early warning and response system (EWRS)<sup>21</sup> component of the EU network, and sets up general procedures for information exchange on those events, for consultation and for coordination of measures among Member States in liaison with the Commission. It also commits national public health authorities of each Member State to collect and exchange all necessary information on events due to communicable diseases by using the national surveillance system, the EWRS or any other collection system.

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<sup>15</sup> The set of priority and secondary importance WBDs identified under the Protocol on Water and Health are already subject to reporting under EU decisions, with the only exception of *Calicivirus*.

<sup>16</sup> See at [http://ec.europa.eu/health/ph\\_threats/com/comm\\_legislation\\_en.htm](http://ec.europa.eu/health/ph_threats/com/comm_legislation_en.htm); and also at [http://www.ecdc.europa.eu/en/aboutus/Pages/AboutUs\\_KeyDocuments.aspx](http://www.ecdc.europa.eu/en/aboutus/Pages/AboutUs_KeyDocuments.aspx).

<sup>17</sup> Decision 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, *OJ L* 268, 3 October 1998, p. 1.

<sup>18</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 L* 21, 26 January 2000, p. 32.

<sup>19</sup> Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, *OJ L* 28, 3 February 2000, p. 50, as recently amended by Commission Decision 2009/312/EC of 2 April 2009, *OJ L* 91, 3 April 2009, p. 27.

<sup>20</sup> Commission Decision 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, *OJ L* 86, 3 April 2002, p. 44.

<sup>21</sup> An event is to be reported to the EWRS if one or more of the following criteria are met: outbreaks of communicable diseases extending to more than one Member State; spatial or temporal clustering of cases of disease of a similar type, if pathogenic agents are a possible cause and there is a risk of propagation between Member States or within the Union; the appearance or resurgence of a communicable disease or an infectious agent which may require timely coordinated Community action to contain it; pathological events or facts creating a risk of a communicable disease; events due to communicable diseases notified by the Member States to the WHO under the new International Health Regulations.

The European Centre for Disease Prevention and Control, instituted under Regulation No. 851/2004<sup>22</sup> with the objective of developing an integrated communicable disease surveillance system for the European Union<sup>23</sup> and strengthening surveillance systems in Member States, has been operating the EWRS application since 17 November 2007. In 2008 ECDC also launched The European Surveillance System (TESSy), a new regional system of data collection and analysis, destined to replace the systems operating for the present Dedicated Surveillance Networks, to which EU and EEA/EFTA States are requested to report all data relating to communicable diseases as provided for in Decision 2119/98/EC.

Despite lack of express provision, the relevance of ECDC's functions to the implementation of the Protocol is clearly acknowledged by the Protocol Bodies and has gained much more impetus over time.

For instance, ever since their second meeting, the Signatories to the Protocol urged the development of a more streamlined reporting mechanism in line with the disposition on international cooperation.<sup>24</sup> The expert group that met in Budapest in 2004 recognised the reporting burden imposed on the Parties by national and supranational legislation, considered the risk of duplicating efforts, and suggested a more intense cooperation with specialised agencies and organisations in order to come to a common and comprehensive data capture system.<sup>25</sup> The expert group recognised the ECDC's effort to develop an integrated approach for disease surveillance, including priority and secondary waterborne diseases as defined under the Protocol;<sup>26</sup> it welcomed the commitment of both

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<sup>22</sup> Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control, *OJ L* 142, 30 April 2004, p. 1. One of the key functions of the ECDC is to standardise European surveillance and especially to harmonise the procedures of the surveillance networks that developed independently of each other. ECDC is mandated to identify and assess emerging threats to public health from communicable diseases and establish, in cooperation with the Member States, procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging health risks which could affect public health in the European Union.

<sup>23</sup> Before the foundation of ECDC seventeen Dedicated Surveillance Networks were set up at EU level; coordination of some of these has already been transferred to the ECDC (see at [http://www.ecdc.europa.eu/en/activities/surveillance/Pages/Surveillance\\_EvaluationAssessment.aspx](http://www.ecdc.europa.eu/en/activities/surveillance/Pages/Surveillance_EvaluationAssessment.aspx)).

<sup>24</sup> Report on the Second Meeting of the Signatories to the Protocol on Water and Health, edited by Roger Aertgeerts, Geneva, 2–4 July 2003, MPWAT/AC.2/2003/2 – EUR/03/5041120, p. 6, para. 6.

<sup>25</sup> Consultation on Waterborne Disease Surveillance, *supra* note 2, p. 5.

<sup>26</sup> The ECDC programme on food- and water-borne diseases and zoonoses (FWD) was launched in 2006 and currently covers 20 diseases including those labelled by the Protocol as priority and secondary diseases (campylobacteriosis, cholera, cryptosporidiosis, giardiasis, hepatitis A, shigellosis, typhoid/paratyphoid fever). Only two among these (campylobacteriosis and shigellosis) belong to the set of the six ECDC priority diseases. The ECDC programme is meant to improve surveillance in the European Union, strengthen the capacity of EU Member States to prevent and respond to FWD, improve early detection and coordinated response to outbreaks with a European dimension. Existing partners, among others, are the European Commission, EU Member States, EFSA, RASFF, Centres for Disease Control and Prevention and WHO (WHO Europe, WHO Geneva and WHO Regional Office for Foodborne Diseases).

the WHO Regional Office for Europe and the ECDC to avoid duplication of reporting efforts by countries, taking also into account EU legal obligations and the voluntary reporting systems used by the other States of the European Region; it encouraged the use of the WHO Centralized Information System for Infectious Diseases (CISID) data capture system<sup>27</sup> and the EU/ECDC data reporting system for diseases identified as being of particular importance under the Protocol. It thus reached consensus on the need to implement an integrated strategy for surveillance of WBDs, taking into account the work of both the ECDC and WHO Regional Office for Europe aimed at the progressive harmonisation of national systems.

In the same wake, the Parties to the Protocol, meeting for the first time after the entry into force of the agreement, acknowledged the possible synergy with the work of the ECDC.<sup>28</sup> Since then, the process has gradually evolved and is striving to move towards the achievement of a pan-European integrated surveillance system.

## *2.2. WBD Surveillance at the Global Level: The IHR 2005 and the Risk of Duplicating Obligations*

National and regional surveillance systems support and complement global surveillance. The most recent public health crises caused by emergent communicable diseases (like SARS, avian influenza and the latest pandemic influenza), have marked a watershed in global disease surveillance. The international community has become fully aware that the most critical health challenges call for effective measures of prevention, control and early response, especially when the outbreak of new or re-emerging diseases can pose a serious threat to human health worldwide.<sup>29</sup>

Faced with the menace of new human pandemics, zoonoses and food-borne or waterborne hazards, the WHO worked out a new global strategy inspired to the principles of timeliness and effectiveness. To meet the general demand for global health security this strategy relies on updated rules and cooperative procedures applied to monitoring, alert and response functions; it mainly operates

<sup>27</sup> CISID is managed by WHO Europe and is aimed to provide complete epidemiologic data of important infectious diseases, esteem the disease burden on public health, identify priority areas of intervention, share data at the sub-regional/sub-national level and develop early warning systems.

<sup>28</sup> Report of the Meeting of the Parties to the Protocol on Water and Health to the Convention on the Protection and Use of Transboundary Watercourses and International Lakes on Its First Meeting, Geneva, 17–19 January 2007, ECE/MP:WH/2 – EUR/06/5069385/1, p. 10, para. 41.

<sup>29</sup> The United Nations General Assembly expressed its serious concern about the new public health emergencies that threaten global health, underscoring the need for closer international cooperation, even beyond emergency, and towards a strengthened capacity of response. See, e.g., General Assembly resolutions 58/3 of 27 October 2003, 59/27 of 23 November 2004, 60/35 of 30 November 2005, entitled *Enhancing Capacity-building in Global Public Health*. See also General Assembly resolution 63/33 of 26 November 2008, *Global Health and Foreign Policy*.

through the sharing of information and of the necessary technical and operational support. The basic legal framework is provided by the revised International Health Regulations (IHR 2005), in force from 15 June 2007.<sup>30</sup>

The Regulations are an international legal instrument binding on nearly all States of the international community.<sup>31</sup> In order to provide the global community with adequate instruments to face acute public health risks that threaten people worldwide, the Regulations try to strike a balance between sovereign rights, human rights, freedom of traffic and trade and shared commitment to protect global health.<sup>32</sup> To this end, they contain a significant range of innovations, including: a broader scope of application which is not limited to specific diseases;<sup>33</sup> obligations for States Parties to develop certain minimum core public health capacities within the deadline of five years from coming into force;<sup>34</sup> procedures aimed to compensate for weak detection and response capacities by national health authorities; obligations to notify WHO of events that may constitute a public health emergency of international concern according to defined

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<sup>30</sup> World Health Assembly, Fifty-Eighth plenary meeting, 23 May 2005, Resolution WHA58.3, *Revision of the International Health Regulations*. See David P. Fidler, “From International Sanitary Conventions to Global Health Security: The New International Health Regulations”, 4 *Chinese Journal of International Law* (2005) 325–392; David P. Fidler and Lawrence O. Gostin, “The New International Health Regulations: An Historic Development for International Law and Public Health”, 34 *Journal of Law, Medicine & Ethics* (2006) 85–94; Michael G. Baker and David P. Fidler, “Global Public Health Surveillance under New International Health Regulations”, 12 *Emerging Infectious Diseases* (2006) 1058–1065; Erik Mack, “The World Health Organization’s New International Health Regulations: Incursion on State Sovereignty and Ill-Fated Response to Global Health Issues”, 7 *Chicago Journal of International Law* (2006) 365–377.

<sup>31</sup> At present the IHR 2005 are binding on 194 States, including all WHO Members, of which only two (India and the United States of America) submitted reservations under Article 62 of the Regulations. According to Articles 21 and 22 of the Constitution of WHO, regulations produce compulsory effects for all Member States that do not expressly “opt out” or make reservations to them within a limited deadline. In this case, the IHR 2005 can be said to have been unanimously agreed by consensus among all WHO Member States.

<sup>32</sup> According to Article 2 of the IHR 2005 “The purpose and scope of these Regulations are 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.”

<sup>33</sup> The IHR 1969 only concerned more serious illnesses such as cholera, plague, yellow fever, smallpox, typhus. In addition to these illnesses, the revised Regulations also apply to new and “emerging” infectious diseases, such as SARS, human influenza caused by new virus subtypes, viral haemorrhagic and other fevers known as Ebola, Lassa, Marburg, West Nile, Dengue and Rift Valley fevers, and to any other disease which may spread rapidly internationally and represent a serious risk to public health. They apply as well to any event of potential international public health concern, including those of unknown causes or sources.

<sup>34</sup> These obligations thus require gradual implementation by 2012, or 2016 at the latest. Annex 1 of the IHR 2005 stipulates the minimum core capacity requirements for surveillance and response to communicable diseases at the local community level, at the intermediate level, and also at the national level. They call upon Member States to develop and enhance their capacities for surveillance, reporting, notification, verification, response, and collaboration, and their activities concerning designated airports, ports and ground crossings.

criteria; provisions authorising WHO to take into consideration unofficial reports of public health events and to ask States for verification; procedures for the determination of a “public health emergency of international concern” and issuance of corresponding temporary recommendations; protection and full respect for dignity, human rights and fundamental freedoms;<sup>35</sup> the establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and WHO.<sup>36</sup> In this perspective, the IHR 2005 define specific rights and obligations of States Parties and indicate the proper procedures to establish a global health governance system, which places at the heart of decision-making and operative activities the interaction between national and international health authorities with a view to sharing responsibilities and fulfilling the duty to cooperate.<sup>37</sup>

One of the most important innovations introduced by the revised Regulations is their capacity to encompass a much broader spectrum of infectious diseases, that require continuous epidemiologic surveillance and compulsory notification to WHO in case of unusual and unforeseen events of international relevance. In case of outbreak, States Parties are under the obligation to promptly notify the WHO of the events detected at national level which meet at least two of the conditions laid down in Annex 2: unusualness of the event, emergence of a new disease with significant zoonotic potential, high rate of mortality or morbidity, potential transboundary diffusion, and potential interference with international travel or trade.<sup>38</sup> A case in point is cholera, which is one of the communicable diseases for which mandatory notification is required when the conditions above recur. However, it is evident that within the expanded scope of the IHR 2005 may fall any waterborne disease with international implications that requires action under the legal provisions of the Regulations. Expanding their field of action also to “emerging” diseases, the IHR 2005 are meant to guarantee an effective response to the new health challenges of a globalised world. The Regu-

<sup>35</sup> Article 3 (1) of the IHR 2005 provides: “The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons.” For further considerations on this issue, see Stefania Negri, “Emergenze sanitarie e diritto internazionale: il paradigma salute–diritti umani e la strategia globale di lotta alle pandemie ed al bioterrorismo” (Public health emergencies and international law: the health–human rights paradigm and the global fight against pandemics and bioterrorism), in *Scritti in onore di Vincenzo Starace* (2008) 571–605.

<sup>36</sup> See in particular Articles 2 to 12 of the Regulations.

<sup>37</sup> Professor David Fidler lays special stress on this specific aspect of the revised Regulations, which he deems to be the most relevant: “the new IHR create a strategy and framework for integrated, flexible and forward-looking governance for addressing serious threats to public health. The new IHR engage State and non-State actors, address numerous public health threats and draw together objectives found in multiple international legal regimes – specifically those concerning infectious disease control, human rights, trade, environmental protection and security – and configure them in a way that has no precedent in international law on public health.” (Fidler, “From International Sanitary Conventions”, *supra* note 30, p. 326).

<sup>38</sup> See IHR 2005, Annex 2: “Decision Instrument for the Assessment and Notification of Events that may Constitute a Public Health Emergency of International Concern”.

lations in fact constitute the only global health agreement governing the reporting of disease outbreaks and the prevention of their international spread. It is indeed in this perspective that the Regulations have become an essential tool for global health protection and a true pillar of international health law.

On the operational side, the implementation of the IHR 2005 mainly relies on the relevant initiatives launched by the WHO in order to support surveillance, early warning and reaction systems worldwide. The Global and Alert Response (GAR), for instance, is an integrated global alert and response system for epidemics and other public health emergencies, which is based on coordinated response through cooperation between national public health systems and the international surveillance system.<sup>39</sup> Another example is provided by the Global Outbreak Alert and Response Network (GOARN), a global network launched in 2000 with the aim of combating the international spread of outbreaks, ensuring that appropriate technical assistance reaches affected States rapidly, and contributing to long-term epidemic preparedness and capacity building. GOARN is meant to promote technical collaboration of existing institutions and networks that streamline human and technical resources for the rapid identification, confirmation and response to outbreaks of international importance.

Evidence shows that implementation of the IHR 2005 and the operation of global surveillance networks inevitably risk to create duplication of efforts, especially in terms of double reporting obligations. This concern especially applies to European countries, which are subject to multiple mechanisms of data collection, analysis, interpretation and dissemination for public health outcomes.

Mainstreaming the work and resources of existing national and regional networks under the general framework of the WHO and its global health policy is one of the most challenging endeavours that the international community must face.

### **3. A Global Integrated System for Improved European-Wide WBD Surveillance**

#### *3.1. Harmonisation between EU Legislation and the IHR 2005: A First Relevant Step*

Tackling major public health hazards of international concern, especially in the field of communicable disease preparedness and response, requires a level of coordination that goes beyond countries, institutions and procedures at regional level; it also calls for closer cooperation with all relevant actors operating in the international scenario. The major challenge of achieving a globally integrated

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<sup>39)</sup> With regard to waterborne diseases GAR covers Hepatitis A events but Alert and Response Operations also address food and water safety as well as chemical events.

surveillance system – that may support and advantage regional networks – is to ensure overall consistency of obligations and avoidance of duplications in a move towards increased efficiency.<sup>40</sup>

To make the first significant step in this direction it is crucial that regional legal frameworks, especially those with a high degree of integration, find a synergy with concurring global regulations. In Europe this means that harmonisation between EU law and the IHR 2005, leading to improved cooperation between the two, is the basic point of departure to guarantee a more effective and comprehensive system of disease surveillance that may optimise existing structures and resources.

This approach seems to be shared by the EU institutions, eager to strengthen the European Union's voice in global health but conscious that the key role of the WHO and its universally agreed rules cannot be neglected.<sup>41</sup> Awareness of this is reflected in the European Commission's White Paper on a new Health Strategy, where it is stated that: "In our globalised world it is hard to separate national or EU-wide actions from global policy, as global health issues have an impact on internal Community health policy and vice versa."<sup>42</sup>

Consistently with this perspective, the Commission expressed its views that efforts ought to be supported in order to encourage implementation of the IHR 2005 in the European Region and, hence, to ensure coherence between internal and external health policies aimed to attain global health goals.<sup>43</sup>

The Commission immediately put into practice its own directives and played a proactive role in harmonising EU law with the Regulations. In this respect, several actions were put in place in the last biennium to adapt the current EU legislation on communicable diseases to the IHR 2005. First of all, the annexes to Decisions 2119/98/EC, 2000/96/EC and 2000/57/EC were amended in

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<sup>40</sup> For insights on the concept of integrated surveillance systems at national level, see WHO, "An Integrated Approach to Communicable Disease Surveillance", 75 *Weekly Epidemiological Record* (2000) 1–7 (7 January 2000).

<sup>41</sup> The EU is not a party to the International Health Regulations. It should be noted, however, that Article 168, para. 3, of the Treaty on the Functioning of the European Union (*supra* note 14), sets out the Union's obligation to foster cooperation with the competent international organisations in the sphere of public health. Moreover, it is also worth considering that the IHR 2005 involve matters of mixed competence between national governments and the EU. Article 57(3) of the Regulations states that "Without 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."

<sup>42</sup> Commission of the European Communities, White Paper: *Together for Health: A Strategic Approach for the EU 2008–2013*, COM(2007) 630 final, 23 October 2007, p. 6. See also Commission Decision 2008/170/EC of 27 February 2008 on the adoption of the work plan for 2008 for the implementation of the second programme of Community action in the field of health (2008–2013), and on the selection, award and other criteria for financial contributions to the actions of this programme, *OJ L* 56, 29 February 2008, pp. 36–62.

<sup>43</sup> *Ibid.*; see also European Parliament resolution of 6 September 2007 on International Health Regulations, *OJ C* 187E, 24 July 2008, pp. 210–212.

order to introduce the obligation to report through the EWRS all health events notifiable to the WHO for their potential to constitute an emergency with international impact.<sup>44</sup>

Further, as explained in its recent report to the Council and the Parliament on the operation of EWRS,<sup>45</sup> the Commission established a group of National IHR Focal Points entrusted with coordinating the practical aspects of IHR implementation. In most of the Member States, as well as in Norway and Iceland, those appointed as National IHR Focal Points were the same institutions designated as EWRS contact points. The Commission thereby envisaged strengthening IHR notifications by closely associating them with the existing EU electronic notification systems.<sup>46</sup> Moreover, to ensure consistency between the notifications made to the EWRS in compliance of EU obligations and those made to the WHO under the IHR, an IT function was developed to keep the WHO informed about events notified under Decision 2119/98/EC.<sup>47</sup>

Along with these initiatives fostering application of the Regulations in Europe, the Commission has further set other priority actions concerning the streamlining of current surveillance structures, the reconsideration of the mandate of ECDC together with the revision of the network for the epidemiological surveillance in the Union, and, last but not least, the clarification of the articulation between the EWRS and the alert and response system operating within the IHR framework. Even in the field of external relations and assistance to third countries, actions aimed at promoting the implementation of international health agreements and addressing IHR commitments are being considered.<sup>48</sup>

Enhanced harmonisation between EU legislation and the IHR 2005, to be attained also through strict coordination among relevant operational networks, is the very first step towards vertical integration between regional and global surveillance systems and their mutual improvement.

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<sup>44</sup> See Commission Decision 2007/875/EC of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions, *OJ L* 344, 28 December 2007, pp. 48–49; Commission Decision 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases, *OJ L* 117, 1 May 2008, pp. 40–41.

<sup>45</sup> Commission of the European Communities, Report from the Commission to the Council and the European Parliament, Operation of the Early Warning and Response System (EWRS) of the Community Network for the epidemiological surveillance and control of communicable diseases during 2006 and 2007 (Decision 2000/57/EC), COM (2009) 228 final, 15 May 2009, p. 8, para. 7.

<sup>46</sup> This is in line with what is stated in the Communication from the Commission to the European Parliament and the Council on the International Health Regulations, COM (2006) 552 final, 26 September 2006: “the European Centre for Disease Prevention and Control... and the EU Early Warning and Response System for public health threats... can help us to implement the IHR in a stronger, more coherent way”.

<sup>47</sup> These actions put in practice the proposals suggested by the Commission in the above-mentioned Communication of 2006, at paras. 9–15.

<sup>48</sup> See Commission White Paper (*supra* note 42), pp. 6–7.

In this respect the process is half way through, since the WHO is already one of ECDC's most important strategic partners; in particular, ECDC participates in GOARN and the WHO Regional Office for Europe has tasks and responsibilities that interlink with those of ECDC, thus ensuring coordination between the two for efficient use of limited resources and reduced duplication of work.

### 3.2. *Exploring Interactions Between the UNECE Protocol and the IHR 2005*

As for the case of EU legislation, it is necessary to explore a closer interaction between the Protocol on Water and Health and the IHR 2005 towards a more effective and economically efficient integrated surveillance system.

The two agreements share core objectives and procedures and both make monitoring, early warning and response to communicable diseases the key premise of public health security. In consideration of their common features and goals, a better synergy between the Protocol and the Regulations can foster multi-level cooperation leading to mutually beneficial results for implementation.

This notwithstanding, potential interface with the IHR 2005 has only recently received stronger consideration by the Protocol Bodies. In fact, it was only at the first meeting of the Parties that the co-secretary of the Protocol stressed the relevance of the IHR 2005 as pertaining to water-related diseases.<sup>49</sup>

The programme of work for 2007–2009, which was adopted on that same occasion, included activities aimed to enhance the development of surveillance, early warning and response systems – as required by Articles 8 and 11 to 14 – in cooperation with other partners, such as the WHO CISID, the WHO Health for All database, the WHO Epidemic and Pandemic Alert and Response system, and the WHO Collaborating Centre for Health-Promoting Water Management and Risk Communication.<sup>50</sup> However, no specific mention of the IHR was made in that document, nor in any other relevant document issued from the Meeting. It was even neglected in the context of an overview of existing reporting mechanisms of relevance for the Protocol.<sup>51</sup>

At its first meeting in 2007 the Task Force on Water-related Disease Surveillance “took note of the entry into force of the International Health Regulations (IHR 2005) and their relevance to the work under the Protocol on Water and Health”.<sup>52</sup> It also endorsed some major WHO technical guidance documents

<sup>49</sup> Report of the Meeting of the Parties to the Protocol on Water and Health to the Convention on the Protection and Use of Transboundary Watercourses and International Lakes on Its First Meeting, Geneva, 17–19 January 2007, ECE/MP.WH/2 – EUR/06/5069385/1, Part 1: Proceedings, p. 10, para. 41.

<sup>50</sup> *Id.*, Addendum: Programme of Work for 2007–2009 adopted by the Meeting of the Parties, ECE/MP.WH/2/Add.5 – EUR/06/5069385/1/Add.5, pp. 3–4.

<sup>51</sup> *Id.*, Overview of Existing Reporting Mechanisms of Relevance for the Protocol, Note by the Secretariat, ECE/MP.WH/2007/3 – EUR/06/5069385/10.

<sup>52</sup> First meeting of the Task Force on water related diseases surveillance, Rome, 24–25 September 2007, pp. 5–6. The Task Force was instituted at the first meeting of the Parties to the Protocol. It is led by Italy and is entrusted with providing assistance to the Parties in establishing and/or strengthening outbreak

concerning epidemic and pandemic alert response, thus establishing an indirect liaison between the operation of the Protocol and the Regulations.<sup>53</sup> The Guidance Document on Water-Related Disease Surveillance – which was drafted by the Task Force to give impetus to national efforts towards national and international health security in line with the IHR 2005 – acknowledged the importance of the Regulations’ achievement of harmonisation of notifiable diseases at global level.<sup>54</sup>

At its second meeting, held in April 2009, the Task Force finally recognised the relevance of the Regulations to the aims of the Protocol and called for proposals for closer cooperation, consistently with the guiding principle that existing resources and structures should be built on to minimise duplication and optimise functional integration.<sup>55</sup>

#### **4. The Case for Better Synergy: Networking Networks under the Umbrella of the IHR 2005**

Following the considerations above, the argument is proposed that in implementing the UNECE Protocol on Water and Health special attention should be increasingly paid to the possible overlapping of its obligations with those laid down by the IHR 2005. More intense coordination between the two legal instruments and the surveillance frameworks they shape should lead to optimisation of complementary performances and avoidance of duplications. Possible developments in this direction could follow in the wake of what is being experienced in the context of the ongoing harmonisation between the EU legislation

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detection and response systems, including assessment and improvement of national and/or local surveillance, outbreak detection and early warning systems, contingency plans and capacity response.

<sup>53</sup> Among such guidelines notice should be taken in particular of WHO Recommended Surveillance Standards, that help setting priorities and acknowledge the importance of coordination between national surveillance systems and WHO programmes, including obligations stemming from the IHR. In fact, in identifying the need to list priority diseases as an essential component of national surveillance plans, the WHO recommends that a broader approach be adopted and that a regional and possibly international viewpoint be aptly taken into consideration when assessing the impact and the epidemic potential of communicable diseases, their being relevant under any specific WHO programme, or their being notifiable according to the IHR. Moreover, the document also stresses that in cases relevant for the IHR, when the disease outbreak triggers an appropriate response on a wider scale, national authorities must liaise with other foreign counterparts and with international agencies as well (Recommended Surveillance Standards, 2nd edition, WHO/CDS/CSR/ISR/99.2, pp. 10, 14; see also *Setting Priorities in Communicable Disease Surveillance – WHO Epidemic and Pandemic Alert and Response*, WHO/CDS/EPR/LYO/2006.3, p. 13).

<sup>54</sup> Working Group on Water and Health, Second meeting, Geneva, 2–3 July 2009, Agenda item 4, Information paper 1, Guidance Document on Water-Related Disease Surveillance – Part 1: Technical guidance related to drinking-water, p. 3.

<sup>55</sup> *Id.*, Information paper 3, Surveillance and Early-Warning Systems, Contingency Plans and Response Capacities, Report from the second meeting of the Task Force on water related disease surveillance, Rome, 28–29 April 2009, pp. 7–8, paras. 39–42.

on communicable diseases and the Regulations. Designating the same public authorities as National Focal Points for both the Protocol and the IHR 2005 could be a first useful step. Expanding the scope of GAR and GOARN so as to encompass all waterborne diseases prioritised by the Protocol could represent another relevant goal; this would in fact enable European States to exploit at best the same structures, processes and personnel employed at the global level. Further arrangements could be explored in order to make stronger liaisons possible and successful.

From a legal viewpoint, harmonisation between the Protocol and the IHR 2005 would find support in Article 57 of the Regulations, which provides that States Parties recognise that the Regulations and other relevant international agreements “should be interpreted so as to be compatible”.

Moving to practical aspects, a shift in paradigm could reverse the generally shared view that the UNECE Protocol contributes to the implementation of the Regulations. In fact, the opposite might be true if due consideration is taken of the fact that several Signatories of the Protocol have not ratified it so far.<sup>56</sup> Some of these countries, which are not even EU Member States (Armenia, Georgia, Iceland<sup>57</sup> and Monaco), are only bound by the international surveillance obligations stemming from the IHR 2005. For them, the performance of IHR surveillance requirements imposes deadlines for compliance that in any case predate the implementation of the Protocol. In this perspective, the Regulations can act as a driving force for strengthening national and regional surveillance activities, thus paving the way to the future operation of the Protocol.

This is in tune with the WHO’s commitment to promote a more coordinated and synergistic approach to the surveillance and control of communicable diseases. On the other hand, it is evident that a globally integrated surveillance system for waterborne diseases envisages the need to streamline programmes and policies, seek opportunities for integration of core and support surveillance functions at all levels, share experiences and progresses, make recourse to common communication channels and build on common resources.

Such a challenging public health goal can be achieved through closer and more efficient interaction among existing networks operating under the general umbrella of the IHR 2005. This approach would enhance global health security while ensuring greater consistency and coherence in the whole body of international law on public health.

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<sup>56</sup> Armenia, Bulgaria, Cyprus, Denmark, Georgia, Greece, Iceland, Italy, Malta, Monaco, Poland, Slovenia, Sweden, the United Kingdom of Great Britain and Northern Ireland.

<sup>57</sup> The situation of Iceland is slightly different, since some reporting obligations stemming from EU legislation are also binding on EEA States.